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FEDERAL RESERVE SYSTEM

12 CFR Parts 225 and 252

[Regulations Y and YY; Docket No. R–1517]

RIN 7100 AE 33

Amendments to the Capital Plan and Stress Test Rules

AGENCY: Board of Governors of the Federal Reserve System (Board).

ACTION: Final rule.

SUMMARY: The Board is adopting a final rule that makes targeted amendments to its capital plan and stress test rules. For bank holding companies with more than $10 billion but less than $50 billion in total consolidated assets and savings and loan holding companies with total consolidated assets of more than $10 billion, the final rule modifies certain mandatory capital action assumptions in the stress test rules and delays the application of the company-run stress test requirements to savings and loan holding companies until January 1, 2017. For bank holding companies that have total consolidated assets of $50 billion or more and state member banks that are subject to the Board's advanced approaches capital requirements, the final rule delays the use of the supplementary leverage ratio for one year and indefinitely defers the use of the advanced approaches risk-based capital framework in the capital plan and stress test rules. For bank holding companies that have total consolidated assets of $50 billion or more, the final rule removes the tier 1 common capital ratio requirement, and modifies certain mandatory capital action assumptions. To reflect other recent rulemakings, the final rule also makes other amendments to the capital plan and stress test rules. All changes in the final rule apply as of January 1, 2016, which is the beginning of the next capital planning and stress test cycle.

DATES: *Effective Date:* January 1, 2016.

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SUPPLEMENTARY INFORMATION:

I. Background

Capital planning and stress testing are two key components of the Board's supervisory framework for large financial companies.[1] There are two related components of the framework: the Comprehensive Capital Analysis and Review (CCAR), which is conducted pursuant to the Board's capital plan rule (12 CFR 225.8), and stress testing, which is conducted pursuant to the Board's stress test rules (subparts E and F of Regulation YY) and section 165(i) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act).[2] In CCAR, bank holding companies that have total consolidated assets of $50 billion or more (large bank holding companies) submit capital plans to the Board, and the Board assesses the internal capital planning processes and ability of these firms to maintain sufficient capital to continue their operations under expected and stressful conditions. If the Board objects to the capital plan of a large bank holding company, the company may only make capital distributions for which it has received a non-objection from the Board in writing.[3]

As required under with the Dodd-Frank Act and as a complement to CCAR, the Board conducts annual supervisory stress tests of large bank holding companies, and these bank holding companies must conduct annual and mid-cycle company-run stress tests.[4] In addition, bank holding companies that have total consolidated assets of more than $10 billion but less than $50 billion, savings and loan holding companies that have total consolidated assets of more than $10 billion, and state member banks that have total consolidated assets of more than $10 billion are all required to conduct annual company-run stress tests under the Dodd-Frank Act.[5]

A. Overview of Proposed Changes

On July 17, 2015, the Board issued a proposal to make targeted adjustments to the Board's capital plan and stress test rules for the 2016 capital plan and stress test cycles.[6] For bank holding companies with total consolidated assets of more than $10 billion but less than $50 billion and savings and loan holding companies that have total consolidated assets of more than $10 billion, the proposal would have modified certain mandatory capital action assumptions under the stress test rules and delayed the application of the company-run stress test requirements to these savings and loan holding companies until January 1, 2017. For large bank holding companies and state member banks that are subject to the Board's advanced approaches capital requirements, the proposal would have delayed the use in capital planning and stress testing of the supplementary leverage ratio for one year and deferred the use of the advanced approaches risk-based capital framework indefinitely. For large bank holding companies, the proposal would have removed the tier 1 common capital ratio requirement; and

[1] The changes in this final rule will apply to any nonbank financial company supervised by the Board that become subject to the capital planning and stress test requirements. The changes also will apply to U.S. intermediate holding companies of foreign banking organizations in accordance with the transition provisions of the final rule adopting enhanced prudential standards for U.S. bank holding companies and foreign banking organizations with total consolidated assets of $50 billion or more. (79 FR 17240 (March 27, 2014)). In the interest of brevity, references to ''large bank holding companies'' in the preamble should be read to include all of these companies.

[2] 12 U.S.C. 5365(i).

[3] 12 CFR 225.8(f)(2)(iv).

[4] *See* 12 U.S.C. 5365(i)(1) and 12 CFR part 252.

[5] 77 FR 62378 (October 12, 2012) (codified at 12 CFR part 252, subparts E and F). The stress test requirements apply to savings and loan holding companies that are subject to the minimum regulatory capital requirements in 12 CFR part 217. The Board has not applied capital requirements to savings and loan holding companies that are substantially engaged in commercial activities or insurance underwriting activities to date.

[6] 80 FR 43637 (July 23, 2015).

modified certain mandatory capital action assumptions under the stress test rules. The proposal also would have revised the capital plan and stress test rules to clarify the requirement that banking organizations take into account deductions required by 12 CFR 248.12(d) (the Volcker Rule) in calculating their capital ratios.

The Board received five comments on the proposal from banking organizations and trade associations. Commenters generally expressed support for the proposal and also recommended certain additional changes to the capital plan and stress test framework that were not included in the proposal. This preamble provides a summary of comments received on the proposal and the Board's responses to those comments. With respect to the comments that fell outside of the scope of the targeted proposal, the Board will consider these comments if it makes changes to its overall capital plan and stress testing framework in the future.[7]

Section II of the preamble describes revisions to the stress test rules for bank holding companies that have total consolidated assets between $10 billion and $50 billion and savings and loan holding companies that have total consolidated assets of more than $10 billion. Section III of the preamble describes revisions to the capital plan and stress test rules for large bank holding companies and state member banks that are subject to the Board's advanced approaches capital requirements. Section IV of the preamble describes revisions to the capital plan and stress test rules for large bank holding companies. Section V of the preamble describes technical amendments to the capital plan and stress test rules.

B. Interaction of the Capital Plan and Stress Test Rules With the Regulatory Capital Rules

The proposal stated that the Board was considering a broad range of issues relating to the capital plan and stress test rules, including how the rules interact with other elements of the regulatory capital rule and whether any modifications may be appropriate.[8] The proposal also stated that the Board did not anticipate proposing further changes that would affect the 2016 capital plan and stress test cycle.

The capital plan rule requires companies to assume that capital actions planned in baseline conditions will be executed throughout the adverse and severely adverse supervisory scenarios. While the proposal did not include changes to this requirement, commenters nevertheless provided views on it. In particular, commenters argued that this requirement does not reflect bank holding companies' internal capital management policies, and noted that the Board has supervisory authority to require banks to preserve capital in times of stress. In addition, commenters asserted that the assumption that planned capital distributions would be made in times of stress would be inconsistent with restrictions on capital distributions and certain discretionary bonus payments imposed by the regulatory capital rule's capital conservation buffer. Commenters recommended that the Board revise its approach to capital action assumptions before the next stress test and capital plan cycle in light of the phase-in of the capital conservation buffer. In addition, several commenters expressed the view that large bank holding companies' capital plans should continue to be evaluated with regard to only minimum regulatory capital requirements. The commenters stated that such firms should not be evaluated against post-stress requirements that are increased by the amount of the capital conservation buffer or the risk-based capital surcharge for global systemically important bank holding companies (GSIB surcharge).

In its assessment of a large bank holding company's capital plan, the Federal Reserve generally makes conservative assumptions to account for uncertainty in the timing and nature of losses that a large bank holding company may experience under stress. During a financial crisis, losses tend to occur suddenly and unpredictably. Because of this, the Federal Reserve requires large bank holding companies to assume that they continue to make capital distributions—even during a period of financial stress—until losses are unavoidable or realized. This assumption helps to ensure that a large bank holding company would remain sufficiently capitalized even if the timing of the losses were different or more sudden than those projected in the severely adverse scenario.

With regard to the capital conservation buffer, the Board continues to assess how and to what extent, if any, to incorporate it into the capital plan and stress test rules. As noted, the conservative assumptions in the capital plan and stress test rules, such as the assumption that large bank holding companies will not cut dividends in a stress period, help to promote greater resiliency, and incorporating the capital conservation buffer into the rules in a mechanical manner could work at cross purposes with the goal of greater resiliency.

II. Revisions to Stress Test Rules for Bank Holding Companies With Total Consolidated Assets Between $10 Billion and $50 Billion, and Savings and Loan Holding Companies With Total Consolidated Assets of More Than $10 Billion

A. Modification of Mandatory Dividend Assumptions

Since they were first adopted in 2012, the stress test rules have required bank holding companies and savings and loan holding companies to assume that they continue to pay dividends at their current rate and issue no capital (other than that related to expensed employee compensation) and redeem no capital instruments in the second through ninth quarters of the planning horizon. The proposed rule would have eliminated the requirement that bank holding companies that have total consolidated assets between $10 billion and $50 billion and savings and loan holding companies that have total consolidated assets of more than $10 billion use fixed assumptions regarding dividends in their stress tests.[9] These bank holding companies and savings and loan holding companies instead would have been required to incorporate reasonable assumptions regarding payments of dividends consistent with internal capital needs and projections.

This aspect of the proposal was intended to be responsive to concerns raised by banking organizations that dividends paid at the holding company level are often funded directly through a subsidiary bank's capital distributions to the holding company. Subsidiary banks may be subject to dividend restrictions, which would impair the funding of the holding company's dividends, and in such cases the assumptions required under the stress test rules would be inconsistent with the bank holding company's actual dividend capacity. Commenters generally supported the removal of fixed dividend assumptions in the stress testing requirements for these firms. After considering the comments, the Board is finalizing the revision as proposed.

Commenters separately requested that the Board eliminate the fixed dividend

[7] See section VI of this preamble, which addresses comments that fell outside of the scope of the proposal.

[8] 12 CFR part 217.

[9] The proposed rule and final rule maintain the mandatory assumptions relating to the redemption or repurchase of any regulatory capital instrument that is eligible for inclusion in the numerator of a regulatory capital ratio.

assumptions for large bank holding companies. Commenters argued that large bank holding companies also rely on their subsidiary banks to fund dividends at the holding company level. Several commenters asserted that this revision for large bank holding companies would make the dividend payment assumptions more realistic and would result in stress tests that more closely reflect large bank holding companies' internal policies and practices.

Unlike bank holding companies with total consolidated assets between $10 billion and $50 billion, large bank holding companies are subject to the capital plan rule, and are required to incorporate their planned capital actions in their post-stress capital analysis. Thus, large bank holding companies already incorporate more realistic dividend assumptions into their capital plans. In addition, providing a common set of fixed dividend assumptions in the stress test rule for large bank holding companies supports the goal of comparability in stress test disclosures. Accordingly, the final rule does not eliminate fixed dividend assumptions for large bank holding companies.

B. Modification to the Mandatory Capital Action Issuance Assumptions

The proposed rule would have modified the mandatory capital action assumptions in the stress test rules to permit a bank holding company or savings and loan holding company to assume that it issues capital associated with funding a planned acquisition.[10] Specifically, to the extent that a bank holding company or savings and loan holding company includes a merger or acquisition in its balance sheet projections, it would have been required to reflect any related stock issuance in its stress test.

Commenters supported the proposed revisions to the issuance assumptions in the stress test rules, indicating that they would better align capital action assumptions. After considering the comments, the Board is finalizing these provisions as proposed.

C. Company Run Stress Test Transition Provisions for Certain Savings and Loan Holding Companies

Savings and loan holding companies that have total consolidated assets of more than $10 billion must conduct annual company-run stress tests under the Dodd-Frank Act.[11] Under the Board's stress test rule implementing this requirement, a savings and loan holding company that is subject to the Board's minimum regulatory capital requirements and that has total consolidated assets greater than $10 billion is subject to these requirements. The stress test rules that the Board adopted in October 2012 provided a two-year transition period for these savings and loan holding companies to comply with the stress test requirements. However, the October 2014 revisions to the capital plan and stress test rules (October 2014 revisions) resulted in a shortening of this initial transition period to one year.[12]

The proposed rule would have delayed for one additional stress test cycle the application of the company-run stress test rules to saving and loan holding companies that have total consolidated assets of more than $10 billion, such that these savings and loan holding companies would have become subject to the stress test rules for the first time beginning on January 1, 2017. Accordingly, savings and loan holding companies that have total consolidated assets of more than $50 billion would have reported their stress test results by April 5, 2017, and those that have total consolidated assets of less than $50 billion would have reported results by July 31, 2017.

Commenters supported the proposed delay in the initial application of the stress test requirements for these savings and loan holding companies, and requested that the application of the stress testing requirements to other savings and loan holding companies and nonbank financial companies supervised by the Board be delayed even further. Commenters argued that companies primarily engaged in insurance underwriting activity will need a reasonable amount of time to implement the stress testing requirements after becoming subject to regulatory capital requirements. One commenter suggested a minimum two-year transition period for savings and loan holding companies engaged in insurance underwriting activity and for insurance companies designated as systemically important by the Financial Stability Oversight Council, which are not subject to the stress test rules unless made subject pursuant to a rule or order of the Board.

Consistent with the proposal, under the final rule, savings and loan holding companies that are currently subject to the Board's regulatory capital rules would have an additional year, until 2017, to conduct their first stress test. Savings and loan holding companies that are not subject to the Board's regulatory capital rules will not be required to conduct their first stress test until after they become subject to the regulatory capital rules and thus should have adequate time to develop the systems necessary to conduct stress testing. With respect to nonbank financial companies supervised by the Board that are engaged in insurance activities, the Board will continue to monitor and assess their activities and would consider these activities, as well as their risk profile, in considering whether to apply the stress test rules to such companies by rule or order.

III. Revisions to the Capital Plan and Stress Test Rules for Large Bank Holding Companies and State Member Banks Subject to the Advanced Approaches

The changes relating to the use of the supplementary leverage ratio and the advance approaches only apply to bank holding companies and state member banks that are subject to the advanced approaches risk-based capital framework, as well as any savings and loan holding company that becomes subject to the advanced approaches in the future.

A. Delay of Inclusion of the Supplementary Leverage Ratio Requirement

The supplementary leverage ratio requirement in the Board's capital rules applies to large bank holding companies and state member banks that are subject to the advanced approaches risk-based capital framework.[13] For these banking organizations, the proposed rule would have delayed the incorporation of the supplementary leverage ratio requirement into the capital plan and stress test rules for one year, until 2017.

Commenters were generally supportive of delaying the incorporation of the supplementary leverage ratio requirement until 2017, and noted that this provision would allow banking organizations time to develop the systems necessary to project the supplementary leverage ratio under

[10] While the preamble did not address this change, the proposed regulatory text applied this change to all holding companies.

[11] Currently, savings and loan holding companies are not subject to the Board's capital plan rule or supervisory stress tests, regardless of size.

[12] 79 FR 64026 (October 27, 2014).

[13] Banking organizations that are subject to the advanced approaches risk-based capital framework are banking organizations with total consolidated assets of $250 billion or more, that have total consolidated on-balance sheet foreign exposure of $10 billion or more, are a subsidiary of a depository institution that uses the advanced risk-based capital approaches framework, or that elect to use the advanced risk-based capital approaches framework. *See* 12 CFR part 217, subpart E.

stressed conditions. One commenter argued that the supplementary leverage ratio requirement should be excluded indefinitely from the capital plan and stress test rules. The commenter asserted that the supplementary leverage ratio was intended to be a backstop to the Board's risk-based capital rule, and expressed concern that it could become a binding constraint on regulatory capital if included in the capital plan and stress test requirements. The commenter noted that a binding supplementary leverage ratio may distort firms' incentives with respect to risk-taking because it does not reflect the level of risk associated with particular assets in determining capital requirements, and could compromise other regulatory initiatives, such as the liquidity coverage ratio and margin requirements.

Notwithstanding these arguments, a post-stress leverage ratio requirement has been a requirement in the stress test and capital plan rules since their inception. The leverage ratio requirement continues to serve as an important backstop as it guards against possible weaknesses in the risk-based capital requirements, such as the possibility of understating the risk of certain assets. The addition of the supplementary leverage ratio requirement in the capital plan and stress test rules will further strengthen this backstop function as it will include a measure of off-balance sheet exposures in addition to all on-balance sheet items. Accordingly, the final rule retains the one-year delay in implementation of the supplementary leverage ratio for purposes of capital planning and stress testing. The Federal Reserve will continue to monitor the amount of capital required under both the risk-based and leverage ratios in CCAR and under the related stress tests.

B. Deferral of Use of the Advanced Approaches

The proposed rule would have deferred indefinitely the use of the advanced approaches for calculating risk-based capital ratios under the capital plan and stress test rules. Thus, large bank holding companies and state member banks that are subject to the advanced approaches risk-based capital framework would have been required to project risk-weighted assets using only the standardized approach until such time as the Board requires the use of advanced approaches in stress testing and capital planning. The Board proposed this revision in light of banking organizations' concerns that the use of advanced approaches in the capital plan and stress test rules would require significant resources and would introduce complexity and opacity without a clear prudential benefit.

Commenters supported the proposed revision to delay the use of advanced approaches until further notice. After reviewing these comments, the Board is finalizing this revision as proposed.

IV. Revisions to the Capital Plan and Stress Test Rules for Large Bank Holding Companies

A. Elimination of the Tier 1 Common Capital Ratio Requirement

The proposed rule would have removed the requirement that a large bank holding company demonstrate its ability to maintain a pro forma tier 1 common capital ratio of five percent of risk-weighted assets under expected and stressed scenarios. The Board introduced the tier 1 common capital ratio requirement in 2009 as part of the Supervisory Capital Assessment Program to assess the level of high-quality, loss-absorbing capital held at the largest U.S. bank holding companies.[14] At that time, the Board noted that it expected the tier 1 common capital ratio requirement to remain in force until the Board adopted a minimum common equity capital requirement.[15] In 2013, the Board revised its regulatory capital rules to strengthen the quality and quantity of regulatory capital held by banking organizations and, introduced a minimum common equity tier 1 capital requirement of 4.5 percent of risk-weighted assets.[16]

Nearly all commenters expressed support for the proposed removal of the tier 1 common capital ratio requirement from the capital plan and stress test rules. The Board agrees with commenters that removing the tier 1 common capital ratio requirement at this time is appropriate in light of the implementation in the regulatory capital rules of the minimum common equity tier 1 capital requirement equal to 4.5 percent of risk-weighted assets, effective on January 1, 2015.[17]

The regulatory capital rule's required adjustments and deductions from common equity tier 1 capital will be fully phased in by January 1, 2018, which is the ninth quarter of the planning horizon of the capital plan and stress test cycle that begins on January 1, 2016.[18] Due to the implementation of these mandatory adjustments and deductions, the minimum common equity tier 1 capital requirement is generally expected to require more capital than the current tier 1 common capital ratio requirement in forthcoming stress test and capital plan cycles. Further, removing the tier 1 common capital ratio requirement would reduce the burden on large bank holding companies by no longer requiring them to maintain legacy systems and processes necessary for calculating the tier 1 common capital ratio requirement. The Board is therefore finalizing the provision as proposed.

B. Modification of Certain Mandatory Capital Action Assumptions

As noted above, the stress test rules require large bank holding companies to assume that they continue to pay dividends at their current rate, issue no capital (other than that related to expensed employee compensation), and redeem no capital instruments in the second through ninth quarters of the planning horizon. These assumptions were designed to ensure that the publicly disclosed results of company run stress tests would be comparable across institutions, and to reflect common macroeconomic scenarios on firms' net income and capital rather than company-specific assumptions about capital issuances and redemptions.

The proposal would have included two modifications to these capital action assumptions. First, it would have required a large bank holding company to assume it issues capital associated with funding a planned merger or acquisition. Under the proposal, to the extent that a large bank holding company is required to include an acquisition in its balance sheet projections, the large bank holding company would have been required to include any stock issuance associated with funding the acquisition in its stress test. Second, the proposal would have modified dividend assumptions in the stress test rules to require large bank holding companies to reflect dividends associated with expensed employee compensation. Specifically, the proposal would have required a firm to assume that it pays planned dividends on any issuance of stock related to expensed employee compensation.

[14] *See* ''The Supervisory Capital Assessment Program: Overview of Results,'' May 7, 2009, available at *http://www.federalreserve.gov/newsevents/press/bcreg/bcreg20090507a1.pdf.*

[15] *Id.*

[16] The Board and the OCC issued a joint final rule on October 11, 2013 (78 FR 62018), and the FDIC issued a substantially identical interim final rule on September 10, 2013 (78 FR 55340). In April 2014, the FDIC adopted the interim final rule as a final rule with no substantive changes. 79 FR 20754 (April 14, 2014).

[17] *Id.*

[18] *Id.*

Commenters supported the proposed revisions to the dividend and issuance assumptions in the stress test rules. Commenters indicated that these changes would better align capital action assumptions with business plan changes required when a banking organization is considering an acquisition and would enhance the efficiency of the stress test process.

While not included in the proposal, to remain consistent with the treatment of dividends related to expensed employee compensation discussed above, the final rule also requires a large bank holding company to assume that it pays planned dividends on any issuance of stock related to the funding of a planned merger or acquisition to the extent that the company is required to include such merger or acquisition in its balance sheet projections.

The modification to the capital action assumptions in the stress test rules regarding dividends and issuances associated with business plan changes is in keeping with the general principle that stress tests should capture the expected impact to both assets and capital related to business plan changes. For example, the capital action assumptions allow a company to include planned issuances of stock associated with expensed employee compensation. This is because expensed employee compensation will appear as an expense, thus the company should also receive recognition for a related issuance of capital.

V. Technical Amendments to the Capital Plan and Stress Test Rules

The proposed rule included amendments to the capital plan and stress test rules to incorporate changes related to other rulemakings. The proposed rule would have removed references to the risk-based capital rules in Regulation Y (12 CFR part 225) that were no longer operative. In addition, the proposal would have amended the definition of minimum regulatory capital ratio in 12 CFR 225.8(d)(8) and the definition of regulatory capital ratio in 12 CFR 252.12(n), 12 CFR 252.42(m), and 12 CFR 252.52(n) to incorporate the deductions required under 12 CFR 248.12(d) (the Volcker Rule). Although the Volcker Rule requires a banking organization to deduct from tier 1 capital its aggregate investments in covered funds (as defined in 12 CFR. 248.10(b)), these required deductions are not, however, reflected in Regulation Q (12 CFR part 217). Accordingly, the proposed rule would have revised the regulatory text of the above-referenced definitions to include the required deductions under the Volcker Rule in the definition of regulatory capital ratio and minimum regulatory capital ratio.

Commenters expressed that the view that incorporating the Volcker Rule deductions into the capital plan and stress test rules was premature. At least one commenter argued that in issuing the proposed rule, the Board interpreted the Volcker deductions without the consensus of the other U.S. banking agencies, and that these interpretations could have implications for the broader industry beyond the institutions covered by the stress test and capital plan rules. These commenters requested that the Board delay incorporating deductions associated with the Volcker Rule in the capital plan and stress test rules until the U.S. banking agencies provide guidance regarding the operation and calculation of the deduction for purposes of the regulatory capital framework, subject to proper notice and comment.

The proposed modifications to the capital plan and stress test rules would not establish new expectations or requirements regarding the interaction between the Volcker Rule and the regulatory capital framework. The Board has provided additional guidance to bank holding companies on how to reflect Volcker deductions in their pro forma regulatory capital ratios under the stress test and capital plan rules.[19] Thus, the Board is finalizing these two aspects of the proposal, specifically, the deletion of references to Regulation Y and incorporation of deductions from capital required under the Volcker Rule, without change.

VI. Other Comments Received on the Proposal

A. Regulatory Burden and Transparency

Commenters encouraged the Board to continue efforts to increase transparency and understanding of the capital plan and stress test processes. In particular, commenters noted that in recent years, greater emphasis has been placed on qualitative factors in capital plan and stress test assessments and thus requested that the Board provide more information regarding the qualitative factors that are used to evaluate a firm's capital plan. These commenters requested that the Board provide instructions and scenarios as early as possible to facilitate a more robust capital planning process. A commenter noted that the Board's ''Capital Planning at Large Bank Holding Companies: Supervisory Expectations and Range of Current Practice'' document issued in August 2013 was extremely useful and requested that it be updated annually to aid large bank holding companies in improving their capital planning processes and preparing their annual capital plans. One commenter also supported efforts by the Board to review the regulatory burden placed on financial institutions as a result of the establishment of Dodd-Frank Act regulations.

The Board continues to seek ways to improve its capital plan and stress test framework, including by taking into consideration industry feedback. For instance, last year, the Board adjusted the timeframe for the annual capital plan and stress test exercise in order to address resource constraints for banking organizations near the end of the year. This final rule also includes several changes that are responsive to public comments, including removal of the tier 1 common ratio and deferral of the supplementary leverage ratio for one year.

B. Uniform Tax Rate Assumption

For purposes of the stress test and capital plan rules, the Board applies a uniform tax rate to project after-tax net income for all bank holding companies. One commenter raised the concern that this assumption could have a material impact on after-tax income, and accordingly, on capital positions and the Board's assessment decision of whether to object to a capital plan. The commenter further noted that there are a number of circumstances where a simplifying tax assumption could materially understate capital, and requested that the Board use the tax calculations prepared by the bank holding company in accordance with Generally Accepted Accounting Principles as a starting point for supervisory tax projections. The commenter also requested that the Board should only apply the common tax rate to the marginal pre-tax net income (loss) and pre-tax other comprehensive income that exceeds the firm's projections. As an alternative, the commenter suggested that additional tax information be collected in the annual submissions to inform the Board's tax calculations.

The use of a common supervisory tax rate supports the consistent application of assumptions and models across firms. Accordingly, the final rule does not alter the assumption of a common supervisory tax rate.

[19] *See* Supervision and Regulation Letter SR 15–13 (November 6, 2015), available at: *https://fedweb.frb.gov/fedweb/bsr/srltrs/sr1513.pdf.*

VII. Administrative Law Matters

a. Riegle Act

Section 302 of the Riegle Community Development and Regulatory Improvement Act of 1994 (Riegle Act) requires a federal banking agency to consider the benefits and any administrative burdens that new regulations and amendments to regulations prescribed by a federal banking agency that impose additional reporting, disclosures, or other new requirements on an insured depository institution, and, subject to certain exceptions, provides that such regulations shall take effect on the first day of a calendar quarter which begins on or after the date on which the regulations are published in final form.[20] As noted, the final rule clarifies the interaction between the Volcker Rule and the regulatory capital framework but does not impose new requirements in this regard. In addition, the delay of the use of the supplementary leverage ratio and of the advanced approaches risk-based capital framework generally reduce burden on state member banks that are subject to the advanced approaches. Accordingly, the final rule does not impose any additional reporting or disclosure requirements on state member banks. In addition, consistent with Section 302 of the Riegle Act, the requirements in the final rule will take effect on the first day of a calendar quarter after the date on which the final rule is published in final form.

b. Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), the Board may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The Board reviewed this final rule under the authority delegated to the Board by the OMB and determined that it contains no collections of information. No public comments on the PRA were received when the proposed rule was published.

c. Regulatory Flexibility Act Analysis

The Board has considered the potential impact of the final rule on small companies in accordance with the Regulatory Flexibility Act (5 U.S.C. 603(b)). Based on its analysis and for the reasons stated below, the Board believes that the final rule will not have a significant economic impact on a substantial number of small entities. Nevertheless, the Board is publishing a final regulatory flexibility analysis.

Under regulations issued by the Small Business Administration (''SBA''), a small entity includes a depository institution, bank holding company, or savings and loan holding company with total assets of $550 million or less (a small banking organization).[21] The final rule will apply to bank holding companies, savings and loan holding companies, and state member banks with total consolidated assets of $10 billion or more. Companies that will be subject to the final rule therefore substantially exceed the $550 million total asset threshold at which a company is considered a small company under SBA regulations. In light of the foregoing, the Board does not believe that the final rule will have a significant economic impact on a substantial number of small entities.

d. Solicitation of Comments on Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act (Pub. L. 106–102, 113 Stat. 1338, 1471, 12 U.S.C. 4809) requires the federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. The Board sought to present the proposed rule in a simple and straightforward manner and solicited comment on how to make the proposed rule easier to understand. No comments were received on the use of plain language.

List of Subjects

12 CFR Part 225

Administrative practice and procedure, Banks, Banking, Capital planning, Holding companies, Reporting and recordkeeping requirements, Securities, Stress testing.

12 CFR Part 252

Administrative practice and procedure, Banks, Banking, Capital planning, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements, Securities, Stress testing.

Authority and Issuance

For the reasons stated in the **SUPPLEMENTARY INFORMATION**, the Board of Governors of the Federal Reserve System amends 12 CFR chapter II as follows:

[20] 12 U.S.C. 4802.

[21] *See* 13 CFR 121.201. Effective July 14, 2014, the SBA revised the size standards for banking organizations to $550 million in assets from $500 million in assets. 79 FR 33647 (June 12, 2014).

PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL (REGULATION Y)

■ 1. The authority citation for part 225 is revised to read as follows:

Authority: 12 U.S.C. 1817(j)(13), 1818, 1828(o), 1831i, 1831p–1, 1843(c)(8), 1844(b), 1972(1), 3106, 3108, 3310, 3331–3351, 3906, 3907, and 3909; 15 U.S.C. 1681s, 1681w, 6801 and 6805.

Subpart A—General Provisions

■ 2. Section 225.8 is amended by:
■ a. Revising paragraphs (c)(3) and (d)(8) and (11);
■ b. Removing paragraphs (d)(12) and (13);
■ c. Redesignating paragraph (d)(14) as paragraph (d)(12);
■ d. Removing and reserving paragraph (e)(2)(i)(B); and
■ e. Revising paragraphs (e)(2)(ii)(A), (f)(1)(i)(C), (f)(2)(ii)(C), and (g)(1)(i).

The revisions read as follows:

§ 225.8 Capital planning.

* * * * *

(c) * * *

(3) *Transition periods for bank holding companies subject to the supplementary leverage ratio.* Notwithstanding paragraph (d)(8) of this section, only for purposes of the capital plan cycle beginning on January 1, 2016, a bank holding company shall not include an estimate of its supplementary leverage ratio.

(d) * * *

(8) *Minimum regulatory capital ratio* means any minimum regulatory capital ratio that the Federal Reserve may require of a bank holding company, by regulation or order, including the bank holding company's tier 1 and supplementary leverage ratios as calculated under 12 CFR part 217, including the deductions required under 12 CFR 248.12, as applicable, and the bank holding company's common equity tier 1, tier 1, and total risk-based capital ratios as calculated under 12 CFR part 217, including the deductions required under 12 CFR 248.12 and the transition provisions at 12 CFR 217.1(f)(4) and 217.300; except that the bank holding company shall not use the advanced approaches to calculate its regulatory capital ratios.

* * * * *

(11) *Tier 1 capital* has the same meaning as under 12 CFR part 217.

* * * * *

(e) * * *

(2) * * *

(i) * * *

(B) [Reserved]

* * * * *

(ii) * * *

(A) A discussion of how the bank holding company will, under expected and stressful conditions, maintain capital commensurate with its risks, maintain capital above the minimum regulatory capital ratios, and serve as a source of strength to its subsidiary depository institutions;

* * * * *

(f) * * *

(1) * * *

(i) * * *

(C) The bank holding company's ability to maintain capital above each minimum regulatory capital ratio on a pro forma basis under expected and stressful conditions throughout the planning horizon, including but not limited to any scenarios required under paragraphs (e)(2)(i)(A) and (e)(2)(ii) of this section.

* * * * *

(2) * * *

(ii) * * *

(C) The bank holding company has not demonstrated an ability to maintain capital above each minimum regulatory capital ratio on a pro forma basis under expected and stressful conditions throughout the planning horizon; or

* * * * *

(g) * * *

(1) * * *

(i) After giving effect to the capital distribution, the bank holding company would not meet a minimum regulatory capital ratio;

* * * * *

PART 252—ENHANCED PRUDENTIAL STANDARDS (REGULATION YY)

■ 3. The authority citation for part 252 continues to read as follows:

Authority: 12 U.S.C. 321–338a, 1467a(g), 1818, 1831p–1, 1844(b), 1844(c), 5361, 5365, 5366.

■ 4. Section 252.12 is amended by revising paragraph (n) to read as follows:

§ 252.12 Definitions.

* * * * *

(n) *Regulatory capital ratio* means a capital ratio for which the Board established minimum requirements for the company by regulation or order, including a company's tier 1 and supplementary leverage ratio as calculated under 12 CFR part 217, including the deductions required under 12 CFR 248.12, as applicable, and the company's common equity tier 1, tier 1, and total risk-based capital ratios as calculated under 12 CFR part 217, including the deductions required under 12 CFR 248.12 and the transition provisions at 12 CFR 217.1(f)(4) and 217.300; except that the company shall not use the advanced approaches to calculate its regulatory capital ratios.

* * * * *

■ 5. Section 252.13 is amended by revising paragraphs (b)(2) and (3) to read as follows:

§ 252.13 Applicability.

* * * * *

(b) * * *

(2) *Transition period for savings and loan holding companies.* (i) A savings and loan holding company that is subject to minimum regulatory capital requirements and exceeds the asset threshold for the first time on or before March 31 of a given year, must comply with the requirements of this subpart beginning on January 1 of the following year, unless that time is extended by the Board in writing;

(ii) A savings and loan holding company that is subject to minimum regulatory capital requirements and exceeds the asset threshold for the first time after March 31 of a given year must comply with the requirements of this subpart beginning on January 1 of the second year following that given year, unless that time is extended by the Board in writing; and

(iii) Notwithstanding paragraph (b)(2)(i) of this section, a savings and loan holding company that is subject to minimum regulatory capital requirements and exceeded the asset threshold for the first time on or before March 31, 2015, must comply with the requirements of this subpart beginning on January 1, 2017, unless that time is extended by the Board in writing.

(3) *Transition periods for companies subject to the supplementary leverage ratio.* Notwithstanding § 252.12(n), for purposes of the stress test cycle beginning on January 1, 2016, a company shall not include an estimate of its supplementary leverage ratio.

■ 6. Section 252.15 is amended by revising paragraph (b)(2) to read as follows:

§ 252.15 Methodologies and practices.

* * * * *

(b) * * *

(2) For each of the second through ninth quarters of the planning horizon, the bank holding company or savings and loan holding company must:

(i) Assume no redemption or repurchase of any capital instrument that is eligible for inclusion in the numerator of a regulatory capital ratio;

(ii) Assume no issuances of common stock or preferred stock, except for issuances related to expensed employee compensation or in connection with a planned merger or acquisition to the extent that the merger or acquisition is reflected in the company's pro forma balance sheet estimates; and

(iii) Make reasonable assumptions regarding payments of dividends consistent with internal capital needs and projections.

* * * * *

■ 7. Section 252.42 is amended by:

■ a. Revising paragraph (m); and

■ b. Removing paragraph (r).

The revision reads as follows:

§ 252.42 Definitions.

* * * * *

(m) *Regulatory capital ratio* means a capital ratio for which the Board established minimum requirements for the company by regulation or order, including the company's tier 1 and supplementary leverage ratios as calculated under 12 CFR part 217, including the deductions required under 12 CFR 248.12, as applicable, and the company's common equity tier 1, tier 1, and total risk-based capital ratios as calculated under 12 CFR part 217, including the deductions required under 12 CFR 248.12 and the transition provisions at 12 CFR 217.1(f)(4) and 217.300; except that the company shall not use the advanced approaches to calculate its regulatory capital ratios.

* * * * *

■ 8. Section 252.43 is amended by revising paragraph (c) to read as follows:

§ 252.43 Applicability.

* * * * *

(c) *Transition periods for covered companies subject to the supplementary leverage ratio.* Notwithstanding § 252.42(m), only for purposes of the stress test cycle beginning on January 1, 2016, the Board will not include an estimate of a covered company's supplementary leverage ratio.

■ 9. Section 252.44 is amended by revising paragraph (a)(2) to read as follows:

§ 252.44 Annual analysis conducted by the Board.

(a) * * *

(2) The analysis will include an assessment of the projected losses, net income, and pro forma capital levels and regulatory capital ratios and other capital ratios for the covered company and use such analytical techniques that the Board determines are appropriate to identify, measure, and monitor risks of the covered company that may affect the financial stability of the United States.

* * * * *

■ 10. Section 252.45 is amended by revising paragraph (b)(2) to read as follows:

§ 252.45 Data and information required to be submitted in support of the Board's analyses.

* * * * *

(b) * * *

(2) Project a company's pre-provision net revenue, losses, provision for loan and lease losses, and net income; and pro forma capital levels, regulatory capital ratios, and any other capital ratio specified by the Board under the scenarios described in § 252.44(b).

* * * * *

■ 11. Section 252.52 is amended by:

■ a. Revising paragraph (n); and

■ b. removing paragraph (t).

The revision reads as follows:

§ 252.52 Definitions.

* * * * *

(n) *Regulatory capital ratio* means a capital ratio for which the Board established minimum requirements for the company by regulation or order, including the company's tier 1 and supplementary leverage ratios as calculated under 12 CFR part 217, including the deductions required under 12 CFR 248.12, as applicable, and the company's common equity tier 1, tier 1, and total risk-based capital ratios as calculated under 12 CFR part 217, including the deductions required under 12 CFR 248.12 and the transition provisions at 12 CFR 217.1(f)(4) and 217.300; except that the company shall not use the advanced approaches to calculate its regulatory capital ratios.

* * * * *

■ 12. Section 252.53 is amended by revising paragraph (b)(3) to read as follows:

§ 252.53 Applicability.

* * * * *

(b) * * *

(3) *Transition periods for covered companies subject to the supplementary leverage ratio.* Notwithstanding § 252.52(n), only for purposes of the stress test cycle beginning on January 1, 2016, a bank holding company shall not include an estimate of its supplementary leverage ratio.

■ 13. Section 252.56 is amended by revising paragraphs (a)(2), (b)(2)(i), and (b)(2)(iv) to read as follows:

§ 252.56 Methodologies and practices.

(a) * * *

(2) The potential impact on pro forma regulatory capital levels and pro forma capital ratios (including regulatory capital ratios and any other capital ratios specified by the Board), incorporating the effects of any capital actions over the planning horizon and maintenance of an allowance for loan losses appropriate for credit exposures throughout the planning horizon.

(b) * * *

(2) * * *

(i) Common stock dividends equal to the quarterly average dollar amount of common stock dividends that the company paid in the previous year (that is, the first quarter of the planning horizon and the preceding three calendar quarters) plus common stock dividends attributable to issuances related to expensed employee compensation or in connection with a planned merger or acquisition to the extent that the merger or acquisition is reflected in the covered company's pro forma balance sheet estimates;

* * * * *

(iv) An assumption of no issuances of common stock or preferred stock, except for issuances related to expensed employee compensation or in connection with a planned merger or acquisition to the extent that the merger or acquisition is reflected in the covered company's pro forma balance sheet estimates.

* * * * *

■ 14. Section 252.58 is amended by revising paragraphs (b)(3)(v), (b)(4), and (c)(2) to read as follows:

§ 252.58 Disclosure of stress test results.

* * * * *

(b) * * *

(3) * * *

(v) Pro forma regulatory capital ratios and any other capital ratios specified by the Board;

(4) An explanation of the most significant causes for the changes in regulatory capital ratios; and

* * * * *

(c) * * *

(2) The disclosure of pro forma regulatory capital ratios and any other capital ratios specified by the Board that is required under paragraph (b) of this section must include the beginning value, ending value, and minimum value of each ratio over the planning horizon.

By order of the Board of Governors of the Federal Reserve System, November 25, 2015.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2015–30471 Filed 12–1–15; 8:45 am]

BILLING CODE P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0681; FRL–9934–60]

Etoxazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of etoxazole in or on orange and orange oil. Sumitomo Chemical Latin America through Valent USA Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 2, 2015. Objections and requests for hearings must be received on or before February 1, 2016, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2014–0681, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

applies to them. Potentially affected entities may include:

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2014–0681 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 1, 2016. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2014–0681, by one of the following methods:

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

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

II. Summary of Petitioned-for Tolerance

In the **Federal Register** of March 4, 2015 (80 FR 11611) (FRL–9922–68), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E8304) by Sumitomo Chemical Latin America through Valent USA Corporation, 1600 Riviera Avenue, Suite 200, Walnut Creek, CA 94596. The petition requested that 40 CFR 180.593 be amended by establishing tolerances for residues of the insecticide etoxazole (2-(2,6-difluorophenyl)-4-[4-(1,1-dimethylethyl)-2-ethoxyphenyl]-4,5dihydrooxazole), in or on orange and orange oil at 0.08 and 1.8 parts per million (ppm), respectively. That document referenced a summary of the petition prepared by Valent USA Corporation on behalf of Sumitomo Chemical Latin America, the registrant, which is available in the docket, *http://www.regulations.gov.*

EPA received one comment to the Notice of Filing concerning another chemical (azoxystrobin) and not etoxazole. The commenter stated, in part, that zero residues should be allowed for pesticide residues. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the FFDCA states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

Based upon review of the data supporting the petition, EPA has revised the petitioned-for tolerance levels of 0.08 and 1.8 ppm for orange and orange, oil to 0.10 and 1.0 ppm, respectively. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

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

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The effects in the etoxazole database show liver toxicity in all species tested (enzyme release, hepatocellular swelling, and histopathological indicators), and the severity does not appear to increase with time. In rats only, there were effects on incisors (elongation, whitening, and partial loss of upper and/or lower incisors). There is no evidence of neurotoxicity or immunotoxicity. No toxicity was seen at the limit dose in a 28-day dermal toxicity study in rats. Etoxazole was not mutagenic. No increased quantitative or qualitative susceptibilities were observed following *in utero* exposure to

rats or rabbits in the developmental studies; however, offspring toxicity was more severe (increased pup mortality) than maternal toxicity (increased liver and adrenal weights) at the same dose (158.7 milligram/kilogram/day (mg/kg/day)) in the rat reproduction study indicating increased qualitative susceptibility. Etoxazole is not likely to be carcinogenic based on the lack of carcinogenicity effects in the database.

Specific information on the studies received and the nature of the adverse effects caused by etoxazole as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document, ''Etoxazole: Human Health Risk Assessment in Support of the Proposed Tolerances for Residues in/on Imported Oranges and Orange Oil'' at pp. 16–18 in docket ID number EPA–HQ–OPP–2014–0681.

B. Toxicological Points of Departure/Levels of Concern

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

A summary of the toxicological endpoints for etoxazole used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR ETOXAZOLE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (all populations) ..	N/A	N/A	A dose and endpoint attributable to a single dose were not identified in the database including the hazard database. An acute dietary assessment was not performed.
Chronic dietary (all populations)	NOAEL = 4.62 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.046 mg/kg/day cPAD = 0.046 mg/kg/day	Chronic Oral Toxicity Study—Dog. LOAEL = 23.5 mg/kg/day based upon increased alkaline phosphatase activity, increased liver weights, liver enlargement (females), and incidences of centrilobular hepatocellular swelling in the liver.
Cancer (Oral, dermal, inhalation).	EPA classified etoxazole as ''not likely to be carcinogenic to humans.		

Point of departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no-observed adverse-effect level. LOAEL = lowest-observed adverse-effect level. UF = uncertainty factor. UFA = extrapolation from animal to human (interspecies). UFH = potential variation in sensitivity among members of the human population (intraspecies). Food Quality Protection Act Safety Factor = FQPA SF. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. N/A = not applicable.

Since the current proposal pertains to an import tolerance (no occupational exposure for workers in the U.S.) and since residential exposure is not anticipated from the proposed/registered uses, only dietary toxicological endpoints are listed in Table 1.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to etoxazole, EPA considered exposure under the petitioned-for tolerances as well as all existing etoxazole tolerances in 40 CFR 180.593. EPA assessed dietary exposures from etoxazole in food as follows:

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

No such effects were identified in the toxicological studies for etoxazole; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA; 2003–2008). As to residue levels in food, EPA assumed tolerance-level residues, 100% crop treated (PCT), and in the absence of empirical data, DEEM (ver 7.81) default processing factors. In addition, based on EPA's conclusion that etoxazole has a high potential to bioaccumulate, residue estimates for fish/shellfish were included.

iii. *Cancer.* EPA classified etoxazole as ''not likely to be carcinogenic to humans''. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

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

2. *Dietary exposure from drinking water.* Although the orange and orange, oil tolerances will not result in residues in drinking water, as those uses are not

associated with a U.S. registration, the Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment to assess etoxazole in drinking water resulting from existing U.S. registrations. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of etoxazole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the First Index Reservoir Screening Tool (FIRST), and Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), the estimated drinking water concentrations (EDWCs) of etoxazole for chronic exposures for non-cancer assessments are estimated to be 4.761 parts per billion (ppb) for surface water and <0.1 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For chronic dietary risk assessment, the water concentration of value 4.761 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Etoxazole is not registered for any specific use patterns that would result in residential exposure.

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

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

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* No increased quantitative or qualitative susceptibilities were observed following in utero exposure to rats or rabbits in the developmental studies. There is evidence of increased qualitative offspring susceptibility in the rat reproduction study, but the concern is low since: (1) The effects in pups are well-characterized with a clear NOAEL; (2) the selected endpoints are protective of the doses where the offspring toxicity is observed; and (3) offspring effects occur in the presence of parental toxicity. There are no residual uncertainties for pre-/post-natal toxicity.

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

i. The toxicity database for etoxazole is complete.

ii. There is no indication that etoxazole is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. The observed qualitative postnatal susceptibility is protected for by the selected endpoints.

iv. There are no residual uncertainties identified in the exposure databases.

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

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, etoxazole is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to etoxazole from food and water will utilize 15% of the cPAD for children 1–2 years old the population group receiving the greatest exposure. There are no residential uses for etoxazole.

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

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology gas chromatography/nitrogen phosphorus detector (GC/NPD) is available to enforce the recommended tolerances.

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

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as

required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for etoxazole in or on citrus fruits at 0.1 ppm. EPA is establishing a tolerance for residues in or on orange of 0.10 ppm in order to harmonize with the Codex MRL.

C. Revisions to Petitioned-For Tolerances

EPA has revised the proposed tolerance levels for orange and orange oil from 0.08 and 1.8 ppm to 0.10 and 1.0 ppm, respectively. EPA is establishing a tolerance of 0.10 ppm for orange in order to harmonize with the Codex MRL. Additionally, based on the orange raw agricultural commodity highest-average field-trial residue of 0.048 ppm and the median orange oil processing factor of 20x, EPA is establishing a tolerance for orange, oil at 1.0 ppm. In addition, EPA is revising the commodity terms for orange oil to read as orange, oil to be consistent with the Agency's commodity vocabulary.

V. Conclusion

Therefore, tolerances are established for residues of etoxazole (2-(2,6-difluorophenyl)-4-[4-(1,1-dimethylethyl)-2-ethoxyphenyl]-4,5-dihydrooxazole), in or on orange and orange, oil at 0.10 ppm and 1.0 ppm, respectively.

VI. Statutory and Executive Order Reviews

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

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

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

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: November 23, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.593, add alphabetically the following commodities and footnote 2 to the table in paragraph (a) to read as follows:

§ 180.593 Etoxazole; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Orange [2]	0.10
Orange, oil [2]	1.0
* * * * *	

[2] There are no U.S. registrations for orange and orange, oil as of December 2, 2015.

* * * * *

[FR Doc. 2015–30513 Filed 12–1–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0804; FRL–9937–02]

Hexythiazox; Pesticide Tolerances; Technical Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical correction.

SUMMARY: EPA issued a final rule in the **Federal Register** of August 14, 2015, concerning the establishment of tolerances with regional registrations for residues of hexythiazox in or on wheat. This document corrects a technical error, specifically, the omission of regions in the commodity definitions.

DATES: This final rule correction is effective December 2, 2015.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2014–0804 is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

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

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

The Agency included in the August 14, 2015 final rule a list of those who may be potentially affected by this action.

II. What does this technical correction do?

EPA issued a final rule in the **Federal Register** of August 14, 2015 (80 FR 48753) (FRL–9931–30) that established tolerances with regional registrations for residues of hexythiazox in or on wheat. EPA inadvertently limited the tolerances to Region 11 in the table in 180.448(c) of the regulatory text, when in fact Regions 9–12 are covered by the data supporting the tolerances and the regional registrations. This technical correction revises the table in 180.488(c) to include all the regions intended for the tolerances.

The preamble for FR Doc. 2015–20012 published in the **Federal Register** issue of August 14, 2015 (80 FR 48753) (FRL–9931–30) is corrected as follows:

1. On page 48757, second column, under the heading ''Part 180—[Amended]'', paragraph 3, line 12, correct ''Wheat, forage (EPA Region 11 only)'' to read ''Wheat, forage (EPA Regions 9–12 only)''.

2. On page 48757, second column, under the heading ''Part 180—[Amended]'', paragraph 3, line 14, correct ''Wheat, hay (EPA Regions 11 only)'' to read ''Wheat, hay (EPA Regions 9–12 only)''.

3. On page 48757, second column, under the heading ''Part 180—[Amended],'' paragraph 3, line 16, correct ''Wheat, grain (EPA Regions 11 only'' to read ''Wheat, grain (EPA Regions 9–12 only)''.

4. On page 48757, second column, under the heading ''Part 180—[Amended],'' paragraph 3, line 18, correct ''Wheat, straw (EPA Region 11 only'' to read ''Wheat, straw (EPA Regions 9–12 only)''.

III. Why is this correction issued as a final rule?

Section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)(3)(B)) provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a final rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making this technical correction final without prior proposal and opportunity for comment, because this action merely corrects an omission and does not otherwise change the original requirements of the final rule. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(3)(B).

IV. Do any of the statutory and executive order reviews apply to this action?

No. For a detailed discussion concerning the statutory and executive order review, refer to Unit VI of the August 14, 2015 final rule.

V. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: November 23, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is corrected as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.448(c), remove the commodities ''Wheat, forage (EPA Region 11 only)'', ''Wheat, grain (EPA Region 11 only)'', ''Wheat, hay (EPA Region 11 only)'', and ''Wheat, straw (EPA Region 11 only)''; and add in alphabetical order the commodities listed below to read as follows:

§ 180.448 Hexythiazox; tolerances for residues.

* * * * *

(c) * * *

Commodity	Parts per million
Wheat, forage (EPA Regions 9–12 only)	6.0
Wheat, grain (EPA Regions 9–12 only)	0.02
Wheat, hay (EPA Regions 9–12 only)	30
Wheat, straw (EPA Regions 9–12 only)	8.0

[FR Doc. 2015–30514 Filed 12–1–15; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 73

[GN Docket No. 12–268; FCC 14–50]

Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Commission announces that, the Office of Management and Budget (OMB) approved, on an emergency basis, for a period for six months, an information collection for FCC Form 177, Application to Participate in a Reverse Incentive Auction, and certain Commission's rules contained in the *Report and Order,* Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions, FCC 14–50. This document is consistent with the *Report and Order,* which stated that the Commission would publish a document in the **Federal Register** announcing OMB approval and the effective date of the rules and requirements.

DATES: 47 CFR 1.2204(a), (c), (d)(3), and (d)(5) and 73.3700(h)(4) and (6) and FCC Form 177, Application to Participate in a Reverse Incentive Auction, published at 79 FR 48442, August 15, 2014, are effective on December 2, 2015.

FOR FURTHER INFORMATION CONTACT: Contact Cathy Williams, *Cathy.Williams@fcc.gov,* (202) 418–2918.

SUPPLEMENTARY INFORMATION: This document announces that, on November 19, 2015, OMB approved on an emergency basis the information collection requirements for FCC Form 177, Application to Participate in a Reverse Incentive Auction and 47 CFR 1.2204(a), (c), (d)(3), and (d)(5) and 73.3700(h)(4) and (6), published at 79 FR 48442 on August 15, 2014. The OMB Control Number is 3060–1213. The Commission publishes this document as an announcement of the effective date of the rules and requirements. If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street SW., Washington, DC 20554. Please include the OMB Control Number, 3060–1213, in your correspondence. The Commission will also accept your comments via the Internet if you send them to *PRA@fcc.gov*.

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the Commission is notifying the public that it received emergency approval from OMB on November 19, 2015, for the information collection requirements contained in the information collection 3060–1213.

Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number is 3060–1213. The foregoing document is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–1213.

OMB Approval Date: November 19, 2015.

OMB Expiration Date: May 31, 2016.

Title: Application to Participate in a Reverse Incentive Auction, FCC Form 177.

Form No.: FCC Form 177.

Respondents: Business or other for-profit entities; Not-for-profit institutions; State, local or Tribal government.

Number of Respondents and Responses: 600 respondents; 600 responses.

Estimated Time per Response: 90 minutes.

Frequency of Response: One-time reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is contained in sections 154(i) and 309(j)(5) of the Communications Act of 1934, as amended, 47 U.S.C. 4(i), 309(j)(5), and sections 1.2204(a), (c), (d)(3), and (d)(5) and 73.3700(h)(4) and (6) of the Commission's rules, 47 CFR 1.2204(a), (c), (d)(3), (d)(5), 73.3700(h)(4) and (6).

Total Annual Burden: 900 hours.

Total Annual Cost: None.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: Certain information collected on FCC Form 177 will be treated as confidential for various periods of time during the course of the broadcast incentive auction (BIA) pursuant to 47 U.S.C. 1452(a)(3) and section 1.2206(b) of the Commission's rules, 47 CFR 1.2206(b). To the extent necessary, respondents may request confidential treatment of information collected on FCC Form 177 that is not already being treated as confidential pursuant to section 0.459 of the Commission's rules. *See* 47 CFR 0.459.

Needs and Uses: In the *Report and Order,* the Commission adopted a requirement that entities interested in participating in the reverse auction component of the BIA submit a pre-auction application to establish their eligibility to participate in the auction, and adopted rules and requirements concerning the types of information that broadcast licensees would be required to disclose in their pre-auction applications. FCC Form 177 implements sections 1.2204(a), (c), (d)(3), (d)(5) and 73.3700(h)(4) and (6) of the Commission's rules and will be used by the public to apply to participate in reverse incentive auctions, including the Commission's upcoming broadcast incentive reverse auction. The information collected on FCC Form 177 will be used by the Commission to determine if an applicant is legally qualified to participate in the reverse auction. Commission staff will review the information collected on FCC Form 177 as part of the pre-auction process, prior to the start of the reverse auction. Staff will determine whether each applicant satisfies the Commission's requirements to participate in the reverse auction. This approach provides an appropriate screen to ensure serious participation and deter possible abuse of the bidding process without being unduly burdensome.

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2015–30476 Filed 12–1–15; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 150817720–5999–02]

RIN 0648–BF21

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

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

ACTION: Final rule.

SUMMARY: NMFS issues regulations to implement management measures described in a framework action to the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP), as prepared by the Gulf of Mexico Fishery Management Council (Council). This final rule revises the commercial and recreational annual catch limits (ACLs) and annual catch targets (ACTs), the commercial trip limit, and the recreational minimum size limit for greater amberjack in the Gulf of Mexico (Gulf) exclusive economic zone. Additionally, this rule corrects an error in the Gulf gray triggerfish recreational accountability measures (AMs). The purpose of this rule is to modify Gulf greater amberjack management measures to end

overfishing and achieve optimal yield for the greater amberjack resource.

DATES: This rule is effective January 4, 2016.

ADDRESSES: Electronic copies of the framework action, which includes an environmental assessment, a regulatory impact review, and a Regulatory Flexibility Act (RFA) analysis may be obtained from the Southeast Regional Office Web site at *http://sero.nmfs.noaa.gov/sustainable_fisheries/gulf_fisheries/reef_fish/2015/greater_amberjack_framework/index.html.*

FOR FURTHER INFORMATION CONTACT: Richard Malinowski, Southeast Regional Office, NMFS, telephone: 727–824–5305, email: *rich.malinowski@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Gulf reef fish 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 September 17, 2015, NMFS published a proposed rule for the framework action and requested public comment (80 FR 55821). The proposed rule and the framework action outline the rationale for the actions contained in this final rule. A summary of the management measures described in the framework action and implemented by this final rule is provided below.

Management Measures Contained in This Final Rule

This final rule revises the commercial and recreational ACLs and ACTs (which are expressed as quotas in the regulatory text), the commercial trip limit, and the recreational minimum size limit for greater amberjack in the Gulf.

Commercial and Recreational ACLs and ACTs

This final rule revises the commercial and recreational ACLs and ACTs for Gulf greater amberjack. All ACL and ACT weights are described in pounds (lb) round weight. The current sector allocation for the greater amberjack stock ACL of 27 percent for the commercial sector and 73 percent for the recreational sector does not change through this framework action. The commercial ACL is set at 464,400 lb (210,648 kg) and the commercial ACT is set at 394,740 lb (179,051 kg). The recreational ACL is set at 1,255,600 lb (569,531 kg) and the recreational ACT is set at 1,092,372 lb (495,492 kg).

Commercial Trip Limit

This final rule revises the commercial trip limit to 1,500 lb (680 kg), gutted weight; 1,560 lb (708 kg), round weight. The Council determined that this trip limit would further reduce the likelihood of exceeding the commercial ACL and ACT and could extend the length of the commercial fishing season.

Recreational Minimum Size Limit

This rule revises the greater amberjack recreational minimum size limit to 34 inches (86.4 cm), fork length. The Council determined that this increased recreational minimum size limit would provide an opportunity for a greater number of sexually mature greater amberjack to spawn, which could assist in Council efforts to end overfishing and rebuild the stock.

Other Actions Contained in the Framework Action

In addition to the measures being implemented in this rule, the framework action revises the greater amberjack acceptable biological catch (ABC) and overfishing limit (OFL). All ABC and OFL weights are described in pounds (lb) round weight. This framework action revises the ABC and OFL for 4 years, beginning in 2015. The ABC, which is equal to the stock ACL is set at 1,720,000 lb (780,179 kg). The OFL is set at 2,660,000 lb (1,206,556 kg) for 2015; 3,210,000 lb (1,456,032 kg) for 2016; 3,420,000 lb (1,551,286 kg) for 2017; and 3,510,000 lb (1,592,109 kg) for 2018, and subsequent years.

Additional Proposed Changes to Codified Text

In Amendment 37 to the FMP, an in-season AM was implemented for gray triggerfish (which is based on a single season of landings data), so the recreational sector closes when the recreational ACT is reached or projected to be reached (78 FR 27084, May 9, 2013). However, during the implementation of Amendment 37, the last sentence in § 622.41(b)(2)(iii), which states that ''Recreational landings will be evaluated relative to the ACL based on a moving multi-year average of landings, as described in the FMP,'' was not removed. NMFS has only recently noticed this error. This rule corrects this error by removing this sentence. The recreational ACL and ACT for gray triggerfish implemented in Amendment 37 to the FMP remains unchanged.

Comments and Responses

NMFS received 12 comment submissions on the framework action and the proposed rule from individuals, the charter vessel and headboat industry, and non-governmental organizations. The comments that oppose one or more of the management measures in the framework action and the proposed rule are categorized into the comments summarized and responded to below.

Comment 1: The greater amberjack minimum size limit should not be revised, or if revised, should instead be set to 32 inches (81 cm), fork length. Further, enforcement of the current size limit should be increased because under-sized greater amberjack are already observed after fishing trips.

Response: NMFS disagrees. The 2014 greater amberjack stock assessment indicated that the stock continues to be overfished and undergoing overfishing. The Council determined, and NMFS agrees, that increasing the minimum size limit from 30 inches (76 cm), fork length, to 34 inches (86 cm), fork length, will help end overfishing and rebuild the stock.

As described in the framework action, studies have found that at a size limit of 34 inches (86 cm), 85 percent of greater amberjack females reach sexually maturity. However, at the status quo size limit of 30 inches (76 cm) only 11 percent of females reach sexual maturity and at a size limit of 32 inches (81 cm), only 45 percent of females reach sexual maturity. A minimum size limit that is less than the revised 34 inch (86 cm) size limit would allow for a much greater number of greater amberjack to be retained that have not reached sexual maturity, which will lessen the effectiveness of measures being implemented to end overfishing of the stock.

With respect to enforcement, the NMFS Office of Law Enforcement (OLE) is committed to continuing to monitor reef fish harvest and increase awareness and compliance with regulations. Its Enforcement Officer Program is being expanded to better address compliance assistance and fisheries monitoring. Additionally, OLE Enforcement Officers work with state partners providing inspection services for enforcement of Federal regulations through the Joint Enforcement Agreement to better monitor landings.

Comment 2: Instead of increasing the greater amberjack recreational minimum size limit, the current June through July greater amberjack recreational closed season should be extended to include August and September each year. This change to the recreational closed season would work to end overfishing of greater amberjack better than a change to the size limit.

Response: NMFS disagrees. Extending the recreational closed season into the

months of August and September would be expected to result in a longer opportunity to fish during the rest of the recreational fishing season. However, increasing the length of the recreational closed season would not provide greater benefit to the stock than increasing recreational minimum size limit. The increase of the recreational minimum size limit to 34 inches (86 cm) is expected to better allow a greater percentage (85 percent) of the sexually mature females to spawn, which will work towards reducing the risk of overfishing of the stock. The Council did consider revising the recreational closed season in this framework action but decided to retain the current closed season of June 1 through July 31.

Comment 3: Greater amberjack has failed to meet its rebuilding plan deadline and is currently without a rebuilding plan, despite its status as being overfished and undergoing overfishing. NMFS and the Council must formalize a rebuilding plan to comply with the Magnuson-Stevens Act and give Gulf greater amberjack rebuilding the greatest likelihood of success.

Response: NMFS disagrees that greater amberjack is without a rebuilding plan. As explained in the proposed rule, a greater amberjack rebuilding plan was implemented in 2003 with a rebuilding target of 2012. In August 2014, pursuant to section 304(e)(2) of the Magnuson-Stevens Act, NMFS notified the Council of the 2014 stock assessment results that indicated that the greater amberjack stock continued to be overfished and undergoing overfishing. Following that notification, the Council was required under section 304(e)(3) of the Magnuson-Stevens Act to prepare a plan amendment or regulations within 2 years to end overfishing immediately and rebuild the greater amberjack stock.

Although the Council did not explicitly discuss its obligations under section 304(e)(3) of the Magnuson-Stevens Act, the framework action and this final rule fulfill the Council's responsibility to ''prepare and implement a fishery management plan, plan amendment, or proposed regulations for the fishery'' under that provision. Consistent with the requirements of sections 304(e)(3) and (4) of the Magnuson-Stevens Act, the framework action and this final rule are projected to end overfishing immediately and rebuild the stock in as short a time as possible, taking into account the needs of fishing communities. The specified time for rebuilding is 4 years, well below the maximum time of 10 years specified in section 304(4)(A)(ii) of the Magnuson-Stevens Act.

Classification

The Regional Administrator, Southeast Region, NMFS, has determined that this final rule is necessary for the conservation and management of Gulf greater amberjack and is consistent with the framework action, 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 follows.

No public comments specific to the initial regulatory flexibility analysis were received and, therefore, no public comments are addressed in this FRFA.

NMFS agrees that the Council's choice of preferred alternatives will best achieve the Council's objectives for the framework action while minimizing, to the extent practicable, the adverse effects on fishers, support industries, and associated communities. The preamble to the final rule provides a statement of the need for and objectives of this rule.

NMFS expects this final rule to directly affect all commercial vessels that harvest Gulf greater amberjack under the FMP. Changes to recreational ACLs, ACTs, and minimum size limits in this final rule will not directly apply to or regulate charter vessel and headboat (for-hire) businesses. Any impact to the profitability or competitiveness of for-hire fishing businesses will be the result of changes in for-hire angler demand and will therefore be indirect in nature. The RFA does not consider recreational anglers, who will be directly affected by this final rule, to be small entities, so they are outside the scope of this analysis and only the effects on commercial vessels were analyzed.

As of March 25, 2015, there were 863 vessels with valid or renewable Gulf reef fish commercial vessel Federal permits. On average (2009 through 2013), 211 vessels commercially landed greater amberjack each year from Gulf Federal waters. Their average annual vessel-level revenue for 2009 through 2013 was approximately $130,000 (2013 dollars), of which $2,400 was from greater amberjack.

No other small entities that will be directly affected by this final rule have been identified.

The Small Business Administration (SBA) has established size criteria for all major industry sectors in the U.S., including commercial finfish harvesters (NAICS code 114111). A business primarily involved in finfish harvesting is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $20.5 million for all its affiliated operations worldwide. All of the vessels directly regulated by this rule are believed to be small entities based on the SBA size criteria.

Because all entities expected to be affected by this final rule are small entities, NMFS has determined that this final rule will affect a substantial number of small entities. Moreover, the issue of disproportionate effects on small versus large entities does not arise in the present case.

This final rule reduces the greater amberjack commercial ACT by 3.5 percent or 14,260 lb (6,468 kg), round weight, from 409,000 lb (185,519 kg) to 394,740 lb (179,051 kg), round weight. Additionally, this final rule reduces the greater amberjack commercial trip limit from 2,000 lb (907 kg), round weight, to 1,560 lb (708 kg), round weight; 1,500 lb (680 kg), gutted weight. On its own, the reduction in the commercial ACT would be expected to result in a shorter fishing season and fewer commercial trips that harvest greater amberjack. Conversely, the reduced commercial trip limit would be expected to increase the commercial fishing season length and the overall number of trips necessary to harvest the entire commercial ACT. When the actions to reduce the commercial ACT and trip limit are analyzed together, the expected recurring annual reduction in total ex-vessel revenue from this final rule is estimated to be $20,703 (2013 dollars), assuming there is no substitution of other species and no change in effort, harvest rates, or prices. In addition, the commercial season length is predicted to be 5 days longer under the preferred commercial ACT and trip limit alternatives than under the no action alternatives for these actions. Assuming the reduction in greater amberjack revenues is distributed evenly across the average number of vessels that commercially harvest greater amberjack per year (211 vessels), the annual per-vessel loss is estimated to be $98 (2013 dollars), or less than 1 percent of the

average annual revenue earned by these vessels for all species harvested. Because this estimate is based on average performance, some vessels may be affected differently than others, depending on their overall catch composition, landing capacity, and fishing behavior.

Thirty vessels, on average per year (2009 through 2013), were identified that commercially landed greater amberjack in excess of the selected 1,500 lb (680 kg), gutted weight, trip limit on a single trip (14 percent of the average number of vessels that harvested greater amberjack each year). In 2013, the total weight of greater amberjack harvested in excess of 1,500 lb (680 kg), gutted weight, per trip, accounted for approximately 10 percent of total greater amberjack landings. Thus, for the 211 vessels that commercially harvest greater amberjack, the reduction in the commercial trip limit, assuming effort remains constant, is expected to reduce total commercial greater amberjack harvests by approximately 39,000 lb (17,690 kg), round weight, and $46,800 (2013 dollars) in total ex-vessel revenue annually. Averaged across the 30 vessels per year with trip harvests above 1,500 lb (680 kg), gutted weight, this reduction equals approximately $1,560 (2013 dollars) per vessel, or approximately 1 percent of their average annual revenue. These losses would be reduced if increased landings of other species can be substituted for greater amberjack landings or if new trips harvesting greater amberjack were to occur. It is assumed that the entire commercial ACT will be harvested under the preferred trip limit alternative. Therefore, if the trip limit change implemented by this final rule results in a decrease in greater amberjack landings and revenues for some vessels, it will result in an increase in greater amberjack landings and revenues for other vessels.

The following discussion analyzes the alternatives that were not selected as preferred by the Council. Only the actions which contain alternatives that will have direct economic effects on small entities are included in the following discussion.

Four alternatives were considered for the action to modify the commercial and recreational ACLs and ACTs for Gulf greater amberjack. The first alternative, the no action alternative, would not be expected to have any direct economic effects. This alternative was not selected because the stock ACL would exceed the ABC calculated by the most recent greater amberjack assessment and recommended by the Council's Scientific and Statistical Committee (SSC) and would, therefore, be inconsistent with the Magnuson-Stevens Act National Standard 1 guidelines. The second alternative would set the stock ACL from 2015 through 2018 equal to the ABC values recommended by the Council's SSC. This alternative included two sub-options. The first sub-option would use the Council's ACL/ACT control rule as established in the Generic ACL/AM Amendment (76 FR 82044, December 29, 2011), which would set the commercial ACT at a level reduced by 15 percent from the commercial ACL for greater amberjack and set the recreational ACT at a level reduced by 13 percent from the recreational ACL. The second sub-option would not use the ACL/ACT control rule and would instead apply a 20-percent buffer that would reduce both the recreational and commercial ACLs by 20 percent to establish the recreational and commercial ACTs. This alternative would increase the stock ACL each year from 2015 through 2018, which would be expected to result in greater economic benefits than the preferred alternative in the framework action. However, this alternative was not selected as preferred by the Council because the 2014 stock assessment results indicated that the greater amberjack stock continued to be overfished and undergoing overfishing and the Council determined that maintaining the catch limit at the more conservative 2015 level was appropriate. The third alternative, the preferred alternative, sets a constant stock ACL equal to the 2015 ABC value recommended by the Council's SSC. The same two sub-options for setting the ACT that were considered for the second alternative were also considered for the third alternative. The first sub-option, selected as preferred by the Council, applies a 15-percent buffer to the commercial ACL to set the commercial ACT and applies a 13-percent buffer to the recreational ACL to set the recreational ACT. The second sub-option would not use the ACL/ACT control rule and instead would apply a 20-percent buffer that would reduce both the recreational and commercial ACLs by 20 percent to establish the recreational and commercial ACTs. The fourth alternative would set the stock ACL and stock ACT at zero. The fourth alternative would stop all directed harvest of greater amberjack by both sectors and would be expected to result in greater economic losses than the Council's preferred ACL/ACT alternative.

Five alternatives were considered for the action to modify the greater amberjack commercial trip limit. The first alternative, the no action alternative, would maintain the current 2,000 lb (907 kg), round weight, trip limit and would not be expected to have any direct economic effects. The third, fourth, and fifth alternatives would have established 1,000 lb (454 kg), 750 lb (340 kg), and 500 lb (227 kg), gutted weight trip limits, respectively. Although these three alternatives would be expected to extend the commercial fishing season, they would increase the likelihood that trips are no longer profitable and decrease the likelihood that the entire commercial ACT would be harvested during the fishing year. Therefore, these three alternatives would be expected to result in greater economic losses to affected small entities than the preferred trip limit alternative.

An item contained in this final rule that is not part of the framework action is the removal of the last sentence in § 622.41(b)(2)(iii), ''Recreational landings will be evaluated relative to the ACL based on a moving multi-year average of landings, as described in the FMP.'' This sentence, which pertains to the evaluation of recreational landings of gray triggerfish relative to the ACL, was inadvertently not removed in the final rule implementing Amendment 37 to the FMP (78 FR 27084, May 9, 2013). The removal of this sentence will clarify the criteria used to trigger recreational AMs as written in the Federal regulations; however, it is not expected to have any effect on current management practices. This is because NMFS has managed gray triggerfish in accordance with the preferred alternatives specified in Amendment 37 since its implementation. Therefore, this is an administrative change only and is not expected to have any direct economic effects on small entities. As such, this component of the final rule is outside the scope of the RFA.

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

List of Subjects in 50 CFR Part 622

Commercial, Fisheries, Fishing, Greater amberjack, Gulf, Recreational, Reef fish.

Dated: November 25, 2015.

Eileen Sobeck,

Assistant Administrator for Fisheries, 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 § 622.37, revise paragraph (c)(4) to read as follows:

§ 622.37 Size limits.

* * * * *

(c) * * *

(4) *Greater amberjack*—34 inches (86.4 cm), fork length, for a fish taken by a person subject to the bag limit specified in § 622.38(b)(1) and 36 inches (91.4 cm), fork length, for a fish taken by a person not subject to the bag limit.

* * * * *

■ 3. In § 622.39, revise paragraphs (a)(1)(v) and (a)(2)(ii) to read as follows:

§ 622.39 Quotas.

* * * * *

(a) * * *

(1) * * *

(v) Greater amberjack—394,740 lb (179,051 kg), round weight.

* * * * *

(2) * * *

(ii) *Recreational quota for greater amberjack.* The recreational quota for greater amberjack is 1,092,372 lb (495,492 kg), round weight.

* * * * *

■ 4. In § 622.41, revise paragraphs (a)(1)(iii), (a)(2)(iii), and (b)(2)(iii) to read as follows:

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

(a) * * *

(1) * * *

(iii) The commercial ACL for greater amberjack is 464,400 lb (210,648 kg), round weight.

(2) * * *

(iii) The recreational ACL for greater amberjack is 1,255,600 lb (569,531 kg), round weight.

(b) * * *

(2) * * *

(iii) The recreational ACL for gray triggerfish is 241,200 lb (109,406 kg), round weight. The recreational ACT for gray triggerfish is 217,100 lb (98,475 kg), round weight.

* * * * *

■ 5. In § 622.43, revise paragraph (a) to read as follows:

§ 622.43 Commercial trip limits.

* * * * *

(a) *Gulf greater amberjack.* Until the quota specified in § 622.39(a)(1)(v) is reached, 1,500 lb (680 kg), gutted weight; 1,560 lb (708 kg), round weight. See § 622.39(b) for the limitations regarding greater amberjack after the quota is reached.

* * * * *

[FR Doc. 2015–30543 Filed 12–1–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 140429387–4971–02]

RIN 0648–XE334

Atlantic Highly Migratory Species; Commercial Non-Blacknose Small Coastal Sharks in the Gulf of Mexico Region

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is closing the fishery for commercial non-blacknose small coastal sharks (SCS) in the Gulf of Mexico region. This action is necessary because the commercial landings of Gulf of Mexico non-blacknose SCS for the 2015 fishing season are projected to exceed 80 percent of the available commercial quota as of November 27, 2015.

DATES: The commercial fishery for non-blacknose SCS in the Gulf of Mexico region is closed effective 11:30 p.m. local time December 5, 2015, until the end of the 2015 fishing season on December 31, 2015, and will reopen on January 1, 2016.

FOR FURTHER INFORMATION CONTACT: Guy DuBeck or Karyl Brewster-Geisz 301–427–8503; fax 301–713–1917.

SUPPLEMENTARY INFORMATION: The Atlantic and Gulf of Mexico shark fisheries are managed under the 2006 Consolidated Highly Migratory Species (HMS) Fishery Management Plan (FMP), its amendments, and its implementing regulations (50 CFR part 635) issued under authority of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*).

Under § 635.5(b)(1), dealers must report weekly on sharks they first receive from vessels through a NMFS-approved electronic reporting system. Under § 635.28(b)(2), when NMFS calculates that the landings for any species and/or management group with a ''non-linked'' quota has reached or is projected to reach 80 percent of the available quota, NMFS will file for publication with the Office of the Federal Register a notice of closure that will be effective no fewer than 5 days from date of filing. From the effective date and time of the closure until and if NMFS announces, via a notification in the **Federal Register**, that additional quota is available and the season is reopened, the fisheries remain closed, even across fishing years.

On December 2, 2014 (79 FR 71331), NMFS announced that the 2015 commercial Gulf of Mexico non-blacknose SCS quota was 45.5 metric tons (mt) dressed weight (dw) (100,317 lb dw), while and the blacknose shark quota was 1.8 mt dw (4,076 lb dw). Dealer reports received through June 26, 2015, indicated that 36.9 mt dw or 81 percent of the available Gulf of Mexico non-blacknose SCS quota had been landed and 1.0 mt dw or 52 percent of the available Gulf of Mexico blacknose shark quota had been landed. Since the dealer landings of non-blacknose SCS exceeded 80 percent of the quota, and the non-blacknose SCS and blacknose shark fisheries were quota-linked, NMFS closed the blacknose shark and non-blacknose SCS fisheries on July 4, 2015 (80 FR 38016; July 2, 2016).

On August 18, 2015 (80 FR 50073), NMFS published the final rule for Amendment 6 to the 2006 Consolidated HMS FMP which, among other things, established a new Gulf of Mexico non-blacknose SCS commercial quota of 112.6 mt dw (248,215 lb dw), prohibited the retention of blacknose sharks in the Gulf of Mexico, and removed the quota linkage between the blacknose shark fishery and the non-blacknose SCS commercial fishery. At that time, NMFS estimated that approximately 66.4 mt dw of the new Gulf of Mexico non-blacknose SCS commercial quota was available and re-opened the Gulf of Mexico non-blacknose SCS commercial fishery. Dealer reports received through November 20, 2015, indicated that a total of 89.4 mt dw or 79 percent of the available Gulf of Mexico non-blacknose SCS commercial quota had been landed. Based on these dealer reports, NMFS

estimates that the 80 percent limit specified for closure will be exceeded by November 27, 2015. Accordingly, NMFS is closing the commercial non-blacknose SCS management group in the Gulf of Mexico region as of 11:30 p.m. local time December 5, 2015. The only shark species or management groups that remain open in the Gulf of Mexico region are the research large coastal sharks, sandbar sharks within the shark research fishery, the blue shark, and pelagic sharks other than porbeagle or blue shark management groups.

At § 635.27(b)(1), the boundary between the Gulf of Mexico region and the Atlantic region is defined as a line beginning on the East Coast of Florida at the mainland at 25°20.4′ N. latitude, proceeding due east. Any water and land to the south and west of that boundary is considered, for the purposes of monitoring and setting quotas, to be within the Gulf of Mexico region.

During the closure, retention of non-blacknose SCS in the Gulf of Mexico region is prohibited for persons fishing aboard vessels issued a commercial shark limited access permit (LAP) under § 635.4. However, persons aboard a commercially permitted vessel that is also properly permitted to operate as a charter vessel or headboat for HMS and is engaged in a for-hire trip could fish under the recreational retention limits for sharks and ''no sale'' provisions (§ 635.22(a) and (c)).

During this closure, a shark dealer issued a permit pursuant to § 635.4 may not purchase or receive non-blacknose SCS in the Gulf of Mexico region from a vessel issued a shark LAP, except that a permitted shark dealer or processor may possess non-blacknose SCS in the Gulf of Mexico region that were harvested, off-loaded, and sold, traded, or bartered prior to the effective date of the closure and were held in storage consistent with § 635.28(b)(6). Similarly, a shark dealer issued a permit pursuant to § 635.4 may, in accordance with relevant state regulations, purchase or receive non-blacknose SCS in the Gulf of Mexico region if the sharks were harvested, off-loaded, and sold, traded, or bartered from a vessel that fishes only in state waters and that has not been issued a shark LAP, HMS Angling permit, or HMS Charter/Headboat permit pursuant to § 635.4.

Classification

Pursuant to 5 U.S.C. 553(b)(B), the Assistant Administrator for Fisheries, NOAA (AA), finds that providing prior notice and public comment for this action is impracticable and contrary to the public interest because the fisheries are currently underway and any delay in this action would result in overharvest of the Gulf of Mexico non-blacknose SCS quota and be inconsistent with management requirements and objectives. Similarly, affording prior notice and opportunity for public comment on this action is contrary to the public interest because if the quota is exceeded, the stock may be negatively affected and fishermen ultimately could experience reductions in the available quota and a lack of fishing opportunities in future seasons. For these reasons, the AA also finds good cause to waive the 30-day delay in effective date pursuant to 5 U.S.C. 553(d)(3). This action is required under § 635.28(b)(2) and is exempt from review under Executive Order 12866.

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

Dated: November 27, 2015.

Emily H. Menashes,

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

[FR Doc. 2015–30540 Filed 11–30–15; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

RIN 0648–XD998

Pacific Island Pelagic Fisheries; 2015 U.S. Territorial Longline Bigeye Tuna Catch Limits for Guam

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

ACTION: Announcement of a valid specified fishing agreement.

SUMMARY: NMFS announces a valid specified fishing agreement that allocates 1,000 mt of the 2015 Guam bigeye tuna limit to U.S. longline fishing vessels. The agreement supports the long-term sustainability of fishery resources of the U.S. Pacific Islands.

DATES: November 27, 2015.

ADDRESSES: Copies of the environmental assessment and finding of no significant impact for this action, identified by NOAA–NMFS–2015–0077, are available from *www.regulations.gov,* or from Michael D. Tosatto, Regional Administrator, NMFS Pacific Islands Region (PIR), 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818.

Copies of the fishery ecosystem plans are available from the Western Pacific Fishery Management Council (Council), 1164 Bishop St., Suite 1400, Honolulu, HI 96813, tel 808–522–8220, fax 808–522–8226, or *www.wpcouncil.org.*

FOR FURTHER INFORMATION CONTACT: Jarad Makaiau, NMFS PIRO Sustainable Fisheries, 808–725–5176.

SUPPLEMENTARY INFORMATION: In a final rule published on November 6, 2015, NMFS specified a 2015 limit of 2,000 metric tons (mt) of longline-caught bigeye tuna for Guam (80 FR 68778). Of the 2,000 mt, NMFS allows the territory to allocate up to 1,000 mt to U.S. longline fishing vessels identified in a specified fishing agreement that meets established criteria.

On November 25, 2015, NMFS received from the Western Pacific Fishery Management Council a specified fishing agreement between the Government of Guam and Quota Management, Inc. (QMI). In the transmittal memorandum, the Council's Executive Director noted that the specified fishing agreement was consistent with the criteria set forth in 50 CFR 665.819(c)(1). NMFS reviewed the agreement and determined that it is consistent with the Fishery Ecosystem Plan for Pelagic Fisheries of the Western Pacific Region, the Magnuson-Stevens Fishery Conservation and Management Act, implementing regulations, and other applicable laws.

In accordance with 50 CFR 300.224(d) and 50 CFR 665.819(c)(9), vessels identified in the agreement may retain and land bigeye tuna in the western and central Pacific Ocean under the Guam limit.

NMFS began attributing bigeye tuna caught by vessels identified in the agreement to Guam starting on November 25, 2015. If and when NMFS determines the fishery will reach the 1,000 mt attribution limit, we will restrict harvest of bigeye tuna caught by vessels identified in the agreement.

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

Dated: November 27, 2015.

Emily H. Menashes,

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

[FR Doc. 2015–30544 Filed 11–27–15; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 80, No. 231
Wednesday, December 2, 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 COMMERCE

Bureau of Industry and Security

15 CFR Part 701

[Docket No. 150825780–5780–01]

RIN 0694–AG38

Export Control Reform: Conforming Change to Defense Sales Offset Reporting Requirements

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Proposed rule.

SUMMARY: This proposed rule would require reporting of offsets agreements in connection with sales of items controlled in ''600 series'' Export Control Classification Numbers (ECCNs) on the Commerce Control List (CCL) except for certain submersible and semi-submersible cargo transport vessels and related items that are not on control lists of any of the multilateral export control regimes of which the United States is a member. Since the early 1990s, BIS has required reporting of offsets agreements in connection with sales of items controlled on the United States Munitions List (USML). Those reporting requirements would continue, unchanged by this rule. Beginning on October 15, 2013, some items have been removed from the USML and added to 600 series ECCNs as part of the Administration's Export Control Reform Initiative. These items were subject to offsets reporting requirements prior to being added to 600 series ECCNs. In addition, as part of that same initiative, some items that were subject to the Export Administration Regulations (EAR) have also been added to 600 series ECCNs. These items were not subject to offsets reporting requirements prior to being added to 600 series ECCNs. This proposed rule would require reporting of offsets agreements in connection with sales of items controlled in 600 series ECCNs regardless of whether the item was added to a 600 series ECCN simultaneously with its removal from the USML or was subject to the EAR prior to its inclusion in a 600 series ECCN.

BIS is proposing this action because, except for the vessels and related items noted above, items controlled in 600 series ECCNs are of a military nature. BIS believes that collecting information regarding offsets requirements in connection with the sale of such items is necessary to make a report to Congress mandated by the Defense Production Act complete.

DATES: Comments must be received no later than February 1, 2016.

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

- By the Federal eRulemaking Portal: *http://www.regulations.gov.* The identification number for this rulemaking is BIS–2015–0045.
- By email directly to *publiccomments@bis.doc.gov.* Include RIN 0694–AG38 in the subject line.

FOR FURTHER INFORMATION CONTACT: Ronald DeMarines, Strategic Analysis Division, Office of Strategic Industries and Economic Security, 202–482–3755, or *ronald.demarines@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

Part 701 of Title 15, Code of Federal Regulations—Reporting of Offsets Agreements in Sales of Weapon Systems or Defense-Related Items to Foreign Countries or Foreign Firms—(herein the Offsets Reporting Regulations) requires that U.S. firms report certain offset agreements to BIS annually. BIS uses the information so reported to develop a ''detailed annual report on the impact of offsets on the defense preparedness, industrial competitiveness, employment, and trade of the United States'' (herein ''the offset report to Congress''), that is submitted to the Committee on Banking, Housing, and Urban Affairs of the Senate, and the Committee on Financial Services of the House of Representatives, as required by Section 723 of the Defense Production Act of 1950, as amended (DPA) (50 U.S.C. app. 2172(a)(1). An offset for purposes of the Offsets Reporting Regulations is compensation required by the purchaser as a condition of the purchase in government-to-government or commercial sales of defense articles or services. This compensation can take a variety of forms, including: Co-production, technology transfer, subcontracting, credit assistance, training, licensed production, investment, and purchases. An agreement to provide offsets with a value exceeding $5,000,000 must be reported to BIS. Performance of an existing offset commitment for which offset credit of $250,000 or more has been claimed must also be reported to BIS.

The Defense Production Act describes the items for which the offset report to Congress must be submitted as ''weapon system[s] or defense-related item[s].'' (*See* section 723 of the DPA) (50 U.S.C. app. 2172(c)(1). The Offsets Reporting Regulations currently require reporting of offsets in connection with ''defense articles and/or defense services'' as defined by the Arms Export Control Act and the International Traffic in Arms Regulations (22 CFR parts 120–130) (ITAR). *See* 15 CFR 701.2(a). The ITAR includes the USML (22 CFR part 121), which describes the defense articles that it regulates. Beginning on October 15, 2013, as part of the Administration's Export Control Reform Initiative, a series of rules removed a number of defense articles from the USML and added them to the CCL (15 CFR part 774, Supp. No. 1). BIS created a new series of ECCNs in the EAR, identified as the ''600 series'' because the third character in the ECCN is the numeral ''6,'' for those defense articles. The 600 series items formerly controlled on the USML were subject to offsets reporting requirements before being added to the 600 series.

Simultaneously with adding former USML defense articles to the 600 series ECCNs, BIS added to those ECCNs some items that are of a military nature but that were already subject to the EAR. BIS took this step to provide consistent treatment for all military items that are subject to the EAR. Some of these items were in existing ECCNs. Others were subject to the EAR, but not set forth in any ECCN. Such items are designated under the EAR as EAR99 items. Items that were subject to the EAR prior to being added to 600 series ECCNs were not subject to offsets reporting requirements.

This proposed rule would require reporting of offsets agreements in connection with sales of all items controlled in 600 series ECCNs, except for certain submersible and semi-

submersible cargo transport vessels and related items that are not on control lists of any of the multilateral export control regimes of which the United States is a member, regardless of whether the item was controlled on the USML or subject to the EAR prior to being controlled under a 600 series ECCN.

Nature of 600 Series ECCNs

600 series ECCNs control items of a military nature. They are structured in the same manner as other ECCNs. That structure is described in detail at 15 CFR 738.2. However, a brief overview is given here. An ECCN has five characters. The first character identifies the category on the CCL to which the ECCN belongs. There are ten categories numbered 0 through 9. The second character identifies the product group and is one of the letters A through E. In the 600 series ECCNs, the third character identifies the ECCN as part of the 600 series. The fourth and fifth characters identify the category on the Wassenaar Arrangement Munitions List to which the ECCNs most closely relate. These last two characters also serve to identify related ECCNs across different product groups. The product groups and illustrative examples of their application in the 600 series are as follows:

Product Group A—End items, equipment, accessories, attachments, parts, components, and systems. For example, ECCN 0A606 applies to ground vehicles and related commodities.

Product Group B—Test, inspection and production equipment. For example, 0B606 applies to equipment specially designed for the development, production, repair, overhaul, or refurbishing of commodities enumerated in ECCN 0A606 or USML Category VII (the USML category that applies to ground vehicles).

Product Group C—Materials. For example 0C606 applies to materials specially designed for commodities controlled by ECCN 0A606 not elsewhere specified in the USML. In some instances a product group C ECCN may apply to materials for its related product group B ECCN as well as to its related product group A ECCN.

Product Group D—Software. For example, ECCN 0D606 applies to software specially designed for the development, production, operation, or maintenance of ground vehicles and related commodities controlled by ECCNs 0A606, 0B606, or 0C606. A software ECCN may apply to software for any or all of the items in its related product groups A, B or C.

Product Group E—Technology. For example, ECCN 0E606 applies to technology required for the development, production, operation, installation, maintenance, repair, overhaul, or refurbishing of ground vehicles and related commodities in 0A606, 0B606, 0C606, or software in 0D606. A technology ECCN may apply to technology for items in any or all of its related product groups A, B, C or D.

For brevity, the discussions of ECCNs below generally will refer to ''related'' test, inspection and production equipment, materials, software or technology rather than spell out the full relationship in terms such as ''required,'' ''specially designed,'' ''development,'' ''production,'' etc. Detailed terms will be used only where necessary to draw accurate distinctions between the items being discussed. Readers who desire a fuller description of the relationship than that provided above may refer to the full text of the ECCNs in 15 CFR part 774, Supplement No. 1.

600 Series ECCNs

Most of the items controlled in the 600 series ECCNs were, prior to the creation of those ECCNs, subject to the ITAR. Those items that were subject to the EAR prior to inclusion in a 600 series ECCN will be discussed separately below.

Military explosive devices: ECCNs 0A604, 0B604, 0D604 and 0E604. These ECCNs control commodities related to military explosive devices and parts, components, accessories and attachments therefor; related test, inspection and production equipment; related software and related technology. These ECCNs became effective on July 1, 2014.

Ground vehicles: ECCNs 0A606, 0B606, 0C606, 0D606 and 0E606. These ECCNs control ground vehicles and parts, components, accessories, and attachments therefor; related test, inspection and production equipment; related materials; related software and related technology. These ECCNs became effective on January 6, 2014.

Military training equipment: ECCNs 0A614, 0B614, 0D614 and 0E614. These ECCNs control military training equipment and parts, components, accessories and attachments therefor; related test, inspection and production equipment; related software and related technology. These ECCNs became effective on July 1, 2014.

Miscellaneous military equipment: ECCNs 0A617, 0B617, 0C617, 0D617 and 0E617. These ECCNs control miscellaneous military equipment and parts, components, accessories and attachments therefor; related test, inspection and production equipment; related materials; related software and related technology. These ECCNs became effective on January 6, 2014.

Energetic materials: ECCNs 1B608, 1C608, 1D608 and 1E608. These ECCNs control energetic materials and related commodities; related test, inspection and production equipment; related materials; related software and related technology. These ECCNs became effective on July 1, 2014.

Armored and protective equipment: ECCNs 1A613, 1B613, 1D613 and 1E613. These ECCNs control armored and protective equipment and parts, components, accessories and attachments therefor; inspection and production equipment; related software and related technology. These ECCNs became effective on July 1, 2014.

Surface vessels: ECCNs 8A609, 8B609, 8C609, 8D609 and 8E609. These ECCNs control surface vessels of war and parts, components, accessories and attachments therefor; related test, inspection and production equipment; related materials; related software and related technology. These ECCNs became effective on January 6, 2014.

Submersible vessels: ECCNs 8A620, 8B620, 8D620, 8E620. These ECCNs control submersible vessels, oceanographic and associated commodities and parts, components, accessories and attachments therefor; related test, inspection and production equipment; related software and related technology. These ECCNs became effective on January 6, 2014.

Launch vehicles, missiles, and rockets: ECCNs 9A604, 9B604, 9D604, 9E604: These ECCNs control commodities related to launch vehicles, missiles, and rockets and parts, components, accessories and attachments therefor; related test, inspection and production equipment; related software and related technology. These ECCNs became effective on July 1, 2014.

Military aircraft: ECCNs 9A610, 9B610, 9C610, 9D610 and ECCN 9E610. These ECCNs control military aircraft and parts, components, accessories, and attachments therefor; related test, inspection and production equipment; related materials; related software and related technology. These ECCNs became effective on October 15, 2013.

Military gas turbine engines: ECCNs 9A619, 9B619, 9D619 and 9E619. These ECCNs control military gas turbine engines and parts, components, accessories and attachments therefor; related test, inspection and production equipment; related software and related

technology. These ECCNs became effective on October 15, 2013.

Military electronics: ECCNs 3A611, 3B611, 3D611 and 3E611. These ECCNs control military electronics and parts, components accessories and attachments therefor; related test, inspection and production equipment; related software and related technology. These ECCNs became effective on December 30, 2014.

Cryogenic and superconducting equipment for vehicles: ECCNs 9A620, 9B620, 9D620, 9E620: These ECCNs control cryogenic and superconducting equipment for military vehicles (land, sea or air); related test, inspection and production equipment; related software and related technology. These ECCNs became effective on December 20, 2014.

All of the items in the 600 series ECCNs discussed above were on the USML, and therefore subject to offsets reporting requirements, prior to the dates on which the ECCNs became effective except the items discussed below.

Items Controlled in 600 Series ECCNs That Previously Were Subject to the EAR

Certain unarmed armored vehicles that are derived from civilian vehicles are controlled under ECCN 0A606.b. Prior to the effective date of ECCN 0A606, these vehicles were controlled under ECCN 9A018.b.

Induction hardening machines for tank turret rings and sprockets are controlled within the general paragraph 0B606.a. Prior to the effective date of ECCN 0A606, these machines were controlled under ECCN 2B018.m. Related software for these machines is controlled in ECCN 0D606. Prior to the effective date of ECCN 0D606, this software was EAR99. Related technology for these machines is controlled in ECCN 0E606. Prior to the effective date of ECCN 0E606, this software was EAR99.

Construction equipment built to military specifications, including equipment specially designed for airborne transport; and specially designed parts and accessories for such construction equipment, including crew protection kits used as protective cabs, is controlled in ECCN 0A617.y.1 and .y.2. Prior to the effective date of ECCN 0A617, this equipment was controlled in ECCN 0A018.m. Related test, inspection and production equipment, software and technology were EAR99. The related software and technology for the test, inspection and production equipment was also EAR99.

Power controlled searchlights controlled in ECCN 0A617.y.5 were, prior to the effective date of ECCN 0A617, controlled in 0A918.a. Related test, inspection and production equipment, related software and related technology were EAR99. Related software and technology for the test, inspection and production equipment was also EAR99.

Test, inspection and production equipment in ECCN 1B608.a (related to energetic materials in ECCN 1C608.a) prior to the effective date of ECCN 1B608 were controlled in ECCN 1B018.a, .b and .x. Related software for 1B608.a was EAR99. Related technology for *development* and *production* of equipment in ECCN 1B608.a was controlled in ECCN 1E001. Related technology for *operation, installation, maintenance, repair, overhaul* or *refurbishing* of energetic materials in ECCN 1C608.a was EAR99.

Energetic materials and related commodities in ECCN 1C608.b through .m were controlled under ECCN 1C018.b through .m prior to the effective date of ECCN 1C608. Related technology for the development and production of equipment in 1B608.a was controlled in ECCN 1E001. Related software for the energetic materials in ECCN 1C608.b through .m was EAR99. Related technology for the *development* and *production* of energetic materials in ECCN 1C608.b through .m was controlled in ECCN 1E001. Related technology for *operation, installation, maintenance, repair, overhaul* or *refurbishing* of energetic materials in ECCN 1C608.b through .m was EAR99.

Military helmets providing less than National Institute of Justice (NIJ) level III protection controlled in ECCN 1A613.c and conventional military steel helmets controlled in ECCN 1A613.y were controlled under ECCN 0A018 prior to the effective date of ECCN 1A613. Related test, inspection and production equipment for these helmets controlled in ECCN 1B613, and related software controlled in 1D613 for the helmets and the test, inspection and production equipment was EAR99. Related technology controlled in 1E613 for the helmets, the test, inspection and production equipment and the software was also EAR99.

Diesel engines controlled in ECCN 8A609.b were controlled in ECCN 8A018.b.3 prior to the effective date of ECCN 8A609. Related test, inspection and production equipment for those engines controlled in ECCN 8B609, related materials for those engines controlled in ECCN 8C609, related software for those engines controlled in ECCN 8D609 and related technology controlled in ECCN 8E609 for those engines were EAR99. Additionally, related software controlled in ECCN 8D609 for the test, inspection and production equipment and the materials was EAR99. Related technology controlled in 8E609 for the test, inspection and production equipment, the materials and the software was EAR99.

Submarine and torpedo nets controlled in ECCN 8A620.e, and closed circuit and semi-closed circuit rebreathing apparatus controlled in ECCN 8A620.f were controlled in ECCN 8A018.b.4 and 8A018.a, respectively, prior to the effective date of ECCN 8A620. Test, inspection and production equipment for those nets and rebreathing apparatus was EAR99. Software for those nets, rebreathing apparatus and test, inspection and production equipment was EAR99. Technology for those nets, rebreathing apparatus, test inspection and production equipment was EAR99.

Ground equipment for aircraft controlled in ECCN 9A610.f, pressurized breathing equipment controlled in ECCN 9A610.g and military parachutes, canopies, harnesses, platforms and electronic release mechanisms controlled in ECCN 9A610.h were controlled in ECCN 9A018.c, .d and .e, respectively, prior to the effective date of ECCN 9A610. Related test, inspection and production equipment controlled in ECCN 9B610 for that ground equipment, pressurized breathing equipment, and those military parachutes, canopies, harnesses, platforms and electronic release mechanisms were EAR99 prior to the effective date of ECCN 9B610. Related materials controlled in ECCN 9C610 for that ground equipment, pressurized breathing equipment, those military parachutes, canopies, harnesses, platforms and electronic release mechanisms, and that test, inspection and production equipment was EAR99 prior to the effective date of ECCN 9C610. Related software controlled in ECCN 9D610 for the *development* or *production* of that ground equipment, pressurized breathing equipment, and those military parachutes, canopies, harnesses, platforms and electronic release mechanisms was controlled in ECCN 9D018 prior to the effective date of ECCN 9D610, and related software for the *operation* or *maintenance* of those commodities was EAR99. Related software for that test, inspection and production equipment and those materials was EAR99. Related technology controlled in ECCN 9E610 for the *use* of that ground equipment, pressurized breathing equipment, those military parachutes, canopies, harnesses, platforms and electronic

release mechanisms was controlled in ECCN 9E018 prior to the effective date of ECCN 9E610. Related technology controlled in ECCN 9E610 for the *operation, installation, maintenance, repair, overhaul* or *refurbishing* of those commodities was EAR99 prior to the effective date of ECCN 9E610. Related technology controlled in ECCN 9E610 for the test, inspection and production equipment; materials and software was EAR99 prior to the effective date of ECCN 9E610.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 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). This rule does not impose any regulatory burden on the public and is consistent with the goals of Executive Order 13563. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. 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 of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. The collection of offset reports has been approved by OMB under control number 0694–0084. The estimated number of annual responses is 30 and the estimated number of burden hours is 360. BIS believes that this rule would not materially change the number of responses or burden hours authorized under 0694–0084 because the primary impact of this rule is to restore reporting requirements that have lapsed since those estimates were made, and to retain reporting requirements that otherwise would lapse in the coming months. Although this rule would create new reporting requirements for some items that were subject to Department of Commerce export control jurisdiction prior to being added to 600 series ECCNs, the impact of those additions on the burden is likely to be insignificant because those items are primarily low value items such as military ground vehicles designed for non-combat use, which are not usually the subject of offset agreements. The higher value items that typically trigger offset requirements by the foreign government purchaser, such as combat aircraft, strategic airlifter aircraft, ships, missiles and missile defense systems, are remaining on the USML and their offset reporting requirements have not changed. In addition, any increase in the reporting burden by the imposition of offsets reporting requirements on items that have moved to 600 series ECCNs is likely to be offset by a reduction in that burden resulting from the removal of items from the USML and additions to non-600 series ECCNs, which are not subject to offsets reporting requirements. Those items are: commercial spacecraft including satellites and related items, and certain energetic materials. Send comments regarding this burden estimate or any other aspect of these collections of information, including suggestions for reducing the burden, to Jasmeet K. Seehra, Office of Management and Budget, by email at *jseehra@omb.eop.gov* or by fax to (202) 395–7285 and to William Arvin at *william.arvin@bis.doc.gov.*

3. This proposed rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.

4. The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.,* generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to the notice and comment rulemaking requirements under the Administrative Procedure Act (5 U.S.C. 553) or any other statute, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Under section 605(b) of the RFA, however, if the head of an agency certifies that a rule will not have a significant impact on a substantial number of small entities, the statute does not require the agency to prepare a regulatory flexibility analysis. Pursuant to section 605(b), the Chief Counsel for Regulation, Department of Commerce, certified to the Chief Counsel for Advocacy, Small Business Administration that this proposed rule, if promulgated, will not have a significant impact on a substantial number of small entities for the reasons explained below. Consequently, BIS has not prepared a regulatory flexibility analysis.

Small entities include small businesses, small organizations and small governmental jurisdictions. For purposes of assessing the impact of this proposed rule on small entities, a small entity is defined as: (1) A small business according to the ''Table of Small Business Size Standards Matched to North American Industry Classification System Codes,'' effective January 22, 2014, published by the Small Business Administration (the SBA size standards); (2) a small governmental jurisdiction that is a government of a city, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. BIS has determined that this proposed rule would not affect any of these categories of small entities.

SBA's size standards classify businesses in various North American Industry Classification System (NAICS) codes as small based on their annual revenue or number of employees. For example, in 2014, the maximum annual revenue for a small business was $33.5 million and the maximum number of employees was 1,500. Since BIS began collecting data in 1994, virtually all of the submissions that it has received have been from a small number of very large companies that exceed the SBA size standards for a small business. Since 1994, the number of companies that submitted data to BIS pursuant to this regulation has not exceeded 26 per year. On average, the companies that submit data to BIS have annual revenues well in excess of $1 billion. For instance, in 2013, the most recent year in which BIS collected data pursuant to this regulation, only one of the 26 companies that submitted data had reported revenue of less than $1 billion. That company had revenue of $120 million.

Some small businesses likely are involved in fulfilling offset obligations by acting as subcontractors to the large prime contractors that report directly to BIS, meaning that they report indirectly to BIS pursuant to this section. However, this proposed rule will not significantly increase the burden on such companies. The information collected by BIS pursuant to this section is already collected by such small businesses so that they can accurately account for their obligations under the offset agreement (which is imposed at the behest of the foreign buyer) and report them to the prime contractor. The only new reporting requirement in this proposed rule is the classification of offset agreements and transactions by NAICS code. Even subcontractors involved in the manufacture of defense articles are likely to conduct business with the U.S. government and, therefore, be required to classify their products and services in accordance with the NAICS (*See* System for Award

Management User Guide—V. 1.8, July 23, 2012, Section 3.4, page 92, available at *https://www.sam.gov/sam/transcript/SAM_User_Guide_v1.8.pdf*). In addition, the U.S. government takes steps to facilitate selection of the correct NAICS code by private parties. The U.S. Census Bureau posts instructions on its Web site on how to properly classify products and services in accordance with the NAICS. BIS has included illustrative examples in § 701.4(c)(1)(iii) and § 701.4(c)(2)(iv) on classifying military export sales and offset transactions by NAICS codes.

In addition, small governmental entities and small organizations are not likely to be involved in international defense trade, and would therefore have no reason to submit data to BIS pursuant to this regulation. Consequently, this proposed rule, if promulgated, will not have a significant impact on a substantial number of small entities.

List of Subjects in 15 CFR Part 701

Administrative practice and procedure, Arms and munitions, Business and industry, Exports, Government contracts, Reporting and recordkeeping requirements.

Accordingly, 15 CFR part 701 is proposed to be amended as follows:

PART 701—[AMENDED]

■ 1. The authority citation for 15 CFR part 701 is revised to read as follows:

Authority: 50 U.S.C. app. 2061 *et. seq.,* E.O. 13603, 77 FR 16651, 3 CFR, 2012 Comp., p. 225.

■ 2. Revise paragraphs (a) and (b) of § 701.2 to read as follows:

§ 701.2 Definitions.

(a) *Offsets*—Compensation practices required as a condition of purchase in either government-to-government or commercial sales of:

(1) Defense articles and/or defense services as defined by the Arms Export Control Act and the International Traffic in Arms Regulations; or

(2) Items controlled under an Export Control Classification Number (ECCN) that has the numeral ''6'' as its third character in the Commerce Control List found in Supplement No. 1 to part 774 of this chapter other than semi-submersible and submersible vessels specially designed for cargo transport and parts, components, accessories and attachments specially designed therefor controlled under ECCN 8A620.b; test, inspection and production equipment controlled in ECCN 8B620.b, software controlled in ECCN 8D620.b and technology controlled in ECCN 8E620.b.

(b) *Military Export Sales*—Exports that are either Foreign Military Sales (FMS) or commercial (direct) sales of:

(1) Defense articles and/or defense services as defined by the Arms Export Control Act and International Traffic in Arms Regulations; or

(2) Items controlled under an Export Control Classification Number (ECCN) that has the numeral ''6'' as its third character in the Commerce Control List found in Supplement No. 1 to part 774 of this chapter other than semi-submersible and submersible vessels specially designed for cargo transport and parts, components, accessories and attachments specially designed therefor controlled under ECCN 8A620.b; test, inspection and production equipment controlled in ECCN 8B620.b; software controlled in ECCN 8D620.b; and technology controlled in ECCN 8E620.b.

* * * * *

■ 3. Revise paragraph (a) of § 701.3 to read as follows:

§ 701.3 Applicability and scope.

(a) This part applies to U.S. firms entering contracts that are subject to an offset agreement exceeding $5,000,000 in value and that are for the sale to a foreign country or foreign firm of: (1) Defense articles and/or defense services as defined by the Arms Export Control Act and International Traffic in Arms Regulations; or

(2) Items controlled under an Export Control Classification Number (ECCN) that has the numeral ''6'' as its third character in the Commerce Control List found in Supplement No. 1 to part 774 of this chapter other than semi-submersible and submersible vessels specially designed for cargo transport and parts, components, accessories and attachments specially designed therefor controlled under ECCN 8A620.b; test, inspection and production equipment controlled in ECCN 8B620.b; software controlled in ECCN 8D620.b and technology controlled in ECCN 8E620.b.

* * * * *

Dated: November 24, 2015.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2015–30421 Filed 12–1–15; 8:45 am]

BILLING CODE 3510–JT–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2015–0751; FRL–9939–64–Region 9]

Revisions to the California State Implementation Plan, San Joaquin Valley Unified Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD) portion of the California State Implementation Plan (SIP). This revision concerns volatile organic compound (VOC), oxides of nitrogen (NO_X), and particulate matter (PM) emissions from internal combustion engines. We are proposing to approve a local rule to regulate these emission sources under the Clean Air Act (CAA or the Act). We are taking comments on this proposal and plan to follow with a final action.

DATES: Any comments must arrive by January 4, 2016.

ADDRESSES: Submit comments, identified by docket number [EPA–R09–OAR–2015–0751, by one of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the on-line instructions.

2. *Email: steckel.andrew@epa.gov.*

3. *Mail or deliver:* Andrew Steckel (Air–4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. If you need to include CBI as part of your comment, please visit *http://www.epa.gov/dockets/comments.html* for further instructions. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. For the full EPA public comment policy and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

Docket: Generally, documents in the docket for this action are available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed at *www.regulations.gov,* some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material, large maps), and some may not be publicly available in either location (*e.g.,* CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Nicole Law, EPA Region IX, (415) 947–4126, *Law.Nicole@epa.gov.*

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

Table of Contents

I. The State's Submittal

A. What rule did the State submit?

Table 1 lists the rule addressed by this proposal with the dates that it was adopted by the local air agency and submitted by the California Air Resources Board (CARB).

TABLE 1—SUBMITTED RULE

Local agency	Rule number	Rule title	Adopted	Submitted
SJVUAPCD	4702	Internal Combustion Engines	11/14/13	05/13/14

On July 18, 2014, EPA determined that the submittal for SJVUAPCD Rule 4702 met the completeness criteria in 40 CFR part 51 Appendix V, which must be met before formal EPA review.

B. Are there other versions of this rule?

We approved an earlier version of Rule 4702 into the SIP on January 10, 2008 (73 FR 1819). The SJVUAPCD adopted revisions to the SIP-approved version on November 14, 2013 and CARB submitted them to us on May 13, 2014. While we can act on only the most recently submitted version, we have reviewed materials provided with previous submittals.

C. What is the purpose of the submitted rule revisions?

VOCs and NO_X help produce ground-level ozone and smog, which harm human health and the environment. PM contributes to effects that are harmful to human health and the environment, including premature mortality, aggravation of respiratory and cardiovascular disease, decreased lung function, visibility impairment, and damage to vegetation and ecosystems. Section 110(a) of the CAA requires States to submit regulations that control emissions of VOC, NO_X, and PM, among other pollutants.

The primary changes to Rule 4702 include expanding the applicability of the rule, establishing lower NO_X limits for spark-ignited non-Agricultural Operation (non-AO) IC engines, and adding a fee compliance option. EPA's technical support document (TSD) contains more information about this rule.

II. EPA's Evaluation and Proposed Action

A. How is EPA evaluating the rule?

Generally, SIP rules must be enforceable (see CAA section 110(a)(2)), must not interfere with applicable requirements concerning attainment and reasonable further progress or other CAA requirements (see CAA section 110(l)), and must not modify certain SIP control requirements in nonattainment areas without ensuring equivalent or greater emissions reductions (see CAA section 193).

Guidance and policy documents that we use to evaluate pollution control requirements, rule enforceability, and SIP revisions under CAA section 110 include the following:

1. ''State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990,'' 57 FR 13498 (April 16, 1992); 57 FR 18070 (April 28, 1992).
2. ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations,'' EPA, May 25, 1988 (the Bluebook, revised January 11, 1990).
3. ''Guidance Document for Correcting Common VOC & Other Rule Deficiencies,'' EPA Region 9, August 21, 2001 (the Little Bluebook).
4. ''State Implementation Plans; Nitrogen Oxides Supplement to the General Preamble; Clean Air Act Amendments of 1990 Implementation of Title I; Proposed Rule,'' (the NO_X Supplement), 57 FR 55620, November 25, 1992.
5. ''Alternative Control Techniques Document—NO_X Emissions from Stationary Reciprocating Internal Combustion Engines,'' EPA–453/R–93–032, July 1993.
6. ''Determination of Reasonable Available Control Technology and Best Available Retrofit Control Technology for Stationary Spark-Ignited Internal Combustion Engines,'' CARB, November 2011.
7. ''Review of State Implementation Plans and Revisions for Enforceability and Legal Sufficiency,'' September 23, 1987.

In ozone nonattainment areas classified as moderate or above, all major stationary sources of NO_X or VOCs must be subject to Reasonably Available Control Technology (RACT) (see sections 182(b)(2) and 182(f)). The SJVUAPCD regulates an ozone nonattainment area classified as extreme nonattainment for the 1-hour, 1997 8-hour, and 2008 8-hour ozone NAAQS (see 40 CFR 81.305).

Additionally, moderate $PM_{2.5}$ nonattainment areas must implement Reasonably Available Control Measures (RACM), including Reasonably Available Control Technology (RACT) (see CAA sections 172(c)(1) and 189(a)(1)(C)), and serious $PM_{2.5}$ nonattainment areas must implement Best Available Control Measures (BACM), including Best Available Control Technology (BACT) (see CAA section 189(b)(1)(B)). The SJVUAPCD regulates a $PM_{2.5}$ nonattainment area classified as serious nonattainment for the 1997 $PM_{2.5}$ NAAQS and moderate nonattainment for the 2006 and 2012 $PM_{2.5}$ NAAQS. Therefore, we are evaluating this rule for compliance with both RACT and BACT requirements for NO_X control.

B. Does the rule meet the evaluation criteria?

We believe this rule is consistent with the relevant policy and guidance regarding enforceability, RACT, BACT, and SIP revisions. Although the new NO_X emission limits for spark-ignited IC engines used in non-agricultural

operations in Table 2 of the revised rule are not enforceable because of the option to pay fees in lieu of compliance with the limits (section 5.2.2.2), the rule clearly requires that all engines in the fee program comply with the applicable limits in Table 1 of the rule (section 5.2.2.2.1), which are identical to the control requirements in the SIP-approved version of Rule 4702. Based on our evaluation of the control requirements in the rule and related support documents in the SIP submission, we propose to determine that Rule 4702 implements BACT for NO_X emissions from stationary internal combustion engines operating in the SJV. The TSD has more information on our evaluation.

C. EPA Recommendations to Further Improve the Rule

The TSD describes additional rule revisions that we recommend for the next time SJVUAPCD modifies the rule but are not currently the basis for rule disapproval.

D. Public Comment and Proposed Action

As authorized in section 110(k)(3) of the Act, EPA is proposing to fully approve the submitted rule based on our conclusion that the rule satisfies all applicable CAA requirements. We will accept comments from the public on this proposal until January 4, 2016.

III. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the SJVUAPCD rule as described in Table 1 of this notice. The EPA has made, and will continue to make, these documents available electronically through *www.regulations.gov* and in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

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

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

In addition, this proposed action 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 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 will not have tribal implications and 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, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: November 12, 2015.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2015–30542 Filed 12–1–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2013–0613; FRL–9939–46–Region 6]

Approval and Promulgation of Implementation Plans; State of New Mexico/Albuquerque-Bernalillo County; Infrastructure and Interstate Transport SIP 2010 Nitrogen Dioxide National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Under the Federal Clean Air Act (CAA or the Act), the Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) submission from the State of New Mexico on behalf of the City of Albuquerque-Bernalillo County for the Nitrogen Dioxide (NO_2) National Ambient Air Quality Standards (NAAQS). The submittal addresses how the existing SIP provides for implementation, maintenance, and enforcement of the 2010 NO_2 NAAQS (infrastructure SIP or i-SIP). This i-SIP ensures that the State's SIP for Albuquerque-Bernalillo County is adequate to meet the state's responsibilities under the CAA, including the four CAA requirements for interstate transport of NO_2 emissions.

DATES: Written comments must be received on or before January 4, 2016.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R06–OAR–2013–0613, by one of the following methods:

- *www.regulations.gov.* Follow the online instructions.
- *Email:* Tracie Donaldson at *Donaldson.tracie@epa.gov.*
- *Mail or delivery:* Mary Stanton, Chief, State Implementation B Section (6MM–AB), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. Deliveries are accepted only between the hours of 8 a.m. and 4 p.m. weekdays, and not on legal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R06–OAR–2013–0613. 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 electronically any information that you consider to be CBI or other information whose disclosure is restricted by statute. 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. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional information on submitting comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

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: Tracie Donaldson, telephone 214–665–6633, *donaldson.tracie@epa.gov.* To inspect the hard copy materials, please schedule an appointment with Tracie Donaldson or Bill Deese at 214–665–7253.

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

I. Background

On January 22, 2010, EPA revised the primary NO_2 NAAQS (hereafter the 2010 NO_2 NAAQS) to establish a new 1-hour standard, with a level of 100 parts per billion (ppb), based on the 3-year average of the annual 98th percentile of the yearly distributions of 1-hour daily maximum concentrations (75 FR 6474). Each state must submit an i-SIP within three years after the promulgation of a new or revised NAAQS. Section 110(a)(2) of the CAA includes a list of specific elements the i-SIP must meet. EPA issued guidance addressing the i-SIP elements for NAAQS.[1] The Secretary of the New Mexico Environmental Department (NMED) submitted an i-SIP revision on behalf of Albuquerque-Bernalillo County to address this revised NAAQS on July 26, 2013.

EPA is proposing to approve the Albuquerque-Bernalillo County, New Mexico i-SIP submittal for the 2010 NO_2 NAAQS,[2] as meeting the requirements of an i-SIP.

II. EPA's Evaluation of New Mexico's i-SIP and Interstate Transport Submittal

Below is a summary of EPA's evaluation of the Albuquerque-Bernalillo County, New Mexico i-SIP for each applicable element of 110(a)(2) A–M. The Albuquerque-Bernalillo County Air Quality Control Board (Air Board) provided a demonstration of how the existing Albuquerque-Bernalillo County, New Mexico SIP met all the requirements of the 2010 NO_2 NAAQS on July 26, 2013. This SIP submission is complete by operation of law on January 26, 2014. *See* CAA section 110(k)(1)(B).

(A) Emission limits and other control measures: CAA section 110(a)(2)(A) requires SIPs to include enforceable emission limits and other control measures, means or techniques, as well as schedules and timetables for compliance, as may be necessary or appropriate to meet the applicable requirements of the Act, and other related matters as needed to implement, maintain and enforce each of the NAAQS.[3]

Legislative authority for Albuquerque-Bernalillo County's air quality program codified in Chapter 74 *Environmental Improvement,* Article 2, *Air Pollution,* of the New Mexico statutes, gives the Air Board and the Albuquerque Environmental Health Department's Air Quality Program (AQP) the authority to implement the CAA in Albuquerque-Bernalillo County, New Mexico. Enforceable emission limitations and other control measures are authorized by the New Mexico Air Quality Control Act (AQCA) which established the Air Board and those provisions of New Mexico Administrative Code (NMAC) Title 20, *Environmental Protection,* Chapter 11, *Albuquerque-Bernalillo County Air Quality Control Board.* They can adopt emission standards and compliance schedules applicable to regulated entities; emission standards and limitations and any other measures necessary for attainment and maintenance of national standards; and, enforce applicable laws, regulations, standards and compliance schedules, and seek injunctive relief within the boundaries of Bernalillo County. This authority has been employed to adopt and submit multiple revisions to the Albuquerque-Bernalillo County, New Mexico State Implementation Plan. The approved SIP for Albuquerque-Bernalillo County, New Mexico is documented at 40 CFR part 52.1620, Subpart GG.[4]

(B) Ambient air quality monitoring/data system: The SIP must provide for

[1] ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act sections 110(a)(1) and 110(a)(2),'' Memorandum from Stephen D. Page, September 13, 2013.

[2] Additional information on: The history of NO_2, its levels, forms and, determination of compliance; EPA's approach for reviewing i-SIPs; the details of the SIP submittal and EPA's evaluation; the effect of recent court decisions on i-SIPs; the statute and regulatory citations in the New Mexico SIP specific to this review; the specific i-SIP applicable CAA and EPA regulatory citations; **Federal Register** Notice citations for New Mexico SIP approvals; New Mexico's minor New Source Review program and EPA approval activities; and, New Mexico's Prevention of Significant Deterioration (PSD) program can be found in the Technical Support Document (TSD).

[3] The specific nonattainment area plan requirements of section 110(a)(2)(I) are subject to the timing requirements of section 172, not the timing requirement of section 110(a)(1). Thus, section 110(a)(2)(A) does not require that states submit regulations or emissions limits specifically for attaining the 2010 NO_2 NAAQS. Those SIP provisions are due as part of each state's attainment plan, and will be addressed separately from the requirements of section 110(a)(2)(A). In the context of an infrastructure SIP, EPA is not evaluating the existing SIP provisions for this purpose. Instead, EPA is only evaluating whether the state's SIP has basic structural provisions for the implementation of the NAAQS.

[4] *http://www.ecfr.gov/cgi-bin/text-idx?SID=64943a7422504656d8d72e9d6f87f177&mc=true&node=sp40.5.52.ss&rgn=div6.*

establishment and implementation of ambient air quality monitors, collection and analysis of monitoring data, and providing the data to EPA upon request.

The AQCA provides AQP with the authority to monitor ambient air quality in the county (NMSA 1978, section 74–2–5). AQP maintains a monitoring network for the NAAQS and submits an annual Network Assessment to EPA. AQP's 2014 Air Monitoring Network Plan is the most recently EPA-approved network monitoring plan—approved by EPA on February 3, 2015. All monitoring data is measured using EPA approved methods and subject to the EPA quality assurance requirements. AQP submits all required data to EPA, following the EPA regulations. The monitoring network was approved into the SIP (46 FR 4005, August 6, 1981) and undergoes annual review by the EPA.[5] In addition, AQP conducts an assessment of the monitoring network every 5 years. The most recent of these 5-year monitoring network assessments was conducted by AQP and approved by EPA. Data is available upon request and in the EPA Air Quality System (AQS) database.

(C) Program for enforcement The SIP must include the following three elements: (1) A program providing for enforcement of the measure in paragraph *A* above; (2) a program for the regulation of the modification and construction of stationary sources as necessary to protect the applicable NAAQS (*i.e.,* state-wide permitting of minor sources); and (3) a permit program to meet the major source permitting requirements of the CAA (for areas designated as attainment or unclassifiable for the NAAQS in question).[6]

(1) Enforcement of SIP Measures. As noted in (*A*), the state statutes provide authority for the AQP to enforce the requirements of the AQCA within Albuquerque-Bernalillo County, and any regulations, permits, or final compliance orders. Its statutes also provide the AQP with general enforcement powers. Among other things, they can file lawsuits to compel compliance with the statutes and regulations; commence civil actions; issue field citations; conduct investigations of regulated entities; collect criminal and civil penalties; develop and enforce rules and standards related to protection of air quality; issue compliance orders; pursue criminal prosecutions; investigate, enter into remediation agreements; and issue emergency cease and desist orders. The AQCA also provides additional enforcement authorities and funding mechanisms.

(2) Minor New Source Review (NSR). The CAA requires the SIP to include measures to regulate construction and modification of stationary sources to protect the NAAQS. Albuquerque-Bernalillo County's minor NSR permitting requirements are approved as part of the SIP.[7]

(3) Prevention of Significant Deterioration (PSD) permit program. Albuquerque-Bernalillo County's PSD portion of the SIP covers all NSR regulated pollutants as well as the requirements for the 2010 NO_2 NAAQS and has been approved by EPA.[8] EPA approved revisions that address the requirements of the EPA's May 2008, July 2010, and October 2012 $PM_{2.5}$ PSD Implementation Rules and to incorporate revisions consistent with the EPA's March 2011 Fugitives Interim Rule, July 2011 Greenhouse Gas (GHG) Biomass Deferral Rule, and July 2012 GHG Tailoring Rule Step 3 and GHG PALs Rule (80 FR 52401, August 31, 2015).

(D) Interstate and international transport: The requirements for interstate transport of NO_2 emissions are that the SIP contain adequate provisions prohibiting emissions to other states which will (1) contribute significantly to nonattainment of the NAAQS, (2) interfere with maintenance of the NAAQS, (3) interfere with measures required to prevent significant deterioration or (4) interfere with measures to protect visibility (CAA 110(a)(2)(D)(i)).

In the original submission, Albuquerque-Bernalillo County requested that EPA not consider element 110(a)(2)(D)(i)(I) as a revision to the SIP at that time stating that this element would be addressed at a future date. In a letter dated October 2, 2015, from NMED Secretary Ryan Flynn to Regional Administrator Ron Curry, a request was made that we now consider and act on this element of the i-SIP. As all the information needed to make this determination was included in the original submission, as well as monitored NO_2 concentrations indicating design values below the standard, and the lack of NO_2 nonattainment areas in New Mexico (including Albuquerque-Bernalillo County) or within close proximity, we find that Albuquerque-Bernalillo County does not contribute to nonattainment nor interfere with maintenance of the NAAQS.

With respect to the interstate transport and PSD requirements of section 110(a)(2)(D)(i)(II), we note that Albuquerque-Bernalillo County's satisfaction of the applicable infrastructure SIP PSD requirements for attainment/unclassifiable areas with regards to the 2010 NO_2 NAAQS have been detailed in the section addressing section 110(a)(2)(C). Two revisions to the SIP to update the Albuquerque-Bernalillo County PSD SIP permitting program consistent with federal requirements have been approved (80 FR 52401, August 31, 2015). These approvals contain revisions to address the requirements of the EPA's May 2008, July 2010, and October 2012 $PM_{2.5}$ PSD Implementation Rules and to incorporate revisions consistent with the EPA's March 2011 Fugitives Interim Rule, July 2011 Greenhouse Gas (GHG) Biomass Deferral Rule, and July 2012 GHG Tailoring Rule Step 3 and GHG PALs Rule.

For sources not subject to PSD for any one of the pollutants subject to regulation under the CAA because they are in a nonattainment area for a NAAQS, Albuquerque-Bernalillo County has adopted the nonattainment new source review (NNSR) provisions required for the 2010 NO_2 NAAQS and other NAAQS at 20.11.60 NMAC—*Permitting in Nonattainment Areas.*

With regard to the applicable requirements for visibility protection of section 110(a)(2)(D)(i)(II), this requirement was met by our approval of the regional haze and visibility component of the SIP.

There are no final findings by EPA that New Mexico air emissions affect other countries. Therefore, New Mexico has no international obligations. If EPA makes such a finding, AQP will consult with EPA.

Section 110(a)(2)(D)(ii) also requires that the SIP ensure compliance with the applicable requirements of sections 126 and 115 of the CAA, relating to interstate and international pollution abatement, respectively. Section 126(a) of the CAA requires new or modified

[5] A copy of the 2014 Annual Air Monitoring Network Plan and EPA's approval letter dated February 3, 2015, are included in the docket for this proposed rulemaking.

[6] As discussed in further detail in the TSD.

[7] EPA is not proposing to approve or disapprove Albuquerque-Bernalillo County's existing minor NSR program to the extent that it may be inconsistent with EPA's regulations governing this program. EPA has maintained that the CAA does not require that new infrastructure SIP submissions correct any defects in existing EPA-approved provisions of minor NSR programs in order for EPA to approve the infrastructure SIP for element C (*e.g.,* 76 FR 41076–41079, July 13, 2011). EPA believes that a number of states may have minor NSR provisions that are contrary to the existing EPA regulations for this program. The statutory requirements of section 110(a)(2)(C) provide for considerable flexibility in designing minor NSR programs.

[8] As discussed further in the TSD.

sources to notify neighboring states of potential impacts from sources within the State. Albuquerque-Bernalillo County regulations require that affected states, tribes and federal land managers receive notice prior to the commencement of any construction or significant modification of a major source. In addition, no sources located in Albuquerque-Bernalillo County have been identified by EPA as having any interstate impacts under section 126 in any pending actions relating to any air pollutant.

Section 115 of the CAA authorizes EPA to require a state to revise its SIP under certain conditions to alleviate international transport into another country. There are no final findings under section 115 of the CAA against New Mexico with respect to any air pollutant. Thus, the State's SIP does not need to include any provisions to meet the requirements of section 115.

Based upon review of the County's infrastructure SIP submission for the 2010 NO_2 NAAQS, and relevant statutory and regulatory authorities and provisions referenced in the submission or referenced in New Mexico's SIP, EPA believes that Albuquerque-Bernalillo County has the adequate infrastructure needed to address sections 110(a)(2)(D)(i)(I) and (II)(all 4 interstate transport requirements), as well as 110(a)(2)(D)(ii) for the 2010 NO_2 NAAQS and is proposing to approve this element of the July 26, 2013, submission.

(E) Adequate authority, resources, implementation, and oversight: The SIP must provide for the following: (1) Necessary assurances that the state (and other entities within the state responsible for implementing the SIP) will have adequate personnel, funding, and authority under state or local law to implement the SIP, and that there are no legal impediments to such implementation; (2) requirements relating to state boards; and (3) necessary assurances that the state has responsibility for ensuring adequate implementation of any plan provision for which it relies on local governments or other entities to carry out that portion of the plan.

Both elements A and E herein address the requirement that there is adequate authority to implement and enforce the SIP and that there are no legal impediments.

This i-SIP submission for the 2010 NO_2 NAAQS describes the SIP regulations governing the various functions of personnel within the AQP and the Air Board, including the administrative, technical support, planning, enforcement, and permitting functions of the program.

With respect to funding, the resources to carry out the plan are provided through General Funds, Permit Fees and the CAA grant process. Permit Fees are collected under the authority of section 74–2–7.

As required by the CAA and the Environmental Improvement Act (EIA), the SIP stipulates that any members of the board or body, or the head of an agency with similar powers, adequately disclose any potential conflicts of interest. NMSA 1978 section 74–1–4 provides the Air Board contain at least a majority of members who represent the public interest and do not derive any significant portion of their income from persons subject to or who appear before the board on issues related to the CAA or the AQCA. Board members are required to recuse themselves from rule-makings in which their impartiality may reasonably be questioned.

With respect to assurances that the Air Board has responsibility to implement the SIP adequately when it authorizes local or other agencies to carry out portions of the plan, the EIA and the AQCA designate the Air Board as the primary air pollution control agency within Albuquerque-Bernalillo County. The statutes allow for local agencies to carry out some or all of the Act's responsibilities.

The Albuquerque/Bernalillo County Air Quality Control Board assumes jurisdiction for local administration and enforcement of the AQCA in Bernalillo County. There are Albuquerque/Bernalillo County SIP provisions which are part of the New Mexico SIP.[9]

(F) Stationary source monitoring system: The SIP requires the establishment of a system to monitor emissions from stationary sources and to submit periodic emission reports. It must require the installation, maintenance, and replacement of equipment, and the implementation of other necessary steps, by owners or operators of stationary sources, to monitor emissions from sources. The SIP shall also require periodic reports on the nature and amounts of emissions and emissions-related data from sources, and require that the state correlate the source reports with emission limitations or standards established under the CAA. These reports must be made available for public inspection at reasonable times.

Requirements in 20.11.47 NMAC, *Emission Inventory Requirements* provide for the reporting of emissions inventories in a format established by AQP on a schedule prescribed by the regulation. There also are SIP state regulations pertaining to sampling and testing and requirements for reporting of emissions inventories. In addition, SIP rules establish general requirements for maintaining records and reporting emissions. This information is used to track progress towards measuring the NAAQS, developing control and maintenance strategies, identifying sources and general emission levels, and determining compliance with SIP regulations and additional EPA requirements.

(G) Emergency authority: The SIP must provide for authority to address activities causing imminent and substantial endangerment to public health or welfare or the environment and to include contingency plans to implement such authorities as necessary.

The AQCA provides the New Mexico Environment Department with authority to address environmental emergencies, including the use of contingency plans to implement emergency episode provisions.

Pursuant to 40 CFR part 51, subpart H, *Prevention of Air Pollution Emergency Episodes,* on January 26, 1989, the Air Board adopted the *Air Pollution Contingency Plan for Bernalillo County* [August 21, 1991, 56 FR 38074; 40 CFR 52.1639, *Prevention of Air Emergency Episodes*], which is part of the SIP and covers air pollution episodes and the occurrence of an emergency due to the effects of the pollutants on the health of persons.

(H) Future SIP revisions: States must have the authority to revise their SIPs in response to changes in the NAAQS, availability of improved methods for attaining the NAAQS, or in response to an EPA finding that the SIP is substantially inadequate to attain the NAAQS.

Albuquerque-Bernalillo County's SIP is a compilation of regulations, plans and submittals that act to improve and maintain air quality in accordance with national standards. The authority to develop or revise the SIP is based on the authority to adopt new regulations and revise existing regulations to meet the NAAQS. NMSA 1978 section 74–7–5 gives the board the authority to perform these functions. Section 74–7–5 also gives the board the authority to adopt regulations to abate, control and prohibit air pollution throughout Albuquerque-Bernalillo County in accordance with the *State Rules Act.* Nothing in New Mexico's statutory or regulatory authority prohibits

[9] Albuquerque/Bernalillo County SIP *http://yosemite.epa.gov/r6/Sip0304.nsf/home!OpenView&Start=1&Count=30&Collapse=4.4#4.4* or *https://www.law.cornell.edu/cfr/text/40/52.1620.*

Albuquerque-Bernalillo County from revising the SIP in the event of a revision to the NAAQS. The AQCA specifically requires revisions to the SIP if the scenarios set forth in Section 110(a)(2)(H) occur.

(I) Nonattainment areas: The CAA section 110(a)(2)(I) requires that in the case of a plan or plan revision for areas designated as nonattainment areas, states must meet applicable requirements of part D of the CAA, relating to SIP requirements for designated nonattainment areas.

As noted earlier, EPA does not expect infrastructure SIP submissions to address subsection (I). The specific SIP submissions for designated nonattainment areas, as required under CAA title I, part D, are subject to different submission schedules than those for section 110 infrastructure elements. Instead, EPA will take action on part D attainment plan SIP submissions through a separate rulemaking process governed by the requirements for nonattainment areas, as described in part D.

(J) Consultation with government officials, public notification, PSD and visibility protection: The SIP must meet the following three requirements: (1) Relating to interagency consultation regarding certain CAA requirements; (2) relating to public notification of NAAQS exceedances and related issues; and, (3) prevention of significant deterioration of air quality and visibility protection.

(1) *Interagency consultation:* As required by the AQCA, there must be a public hearing before the adoption of any regulations or emission control requirements and all interested persons must be given a reasonable opportunity to submit data, view documents, or argue orally or in writing and to examine testimony of witnesses from the hearing. In addition, the AQCA provides for the power and duty to ''advise, consult, contract with and cooperate with local authorities, other states, the federal government and other interested persons or groups in regard to matters of common interest in the field of air quality control''.

(2) *Public Notification:* The i-SIP provides the SIP regulatory citations requiring the Air Board to regularly notify the public of instances or areas in which any NAAQS are exceeded, advise the public of the health hazard associated with such exceedances, and enhance public awareness of measures that can prevent such exceedances and ways in which the public can participate in efforts to improve air quality. 20.11.82 NMAC, *Rulemaking Procedures—Air Quality Control Board,* stipulates notice requirements for rulemaking and is used as a guide for notice requirements when adopting SIPs.

(3) *PSD and Visibility Protection:* The PSD requirements here are the same as those addressed under (C). The Albuquerque-Bernalillo County, New Mexico SIP requirements relating to visibility and regional haze are not affected when EPA establishes or revises a NAAQS. Therefore, EPA believes that there are no new visibility protection requirements due to the revision of the NAAQS, and consequently there are no newly applicable visibility protection obligations pursuant to infrastructure element J after the promulgation of a new or revised NAAQS.

(K) Air quality and modeling/data: The SIP must provide for performing air quality modeling, as prescribed by EPA, to predict the effects on ambient air quality of any emissions of any NAAQS pollutant, and for submission of such data to EPA upon request.

AQP has the duty, authority and technical capability to conduct air quality modeling, pursuant to the AQCA, in order to assess the effect on ambient air quality of relevant pollutant emissions; and can provide relevant data as part of the permitting and NAAQS implementation process. AQP follows EPA guidelines for air dispersion modeling. Upon request, AQP will submit current and future data relating to air quality modeling to EPA.

(L) Permitting Fees: The SIP must require each major stationary source to pay permitting fees to the permitting authority, as a condition of any permit required under the CAA, to cover the cost of reviewing and acting upon any application for such a permit, and, if the permit is issued, the costs of implementing and enforcing the terms of the permit. The fee requirement applies until a fee program established by the state pursuant to Title V of the CAA, relating to operating permits, is approved by EPA.

The fee requirements of 20.11.2 NMAC have been approved by EPA as meeting the CAA requirements and were incorporated into the Albuquerque-Bernalillo County, New Mexico SIP [4/10/80, 45 FR 24468]. Albuquerque-Bernalillo County's title V operating permit program codified at 20.11.42 NMAC, *Operating Permits,* was approved by EPA on 9/8/04 [FR vol. 69, No. 173, pp. 54244–47]. In addition, see element (E) above for the description of the mandatory collection of permitting fees outlined in the SIP.

(M) Consultation/participation by affected local entities: The SIP must provide for consultation and participation by local political subdivisions affected by the SIP.

New Mexico State Statute Section 74–2–5.2 *State Air Pollution Control Agency; Specific Duties and Powers of the Department,* states that, ''The department is the state air pollution control agency for all purposes under federal legislation relating to pollution. The department is required to ''advise, consult, contract and cooperate with local authorities, other states, the federal government and other interested persons or groups in regard to matters of common interest in the field of air quality control.'' Also see element (J) above for a discussion of the SIP's public participation process, the authority to advise and consult, and the PSD SIP's public participation requirements.

III. Proposed Action

EPA is proposing to approve the July 26, 2013, infrastructure SIP submission from Albuquerque-Bernalillo County, New Mexico, which addresses the requirements of CAA sections 110(a)(1) and (2) as applicable to the 2010 NO_2 NAAQS. Specifically, EPA is proposing to approve the following infrastructure elements: 110(a)(2)(A), (B), (C), (D), (E), (F), (G), (H), (J), (K), (L), and (M). EPA is not proposing action pertaining to section 110(a)(2)(I)—Nonattainment Area Plan or Plan Revisions as EPA believes these need not be addressed in the i-SIP. Based upon review of the state's infrastructure SIP submissions and relevant statutory and regulatory authorities and provisions referenced in these submissions or referenced in Albuquerque-Bernalillo County, New Mexico's SIP, EPA believes that Albuquerque-Bernalillo County, New Mexico has the infrastructure in place to address all applicable required elements of sections 110(a)(1) and (2) to ensure that the 2010 NO_2 NAAQS are implemented in the county. We also are proposing to approve the State's demonstration that it meets the four statutory requirements for interstate transport of NO_2 emissions.

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 proposes to approve state law as meeting Federal requirements and does not impose additional requirements

beyond those imposed by state law. For that reason, this 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 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, 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 proposed rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Nitrogen dioxide (NO_2).

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

Dated: November 17, 2015.

Ron Curry,

Regional Administrator, Region 6.

[FR Doc. 2015–30490 Filed 12–1–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0008; FRL–9939–55]

Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing of petitions and request for comment.

SUMMARY: This document announces the Agency's receipt of several initial filings of pesticide petitions requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

DATES: Comments must be received on or before January 4, 2016.

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the pesticide petition number (PP) 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 (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

• Crop production (NAICS code 111).

• Animal production (NAICS code 112).

• Food manufacturing (NAICS code 311).

• Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT** for the division listed at the end of the pesticide petition summary of interest.

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. What action is the Agency taking?

EPA is announcing its receipt of several pesticide petitions filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, requesting the establishment or modification of regulations in 40 CFR part 180.377 and part 180.510 for residues of pesticide chemicals in or on various food commodities. The Agency is taking public comment on the requests before responding to the petitioners. EPA is not proposing any particular action at this time. EPA has determined that the pesticide petitions described in this document contain the data or information prescribed in FFDCA section 408(d)(2), 21 U.S.C. 346a(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the pesticide petitions. After considering the public comments, EPA intends to evaluate whether and what action may be warranted. Additional data may be needed before EPA can make a final determination on these pesticide petitions.

Pursuant to 40 CFR 180.7(f), a summary of each of the petitions that are the subject of this document, prepared by the petitioner, is included in a docket EPA has created for each rulemaking. The docket for each of the petitions is available at *http://www.regulations.gov*.

As specified in FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), EPA is publishing notice of the petition so that the public has an opportunity to comment on this request for the establishment or modification of regulations for residues of pesticides in or on food commodities. Further information on the petition may be obtained through the petition summary referenced in this unit.

New Tolerance

PP 4E8306 (EPA–HQ–OPP–2014–0672). IR–4, IR–4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W., Princeton, NJ 08540 requests the following: (1) To establish tolerances in 40 CFR 180.377 for the combined residues of the insecticide, diflubenzuron (N-[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide) and its metabolites 4-chlorophenlyurea and 4-chloroaniline, in or on the raw agricultural commodities carrot, roots at 0.2 ppm; peach subgroup 12–12B at 0.5 ppm; plum subgroup 12–12C at 0.5 ppm; plum, prune, dried at 0.5 ppm; nut, tree, group 14–12 at 0.2 ppm; pepper/eggplant subgroup 8–10 B at 1.0 ppm, and cottonseed subgroup 20C at 0.2 ppm. Upon the approval of these tolerances, to remove established tolerances in or on fruit, stone, group 12, except cherry at 0.07 ppm; nut, tree, group 14 at 0.06 ppm; pistachio at 0.06 ppm; pepper at 1.0 ppm; and cotton, undelinted seed at 0.2 ppm. (2) to establish a regional tolerance for the combined residues of diflubenzuron and its metabolites 4-chlorophenlyurea and 4-chloroaniline in or on the raw agricultural commodities alfalfa, forage at 6 ppm; alfalfa, hay at 20 ppm; and alfalfa, seed at 0.9 ppm. Adequate enforcement analytical methods for determining diflubenzuron and its metabolites in/on appropriate raw agricultural commodities and processed commodities are available for the established and proposed tolerances. Contact: RD.

Amended Tolerances

1. PP 4E8306 (EPA–HQ–OPP–2014–0672). IR–4, IR–4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W., Princeton, NJ 08540, requests that the existing tolerances in 40 CFR 180.377 for the insecticide, diflubenzuron, in or on the following raw agricultural commodities be modified: Egg from 0.05 to 0.15 ppm; poultry, fat from 0.05 to 0.15 ppm; and poultry, meat byproducts from 0.05 to 0.06 ppm. Adequate enforcement analytical methods for determining diflubenzuron and its metabolites, 4-chlorophenlyurea and 4-chloroaniline in/on appropriate raw agricultural commodities and processed commodities are available for the established and proposed tolerances. Contact: RD.

2. PP 4E8326 (EPA–HQ–OPP–2011–1012). Sumitomo Chemical Company (through their Agent, Valent U.S.A. Corporation), 1600 Riviera Avenue, Suite 200, Walnut Creek, CA 94596, requests to amend the tolerances in 40 CFR 180.510 by raising the tolerance for residues of pyriproxyfen in or on the raw agricultural commodity tea from 0.02 ppm to 15 ppm. Contact: RD.

Authority: 21 U.S.C. 346a.

Dated: November 25, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2015–30539 Filed 12–1–15; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register
Vol. 80, No. 231
Wednesday, December 2, 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 COMMERCE

International Trade Administration

[A–583–837]

Polyethylene Terephthalate Film, Sheet, and Strip (PET Film) From Taiwan: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2013–2014

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On July 29, 2015, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty (AD) order on polyethylene terephthalate film, sheet, and strip (PET Film) from Taiwan in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act).[1] This review covers Nan Ya Plastics Corporation (Nan Ya) and Shinkong Materials Technology Corporation (SMTC). We invited interested parties to comment on the *Preliminary Results.* We received no comments or requests for a hearing. Therefore, for the final results, we continue to find that sales of subject merchandise by Nan Ya were not made at less than normal value during the period of review (POR). We continue to find that SMTC had no shipments during the POR.

DATES: *Effective Date:* December 2, 2015.

FOR FURTHER INFORMATION CONTACT: Jacqueline Arrowsmith, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–5255.

Background

On July 29, 2015, the Department published the *Preliminary Results.* The POR is July 1, 2013, through June 30, 2014. We invited interested parties to comment on the *Preliminary Results.* We received no comments or requests for a hearing from any party. The Department conducted this administrative review in accordance with section 751(a)(2) of the Act.

Scope of the Order

The products covered by the antidumping duty order are all gauges of raw, pretreated, or primed PET film, whether extruded or coextruded. Excluded are metalized films and other finished films that have had at least one of their surfaces modified by the application of a performance-enhancing resinous or inorganic layer of more than 0.00001 inches thick. Imports of polyethylene terephthalate film, sheet, and strip are currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under item number 3920.62.00.90. HTSUS subheadings are provided for convenience and customs purposes. The written description of the scope of the antidumping duty order is dispositive.

Final Results of Review

As noted above, the Department received no comments concerning the *Preliminary Results.* As there are no changes from, or comments upon, the *Preliminary Results*, the Department finds that there is no reason to modify its analysis and calculations. Thus, we continue to find that sales of subject merchandise by Nan Ya were not made at less than normal value during the POR. We continue to find that SMTC had no shipments during the POR. Accordingly, no decision memorandum accompanies this **Federal Register** notice. For further details of the issues addressed in this proceeding, *see* the *Preliminary Results* and the accompanying Preliminary Decision Memorandum.[2] The final weighted-average dumping margin for the period July 1, 2013, through June 30, 2014, for Nan Ya is as follows:

Producer/Exporter	Weighted-average margin (percentage)
Nan Ya Plastics Corporation	0.00

Final Determination of No Shipments

Based on our analysis of U.S. Customs and Border Protection (CBP) information and information provided by SMTC and its affiliate Shinkong Synthetic Fibers Corporation (SSFC), we determine that SMTC had no shipments of the subject merchandise, and, therefore, no reviewable transactions, during the POR. For a full discussion of this determination, *see* the Preliminary Decision Memorandum.

Assessment Rates

The Department will determine, and CBP shall assess, antidumping duties on all appropriate entries in this review, in accordance with section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(1). The Department intends to issue assessment instructions directly to CBP 15 days after publication of these final results of review. Because we have calculated a zero margin for Nan Ya in the final results of this review, in accordance with 19 CFR 351.212 we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

The Department clarified its ''automatic assessment'' regulation on May 6, 2003 in its *Assessment Policy Notice*.[3] This clarification applies to entries of subject merchandise during the POR produced and exported by Nan Ya for which it did not know that the merchandise was destined for the United States. Furthermore, this clarification applies to all POR entries entered under the case number for SMTC because it certified that it made no POR shipments of subject merchandise for which it had knowledge of the U.S. destination. In such instances, consistent with the

[1] *See Polyethylene Terephthalate Film, Sheet, and Strip From Taiwan: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2013–2014*, 80 FR 45182 (July 29, 2015) (*Preliminary Results*).

[2] *See* ''Decision Memorandum for Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments: Polyethylene Terephthalate Film, Sheet, and Strip from Taiwan; 2013–2014,'' from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, dated July 22, 2015 (Preliminary Decision Memorandum), which can be accessed directly at *http://enforcement.trade.gov/frn/index.html.*

[3] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003) (*Assessment Policy Notice*).

Assessment Policy Notice, we will instruct CBP to liquidate un-reviewed entries at the all-others rate established in the less-than fair-value (LTFV) investigation, 2.40 percent,[4] if there is no rate for the intermediate company(ies) involved in the transaction.[5]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for Nan Ya will be 0.00%, the rate established in the final results of this review; (2) for previously reviewed or investigated companies not covered in this review, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this or any previous review or in the original LTFV investigation but the manufacturer is, the cash-deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in this or any previous review or the investigation, the cash-deposit rate will continue to be the all-others rate of 2.40 percent, which is the all-others rate established by the Department in the LTFV investigation.[6] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Reimbursement of Duties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation, which is subject to sanction.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(h).

Dated: November 20, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2015–30339 Filed 12–1–15; 8:45 am]

BILLING CODE 3510–DS–P

[4] *See Notice of Amended Final Antidumping Duty Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Polyethylene Terephthalate Film, Sheet, and Strip (PET Film) from Taiwan*, 67 FR 44174, 44175 (July 1, 2002) (*PET Film from Taiwan Amended Final Determination*), unchanged in *Notice of Amended Final Antidumping Duty Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Polyethylene Terephthalate Film, Sheet, and Strip (PET Film) from Taiwan*, 67 FR 46566 (July 15, 2002) (*Correction Notice*).

[5] *See Assessment Policy Notice* for a full discussion of this clarification.

[6] *See PET Film from Taiwan Amended Final Determination,* 67 FR at 44175, unchanged in *Correction Notice*, 67 FR at 46566.

DEPARTMENT OF EDUCATION

Privacy Act of 1974; System of Records—Impact Evaluation of Data-Driven Instruction Professional Development for Teachers

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 Data-Driven Instruction Professional Development for Teachers'' (#18–13–39). The National Center for Education Evaluation and Regional Assistance at the Department's Institute of Education Sciences (IES) awarded a contract in September 2012 to Mathematica Policy Research, Abt Associates, Synergy Enterprises, Evidence-Based Education Research & Evaluation, and Public Consulting Group Education—Focus on Results to provide evidence on the effectiveness of data-driven instruction professional development.

DATES: Submit your comments on this proposed new system of records on or before January 4, 2016.

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 November 20, 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 January 2, 2016, unless OMB waives 10 days of the 40–day review period for compelling reasons shown by the Department, or (2) January 4, 2016, 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: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID and the term ''Impact Evaluation of Data-Driven Instruction Professional Development for Teachers'' at the top of your comments.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using Regulations.gov, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''Are you new to the site.''
- *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments about these proposed priorities, requirements, definitions, and selection criterion address them 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.

Privacy Note: The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore,

commenters should be careful to include in their comments only information that they wish to make publicly available.

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 12,000 students, 500 teachers, and 104 principals from 104 schools in 12 school districts and will include, but will 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 plan status, school enrollment dates, attendance records, and discipline records, and (2) for principals and teachers, individual district identifiers, school assignments, grades and subjects taught, and principal and teacher background characteristics, including age, sex, race/ethnicity, certifications, degrees, years of teaching experience, scores on licensure or certification tests.

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: November 23, 2015.

Ruth Curran Neild,

Deputy Director for Policy and Research, Delegated Duties of the Director of the 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:

#18–13–39.

SYSTEM NAME:

Impact Evaluation of Data-Driven Instruction Professional Development for Teachers.

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) Mathematica Policy Research, P.O. Box 2393, Princeton, NJ 08543–2393 (contractor).

(3) Abt Associates, 55 Wheeler Street, Cambridge MA 02138–1168 (sub-contractor).

(4) Synergy Enterprises, 8757 Georgia Avenue, Suite 1440, Silver Spring, MD 20910 (sub-contractor).

(5) Evidence-Based Education Research & Evaluation, 34 Washburn Avenue, Cambridge, MD 02140 (sub-contractor).

(6) Public Consulting Group Education—Focus on Results, 148 State Street, Boston, MA 02109 (sub-contractor).

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system of records will include personally identifying information about the students, teachers, and principals who participate in the study. The system will contain records on approximately 12,000 students, 500 teachers, and 104 principals from 104 schools in 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 plan status, school enrollment dates, attendance records, and discipline records. For principals and teachers, this information will include, but will not necessarily be limited to, individual district identifiers, school assignments, grades and subjects taught, and principal and teacher background characteristics, including age, sex, race/ethnicity, certifications, degrees, years of teaching experience, and scores on licensure or certification tests.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The study is authorized under sections 2121–2123 of the Elementary and Secondary Education Act of 1965, as amended (ESEA) (20 U.S.C. 6621–6623), section 9601 of the ESEA (20 U.S.C. 7941), and section 171(b) of the Education Sciences Reform Act of 2002 (ESRA) (20 U.S.C. 9561).

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 data-driven instruction professional development to teachers and principals.

The study will address the following central research question: What are the impacts of data-driven instruction professional development on student achievement, teachers' instructional strategies, and school supports for using data? Secondary research questions for the study are: How are schools implementing data-driven instruction? What challenges do schools face in its implementation?

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. Any disclosure of personally identifiable information from student education records that were obtained from schools or school districts 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.

Contract Disclosure. If the Department contracts with an entity to perform any function that requires disclosing records in this system to the contractor's employees, 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 establish and maintain the safeguards required under the Privacy Act (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 and sub-contractors 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 will be cross-referenced by the individual's name on a separate list.

SAFEGUARDS:

All physical access to the Department's site and to the site of the Department's contractor and sub-contractors, where this system of records will be maintained, will be 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 will establish similar procedures at its site to ensure confidentiality of data. The contractor is 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 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 will be also 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 and the contractor'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 principals, teachers, and students participating in an impact evaluation of data-driven instruction professional development. Data will be obtained from human resource and student administrative records maintained by the schools and school districts, a survey of principals and teachers, and teacher activity logs to document teachers' planning and classroom activities over four school days.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 2015–30526 Filed 12–1–15; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2015–0771; FRL–9939–41–OAR]

Protection of Stratospheric Ozone: Notice of Revocation of Certification for Refrigerant Reclaimers

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of revocation.

SUMMARY: In accordance with 40 CFR 82.164, no person may sell or offer for sale or use as a refrigerant, any class I or class II ozone-depleting substance consisting wholly or in part of used refrigerant unless the substance has been reclaimed by an Environmental Protection Agency (EPA)-certified refrigerant reclaimer. All persons reclaiming used refrigerant for sale to a new owner are required to certify to the EPA Administrator in accordance with 40 CFR 82.164 and to maintain records and submit reports in accordance with 40 CFR 82.166.

Through this action, the EPA is giving notice of the impending revocation of one refrigerant reclaimer, Refrigerants Exchange, Inc. (RefEx) of Irwindale, CA, in accordance with 40 CFR part 82, subpart F. In addition, the EPA is announcing the previous revocation of certification of eight refrigerant reclaimers. An up-to-date list of EPA-certified refrigerant reclaimers is available online at *www.epa.gov/ozone/title6/608/reclamation/reclist.html.*

DATES: If RefEx wishes to request a hearing for the impending revocation of its reclaimer certification, it must request a hearing in writing on or before January 4, 2016. If a written request and supporting data are not received by that date, RefEx's certification to reclaim refrigerants is revoked effective February 1, 2016.

The following entities had their certification as refrigerant reclaimers revoked previously, effective as of the dates listed below and on EPA's Web site:

November 2009: Polar Refrigerant in South Hampton, NH

March 19, 2009: Refrigerant Services, Inc in Imperial Beach, CA

January 10, 2008: Rocky Mountain Reclamation, Inc in Denver, CO; Star Refrigerants in Fort Worth, TX

March 9, 2007: Teris, LLC in El Dorado, AR

March 13, 2006: Cryo-Line Supplies USA, Inc. in Henderson, NV; Refrigerant Recovery, Inc. in Milwaukee, WI; South Florida Trane Service in Miami, FL

FOR FURTHER INFORMATION CONTACT: Luke Hall-Jordan, Stratospheric Protection Division, Office of Atmospheric Programs, (6205T), 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number (202) 343–9591; email address *hall-jordan.luke@epa.gov.*

SUPPLEMENTARY INFORMATION:

Impending Revocation

On June 10, 2011, the EPA issued a request for information (June 10, 2011 Request or Request, available in the docket for this notice) to RefEx pursuant to Section 114 of the Clean Air Act (CAA). Section 114 of the CAA authorizes the EPA to request such information from anyone who is subject to any requirement of the CAA in order to determine the compliance status of that person or entity. RefEx is subject to regulations at 40 CFR 82.164 and 82.166 implementing section 608 of the Clean Air Act.

The June 10, 2011 Request asked, in part, for records documenting that reclaimed refrigerant sold by RefEx met the ARI 700 standard (upon which the *Specifications for Fluorocarbon and Other Refrigerants* in appendix A to 40 CFR part 82, subpart F are based), for the two-year period prior to RefEx's receipt of the request. RefEx responded to the Request in part on July 7, 2011. Records provided by RefEx in its response did not demonstrate that all refrigerant sold by RefEx in the relevant time frame was reprocessed to meet all of the applicable specifications in appendix A to 40 CFR part 82, subpart F. As part of its reclaimer certification, RefEx is required to verify that the reprocessed refrigerant meets all of the specifications in appendix A. *See* 40 CFR 82.164(b), (e)(3), and (g). In addition, among other things, the June 10, 2011 Request asked for the names and addresses of persons that sent RefEx material for reclamation in the 12 months prior to the Request. RefEx's July 7, 2011 response also did not provide that information. RefEx is required to keep this information under 40 CFR 82.164(e)(3) and 82.166(g).

EPA sent two follow-up letters (also available in the docket for this notice), dated August 19, 2011 and October 25, 2011, noting deficiencies in RefEx's July 7, 2011 response and requesting a full and complete response to the June 10, 2011 Request. Further, EPA offered RefEx the opportunity to provide any additional documentation in response to the June 10, 2011 Request that EPA may use to determine RefEx's compliance with 40 CFR 82.164 and 82.166 in a letter dated March 16, 2015 (also available in the docket for this notice). To date, EPA has not received the requested information.

In the March 16, 2015 letter, the EPA warned that if RefEx did not provide additional information to demonstrate compliance with 40 CFR 82.164, EPA would consider initiating procedures to revoke RefEx's status as a certified reclaimer pursuant to 40 CFR 82.164(g) and 82.169. Since many of the letters sent to RefEx have been returned as undeliverable, in addition to the copy of the letter sent by certified mail, the EPA emailed the March 16, 2015 letter to the email address that RefEx uses to provide its annual report of the amount of refrigerant reclaimed on May 7, 2015. The last report was received by the EPA from this email address on March 24, 2015.

Since RefEx failed to fully respond to the information requests and has not shown that it is complying with 40 CFR 82.164 and 82.166, including particularly 40 CFR 82.164(b) and 82.166(g), the EPA is revoking RefEx's certification to reclaim refrigerants. Under 40 CFR 82.169, the EPA has the ability to revoke a reclaimer's certification for failing ''to abide by any of the provisions of this subpart . . . . In such cases, the Administrator or her or his designated representative shall give notice of an impending suspension [or revocation] to the person or organization setting forth the facts or conduct that provide the basis for the revocation or suspension.'' *See also* 40 CFR 82.164(g) (providing that ''[f]ailure to abide by any of the provisions of this subpart may result in revocation . . . of the certification of the reclaimer in accordance with 40 CFR 82.169'' and including an analogous notice requirement).

If RefEx believes that its certification to reclaim refrigerants should not be revoked, it may request a hearing under 40 CFR 82.169 by filing a written request within 30 days of this notice to the individual identified in **FOR FURTHER INFORMATION CONTACT**. The request must include RefEx's objections to the revocation and data to support the objections. If the Agency does not receive a written request for a hearing within 30 days of the date of this notice, the revocation will become effective 60 days after the publication of this notice.

Notice of Previous Revocations

To ensure that all stakeholders are aware of past revocations, EPA is also

providing notice in this action of eight former refrigerant reclaimers that no longer are certified to reclaim refrigerants. All of these revocations have previously been noted on EPA's Web site at *www.epa.gov/ozone/title6/608/reclamation/recrevoke.html.* Six of these reclaimers have requested to be removed from the list of certified reclaimers. They are: Rocky Mountain Reclamation, Inc. in Denver, CO; Star Refrigerants in Fort Worth, TX; Teris, LLC in El Dorado, AR; Cryo-Line Supplies USA, Inc. in Henderson, NV; Refrigerant Recovery, Inc. in Milwaukee, WI; and South Florida Trane Service in Miami, FL.

Two other reclaimers, Polar Refrigerant in South Hampton, NH, and Refrigerant Services, Inc. in Imperial Beach, CA, had their certification revoked for failing to comply with the recordkeeping and reporting requirements in 40 CFR 82.166. The dates of revocation are noted on EPA's Web site and in the **DATES** section of this notice. EPA sent letters to these two companies in November 2009, and February 12, 2009, respectively, that included an explanation of the basis for EPA's decision.

Dated: November 16, 2015.

Drusilla Hufford,

Director, Stratospheric Protection Division.

[FR Doc. 2015–30363 Filed 12–1–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2015–0272; FRL–9939–42–OAR]

Protection of Stratospheric Ozone: Notice of Pending Suspension and Revocation of 15 Programs From EPA's List of Section 608 Technician Certifying Programs and Voluntary Withdrawals for 3 Programs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of pending suspension and revocations and voluntary withdrawals.

SUMMARY: The Environmental Protection Agency (EPA) is updating its list of Section 608 Technician Certification Programs approved to provide the technician certification exam. EPA's list is found here: *http://www.epa.gov/ozone/title6/608/technicians/608certs.html.*

DATES: On January 4, 2016 each program in the below Table: Delinquent Technician Certification Programs will be automatically suspended from their authorization to provide the technician certification exam and newly issue certification cards, except for any organization that provides its delinquent biannual reports such that they are received before that date. Each such suspended program will be automatically revoked on February 1, 2016, unless a hearing is requested consistent with 40 CFR 82.169 before that date. Please send a copy of any hearing request to the person listed in the **FOR FURTHER INFORMATION CONTACT** section below. Technicians certified by these programs will remain certified, in accordance with 40 CFR 82.161(a).

FOR FURTHER INFORMATION CONTACT: Robert Burchard, Stratospheric Protection Division, Office of Atmospheric Programs (6205T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number (202) 343–9126; fax number: (202) 343–2338; email address: *burchard.robert@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

How can I get copies of this document and other related information?

Docket. EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2015–0272. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Docket, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Avenue NW., Washington DC. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (202) 566–1742.

Electronic Access. You may access this **Federal Register** document electronically from the Government Printing Office under the ''**Federal Register**'' listings at the FDSys Web site (*http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR).*

II. Pending Suspensions and Revocations and Voluntary Withdrawals

In accordance with the standards for certifying programs, codified at appendix D of 40 CFR part 82, subpart F, technician certifying programs must submit an activity report to EPA on a biannual basis (by every January 30 and June 30) that provides certain information about the certification tests submitted. 15 programs have repeatedly failed to submit their activity reports.

40 CFR 82.161(e) says that ''If at any time an approved program violates any of the above requirements,'' which reference the standards in appendix D in 82.161(c), ''the Administrator reserves the right to revoke approval in accordance with Section 82.169.'' Today's notice concerns the revocation of the approval of 15 programs.

These 15 programs were sent certified letters explaining that EPA was missing required activity reports and listing which reports were missing. In the letters, the programs were offered the opportunity to come into compliance by submitting missing reports.[1] The Agency received no replies. The programs in the table below have thirty days from the date of publication of this notice to submit their missing reports. Failure to submit these reports so that they are received by January 4, 2016 will result in an automatic suspension of the program's approval to offer the technician certification exam and of its approval to newly issue Section 608 technician certification cards. Automatic program revocation will occur on February 1, 2016 for any certifying organization that fails to provide missing reports, unless the organization receiving this notice of impending suspension and revocation requests a hearing in accordance with the regulations published at 40 CFR 82.169 before that date. The EPA expects to announce the final revocations in a separate **Federal Register** notice and to accordingly update the list of approved technician certification programs mentioned above.

TABLE—DELINQUENT TECHNICIAN CERTIFICATION PROGRAMS

Number	Technician certification program	Year of most recent activity report
1	ACI Environmental Safety Training Institute	2009.
2	California Career Center	No record of a submitted report.
3	Delaware County Community College	2011.

[1] Some of these organizations also received notice in these letters of impending suspensions and revocations, but because some of these letters were returned to us unopened, we are providing a second notice in this **Federal Register** notice.

TABLE—DELINQUENT TECHNICIAN CERTIFICATION PROGRAMS—Continued

Number	Technician certification program	Year of most recent activity report
4	Delaware Skills Center Building Maintenance	2013.
5	Delaware Technical & Community College	2009.
6	Educational Services	2012.
7	HVAC/R Training, Inc	2010.
8	InSolution	No record of a submitted report.
9	Kellogg Community College	2011.
10	Niagara County Community College	2010.
11	Nugent Associates	2011.
12	San Diego City College	2010.
13	Southern Technical College	2012.
14	Unified Industries, Inc	No record of a submitted report.
15	Vatterott College	2011.

Additionally, the following 608 Technician Certification Programs voluntarily withdrew their certification and will be removed from the Agency's list of Section 608 Certified Programs: Air-Conditioning & Refrigeration Institute (ARI); CDTA, Inc.; and Motorcoach Training Specialist. Technicians certified by these programs remain certified, in accordance with 40 CFR 82.161(a). Requests for replacement cards should be sent to: *spdcomments@epa.gov.*

Drusilla Hufford,

Director, Stratospheric Protection Division.

[FR Doc. 2015–30374 Filed 12–1–15; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*www.fmc.gov*) or by contacting the Office of Agreements at (202)523–5793 or *tradeanalysis@fmc.gov*.

Agreement No.: 011261–010.

Title: ACL/WWL Agreement.

Parties: Atlantic Container Line AB and Wallenius Wilhelmsen Logistics AS.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor; 1200 19th Street NW., Washington, DC 20036.

Synopsis: The amendment deletes the December 31, 2015 expiration date and gives the agreement an indefinite duration.

Agreement No.: 012225–001.

Title: King Ocean/Seaboard Space Charter Agreement.

Parties: Seaboard Marine, Ltd. and King Ocean Services Limited, Inc.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor; 1200 19th Street NW., Washington, DC 20036.

Synopsis: The amendment would revise the amount of space being chartered under the agreement.

Agreement No.: 012237–001.

Title: Liberty Global Logistics LLC/Hapag-Lloyd USA, LLC Cooperative Working Agreement.

Parties: Liberty Global Logistics LLC and Hapag-Lloyd USA, LLC.

Filing Parties: Wayne R. Rohde, Esq.; Cozen O'Connor; 1200 19th Street NW., Washington, DC 20036.

Synopsis: The amendment updates the address of Hapag Lloyd USA.

Dated: November 27, 2015.

Karen V. Gregory,

Secretary.

[FR Doc. 2015–30537 Filed 12–1–15; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board of Governors of the Federal Reserve System (Board) its approval authority under the Paperwork Reduction Act (PRA) to approve of and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act Submission, supporting statements and approved collection of information instruments are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before February 1, 2016.

ADDRESSES: You may submit comments, identified by *FR Y–9C, FR Y–9LP, FR Y–9SP, FR Y–9ES, FR Y–9CS, FR Y–6, FR Y–7, FR Y–10, or FR Y–10E,* by any of the following methods:

- *Agency Web site: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: regs.comments@federalreserve.gov.* Include OMB number in the subject line of the message.
- *FAX:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Robert deV. Frierson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW., Washington, DC 20551.

All public comments are available from the Board's Web site at *http://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper form in Room 3515, 1801 K Street (between 18th and 19th Streets NW.) Washington, DC 20006 between 9:00 a.m. and 5:00 p.m. on weekdays.

Additionally, commenters may send a copy of their comments to the OMB

Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235 725 17th Street NW., Washington, DC 20503 or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of the PRA OMB submission, including the proposed reporting form and instructions, supporting statement, and other documentation will be placed into OMB's public docket files, once approved. These documents will also be made available on the Federal Reserve Board's public Web site at: *http://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears below.

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

Request for Comment on Information Collection Proposal

The following information collection, which is being handled under this delegated authority, has received initial Board approval and is hereby published for comment. At the end of the comment period, the proposed information collection, along with an analysis of comments and recommendations received, will be submitted to the Board for final approval under OMB delegated authority. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Federal Reserve's functions; including whether the information has practical utility;

b. The accuracy of the Federal Reserve's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or start up costs and costs of operation, maintenance, and purchase of services to provide information.

Proposal To Approve Under OMB Delegated Authority the Extension for Three Years, With Revision, of the Following Reports

1. Report title: Annual Report of Holding Companies; Annual Report of Foreign Banking Organizations; Report of Changes in Organizational Structure; Supplement to the Report of Changes in Organizational Structure.

Agency form number: FR Y–6; FR Y–7; FR Y–10; FR Y–10E.

OMB control number: 7100–0297.

Frequency: FR Y–6: Annual; FR Y–7: Annual; FR Y–10: Event-generated; FR Y–10E: Event-generated.

Reporters: Bank holding companies (BHCs) and savings and loan holding companies (SLHCs) (collectively, holding companies (HCs)), securities holding companies, foreign banking organizations (FBOs), state member banks unaffiliated with a BHC, Edge Act and agreement corporations, and nationally chartered banks that are not controlled by a BHC (with regard to their foreign investments only).

Estimated annual reporting hours: FR Y–6: 26,477 hours; FR Y–7: 1,094 hours; FR Y–10 initial: 530 hours; FR Y–10 ongoing: 39,735 hours; FR Y–10E: 2,649 hours.

Estimated average hours per response: FR Y–6: 5.5 hours; FR Y–7: 4.5 hours; FR Y–10 initial: 1 hour; FR Y–10 ongoing: 2.5 hours; FR Y–10E: 0.5 hours.

Number of respondents: FR Y–6: 4,814; FR Y–7: 243; FR Y–10 initial: 530; FR Y–10 ongoing: 5,298; FR Y–10E: 5,298.

General description of report: These information collections are mandatory as follows:

FR Y–6: Section 5(c)(1)(A) of the Bank Holding Company Act (BHC Act) (12 U.S.C. 1844(c)(1)(A)), sections 8(a) and 13(a) of the International Banking Act (IBA) (12 U.S.C. 3106(a) and 3108(a)), sections 11(a)(1), 25, and 25A of the Federal Reserve Act (12 U.S.C. 248(a)(1), 602, and 611a), and sections 113, 312, 618, and 809 of the Dodd-Frank Act (12 U.S.C. 5361, 5412, 1850a(c)(1), and 5468(b)(1), respectively).

FR Y–7: Sections 8(a) and 13(a) of the IBA (12 U.S.C. 3106(a) and 3108(a)) and sections 113, 312, 618, and 809 of the Dodd-Frank Act (12 U.S.C. 5361, 5412, 1850a(c)(1), and 5468(b)(1), respectively).

FR Y–10 and FR Y–10E: Sections 4(k) and 5(c)(1)(A) of the BHC Act (12 U.S.C. 1843(k), 1844(c)(1)(A)), section 8(a) of the IBA (12 U.S.C. 3106(a)), sections 11(a)(1), 25(7), and 25A of the Federal Reserve Act (12 U.S.C. 248(a)(1), 321, 601, 602, 611a, 615, and 625), and sections 113, 312, 618, and 809 of the Dodd-Frank Act (12 U.S.C. 5361, 5412, 1850a(c)(1), and 5468(b)(1), respectively).

The data collected in the FR Y–6, FR Y–7, FR Y–10, and FR Y–10E are not considered confidential. With regard to information that a banking organization may deem confidential, the institution may request confidential treatment of such information under one or more of the exemptions in the Freedom of Information Act (FOIA) (5 U.S.C. 552). The most likely case for confidential treatment will be based on FOIA exemption 4, which permits an agency to exempt from disclosure ''trade secrets and commercial or financial information obtained from a person and privileged and confidential,'' (5 U.S.C. 552(b)(4)). To the extent an institution can establish the potential for substantial competitive harm, such information would be protected from disclosure under the standards set forth in *National Parks & Conservation Association* v. *Morton,* 498 F.2d 765 (D.C. Cir. 1974). Exemption 6 of FOIA might also apply with regard to the respondents' submission of non-public personal information of owners, shareholders, directors, officers and employees of respondents. Exemption 6 covers ''personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy,'' (5 U.S.C. 552(b)(6)). All requests for confidential treatment would need to be reviewed on a case-by-case basis and in response to a specific request for disclosure.

Abstract: The FR Y–6 is an annual information collection submitted by top-tier HCs and non-qualifying FBOs. It collects financial data, an organization chart, verification of domestic branch data, and information about shareholders. The Federal Reserve uses the data to monitor holding company operations and determine holding company compliance with the provisions of the BHC Act, Regulation Y (12 CFR 225), the Home Owners' Loan Act (HOLA), and Regulation LL (12 CFR 238).

The FR Y–7 is an annual information collection submitted by qualifying FBOs to update their financial and organizational information with the Federal Reserve. The FR Y–7 collects financial, organizational, and managerial information. The Federal Reserve uses information to assess an FBO's ability to be a continuing source of strength to its U.S. operations, and to determine compliance with U.S. laws and regulations.

The FR Y–10 is an event-generated information collection submitted by

FBOs; top-tier HCs; security holding companies as authorized under Section 618 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (12 U.S.C. 1850a(c)(1)); state member banks unaffiliated with a BHC; Edge Act and agreement corporations that are not controlled by a member bank, a domestic BHC, or a FBO; and nationally chartered banks that are not controlled by a BHC (with regard to their foreign investments only) to capture changes in their regulated investments and activities. The Federal Reserve uses the data to monitor structure information on subsidiaries and regulated investments of these entities engaged in banking and nonbanking activities. The FR Y–10E is a free-form supplement that may be used to collect additional structural information deemed to be critical and needed in an expedited manner.

Current Actions: The Board proposes to add line items to the FR Y–7 to collect information from an FBO on its compliance with applicable U.S. risk committee and home country stress test requirements under the Board's Regulation YY and section 165 of the Dodd-Frank Act.[1]

Section 165 of the Dodd-Frank Act directs the Board to establish prudential standards for BHCs and FBOs with total consolidated assets of $50 billion or more and nonbank financial companies that the Financial Stability Oversight Council has designated for supervision by the Board. In addition, the statute directs the Board to issue regulations applying certain standards to BHCs and FBOs with total consolidated assets of $10 billion or more. In particular, the Board is directed to require publicly traded BHCs and FBOs with total consolidated assets of $10 billion or more to establish risk committees.[2] In addition, the Board is required to issue regulations imposing company-run stress test requirements on BHCs, FBOs, state member banks, and savings and loan holding companies with total consolidated assets of more than $10 billion.[3]

In February of 2014, the Board adopted enhanced prudential standards for FBOs, including risk committee and stress testing requirements for FBOs with total consolidated assets of more than $10 billion. These standards are contained in the Board's Regulation YY, which is organized into subparts that apply to FBOs depending on their asset size. The risk committee and stress testing requirements are located in the following subparts:

- Subpart L establishes stress testing requirements for FBOs with total consolidated assets of more than $10 billion;
- Subpart M establishes risk committee requirements for publicly traded FBOs with total consolidated assets between $10-$50 billion;
- Subpart N establishes enhanced prudential standards (including risk committee and stress testing requirements) for FBOs with total consolidated assets of $50 billion or more but combined U.S. assets of less than $50 billion; and
- Subpart O establishes enhanced prudential standards (including risk committee and stress testing requirements) for FBOs with total consolidated assets of $50 billion or more and combined U.S. assets of $50 billion or more.

With regards to risk committee requirements, an FBO subject to subpart M or N is required to certify that it has a risk committee that oversees the risk management practices of the combined U.S. operations of the company and has at least one member with appropriate risk expertise.[4] This certification must be filed on an annual basis with the Board concurrently with the FR Y–7. FBOs subject to subpart O are subject to more prescriptive U.S. risk committee requirements and must employ a U.S. chief risk officer in the United States.[5]

With regards to stress testing, an FBO subject to subpart L, N, or O must be subject to a consolidated capital stress testing regime administered by the FBO's home-country supervisor, meet the home-country supervisor's minimum standards, and in some cases provide information to the Board about the results of home country stress testing. If these conditions are not met, the U.S. branches and agencies of the foreign bank are subject to an asset maintenance requirement, and generally must conduct an annual stress test of its U.S. subsidiaries. An FBO subject to subpart O must also conduct stress testing at its U.S. intermediate holding company. The proposed revisions to the FR Y–7 would implement the U.S. risk committee certification requirement and provide FBOs with a standardized way to indicate compliance with the home country stress testing requirements (if not, the FBO would be subject to additional requirements in the United States). Specifically, the proposal would require an FBO to certify that it meets, does not meet, or is not subject to the relevant U.S. risk committee certification requirement and indicate that it meets, does not meet, or is not subject to the relevant home-country stress testing requirement. The instructions to the line item would describe the requirements and the scope of applicability so that an FBO would be able to identify and confirm compliance with the applicable requirements.

2. Report title: Consolidated Financial Statements for Holding Companies, Parent Company Only Financial Statements for Large Holding Companies, Parent Company Only Financial Statements for Small Holding Companies, Financial Statement for Employee Stock Ownership Plan Holding Companies, and the Supplemental to the Consolidated Financial Statements for Holding Companies.

Agency form number: FR Y–9C, FR Y–9LP, FR Y–9SP, FR Y–9ES, and FR Y–9CS.

OMB control number: 7100–0128.

Frequency: Quarterly, semiannually, and annually.

Reporters: Bank holding companies (BHCs), savings and loan holding companies (SLHCs), and securities holding companies (SHCs) (collectively, holding companies).

Estimated annual reporting hours: FR Y–9C (non advanced approaches holding companies): 131,514 hours; FR Y–9C (advanced approached holding companies): 2,683 hours; FR Y–9LP: 16,695 hours; FR Y–9SP: 45,425 hours; FR Y–9ES: 44 hours; FR Y–9CS: 472 hours.

Estimated average hours per response: FR Y–9C (non advanced approaches holding companies): 50.35 hours; FR Y–9C (advanced approached holding companies HCs): 51.60 hours; FR Y–9LP: 5.25 hours; FR Y–9SP: 5.40 hours; FR Y–9ES: 0.50 hours; FR Y–9CS: 0.50 hours.

Number of respondents: FR Y–9C (non advanced approaches holding companies): 653; FR Y–9C (advanced approached holding companies): 13; FR Y–9LP: 795 hours; FR Y–9SP: 4,206; FR Y–9ES: 88; FR Y–9CS: 236.

General description of report: This information collection is mandatory for BHCs (12 U.S.C. 1844(c)(1)(A)). Additionally, 12 U.S.C. 1467a (b)(2)(A) and 1850a(c)(1)(A), respectively, authorize the Federal Reserve to require that Savings and Loan Holding

[1] 79 FR 17239 (March 27, 2014).

[2] *See* 12 U.S.C. 5365(h).

[3] 12 U.S.C. 5365(i).

[4] The combined U.S. operations of a FBO include its U.S. branches and agencies and U.S. subsidiaries (other than any section 2(h)(2) company, if applicable).

[5] FBOs subject to subpart O are not required to certify that they have a U.S. risk committee because the Board expects to gain sufficient information through the supervisory process to evaluate whether the U.S. risk committee meets the requirements of this section.

Companies (SLHCs) and supervised Securities Holding Companies (SHCs) file the FR Y–9LP, and FR Y–9SP with the Federal Reserve. Confidential treatment is not routinely given to the financial data in this report. However, confidential treatment for the reporting information, in whole or in part, can be requested in accordance with the instructions to the form, pursuant to sections (b)(4), (b)(6), or (b)(8) of FOIA (5 U.S.C. 522(b)(4), (b)(6), and (b)(8)). The applicability of these exemptions would need to be reviewed on a case by case basis.

Abstract: The FR Y–9 family of reporting forms continues to be the primary source of financial data on holding companies that examiners rely on in the intervals between on-site inspections. Financial data from these reporting forms are used to detect emerging financial problems, to review performance and conduct pre-inspection analysis, to monitor and evaluate capital adequacy, to evaluate holding company mergers and acquisitions, and to analyze a holding company's overall financial condition to ensure the safety and soundness of its operations. The FR Y–9C serves as standardized financial statements for the consolidated holding company. The FR Y–9LP, and FR Y 9SP serve as standardized financial statements for parent holding companies; the FR Y–9ES is a financial statement for holding companies that are Employee Stock Ownership Plans (ESOPs). The Federal Reserve also has the authority to use the FR Y–9CS (a free-form supplement) to collect additional information deemed to be (1) critical and (2) needed in an expedited manner.

Current Actions: The Federal Reserve proposes to implement a number of revisions to the FR Y–9C requirements in March 2016. All of these proposed changes except for those related to Schedule HC–I are consistent with proposed changes to the Call Reports. The proposed changes include:

- Deletions of certain existing data items pertaining to other-than-temporary impairments from Schedule HI, Income Statement; troubled debt restructurings from Schedule HC–C, Loans and Leases, and Schedule HC–N, Past Due and Nonaccrual Loans, Leases, and Other Assets; loans covered by FDIC loss-sharing agreements from Schedule HC–M, Memoranda, and Schedule HC–N; and unused commitments to asset-backed commercial paper conduits with an original maturity of one year or less in Schedule HC–R, Part II, Risk-Weighted Assets;
- Increases and additions to reporting thresholds for certain data items in four FR Y–9C schedules;
- Instructional revisions addressing the reporting of home equity lines of credit that convert from revolving to non-revolving status in Schedule HC–C; securities for which a fair value option is elected in Schedule HC, Balance Sheet; and net gains (losses) and other-than-temporary impairments on equity securities that do not have readily determinable fair values in Schedule HI;
- New and revised data items, including:
  - Increasing the time deposit size threshold from $100,000 to $250,000 in Schedule HC–E, Deposit Liabilities
  - Revising the reporting of certain securities measured under a fair value option in Schedule HC–Q and moving the existing Memorandum items for the fair value and unpaid principal balance of loans (not held for trading) from Schedule HC–C, to Schedule HC–Q;
  - Eliminating the concept of extraordinary items and revising affected data items in Schedule HI.

Proposed FR Y–9C Revisions

A. Deletions of Existing Data Items

Based on the Federal Reserve's review of the information that holding companies are required to report in the FR Y–9C, the Federal Reserve has determined that the continued collection of the following items is no longer necessary and are proposing to eliminate them effective March 31, 2016:

(1) Schedule HI, Memorandum items 17(a) and 17(b), on other-than-temporary impairments; [6]

(2) Schedule HC–C, Memorandum items 1(f)(2), 1(f)(5), and 1(f)(6) on troubled debt restructurings in certain loan categories that are in compliance with their modified terms;

(3) Schedule HC–N, Memorandum items 1(f)(2), 1(f)(5), and 1(f)(6) on troubled debt restructurings in certain loan categories that are 30 days or more past due or on nonaccrual;

(4) Schedule HC–M, items 6(a)(5)(a) through (d) on loans in certain loan categories that are covered by FDIC loss-sharing agreements; and

(5) Schedule HC–N, items 12(e)(1) through (4) on loans in certain loan categories that are covered by FDIC loss-sharing agreements and are 30 days or more past due or on nonaccrual.

In addition, when Schedule HC–R, Part II, is completed properly, item 18(b) on unused commitments to asset-backed commercial paper conduits with an original maturity of one year or less is not needed because such commitments should already have been reported in item 10 as off-balance sheet securitization exposures. The instructions for item 18(b) explain that these unused commitments should be reported in item 10 and that amounts should not be reported in item 18(b). Accordingly, the Federal Reserve proposes to delete existing item 18(b) from Schedule HC–R, Part II. Existing item 18(c) of Schedule HC–R, Part II, for unused commitments with an original maturity exceeding one year would then be renumbered as item 18(b).

B. New Reporting Threshold and Increases in Existing Reporting Thresholds.

In three FR Y–9C schedules, holding companies are currently required to itemize and describe each component of an existing item when the component exceeds both a specified percentage of the item and a specified dollar amount Based on a preliminary evaluation of the existing reporting thresholds, the Federal Reserve has concluded that the dollar portion of the thresholds that currently apply to these items can be increased to provide a reduction in reporting burden without a loss of data that would be necessary for supervisory or other public policy purposes. The percentage portion of the existing thresholds would not be changed. Accordingly, the Federal Reserve proposes to raise from $25,000 to $100,000 the dollar portion of the threshold for itemizing and describing components of:

(1) Schedule HI, memo item 6, ''Other noninterest income;''

(2) Schedule HI, memo item 7, ''Other noninterest expense;''

(3) Schedule HC–Q, Memorandum item 1, ''All other assets;'' and

(4) Schedule HC–Q, Memorandum item 2, ''All other liabilities.''

To reduce burden, the Federal Reserve also proposes to raise from $25,000 to $1,000,000 the dollar portion of the threshold for itemizing and describing components of ''Other trading assets'' and ''Other trading liabilities'' in Schedule HC–D, Memorandum items 9(b) and 10.

Based on the Federal Reserve's review of items reported on Schedule HC–I, Insurance-Related Underwriting Activities (Including Reinsurance), the Federal Reserve proposes that a $10,000,000 threshold be added to provide a reduction in reporting burden for reinsurance recoverables reported on Schedule HC–I, Part I line item 1 and HC–I, Part II line item 1 due to the

[6] Institutions would continue to complete Schedule HI, Memorandum item 17(c), on net impairment losses recognized in earnings.

limited activity and immateriality on these line items. Reporting of these data items would be determined as of end of each quarter.

C. Instructional Revisions

1. Reporting Home Equity Lines of Credit That Convert From Revolving to Non Revolving Status

Holding companies report the amount outstanding under revolving, open-end lines of credit secured by 1–4 family residential properties (commonly known as home equity lines of credit or HELOCs) in item 1(c)(1) of Schedule HC–C, Loans and Leases. Closed-end loans secured by 1–4 family residential properties are reported in Schedule HC–C, item 1(c)(2)(a) or (b), depending on whether the loan is a first or a junior lien.[7]

A HELOC is a line of credit secured by a lien on a 1–4 family residential property that generally provides a draw period followed by a repayment period. During the draw period, a borrower has revolving access to unused amounts under a specified line of credit. During the repayment period, the borrower can no longer draw on the line of credit, and the outstanding principal is either due immediately in a balloon payment or is repaid over the remaining loan term through monthly payments. The FR Y–9C instructions do not address the reporting treatment for a home equity line of credit when it reaches its end-of-draw period and converts from revolving to nonrevolving status. Such a loan no longer has the characteristics of a revolving, open-end line of credit and, instead, becomes a closed-end loan. In the absence of instructional guidance that specifically addresses this situation, Board staff has found diversity in how these credits are reported in Schedule HC–C. Some holding companies continue to report home equity lines of credit that have converted to non-revolving closed-end status in item 1(c)(1) of Schedule HC–C, as if they were still revolving open-end lines of credit, while other holding companies recategorize such loans and report them as closed-end loans in item 1(c)(2)(a) or (b), as appropriate.

Therefore, to address this absence of instructional guidance and promote consistency in reporting, the Federal Reserve proposes to clarify the instructions for reporting loans secured by 1–4 family residential properties to specify that after a revolving open-end line of credit has converted to non-revolving closed-end status, the loan should be reported in Schedule HC–C, item 1(c)(2)(a) or (b), as appropriate. In proposing this clarification, the Federal Reserve is requesting comment on whether an instructional requirement to recategorize HELOCs as closed-end loans for FR Y–9C purposes would create difficulties for holding company's loan recordkeeping systems. If so, please describe the difficulties this recategorization would create.

2. Reporting Treatment for Securities for Which a Fair Value Option Is Elected

The FR Y–9C Glossary entry for ''Trading Account'' currently states that ''all securities within the scope of the Financial Accounting Standards Board's (FASB) Accounting Standards Codification (ASC) Topic 320, Investments-Debt and Equity Securities (formerly FASB Statement No. 115, ''Accounting for Certain Investments in Debt and Equity Securities''), that a holding company has elected to report at fair value under a fair value option with changes in fair value reported in current earnings should be classified as trading securities.'' This reporting treatment was based on language contained in former FASB Statement No. 159, ''The Fair Value Option for Financial Assets and Financial Liabilities,'' but that language was not codified when Statement No. 159 was superseded by current ASC Topic 825, Financial Instruments. Thus, under U.S. GAAP as currently in effect, the classification of all securities within the scope of ASC Topic 320 that are accounted for under a fair value option as trading securities is no longer required. Accordingly, to bring the ''Trading Account'' Glossary entry into conformity with current U.S. GAAP, the Federal Reserve proposes to revise the statement from the Glossary entry quoted above by replacing ''should be classified'' with ''may be classified.''

This revision to the ''Trading Account'' Glossary entry means that a holding company that elects the fair value option for securities within the scope of ASC Topic 320 would be able to classify such securities as held-to-maturity or available-for-sale in accordance with this topic based on the holding company's intent and ability with respect to the securities. In addition, a holding company could choose to classify securities for which a fair value option is elected as trading securities.

Holding companies that have been required to classify all securities within the scope of ASC Topic 320 that are accounted for under a fair value option as trading securities also should consider the related proposed changes to Schedule HC–Q, Assets and Liabilities Measured at Fair Value on a Recurring Basis, which are discussed below.

3. Net Gains (Losses) on Sales of, and Other-Than-Temporary Impairments on, Equity Securities That Do Not Have Readily Determinable Fair Values

Holding companies report investments in equity securities that do not have readily determinable fair values and are not held for trading (and to which the equity method of accounting does not apply) in FR Y–9C Schedule HC–F, item 4, and on the FR Y–9C balance sheet in Schedule HC, item 11, ''Other assets.'' If such equity securities are held for trading, they are reported in Schedule HC, item 5, and in Schedule HC–D, item 9 and Memorandum item 7.b, if applicable. In contrast, investments in equity securities with readily determinable fair values that are not held for trading are reported as available-for-sale securities in Schedule HC, item 2(b), and in Schedule HC–B, item 7, whereas those held for trading are reported in Schedule HC, item 5, and in Schedule HC–D, item 9 and Memorandum item 7(a), if applicable.

In general, investments in equity securities that do not have readily determinable fair values are accounted for in accordance with ASC Subtopic 325–20, Investments-Other—Cost Method Investments (formerly Accounting Principles Board Opinion No. 18, ''The Equity Method of Accounting for Investments in Common Stock''), but are subject to the impairment guidance in ASC Topic 320, Investments-Debt and Equity Securities (formerly FASB Staff Position No. FAS 115–2 and FAS 124–2, ''Recognition and Presentation of Other-Than-Temporary Impairments'').

The FR Y–9C instructions for Schedule HI, Income Statement, address the reporting of realized gains (losses), including other-than-temporary impairments, on held to-maturity and available-for-sale securities as well as the reporting of realized and unrealized gains (losses) on trading securities and other assets held for trading. However, the Schedule HI instructions do not specifically explain where to report realized gains (losses) on sales or other disposals of, and other-than-temporary impairments on, equity securities that do not have readily determinable fair values and are not held for trading (and to which the equity method of accounting does not apply).

[7] Information also is separately reported for open-end and closed-end loans secured by 1–4 family residential properties in Schedule HI–B, Part I, Charge-offs and Recoveries on Loans and Leases; Memorandum items in Schedule HC–C; Schedule HC–D; Schedule HC–M; and Schedule HC–N.

The instructions for Schedule HI, item 5.k, ''Net gains (losses) on sales of other assets (excluding securities),'' direct holding companies to ''report the amount of net gains (losses) on sales and other disposals of assets not required to be reported elsewhere in the income statement (Schedule HI).'' The instructions for item 5(k) further advise holding companies to exclude net gains (losses) on sales and other disposals of securities and trading assets. The intent of this wording was to cover securities designated as held-to-maturity, available-for-sale, and trading securities because there are separate specific items elsewhere in Schedule HI for the reporting of realized gains (losses) on such securities (items 6(a), 6(b), and 5(c), respectively). Thus, the Federal Reserve to revise the instructions for Schedule HI, item 5(k), by clarifying that the exclusions from this item of net gains (losses) on securities and trading assets apply to held-to-maturity, available-for-sale, and trading securities and other assets held for trading. At the same time, the Federal Reserve to add language to the instructions for Schedule HI, item 5(k), that explains that net gains (losses) on sales and other disposals of equity securities that do not have readily determinable fair values and are not held for trading (and to which the equity method of accounting does not apply), as well as other-than-temporary impairments on such securities, should be reported in item 5(k). In addition, the Federal Reserve proposes to remove the parenthetic ''(excluding securities)'' from the caption for item 5(k) and add in its place a footnote to this item advising holding companies to exclude net gains (losses) on sales of trading assets and held-to-maturity and available-for-sale securities.

D. New and Revised Data Items

1. Increase in the Time Deposit Size Threshold

The Federal Reserve is proposing to increase the time deposit size threshold from $100,000 to $250,000 in Schedule HC–E, memorandum item 3, Time Deposits of $100,000 or more with a remaining maturity of one year or less. The comparable line item on the Call Report is being revised to reflect the permanent $250,000 deposit insurance limit. Therefore, the Federal Reserve is proposing this change to maintain consistency between the two reports.

2. Changes to Schedule HC–Q, Assets and Liabilities Measured at Fair Value on a Recurring Basis

Holding companies reporting on Schedule HC–Q are currently required to treat securities they have elected to report at fair value under a fair value option as part of their trading securities. As a consequence, institutions must include fair value information for their fair value option securities, if any, in Schedule HC–Q two times: First, as part of the fair value information they report for their ''Other trading assets'' in item 5(b) of the schedule, and then on a standalone basis in item 5(b)(1), ''Nontrading securities at fair value with changes in fair value reported in current earnings.'' This reporting treatment flows from the existing provision of the Glossary entry for ''Trading Account'' that, as discussed above, requires an institution that has elected to report securities at fair value under a fair value option to classify the securities as trading securities. However, as further discussed above, Board staff is proposing to remove this requirement because it is not consistent with current U.S. GAAP. As a result, holding company's fair value option securities can be classified as held-to-maturity, available-for-sale, or trading securities in accordance with the guidance in Topic 320, Investments-Debt and Equity Securities.

In its current form, Schedule HC–Q contains an item for available-for-sale securities along with the items identified above for ''Other trading assets,'' which includes securities designated as trading securities, and ''Nontrading securities at fair value with changes in fair value reported in current earnings.'' However, Schedule HC–Q does not include an item for held-to-maturity securities because, given the existing instructional requirements for fair value option securities, the held-to-maturity category includes only securities reported at amortized cost. In addition to removing the requirement to report all fair value option securities within the scope of ASC Topic 320 as trading securities, as proposed earlier in this notice, the Federal Reserve is further proposing to replace item 5(b)(1) of Schedule HC–Q for nontrading securities accounted for under a fair value option with a new item for any ''Held-to-Maturity securities'' to which a fair value option is applied. In this regard, existing item 1 for ''Available-for-sale securities'' would be renumbered as item 1(b) and fair value information for any fair value option securities designated as ''Held-to-maturity securities'' would be reported in a new item 1(a) of Schedule HC–Q. These changes to Schedule HC–Q would take effect March 31, 2016.

In addition, at present, holding companies that have elected to measure loans (not held for trading) at fair value under a fair value option are required to report the fair value and unpaid principal balance of such loans in Memorandum items 10 and 11 of Schedule HC–C, Loans and Lease Financing Receivables. This information is also collected on the Call Report Schedule RC–C Loans and Leases. The Federal Deposit Insurance Corporation and the Office of the Comptroller of the Currency (the agencies) have proposed to move this information from Schedule RC–C to Schedule RC–Q, Assets and Liabilities Measured at Fair Value on a Recurring Basis. Holding companies have commented in the past that retaining a consistent format between the Call Report and the FR Y–9C on the reporting of comparable information reduces reporting burden to the holding companies. Accordingly, the Board proposes to move Memorandum items 10 and 11 on the fair value and unpaid principal balance of fair value option loans from Schedule HC–C, to Schedule HC–Q effective March 31, 2016, and to designate them as Memorandum items 3 and 4.

3. Extraordinary Items

In January 2015, the FASB issued ASU No. 2015–01, ''Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items.'' This ASU eliminates the concept of extraordinary items from U.S. GAAP. At present, ASC Subtopic 225–20, Income Statement—Extraordinary and Unusual Items (formerly Accounting Principles Board Opinion No. 30, ''Reporting the Results of Operations''), requires an entity to separately classify, present, and disclose extraordinary events and transactions. An event or transaction is presumed to be an ordinary and usual activity of the reporting entity unless evidence clearly supports its classification as an extraordinary item. For FR Y–9C purposes, if an event or transaction currently meets the criteria for extraordinary classification, a holding company must segregate the extraordinary item from the results of its ordinary operations and report the extraordinary item in its income statement in Schedule HI, item 11, ''Extraordinary items and other adjustments, net of income taxes.''

ASU 2015–01 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. Thus, for example, holding companies with a calendar year fiscal

year must begin to apply the ASU in their FR Y–9C for March 31, 2016.[8] After a holding company adopts ASU 2015–01, any event or transaction that would have met the criteria for extraordinary classification before the adoption of the ASU should be reported in Schedule HI, item 5(l), ''Other noninterest income,'' or item 7(d), ''Other noninterest expense,'' as appropriate, unless the event or transaction would otherwise be reportable in another item of Schedule HI.

Consistent with the elimination of the concept of extraordinary items in ASU 2015–01, the Federal Reserve proposes to revise the instructions for Schedule HI, item 11, and remove the term ''extraordinary items'' and revise the captions for Schedule HI, item 8, ''Income (loss) before income taxes and extraordinary items and other adjustments,'' item 10, ''Income (loss) before extraordinary items and other adjustments,'' and item 11, ''Extraordinary items and other adjustments, net of income taxes,'' effective March 31, 2016. After the concept of extraordinary items has been eliminated and such items would no longer be reportable in Schedule HI, item 11, only the results of discontinued operations would be reportable in item 11. Accordingly, effective March 31, 2016, the revised captions for Schedule HI, items 8, 10 and 11 would become ''Income (loss) before income taxes and discontinued operations,'' ''Income (loss) before discontinued operations,'' and ''discontinued operations, net of applicable income taxes'' respectively. The captions for Schedule HI, memorandum items 2, 8, items 8 and 11 on the Predecessor Financial Items and applicable Glossary references would also be revised to eliminate the concept of extraordinary items.

Board of Governors of the Federal Reserve System, November 27, 2015.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2015–30538 Filed 12–1–15; 8:45 am]

BILLING CODE 6210–01–P

[8] Early adoption of ASU 2015–01 is permitted provided that the guidance is applied from the beginning of the fiscal year of adoption.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10430, CMS–10593, CMS–10592, CMS–10440]

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 February 1, 2016.

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–10430 Information Collection Requirements for Compliance With Individual and Group Market Reforms Under Title XXVII of the Public Health Service Act

CMS–10593 Establishment of an Exchange by a State and Qualified Health Plans

CMS–10592 Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers

CMS–10440 Data Collection To Support Eligibility Determinations for Insurance Affordability Programs and Enrollment Through Health Benefits Exchanges, Medicaid and Children's Health Insurance Program Agencies

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. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Information Collection Requirements for Compliance with Individual and Group Market Reforms under Title XXVII of the Public Health Service Act; *Use:* Sections 2723 and 2761 of the Public Health Service Act (PHS Act) direct the Centers for Medicare and Medicaid Services (CMS) to enforce a provision (or provisions) of title XXVII of the PHS Act (including the implementing regulations in parts 144, 146, 147, and 148 of title 45 of the Code of Federal Regulations) with respect to health insurance issuers when a state has notified CMS that it has not enacted legislation to enforce or that it is not otherwise enforcing a provision (or provisions) of the group and individual market reforms with respect to health insurance issuers, or when CMS has determined that a state is not substantially enforcing one or more of those provisions. This collection of information includes requirements that are necessary for CMS to conduct compliance review activities. *Form Number:* CMS–10430 (OMB Control Number: 0938–0702); *Frequency:* Annually; *Affected Public:* Private sector, State or local governments; *Number of Respondents:* 983; *Total Annual Responses:* 100,759; *Total Annual Hours:* 2,554.5. (For policy questions regarding this collection contact Russell Tipps at 301–492–4371.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Establishment of an Exchange by a State and Qualified Health Plans; *Use:* The Patient Protection and Affordable Care Act, Public Law 111–148, enacted on March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111–152, enacted on March 30, 2010 (collectively, ''Affordable Care Act''), expand access to health insurance for individuals and employees of small businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), including the Small Business Health Options Program (SHOP). As directed by the rule *Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers* (77 FR 18310) (Exchange rule), each Exchange will assume responsibilities related to the certification and offering of Qualified Health Plans (QHPs). To offer insurance through an Exchange, a health insurance issuer must have its health plans certified as QHPs by the Exchange. A QHP must meet certain minimum certification standards, such as network adequacy, inclusion of Essential Community Providers (ECPs), and non-discrimination. The Exchange is responsible for ensuring that QHPs meet these minimum certification standards as described in the Exchange rule under 45 CFR parts 155 and 156, based on the Affordable Care Act, as well as other standards determined by the Exchange. The reporting requirements and data collection in the Exchange rule address Federal requirements that various entities must meet with respect to the establishment and operation of an Exchange; minimum requirements that health insurance issuers must meet with respect to participation in a State based or Federally-facilitated Exchange; and requirements that employers must meet with respect to participation in the SHOP and compliance with other provisions of the Affordable Care Act. *Form Number:* CMS–10593 (OMB Control Number: 0938–NEW); *Frequency:* Annually, Monthly; *Affected Public:* Private sector (Business or other for-profit); *Number of Respondents:* 20; *Total Annual Responses:* 400; *Total Annual Hours:* 36,900. (For policy questions regarding this collection contact Christy Woods at 301–492–5140.)

3. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers; *Use:* Section 1321(a) requires HHS to issue regulations setting standards for meeting the requirements under Title I of the Affordable Care Act including the offering of qualified health plans through the Marketplaces. On March 27, 2012, HHS published the rule *CMS–9989–F: Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers.* The Exchange rule contains provisions that mandate reporting and data collections necessary to ensure that health insurance issuers are meeting the requirements of the Affordable Care Act. These information collection requirements are set forth in 45 CFR part 156. The data collection and reporting requirements will assist HHS in creating a seamless and coordinated system of eligibility and enrollment. The data collected by health insurance issuers will help to inform HHS, Marketplaces, and health insurance issuers as to the participation of individuals, employers, and employees in the individual Exchange. *Form Number:* CMS–10592 (OMB control number: 0938–NEW); *Frequency:* Annually, Monthly, Occasionally; *Affected Public:* Private sector (Business or other for-profit); *Number of Respondents:* 1,200; *Total Annual Responses:* 1,200; *Total Annual Hours:* 590,460. (For policy questions regarding this collection contact Beth Liu at 301–492–4135.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment through Health Benefits Exchanges, Medicaid and Children's Health Insurance Program Agencies; *Use:* Section 1413 of the Affordable Care Act directs the Secretary of Health and Human Services to develop and provide to each State a single, streamlined form that may be used to apply for coverage through the Exchange and Insurance Affordability Programs, including Medicaid, the Children's Health Insurance Program (CHIP), and the Basic Health Program, as applicable. The application must be structured to maximize an applicant's ability to complete the form satisfactorily, taking into account the characteristics of individuals who qualify for the programs. A State may develop and use its own single streamlined application if approved by the Secretary in accordance with section 1413 and if it meets the standards established by the Secretary.

Section 155.405(a) of the Exchange Final Rule (77 FR 18310) provides more detail about the application that must be used by the Exchange to determine eligibility and to collect information necessary for enrollment. The regulations in § 435.907 and § 457.330 establish the requirements for State Medicaid and CHIP agencies related to the use of the single streamlined application. We are designing the single streamlined application to be a dynamic electronic application that will tailor the amount of data required from an applicant based on the applicant's circumstances and responses to particular questions. The paper version of the application will not be able to be tailored in the same way but is being designed to collect only the data required to determine eligibility. Individuals will be able to submit an application electronically, through the mail, over the phone through a call center, or in person, per § 155.405(c)(2) of the Exchange Final Rule, as well as through other commonly available electronic means as noted in § 435.907(a) and § 457.330 of the Medicaid Final Rule. The application

may be submitted to an Exchange, Medicaid or CHIP agency. The electronic application process will vary depending on each applicant's circumstances, their experience with health insurance applications and online capabilities. The goal is to solicit sufficient information so that in most cases no further inquiry will be needed. *Form Number:* CMS–10440 (OMB control number: 0938–1191); *Frequency:* Annually; *Affected Public:* Individuals and Households; *Number of Respondents:* 7,200,000; *Total Annual Responses:* 7,200,000; *Total Annual Hours:* 2,410,767. (For policy questions regarding this collection contact Beth Liu at 301–492–4135.)

Dated: November 27, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–30534 Filed 12–1–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Deafness and Other Communication Disorders Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Deafness and Other Communication Disorders Advisory Council.

Date: January 22, 2016.

Closed: 8:30 a.m. to 9:50 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Open: 9:50 a.m. to 2:00 p.m.

Agenda: Staff reports on divisional, programmatic, and special activities.

Place: National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Craig A. Jordan, Ph.D., Director, Division of Extramural Activities, NIDCD, NIH, Room 8345, MSC 9670, 6001 Executive Blvd., Bethesda, MD 20892–9670, 301–496–8693, *jordanc@nidcd.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://www.nidcd.nih.gov/about/Pages/Advisory-Groups-and-Review-Committees.aspx,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: November 25, 2015.

Sylvia Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–30518 Filed 12–1–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Hematology Small Business.

Date: December 10, 2015.

Time: 4:30 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Bukhtiar H. Shah, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892, 301–806–7314, *shahb@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 25, 2015.

Sylvia Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–30516 Filed 12–1–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer (NIEHS)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of

the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Dale P. Sandler, Chief, Epidemiology Branch, NIEHS, Rall Building A3–05, P.O. Box 12233, Research Triangle Park, NC 27709, or call non-toll free number (919) 541–4668 or email your request, including your address to: *sandler@niehs.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer, Revision OMB #0925–0522 Expiration Date: 2/29/2016, National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH).

Need and Use of Information Collection: This is to continue the long-term follow-up of the Sister Study—a study of genetic and environmental risk factors for the development of breast cancer in a high-risk cohort of sisters of women who have had breast cancer. The etiology of breast cancer is complex, with both genetic and environmental factors likely playing a role. Environmental risk factors, however, have been difficult to identify. By focusing on genetically susceptible subgroups, more precise estimates of the contribution of environmental and other non-genetic factors to disease risk may be possible. Sisters of women with breast cancer are one group at increased risk for breast cancer; we would expect at least 2 times as many breast cancers to accrue in a cohort of sisters as would accrue in a cohort identified through random sampling or other means. In addition, a cohort of sisters should be enriched with regard to the prevalence of relevant genes and/or exposures, further enhancing the ability to detect gene-environment interactions. Sisters of women with breast cancer will also be at increased risk for ovarian cancer and possibly for other hormonally-mediated diseases. From August 2003 through July 2009, we enrolled a cohort of 50,884 women who had not had breast cancer. We estimated that after the cohort was fully enrolled, approximately 300 new cases of breast cancer will be diagnosed during each year of follow-up. Thus far 2,904 participants have reported being diagnosed with breast cancer.

Activity	Estimated annual number of respondents	Number of reponses per respondent	Average burden per response (in hours)	Total burden hours per year
Annual Update	32,215	1	10/60	5,369
Follow-Up III (triennial)	16,108	1	40/60	10,739

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 16,108.

Dated: November 23, 2015.

Laurie K. Johnson,

Acting Deputy Associate Director for Management, NIEHS.

[FR Doc. 2015–30527 Filed 12–1–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics on Pregnancy and Neonatology.

Date: December 21, 2015.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2200, MSC 7890, Bethesda, MD 20892, 301 435–2514, *riverase@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 25, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–30519 Filed 12–1–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which

would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel—Neural Biophysics.

Date: December 8, 2015.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Peter B. Guthrie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC 7850, Bethesda, MD 20892, (301) 435–1239, *guthriep@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 25, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–30520 Filed 12–1–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel; NHGRI Training Program Data Coordinating Center.

Date: December 11, 2015.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, 3rd Floor Conference Room, 5635 Fishers Lane, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Rudy O. Pozzatti, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, 5635 Fishers Lane, Suite 4076, MSC 9306, Rockville, MD 20852, (301) 402–0838, *pozzattr@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: November 25, 2015.

Sylvia Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–30517 Filed 12–1–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2015–XXXX]

DHS Data Privacy and Integrity Advisory Committee

AGENCY: Privacy Office, DHS.

ACTION: Committee Management; Request for Applicants for Appointment to the DHS Data Privacy and Integrity Advisory Committee.

SUMMARY: The Department of Homeland Security Privacy Office seeks applicants for appointment to the DHS Data Privacy and Integrity Advisory Committee.

DATES: Applications for membership must reach the Department of Homeland Security Privacy Office at the address below on or before January 4, 2016.

ADDRESSES: If you wish to apply for membership, please submit the documents described below to Sandra Taylor, Designated Federal Officer, DHS Data Privacy and Integrity Advisory Committee, by *either* of the following methods:

- *E-mail: PrivacyCommittee@hq.dhs.gov.* Include the Docket Number (DHS–2015–XXXX) in the subject line of the message.
- *Fax:* (202) 343–4010.

FOR FURTHER INFORMATION CONTACT: Sandra Taylor, Designated Federal Officer, DHS Data Privacy and Integrity Advisory Committee, Department of Homeland Security, Washington, DC 20528, by telephone (202) 343–1717, by fax (202) 343–4010, or by email to *PrivacyCommittee@hq.dhs.gov.*

SUPPLEMENTARY INFORMATION: The DHS Data Privacy and Integrity Advisory Committee is an advisory committee established in accordance with the provisions of the *Federal Advisory Committee Act* (FACA), 5 U.S.C. Appendix. The Committee was established by the Secretary of Homeland Security under the authority of 6 U.S.C. 451 and provides advice at the request of the Secretary and the DHS Chief Privacy Officer on programmatic, policy, operational, administrative, and technological issues within DHS that relate to personally identifiable information (PII), as well as data integrity and other privacy-related matters. The duties of the Committee are solely advisory in nature. In developing its advice and recommendations, the Committee may, consistent with the requirements of the FACA, conduct studies, inquiries, or briefings in consultation with individuals and groups in the private sector and/or other governmental entities. The Committee typically hosts two public meetings per calendar year.

Committee Membership: The DHS Privacy Office is seeking 17 applicants for terms of three years from the date of appointment. Members are appointed by and serve at the pleasure of the Secretary of the Department of Homeland Security, and must be specially qualified to serve on the Committee by virtue of their education, training, and experience in the fields of data protection, privacy, and/or emerging technologies, including cybersecurity. Members are expected to actively participate in Committee and Subcommittee activities and to provide material input into Committee research and recommendations. Pursuant to the FACA, the Committee's Charter requires that Committee membership be balanced to include:

1. Individuals who are currently working in higher education, state or local government, or not-for-profit organizations;

2. Individuals currently working in for-profit organizations including at least one who shall be familiar with the data privacy-related issues addressed by small- to medium-sized enterprises; and

3. Other individuals, as determined appropriate by the Secretary.

Committee members serve as Special Government Employees (SGE) as defined in section 202(a) of title 18 United States Code. As such, they are subject to Federal conflict of interest laws and government-wide standards of conduct regulations. Members must annually file Confidential Financial Disclosure Reports (OGE Form 450) for review and approval by Department ethics officials. DHS may not release these reports or the information in them to the public except under an order issued by a Federal court or as otherwise provided under the *Privacy*

Act (5 U.S.C. 552a). Committee members are also required to obtain and retain at least a secret-level security clearance as a condition of their appointment. Members are not compensated for their service on the Committee; however, while attending meetings or otherwise engaged in Committee business, members may receive travel expenses and per diem in accordance with Federal regulations.

Committee History and Activities: All individuals interested in applying for Committee membership should review the history of the Committee's work. The Committee's charter and current membership, transcripts of Committee meetings, and all of the Committee's reports and recommendations to the Department are posted on the Committee's Web page on the DHS Privacy Office Web site (*www.dhs.gov/privacy*).

Applying for Membership: If you are interested in applying for membership on the DHS Data Privacy and Integrity Advisory Committee, please submit the following documents to Sandra Taylor, Designated Federal Officer, at the address provided below within 30 days of the date of this notice:

1. A current resume; and

2. A letter that explains your qualifications for service on the Committee and describes in detail how your experience is relevant to the Committee's work.

Your resume and your letter will be weighed equally in the application review process. Please note that by Administration policy, individuals who are registered as Federal lobbyists are not eligible to serve on Federal advisory committees. If you are registered as a Federal lobbyist and you have actively lobbied at any time within the past two years, you are not eligible to apply for membership on the DHS Data Integrity and Privacy Advisory Committee. Applicants selected for membership will be required to certify, pursuant to 28 U.S.C. 1746, that they are not registered as Federal lobbyists.

Please send your documents to Sandra Taylor, Designated Federal Officer, DHS Data Privacy and Integrity Advisory Committee, by *either* of the following methods:

- *E-mail: PrivacyCommittee@hq.dhs.gov* or
- *Fax:* (202) 343–4010.

Privacy Act Statement: DHS's Use of Your Information

Authority: DHS requests that you voluntarily submit this information under its following authorities: The *Federal Records Act,* 44 U.S.C. 3101; the FACA, 5 U.S.C. Appendix; and the *Privacy Act of 1974,* 5 U.S.C. 552a.

Principal Purposes: When you apply for appointment to the DHS Data Privacy and Integrity Advisory Committee, DHS collects your name, contact information, and any other personal information that you submit in conjunction with your application. We will use this information to evaluate your candidacy for Committee membership. If you are chosen to serve as a Committee member, your name will appear in publicly-available Committee documents, membership lists, and Committee reports.

Routine Uses and Sharing: In general, DHS will not use the information you provide for any purpose other than the Principal Purposes, and will not share this information within or outside the agency. In certain circumstances, DHS may share this information on a case-by-case basis as required by law or as necessary for a specific purpose, as described in the DHS/ALL–009 Department of Homeland Security Advisory Committees System of Records Notice (October 3, 2008, 73 FR 63181).

Effects of Not Providing Information: You may choose not to provide the requested information or to provide only some of the information DHS requests. If you choose not to provide some or all of the requested information, DHS may not be able to consider your application for appointment to the Data Privacy and Integrity Advisory Committee.

Accessing and Correcting Information: If you are unable to access or correct this information by using the method that you originally used to submit it, you may direct your request in writing to the DHS Chief FOIA Officer at *foia@hq.dhs.gov.* Additional instructions are available at *http://www.dhs.gov/foiaandintheDHS/ALL-002* Mailing and Other Lists System of Records referenced above.

Dated: November 23, 2015.

Karen L. Neuman,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2015–30545 Filed 12–1–15; 8:45 am]

BILLING CODE 9110–9L–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R6–ES–2015–N205; FXES11130600000–167–FF06E00000]

Endangered and Threatened Wildlife and Plants; Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct activities intended to enhance the survival of target endangered or threatened species.

DATES: To ensure consideration, please send your written comments by January 4, 2016.

ADDRESSES: You may submit comments or requests for copies or more information by any of the following methods. Alternatively, you may use one of the following methods to request hard copies or a CD–ROM of the documents. Please specify the permit you are interested in by number (*e.g.,* Permit No. TE–XXXXXX).

- *Email: permitsR6ES@fws.gov.* Please refer to the respective permit number (*e.g.,* Permit No. TE–XXXXXX) in the subject line of the message.
- *U.S. Mail:* Ecological Services, U.S. Fish and Wildlife Service, P.O. Box 25486–DFC, Denver, CO 80225.
- *In-Person Drop-off, Viewing, or Pickup:* Call (719) 628–2670 to make an appointment during regular business hours at 134 Union Blvd., Suite 645, Lakewood, CO 80228.

FOR FURTHER INFORMATION CONTACT: Kathy Konishi, Recovery Permits Coordinator, Ecological Services, (719) 628–2670 (phone); *permitsR6ES@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

Background

The Act (16 U.S.C. 1531 *et seq.*) prohibits certain activities with endangered and threatened species unless authorized by a Federal permit. Along with our implementing regulations at 50 CFR 17, the Act provides for permits and requires that we invite public comment before issuing these permits for endangered species.

A permit granted by us under section 10(a)(1)(A) of the Act authorizes the permittees to conduct activities with U.S. endangered or threatened species for scientific purposes, enhancement of

propagation or survival, or interstate commerce (the latter only in the event that it facilitates scientific purposes or enhancement of propagation or survival). Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Applications Available for Review and Comment

We invite local, State, and Federal agencies and the public to comment on the following applications. Documents and other information the applicants have submitted with their applications are available for review, subject to the requirements of the Privacy Act (5 U.S.C. 552a) and Freedom of Information Act (5 U.S.C. 552).

Permit Application Number TE65611B

Applicant: Dennis Skadsen, Grenville, SD.

The applicant requests a permit to conduct presence/absence surveys for Poweshiek skipperling (*Oarisma poweshiek*) in Minnesota, North Dakota, and South Dakota to identify occupied habitat for the purpose of enhancing the species' survival.

Permit Application Number TE100193

Applicants: Central Platte Natural Resources District, Grand Island, NE.

The applicants request a renewal to their existing permit for survey and monitoring activities of the interior least tern (*Sterna antillarum athalassos*) in Nebraska for the purpose of enhancing the species' survival.

Permit Application Number TE049623

Applicant: Department of the Army, DPW Environmental Division, Fort Riley, KS.

The applicant requests a renewal of their permit to conduct presence/absence surveys for Topeka shiner (*Notropis topeka*) in Kansas for the purpose of enhancing the species' survival.

National Environmental Policy Act

In compliance with the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), we have made an initial determination that the proposed activities in these permits are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement (516 DM 6 Appendix 1, 1.4C(1)).

Public Availability of Comments

All comments and materials we receive in response to these requests will be available for public inspection, by appointment, during normal business hours at the address listed in the **ADDRESSES** section of this notice.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

We provide this notice under section 10 of the Act (16 U.S.C. 1531 *et seq.*).

Michael G. Thabault,

Assistant Regional Director, Mountain-Prairie Region.

[FR Doc. 2015–30532 Filed 12–1–15; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Cooperative Research Group on Automotive Consortium for Embedded Security™

Notice is hereby given that, on November 2, 2015, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Southwest Research Institute—Cooperative Research Group on Automotive Consortium for Embedded Security™ (''ACES'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, GM Global Technology Operations LLC, Detroit, MI, has withdrawn as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and ACES intends to file additional written notification disclosing all changes in membership.

On March 20, 2015, ACES filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice Published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on April 30, 2015 (80 FR 24279).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2015–30524 Filed 12–1–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Cooperative Research Group on Advanced Engine Fluids

Notice is hereby given that, on October 26, 2015, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Southwest Research Institute—Cooperative Research Group on Advanced Engine Fluids (''AEF'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Lubricants UK Limited, Middlesex, UNITED KINGDOM, has been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and AEF intends to file additional written notifications disclosing all changes in membership.

On March 20, 2015, AEF filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on April 22, 2015 (80 FR 22551).

The last notification was filed with the Department on September 22, 2015. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on October 23, 2015 (80 FR 64449).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2015–30525 Filed 12–1–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Foreign Claims Settlement Commission

[F.C.S.C. Meeting and Hearing Notice No. 11–15]

Sunshine Act Meeting

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR part 503.25) and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of open meetings as follows:

Thursday, December 10, 2015:

10:00 a.m.—Oral hearings on Objection to Commission's Proposed Decisions in Claim Nos. LIB–III–024 and LIB–III–015.

11:45 a.m.—Issuance of Proposed Decisions in claims against Libya.

Status: Open.

All meetings are held at the Foreign Claims Settlement Commission, 600 E Street NW., Washington, DC. Requests for information, or advance notices of intention to observe an open meeting, may be directed to: Patricia M. Hall, Foreign Claims Settlement Commission, 600 E Street NW., Suite 6002, Washington, DC 20579. Telephone: (202) 616–6975

Brian M. Simkin,

Chief Counsel.

[FR Doc. 2015–30564 Filed 11–30–15; 11:15 am]

BILLING CODE 4410–BA–P

DEPARTMENT OF LABOR

Office of the Assistant Secretary for Administration and Management; Agency Information Collection Activities; Extension Without Change; Comment Request; DOL Generic Solution for Solicitation for Funding Opportunity Announcement Responses

ACTION: Notice.

SUMMARY: The Department of Labor (DOL), as part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), is soliciting comments concerning a proposed extension of the authorization to conduct the DOL Generic Solution for Solicitation for Funding Opportunity Announcement Responses information collection.

DATES: Submit written comments on or before February 1, 2016.

ADDRESSES: Contact Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov* to request additional information, including requesting a copy of this Information Collection Request (ICR).

Submit comments regarding this ICR, including suggestions for reducing the burden, by sending an email to *DOL_PRA_PUBLIC@dol.gov.* Comments may also be sent to Michel Smyth, Departmental Clearance Officer, U.S. Department of Labor, Office of the Chief Information Officer, 200 Constitution Avenue NW., Room N–1301, Washington, DC 20210.

Authority: 44 U.S.C. 3506(c)(2)(A).

SUPPLEMENTARY INFORMATION: Periodically the DOL solicits grant applications by issuing a Funding Opportunity Announcement. To ensure grants are awarded to the applicant(s) best suited to perform the functions of the grant, applicants are generally required to submit a two-part application. The first part of DOL grant applications consists of submitting Standard Form 424, Application for Federal Assistance. The second part of a grant application usually requires a technical proposal demonstrating the applicant's capabilities in accordance with a statement of work and/or selection criteria. 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 Office of Management and Budget (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 if the collection of information 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 1225–0086. The DOL intends to seek continued approval for this collection of information, without change, for an additional three years.

The DOL, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed, revised, and continuing information collections before submitting them to the OMB. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed. Interested parties are encouraged to provide comments to the individual listed in the **ADDRESSES** section above. Comments must be written to receive consideration, and they will be summarized and may be included in the request for OMB approval of the final ICR. The comments will also become a matter of public record.

The DOL 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-Office of the Assistant Secretary for Administration and Management.

Type of Review: Extension without change of a currently approved collection.

Title of Collection: DOL Generic Solution for Solicitation for Funding Opportunity Announcement Responses.

OMB Control Number: 1225–0086.

Affected Public: State, Local, and Tribal Governments and Private Sector—not for-profit institutions.

Estimated Number of Respondents: 7,500.

Frequency: On occasion.

Total Estimated Annual Responses: 7,500.

Estimated Average Time per Response: 25 hours.

Estimated Total Annual Burden Hours: 187,500 hours.

Total Estimated Annual Cost Burden: $0.

Dated: November 25, 2015.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2015–30528 Filed 12–1–15; 8:45 am]

BILLING CODE 4510–04–P

DEPARTMENT OF LABOR

Office of the Assistant Secretary for Administration and Management

Agency Information Collection Activities; Revision; Comment Request; DOL Generic Solution for ''Touch-Base'' Activities

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is soliciting comments concerning the proposed extension of the DOL Generic Solution for ''Touch-Base'' Activities information collection request (ICR), as part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*).

DATES: Submit written comments on or before February 1, 2016.

ADDRESSES: Contact Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov* to request additional information, including requesting a copy of this ICR. Submit comments regarding this ICR, including suggestions for reducing the burden, by sending an email to *DOL_PRA_PUBLIC@dol.gov.* Comments may also be sent to Michel Smyth, Departmental Clearance Officer, U.S. Department of Labor, Office of the Chief Information Officer, 200 Constitution Avenue NW., Room N–1301, Washington, DC 20210.

Authority: 44 U.S.C. 3506(c)(2)(A).

SUPPLEMENTARY INFORMATION: The DOL has a need periodically to collect information from the public that help assess Departmental policies, products, and services and lead to improvements in areas deemed necessary. This information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner. By qualitative feedback the DOL means information that provides useful insights on perceptions and opinions, but does not entail statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues interest, or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative, and actionable communications between the DOL and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management. This information collection is subject to the PRA.

More specifically, the DOL will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collection is voluntary;
- The collection is low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and is low-cost for both the respondents and the Federal Government;
- The collection may focus on high-level stakeholder views regarding emerging topics of pressing policy interest or on operational issues and DOL products and services that may not be suitable for clearance under the DOL generic solution for qualitative feedback on service delivery;
- The collection is targeted to the solicitation of opinions from respondents who have experience with the program or issues under consideration;
- Information gathered will yield qualitative information; the collection will not be designed or be expected to yield statistically reliable results or be used as though the results are generalizable to the population of study.

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 Office of Management and Budget (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 if the collection of information 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 1225–0059. This ICR would revise the collection to clarify that it may be used for policy choices, and would be similar to an ICR approved specifically for the Employment and Training Administration that is designed to get quick feedback on issues of interest to that agency.

The DOL, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before they are submitted to the OMB. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed. Interested parties are encouraged to provide comments to the individual listed in the **ADDRESSES** section above. Comments must be written to receive consideration, and they will be summarized and may be included in the request for OMB approval of the final ICR. The comments will become a matter of public record.

The DOL 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: Office of the Assistant Secretary for Administration and Management.

Type of Review: Revision of a currently approved collection.

Title of Collection: DOL Generic Solution for ''Touch-Base'' Activities.

OMB Control Number: 1225–0059.

Affected Public: Individuals or households; Private Sector—businesses or other for-profits, farms, and not for-profit institutions; and State, Local, and Tribal Governments.

Estimated Number of Respondents: 375,000.

Frequency: On occasion.

Total Estimated Annual Responses: 375,000.

Estimated Average Time per Response: 6 minutes.

Estimated Total Annual Burden Hours: 37,500 hours.

Total Estimated Annual Cost Burden: $0.

Dated: November 25, 2015.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2015–30529 Filed 12–1–15; 8:45 am]

BILLING CODE 4510–04–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2014–0022]

Nucor Steel Connecticut Incorporated; Application for Permanent Variance and Interim Order; Grant of Interim Order; Request for Comments

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces the application of Nucor Steel Connecticut Incorporated for a permanent variance and interim order from the provisions of OSHA standards that regulate the control of hazardous energy (lockout/tagout) and presents the Agency's preliminary finding to grant the permanent variance. OSHA invites the public to submit comments on the variance application to assist the Agency in determining whether to grant the applicant a permanent variance based on the conditions specified in this notice of the application.

DATES: Submit comments, information, documents in response to this notice, and requests for a hearing on or before January 4, 2016. The interim order described in this notice became effective on December 2, 2015, and shall remain in effect until December 2, 2016 or until it is modified or revoked, whichever occurs first.

ADDRESSES: Submit comments by any of the following methods:

1. *Electronically:* Submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for making electronic submissions.

2. *Facsimile:* If submissions, including attachments, are not longer than 10 pages, commenters may fax them to the OSHA Docket Office at (202) 693–1648.

3. *Regular or express mail, hand delivery, or messenger (courier) service:* Submit comments, requests, and any attachments to the OSHA Docket Office, Docket No. OSHA–2014–0022, Technical Data Center, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–2625, Washington, DC 20210; telephone: (202) 693–2350 (TTY number: (877) 889–5627). Note that security procedures may result in significant delays in receiving comments and other written materials by regular mail. Contact the OSHA Docket Office for information about security procedures concerning delivery of materials by express mail, hand delivery, or messenger service. The hours of operation for the OSHA Docket Office are 8:15 a.m.–4:45 p.m., e.t.

4. *Instructions:* All submissions must include the Agency name and the OSHA docket number (OSHA–2014–0022). OSHA places comments and other materials, including any personal information, in the public docket without revision, and these materials will be available online at *http://www.regulations.gov*. Therefore, the Agency cautions commenters about submitting statements they do not want made available to the public, or submitting comments that contain personal information (either about themselves or others) such as Social Security numbers, birth dates, and medical data.

5. *Docket:* To read or download submissions or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the address above. All documents in the docket are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

6. *Extension of comment period:* Submit requests for an extension of the comment period on or before January 4, 2016 to the Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3655, Washington, DC 20210, or by fax to (202) 693–1644.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3647, Washington, DC 20210; telephone: (202) 693–1999; email: *Meilinger.francis2@dol.gov*.

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–3655, Washington, DC 20210; phone: (202) 693–2110 or email: *Robinson.kevin@dol.gov*.

SUPPLEMENTARY INFORMATION:

Copies of this **Federal Register** *notice.* Electronic copies of this **Federal Register** notice are available at *http://www.regulations.gov*. This **Federal Register** notice, as well as news releases and other relevant information, also are available at OSHA's Web page at *http://www.osha.gov*.

Hearing Requests. According to 29 CFR 1905.15, hearing requests must include: (1) A short and plain statement detailing how the proposed variance would affect the requesting party; (2) a specification of any statement or representation in the variance application that the commenter denies, and a concise summary of the evidence adduced in support of each denial; and (3) any views or arguments on any issue of fact or law presented in the variance application.

I. Notice of Application

On September 22, 2014, Nucor Steel Connecticut Incorporated (hereafter, ''NSCI'' or ''the applicant'') 35 Toelles Road, Wallingford, CT 06492, submitted under Section 6(d) of the Occupational Safety and Health Act of 1970 (''OSH Act''; 29 U.S.C. 655) and 29 CFR 1905.11 (''Variances and other relief under section 6(d)'') an application for a permanent variance from several provisions of the OSHA standard that regulates the control of hazardous energy (''lockout/tagout'' or ''LOTO''), as well as a request for an interim order pending OSHA's decision on the application for variance (Ex. OSHA–2014–0022–0003) at its Wallingford, Connecticut facility. Specifically, NSCI seeks a variance from the provisions of the standard that require: (1) Lockout or tagout devices be affixed to each energy isolating device by authorized employees (29 CFR 1910.147(d)(4)(i)); and (2) lockout devices, where used, be affixed in a manner to that will hold the energy isolating devices in a ''safe'' or ''off'' position (29 CFR 1910.147(d)(4)(ii)). NSCI also requested an interim order pending OSHA's decision on the application for variance.

According to its application, NSCI manufactures steel wire rod and coiled rebar from billets of steel by using rolling and forming processes. Further, NSCI's description of its operation indicates that the hot steel billets are

shaped and formed into steel wire rod and coiled rebar by running them through a series of rolls. The rolls shape and form the steel as it moves from one stand to the next. Each roll has several passes (or grooves), only one of which is used at a time. The pass is designed to shape the bar to a certain size as it goes through the mill by compressing, squeezing, and stretching the bar. Rolls are designed with passes to bring a bar down through roughing, intermediate and finish mills to a finished size.

As with any shaping tool, the passes wear during use and from time to time need to be changed. As the pass wears, the shape of the bar and the appearance of the bar are affected. When new rolls are brought into production, every pass is prepared with a spray that provides friction which allows the rolls to bite the bar between the rolls. Once rolls are in operation, roll grinding is regularly required, because during the operation of the mill stands water is used to cool the rolls to prevent fracturing and damage to the rolls. The water protects the pass while in use, but it also creates rust in the other passes. The rust can affect the final quality of the bar being processed, so steps are taken to remove the rust prior to restarting the operations. Rust is removed from the passes using a common 4-inch hand grinder. Since January 2012, the rolls have been ground with the rolls stopped and locked out.

NSCI asserts that grinding the rolls requires access to the Motor Control Room (MCR), in order to operate the energy isolation disconnects for the roll mills. Employees who perform the particular task of grinding the passes would be exposed to potentially serious arc flash hazards if they accessed the MCR in order to perform energy isolation functions. To control exposure to the arc flash hazards, NSCI instituted safe work rules that: (1) Designate the MCR as a restricted entry work area; (2) restrict MCR access to qualified electricians only; and (3) prohibit employees who perform pass grinding from entering the MCR because they are not qualified electrical employees trained in recognition and mitigation of electrical hazards. Further, NSCI asserts that as a consequence of following these safe work rules the employees performing pass grinding cannot lockout the energy isolation disconnects located in the MCR or personally verify that a lockout has been performed.

OSHA initiated a preliminary technical review of NSCI's variance application and developed a set of follow-up questions regarding the assertions of equivalent worker protection included in the application. On November 26, 2014, OSHA sent NSCI a letter containing a set of follow-up questions (Ex. OSHA–2014–0022–0006). On December 19, 2014, NSCI provided its responses to the follow-up questions (Ex. OSHA–2014–0022–0007). Based on these responses to the follow-up questions and the alternate safety measures proposed in NSCI's application, on May 22, 2015, the Agency sent NSCI a letter (Ex. OSHA–2014–0022–0009) describing its preliminary findings on the technical merits of the application. OSHA's letter also included a set of proposed conditions for the grant of an interim order and permanent variance and a request for NSCI's comments on these proposed conditions. On July 10, 2015, NSCI provided its response (Ex. OSHA–2014–0022–0010) indicating acceptance of the proposed conditions and including a few recommended changes. OSHA carefully reviewed NSCI's recommended changes and incorporated the majority of the changes into this notice.

Following this review, OSHA determined that the applicant proposed an alternative that will provide a workplace as safe and healthful as that provided by the standard. OSHA is granting NSCI an interim order in order to permit it to continue work while OSHA continues to consider its application for a permanent variance.

II. The Variance Application

A. Background

NSCI's variance application and the responses to OSHA's follow-up questions include the following: Detailed descriptions of the manufacturing process; the equipment used; the proposed alternative to lockout/tagout (LOTO) devices and procedures implemented during servicing and maintenance of specific equipment (*e.g.,* grinding of roll mill passes located in the roll mill stands); and technical evidence supporting NSCI's assertions of equivalency of worker protection.

According to the information included in its application, performing lockout on the roll mill stands requires access to the MCR, an area restricted to qualified electricians. Because NSCI employees who perform the particular task of grinding the passes are not qualified electrical employees trained in recognition and mitigation of electrical hazards, they may not access the MCR. Therefore, they cannot use the EID in that location to isolate the hazardous electrical energy or personally verify that energy isolation has been achieved if the EID is operated by a qualified employee.

To address these issues, NSCI has developed an alternative method of preventing the unexpected startup or energization of the roll mill passes located in the roll mill stands. NSCI proposes to use a comprehensive engineered system and appropriate administrative procedures to meet the energy isolation requirements. The engineered system uses a ''trapped key'' concept and monitored safety-rated power relays in combination with administrative procedures the trapped key system described above to replace a locked out energy isolating device. The trapped key functions similar to a lockout device, in that only the employee in possession of the key can restart the machine undergoing maintenance. The single key is controlled through administrative group lockout procedures that NSCI believes match the requirements of 29 CFR 1910.147.

Further, NSCI asserts that its proposed trapped key energy control system has been evaluated [1] for three scenarios that could result in unexpected energization of the rolls including: (1) Intentional de-energization; (2) intentional re-energization; and (3) potential faults. The system prevents unexpected startup or energization in all three scenarios.

The applicant contends that the alternative safety measures included in its application provide its workers with a place of employment that is at least as safe and healthful as they would obtain under the existing provisions of OSHA's control of hazardous energy (lockout/tagout) standard. The applicant certifies that it provided employee representatives with a copy of the variance application. The applicant also certifies that it notified its workers of the variance application by posting, at prominent locations where it normally posts workplace notices, a summary of the application and information specifying where the workers can examine a copy of the application. In addition, the applicant informed its

[1] NSCI provided documentation that TUV Rheinland, an independent third-party testing laboratory reviewed and certified that the trapped key interlock system is a suitable component for use in safety category 2, 3, and 4 safety systems as specified in International Electrotechnical Commission (IEC) and International Organization for Standardization (ISO) machinery standards. Further, NSCI asserted that several independent experts (including Dr. James Barrett, Mr. Ed Grund, Mr. Bruce Main, and Mr. Alan Metelsky) skilled in the evaluation of electrical circuitry, guarding, and the control of hazardous energy evaluated the circuitry of the trapped key system and found that it was appropriately designed and installed for this application.

workers of their rights to petition the Assistant Secretary of Labor for Occupational Safety and Health for a hearing on the variance application.

B. Variance From Paragraph (d)(4)(i) and (d)(4)(ii) of 29 CFR 1910.147

As an alternative means of compliance to the requirements of 1910.147(d)(4(i) and (ii), NSCI is proposing to use a comprehensive engineered system and appropriate administrative procedures to meet these requirements. The engineered system uses a ''trapped key'' concept and monitored safety-rated power relays in combination with administrative procedures the trapped key system described above to replace a locked out energy isolating device. The trapped key functions similar to a lockout device, in that only the employee in possession of the key can restart the machine undergoing maintenance. The single key is controlled through administrative group lockout procedures identical to those required by 29 CFR 1910.147. Although the trapped key prevents normal intended startup of the equipment being serviced, it is not being used on an EID, as required by OSHA's standards. To meet this requirement, NSCI proposes to use a monitored safety-relay system that uses approved components, redundant systems, and control-reliable circuitry. Use of the proposed trapped key system in combination with detailed administrative energy control policies and procedures, as well as providing effective training would allow NSCI's authorized and affected employees to complete the required grinding of its stationary rolls in a manner that provides equivalency in energy isolation to compliance with the applicable provisions of the LOTO standard. The proposed trapped key system is based on use of an Allen Bradley *GuardMaster* safety-rated relay, which is specifically designed for safety applications. However, the use of the proposed Allen Bradley *GuardMaster* safety-rated relay does not meet the LOTO standard's definition of EID because this relay is a form of control circuitry.

The applicant maintains that use of the proposed trapped key system provides equivalent safety with what can be achieved by strict compliance with the 1910.147(d)(4)(i) and (ii) requirements. According to NSCI's variance application, equivalent safety is achieved by prohibiting roll movement during de-energization while grinding is being performed, as well as prohibiting mistaken intentional re-energization and re-energization due to fault conditions, without exposing employees to hazards within the MCR. To protect against system faults causing re-energization, the proposed trapped key system meets the requirements for control reliability as stated in ANSI B11.19 (2010) *Performance of Safeguarding,* in that no single fault will result in the loss of the safety function. In addition, the system includes system fault monitoring, tamper resistance, and exclusive employee control over lockout devices.

Further, the applicant asserts that the trapped key system uses well tried components, which is a key factor in the reliability of a control system. The system is based on an Allen Bradley *GuardMaster* safety rated relay which is specifically designed for safety applications. The trapped key is a specially manufactured unique key that is only available from the manufacturer at a significant cost, and cannot be otherwise duplicated.

C. Technical Review

OSHA conducted a review of NSCI's application and the supporting technical documentation. After completing the review of the application and supporting documentation, OSHA concludes that NSCI:

1. Modified the electrical controls at the pulpit (central control station located on the roll mill floor for the 15 roll mill stands), to prevent employee exposure to hazards associated with movement of the roll mill while performing the task of grinding roll mill passes located in the roll mill stands;

2. Installed a trapped key control system and implemented administrative energy control procedures that prevent employee exposure to hazards associated with energy while grinding on the roll mill passes;

3. Utilizing qualified engineering safety experts, performed a job hazard analysis for roll grinding associated tasks, conducted and documented an electrical isolation analysis, system and functional safety reviews, and control reliability analysis to verify that the use of the trapped key system and administrative energy control procedures prevent the movement of roll mill passes; prevent mistaken or intentional re-energization; and maintain immobility in the event of fault conditions;

4. Developed a two-tiered system of securing the trapped key as follows:

a. Stopping the operation and energization of the roll mill passes by removing the trapped key from the system, and securing the key within a lockbox inside the pulpit area (central control station located on the roll mill floor for the 15 roll mill stands); and

b. Locking the key to the lockbox in the pulpit area inside a secondary group lock box installed on the roll mill floor, with each employee performing roll mill grinding applying their personal lock to the lockbox;

5. Developed detailed administrative energy control procedures for use of the trapped key system;

6. Implemented detailed administrative energy control procedures designed to ensure that each authorized employee applies a personal lock to the secondary group lock box;

7. Procured and provided appropriate equipment and supplies;

8. Made the administrative energy control policies and procedures available in English and Spanish;

9. Trained authorized and affected employees on the application of the trapped key system and associated administrative energy control policies and procedures;

10. Ensured that grinding on the passes is conducted only while using the administrative energy control procedures based on the trapped key system;

11. Installed guarding on the entry/infeed and exit/outfeed sides of each roll mill stand to prevent employees from standing between turning mills and being exposed to the crushing hazards of in-running nip points;

12. Developed additional administrative controls and procedures to minimize the potential for authorized and affected employees to enter between the mill stands when harm could occur; and

13. Designated and posted the areas as ''No Entry'' unless the procedures (1–12 above) are followed.

III. Description of the Conditions Specified by the Interim Order and the Application for a Permanent Variance

This section describes the conditions that comprise the alternative means of compliance with 29 CFR 1910.147(d)(4)(i) and (d)(4)(ii). These conditions form the basis of the interim order and NSCI's application for a permanent variance.[2]

Proposed Condition A: Scope

The scope of the interim order/proposed permanent variance limits/would limit coverage of the conditions of the interim order/proposed permanent variance to the work situations specified under this proposed

[2] In these conditions, the present tense form of the verb (*e.g.,* ''must'') pertains to the interim order, while the future conditional form of the verb (*e.g.,* ''would'') pertains to the application for a permanent variance (designated as ''permanent variance'').

condition. Clearly defining the scope of the interim order/proposed permanent variance provides/would provide NSCI, NSCI's employees, other stakeholders, the public, and OSHA with necessary information regarding the work situations in which the proposed permanent variance does/would apply and does not/would not apply. For example, condition A limits/would limit coverage of the interim order/proposed permanent variance only to the task of grinding roll mill passes located in the roll mill stands. The condition clarifies/would clarify that no other maintenance work, including electrical maintenance, may be/would be performed on the roll mill passes, the roll mill motors, other residual or stored energy sources, or electric circuits connected to the trapped key system or roll mill stands using the trapped key system to control hazardous energy.

According to 29 CFR 1905.11, an employer or class or group of employers [3] may request a permanent variance for a specific workplace or workplaces. If granted, the variance would apply to the specific employer(s) that submitted the application. In this instance, if OSHA were to grant a permanent variance, it would apply to the applicant, NSCI at the Wallingford, CT plant only. As a result, it is important to understand that the interim order and proposed variance would not apply to any other employers or NSCI plant locations.

Proposed Condition B: Definitions

Proposed condition B defines/would define a series of terms, mostly technical terms, used in the interim order and proposed permanent variance to standardize and clarify their meaning. Defining these terms serves to enhance the applicant's and its employees' understanding of the conditions specified by interim order and the proposed permanent variance.

Proposed Condition C: Safety and Health Practices

Proposed condition C requires/would require the applicant to: (1) Modify certain controls at the pulpit by installing and operating a trapped key system designed to replace an energy isolating device; (2) develop and implement certain trapped key system-related alternate energy control policies and procedures; and (3) develop and implement a series of trapped key system-related hazard prevention and control requirements and methods designed to ensure the continued effective functioning of the alternate energy control equipment, policies, and procedures. Examples of such hazard control measures include, but are not limited to: (1) Conducting grinding on the passes only after using the steps required to properly de-energize the system; (2) under the direction of a qualified person,[4] ensuring that the trapped key system is installed, inspected, serviced, maintained, used, and when appropriate modified in accordance with good engineering practices, and/or in strict accordance with the manufacturers' specifications and instructions, where available; and (3) no other maintenance is/would be performed on the roll mill stands while grinding is taking place.

Proposed Condition D: Steps Required To De-Energize the System

Proposed condition D requires/would require the applicant to develop and implement a detailed procedure for de-energizing the roll mill passes located in the roll mill stands in order to perform the grinding task. The procedure for de-energizing the roll mill passes includes/would include a series of steps to ensure that all authorized and effected employees are/would be notified that: The roll mill passes are/would be effectively de-energized; the task of grinding the roll mill passes is ready to begin; and no other servicing or maintenance is/would be performed on the roll mill stands while grinding is taking place.

Proposed Condition E: Steps Required To Start Motion Intentionally

Proposed condition E requires/would require the applicant to develop and implement a detailed procedure for re-energizing and intentionally starting motion in the roll mill passes located in the roll mill stands in order to resume normal operations at the conclusion of the grinding task. The procedure for re-energizing the roll mill passes includes/would include a series of steps to ensure that all authorized and effected employees are/would be notified that the task of grinding the roll mill passes is complete and that the roll mill passes are/would be ready for use.

Proposed Condition F: Training and Methods of Operation

Proposed condition F requires/would require the applicant to develop and implement an effective hazardous energy control qualification and training program for authorized employees involved in using the trapped key system while grinding roll mill passes. The condition specifies/would specify the factors that an employee must know following completion of the training program. Elements to be/would be included in the training program encompass, among others: The program to be/would be presented in language that the employees can understand; the instruction be/would be reviewed periodically to accommodate changes in the energy control program; the contents and conditions included in the interim order/proposed variance; and a job hazard analysis (JHA) in the use of the trapped key system, the identification of associated hazards, and safe application of the associated energy control procedures be/would be prepared and instructed. Additionally, proposed condition F also requires/would require the applicant to train each affected employee in the purpose and use of the alternative energy control procedures using the trapped key system.

Proposed Condition G: Inspections, Tests, and Accident Prevention

Proposed condition G requires/would require the applicant to develop, implement and operate an effective program for completing inspections, tests, program evaluations, and accident prevention for the use of the trapped key system and safe application of the hazardous energy control procedures in the roll mill stands and associated work areas. This condition will/would help to ensure the safe operation and physical integrity of the equipment and work area necessary for use of the trapped key system while conducting roll mill grinding operations, thereby enhancing worker safety by reducing the risk of unexpected energization of the equipment.

This condition also requires/would require the applicant to document tests, inspections, corrective actions and repairs involving the use of the trapped key system, and maintain these documents. Further, this requirement will/would provide the applicant with information needed to schedule tests and inspections to ensure the continued safe operation of the equipment and systems, and to determine that the actions taken to correct defects were/would be appropriate.

Proposed Condition H: Recordkeeping

Proposed condition H requires/would require the applicant to maintain records of specific factors associated with use of the trapped key system to prevent the unexpected energization of the equipment while grinding roll mill

[3] A class or group of employers (such as members of a trade alliance or association) may apply jointly for a variance provided an authorized representative for each employer signs the application and the application identifies each employer's affected facilities.

[4] See footnote 9.

passes. The information gathered and recorded under this provision, in concert with the information provided under proposed condition I (Notifications, for using the OSHA 301 Incident Report form to investigate and record energy isolation failure-related injuries as defined by 29 CFR 1904.4, 1904.7, 1904.8 through 1904.12), enabels/would enable the applicant and OSHA to determine the effectiveness of the permanent variance in preventing recordable injuries.[5]

Proposed Condition I: Notifications

Proposed condition I requires/would require the applicant, within specified periods to: (1) Notify OSHA (*i.e.,* Office of Technical Programs and Coordination Activities (OTPCA), and the Bridgeport, CT, Area Office) of any recordable injuries, illnesses, fatalities, work-related in-patient hospitalizations, amputations and all losses of an eye (as defined by 29 CFR 1904.4, and 1904.7 through 1904.12) that occur/would occur as a result of complying with the alternative energy control conditions of the variance (*e.g.,* as a result of performing roll mill pass grinding operations) within 8 hours of the incident (or becoming aware of the incident); (2) provide OSHA (*i.e.,* OTPCA and the Bridgeport, CT, Area Office) with a copy of the preliminary incident investigation report (using OSHA 301 form) within 24 hours of the incident (or becoming aware of the incident); (3) provide OSHA (*i.e.,* OTPCA and the Bridgeport, CT, Area Office) with a copy of the full incident investigation within 7 calendar days of the incident (or becoming aware of the incident); (4) include on the 301 form information on the energy isolation procedures and conditions associated with the recordable injury or illness, the root-cause determination, and preventive and corrective actions identified and implemented; (5) provide its certification that it informed affected workers of the incident and the results of the incident investigation; (6) notify OTPCA and the Bridgeport, CT, Area Office within 15 working days should the applicant need to revise its energy isolation procedures to accommodate changes in the application of its trapped key system that affect/would affect its ability to comply with the conditions of the proposed permanent variance; and (7) provide/would provide OTPCA and the Bridgeport, CT, Area Office, by January 31st at the beginning of each calendar year, with a report covering the year just ended, evaluating the effectiveness of the alternate energy isolation program.

The proposed requirement of this condition for completing and submitting the variance conditions-related (recordable) preliminary incident investigation report (OSHA 301 form) is/would be more restrictive than the current recordkeeping requirement of completing the OSHA 301 form within 7 calendar days of the incident (1904.29(b)(3)). Submittal of the preliminary incident investigation report will/would be followed by submittal of the full incident investigation report within 7 calendar days. This modified and more stringent incident investigation and reporting requirement is/would be restricted to variance conditions-related (recordable) incidents only. Providing this notification is/would be essential because time is/would be a critical element in OSHA's ability to determine the continued effectiveness of the variance conditions in preventing recordable incidents, and the employer's identification of appropriate hazard control measures and implementation of corrective and preventive actions. Further, these notification requirements enable/would enable the applicant, its employees, and OSHA to determine the effectiveness of the permanent variance in providing the requisite level of safety to the employer's workers and, based on this determination, whether to revise or revoke the conditions of the proposed permanent variance. Timely notification permits/would permit OSHA to take whatever action is necessary and appropriate to prevent further variance conditions-related recordable injuries and illnesses. Providing notification to employees informs/would inform them of the precautions taken by the employer to prevent similar incidents in the future. Additionally, these notification requirements allow/would allow OSHA to: communicate effectively, expedite administration, and enforce the conditions of the interim order/proposed permanent variance.

This proposed condition also requires/would require the applicant to notify OSHA if it ceases to do business, has a new address or location for its main office, or transfers the operations covered by the interim order/proposed permanent variance to a successor company. In addition, the condition specifies/would specify that OSHA must approve the transfer of the interim order/permanent variance to a successor company. These requirements allow/would allow OSHA to communicate effectively with the applicant regarding the status of the interim order/proposed permanent variance, and expedite the Agency's administration and enforcement of the interim order/permanent variance. Stipulating that an applicant is/would be required to have OSHA's approval to transfer an interim order/permanent variance to a successor company provides/would provide assurance that the successor company has/would have knowledge of, and will/would comply with, the conditions specified by the interim order/proposed permanent variance, thereby ensuring the safety of workers involved in performing the operations covered by the interim order/proposed permanent variance.

IV. Grant of Interim Order

As noted earlier, on September 22, 2014, NSCI requested an interim order that will/would remain in effect until: December 2, 2016, or the Agency makes a decision on its application for a permanent variance, or it is modified or revoked, whichever occurs first. During the period starting with the publication of this notice and until the interim order expires, or the Agency modifies or revokes the interim order, or makes a decision on its application for a permanent variance, the applicant is required to comply fully with the conditions of the interim order (as an alternative to complying with the requirements of 29 CFR 1910.147(d)(4)(i) and 1910.147(d)(4)(ii) (hereafter, ''the standard'') that requires:

A. Lockout or tagout devices be affixed to each energy isolating device by authorized employees (1910.147(d)(4)(i)); and

B. Lockout devices, where used, be affixed in a manner to that will hold the energy isolating devices in a ''safe'' or ''off'' position (29 CFR 1910.147(d)(4)(ii)).

As described earlier in this notice (section II(C) Technical Review), after reviewing the proposed alternatives OSHA preliminarily determined that NSCI developed, and proposed to implement, effective alternative means of protection that protect its employees as effectively as paragraphs 1910.147(d)(4)(i) and (ii) of OSHA's LOTO standard during the servicing and maintenance task of grinding roll mill passes located in the roll mill stands.

Based on a review of available evidence and the information provided in the applicant's variance application, OSHA is issuing an interim order.

[5] *See* 29 CFR 1904 Recording and Reporting Occupational Injuries and Illnesses (*http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9631*); recordkeeping forms and instructions (*http://www.osha.gov/recordkeeping/RKform300pkg-fillable-enabled.pdf*); and Updates to OSHA's Recordkeeping Rule (*http://www.osha.gov/recordkeeping2014/index.html*).

Under the interim order and variance application, instead of complying with the requirements of 29 CFR 1910.147(d)(4)(i) and (ii) of OSHA's LOTO standard, NSCI will: (1) Comply with the conditions listed below under ''Specific Conditions of the Interim Order and the Application for a Permanent Variance'' for as long as the Interim Order remains in effect; (2) comply fully with all other applicable provisions of 29 CFR part 1910; and (3) provide a copy of this **Federal Register** notice to all employees affected by the conditions using the same means it used to inform these employees of its application for a permanent variance. Additionally, this interim order will remain in effect until December 2, 2016; OSHA publishes its final decision on the variance application in the **Federal Register**; or OSHA modifies or revokes the interim order in accordance with 29 CFR 1905.13, whichever occurs first.

V. Specific Conditions of the Interim Order and the Application for a Permanent Variance

The following conditions apply to the interim order OSHA is granting to NSCI. In addition, these conditions specify the alternative means of compliance with the requirements of paragraphs 29 CFR 1910.147(d)(4)(i) and (ii) that NSCI is proposing for its permanent variance. The conditions apply to all NSCI employees located at the 35 Toelles Road, Wallingford, CT 06492 establishment during the servicing and maintenance task of grinding roll mill passes located in the roll mill stands. These conditions are: [6]

A. Scope

1. This interim order/permanent variance applies/would apply only to the task of grinding roll mill passes located in the roll mill stands of NSCI's Wallingford, CT establishment. This work is to be/would be performed by authorized employees under alternative energy control procedures using a trapped key system and lockboxes.

2. No other maintenance work, including electrical maintenance (such as troubleshooting or maintenance covered under 29 CFR 1910.333), may be/would be performed on the roll mill passes, the roll mill motors, or electric circuits connected to the trapped key system or roll mill stands using the trapped key system to control hazardous energy.

3. If any other maintenance or servicing work is/would be performed, even if that work is performed at the same time as grinding roll mill passes, all of the maintenance work at that time must be/would be performed under full lockout as required by 29 CFR 1910.147.

4. Except for the requirements specified by 29 CFR 1910.147(d)(4)(i) and (ii), NSCI must comply/would comply fully with all other applicable provisions of 29 CFR part 1910.147 during servicing and maintenance of roll mills during the task of grinding roll mill passes.

5. The interim order will remain in effect until December 2, 2016; OSHA modifies or revokes it; or OSHA publishes the **Federal Register** notice granting the permanent variance in accordance with 29 CFR 1905.13, whichever occurs first.

B. Definitions

The following definitions apply/would apply to this interim order/proposed permanent variance:

1. *Affected employee*—an employee whose job requires him/her to work in an area in which grinding of roll mill passes located in the roll mill stands is being performed.

2. *Authorized employee*—an employee who uses the trapped key system in order to perform grinding of roll mill passes located in the roll mill stands. An affected employee becomes an authorized employee when that employee's duties include performing grinding of roll mill passes located in the roll mill stands covered under this section.

3. *Competent person*—an employee who is capable of identifying existing and predictable hazards in the surroundings associated with grinding of roll mill passes located in the roll mill stands or working conditions that are unsanitary, hazardous, or dangerous to employees, and who has authorization to take prompt corrective measures to eliminate them.[7]

4. *Equipment lock box*—a part of the trapped key system consisting of any group lock box designated for and mounted on or near equipment used for securing the equipment lock box key by use of a personal lockout device.

5. *Equipment lock box lock and key*—a part of the trapped key system consisting of a uniquely identified equipment specific lock (red) and key used to secure the pulpit designated lock box containing and securing the trapped key.

6. *Group lock box*—a purchased lock box labeled as ''TRAPPED KEY SYSTEM'' that is used to enable more than one lock to be applied to the box. There are two types of lock boxes used in association with the trapped key system (see definitions for pulpit designated lock box and secondary group lock box).

7. *Job Hazard Analysis/Job Safety Analysis*—an evaluation of tasks or operations to identify potential hazards and to determine the necessary controls.

8. *Personal lock and key*—a durable, standardized substantial and uniquely identified device (a lock) that is maintained and controlled by a single authorized employee whose name is attached to the device. The key is unique to this device and is equally maintained and controlled by the authorized employee [8] whose name is attached to the device. The personal lock and key is used to secure the equipment lock box key in the secondary group lock box.

9. *Pulpit designated lock box*—a group lock box mounted inside the pulpit designated for use with the ''TRAPPED KEY SYSTEM'' and including the: (a) Trapped key; (b) equipment lock box lock and key; and (c) pulpit operator personal lock and key placed on the pulpit designated lock box to secure the trapped key.

10. *Pulpit operator*—an authorized employee who: (a) Is designated to work on a roll mill crew; (b) is authorized to use the trapped key system during the grinding of roll mill passes; and (c) is trained to operate the pulpit panel. The pulpit panel has the ability to control the following equipment systems: Reheat furnace, discharge roll line, turntable, roll mill stands A & B; roll mill stands 1–15; water system; finishing mill; laying head; and stelmore conveyor.

11. *Pulpit operator trapped key system personal lock and key*—a part of the trapped key system consisting of a uniquely identified lock (green) and key used by the pulpit operator to secure the pulpit designated lock box containing and securing the trapped key.

12. *Qualified person*—an employee who, by possession of a recognized degree, certificate, or professional standing, or who, by extensive knowledge, training, and experience, successfully demonstrates an ability to solve or resolve problems relating to the subject matter, the work, or the project.[9]

13. *Roll mill operator and/or lead*—an authorized employee who is designated and trained to operate specific and multiple equipment systems or perform a specific job task that is part of the rolling process, including application of

[6] See footnote 2.

[7] Adapted from 29 CFR 1926.32(f).

[8] See 29 CFR part 1910 [Docket No. S–012A], RIN 1218–AA53. Control of Hazardous Energy Sources (Lockout/Tagout), regarding ''one person, one lock, one key.''

[9] Adapted from 29 CFR 1926.32(m).

the trapped key system for the grinding of roll mill passes.

14. *Secondary group lock box*—a group lock box located on the mill floor just below the pulpit where authorized employees apply personal locks and follow trapped key system alternative energy isolation procedures to secure the equipment lock box key.

15. *Safety-rated relay*—a device specifically designed for safety applications that meets the requirements for control reliability as stated in ANSI B11.19 (2010) Performance of Safeguarding. The term ''control reliable'' means that no single fault will result in the loss of the safety function. In addition, the relay must include monitoring and tamper resistance.

16. *Team member*—an employee who is trained and authorized to use the trapped key system in order to perform grinding of roll mill passes located in the roll mill stands.

17. *Trapped key*—a specially manufactured unique key only available from its manufacturer that is inserted into the trapped key system's rotary switch. The rotary switch trapped key is mechanically attached by a chain to the pulpit designated lock box.

18. *Trapped key system*—the alternative method of preventing the unexpected startup or energization during grinding of roll mill passes located in the roll mill stands. NSCI presented the trapped key system to OSHA in its variance application of September 22, 2014, as supplemented by its responses to OSHA's questions during the Agency's application review. The system is based on an Allen Bradley *GuardMaster* safety-rated relay which is specifically designed for safety applications and use of a trapped key that is a specially manufactured unique key only available from its manufacturer, and the administrative controls described in this variance.

C. Safety and Health Practices

1. NSCI shall/would modify the electrical controls at the pulpit (central control station located on the roll mill floor for the 15 roll mill stands), to prevent employee exposure to hazards associated with movement of the roll mill during the task of grinding roll mill passes;

2. NSCI shall/would install a trapped key system;

3. NSCI shall/would install a pulpit designated lock box for the trapped key in the pulpit area;

4. NSCI shall/would install a secondary group lock box in the roll mills floor area for securing the pulpit designated lock box key;

5. NSCI shall/would develop administrative energy control procedures for use of the trapped key system as described below;

6. NSCI shall/would implement detailed energy control procedures designed to ensure that each authorized employee applies a personal lock to the secondary group lock box, and has the ability to personally verify de-energization of the system, as described below;

7. NSCI shall/would make the energy control policies and procedures available to authorized and affected employees in English and Spanish;

8. NSCI shall/would ensure that grinding on the passes is conducted only while using the administrative energy control procedures based on the trapped key system, or using full lockout procedures that comply with 29 CFR 1910.147 when the roll stands must be de-energized so that other maintenance operations can be performed simultaneously with roll grinding;

9. NSCI shall/would install guarding on the entry/infeed and exit/outfeed sides of each roll mill stand to prevent employees from standing between turning mills and being exposed to the crushing hazards of in-running nip points;

10. NSCI shall/would develop additional administrative controls and procedures to minimize the potential for authorized and affected employees to enter between the mill stands when harm could occur; and

11. NSCI shall/would designate and post the areas as ''No Entry'' unless the procedures (1–10) are followed.

12. NSCI shall/would ensure that the trapped key system and its components are properly installed, inspected, maintained, and used so that it works as designed. NSCI shall strictly follow, where applicable, manufacturers' recommendations for the installation, inspection, maintenance, and use of the system and its components.

13. NSCI shall/would ensure that the trapped key system is only altered or modified for uses specified and approved by a qualified person by following good engineering practices. Where available, such alterations and modifications shall strictly follow the manufacturers' specifications, instructions, and written authorization. No changes or modifications may be made to the trapped key system or its components that diminish the protection provided to affected employees.

14. NSCI shall/would ensure that alteration or modification of the trapped key system is fully justified and documented when the manufacturers' specifications, instructions, and written authorization are lacking.

15. NCSI shall/would implement a procedure to ensure that no other maintenance will be performed on the roll mill stands while grinding is taking place, unless full lockout is used for all maintenance tasks being performed at that time.

D. Steps Required To De-Energize the System

NSCI shall/would develop and implement a detailed procedure for de-energizing the roll mill passes located in the roll mill stands in order to perform the grinding task. The procedure for de-energizing the roll mill passes shall/would include the following steps:

1. The authorized employee de-energizing the roll mill passes shall/would notify all affected employees that the equipment will be/would be shut down and locked out to perform grinding of the passes;

2. The pulpit operator shall/would turn off the control leveler on the control panel;

3. The pulpit operator shall/would activate the E-stop;

4. The pulpit operator verifies/would verify that the red ''system functional'' indicator is illuminated, then turns/would turn the trapped lockout key 90° to OFF position, and removes/would remove the trapped key from the panel. The operator verifies/would verify that the green ''safe to work indicator'' illuminates, and that the red ''system functional'' indicator goes out;

5. The pulpit operator:

a. Places/would place the trapped key in the pulpit designated lock box and applies/would apply his or her personal lock to the pulpit designated lock box; and

b. Applies/would apply the equipment lock box lock designated for this energy control procedure;

6. The pulpit operator hands/would hand the equipment lock box lock key to the roll mill operator and/or lead;

7. The roll mill operator and/or lead takes/would take the equipment lock box lock key to the secondary group lock box;

8. The roll mill operator and/or lead places/would place the equipment lock box lock key in the secondary group lock box and attaches his or her personal lock;

9. Authorized employees (team members) place/would place their personal locks on the secondary group lock box;

10. The roll mill operator and/or lead verifies/would verify that the equipment is de-energized and locked out by trying

to operate the equipment (using the start button);

11. The roll mill operator and/or lead ensures/would ensure that there are no additional sources of energy that could lead to the unexpected energization of the roll mill passes;

12. Authorized employees who placed/would place their personal trapped key system locks on the secondary group lockout box shall/would also confirm that the equipment is fully de-energized;

13. Authorized employees who placed/would place their personal locks on the secondary group lock box shall/would maintain their personal key in their possession while performing grinding of the roll mill passes; and

14. Authorized employees shall/would perform the task of grinding the passes only while these procedures are/would be used.

E. Steps Required To Start Motion Intentionally

NSCI shall/would develop and implement a detailed procedure for re-energizing and intentionally starting motion in the roll mill passes located in the roll mill stands in order to resume normal operations at the conclusion of the grinding task. The procedure for re-energizing the roll mill passes shall/would include the following steps:

1. The roll mill operator and/or lead shall/would check the equipment and the immediate area around the equipment to ensure that necessary items have been removed and that the equipment components are operationally intact;

2. The roll mill operator and/or lead shall/would check the work area to ensure that all affected employees have been safely positioned or removed from the area;

3. The roll mill operator and/or lead shall/would check that all controls are in the neutral or off position;

4. Authorized employees shall/would remove their personal trapped key system locks from the secondary group lock box;

5. The roll mill operator and/or lead shall/would remove the equipment lock box lock key from the secondary group lock box and take it to the pulpit;

6. The roll mill operator and/or lead shall/would hand the equipment lock box lock key to the pulpit operator;

7. The pulpit operator shall/would verify that all personnel are clear of the equipment before starting to re-energize the roll mill passes;

8. The pulpit operator shall/would remove his or her trapped key system personal lock from the pulpit designated lock box;

9. Using the equipment lock box lock key, the pulpit operator shall/would remove the equipment lock box lock;

10. The pulpit operator shall/would remove the trapped key from the pulpit designated lock box and shall/would insert the key into the rotary switch and turn it 90° to the ON position;

11. The pulpit operator shall/would press the reset button to re-energize the roll mill passes;

12. The pulpit operator shall/would confirm that the green light clears and the red light activates indicating that the system is powered and that the trapped key system will no longer prevent roll mill motion; and

13. The pulpit operator shall/would notify affected employees that the task of grinding the roll mill passes is complete and that the roll mill passes are ready for use.

F. Training and Methods of Operation

NSCI shall/would develop and implement a detailed worker qualifications and training program. NSCI must/would:

1. Develop an energy control training program and train each authorized employee, pulpit operator, roll mill designated person, and their supervisors on the trapped key system, and the procedures each must perform under it. The training program will be provided in a language that the employees can understand;

2. Develop a training program and train each affected employee in the purpose and use of the alternative energy control procedures using the trapped key system before commencing operations under this interim order/proposed variance, and document this instruction. The training program will be provided in a language that the employees can understand;

3. Repeat the instruction specified in paragraph (1) of this condition periodically and as necessary (*e.g.,* after making changes, in accordance with condition I–5, to the use of the trapped key system that affect its component configuration or operation and associated energy control procedures);

4. Ensure that each authorized and affected employee, designated pulpit operator, roll mill designated person, and each of their supervisors have effective and documented training in the contents and conditions covered by this proposed variance;

5. Ensure that only trained and authorized employees, designated pulpit operators, and roll mill designated persons, perform energy control procedures for the task of grinding roll mill passes;

6. Prepare a JHA for the safe application of energy control procedures; and

7. Review periodically and as necessary (*e.g.,* after making changes, in accordance with conditions C–13 and I–5, to the component configuration or operation of the trapped key system and energy control procedures that affect the grinding of roll mill passes located in the roll mill stands), the contents of the JHA with affected personnel.

G. Inspections, Tests and Incident Prevention

NSCI shall/would develop and implement a detailed program for completing inspections, tests, program evaluations and incident prevention. NSCI must/would:

1. Initiate and maintain a program of frequent and regular inspections of the trapped key system and associated work areas by:

a. Ensuring that a competent person (authorized employee) conducts daily visual checks and quarterly inspections and functionality tests of the trapped key system components and configuration or operation and energy control procedures that affect the grinding of roll mill passes located in the roll mill stands to ensure that the procedure and the conditions of this variance are being followed;

b. Ensuring that a competent person conducts weekly inspections of the work areas associated with the grinding of roll mill passes located in the roll mill stands; and

c. Developing a set of checklists to be used by a competent person in conducting the weekly inspections of the work areas associated with the grinding of roll mill passes located in the roll mill stands and the quarterly inspections and functionality tests of the trapped key system components and configuration or operation and energy control procedures that affect the grinding of roll mill passes.

2. Remove the equipment from service if the competent person determines that the equipment constitutes a safety hazard. NSCI must not return the equipment to service until the hazardous condition is corrected and the correction has been approved by a qualified person.

3. All maintenance, servicing, and installation of replacement parts must be performed in strict accordance with good engineering practices. Where available, the maintenance, servicing and installation of replacement parts must strictly follow the manufacturers' specifications, instructions, and limitations.

H. Recordkeeping

1. NSCI must/would maintain a record of any recordable injury, illness, in-patient hospitalizations, amputations, loss of an eye or fatality (using the OSHA 301 Incident Report form to investigate and record energy control-related recordable injuries as defined by 29 CFR 1904.4, 1904.7, 1904.8 through 1904.12 [10]), resulting from the task of grinding roll mill passes located in the roll mill stands by completing the OSHA 301 Incident Report form and OSHA 300 Log of Work-Related Injuries and Illnesses.

2. NSCI must/would maintain records of all tests and inspections of the component configuration or operation, and energy control procedures, as well as associated hazardous condition corrective actions and repairs.

I. Notifications

To assist OSHA in administering the conditions specified herein, NSCI shall/would:

1. Notify the OTPCA and the Bridgeport, CT, Area Office of any recordable injuries, illnesses, in-patient hospitalizations, amputations, loss of an eye or fatality (by submitting the completed OSHA 301 Incident Report form) resulting from implementing the alternative energy control procedures of the proposed variance conditions while completing the task of grinding roll mill passes located in the roll mill stands. The notification must be made within 8 hours of the incident or 8 hours after becoming aware of a recordable injury, illness, in-patient hospitalizations, amputations, loss of an eye, or fatality.

2. Submit a copy of the preliminary incident investigation (OSHA form 301) to the OTPCA and the Bridgeport, CT, Area Office within 24 hours of the incident or 24 hours after becoming aware of a recordable case and submit a copy of the full incident investigation within 7 calendar days of the incident or 7 calendar days after becoming aware of the case. In addition to the information required by the OSHA form 301, the incident-investigation report must include a root-cause determination, and the preventive and corrective actions identified and implemented.

3. Provide certification within 15 working days of the incident that NSCI informed affected workers of the incident and the results of the incident investigation (including the root-cause determination and preventive and corrective actions identified and implemented).

4. Notify the OTPCA and the Bridgeport, CT, Area Office in writing and 15 working days prior to any proposed change in the energy control operations (including changes addressed by condition C–13) that affects NSCI's ability to comply with the conditions specified herein.

5. Obtain OSHA's approval prior to implementing the proposed change in the energy control operations that affects NSCI's ability to comply with the conditions specified herein.

6. Provide a written evaluation report, by January 31st at the beginning of each calendar year, with a report covering the year just ended, to the OTPCA and the Bridgeport, CT, Area Office summarizing the quarterly inspections and functionality tests of the trapped key system components and configuration or operation and energy control procedures that affect the grinding of roll mill passes located in the roll mill stands, to ensure that the energy control procedure and the conditions of this variance are being followed.

Note: The evaluation report is to contain summaries of: (1) The number of variance-related incidents (as recorded on OSHA 301 forms); and (2) root causes of any incidents, and preventive and corrective actions identified and implemented.

7. Inform the OTPCA and the Bridgeport, CT, Area Office as soon as possible after it has knowledge that it will:

a. Cease to do business;

b. change the location and address of the main office for managing the alternative energy control procedures specified herein; or

c. transfer the operations specified herein to a successor company.

8. Notify all affected employees of this interim order/proposed permanent variance by the same means required to inform them of its application for a variance.

9. Request approval from OSHA for the transfer of the interim order/proposed permanent variance to a successor company.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW., Washington, DC 20210, authorized the preparation of this notice. Accordingly, the Agency is issuing this notice pursuant to Section 29 U.S.C. 655(6)(d), Secretary of Labor's Order No. 1–2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1905.11.

Signed at Washington, DC, on November 25, 2015.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2015–30483 Filed 12–1–15; 8:45 am]

BILLING CODE 4510–26–P

[10] See footnote 5.

NUCLEAR REGULATORY COMMISSION

[Docket No. 52–016; NRC–2008–0066]

Dominion Virginia Power Combined License Application for North Anna, Unit 3

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption in a response to a September 23, 2015, letter from Dominion Virginia Power (Dominion or applicant), which requested an exemption from the requirement to submit an annual update of the Final Safety Analysis Report (FSAR) included in Dominion's Combined License (COL) application for calendar year 2015. The NRC staff reviewed this request and determined that it is appropriate to grant the exemption based on the schedule for completion of the applicant's seismic closure plan (SCP) submitted on October 22, 2014, which outlined a revised approach to performing certain aspects of the seismic analysis for the North Anna 3 COL application (COLA) as well as use of the most current NRC-approved ground motion model.

DATES: The effective date of the Dominion FSAR exemption issuance is December 2, 2015.

ADDRESSES: Please refer to Docket ID NRC–2008–0066 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0066. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov*. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- NRC's Agencywide Documents Access and Management System (ADAMS): You may obtain publicly available documents online in the ADAMS Public Documents collection at

http://www.nrc.gov/reading-rm/adams.html. To begin the search, select ''*ADAMS Public Documents''* and then select ''*Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.

- NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: James Shea, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1388; email: *James.Shea@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

By letter dated November 26, 2007 (ADAMS accession number ML073320913), Dominion submitted its application to the NRC for a COL to construct and operate a General Electric-Hitachi Economic Simplified Boiling-Water Reactor (ESBWR) at North Anna Power Station (North Anna), Unit 3 site pursuant to part 52 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Licenses, Certifications, and Approvals for Nuclear Power Plants.'' By letter dated June 28, 2010, Dominion revised its application to incorporate by reference the Mitsubishi Heavy Industries, Ltd. United States–Advanced Pressurized Water Reactor technology to construct and operate at the North Anna, Unit 3 site.

On August 23, 2011, a 5.8 magnitude earthquake occurred near Mineral, Virginia, which is approximately 11 miles from the North Anna Unit 3 site. In view of the earthquake, the NRC staff requested additional analysis of the proposed reactor design to verify that the design, if built at the North Anna site, would satisfy the requirements of 10 CFR part 50, Appendix A, ''General Design Criteria,'' Criterion 2, ''Design Bases for Protection Against Natural Phenomena,'' and 10 CFR part 50, Appendix S, ''Earthquake Engineering Criteria for Nuclear Power Plants.'' During the applicant's seismic evaluation, the NRC staff had requests for additional information and had held public meetings with the applicant to provide staff feedback on the North Anna 3 site seismic analyses.

By letter dated April 25, 2013, Dominion notified the NRC staff that it planned to revert back to ESBWR reactor technology for its North Anna Unit 3 COLA. Dominion then submitted a revised application that incorporated by reference the ESBWR Design Control Document (DCD), Revision 9, by letter dated December 18, 2013. After meeting with the NRC staff in 2014 and performing seismic sensitivity analyses, Dominion modified its site-specific seismic analyses approach intended to simplify it and make it more consistent with the seismic analyses presented in the ESBWR DCD. Therefore, in its SCP submitted on October 22, 2014 (ADAMS accession number ML14297A199), Dominion outlined a schedule for completing all technical reports, analyses, and COLA changes needed to address seismic issues by December 31, 2015.

II. Request/Action

The regulations specified in 10 CFR 50.71(e)(3)(iii) require that an applicant for a COL under 10 CFR part 52 shall, during the period from docketing of a COL application until the NRC makes a finding under 10 CFR 52.103(g) pertaining to facility operation, submit an annual update to the application's FSAR, which is a part of the application.

Pursuant to 10 CFR 50.71(e)(3)(iii), the next annual update of the North Anna, Unit 3, COL application FSAR would be due on or before December 31, 2015. By letter to the NRC dated September 23, 2015, Dominion requested a one-time exemption from the 10 CFR 50.71(e)(3)(iii) requirement to submit the scheduled 2015 COL application FSAR update, and proposed a new submission deadline of June 30, 2016, for the next FSAR update (ADAMS Accession Number ML15268A039). Dominion then proposes to submit the next annual FSAR update required by 10 CFR 50.71(e)(3) in 2017.

Dominion's requested exemption is a one-time schedule change from the requirements of 10 CFR 50.71(e)(3)(iii). The exemption, as requested, would allow Dominion to submit the next FSAR update no later than June 30, 2016. Dominion states that the FSAR, if submitted as requested, would include all the FSAR changes based on the Dominion SCP to allow a more efficient and effective submittal of an updated FSAR reflecting all changes associated with the site-specific seismic analyses.

III. Discussion

Pursuant to 10 CFR 50.12, the NRC may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50, including section 50.71(e)(3)(iii) when: (1) The exemptions are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security; and (2) special circumstances are present. As relevant to the requested exemption, special circumstances exist if: (1) ''Application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule'' (10 CFR 50.12(a)(2)(ii)); or (2) ''The exemption would provide only temporary relief from the applicable regulation and the licensee or applicant has made good faith efforts to comply with the regulation'' (10 CFR 50.12(a)(2)(v)).

The review of the North Anna, Unit 3, ESBWR COL application has been ongoing since Dominion submitted the revised COL application dated December 18, 2013. The technical issues currently under consideration by the NRC staff are primarily associated with the revised North Anna, Unit 3 seismic analyses, which Dominion has been addressing since it submitted the revised COL application, as described in detail in the 2014 SCP. According to the SCP, in December 2015, Dominion is scheduled to submit to the NRC technical reports and COL application markups that incorporate the results of analyses of seismic design capacities of certain structures, systems, and components. In addition, during the week of September 28, 2015, the NRC staff completed an audit associated with the proposed North Anna, Unit 3 site-specific seismic issues. The NRC staff plans to conduct a second audit in the first or second quarter of 2016 relating to the capacities of the systems structures and components to withstand the site-specific seismic ground motion. Therefore, the NRC staff may identify additional requests for information regarding seismic issues in the course of its review through the end of December 2015; as a result of the technical reports and COL application markups due to be submitted in December 2015; and as a result of the second technical audit planned for spring 2016. The COL application markups due in December 2015, together with any NRC staff requests for additional information, will likely result in the need to change the FSAR. These changes could not be completed before the current FSAR update is due at the end of calendar year 2015.

Authorized by Law

The exemption is a one-time schedule exemption from the requirements of 10 CFR 50.71(e)(3)(iii). The exemption, as requested, would allow Dominion to submit the next North Anna, Unit 3, COL application FSAR update on or before June 30, 2016, in lieu of the required scheduled submittal on or before December 31, 2015. As stated above, 10 CFR 50.12 allows the NRC to grant such an exemption. The NRC staff has determined that granting Dominion a one-time exemption from the requirements of 10 CFR 50.71(e)(3)(iii) with updates to the FSAR to be submitted on or before June 30, 2016, will provide only temporary relief from this regulation and will not result in a violation of the Atomic Energy Act of 1954, as amended, or NRC regulations. Therefore, the exemption is authorized by law.

No Undue Risk to Public Health and Safety

The underlying purpose of 10 CFR 50.71(e)(3)(iii) is to provide for a timely and comprehensive update of the FSAR associated with a COL application in order to support an effective and efficient review by the NRC staff and issuance of the NRC staff's safety evaluation report. The requested exemption is solely administrative in nature, in that it pertains to the schedule for submission to the NRC of revisions to an application under 10 CFR part 52, for which a license has not been granted. Based on the nature of the requested exemption as described above, no new accident precursors are created by the exemption; thus, neither the probability, nor the consequences of postulated accidents are increased. Therefore, there is no undue risk to public health and safety.

Consistent With Common Defense and Security

The exemption would allow Dominion to submit the next FSAR update prior to final North Anna, Unit 3 NRC staff safety evaluation. This schedule change has no relation to security issues. Therefore, the common defense and security is not impacted by this exemption.

Special Circumstances

Special circumstances, in accordance with 10 CFR 50.12(a)(2), are present whenever: (1) Application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule'' (10 CFR 50.12(a)(2)(ii)); or (2) The exemption would provide only temporary relief from the applicable regulation and the licensee or applicant has made good faith efforts to comply with the regulation (10 CFR 50.12(a)(2)(v)).

The underlying purpose of 10 CFR 50.71(e)(3)(iii) in the context of a COL application is to provide for a timely and comprehensive update of the FSAR associated with a COL application in order to support an effective and efficient review by the NRC staff and issuance of the NRC staff's safety evaluation report. As discussed above, the requested one-time exemption is solely administrative in nature, in that it pertains to a one-time schedule change for submittal of revisions to an application under 10 CFR part 52, for which a license has not been granted. In addition, since the remaining review of the application primarily relates to the issues discussed in the Dominion SCP, there will not likely be any significant FSAR updates until the elements of the SCP and the NRC staff seismic audits are completed. Completion of the SCP (through submission of technical reports and COL application markups) in December 2015 and the additional information submitted as a result of NRC staff audits scheduled for spring of 2016 cannot be reflected in a December 2015 FSAR update, but will be reflected in an FSAR update scheduled for June 2016. At that time, the revised FSAR update submitted by Dominion will be reviewed by the NRC to confirm that COL markups and changes identified in requests for additional information responses will be reflected in the FSAR prior to completion of the final North Anna, Unit 3 NRC staff safety evaluation. The requested one-time exemption would permit Dominion time to submit all the necessary technical information for NRC staff review and the updated COL markups associated with the revised North Anna, Unit 3, seismic analyses in accordance with the submitted Dominion SCP. The NRC staff has determined that this one-time exemption will support the staff's effective and efficient review of the COL application, as well as issuance of the safety evaluation report, and, therefore, submission of an FSAR update in December 2015 is not necessary to achieve the underlying purpose of 10 CFR 50.71(e)(3)(iii). Accordingly, the NRC staff finds that special circumstances are present under 10 CFR 50.12(a)(2)(ii) in connection with Dominion's requested exemption.

Further, the NRC staff finds that granting a one-time exemption from 10 CFR 50.71(e)(3)(iii) would provide only temporary relief, since Dominion would update the FSAR in June 2016. The 2014 Dominion SCP outlined the approach to meet NRC regulatory requirements and address requests for additional information as a result of NRC staff technical review. Under the Dominion SCP for the proposed North Anna, Unit 3, technical reports and analyses have been submitted as they have been completed to date, and two sets of COLA markups (the first revising geotechnical information and the second incorporating the results of soil-structure interaction analyses, structure-soil-structure interaction analyses, and stability analyses) have been completed and submitted for NRC staff review. As described in the Dominion SCP, the last technical reports and a third set of COLA markups, which incorporate the results of the analyses of the design capacities of certain structures, systems, and components (SSCs), are scheduled in the SCP to be submitted in December 2015. Accordingly, the NRC staff finds that Dominion has made good faith efforts to comply with the regulation, and the special circumstances defined by 10 CFR 50.12(a)(2)(v) are present.

Therefore, the special circumstances required by 10 CFR 50.12(a)(2) for the granting of an exemption from 10 CFR 50.71(e)(3)(iii) exist.

Eligibility for Categorical Exclusion From Environmental Review

With respect to the exemption's impact on the quality of the human environment, the NRC has determined that this specific exemption request is eligible for categorical exclusion as identified in 10 CFR 51.22(c)(25). Under 10 CFR 51.22(c)(25), granting of an exemption from the requirements of any regulation of 10 CFR Chapter 1 (which includes 10 CFR 50.71(e)(3)(iii)) is an action that is a categorical exclusion, provided that:

(i) There is no significant hazards consideration;

(ii) There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite;

(iii) There is no significant increase in individual or cumulative public or occupational radiation exposure;

(iv) There is no significant construction impact;

(v) There is no significant increase in the potential for or consequences from radiological accidents; and

(vi) The requirements from which an exemption is sought involve:

(A) Recordkeeping requirements;

(B) Reporting requirements;

(C) Inspection or surveillance requirements;

(D) Equipment servicing or maintenance scheduling requirements;

(E) Education, training, experience, qualification, requalification or other employment suitability requirements;

(F) Safeguard plans, and materials control and accounting inventory scheduling requirements;

(G) Scheduling requirements;

(H) Surety, insurance or indemnity requirements; or

(I) Other requirements of an administrative, managerial, or organizational nature.

The requirements from which this exemption is sought involve only ''(B) Reporting requirements'' or ''(G) Scheduling requirements'' of those required by 10 CFR 51.22(c)(25)(vi).

The NRC staff's determination that each of the applicable criteria for this categorical exclusion is met as follows:

I. 10 CFR 51.22(c)(25)(i): There is no significant hazards consideration.

Staff Analysis: The criteria for determining if an exemption involves a significant hazards consideration are found in 10 CFR 50.92. The proposed action involves only a schedule change regarding the submission of an update to the application for which the licensing review is ongoing. Therefore, there is no significant hazard consideration because granting the proposed exemption would not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or

(3) Involve a significant reduction in a margin of safety.

II. 10 CFR 51.22(c)(25)(ii): There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite.

Staff Analysis: The proposed action involves only a schedule change, which is administrative in nature, and does not involve any changes in the types or significant increase in the amounts of effluents that may be released offsite.

III. 10 CFR 51.22(c)(25)(iii): There is no significant increase in individual or cumulative public or occupational radiation exposure.

Staff Analysis: Since the proposed action involves only a schedule change, which is administrative in nature, it does not contribute to any significant increase in occupational or public radiation exposure.

IV. 10 CFR 51.22(c)(25)(iv): There is no significant construction impact.

Staff Analysis: The proposed action involves only a schedule change, which is administrative in nature. The NRC has not granted the COL application, and the requested exemption will not allow construction at the North Anna site; therefore, the proposed action does not involve any construction impact.

V. 10 CFR 51.22(c)(25)(v): There is no significant increase in the potential for or consequences from radiological accidents.

Staff Analysis: The proposed action involves only a schedule change which is administrative in nature and does not impact the probability or consequences of accidents.

VI. 10 CFR 51.22(c)(25)(vi): The requirements from which this exemption is sought involve only ''(B) Reporting requirements'' or ''(G) Scheduling requirements.''

Staff Analysis: The exemption request involves requirements in both of these categories because it involves submitting an updated FSAR by Dominion, and also relates to the schedule for submitting FSAR updates to the NRC.

Accordingly, Dominion's exemption requests satisfies the criteria of 10 CFR 51.22(c)(25) for categorical exclusion from environmental review, and the granting of this exemption will not have a significant effect on the quality of the human environment.

IV. Conclusion

The NRC has determined that, pursuant to 10 CFR 50.12, the exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Also, special circumstances as described in 10 CFR 50.12(a)(2)(ii) and (v) are present. Therefore, the NRC hereby grants Dominion a one-time exemption from the requirements of 10 CFR 50.71(e)(3)(iii) pertaining to the North Anna, Unit 3, COL application to allow submission of the next North Anna 3 FSAR update no later than June 30, 2016.

Pursuant to 10 CFR 51.22, the NRC has determined that the exemption request meets the applicable categorical exclusion criteria set forth in 10 CFR 51.22(c)(25), and the granting of this exemption will not have a significant effect on the quality of the human environment.

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 20th day November 2015.

For the Nuclear Regulatory Commission.

Francis M. Akstulewicz,

Director, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2015–30536 Filed 12–1–15; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2016–20 and CP2016–26; Order No. 2842]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Priority Mail Express & Priority Mail Contract 22 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 4, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.,* the Postal Service filed a formal request and associated supporting information to add Priority Mail Express & Priority Mail Contract 22 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. Request, Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

[1] Request of the United States Postal Service to Add Priority Mail Express & Priority Mail Contract 22 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, November 24, 2015 (Request).

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2016–20 and CP2016–26 to consider the Request pertaining to the proposed Priority Mail Express & Priority Mail Contract 22 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than December 4, 2015. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Curtis E. Kidd to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2016–20 and CP2016–26 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Curtis E. Kidd is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. Comments are due no later than December 4, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2015–30485 Filed 12–1–15; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2016–19 and CP2016–25; Order No. 2841]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Priority Mail Contract 155 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 3, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.,* the Postal Service filed a formal request and associated supporting information to add Priority Mail Contract 155 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. Request, Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2016–19 and CP2016–25 to consider the Request pertaining to the proposed Priority Mail Contract 155 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than December 3, 2015. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Lyudmila Y. Bzhilyanskaya to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2016–19 and CP2016–25 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Lyudmila Y. Bzhilyanskaya is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. Comments are due no later than December 3, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2015–30484 Filed 12–1–15; 8:45 am]

BILLING CODE 7710–FW–P

[1] Request of the United States Postal Service to Add Priority Mail Contract 155 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, November 24, 2015 (Request).

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA–2015–0072]

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions and an extension of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB)

Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov.*

(SSA)

Social Security Administration, OLCA, Attn: Reports Clearance Director, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov*,

Or you may submit your comments online through *www.regulations.gov*, referencing Docket ID Number [SSA–2015–0072].

I. The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than February 1, 2016. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. Employer Verification of Records for Children Under Age Seven—20 CFR 404.801–404.803, 404.821–404.822—0960–0505. SSA discovered as many as 70 percent of the wage reports we receive for children under age seven are actually the earnings of someone other than the child. To ensure we credit the correct person with the reported earnings, SSA verifies wage reports for children under age seven with the children's employers before posting to the earnings record. SSA uses Form SSA–L3231–C1, Request for Employer Information, for this purpose. The respondents are employers who report earnings for children under age seven.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of responses	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–L3231–C1	20,000	1	10	3,333

2. Wage Reports and Pension Information—20 CFR 422.122(b)—0960–0547. Pension plan administrators annually file plan information with the Internal Revenue Service, which then forwards the information to SSA. SSA maintains and organizes this information by plan number; plan participant's name; and Social Security number. Section 1131(a) of the Social Security Act entitles pension plan participants to request this information from SSA. The Wage Reports and Pension Information regulation, 20 CFR 422.122(b) of the Code of Federal Regulations, stipulates that before SSA disseminates this information, the requestor must first submit a written request with identifying information to SSA. The respondents are requestors of pension plan information.

Type of Request: Extension of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
Requests for pension plan information	400	1	30	200

II. SSA submitted the information collection below to OMB for clearance. Your comments regarding the information collection would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than January 4, 2016. Individuals can obtain copies of the OMB clearance package by writing to *OR.Reports.Clearance@ssa.gov.*

Pre-1957 Military Service Federal Benefit Questionnaire—20 CFR 404.1301–404.1371—0960–0120. SSA may grant gratuitous military wage credits for active military or naval service (under certain conditions) during the period September 16, 1940 through December 31, 1956, if no other Federal agency (other than the Veterans Administration) credited the service for benefit eligibility or computation purposes. We use Form SSA–2512 to collect specific information about other Federal, military, or civilian benefits the wage earner may receive when the applicant indicates both pre-1957 military service and the receipt of a Federal benefit. SSA uses the data in the claims adjudication process to grant gratuitous military wage credits when applicable, and to solicit sufficient information to determine eligibility. Respondents are applicants for Social Security benefits on a record where the wage earner claims pre-1957 military service.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–2512	5,000	1	10	833

Dated: November 27, 2015.

Naomi R. Sipple,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2015–30530 Filed 12–1–15; 8:45 am]

BILLING CODE 4191–02–P

FEDERAL REGISTER

Vol. 80 Wednesday,
No. 231 December 2, 2015

Part II

Department of Health and Human Services

45 CFR Parts 144, 146, 147, et al.
Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 144, 146, 147, 153, 154, 155, 156, and 158

[CMS–9937–P]

RIN 0938–AS57

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule sets forth payment parameters and provisions related to the risk adjustment, reinsurance, and risk corridors programs; cost sharing parameters and cost-sharing reductions; and user fees for Federally-facilitated Exchanges. It also provides additional standards for the annual open enrollment period for the individual market for the 2017 benefit year; essential health benefits; cost-sharing requirements; qualified health plans; updated standards for Exchange consumer assistance programs; network adequacy; patient safety standards; the Small Business Health Options Program; stand-alone dental plans; acceptance of third-party payments by qualified health plans; the definitions of large employer and small employer; fair health insurance premiums; guaranteed availability; student health insurance coverage; the rate review program; the medical loss ratio program; eligibility and enrollment; exemptions and appeals; and other related topics.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 21, 2015.

ADDRESSES: In commenting, please refer to file code CMS–9937–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–9937–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9937–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:

Jeff Wu, (301) 492–4305, Krutika Amin, (301) 492–5153, or Lindsey Murtagh (301) 492–4106, for general information.

David Mlawsky, (410) 786–6851, for matters related to fair health insurance premiums, the single risk pool, guaranteed availability, guaranteed renewability, and student health insurance coverage.

Kelly Drury, (410) 786–0558, for matters related to risk adjustment.

Adrianne Glasgow, (410) 786–0686, for matters related to reinsurance, distributed data collection, and administrative appeals of financial transfers.

Melissa Jaffe, (301) 492–4129, for matters related to risk corridors.

Lisa Cuozzo, (410) 786–1746, for matters related to rate review.

Jennifer Stolbach, (301) 492–4350, for matters related to establishing a State Exchange, and State-based Exchanges on the Federal Platform.

Emily Ames, (301) 492–4246, and Michelle Koltov, (301) 492–4225, for matters related to Navigators and non-Navigator assistance personnel under part 155.

Joan Matlack, (301) 492–4223, for matters related to certified application counselors under part 155.

Briana Levine, (301) 492–4247, for matters related to agents and brokers.

Dana Krohn, (301) 492–4412, for matters related to employer notification and verification.

Rachel Arguello, (301) 492–4263, for matters related to open enrollment periods and special enrollment periods under part 155.

Anne Pesto, (410) 786–3492, for matters related to eligibility determinations and appeals of eligibility determinations for Exchange participation and insurance affordability programs, and eligibility determinations for exemptions.

Kate Ficke, (301) 492–4256, for matters related to exemptions from the shared responsibility payment.

Christelle Jang, (410) 786–8438, for matters related to the SHOP.

Krutika Amin, (301) 492–5153, for matters related to the Federally-facilitated Exchange user fee.

Leigha Basini, (301) 492–4380, for matters related to essential health benefits, network adequacy, essential community providers, and other standards for QHP issuers.

Ielnaz Kashefipour, (301) 492–4376, for matters related to standardized options and third party payment of premiums and cost sharing.

Rebecca Zimmermann, (301) 492–4396, for matters related to stand-alone dental plans.

Cindy Chiou, (301) 492–5142, for matters related to QHP issuer oversight.

Pat Meisol, (410) 786–1917, for matters related to cost-sharing reductions and the premium adjustment percentage.

Nidhi Singh Shah, (301) 492–5110, for matters related to patient safety standards.

Christina Whitefield, (301) 492–4172, for matters related to the medical loss ratio program.

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.

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Acronyms and Abbreviations

Affordable Care Act—The collective term for the Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), as amended
APTC—Advance payments of the premium tax credit
AV—Actuarial value
CBO—Congressional Budget Office
CFR—Code of Federal Regulations
CHIP—Children's Health Insurance Program
CMP—Civil money penalties
CMS—Centers for Medicare & Medicaid Services
CSR—Cost-sharing reduction
ECN—Exemption certificate number
ECP—Essential community provider
EHB—Essential health benefits
ERISA—Employee Retirement Income Security Act of 1974 (Pub. L. 93–406)
FFE—Federally-facilitated Exchange
FF–SHOP—Federally-facilitated Small Business Health Options Program
FPL—Federal poverty level
FR—**Federal Register**
FTE—Full-time equivalent
GDP—Gross Domestic Product
HCC—Hierarchical condition category
HHS—United States Department of Health and Human Services
HIOS—Health Insurance Oversight System
HIPAA—Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)
IRS—Internal Revenue Service
MEC—Minimum essential coverage
MLR—Medical loss ratio
NAIC—National Association of Insurance Commissioners
NHEA—National Health Expenditure Accounts
OMB—Office of Management and Budget
OPM—United States Office of Personnel Management
PHS Act—Public Health Service Act
PII—Personally Identifiable Information
PMPM—Per member per month
PRA—Paperwork Reduction Act of 1995
PSO—Patient safety organization
QHP—Qualified health plan
SADPs—Stand-alone dental Plans
SBE—State-based Exchange
SBE–FP—State-based Exchange on the Federal platform
SHOP—Small Business Health Options Program
The Code—Internal Revenue Code of 1986 (26 U.S.C. 1, *et seq.*)

I. Executive Summary

The Affordable Care Act enacted a set of reforms that are making high quality health insurance coverage and care more affordable and accessible to millions of Americans. These reforms include the creation of competitive marketplaces called Affordable Insurance Exchanges, or ''Exchanges'' (in this proposed rule, we also call an Exchange a Health Insurance Marketplace℠,[1] or Marketplace℠) through which qualified individuals and qualified employers can purchase health insurance coverage. In addition, many individuals who enroll in qualified health plans (QHPs) through individual market Exchanges are eligible to receive a premium tax credit to make health insurance more affordable, and reductions in cost-sharing payments to reduce out-of-pocket expenses for health care services. These Affordable Care Act reforms also include the premium stabilization programs (that is, risk adjustment, reinsurance and risk corridors) and rules that are intended to mitigate the potential impact of adverse selection and stabilize the price of health insurance in the individual and small group markets. In previous rulemaking, we have outlined the major provisions and parameters related to many Affordable Care Act programs.

In this proposed rule, we seek to improve States' ability to operate efficient Exchanges through a proposal that leverages the economies of scale available through the Federal eligibility and enrollment platform and information technology infrastructure. We propose to codify a new Exchange model—the State-based Exchange on the Federal platform (SBE–FP). This model would enable State-based Exchanges (SBEs) to execute certain processes using the Federal eligibility and enrollment infrastructure. Under the proposal, the SBE–FP would be required to enter into a Federal platform agreement with HHS that would define a set of mutual obligations, including the set of Federal services upon which the SBE–FP relies. Under this Exchange model, certain requirements that were previously only applicable to QHPs offered on a Federally-facilitated Exchange (FFE) and their downstream and delegated entities would apply to QHPs offered on an SBE–FP and their downstream and delegated entities. In addition, we propose that agents and brokers facilitating enrollments through SBE–FPs would need to comply with the FFE registration and training requirements. For 2017, we propose a user fee for QHPs offered through SBE–FPs to offset Federal costs of providing this infrastructure.

[1] Health Insurance Marketplace℠ and Marketplace℠ are service marks of the U.S. Department of Health & Human Services.

We also propose a number of incremental amendments that we believe will improve the stability of the Exchanges while improving the choices available to consumers and supporting consumers' ability to make informed choices when purchasing health insurance. These include the introduction of ''standardized options'' in the individual market, which will improve competition and consumer transparency. These amendments are complemented by a series of additional amendments designed to enhance consumers' ability to make informed choices about their health coverage, increase the accessibility of high quality health insurance, and improve competition, transparency, and affordability.

Our proposal for standardized options is intended to simplify the consumer shopping experience by allowing consumers to more easily compare plans across issuers in the individual market FFEs. We propose a standardized option with a specified cost-sharing structure at each of the bronze, silver (with cost-sharing reduction (CSR) plan variations), and gold metal levels. We do not propose to restrict issuers' non-standardized option offerings. We anticipate differentially displaying these standardized options to allow consumers to compare plans based on differences in price and quality rather than cost-sharing structure.

We are also proposing to standardize a number of policies relating to network adequacy for QHPs on the FFEs. We propose a quantitative network adequacy threshold to be selected by the State and a Federal default network adequacy standard that would apply otherwise, that is based on the standard currently used for review and several provisions relating to provider transition for QHPs. We also discuss in this proposed rule a standardized categorization of network depth for QHPs in these Exchanges and their display on HealthCare.gov. Finally, we propose a standard for when an enrollee receives an essential health benefit at an in-network setting provided by an out-of-network provider.

As part of our efforts to provide consumers simplicity and transparency in their choices, we are considering giving the FFEs the authority to selectively contract with issuers. We would use this authority primarily to strengthen oversight in the short term.

We also seek to improve consumers' ability to make choices regarding health insurance coverage by ensuring they receive high-quality assistance in their interactions with the Exchange. The proposed rule would amend program requirements for Navigators, certain non-Navigator assistance personnel, and certified application counselors. These amendments would require Navigators to assist consumers with certain post-enrollment issues, serve underserved and vulnerable populations, and require Navigators and non-Navigator assistance personnel to complete training prior to conducting outreach and education activities. We would also amend our rules regarding the use of gifts by Navigators, certain non-Navigator assistance personnel and certified application counselors. In addition, we propose that certified application counselor designated organizations would be required to submit data and information related to the organization's certified application counselors, upon the request of the Exchanges in which they operate.

We believe transparency is critical to informed decision-making, and this proposed rule includes several proposals to increase transparency. This proposed rule proposes provisions to enhance the transparency of rates in all States and the effectiveness of the rate review program.

In this proposed rule, we propose several provisions regarding when consumers may choose and enroll in plans. This rule proposes dates for the individual market annual open enrollment period for the 2017 benefit year. For 2017, we propose to maintain the same open enrollment period we adopted for 2016—that is, November 1, 2016, through January 31, 2017.

We also propose to codify a number of Exchange policies relating to exemptions in order to provide certainty and transparency around these policies for all stakeholders.

The HHS Notice of Benefit and Payment Parameters for 2014 (78 FR 15410) (2014 Payment Notice) finalized the risk adjustment methodology that HHS will use when it operates risk adjustment on behalf of a State. Risk adjustment factors reflect enrollee health risk and the costs of a given disease relative to average spending. Last year, we recalibrated the HHS risk adjustment models for 2016 by using 2011, 2012, and 2013 claims data from the Truven Health Analytics 2010 MarketScan® Commercial Claims and Encounters database (MarketScan) to develop updated risk factors. Similarly, this year we propose to do so using the 2012, 2013, and 2014 claims data, when the 2014 MarketScan data become available.

If any reinsurance contribution amounts remain after calculating reinsurance payments for the 2016 benefit year (including after HHS would increase the coinsurance rate to 100 percent for the 2016 benefit year), we propose to lower the 2016 attachment point of $90,000 to pay out any remaining contribution amounts for the 2016 benefit year. We also propose several changes to the risk corridors program for 2015 and 2016. We propose that, for 2015 risk corridors and MLR reporting, if the issuer reported a certified estimate of 2014 cost-sharing reductions on its 2014 MLR and Risk Corridors Annual Reporting Form that is lower than the actual cost-sharing reductions provided, HHS would make an adjustment to the issuer's 2015 risk corridors payment or charge amount in order to address the impact of the inaccurate reporting on the risk corridors and MLR calculations for the 2014 benefit year. We also propose that the issuer must adjust the cost-sharing reduction amounts it reports for the 2015 MLR and risk corridors reporting cycle by any difference between 2014 reported and actual cost-sharing reductions amounts.

We also propose that for the 2015 and later benefit years, the issuer must true up claims liabilities and reserves used to determine the allowable costs reported for the risk corridors program for the preceding benefit year to reflect the actual claims payments made through June 30 of the year following the benefit year. In addition, we propose changes to the definition of ''unpaid claim reserves'' and related requirements for reporting incurred claims for the MLR program beginning with the 2015 reporting year to require issuers to utilize a 6-month (rather than a 3-month) claims run out period.

In addition to provisions aimed at stabilizing premiums, we propose several provisions related to cost sharing. First, we propose the premium adjustment percentage for 2017, which is used to set the rate of increase for several parameters detailed in the Affordable Care Act, including the maximum annual limitation on cost sharing for 2017. We propose the maximum annual limitations on cost sharing for the 2017 benefit year for cost-sharing reduction plan variations. This proposed rule also proposes standards for stand-alone dental plans (SADPs) related to the annual limitation on cost sharing, and would amend standards related to the acceptance of third party payments for premiums and cost sharing by QHP issuers.

This proposed rule includes several incremental improvements that seek to ensure Americans have access to not only affordable, but also robust, high-quality health care coverage. This proposed rule would amend

requirements for QHPs, including essential community providers (ECPs) and meaningful difference requirements. There are also proposed technical amendments to QHP issuer oversight provisions. This rule proposes amendments to further strengthen the patient safety requirements for QHP issuers offering coverage through Exchanges.

For consumers purchasing coverage through the Small Business Health Options Program (SHOP), we propose a new ''vertical choice'' model for Federally-facilitated SHOPs for plan years beginning on or after January 1, 2017, under which employers would be able to offer qualified employees a choice of all plans across all available levels of coverage from a single issuer.

Finally, in this proposed rule, as outlined, we propose adjustments to our programs and rules, as we do each year, so that our rules and policies reflect the latest market developments. We propose the following changes and clarifications to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Affordable Care Act health insurance reform requirements. We propose revisions to the definitions of small employer and large employer to bring them into conformance with recently enacted legislation. We also propose provisions to ensure that a network plan in the small group market with a limited service area can be appropriately rated based on geography. We propose that an issuer subject to the guaranteed availability requirements may—in the limited circumstances of when the exception to the guaranteed renewability requirement related to discontinuing a particular product, or the exception related to discontinuing all coverage in a market, applies—deny coverage to individuals and employers. Lastly, we propose provisions regarding the application of the actuarial value (AV) and single risk pool provisions to student health insurance coverage.

II. Background

A. Legislative and Regulatory Overview

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this proposed rule, we refer to the two statutes collectively as the ''Affordable Care Act.''

Subtitles A and C of title I of the Affordable Care Act reorganized, amended, and added to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets.

Section 2701 of the PHS Act, as added by the Affordable Care Act, restricts the variation in premium rates charged by a health insurance issuer for non-grandfathered health insurance coverage in the individual or small group market to certain specified factors. The factors are: Family size, rating area, age and tobacco use.

Section 2701 of the PHS Act operates in coordination with section 1312(c) of the Affordable Care Act. Section 1312(c) of the Affordable Care Act generally requires a health insurance issuer to consider all enrollees in all health plans (except for grandfathered health plans) offered by such issuer to be members of a single risk pool for each of its individual and small group markets. States have the option to merge the individual market and small group market risk pools under section 1312(c)(3) of the Affordable Care Act.

Section 2702 of the PHS Act, as added by the Affordable Care Act, requires health insurance issuers that offer health insurance coverage in the group or individual market in a State to offer coverage to and accept every employer and individual in the State that applies for such coverage unless an exception applies.[2]

Section 2703 of the PHS Act, as added by the Affordable Care Act, and sections 2712 and 2741 of the PHS Act, as added by HIPAA and codified prior to the enactment of the Affordable Care Act, require health insurance issuers that offer health insurance coverage in the group or individual market to renew or continue in force such coverage at the option of the plan sponsor or individual unless an exception applies.

Section 2718 of the PHS Act, as added by the Affordable Care Act, generally requires health insurance issuers to submit an annual MLR report to HHS, and provide rebates to enrollees if the issuers do not achieve specified MLR thresholds.

Section 2794 of the PHS Act, as added by the Affordable Care Act, directs the Secretary of HHS (the Secretary), in conjunction with the States, to establish a process for the annual review of ''unreasonable increases in premiums for health insurance coverage.'' [3] The law also requires health insurance issuers to submit to the Secretary and the applicable State justifications for unreasonable premium increases prior to the implementation of the increases. Section 2794(b)(2) of the PHS Act further specifies that beginning with plan years starting in 2014, the Secretary, in conjunction with the States, will monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange.

Section 1252 of the Affordable Care Act provides that any standard or requirement adopted by a State under title I of the Affordable Care Act, or any amendment made by title I of the Affordable Care Act, shall be applied uniformly to all health plans in each insurance market to which the standard and requirement apply.

Section 1302 of the Affordable Care Act provides for the establishment of an essential health benefits (EHB) package that includes coverage of EHB (as defined by the Secretary), cost-sharing limits, and actuarial value requirements. The law directs that EHBs be equal in scope to the benefits covered by a typical employer plan and that they cover at least the following 10 general categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.

Section 1301(a)(1)(B) of the Affordable Care Act directs all issuers of QHPs to cover the EHB package described in section 1302(a) of the Affordable Care Act, including coverage of the services described in section 1302(b) of the Affordable Care Act, to adhere to the cost-sharing limits described in section 1302(c) of the Affordable Care Act and to meet the AV levels established in section 1302(d) of the Affordable Care Act. Section 2707(a) of the PHS Act, which is effective for plan or policy years beginning on or after January 1, 2014, extends the coverage of the EHB package to non-grandfathered individual and small group coverage, irrespective of whether such coverage is offered through an Exchange. In addition, section 2707(b)

[2] Before enactment of the Affordable Care Act, the Health Insurance Portability and Accountability Act of 1996 amended the PHS Act (formerly section 2711) to generally require guaranteed availability of coverage for employers in the small group market.

[3] The implementing regulations in part 154 limit the scope of the requirements under section 2794 of the PHS Act to health insurance issuers offering health insurance coverage in the individual market or small group market. *See* Rate Increase Disclosure and Review; Final Rule, 76 FR 29964, 29966 (May 23, 2011).

of the PHS Act directs non-grandfathered group health plans to ensure that cost sharing under the plan does not exceed the limitations described in sections 1302(c)(1) and (2) of the Affordable Care Act.

Section 1302(d) of the Affordable Care Act describes the various levels of coverage based on actuarial value. Consistent with section 1302(d)(2)(A) of the Affordable Care Act, actuarial value is calculated based on the provision of EHB to a standard population. Section 1302(d)(3) of the Affordable Care Act directs the Secretary to develop guidelines that allow for *de minimis* variation in AV calculations.

Section 1311(b)(1)(B) of the Affordable Care Act directs that the Small Business Health Options Program assist qualified small employers in facilitating the enrollment of their employees in qualified health plans offered in the small group market. Sections 1312(f)(1) and (2) of the Affordable Care Act define qualified individuals and qualified employers. Under section 1312(f)(2)(B) of the Affordable Care Act, beginning in 2017, States will have the option to allow issuers to offer QHPs in the large group market through an Exchange.[4]

Section 1311(c)(1)(B) of the Affordable Care Act requires the Secretary to establish minimum criteria for provider network adequacy that a health plan must meet to be certified as a QHP.

Section 1311(c)(5) of the Affordable Care Act requires the Secretary to continue to operate, maintain, and update the Internet portal developed under section 1103 of the Affordable Care Act to provide information to consumers and small businesses on affordable health insurance coverage options.

Section 1311(c)(6)(B) of the Affordable Care Act states that the Secretary is to set annual open enrollment periods for Exchanges for calendar years after the initial enrollment period.

Sections 1311(d)(4)(K) and 1311(i) of the Affordable Care Act direct all Exchanges to establish a Navigator program.

Section 1311(h)(1) of the Affordable Care Act specifies that a QHP may contract with health care providers and hospitals with more than 50 beds only if they meet certain patient safety standards, including use of a patient safety evaluation system, a comprehensive hospital discharge program, and implementation of health care quality improvement activities. Section 1311(h)(2) of the Affordable Care Act also provides the Secretary flexibility to establish reasonable exceptions to these patient safety requirements and section 1311(h)(3) of the Affordable Care Act allows the Secretary flexibility to issue regulations to modify the number of beds described in section 1311(h)(1)(A) of the Affordable Care Act.

Section 1321(a) of the Affordable Care Act provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs and other components of title I of the Affordable Care Act. Section 1321(a)(1) directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the Affordable Care Act with respect to, among other things, the establishment and operation of Exchanges.

Sections 1313 and 1321 of the Affordable Care Act provide the Secretary with the authority to oversee the financial integrity of State Exchanges, their compliance with HHS standards, and the efficient and non-discriminatory administration of State Exchange activities. Section 1321 of the Affordable Care Act provides for State flexibility in the operation and enforcement of Exchanges and related requirements.

When operating an FFE under section 1321(c)(1) of the Affordable Care Act, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the Affordable Care Act to collect and spend user fees. In addition, 31 U.S.C. 9701 permits a Federal agency to establish a charge for a service provided by the agency. Office of Management and Budget (OMB) Circular A–25 Revised establishes Federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public.

Section 1321(c)(2) of the Affordable Care Act authorizes the Secretary to enforce the Exchange standards using civil money penalties (CMPs) on the same basis as detailed in section 2723(b) of the PHS Act. Section 2723(b) of the PHS Act authorizes the Secretary to impose CMPs as a means of enforcing the individual and group market reforms contained in Part A of title XXVII of the PHS Act when a State fails to substantially enforce these provisions

Section 1321(d) of the Affordable Care Act provides that nothing in title I of the Affordable Care Act should be construed to preempt any State law that does not prevent the application of title I of the Affordable Care Act. Section 1311(k) of the Affordable Care Act specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations issued by the Secretary.

Section 1341 of the Affordable Care Act requires the establishment of a transitional reinsurance program in each State to help pay the cost of treating high-cost enrollees in the individual market in benefit years 2014 through 2016. Section 1342 of the Affordable Care Act directs the Secretary to establish a temporary risk corridors program that reduces the impact of inaccurate rate setting from 2014 through 2016. Section 1343 of the Affordable Care Act establishes a permanent risk adjustment program to provide increased payments to health insurance issuers that attract higher-risk populations, such as those with chronic conditions, funded by payments from those that attract lower-risk populations; thereby, reducing incentives for issuers to avoid higher-risk enrollees.

Sections 1402 and 1412 of the Affordable Care Act provide for, among other things, reductions in cost sharing for essential health benefits for qualified low- and moderate-income enrollees in silver level health plans offered through the individual market Exchanges. These sections also provide for reductions in cost sharing for Indians enrolled in QHPs at any metal level.

Section 5000A of the Internal Revenue Code of 1986 (the Code), as added by section 1501(b) of the Affordable Care Act, requires all non-exempt individuals to maintain minimum essential coverage (MEC) for each month or make the individual shared responsibility payment. Section 5000A(f) of the Code defines minimum essential coverage as any of the following: (1) Coverage under a specified government sponsored program; (2) coverage under an eligible employer-sponsored plan; (3) coverage under a health plan offered in the individual market within a State; and (4) coverage under a grandfathered health plan. Section 5000A(f)(1)(E) of the Code authorizes the Secretary of HHS, in coordination with the Secretary of the Treasury, to designate other health benefits coverage as minimum essential coverage.

The Protecting Affordable Coverage for Employees Act (Pub. L. 114–60) amended section 1304(b) of the Patient Protection and Affordable Care Act and section 2791(e) of the PHS Act to amend the definition of small employer in

[4] If a State elects this option, the rating rules in section 2701 of the PHS Act and its implementing regulations will apply to all coverage offered in such State's large group market (except for self-insured group health plans) pursuant to section 2701(a)(5) of the PHS Act.

these statutes to mean, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 50 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. It also amended these statutes to make conforming changes to the definition of large employer, and to provide that a State may treat as a small employer, with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year.

1. Premium Stabilization Programs

In the July 15, 2011 **Federal Register** (76 FR 41929), we published a proposed rule outlining the framework for the premium stabilization programs. We implemented the premium stabilization programs in a final rule, published in the March 23, 2012 **Federal Register** (77 FR 17219) (Premium Stabilization Rule). In the December 7, 2012 **Federal Register** (77 FR 73117), we published a proposed rule outlining the benefit and payment parameters for the 2014 benefit year to expand the provisions related to the premium stabilization programs and set forth payment parameters in those programs (proposed 2014 Payment Notice). We published the 2014 Payment Notice final rule in the March 11, 2013 **Federal Register** (78 FR 15409).

In the December 2, 2013 **Federal Register** (78 FR 72321), we published a proposed rule outlining the benefit and payment parameters for the 2015 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2015 Payment Notice). We published the 2015 Payment Notice final rule in the March 11, 2014 **Federal Register** (79 FR 13743).

In the November 26, 2014 **Federal Register** (79 FR 70673), we published a proposed rule outlining the benefit and payment parameters for the 2016 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2016 Payment Notice). We published the 2016 Payment Notice final rule in the February 27, 2015 **Federal Register** (80 FR 10749).

2. Program Integrity

In the June 19, 2013 **Federal Register** (78 FR 37031), we published a proposed rule that proposed certain program integrity standards related to Exchanges and the premium stabilization programs (proposed Program Integrity Rule). The provisions of that proposed rule were finalized in two rules, the ''first Program Integrity Rule'' published in the August 30, 2013 **Federal Register** (78 FR 54069) and the ''second Program Integrity Rule'' published in the October 30, 2013 **Federal Register** (78 FR 65045).

3. Exchanges

We published a request for comment relating to Exchanges in the August 3, 2010 **Federal Register** (75 FR 45584). We issued initial guidance to States on Exchanges on November 18, 2010. We proposed a rule in the July 15, 2011 **Federal Register** (76 FR 41865) to implement components of the Exchanges, and a rule in the August 17, 2011 **Federal Register** (76 FR 51201) regarding Exchange functions in the individual market, eligibility determinations, and Exchange standards for employers. A final rule implementing components of the Exchanges and setting forth standards for eligibility for Exchanges was published in the March 27, 2012 **Federal Register** (77 FR 18309) (Exchange Establishment Rule).

We established standards for SHOP in the 2014 Payment Notice and in the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, published in the March 11, 2013 **Federal Register** (78 FR 15541). The provisions established in the interim final rule were finalized in the second Program Integrity Rule. We also set forth standards related to Exchange user fees in the 2014 Payment Notice. We established an adjustment to the FFE user fee in the Coverage of Certain Preventive Services Under the Affordable Care Act final rule, published in the July 2, 2013 **Federal Register** (78 FR 39869) (Preventive Services Rule).

In a final rule published in the July 17, 2013 **Federal Register** (78 FR 42823), we established standards for Navigators and non-Navigator assistance personnel in FFEs and for non-Navigator assistance personnel funded through an Exchange establishment grant. This final rule also established a certified application counselor program for Exchanges and set standards for that program.

4. Essential Health Benefits and Actuarial Value

On December 16, 2011, HHS released a bulletin [5] (the EHB Bulletin) that outlined an intended regulatory approach for defining EHB, including a benchmark-based framework. HHS also published a bulletin that outlined its intended regulatory approach to calculations of AV on February 24, 2012.[6] A proposed rule relating to EHBs and AVs was published in the November 26, 2012 **Federal Register** (77 FR 70643). We established requirements relating to EHBs and AVs in the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, which was published in the February 25, 2013 **Federal Register** (78 FR 12833) (EHB Rule).

5. Market Rules

A proposed rule relating to the 2014 health insurance market rules was published in the November 26, 2012 **Federal Register** (77 FR 70584). A final rule implementing the health insurance market rules was published in the February 27, 2013 **Federal Register** (78 FR 13406) (2014 Market Rules).

A proposed rule relating to Exchanges and Insurance Market Standards for 2015 and Beyond was published in the March 21, 2014 **Federal Register** (79 FR 15808) (2015 Market Standards Proposed Rule). A final rule implementing the Exchange and Insurance Market Standards for 2015 and Beyond was published in the May 27, 2014 **Federal Register** (79 FR 30240) (2015 Market Standards Rule).

6. Rate Review

A proposed rule to establish the rate review program was published in the December 23, 2010 **Federal Register** (75 FR 81003). A final rule with comment period implementing the rate review program was published in the May 23, 2011 **Federal Register** (76 FR 29963) (Rate Review Rule). The provisions of the Rate Review Rule were amended in final rules published in the September 6, 2011 **Federal Register** (76 FR 54969), the February 27, 2013 **Federal Register** (78 FR 13405), the May 27, 2014 **Federal Register** (79 FR 30339), and the February 27, 2015 **Federal Register** (80 FR 10749).

[5] ''Essential Health Benefits Bulletin.'' December 16, 2011. Available at: *https://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.*

[6] ''Actuarial Value and Cost-Sharing Reductions Bulletin.'' February 24, 2012. Available at: *https://www.cms.gov/CCIIO/Resources/Files/Downloads/Av-csr-bulletin.pdf.*

7. Medical Loss Ratio

We published a request for comment on section 2718 of the PHS Act in the April 14, 2010 **Federal Register** (75 FR 19297), and published an interim final rule with a 60-day comment period relating to the MLR program on December 1, 2010 (75 FR 74863). A final rule with a 30-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76573). An interim final rule with a 60-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76595). A final rule was published in the **Federal Register** on May 16, 2012 (77 FR 28790).

B. Stakeholder Consultation and Input

HHS has consulted with stakeholders on policies related to the operation of Exchanges, including the SHOP and the premium stabilization programs. We have held a number of listening sessions with consumers, providers, employers, health plans, the actuarial community, and State representatives to gather public input. We consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners (NAIC), regular contact with States through the Exchange Establishment grant and Exchange Blueprint approval processes, and meetings with Tribal leaders and representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties. We considered all public input we received as we developed the policies in this proposed rule.

C. Structure of Proposed Rule

The regulations outlined in this proposed rule would be codified in 45 CFR parts 144, 146, 147, 153, 154, 155, 156 and 158. The proposed regulations in part 144 would, consistent with recent legislation, revise the definitions of ''large employer'' and ''small employer.''

The proposed regulations in parts 146 and 147 would codify an exception to the guaranteed availability requirement when the exception to the guaranteed renewability requirement related to discontinuing a particular product or discontinuing all coverage in a market applies.

The proposed regulations in part 147 would clarify the definition of principal business address for purposes of geographic rating. We further propose provisions regarding the treatment of student health insurance coverage with regard to the AV and single risk pool requirements.

The proposed regulations in part 153 amend the audit provision for the reinsurance program to clarify that this authority also extends to third parties who assist contributing entities with their obligations under this program. The proposed regulations also include the risk adjustment user fee for 2017 and outline certain modifications to the HHS risk adjustment methodology. We propose to clarify reporting requirements for the risk adjustment, reinsurance, and risk corridors.

The proposed regulations in part 154 outline certain modifications to enhance the transparency and effectiveness of the rate review program. We propose to collect a Unified Rate Review Template from all issuers offering single risk pool coverage in the individual and small group market, including coverage with rate decreases or unchanged rates, as well as rates for new plans. We also announce our intention to disclose all proposed rate increases for single risk pool coverage at a uniform time on the CMS Web site, including rates with increases of less than 10 percent. We also reiterate the process for establishing the uniform timeline that proposed rate increases subject to review and all final rate increases (including those not subject to review) for single risk pool coverage must be posted at a uniform time by States with Effective Rate Review Programs. Finally, we specify the rate filing requirements for student health insurance coverage.

The proposed regulations in part 155 include a clarification related to the functions of an Exchange, and would establish the individual market open enrollment period for the 2017 benefit year. Certain proposals in part 155 are related to the eligibility and verification processes related to eligibility for insurance affordability programs. We also propose to amend and clarify rules related to enrollment of qualified individuals into QHPs. We describe changes to the process of submitting certain exemption applications and options for State Exchanges to handle exemptions. The proposed regulations also include a Federal platform agreement through which a State Exchange may rely on the FFE for certain functions as an SBE–FP. We propose that QHP issuers on an SBE–FP be required to comply with certain provisions relating directly to the eligibility and enrollment platform, and propose to require that SBE–FPs promulgate regulations at least as stringent as a number of FFE regulations, to maintain consistency of the HealthCare.gov experience. We also make various proposals related to the SHOPs. We propose to amend the standards applicable to the consumer assistance functions performed by Navigators, non-Navigator assistance personnel, and certified application counselors. We also discuss our approach to denial of QHP certification, and outline proposed modifications to standards for FFE-registered agents and brokers and requirements for HHS-approved vendors of FFE training.

The proposed regulations in part 156 set forth proposals related to cost sharing, including the premium adjustment percentage, the maximum annual limitation on cost sharing, and the reductions in the maximum annual limitation for cost-sharing plan variations for 2017. We propose a clarification to the administrative appeals process applicable to the premium stabilization, Exchange financial assistance, and FFE user fee programs. Part 156 also includes proposals related to essential health benefits, including clarification to the policy regarding additional State-required benefits. We propose amendments to network adequacy requirements (including application of out-of-network costs to the annual limitation on cost sharing for EHBs covered under QHPs in the small group and individual markets), and essential community provider requirements. We propose establishing standardized options for cost-sharing structures, indexing for the stand-alone dental plan annual limitation on cost sharing, changes to our process for updating the AV Calculator for QHPs, meaningful difference standards for QHPs, and minor changes to QHP issuer oversight standards. We also propose additional modifications to acceptance of third party payments by QHP issuers and the next phase for patient safety standards for issuers of QHPs offered on Exchanges.

The proposed amendments to the regulations in part 158 propose revisions related to the definitions of ''large employer'' and ''small employer'' consistent with recent legislation, as well as revisions related to the reporting of incurred claims.

III. Provisions of the Proposed HHS Notice of Benefit and Payment Parameters for 2017

A. Part 144—Requirements Relating to Health Insurance Coverage

1. Definitions (§ 144.103)

Under § 144.103, the term ''plan year'' means, for a group health plan, the year that is designated as the plan year in the plan document of the group health plan. However, if the plan document does not

designate a plan year or if there is no plan document, then the plan year is—

- The deductible or limit year used under the plan;
- If the plan does not impose deductibles or limits on a yearly basis, then the plan year is the policy year;
- If the plan does not impose deductible or limits on a yearly basis, and either the plan is not insured or the insurance policy is not renewed on an annual basis, then the plan year is the employer's taxable year; or
- In any other case, the plan year is the calendar year.[7]

We are not proposing any changes to the definition of ''plan year'' in this proposed rule. However, we note that whichever definition applies under § 144.103, we interpret the term plan year to mean a period that is no longer than 12 months with respect to grandfathered and non-grandfathered group health plans. Plan years that exceed 12 months are inconsistent with the Affordable Care Act, including the rate review and single risk pool requirements, which both contemplate 12-month or shorter plan years. The Departments of Labor and the Treasury, which respectively have jurisdiction over parallel definitions in the Employee Retirement Income Security Act of 1974 (ERISA) and the Code, have advised HHS that they concur with this interpretation.

Also under § 144.103, because of the original Affordable Care Act definitions, the term large employer currently is defined to mean, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 101 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. In the case of plan years beginning before January 1, 2016, a State may elect to define large employer by substituting ''51 employees'' for ''101 employees.'' The term small employer currently is defined to mean, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. In the case of plan years beginning before January 1, 2016, a State may elect to define small employer by substituting ''50 employees'' for ''100 employees.'' These regulatory definitions were consistent with section 1304(b) of the Affordable Care Act and section 2791(e) of the PHS Act.

However, both of those sections have recently been amended by the Protecting Affordable Coverage for Employees Act (Pub. L. 114–60). Therefore, we propose to revise the regulatory definitions of large employer and small employer in § 144.103 to conform to this legislation. Specifically, we propose to revise the regulatory definition of large employer to mean, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 51 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year, but would provide that a State may elect to define large employer by substituting ''101 employees'' for ''51 employees.'' Conversely, we propose to revise the regulatory definition of small employer to mean, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 50 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year, but would provide that a State may elect to define small employer by substituting ''100 employees'' for ''50 employees.'' Consistent with section 1304(b) of the Affordable Care Act and section 2791(e) of the PHS Act, we also propose to codify statutory language providing that in the case of an employer that was not in existence throughout the preceding calendar year, the determination of whether the employer is a large employer or a small employer be based on the average number of employees that it is reasonably expected the employer will employ on business days in the current calendar year.

Finally, we propose to correct a cross-reference in the definition of excepted benefits under § 144.103, which should refer to the group market provisions in § 146.145(b) as opposed to § 146.145(c).

B. Part 146—Requirements for the Group Health Insurance Market

1. Guaranteed Availability of Coverage for Employers in the Small Group Market (§ 146.150)

Part 146 includes pre-Affordable Care Act HIPAA requirements on group health insurance issuers, including § 146.150, which requires health insurance issuers in the small group market to guarantee the availability of coverage, with some specific exceptions. We propose to add paragraph (g) to § 146.150, providing an exception to the guaranteed availability requirement when the exceptions to the guaranteed renewability requirement in § 146.152(c) or (d) related to discontinuing a particular product or all coverage in a market apply. For a further discussion of this proposal, see the discussion of § 147.104, ''Guaranteed Availability of Coverage,'' in this proposed rule at part 147, ''Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets.''

C. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

1. Fair Health Insurance Premiums (§ 147.102)

Under section 2701 of the PHS Act and regulations at § 147.102, the rating area for a small group plan is the group policyholder's principal business address. We propose to amend § 147.102(a)(1)(ii) to provide that if the employer has registered an in-State principal business address with the State, that location is the principal business address. We note that an in-State address registered solely for purposes of service of process would not be considered the employer's principal business address, unless it is a substantial worksite for the employer's business. If an in-State principal business address is not registered with the State or is only registered for purposes of service of process and is not a substantial worksite, the employer would designate as its principal business address the business address within the State where the greatest number of employees work in the applicable State.

When a network plan offered in a State has a limited service area, the policy described above could result in an issuer having to make a plan available to an employer (because the employer has an employee who lives, works, or resides in the service area), but not be able to apply a geographic rating factor under the current rule, because the issuer might not have

[7] Under § 147.104(b)(1)(i), in the small group market, including under § 155.725 in the SHOP, issuers generally must permit small employers to purchase coverage at any point during the year. In the SHOP, the employer's plan year must consist of the 12-month period beginning with the qualified employer's effective date of coverage. With respect to an employer that purchases coverage in the small group market in a State that has elected to merge its individual and small group risk pools under section 1312(c) of the Affordable Care Act, the plan year will begin on the qualified employer's effective date of coverage, which might be any day during the year, and end on December 31 of the calendar year in which coverage first became effective.

established rates applicable to the location of the employer's principal business address outside the plan's service area.

We propose to amend § 147.102 to provide for an additional principal business address to be identified within a plan's service area so that the plan can be appropriately rated for sale to the employer. In such instances, the additional principal business address would be the business address within the plan's service area where the greatest number of employees work as of the beginning of the plan year, or, if there is no such business address, an address within the rating area selected by the employer that reasonably reflects where the greatest number of employees within the plan's service area live or reside as of the beginning of the plan year.

We note that SHOPs, including the Federally-facilitated Small Business Health Options Programs (FF–SHOPs), may use the address that was used to establish a qualified employer's eligibility for participation in the SHOP to determine the applicable geographic rating area when calculating premiums for participating employers. The SHOPs, including the FF–SHOPs, may not be able to accommodate multiple principal business addresses within a State for premium calculation purposes. As a result, when a single application is completed in a State, plan availability and premium calculations will be based on the principal business address entered on the FF–SHOP employer user interface.

Under § 147.102(b), States have considerable flexibility in establishing rating areas. Rating areas must be based on counties, three-digit zip codes, or metropolitan statistical areas and non-metropolitan statistical areas, and generally will be presumed adequate if State-established rating areas are no greater in number than the number of metropolitan statistical areas in the State plus one. States may seek approval from CMS for a greater number of rating areas provided they are actuarially justified, are not unfairly discriminatory, reflect significant differences in health care unit costs, lead to stability in rates over time, and apply uniformly to all issuers in a market.

We have observed wide variations in the size of rating areas in the various States. We are concerned that, within States, this could lead to pockets of smaller rating areas with higher-risk groups, which potentially compromises the risk-spreading objective that the single risk pool requirement is intended to achieve. At the same time, States are the primary regulators of health insurance, and we believe it is important to recognize the unique needs of each State. We also recognize the consumer disruption that could result from changes to rating areas. Therefore, we seek comments on whether we should seek more uniformity in the size of rating areas or establish a minimum size for rating areas, and if so, how that should be achieved, consistent with the principle of flexibility for States. For example, to help ensure uniformity in rating areas, we could require that each rating area in a State be one geographically contiguous area, and that the relative population of each rating area not vary by more than a specified percentage. To help ensure that rating areas are sufficiently large, we could direct that each State have a maximum number of rating areas equal to the number of metropolitan statistical areas in the State, plus one. We also seek comment on how we could improve uniformity and sufficient size for risk pooling in a manner that would preserve flexibility to accommodate the unique needs of each State.

We also recognize the inconsistency that can occur between an issuer's rating area and the service area of some of its network-based plans. Under current § 155.1055, the service area of a QHP must be established without regard to racial, ethnic, language, health status-related factors, or other factors that exclude specific high utilizing, high cost, or medically underserved populations. We believe it could be beneficial from an insurance market perspective for the rating area and the service area to generally be consistent, to provide that health insurance issuers offer a full array of products in larger geographic areas. We seek comment on whether and how to achieve this objective, including whether to achieve it through regulation, and if so, how our regulations should be revised for this purpose.

Section 147.102(e) provides for a uniform age curve in each State. When a State does not specify an age curve, a Federal default uniform age curve will apply. We are investigating the child age rating factor in the Federal uniform age curve, and seek to determine whether the default factor is appropriate, or fails to adequately differentiate the health risk of children of different ages. We seek comment and data on the most appropriate child age curve, and the policy reasons underlying any recommendation.

2. Guaranteed Availability of Coverage (§ 147.104)

a. Product Discontinuance and Market Withdrawal Exceptions to Guaranteed Availability

Section 147.104 includes several exceptions to the guaranteed availability requirement. We have been asked whether there is an exception to this requirement in the small group, large group, and individual markets when an issuer avails itself of the exception to the guaranteed renewability requirement in § 147.106(c) (discontinuing a particular product), or in § 147.106(d) (discontinuing all coverage). The exception to the guaranteed renewability requirement in § 147.106(c) requires an issuer to provide notice in writing, in a form and manner specified by the Secretary, to each plan sponsor or individual, as applicable, (and to all participants and beneficiaries covered under such coverage) of the discontinuation at least 90 calendar days before the date the coverage will be discontinued. The exception to the guaranteed renewability requirement in § 147.106(d) requires an issuer to provide notice in writing to the applicable State authority and to each plan sponsor or individual, as applicable (and to all participants and beneficiaries covered under the coverage) of the discontinuation at least 180 calendar days prior to the date the coverage will be discontinued. We have been asked whether the guaranteed availability requirement requires health insurance issuers discontinuing a product, or all coverage, to guarantee the availability of coverage during these 90- and 180-day (or other applicable) time periods. We do not believe an issuer should be required to guarantee the availability of a product the issuer is in the process of discontinuing, while the issuer is attempting to wind down its operations for that product. Therefore, we propose to redesignate paragraphs (e) through (i) as (f) through (j), and add a new paragraph (e) to § 147.104, providing for an exception to the guaranteed availability requirement when the exceptions to the guaranteed renewability requirement in § 147.106(c) or (d) related to discontinuing a particular product, or the exception related to discontinuing all coverage in a market, apply. The exception would be effective for the duration of the notice periods discussed above. We acknowledge that the statute does not expressly contain such an exception to the guaranteed availability requirement. However, the statutory requirement under the guaranteed renewability

provision requires issuers to provide at least 90-day or 180-day advance notice to enrollees prior to discontinuation of the coverage. If additional consumers continue to enroll after notice is given, the issuer would not be able to provide the required advance notice to these new enrollees before discontinuing coverage. Accordingly, we are interpreting the interaction between the guaranteed availability and guaranteed renewability provisions to permit an issuer to deny enrollments during the applicable product discontinuance or market withdrawal notice period. However, we propose in paragraph (e)(3) that this exception does not relieve issuers of their obligations to existing policyholders, such as enrolling dependents under a special enrollment right during the 90-day or 180-day period.

We understand that some States may wish issuers to guarantee the availability of products until the end of the applicable notice period, and any such requirement would continue to apply.

We also propose a new paragraph (e)(2), under which an issuer that denies coverage under these provisions must apply the denial uniformly to all employers or individuals in the large group, small group, or individual market, as applicable, in the State consistent with applicable State law, and without regard to the claims experience or any health-status related factor relating to those individuals or employers and their employees (or their respective dependents).

We seek comment on these proposals.

b. Minimum Participation and Contribution Rules

Section 2702 of the PHS Act generally requires health insurance issuers in the group and individual markets to guarantee the availability of coverage. In the 2014 Market Rules final rule, we determined that small employers accordingly could not be denied coverage for failure to satisfy minimum participation or contribution requirements. In recognition of the potential for adverse selection, however, under our authority to define open enrollment periods at § 147.104, we permitted health insurance issuers offering non-grandfathered plans in the small group market to limit the availability of coverage to small employers that do not meet an issuer's employer contribution or group participation rules to an annual enrollment period of November 15 to December 15 of each year. We continue to recognize that the use of minimum participation or contribution rules to limit when coverage can be obtained can guard against adverse selection, in that some employers might wait to purchase insurance only when medical need arises. We also acknowledge the possibility that minimum contribution rules might promote employee take-up and help spread insurance risk across a broad and diverse pool of individuals. However, several features of the Affordable Care Act make participation and contribution rules less relevant, including the individual shared responsibility provisions, under which non-exempt individuals must maintain minimum essential coverage (such as might be available through a group health plan) or make an individual shared responsibility payment, and the employer shared responsibility provisions, under which applicable large employers (in general, employers with at least 50 full-time employees (including full-time equivalent employees)) must either offer coverage that is affordable and that provides minimum value to their full-time employees (and their dependents) or potentially make an assessable payment to the IRS.

Based on our experience since the finalization of the rule providing for the November 15 to December 15 enrollment window, we are concerned that the limitation of the enrollment window could result in some applicable large employers that intend to avoid an employer shared responsibility payment by offering coverage being unable to reasonably offer coverage, if a State were to expand the small group market to include employers with up to 100 employees.

In recognition of this dynamic, we note that a State electing to expand its small group market to include employers with up to 100 employees may opt, under its own authority, to prohibit a small group health insurance issuer from restricting the availability of small group coverage based on employer contribution or group participation rules. Alternatively, in cases where a State expands the definition of a small employer to include up to 100 employees, we could amend the guaranteed availability regulations, with respect to small employers with 51–100 employees or with respect to all small employers altogether, to achieve this objective. We seek comment on such an approach.

3. Guaranteed Renewability of Coverage (§ 147.106)

The guaranteed renewability provisions of title XXVII of the PHS Act provide that an issuer may discontinue a product offered in the group or individual market if the issuer offers to each plan sponsor or individual who is enrolled in that particular product the option to purchase all (or, in the case of the large group market, any) other health insurance coverage currently being offered by the issuer in that market, and complies with other requirements of those sections, as well as with any applicable State law. Title XXVII of the PHS Act includes several exceptions to the guaranteed renewability provisions, including when a group health plan sponsor has violated a material plan provision relating to employer contribution or group participation rules, provided applicable State law allows an exception to guaranteed renewability under such circumstances; and for coverage made available in the individual market, or small or large group market only through one or more bona fide associations, if the individual's or employer's membership in the association ceases. Although the Affordable Care Act removed from title XXVII these exceptions as they applied to guaranteed availability, it did not do so with respect to guaranteed renewability. Therefore, a large employer whose coverage is non-renewed for one of these reasons, and a small employer whose coverage is non-renewed due to membership ceasing in an association, could be seen to have a right to immediately purchase that same coverage (if available in the market) from that same issuer in accordance with guaranteed availability. This renders effectively meaningless these two exceptions to guaranteed renewability in these contexts. To address this potential ambiguity regarding the interplay between guaranteed renewability and guaranteed availability, we propose to remove these guaranteed renewability exceptions from the regulations at § 147.106. We seek comment on other ways in which this ambiguity could be addressed.

4. Student Health Insurance Coverage (§ 147.145)

a. Index Rate Setting Methodology for Student Health Insurance Coverage

Under 45 CFR 147.145, student health insurance coverage is a type of individual health insurance coverage that, subject to limited exceptions, must comply with the PHS Act requirements that apply to individual health insurance coverage. However, section 1560(c) of the Affordable Care Act provides that nothing in title I of the Affordable Care Act (or an amendment made by title I) is to be construed to prohibit an institution of higher

education from offering a student health insurance plan to the extent that the requirement is otherwise permitted under applicable Federal, State, or local law. HHS has exercised its authority under section 1560(c) to modify some of its rules as applied to student health insurance coverage, including those related to the guaranteed availability, guaranteed renewability, and single risk pool requirements.

Our intent in exempting student health insurance coverage from the single risk pool requirement was to provide that student health insurance issuers need not include their student health insurance coverage in their overall individual market (or merged market) risk pool, and also need not have one single risk pool composed of their total statewide book of student health insurance business. Rather, we intended that issuers could establish separate risk pools from their individual health insurance market single risk pool (or merged market risk pool, where applicable) for student health insurance coverage, including by establishing separate risk pools for different institutions of higher education, or multiple risk pools within a single institution, provided the risk pools were based on a bona fide school-related classification (for example, graduate students and undergraduate students) and not a health status-related factor as described in § 146.121. However, we have learned that student health insurance issuers may be using certain rating factors that would be prohibited under the single risk pool regulation in § 156.80(d) to establish rates for institutions of higher education, on the basis that student health insurance coverage has been exempted from those single risk pool index rating requirements under our regulations. Examples of such rating factors include the percentage of students enrolled in the coverage, or the length of time the college or university has had coverage through the issuer. Section 156.80(d) requires a health insurance issuer to base its index rate only on the total combined claims costs for providing EHB (subject to certain adjustments).

We do not intend to disrupt rate setting for student health insurance, but we do seek to ensure that rates are based on actuarially justified factors. To clarify our intent, we propose, for plan years beginning on or after January 1, 2017, that student health insurance coverage be subject to the index rate setting methodology of the single risk pool provision in the regulation at § 156.80(d). However, student health insurance issuers still would be permitted to establish separate risk pools from their individual health insurance market single risk pool (or merged market risk pool, where applicable) for student health insurance coverage, including by establishing separate risk pools for different institutions of higher education, or multiple risk pools within a single institution, provided they are based on a bona fide school-related classification (for example, graduate students and undergraduate students) and not a health status-related factor as described in § 146.121. Consistent with our single risk pool policy, the index rates for these risk pools would be based upon actuarially justified estimates of claims. Permissible plan-level adjustments to these index rates would be limited to those permitted under our rules. This approach would continue to allow rates for student health insurance coverage to reflect the unique characteristics of the student population at the particular institution, while more clearly delineating our intent with regard to the treatment of student health insurance coverage. We seek comment on any potential operational challenges associated with this proposal, including potential challenges related to filing rates for student health insurance coverage and how this policy might be adjusted to address those challenges.

b. Actuarial Value Requirements for Student Health Insurance Plans

Many colleges and universities have reported to us that they offer student health insurance plans that are rich in benefits (for example, providing an actuarial value of 96 percent) and that they are reluctant to reduce the level of benefits to meet an actuarial value metal level. Because enrollees in student health insurance plans are not typically selecting among such plans, there is less need for standardization of actuarial levels in this part of the individual market. Therefore, we propose to add an exemption to the requirements for student health insurance coverage in § 147.145, under which, for plan years beginning on or after January 1, 2017, student health insurance coverage would be exempt from the actuarial value requirements under section 1302(d) of the Affordable Care Act, as implemented in §§ 156.135 and 156.140, but would be required to provide an actuarial value of at least 60 percent. To determine a plan's actuarial value for purposes of the application of the 60 percent actuarial value requirement to student health insurance coverage, we propose to require student health insurance coverage issuers to obtain certification by an actuary that the plan provides an actuarial value of at least 60 percent. This determination would be required to be made by a member of the American Academy of Actuaries, based on analysis in accordance with generally accepted actuarial principles and methodologies.

We considered making modifications to the AV Calculator for the purposes of determining the actuarial value for student health insurance plans. However, the standard population in the AV Calculator is more diverse than the expected population in student health insurance plans, such that the AV Calculator's calculations might be less accurate. That said, we solicit comments on whether the AV Calculator should be used for this purpose.

We also solicit comments on whether to require student health insurance issuers to specify, in their SBCs, summary plan descriptions, enrollment materials, marketing materials, or other materials, the actuarial value of the coverage, the next lowest metal level the coverage would otherwise satisfy, based on its actuarial value, or any other data that would give enrollees and prospective enrollees information about the actuarial value of the coverage.

D. Part 153—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment Under the Affordable Care Act

1. Sequestration

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2016,[8] both the transitional reinsurance program and permanent risk adjustment program are subject to the fiscal year 2016 sequestration. The Federal government's 2016 fiscal year began on October 1, 2015. The reinsurance program will be sequestered at a rate of 6.8 percent for payments made from fiscal year 2016 resources (that is, funds collected during the 2016 fiscal year). To meet the sequestration requirement for the risk adjustment program for fiscal year 2016, HHS will sequester risk adjustment payments made using fiscal year 2016 resources in all States where HHS operates risk adjustment at a sequestration rate of 7.0 percent. HHS estimates that increasing the sequestration rate for all risk adjustment payments made in fiscal year 2016 to all issuers in the States where HHS operates risk adjustment by 0.2 percent will permit HHS to meet the required national risk adjustment program

[8] Available at: *https://www.whitehouse.gov/sites/default/files/omb/assets/legislative_reports/sequestration/2016_jc_sequestration_report_speaker.pdf.*

sequestration percentage of 6.8 percent noted in the OMB Report to Congress.

HHS, in coordination with the OMB, has determined that, under section 256(k)(6) of the Balanced Budget and Emergency Deficit Control Act of 1985, as amended, and the underlying authority for these programs, the funds that are sequestered in fiscal year 2016 from the reinsurance and risk adjustment programs will become available for payment to issuers in fiscal year 2017 without further Congressional action. If the Congress does not enact deficit reduction provisions that replace the Joint Committee reductions, these programs would be sequestered in future fiscal years, and any sequestered funding would become available in the fiscal year following that in which it was sequestered.

2. Provisions and Parameters for the Permanent Risk Adjustment Program

In subparts D and G of 45 CFR part 153, we established standards for the administration of the risk adjustment program. The risk adjustment program is a permanent program created by section 1343 of the Affordable Care Act that transfers funds from lower risk, non-grandfathered plans to higher risk, non-grandfathered plans in the individual and small group markets, inside and outside the Exchanges. In accordance with § 153.310(a), a State that is approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf.

a. Overview of the HHS Risk Adjustment Model (§ 153.320)

The HHS risk adjustment model predicts plan liability for an average enrollee based on that person's age, sex, and diagnoses (risk factors), producing a risk score. The HHS risk adjustment methodology utilizes separate models for adults, children, and infants to account for cost differences in each of these age groups. In each of the adult and child models, the relative costs assigned to an individual's age, sex, and diagnoses are added together to produce a risk score. Infant risk scores are determined by inclusion in one of 25 mutually exclusive groups, based on the infant's maturity and the severity of its diagnoses. If applicable, the risk score is multiplied by a cost-sharing reduction adjustment.

The enrollment-weighted average risk score of all enrollees in a particular risk adjustment-covered plan, or the plan liability risk score, within a geographic rating area is one of the inputs into the risk adjustment payment transfer formula, which determines the payment or charge that an issuer will receive or be required to pay for that plan. Thus, the HHS risk adjustment model predicts average group costs to account for risk across plans, which, as we stated in the 2014 Payment Notice, accords with the Actuarial Standards Board's Actuarial Standards of Practice for risk classification.

b. Proposed Updates to the Risk Adjustment Model (§ 153.320)

We propose to continue to use the same risk adjustment methodology finalized in the 2014 Payment Notice. We propose to make certain updates to the risk adjustment model to incorporate preventive services into our simulation of plan liability, and to reflect more current data. The proposed data updates are similar to the ones we effectuated for 2016 risk adjustment in the 2016 Payment Notice. We propose to recalculate the weights assigned to the various hierarchical condition categories (HCCs) and demographic factors in our risk adjustment models using the most recent data available. As we previously described, in the adult and child models, enrollee health risks are estimated using the HHS risk adjustment model, which assigns a set of additive factors that reflect the relative costs attributable to demographics and diagnoses. Risk adjustment factors are developed using claims data and reflect the costs of a given disease relative to average spending. The longer the lag in data used to develop the risk factors, the greater the potential that the costs of treating one disease versus another have changed in a manner not fully reflected in the risk factors.

To provide risk adjustment factors that best reflect more recent treatment patterns and costs, we propose to recalibrate the HHS risk adjustment models for 2017 by using more recent claims data to develop updated risk factors. The risk factors published in the 2016 Payment Notice for use in 2016 were developed using the Truven Health Analytics 2011, 2012 and 2013 MarketScan® Commercial Claims and Encounters database (MarketScan); we are proposing to update the risk factors in the HHS risk adjustment model using 2012, 2013, and 2014 MarketScan data. We would publish and finalize the updated factors in the final rule. We seek comment on this proposal.

We are proposing to incorporate preventive services into our simulation of plan liability in the recalibration of the risk adjustment models for 2017. We identified preventive services for the 2012 and 2013 MarketScan samples using procedure and diagnosis codes, prescription drug therapeutic classes, and enrollee age and sex. We relied on lists of preventive services from several major issuers, the preventive services used for the AV Calculator, and Medicare's preventive services benefit to operationalize preventive services definitions for incorporation in the risk adjustment models. We then adjusted plan liability by adding 100 percent of preventive services covered charges to simulate plan liability for all metal levels. We also applied standard benefit cost sharing rules by metal level to covered charges for non-preventive services. Total adjusted simulated plan liability is the sum of preventive services covered charges, and non-preventive services simulated plan liability.

We re-estimated the risk adjustment models by metal level, predicting plan liability adjusted to account for preventive services without cost sharing. We compared the model coefficients predicting original (that is, non-adjusted for preventive services) and adjusted simulated plan liability. Adjusting for preventive services increases age-sex coefficients relative to HCC coefficients, especially in the higher cost-sharing metal tiers (bronze and silver), and in age/sex ranges with high preventive services expenditures (for example, young adult females). The implication of the changes to the model coefficients is that the risk scores of healthy enrollees (whose risk scores are based solely on model age-sex coefficients) will likely rise relative to the risk scores of the less healthy (whose risk scores include one or more HCC coefficients in addition to an age-sex coefficient), especially in bronze and silver plans. As a result of the risk score changes for individuals, we expect that the incorporation of preventive services would increase the risk scores of bronze and silver plans with healthier enrollees relative to other plans' risk scores when preventive services are taken into account. This incorporation of preventive services will more accurately compensate risk adjustment covered plans with enrollees who use preventive services. We seek comment on this approach.

Additionally, we are evaluating how we may incorporate prescription drug data in the Federally certified risk adjustment methodology that HHS uses when it operates risk adjustment. Prescription drug data could be used in the risk adjustment methodology to supplement diagnostic data by using the prescription drug data as a severity indicator, or as a proxy for diagnoses is in cases where diagnostic data are likely

to be incomplete. We are assessing these approaches, with particular sensitivity to reliability and the potential for strategic behavior with respect to prescribing behavior. As we noted in the 2014 Payment Notice, we did not include prescription drugs to predict expenditures to avoid creating adverse incentives to modify discretionary prescribing. We are evaluating whether we can improve the models' predictive power through the incorporation of prescription drugs without unduly incentivizing altered prescribing behavior. We seek comment and any data that may inform effective methods of incorporating prescription drug data in future recalibrations.

Similarly, we believe we could more accurately account for high-cost conditions with new treatments that are not reflected in our model due to lags in the data available to us for recalibration. We believe that stability across our models is important, but seek comment and data that may inform better methods of accurately compensating for new treatments for high cost conditions. For example, we seek comment on whether there are ways to model the severity of these conditions in a manner that will more fully capture the highest cost enrollees.

Lastly, we would like to explore the effect of partial year enrollment in the HHS risk adjustment methodology. We have received input that issuers are experiencing higher than expected claims costs for partial-year enrollees. We have also received input that the methodology does not capture enrollees with chronic conditions who may not have accumulated diagnoses in their partial year enrollment. At the same time, as compared to full year enrollees of the same relative risk, partial year enrollees are less likely to have spending that exceeds the deductible or annual limitation on cost sharing. We seek comment and data on how the methodology could be made more predictive for partial year enrollees.

c. List of Factors To Be Employed in the Model (§ 153.320)

The HHS risk adjustment models predict annualized plan liability expenditures using age and sex categories and the HHS HCCs included in the HHS risk adjustment model. Dollar coefficients were estimated for these factors using weighted least squares regression, where the weight was the fraction of the year enrolled.

We are including the same HCCs that were included in the original risk adjustment calibration in the 2014 Payment Notice. For each model, the factors are the statistical regression dollar values for each HCC in the model divided by a weighted average plan liability for the full modeling sample. The factors represent the predicted relative incremental expenditures for each HCC. The proposed factors resulting from the blended factors from the 2012 and 2013 separately solved models (with the incorporation of preventive services) are shown in the tables below. For a given enrollee, the sums of the factors for the enrollee's HCCs are the total relative predicted expenditures for that enrollee. Table 1 contains factors for each adult model, including the interactions. Table 2 contains the HHS HHCs in the severity illness indicator variable. Table 3 contains the factors for each child model. Table 4 contains the factors for each infant model.

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 21–24, Male	0.242	0.183	0.117	0.077	0.076
Age 25–29, Male	0.249	0.186	0.117	0.074	0.073
Age 30–34, Male	0.296	0.220	0.135	0.082	0.080
Age 35–39, Male	0.356	0.268	0.170	0.104	0.103
Age 40–44, Male	0.435	0.335	0.221	0.143	0.142
Age 45–49, Male	0.518	0.405	0.277	0.188	0.186
Age 50–54, Male	0.662	0.531	0.380	0.274	0.272
Age 55–59, Male	0.755	0.607	0.439	0.318	0.316
Age 60–64, Male	0.907	0.733	0.538	0.395	0.392
Age 21–24, Female	0.404	0.315	0.211	0.144	0.143
Age 25–29, Female	0.491	0.383	0.262	0.181	0.180
Age 30–34, Female	0.613	0.488	0.350	0.259	0.257
Age 35–39, Female	0.704	0.570	0.423	0.327	0.325
Age 40–44, Female	0.785	0.638	0.477	0.369	0.367
Age 45–49, Female	0.802	0.649	0.480	0.364	0.362
Age 50–54, Female	0.905	0.739	0.554	0.421	0.419
Age 55–59, Female	0.921	0.748	0.554	0.412	0.409
Age 60–64, Female	1.003	0.814	0.601	0.445	0.442
Diagnosis Factors					
HIV/AIDS	5.924	5.438	5.099	5.113	5.114
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	11.809	11.632	11.526	11.587	11.589
Central Nervous System Infections, Except Viral Meningitis	7.068	6.960	6.891	6.914	6.914
Viral or Unspecified Meningitis	4.995	4.743	4.574	4.530	4.530
Opportunistic Infections	9.345	9.238	9.168	9.156	9.156
Metastatic Cancer	24.911	24.456	24.139	24.207	24.209
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	11.344	10.991	10.744	10.751	10.752
Non-Hodgkin's Lymphomas and Other Cancers and Tumors	6.079	5.829	5.643	5.597	5.596
Colorectal, Breast (Age <50), Kidney, and Other Cancers	5.522	5.272	5.082	5.034	5.034
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	3.188	3.005	2.861	2.807	2.806
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.556	1.392	1.248	1.153	1.152

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Pancreas Transplant Status/Complications	5.898	5.665	5.517	5.542	5.543
Diabetes with Acute Complications	1.261	1.113	0.984	0.875	0.873
Diabetes with Chronic Complications	1.261	1.113	0.984	0.875	0.873
Diabetes without Complication	1.261	1.113	0.984	0.875	0.873
Protein-Calorie Malnutrition	14.543	14.553	14.565	14.629	14.630
Mucopolysaccharidosis	2.246	2.121	2.018	1.963	1.962
Lipidoses and Glycogenosis	2.246	2.121	2.018	1.963	1.962
Amyloidosis, Porphyria, and Other Metabolic Disorders	2.246	2.121	2.018	1.963	1.962
Adrenal, Pituitary, and Other Significant Endocrine Disorders	2.246	2.121	2.018	1.963	1.962
Liver Transplant Status/Complications	15.618	15.437	15.325	15.338	15.339
End-Stage Liver Disease	5.957	5.705	5.543	5.560	5.561
Cirrhosis of Liver	2.417	2.245	2.128	2.094	2.093
Chronic Hepatitis	2.212	2.059	1.942	1.881	1.880
Acute Liver Failure/Disease, Including Neonatal Hepatitis	4.584	4.410	4.290	4.284	4.284
Intestine Transplant Status/Complications	35.083	35.028	34.981	35.010	35.009
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	12.704	12.429	12.241	12.279	12.279
Intestinal Obstruction	6.960	6.679	6.497	6.526	6.527
Chronic Pancreatitis	5.898	5.665	5.517	5.542	5.543
Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption	2.929	2.728	2.583	2.538	2.537
Inflammatory Bowel Disease	3.154	2.884	2.680	2.572	2.571
Necrotizing Fasciitis	7.009	6.797	6.650	6.671	6.671
Bone/Joint/Muscle Infections/Necrosis	7.009	6.797	6.650	6.671	6.671
Rheumatoid Arthritis and Specified Autoimmune Disorders	3.718	3.455	3.263	3.242	3.242
Systemic Lupus Erythematosus and Other Autoimmune Disorders	1.235	1.092	0.968	0.880	0.879
Osteogenesis Imperfecta and Other Osteodystrophies	3.474	3.263	3.094	3.035	3.034
Congenital/Developmental Skeletal and Connective Tissue Disorders	3.474	3.263	3.094	3.035	3.034
Cleft Lip/Cleft Palate	1.507	1.336	1.200	1.130	1.130
Hemophilia	42.711	42.402	42.168	42.178	42.179
Myelodysplastic Syndromes and Myelofibrosis	12.218	12.073	11.973	11.984	11.985
Aplastic Anemia	12.218	12.073	11.973	11.984	11.985
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	9.749	9.576	9.446	9.441	9.441
Sickle Cell Anemia (Hb-SS)	9.749	9.576	9.446	9.441	9.441
Thalassemia Major	9.749	9.576	9.446	9.441	9.441
Combined and Other Severe Immunodeficiencies	5.252	5.095	4.985	4.991	4.992
Disorders of the Immune Mechanism	5.252	5.095	4.985	4.991	4.992
Coagulation Defects and Other Specified Hematological Disorders	2.989	2.884	2.801	2.774	2.773
Drug Psychosis	3.809	3.542	3.340	3.241	3.240
Drug Dependence	3.809	3.542	3.340	3.241	3.240
Schizophrenia	3.100	2.840	2.647	2.568	2.567
Major Depressive and Bipolar Disorders	1.777	1.601	1.450	1.346	1.344
Reactive and Unspecified Psychosis, Delusional Disorders	1.777	1.601	1.450	1.346	1.344
Personality Disorders	1.188	1.050	0.913	0.805	0.803
Anorexia/Bulimia Nervosa	2.786	2.612	2.469	2.406	2.405
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	2.824	2.684	2.579	2.531	2.531
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.042	0.933	0.828	0.752	0.751
Autistic Disorder	1.188	1.050	0.913	0.805	0.803
Pervasive Developmental Disorders, Except Autistic Disorder	1.188	1.050	0.913	0.805	0.803
Traumatic Complete Lesion Cervical Spinal Cord	13.957	13.787	13.663	13.665	13.666
Quadriplegia	13.957	13.787	13.663	13.665	13.666
Traumatic Complete Lesion Dorsal Spinal Cord	10.170	10.005	9.884	9.875	9.875
Paraplegia	10.170	10.005	9.884	9.875	9.875
Spinal Cord Disorders/Injuries	6.086	5.864	5.707	5.679	5.679
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	3.246	2.997	2.827	2.787	2.788
Quadriplegic Cerebral Palsy	1.400	1.183	1.020	0.960	0.959
Cerebral Palsy, Except Quadriplegic	0.000	0.000	0.000	0.000	0.000
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	0.126	0.033	0.000	0.000	0.000
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	5.285	5.129	5.018	4.995	4.995
Muscular Dystrophy	2.211	2.034	1.907	1.835	1.834
Multiple Sclerosis	9.367	8.954	8.667	8.708	8.710
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	2.211	2.034	1.907	1.835	1.834
Seizure Disorders and Convulsions	1.485	1.319	1.184	1.109	1.108
Hydrocephalus	7.352	7.229	7.123	7.098	7.097
Non-Traumatic Coma, and Brain Compression/Anoxic Damage	9.834	9.691	9.579	9.574	9.574
Respirator Dependence/Tracheostomy Status	37.369	37.364	37.365	37.433	37.434
Respiratory Arrest	11.456	11.296	11.192	11.262	11.264
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	11.456	11.296	11.192	11.262	11.264

TABLE 1—ADULT RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Heart Assistive Device/Artificial Heart	35.695	35.429	35.257	35.324	35.325
Heart Transplant	35.695	35.429	35.257	35.324	35.325
Congestive Heart Failure	3.387	3.271	3.190	3.186	3.186
Acute Myocardial Infarction	10.835	10.482	10.255	10.380	10.382
Unstable Angina and Other Acute Ischemic Heart Disease	5.666	5.370	5.186	5.209	5.210
Heart Infection/Inflammation, Except Rheumatic	6.510	6.365	6.260	6.240	6.239
Specified Heart Arrhythmias	3.099	2.940	2.818	2.765	2.764
Intracranial Hemorrhage	10.244	9.944	9.743	9.761	9.761
Ischemic or Unspecified Stroke	3.640	3.440	3.319	3.331	3.332
Cerebral Aneurysm and Arteriovenous Malformation	4.354	4.138	3.986	3.947	3.946
Hemiplegia/Hemiparesis	6.079	5.979	5.919	5.967	5.967
Monoplegia, Other Paralytic Syndromes	3.944	3.803	3.705	3.688	3.688
Atherosclerosis of the Extremities with Ulceration or Gangrene	11.784	11.679	11.619	11.694	11.695
Vascular Disease with Complications	8.222	8.025	7.892	7.898	7.898
Pulmonary Embolism and Deep Vein Thrombosis	4.155	3.978	3.852	3.829	3.829
Lung Transplant Status/Complications	35.331	35.127	34.994	35.078	35.080
Cystic Fibrosis	12.237	11.906	11.656	11.667	11.667
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	1.009	0.883	0.768	0.687	0.686
Asthma	1.009	0.883	0.768	0.687	0.686
Fibrosis of Lung and Other Lung Disorders	2.091	1.961	1.867	1.828	1.827
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	8.033	7.949	7.895	7.913	7.914
Kidney Transplant Status	10.464	10.180	9.997	9.991	9.991
End Stage Renal Disease	40.683	40.431	40.270	40.401	40.403
Chronic Kidney Disease, Stage 5	2.212	2.102	2.031	2.026	2.026
Chronic Kidney Disease, Severe (Stage 4)	2.212	2.102	2.031	2.026	2.026
Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism	1.372	1.177	0.993	0.798	0.794
Miscarriage with Complications	1.372	1.177	0.993	0.798	0.794
Miscarriage with No or Minor Complications	1.372	1.177	0.993	0.798	0.794
Completed Pregnancy With Major Complications	3.837	3.331	3.033	2.879	2.880
Completed Pregnancy With Complications	3.837	3.331	3.033	2.879	2.880
Completed Pregnancy with No or Minor Complications	3.837	3.331	3.033	2.879	2.880
Chronic Ulcer of Skin, Except Pressure	2.399	2.270	2.183	2.168	2.168
Hip Fractures and Pathological Vertebral or Humerus Fractures	9.757	9.532	9.381	9.425	9.426
Pathological Fractures, Except of Vertebrae, Hip, or Humerus	1.951	1.817	1.700	1.626	1.624
Stem Cell, Including Bone Marrow, Transplant Status/Complications	32.229	32.225	32.223	32.243	32.243
Artificial Openings for Feeding or Elimination	10.912	10.812	10.748	10.791	10.792
Amputation Status, Lower Limb/Amputation Complications	6.029	5.865	5.760	5.790	5.791
Interaction Factors					
Severe illness x Opportunistic Infections	11.440	11.678	11.854	11.949	11.950
Severe illness x Metastatic Cancer	11.440	11.678	11.854	11.949	11.950
Severe illness x Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	11.440	11.678	11.854	11.949	11.950
Severe illness x Non-Hodgkin's Lymphomas and Other Cancers and Tumors	11.440	11.678	11.854	11.949	11.950
Severe illness x Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	11.440	11.678	11.854	11.949	11.950
Severe illness x Heart Infection/Inflammation, Except Rheumatic	11.440	11.678	11.854	11.949	11.950
Severe illness x Intracranial Hemorrhage	11.440	11.678	11.854	11.949	11.950
Severe illness x HCC group G06 (G06 is HCC Group 6 which includes the following HCCs in the blood disease category: 67, 68)	11.440	11.678	11.854	11.949	11.950
Severe illness x HCC group G08 (G08 is HCC Group 8 which includes the following HCCs in the blood disease category: 73, 74)	11.440	11.678	11.854	11.949	11.950
Severe illness x End-Stage Liver Disease	2.193	2.336	2.443	2.529	2.530
Severe illness x Acute Liver Failure/Disease, Including Neonatal Hepatitis	2.193	2.336	2.443	2.529	2.530
Severe illness x Atherosclerosis of the Extremities with Ulceration or Gangrene	2.193	2.336	2.443	2.529	2.530
Severe illness x Vascular Disease with Complications	2.193	2.336	2.443	2.529	2.530
Severe illness x Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	2.193	2.336	2.443	2.529	2.530
Severe illness x Artificial Openings for Feeding or Elimination	2.193	2.336	2.443	2.529	2.530
Severe illness x HCC group G03 (G03 is HCC Group 3 which includes the following HCCs in the musculoskeletal disease category: 54, 55)	2.193	2.336	2.443	2.529	2.530

TABLE 2—HHS HCCS IN THE SEVERITY ILLNESS INDICATOR VARIABLE

Description
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.
Peritonitis/Gastrointestinal Perforation/Necrotizing Enter colitis.
Seizure Disorders and Convulsions.
Non-Traumatic Coma, Brain Compression/Anoxic Damage.
Respirator Dependence/Tracheostomy Status.
Respiratory Arrest.
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.
Pulmonary Embolism and Deep Vein Thrombosis.

TABLE 3—CHILD RISK ADJUSTMENT MODEL FACTORS

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 2–4, Male	0.251	0.167	0.082	0.032	0.031
Age 5–9, Male	0.176	0.113	0.048	0.012	0.011
Age 10–14, Male	0.224	0.158	0.084	0.045	0.044
Age 15–20, Male	0.290	0.216	0.134	0.084	0.083
Age 2–4, Female	0.205	0.131	0.061	0.024	0.024
Age 5–9, Female	0.140	0.086	0.033	0.006	0.005
Age 10–14, Female	0.210	0.148	0.083	0.050	0.050
Age 15–20, Female	0.348	0.262	0.165	0.105	0.104
Diagnosis Factors					
HIV/AIDS	3.608	3.174	2.855	2.743	2.742
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	18.093	17.932	17.830	17.855	17.856
Central Nervous System Infections, Except Viral Meningitis	12.330	12.136	11.998	12.005	12.005
Viral or Unspecified Meningitis	3.826	3.606	3.444	3.341	3.340
Opportunistic Infections	23.638	23.563	23.513	23.505	23.505
Metastatic Cancer	38.499	38.239	38.029	38.030	38.030
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	13.275	12.966	12.718	12.660	12.660
Non-Hodgkin's Lymphomas and Other Cancers and Tumors	9.665	9.384	9.151	9.061	9.060
Colorectal, Breast (Age <50), Kidney, and Other Cancers	3.995	3.755	3.539	3.419	3.417
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	3.123	2.910	2.725	2.614	2.612
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	1.892	1.713	1.548	1.438	1.436
Pancreas Transplant Status/Complications	33.115	32.960	32.863	32.876	32.877
Diabetes with Acute Complications	2.630	2.290	2.028	1.773	1.770
Diabetes with Chronic Complications	2.630	2.290	2.028	1.773	1.770
Diabetes without Complication	2.630	2.290	2.028	1.773	1.770
Protein-Calorie Malnutrition	14.811	14.720	14.655	14.683	14.683
Mucopolysaccharidosis	6.419	6.134	5.907	5.866	5.865
Lipidoses and Glycogenosis	6.419	6.134	5.907	5.866	5.865
Congenital Metabolic Disorders, Not Elsewhere Classified	6.419	6.134	5.907	5.866	5.865
Amyloidosis, Porphyria, and Other Metabolic Disorders	6.419	6.134	5.907	5.866	5.865
Adrenal, Pituitary, and Other Significant Endocrine Disorders	6.419	6.134	5.907	5.866	5.865
Liver Transplant Status/Complications	33.115	32.960	32.863	32.876	32.877
End-Stage Liver Disease	13.699	13.535	13.419	13.421	13.422
Cirrhosis of Liver	12.715	12.528	12.391	12.343	12.344
Chronic Hepatitis	1.566	1.405	1.257	1.186	1.185
Acute Liver Failure/Disease, Including Neonatal Hepatitis	13.286	13.119	12.987	12.966	12.967
Intestine Transplant Status/Complications	33.115	32.960	32.863	32.876	32.877
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	16.433	16.077	15.815	15.844	15.845
Intestinal Obstruction	6.156	5.905	5.705	5.620	5.619
Chronic Pancreatitis	9.291	9.008	8.815	8.801	8.800
Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption	2.803	2.658	2.528	2.436	2.435
Inflammatory Bowel Disease	5.919	5.531	5.229	5.120	5.118
Necrotizing Fasciitis	5.073	4.814	4.608	4.555	4.554
Bone/Joint/Muscle Infections/Necrosis	5.073	4.814	4.608	4.555	4.554
Rheumatoid Arthritis and Specified Autoimmune Disorders	3.361	3.116	2.901	2.803	2.801
Systemic Lupus Erythematosus and Other Autoimmune Disorders	1.226	1.061	0.899	0.778	0.776
Osteogenesis Imperfecta and Other Osteodystrophies	1.704	1.565	1.432	1.357	1.356
Congenital/Developmental Skeletal and Connective Tissue Disorders	1.704	1.565	1.432	1.357	1.356
Cleft Lip/Cleft Palate	1.660	1.433	1.242	1.127	1.125
Hemophilia	56.279	55.780	55.399	55.383	55.384

TABLE 3—CHILD RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Myelodysplastic Syndromes and Myelofibrosis	17.181	17.007	16.867	16.847	16.847
Aplastic Anemia	17.181	17.007	16.867	16.847	16.847
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	7.999	7.705	7.476	7.409	7.407
Sickle Cell Anemia (Hb-SS)	7.999	7.705	7.476	7.409	7.407
Thalassemia Major	7.999	7.705	7.476	7.409	7.407
Combined and Other Severe Immunodeficiencies	6.480	6.287	6.134	6.076	6.075
Disorders of the Immune Mechanism	6.480	6.287	6.134	6.076	6.075
Coagulation Defects and Other Specified Hematological Disorders	5.201	5.051	4.911	4.837	4.835
Drug Psychosis	5.249	4.979	4.782	4.717	4.717
Drug Dependence	5.249	4.979	4.782	4.717	4.717
Schizophrenia	5.328	4.926	4.626	4.528	4.527
Major Depressive and Bipolar Disorders	1.935	1.707	1.495	1.332	1.329
Reactive and Unspecified Psychosis, Delusional Disorders	1.935	1.707	1.495	1.332	1.329
Personality Disorders	0.781	0.645	0.486	0.344	0.341
Anorexia/Bulimia Nervosa	2.818	2.603	2.423	2.357	2.356
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	3.727	3.503	3.351	3.317	3.317
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.555	1.360	1.203	1.114	1.113
Autistic Disorder	1.867	1.660	1.462	1.308	1.305
Pervasive Developmental Disorders, Except Autistic Disorder	0.923	0.772	0.592	0.421	0.418
Traumatic Complete Lesion Cervical Spinal Cord	13.459	13.418	13.402	13.481	13.482
Quadriplegia	13.459	13.418	13.402	13.481	13.482
Traumatic Complete Lesion Dorsal Spinal Cord	11.430	11.214	11.066	11.066	11.066
Paraplegia	11.430	11.214	11.066	11.066	11.066
Spinal Cord Disorders/Injuries	5.506	5.254	5.060	4.983	4.982
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	8.929	8.672	8.473	8.435	8.435
Quadriplegic Cerebral Palsy	4.067	3.800	3.630	3.648	3.648
Cerebral Palsy, Except Quadriplegic	0.974	0.772	0.616	0.531	0.530
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.210	1.053	0.917	0.845	0.843
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	9.746	9.558	9.412	9.372	9.372
Muscular Dystrophy	3.762	3.552	3.387	3.308	3.307
Multiple Sclerosis	6.689	6.337	6.076	6.037	6.037
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	3.762	3.552	3.387	3.308	3.307
Seizure Disorders and Convulsions	2.136	1.942	1.755	1.619	1.617
Hydrocephalus	6.047	5.916	5.820	5.814	5.814
Non-Traumatic Coma, and Brain Compression/Anoxic Damage	8.776	8.612	8.487	8.448	8.447
Respirator Dependence/Tracheostomy Status	42.997	42.897	42.854	42.982	42.984
Respiratory Arrest	13.335	13.131	12.994	12.998	12.998
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	13.335	13.131	12.994	12.998	12.998
Heart Assistive Device/Artificial Heart	33.115	32.960	32.863	32.876	32.877
Heart Transplant	33.115	32.960	32.863	32.876	32.877
Congestive Heart Failure	7.307	7.189	7.087	7.047	7.046
Acute Myocardial Infarction	11.965	11.749	11.601	11.612	11.613
Unstable Angina and Other Acute Ischemic Heart Disease	6.781	6.652	6.566	6.583	6.584
Heart Infection/Inflammation, Except Rheumatic	16.783	16.643	16.539	16.519	16.519
Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders	6.142	5.922	5.704	5.578	5.575
Major Congenital Heart/Circulatory Disorders	1.945	1.808	1.640	1.529	1.527
Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders	1.370	1.252	1.106	1.021	1.019
Specified Heart Arrhythmias	4.748	4.549	4.375	4.309	4.308
Intracranial Hemorrhage	17.965	17.699	17.514	17.509	17.510
Ischemic or Unspecified Stroke	8.807	8.679	8.600	8.623	8.624
Cerebral Aneurysm and Arteriovenous Malformation	4.116	3.893	3.725	3.664	3.663
Hemiplegia/Hemiparesis	5.352	5.230	5.146	5.127	5.127
Monoplegia, Other Paralytic Syndromes	3.500	3.334	3.220	3.178	3.178
Atherosclerosis of the Extremities with Ulceration or Gangrene	15.636	15.350	15.141	15.046	15.045
Vascular Disease with Complications	18.385	18.204	18.079	18.077	18.077
Pulmonary Embolism and Deep Vein Thrombosis	15.215	15.029	14.908	14.927	14.928
Lung Transplant Status/Complications	33.115	32.960	32.863	32.876	32.877
Cystic Fibrosis	14.859	14.403	14.062	14.084	14.084
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.484	0.390	0.262	0.170	0.169
Asthma	0.484	0.390	0.262	0.170	0.169
Fibrosis of Lung and Other Lung Disorders	3.395	3.241	3.101	3.038	3.037
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	9.223	9.149	9.092	9.104	9.104
Kidney Transplant Status	14.429	14.054	13.797	13.798	13.798
End Stage Renal Disease	39.233	39.038	38.913	38.998	38.999

TABLE 3—CHILD RISK ADJUSTMENT MODEL FACTORS—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Chronic Kidney Disease, Stage 5	10.493	10.315	10.152	10.039	10.037
Chronic Kidney Disease, Severe (Stage 4)	10.493	10.315	10.152	10.039	10.037
Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism	1.160	0.967	0.768	0.565	0.561
Miscarriage with Complications	1.160	0.967	0.768	0.565	0.561
Miscarriage with No or Minor Complications	1.160	0.967	0.768	0.565	0.561
Completed Pregnancy With Major Complications	3.354	2.882	2.584	2.386	2.385
Completed Pregnancy With Complications	3.354	2.882	2.584	2.386	2.385
Completed Pregnancy with No or Minor Complications	3.354	2.882	2.584	2.386	2.385
Chronic Ulcer of Skin, Except Pressure	1.654	1.541	1.428	1.366	1.365
Hip Fractures and Pathological Vertebral or Humerus Fractures	5.891	5.601	5.355	5.259	5.257
Pathological Fractures, Except of Vertebrae, Hip, or Humerus	1.718	1.565	1.392	1.270	1.268
Stem Cell, Including Bone Marrow, Transplant Status/Complications	33.115	32.960	32.863	32.876	32.877
Artificial Openings for Feeding or Elimination	15.795	15.698	15.662	15.783	15.785
Amputation Status, Lower Limb/Amputation Complications	8.011	7.729	7.525	7.418	7.416

TABLE 4—INFANT RISK ADJUSTMENT MODELS FACTORS

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Extremely Immature * Severity Level 5 (Highest)	409.050	407.618	406.498	406.512	406.513
Extremely Immature * Severity Level 4	203.011	201.612	200.519	200.501	200.502
Extremely Immature * Severity Level 3	54.774	53.619	52.671	52.503	52.501
Extremely Immature * Severity Level 2	54.774	53.619	52.671	52.503	52.501
Extremely Immature * Severity Level 1 (Lowest)	54.774	53.619	52.671	52.503	52.501
Immature * Severity Level 5 (Highest)	193.052	191.689	190.621	190.640	190.641
Immature * Severity Level 4	91.573	90.161	89.057	89.058	89.059
Immature * Severity Level 3	54.774	53.619	52.671	52.503	52.501
Immature * Severity Level 2	31.501	30.277	29.298	29.119	29.116
Immature * Severity Level 1 (Lowest)	31.501	30.277	29.298	29.119	29.116
Premature/Multiples * Severity Level 5 (Highest)	180.068	178.688	177.612	177.587	177.588
Premature/Multiples * Severity Level 4	34.716	33.374	32.329	32.210	32.210
Premature/Multiples * Severity Level 3	18.143	17.052	16.164	15.859	15.855
Premature/Multiples * Severity Level 2	9.619	8.708	7.919	7.456	7.447
Premature/Multiples * Severity Level 1 (Lowest)	6.761	6.055	5.326	4.813	4.803
Term * Severity Level 5 (Highest)	148.077	146.787	145.765	145.664	145.663
Term * Severity Level 4	17.881	16.823	15.955	15.592	15.587
Term * Severity Level 3	6.615	5.913	5.209	4.662	4.651
Term * Severity Level 2	3.999	3.438	2.791	2.206	2.195
Term * Severity Level 1 (Lowest)	1.717	1.385	0.811	0.379	0.371
Age 1 * Severity Level 5 (Highest)	55.723	55.014	54.446	54.372	54.371
Age 1 * Severity Level 4	9.659	9.128	8.675	8.484	8.481
Age 1 * Severity Level 3	3.494	3.127	2.751	2.528	2.524
Age 1 * Severity Level 2	2.210	1.911	1.570	1.327	1.323
Age 1 * Severity Level 1 (Lowest)	0.603	0.465	0.288	0.206	0.205
Age 0 Male	0.723	0.672	0.641	0.584	0.582
Age 1 Male	0.168	0.148	0.127	0.101	0.100

TABLE 5—HHS HCCS INCLUDED IN INFANT MODEL MATURITY CATEGORIES

Maturity category	HCC/Description
Extremely Immature	Extremely Immature Newborns, Birthweight <500 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birthweight 500–749 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birthweight 750–999 Grams.
Immature	Premature Newborns, Including Birthweight 1000–1499 Grams.
Immature	Premature Newborns, Including Birthweight 1500–1999 Grams.
Premature/Multiples	Premature Newborns, Including Birthweight 2000–2499 Grams.
Premature/Multiples	Other Premature, Low Birthweight, Malnourished, or Multiple Birth Newborns.
Term	Term or Post-Term Singleton Newborn, Normal or High Birthweight
Age 1	All age 1 infants.

TABLE 6—HHS HCCS INCLUDED IN INFANT MODEL SEVERITY CATEGORIES

Severity category	HCC
Severity Level 5 (Highest)	Metastatic Cancer.
Severity Level 5	Pancreas Transplant Status/Complications.
Severity Level 5	Liver Transplant Status/Complications.

TABLE 6—HHS HCCS INCLUDED IN INFANT MODEL SEVERITY CATEGORIES—Continued

Severity category	HCC
Severity Level 5	End-Stage Liver Disease.
Severity Level 5	Intestine Transplant Status/Complications.
Severity Level 5	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis.
Severity Level 5	Respirator Dependence/Tracheostomy Status.
Severity Level 5	Heart Assistive Device/Artificial Heart.
Severity Level 5	Heart Transplant.
Severity Level 5	Congestive Heart Failure.
Severity Level 5	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders.
Severity Level 5	Lung Transplant Status/Complications.
Severity Level 5	Kidney Transplant Status.
Severity Level 5	End Stage Renal Disease.
Severity Level 5	Stem Cell, Including Bone Marrow, Transplant Status/Complications.
Severity Level 4	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.
Severity Level 4	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.
Severity Level 4	Mucopolysaccharidosis.
Severity Level 4	Major Congenital Anomalies of Diaphragm, Abdominal Wall, and Esophagus, Age <2.
Severity Level 4	Myelodysplastic Syndromes and Myelofibrosis.
Severity Level 4	Aplastic Anemia.
Severity Level 4	Combined and Other Severe Immunodeficiencies.
Severity Level 4	Traumatic Complete Lesion Cervical Spinal Cord.
Severity Level 4	Quadriplegia.
Severity Level 4	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease.
Severity Level 4	Quadriplegic Cerebral Palsy.
Severity Level 4	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.
Severity Level 4	Non-Traumatic Coma, Brain Compression/Anoxic Damage.
Severity Level 4	Respiratory Arrest.
Severity Level 4	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.
Severity Level 4	Acute Myocardial Infarction.
Severity Level 4	Heart Infection/Inflammation, Except Rheumatic.
Severity Level 4	Major Congenital Heart/Circulatory Disorders.
Severity Level 4	Intracranial Hemorrhage.
Severity Level 4	Ischemic or Unspecified Stroke.
Severity Level 4	Vascular Disease with Complications.
Severity Level 4	Pulmonary Embolism and Deep Vein Thrombosis.
Severity Level 4	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.
Severity Level 4	Chronic Kidney Disease, Stage 5.
Severity Level 4	Hip Fractures and Pathological Vertebral or Humerus Fractures.
Severity Level 4	Artificial Openings for Feeding or Elimination.
Severity Level 3	HIV/AIDS.
Severity Level 3	Central Nervous System Infections, Except Viral Meningitis.
Severity Level 3	Opportunistic Infections.
Severity Level 3	Non-Hodgkin's Lymphomas and Other Cancers and Tumors.
Severity Level 3	Colorectal, Breast (Age <50), Kidney and Other Cancers.
Severity Level 3	Breast (Age 50+), Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors.
Severity Level 3	Lipidoses and Glycogenosis.
Severity Level 3	Adrenal, Pituitary, and Other Significant Endocrine Disorders.
Severity Level 3	Acute Liver Failure/Disease, Including Neonatal Hepatitis.
Severity Level 3	Intestinal Obstruction.
Severity Level 3	Necrotizing Fasciitis.
Severity Level 3	Bone/Joint/Muscle Infections/Necrosis.
Severity Level 3	Osteogenesis Imperfecta and Other Osteodystrophies.
Severity Level 3	Cleft Lip/Cleft Palate.
Severity Level 3	Hemophilia.
Severity Level 3	Disorders of the Immune Mechanism.
Severity Level 3	Coagulation Defects and Other Specified Hematological Disorders.
Severity Level 3	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes.
Severity Level 3	Traumatic Complete Lesion Dorsal Spinal Cord.
Severity Level 3	Paraplegia.
Severity Level 3	Spinal Cord Disorders/Injuries.
Severity Level 3	Cerebral Palsy, Except Quadriplegic.
Severity Level 3	Muscular Dystrophy.
Severity Level 3	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders.
Severity Level 3	Hydrocephalus.
Severity Level 3	Unstable Angina and Other Acute Ischemic Heart Disease.
Severity Level 3	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders.
Severity Level 3	Specified Heart Arrhythmias.
Severity Level 3	Cerebral Aneurysm and Arteriovenous Malformation.
Severity Level 3	Hemiplegia/Hemiparesis.
Severity Level 3	Cystic Fibrosis.

TABLE 6—HHS HCCs INCLUDED IN INFANT MODEL SEVERITY CATEGORIES—Continued

Severity category	HCC
Severity Level 3	Fibrosis of Lung and Other Lung Disorders.
Severity Level 3	Pathological Fractures, Except of Vertebrae, Hip, or Humerus.
Severity Level 2	Viral or Unspecified Meningitis.
Severity Level 2	Thyroid, Melanoma, Neurofibromatosis, and Other Cancers and Tumors.
Severity Level 2	Diabetes with Acute Complications.
Severity Level 2	Diabetes with Chronic Complications.
Severity Level 2	Diabetes without Complication.
Severity Level 2	Protein-Calorie Malnutrition.
Severity Level 2	Congenital Metabolic Disorders, Not Elsewhere Classified.
Severity Level 2	Amyloidosis, Porphyria, and Other Metabolic Disorders.
Severity Level 2	Cirrhosis of Liver.
Severity Level 2	Chronic Pancreatitis.
Severity Level 2	Inflammatory Bowel Disease.
Severity Level 2	Rheumatoid Arthritis and Specified Autoimmune Disorders.
Severity Level 2	Systemic Lupus Erythematosus and Other Autoimmune Disorders.
Severity Level 2	Congenital/Developmental Skeletal and Connective Tissue Disorders.
Severity Level 2	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn.
Severity Level 2	Sickle Cell Anemia (Hb-SS).
Severity Level 2	Drug Psychosis.
Severity Level 2	Drug Dependence.
Severity Level 2	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes.
Severity Level 2	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies.
Severity Level 2	Seizure Disorders and Convulsions.
Severity Level 2	Monoplegia, Other Paralytic Syndromes.
Severity Level 2	Atherosclerosis of the Extremities with Ulceration or Gangrene.
Severity Level 2	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis.
Severity Level 2	Chronic Ulcer of Skin, Except Pressure.
Severity Level 1 (Lowest)	Chronic Hepatitis.
Severity Level 1	Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption.
Severity Level 1	Thalassemia Major.
Severity Level 1	Autistic Disorder.
Severity Level 1	Pervasive Developmental Disorders, Except Autistic Disorder.
Severity Level 1	Multiple Sclerosis.
Severity Level 1	Asthma.
Severity Level 1	Chronic Kidney Disease, Severe (Stage 4).
Severity Level 1	Amputation Status, Lower Limb/Amputation Complications.
Severity Level 1	No Severity HCCs.

d. Cost-Sharing Reductions Adjustments (§ 153.320)

We propose to continue including an adjustment for the receipt of cost-sharing reductions in the model to account for increased plan liability due to increased utilization of health care services by enrollees receiving cost-sharing reductions. The proposed cost-sharing reduction adjustment factors for 2017 risk adjustment are unchanged from those finalized in the 2016 Payment Notice and are set forth in Table 7. These adjustments are effective for 2015, 2016, and 2017 risk adjustment, and are multiplied against the sum of the demographic, diagnosis, and interaction factors. We will continue to evaluate this adjustment in future years as more data becomes available. We seek comment on this approach.

TABLE 7—COST-SHARING REDUCTION ADJUSTMENT

Household income	Plan AV	Induced utilization factor
Silver Plan Variant Recipients		
100–150% of FPL	Plan Variation 94%	1.12
150–200% of FPL	Plan Variation 87%	1.12
200–250% of FPL	Plan Variation 73%	1.00
>250% of FPL	Standard Plan 70%	1.00
Zero Cost-Sharing Recipients		
<300% of FPL	Platinum (90%)	1.00
<300% of FPL	Gold (80%)	1.07
<300% of FPL	Silver (70%)	1.12
<300% of FPL	Bronze (60%)	1.15
Limited Cost-Sharing Recipients		
>300% of FPL	Platinum (90%)	1.00

TABLE 7—COST-SHARING REDUCTION ADJUSTMENT—Continued

Household income	Plan AV	Induced utilization factor
>300% of FPL	Gold (80%)	1.07
>300% of FPL	Silver (70%)	1.12
>300% of FPL	Bronze (60%)	1.15

e. Model Performance Statistics (§ 153.320)

To evaluate the model's performance, we examined its R-squared and predictive ratios. The R-squared statistic, which calculates the percentage of individual variation explained by a model, measures the predictive accuracy of the model overall. The predictive ratios measure the predictive accuracy of a model for different validation groups or subpopulations. The predictive ratio for each of the HHS risk adjustment models is the ratio of the weighted mean predicted plan liability for the model sample population to the weighted mean actual plan liability for the model sample population. The predictive ratio represents how well the model does on average at predicting plan liability for that subpopulation. A subpopulation that is predicted perfectly would have a predictive ratio of 1.0. For each of the HHS risk adjustment models, the R-squared statistic and the predictive ratio are in the range of published estimates for concurrent risk adjustment models.[9] Because we are proposing to blend the coefficients from separately solved models based on MarketScan 2012 and 2013 data (and 2012, 2013, and 2014 data in the final rule), we are publishing the R-squared statistic for each model and year separately to verify their statistical validity. The R-squared statistic for each model is shown in Table 8.

TABLE 8—R-SQUARED STATISTIC FOR HHS RISK ADJUSTMENT MODELS

	R-Squared statistic	
Risk adjustment model	2012	2013
Platinum Adult	0.3936	0.3820
Platinum Child	0.2855	0.2774
Platinum Infant	0.2844	0.3215
Gold Adult	0.3895	0.3775
Gold Child	0.2804	0.2722
Gold Infant	0.2823	0.3195
Silver Adult	0.3858	0.3735
Silver Child	0.2757	0.2674
Silver Infant	0.2808	0.3182
Bronze Adult	0.3836	0.3713
Bronze Child	0.2732	0.2649
Bronze Infant	0.2807	0.3181
Catastrophic Adult	0.3836	0.3712
Catastrophic Child	0.2732	0.2648
Catastrophic Infant	0.2807	0.3181

f. Overview of the Payment Transfer Formula (§ 153.320)

We do not propose to alter our payment transfer methodology. Plan average risk scores will continue to be calculated as the member month-weighted average of individual enrollee risk scores. We defined the calculation of plan average actuarial risk and the calculation of payments and charges in the Premium Stabilization Rule. In the 2014 Payment Notice, we combined those concepts into a risk adjustment payment transfer formula. Risk adjustment transfers (payments and charges) will be calculated after issuers have completed risk adjustment data reporting. The payment transfer formula includes a set of cost adjustment terms that require transfers to be calculated at the geographic rating area level for each plan (that is, HHS will calculate two separate transfer amounts for a plan that operates in two rating areas).

The payment transfer formula is designed to provide a per member per month (PMPM) transfer amount. The PMPM transfer amount derived from the payment transfer formula would be multiplied by each plan's total member months for the benefit year to determine the total payment due or charge owed by the issuer for that plan in a rating area.

(1) Overview of the Payment Transfer Formula

Although we do not propose to change the payment transfer formula from what was finalized in the 2014 Payment Notice (78 FR 15430 through 15434), we believe it would be useful to republish the formula in its entirety, since, as noted above, we are proposing to recalibrate the HHS risk adjustment model. Transfers (payments and charges) will be calculated as the difference between the plan premium estimate reflecting risk selection and the plan premium estimate not reflecting risk selection. As finalized in the 2014 Payment Notice, the HHS risk adjustment payment transfer formula is:

[9] Winkleman, Ross and Syed Mehmud. ''A Comparative Analysis of Claims-Based Tools for Health Risk Assessment.'' Society of Actuaries. April 2007.

$$T_i = \left[\frac{PLRS_i \cdot IDF_i \cdot GCF_i}{\sum_i (s_i \cdot PLRS_i \cdot IDF_i \cdot GCF_i)} - \frac{AV_i \cdot ARF_i \cdot IDF_i \cdot GCF_i}{\sum_i (s_i \cdot AV_i \cdot ARF_i \cdot IDF_i \cdot GCF_i)}\right] \overline{P_s}$$

Where:

P_S = State average premium;
$PLRS_I$ = plan i's plan liability risk score;
AV_i = plan i's metal level AV;
ARF_i = allowable rating factor;
IDF_i = plan i's induced demand factor;
GCF_i = plan i's geographic cost factor;
S_i = plan i's share of State enrollment.

The denominator is summed across all plans in the risk pool in the market in the State.

The difference between the two premium estimates in the payment transfer formula determines whether a plan pays a risk transfer charge or receives a risk transfer payment. Note that the value of the plan average risk score by itself does not determine whether a plan would be assessed a charge or receive a payment—even if the risk score is greater than 1.0, it is possible that the plan would be assessed a charge if the premium compensation that the plan may receive through its rating practices (as measured through the allowable rating factor) exceeds the plan's predicted liability associated with risk selection. Risk adjustment transfers are calculated at the risk pool level, and catastrophic plans are treated as a separate risk pool for purposes of risk adjustment.

g. State-Submitted Alternate Risk Adjustment Methodology

The Commonwealth of Massachusetts has expressed interest in having an HHS-operated risk adjustment program, beginning in the 2017 benefit year. If HHS operates risk adjustment in Massachusetts for 2017 using the Federally certified methodology we use in all States in which we operate risk adjustment, we would announce this in the final rule.

h. Risk Adjustment User Fee (§ 153.610(f))

As noted above, if a State is not approved to operate or chooses to forgo operating its own risk adjustment program, HHS will operate risk adjustment on the State's behalf. As described in the 2014 Payment Notice, HHS's operation of risk adjustment on behalf of States is funded through a risk adjustment user fee. Section 153.610(f)(2) provides that an issuer of a risk adjustment covered plan with the meaning of § 153.20 must remit a user fee to HHS equal to the product of its monthly enrollment in the plan and the per enrollee per month risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

OMB Circular No. A–25R establishes Federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. The risk adjustment program will provide special benefits as defined in section 6(a)(1)(b) of Circular No. A–25R to issuers of risk adjustment covered plans because it will mitigate the financial instability associated with potential adverse risk selection. The risk adjustment program also will contribute to consumer confidence in the health insurance industry by helping to stabilize premiums across the individual and small group health insurance markets.

In the 2016 Payment Notice, we estimated Federal administrative expenses of operating the risk adjustment program to be $1.75 per enrollee per year, based on our estimated contract costs for risk adjustment operations. For the 2017 benefit year, we propose to use the same methodology to estimate our administrative expenses to operate the program. These contracts cover development of the model and methodology, collections, payments, account management, data collection, data validation, program integrity and audit functions, operational and fraud analytics, stakeholder training, and operational support. To calculate the user fee, we divide HHS's projected total costs for administering the risk adjustment programs on behalf of States by the expected number of enrollees in risk adjustment covered plans (other than plans not subject to market reforms and student health plans, which are not subject to payments and charges under the risk adjustment methodology HHS uses when it operates risk adjustment on behalf of a State) in HHS-operated risk adjustment programs for the benefit year.

We estimate that the total cost for HHS to operate the risk adjustment program on behalf of States for 2017 will be approximately $52 million, and that the risk adjustment user fee would be $1.80 per enrollee per year. The risk adjustment user fee contract costs for 2017 include costs related to 2017 risk adjustment data validation, and are slightly higher than the 2016 contract costs as the result of some contracts that were rebid. We do not anticipate Massachusetts' decision to use the Federal risk adjustment methodology will substantially affect the risk adjustment user fee rate for 2017.

3. Provisions and Parameters for the Transitional Reinsurance Program

The Affordable Care Act directs that a transitional reinsurance program be established in each State to help stabilize premiums for coverage in the individual market from 2014 through 2016. In the 2014 Payment Notice, we expanded on the standards set forth in subparts C and E of the Premium Stabilization Rule and established the reinsurance payment parameters and uniform reinsurance contribution rate for the 2014 benefit year. In the 2015 Payment Notice, we established the reinsurance payment parameters and uniform reinsurance contribution rate for the 2015 benefit year and certain oversight provisions related to the operation of the reinsurance program. In the 2016 Payment Notice, we established the reinsurance payment parameters and uniform reinsurance contribution rate for the 2016 benefit year and certain clarifying provisions related to the operation of the reinsurance program.

a. Decreasing the Reinsurance Attachment Point for the 2016 Benefit Year

Section 1341(b)(2)(B) of the Affordable Care Act directs the Secretary, in establishing standards for the transitional reinsurance program, to include a formula for determining the amount of reinsurance payments to be made to non-grandfathered, individual market issuers for high-risk claims that provides for the equitable allocation of funds. In the Premium Stabilization Rule (77 FR 17228), we provided that reinsurance payments to issuers of reinsurance-eligible plans will be made for a portion of an enrollee's claims costs paid by the issuer (the coinsurance rate, meant to reimburse a proportion of claims while giving issuers an incentive to contain costs) that exceeds an attachment point (when reinsurance would begin), subject to a reinsurance cap (when the reinsurance program stops paying claims for a high-cost individual). The coinsurance rate, attachment point, and reinsurance cap together constitute the uniform reinsurance payment parameters.

We finalized in the 2015 Payment Notice (79 FR 13777) that HHS will use

any excess contributions for reinsurance payments for a benefit year by increasing the coinsurance rate for that benefit year up to 100 percent before rolling over any remaining funds in the next year. If any contribution amounts remain after calculating reinsurance payments for the 2016 benefit year (and after HHS increases the coinsurance rate to 100 percent for the 2016 benefit year), we propose to decrease the 2016 attachment point of $90,000 to pay out any remaining contribution amounts in an equitable manner for the 2016 benefit year. We believe that expending all remaining reinsurance contribution funds as payments for the 2016 benefit year will support the reinsurance program's goals of promoting nationwide premium stabilization and market stability in the early years of Exchange operations while providing issuers with incentives to continue to effectively manage enrollee costs. The final attachment point and coinsurance rate for the 2016 benefit year will be calculated based on total available reinsuance collections and accepted reinsurance payment requests. We seek comment on this proposal.

b. Audit Authority Extends to Entities That Assist Contributing Entities (§ 153.405(i))

In accordance with § 153.405(i), HHS or its designee has the authority to audit a contributing entity to assess compliance with the reinsurance program requirements. In 2014, HHS implemented a streamlined approach through which a contributing entity, or a third party such as a third party administrator or an administrative services-only contractor acting on behalf of a contributing entity, could register on Pay.gov, calculate the annual enrollment count and schedule reinsurance contribution payments. During the 2014 contribution submission process, many third party administrators and administrative services-only contractors assisted contributing entities by calculating the contributing entity's annual enrollment count and maintaining the records necessary to validate that enrollment. To ensure that reported annual enrollment counts are calculated correctly in accordance with §§ 153.405(d) through 153.405(g) and applicable guidance, we propose to amend § 153.405(i) to specify that the audit authority extends to any third party administrators, administrative services-only contractors, or other third parties that complete any part of the reinsurance contribution submission process on behalf of contributing entities or otherwise assist contributing entities with compliance with the requirements for the transitional reinsurance program. This would include third party administrators, administrative services-only contractors or other third parties that provide contributing entities with their annual enrollment counts or maintain records to substantiate the annual enrollment counts, even if the third party does not submit the annual enrollment count to HHS. Additionally, we propose to amend § 153.405(i) to specify that a contributing entity that chooses to use a third party administrator, administrative services-only contractor, or other third party to complete the reinsurance contribution submission process on its behalf must ensure that this third party administrator, administrative services-only contractor, or other third party cooperate with any audit under this section. Contributing entities, not third party administrators, administrative services-only contractors, or other third parties, remain responsible for the payment of reinsurance contributions. We seek comment on these amendments.

4. Provisions for the Temporary Risk Corridors Program

This section contains proposals related to the temporary risk corridors program, and therefore applies only to issuers of QHPs, as defined at § 153.500, with respect to the benefit years 2014 through 2016.

a. Risk Corridors Payment Methodology (§ 153.510(g))

To ensure the integrity of data used in risk corridors and MLR calculations, in prior guidance [10] we indicated that we would propose in the HHS Notice of Benefit and Payment Parameters for 2017 an adjustment to correct for any inaccuracies in risk corridors payment and charge amounts that could result from issuers reporting a certified estimate of cost-sharing reductions on the 2014 MLR and Risk Corridors Annual Reporting Form.[11] The use of a certified estimate that is lower than the actual cost-sharing reductions provided would affect the MLR calculation and the risk corridors financial transfers by increasing incurred claims and allowable costs, thereby increasing the MLR and potentially increasing the risk corridors payment or lowering the risk corridors charge. We believe that requiring an update of these reported amounts through recalculation of the risk corridors and MLR amounts for the 2014 benefit year will be disruptive to the market and consumers, as well as administratively burdensome and difficult to operationalize for issuers and HHS. Therefore, consistent with our earlier guidance, we are proposing to add a new paragraph (g) to the risk corridors payment methodology set forth in § 153.510 to propose that if the issuer reported a certified estimate of 2014 cost-sharing reductions on its 2014 MLR and Risk Corridors Annual Reporting Form that is lower than the actual cost-sharing reductions provided (as calculated under § 156.430(c) for the 2014 benefit year, which will take place in the spring of 2016), HHS would make an adjustment to the amount of the issuer's 2015 benefit year risk corridors payment or charge measured by the full difference between the certified estimate reported and the actual cost-sharing reductions provided as calculated under § 156.430(c) in order to address the impact of the inaccurate reporting on the risk corridors and MLR calculations for the 2014 benefit year. We seek comment on this proposal.

b. Risk Corridors Data Requirements (§ 153.530)

Due to the fact that the actual value of cost-sharing reductions provided by an issuer was not available in time for risk corridors and MLR reporting for 2014, for the purpose of adjusting allowable costs in the risk corridors calculation and incurred claims in the MLR calculation for 2014, HHS instructed issuers to report the amount of the cost-sharing reduction portion of the advance payments received by the issuer for 2014 (to the extent not reimbursed to the provider furnishing the item or service).[12] Additionally, issuers were permitted to report a certified estimate of the amount of cost-sharing reductions provided in 2014 (to the extent not reimbursed to the provider furnishing the item or service) in their risk corridors and MLR reporting for the 2014 benefit year.

We propose to amend § 153.530 to add a new paragraph (b)(2)(iii) to require an issuer to adjust the cost-sharing reduction amount it reports on its 2015 risk corridors and MLR forms by the difference (if any) between the reported cost-sharing reduction amount used to adjust allowable costs and

[10] *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Advance-CSR-Payment-and-RC-MLR-submission_6192015.pdf.*

[11] *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Advance-CSR-Payment-and-RC-MLR-submission_6192015.pdf*

[12] *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Advance-CSR-Payment-and-RC-MLR-submission_6192015.pdf*

incurred claims on the 2014 MLR Annual Reporting Form and the actual cost-sharing reductions provided by the issuer for the 2014 benefit year (as calculated under § 156.430(c) for the 2014 benefit year, which will take place in the spring of 2016). Issuers must report the amount as calculated under § 156.430(c) when reporting risk corridors and MLR for the applicable benefit year. As discussed elsewhere in this preamble, we are proposing to modify the issuer data reporting requirements in § 153.710(h)(1)(iii) to reflect this change.

In addition, in the May 23, 2012 Premium Stabilization Rule (77 FR 17220), we defined ''allowable costs'' to reference the MLR term ''incurred claims'' and to include quality improvement activity expenditures as defined in the MLR rule. Incurred claims, as defined in § 158.140 for the MLR program, are generally comprised of claims incurred during the reporting year and paid through the applicable run-out period beyond the end of the year, plus the liabilities and reserves estimating claims incurred during the reporting year but still unpaid at the end of the run-out period, with certain other adjustments.

Thus, the MLR definition of incurred claims relies only on reserves and liabilities at the end of the reporting year, rather than a trued up year-over-year change in reserves and liabilities. In the MLR calculation, these drawbacks are mitigated to some extent because the MLR calculation is based on 3 years of data, and consequently the estimates of unpaid claims are trued up over the following 2 years. However, because the risk corridors calculation is based on only a single year of data, an issuer's estimate of unpaid claims is never trued up, and consequently any inaccuracy in these estimates can have a significant impact on the accuracy of the risk corridors payment or charge calculation.

Therefore, to preserve the integrity of the risk corridors program, we propose to amend § 153.530 to add a new paragraph (b)(2)(iv) to require issuers to adjust the claims reported as allowable costs for the 2015 and later benefit years by the amount by which the issuer's estimate of unpaid claims for the preceding benefit year exceeded (or fell below) the actual payments that the issuer made after the date of the estimate for claims attributable to the preceding benefit year. For example, if in calculating its 2014 allowable costs, an issuer overestimated the amount of claims it incurred in 2014 that were unpaid as of March 31, 2015, then under this proposal, in calculating its 2015 allowable costs, the issuer would be required to subtract the amount by which its March 31, 2015 claims estimate exceeded the actual payments for 2014 claims that the issuer made between March 31, 2015 and June 30, 2016 (the claims reserves and liabilities valuation dates for the 2014 and 2015 benefit years, respectively). We seek comment on the most appropriate way to true up estimates of unpaid claims for 2016. For example, we could provide for a 2017 payment or charge (calculated with 2018 MLR), provide for a simplified true-up process, require that the 2016 estimate be based on actual 2014 and 2015 amounts, or provide for no true-up at all in the final year.

5. Distributed Data Collection for the HHS-Operated Programs

a. Interim Dedicated Distributed Data Environment Reports (§ 153.710(d))

Effective for the 2016 benefit year, we propose deleting § 153.710(d), which sets forth an interim discrepancy reporting process by which an issuer must notify HHS of any discrepancy it identifies between the data to which the issuer has provided access to HHS through its dedicated distributed data environment (that is, an issuer's EDGE server) and the interim dedicated distributed data environment report, or confirm to HHS that the information in the interim report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with § 153.700(a) for the timeframe specified in the report. Many issuers viewed the interim discrepancy process for the 2014 benefit year as an additional burden and an administrative reporting exercise that they had to complete in order to preserve their appeal rights. The process also required significant resources and extensive support from HHS. Additionally, the information collected during the 2014 interim formal discrepancy process largely focused on the problems that issuers were encountering with the data submission process, as opposed to issues involving the dedicated distributed data environment report matching the data the issuer made accessible in its environment. HHS is committed to working with issuers prior to the data submission deadline to address any data issues so that reinsurance payment and risk adjustment transfer calculations can be made accurately and timely. After the initial submission period and prior to the data submission deadline (that is, April 30 of the year following the applicable benefit year), issuers should identify any problems that the issuer is experiencing in loading complete and accurate data; HHS must know about these data issues during this period to assist issuers in addressing these issues prior to the data submission deadline and in advance of reinsurance payment and risk adjustment transfer calculations. Throughout the data collection period, HHS will continue to maintain a help desk to assist issuers with data submission errors and to provide technical assistance. We believe that removing the requirement to file an interim discrepancy report starting in the 2016 benefit year will alleviate the administrative burden on issuers and HHS, as well as streamline outreach and communications during the data submission window. In light of this proposal, we propose to remove any cross-references to the interim discrepancy reporting process currently codified at § 153.710(d) in §§ 153.710 and 156.1220. We also propose conforming amendments to redesignate paragraph (e) as paragraph (d), as well as to revise and redesignate paragraph (f) as (e). We seek comment on this proposal and the proposed effective date.

b. Evaluation of Quality and Quantity of EDGE Data Submissions (§ 153.710(f))

Under § 153.740(b), if an issuer of a risk adjustment covered plan fails to provide HHS with access to the required data in a dedicated data environment such that HHS cannot apply the applicable Federally certified risk adjustment methodology to calculate the risk adjustment payment transfer amount for the risk adjustment covered plan in a timely fashion, HHS will assess a default risk adjustment charge. Similarly, under §§ 153.420 and 153.740(a), an issuer of a reinsurance-eligible plan will forfeit reinsurance payments it otherwise might have received if the issuer fails to establish a dedicated data environment or fails to meet certain data requirements. HHS released guidance on April 24, 2015, entitled ''Evaluation of EDGE Data Submissions'' describing the approach it would use, starting with data submissions for the 2014 benefit year, to evaluate whether an issuer provided access in a dedicated data environment to data that was sufficient for HHS to calculate reinsurance payments and apply the HHS risk adjustment methodology.[13] The approach evaluated the sufficiency of an issuer's data in terms of the quantity and quality of the data. In this rulemaking, we propose to

[13] *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/EDGE-guidance-42415-final.pdf.*

codify this practice for future benefit years to support the integrity of payments and charges made under the HHS-operated risk adjustment program and payments under the reinsurance program, both of which depend upon the submission of accurate and complete data by issuers to their EDGE servers.

Consistent with the approach for review of 2014 benefit year data, to determine if an issuer meets data quantity standards, HHS would compare an issuer's self-reported baseline data on its total enrollment and claims counts by market to the issuer's data submitted to its dedicated data environment. An issuer with a low enrollment count following the submission deadline would be subject to a default risk adjustment charge under § 153.740(b). An issuer with a low claims count following the submission deadline would be subject to a default risk adjustment charge if the default charge is lower than the charge it would have received through the risk adjustment transfer calculation. Additionally, an issuer with either a low enrollment count or a low claims count would forgo reinsurance payments for any claims that it failed to submit. HHS proposes to set forth in guidance, on an annual basis, the appropriate threshold by which HHS will deem data sufficient as to quantity for a given benefit year. HHS will also specify in guidance the format and timeline for submission of baseline data to HHS.

To determine if an issuer meets the data quality standards required for HHS to calculate reinsurance payments and apply the HHS risk adjustment methodology, HHS proposes to perform an outlier analysis using select metrics that target reinsurance data quality and risk adjustment data quality. For the 2014 benefit year, HHS used the following five key metrics: Percentage of all enrollees with at least one HCC; average number of conditions per enrollee with at least one HCC; issuer average risk score; percentage of individual market enrollees with reinsurance payments; and average reinsurance payment per enrollee for which the issuer would receive reinsurance payments. Similar to data quantity, HHS plans to describe in guidance, on an annual basis, the metrics used for a given benefit year. An issuer may be assessed a risk adjustment default charge if it does not meet data quality standards on any of the risk adjustment metrics and may forfeit reinsurance payments it might otherwise have received if it does not meet data quality standards for any of the reinsurance metrics.

HHS would conduct these data quality and quantity analyses after the deadline for submission of data specified in § 153.730 (that is, April 30, of the year following the applicable benefit year). In § 153.710, we propose to add a paragraph (f). In the new paragraph (f), we propose to specify that HHS will assess default risk adjustment charges based on these analyses no later than the date of the notification provided by HHS under § 153.310(e) (that is, June 30 of the year following the applicable benefit year); and to describe the responsibilities of issuers in relation to the quality and quantity analyses. In § 153.710(f)(1), we propose to codify the requirement for issuers to provide baseline data on their total enrollment and claims counts by market, in a format and on a timeline that we intend to specify in guidance. In § 153.710(f)(2), we propose that if HHS identifies a data anomaly that would cause the data that a risk adjustment covered plan or a reinsurance-eligible plan made available through a dedicated data environment to fail HHS's quality thresholds, the issuer may, within 10 calendar days of receiving notification of the anomaly, submit an explanation of the anomaly for HHS to consider in determining whether the issuer met the reinsurance and risk adjustment data requirements.

HHS expects to perform informal data sufficiency analyses throughout the data submission process. Issuers are encouraged to provide explanations and corrected enrollment or claims counts at any time during the data submission process. The timeframe we propose in § 153.710(f)(2) would apply to the final data sufficiency analyses only, which are performed following the deadline for submission of data specified in § 153.730 (that is, April 30, of the year following the applicable benefit year). We seek comment on this proposal.

c. Data Requirements (§ 153.710(g))

We are proposing to make conforming amendments to the introductory language at § 153.710(g)(1) to remove the cross-references to the interim discrepancy reporting process currently codified at § 153.710(d). However, because we have learned in the first year of the implementation of the premium stabilization and Exchange financial assistance programs that flexibility is often needed in reporting the amounts on risk corridors and MLR forms, we also propose that HHS have the ability to modify these instructions in sub-regulatory guidance. Our intent in issuing any such guidance would be to avoid having the application of the instructions in exceptional circumstances lead to unfair or misleading financial reporting. We propose to capture this flexibility through a new proposed paragraph at § 153.710(g)(3).

We also propose to change § 153.710(g)(1)(iii) to require an issuer to report the amount of cost-sharing reductions calculated under § 156.430(c) in its annual MLR and risk corridors report, regardless of whether the issuer had any unresolved discrepancy under § 156.1210, or whether the issuer had submitted a request for reconsideration under § 156.1220(a)(1)(v). Additionally, consistent with the process outlined in § 153.710(g)(2), we propose to require an issuer to adjust the cost-sharing reduction amount it reports on its 2015 risk corridors and MLR forms by the difference (if any) between the reported cost-sharing reduction amount used to adjust allowable costs and incurred claims on the 2014 MLR Annual Reporting Form and the amount of cost-sharing reductions as calculated under § 156.430(c) for the 2014 benefit year.

Consistent with the approach currently outlined in § 153.710(g)(2), we propose to amend this paragraph to require an issuer to report any adjustment made or approved by HHS for any risk adjustment payment or charge, reinsurance payment, cost-sharing reduction payment to reflect actual cost-sharing reduction amounts received, or risk corridors payment or charge, where the adjustment has not been accounted for in a prior MLR and Risk Corridors Annual Reporting Form in the next following year. By way of example, if an issuer's risk adjustment charges or payments are adjusted as a result of the administrative appeals process, the issuer should adjust these reported amounts in the next MLR and risk corridors reporting cycle, after the appeal has been resolved. Similarly, if HHS makes changes to an issuer's risk adjustment charges or payments after the risk corridors and MLR reporting cycle has closed for the applicable reporting year, the issuer should adjust these reported amounts in the next MLR and risk corridors reporting cycle to account for the difference between the reported amounts and the amounts actually received or paid for the previous benefit year. However, if an issuer is notified about the modification during an open MLR and risk corridors submission period, it must report the modified amounts in that open reporting cycle.

We also propose to clarify in § 153.710(g)(1)(iii) that cost-sharing reduction amounts to be reported under this section must exclude amounts reimbursed to providers of services or

items. This clarifying language is consistent with how the instructions for cost-sharing reductions amounts are reported under § 153.530(b)(2)(iii) (risk corridors data requirements) and § 158.140(b)(iii) (MLR data requirements).

Lastly, we propose to revise paragraph (g)(1)(iv) to require that for medical loss ratio reporting only, issuers should report the risk corridors payment to be made or charge assessed by HHS, as reflected under § 153.510.

d. Good Faith Safe Harbor

In the second Program Integrity Rule, we finalized § 153.740(a), which permits HHS to impose civil money penalties upon issuers of risk adjustment covered plans and reinsurance-eligible plans for failure to adhere to certain standards relating to their dedicated distributed data environments. In the preamble to that rule, we stated that if we are able to determine that an issuer of a risk adjustment covered plan or reinsurance-eligible plan is making good faith efforts to comply with the standards set forth in § 153.740(a), consistent with our policy codified at § 156.800(c), we would not seek to impose CMPs for noncompliance with those standards during 2014 (78 FR 65061). In the 2016 Payment Notice (80 FR 10780), we extended the good faith safe harbor to the 2015 calendar year, and stated that we would not apply the good faith safe harbor to non-compliance with dedicated distributed data environment standards applicable during the 2016 calendar year, even where the non-compliance relates to data for the 2015 benefit year. As we have previously said, we are not proposing to extend the good-faith safe harbor. Starting in the 2016 calendar year and beyond, civil money penalties may be imposed if an issuer of a risk adjustment covered plan or reinsurance-eligible plan fails to establish a dedicated distributed data environment in a manner and timeframe specified by HHS; fails to provide HHS with access to the required data in such environment in accordance with § 153.700(a) or otherwise fails to comply with the requirements of §§ 153.700 through 153.730; fails to adhere to the reinsurance data submission requirements set forth in § 153.420; or fails to adhere to the risk adjustment data submission and data storage requirements set forth in §§ 153.610 through 153.630, even if the issuer has made good faith efforts to comply with these requirements.

e. Default Risk Adjustment Charge (§ 153.740(b))

In the second Program Integrity Rule and the 2015 Payment Notice, HHS indicated that a default risk adjustment charge will be assessed if an issuer does not establish a dedicated distributed data environment or submits inadequate risk adjustment data. In the 2016 Payment Notice, we established how a default risk adjustment charge will be allocated among risk adjustment covered plans.

As described in the second final Program Integrity Rule, the total risk adjustment default charge for a risk adjustment covered plan would equal a per member per month amount multiplied by the plan's enrollment.

$$T_n = C_n * E_n$$

Where:

T_n = total default risk adjustment charge for a plan *n;*
C_n = the PMPM amount for plan *n*; and
E_n = the total enrollment (total billable member months) for plan *n.*

In the second final Program Integrity Rule, we provided that E_n could be calculated using an enrollment count provided by the issuer, using enrollment data from the issuer's MLR and risk corridors filings for the applicable benefit year, or other reliable data sources.

In the 2015 Payment Notice, we determined that we would calculate C_n—the PMPM amount for a plan—equal to the product of the Statewide average premium (expressed as a PMPM amount) for a risk pool and the 75th percentile plan risk transfer amount expressed as a percentage of the respective Statewide average PMPM premiums for the risk pool. The nationwide percentile would reflect only plans in States where HHS is operating the risk adjustment program and would be calculated based on the absolute value of plan risk transfer amounts. The PMPM amount determined using the method described here would be multiplied by the non-compliant plan's enrollment, as determined using the sources finalized in the second final Program Integrity Rule, to establish the plan's total default risk adjustment charge.

For the second year of risk adjustment, the 2015 benefit year, we are proposing to calculate C_n in the same manner, but increased to the 90th percentile plan risk transfer amount expressed as a percentage of the respective Statewide average PMPM premiums for the risk pool. We believe that the 75th percentile was reasonable for the initial year of risk adjustment, as we did not yet know the distribution of risk adjustment transfers and issuers were more likely to experience technical difficulties in establishing a dedicated distributed data environment. In the second year of risk adjustment, now that issuers have set up EDGE servers and participated in the calculation of risk adjustment transfers, we believe that adjusting the default charge upwards to the 90th percentile of plan risk transfer amounts expressed as a percentage of the respective Statewide average PMPM premiums for the risk pool will encourage continued compliance with risk adjustment data submission requirements. We are concerned that, absent this change, some issuers may prefer receiving a default charge at the 75th percentile over participating in the risk adjustment program; a default charge at this level lacks sufficient deterrent value. In contrast, we believe the proposed 90th percentile default charge will adequately incentivize issuers to participate in the risk adjustment program. We seek comment on this approach.

For the 2016 benefit year, we propose a separate calculation of C_n for issuers where E_n Statewide, in the individual and small group markets combined, is 500 billable member months or less. For these issuers, we are proposing to calculate C_n, or the PMPM charge for a plan, as 14 percent of premium, which we have calculated as the mean charge as a percent of premium of issuers with 500 billable member months or fewer in the 2014 benefit year in the small group market. We are basing the charge itself on the experience of small group issuers in the 2014 benefit year, as we believe that individual market issuers are more likely to set up an EDGE server because of the availability of reinsurance. Limiting the applicability in the 2016 benefit year of this default charge to issuers with 500 billable member months or fewer is intended to ensure that the only issuers with this option are ones that are so small that their removal from the overall risk adjustment risk pool would have a minimal impact on transfers nationwide. In 2014, approximately 125 issuers would have had fewer than 500 member months in the individual and small group markets combined. Of those approximately 125 small issuers, 80 were assessed risk adjustment charges greater than the proposed default charge of 14 percent of premium PMPM. Those charges amounted to less than 0.09 percent of total risk adjustment charges assessed nationally. Assuming every one of those issuers elect to accept the proposed 14 percent default risk charge, and none of

the small issuers that owed risk adjustment payments, or with charges below 14 percent of premium PMPM, did so (which we believe unlikely, due to the administrative expenses of setting up an EDGE server), the assessment of the proposed 14 percent of premium default charge on those 80 issuers (and only those 80 issuers) would have resulted in a 0.05 percent (that is, one twentieth of one percent) reduction in risk adjustment charges collected nationally. Because issuers of this size are immaterial to the overall risk adjustment risk pools and have a disproportionately high operational burden to comply with risk adjustment data submission requirements, we believe that a separate default charge for these issuers would promote efficiency and data quality in the risk adjustment program. We propose to establish this risk adjustment default charge as the mean charge in the small group for these small issuers, or 14 percent of statewide average premium PMPM, to compensate on average for the absence of these immaterial amounts in the affected risk pools. We intend that this policy would apply only to the very smallest issuers, in recognition of the disproportionately high operational burden on these issuers, and seek comment on this approach.

f. Insolvent Issuers

We are aware that a health insurance issuer may become insolvent or exit a market during a benefit year. In some cases, another entity, such as another issuer or liquidator may take over the issuer's operations, or a State guaranty fund may become responsible for paying claims for the insolvent issuer. In some instances when this occurs, both the entity seeking to acquire business from an insolvent issuer and the insolvent issuer lack a full year's data to submit for the risk adjustment or reinsurance programs.

To address this concern, we propose to clarify that an entity acquiring or entering into another arrangement with an issuer to serve the current enrollees under a plan, or a State guaranty fund that is responsible for paying claims on behalf of the insolvent issuer, with substantially the same terms may accrue the previous months of claims experience for purposes of risk adjustment and reinsurance to fully reflect the enrollees' risk and claims costs. We propose the ''substantially the same'' standard because we understand that in many of these situations an acquiring entity's platform may require some adjustments to the plan arrangements. To meet this standard would require the carryover of accumulators for deductibles and annual limitations on cost sharing. If the ''substantially the same'' standard is met, and the insolvent issuer and acquiring entity agree that the acquiring entity will accrue the previous months of claims experience, the acquiring entity must take responsibility for submitting to HHS complete and accurate claims and baseline information for that benefit year (including data from the insolvent issuer) in accordance with HHS's operational guidance. We also recognize that guaranty funds may not meet all of the requirements to be considered a risk adjustment covered plan or reinsurance eligible plan (for example, they may not meet the definition of ''health insurance issuer''), and so we propose to permit a guaranty fund to participate in those programs notwithstanding these definition, to the extent it has taken over liability for a risk adjusted covered plan or reinsurance eligible plan during a benefit year.

We seek comment on these policies, including with respect to permissible ways in which the acquiring entity's arrangements may differ and other ways of ensuring the submission of the data necessary for HHS to calculate the risk adjustment financial transfer amounts and the reinsurance payment amounts when another party will take over operations of the insolvent issuer, or pay claims on behalf of the insolvent issuer, during a benefit year. We also solicit comments on whether additional flexibility is needed with respect to the data submission requirements for the reinsurance and risk adjustment programs, such as with respect to the definition of a ''paid claim'' to account for situations when an issuer is unable to pay claims for covered services, for example, due to insolvency.

E. Part 154—Health Insurance Issuer Rate Increases: Disclosure and Review Requirements

1. General Provisions

This section includes proposals related to the rate review program under part 154. The amendments in this part would apply to rates filed during the 2016 calendar year for coverage effective on or after January 1, 2017.

2. Disclosure and Review Provisions

a. Rate Increases Subject To Review (§ 154.200)

In § 154.200, we propose amending paragraph (c)(2) to provide that a rate increase for single risk pool coverage [14] beginning on or after January 1, 2017 meets or exceeds the applicable threshold for review if the average increase, including premium rating factors described in § 147.102 of the subchapter, for all enrollees weighted by premium volume for any plan within the product meets or exceeds the applicable threshold. We previously provided that a rate increase for single risk pool coverage beginning on or after January 1, 2017 meets or exceeds the applicable threshold if an increase in the plan-adjusted index rate for any plan within the product meets or exceeds the applicable threshold.

We propose this change under paragraph (c)(2) because the plan-adjusted index rate does not reflect changes to adjustments for rating area, family size, age, or tobacco factors. Therefore, it would be possible for an issuer to change geographic rating area factors such that members in a certain rating area receive a larger increase, even though the overall rate increase would not be subject to rate review because the plan-adjusted index rate does not increase by 10 percent or more. We believe the annual review of unreasonable increases must include review of the underlying rates that are used to develop the premiums, as opposed to the actual premiums themselves. We do not expect this to result in additional rate increases that meet the threshold, but will measure rate increases in plans more accurately. We seek comment on this proposal. Consistent with the approach finalized in the 2016 Payment Notice (80 FR 10781), we note that starting with rates filed for single risk pool coverage beginning on or after January 1, 2017, rate increases would be calculated at the plan level as opposed to the product level when determining whether an increase is subject to review. We are not proposing any changes to that policy.

b. Submission of Rate Filing Justification (§ 154.215)

Under § 154.215, health insurance issuers are currently required to submit a Rate Filing Justification for all single

[14] The phrase ''single risk pool coverage'' is used to describe non-grandfathered health insurance coverage in the individual or small group (or merged) market that is subject to all of the single risk pool provisions at 45 CFR 156.80. Although we are proposing that student health insurance plans be subject to the index rating methodology specified in 45 CFR 56.80(d), such plans would not have to be included in an issuers' individual (or merged) market single risk pool. Rather they could be included in one or more separate risk pools. Student health plan issuers submit the required rate filing information using the Rate Review Justification Template rather than the Unified Rate Review Template. Student health insurance plans are referred to as ''non-single risk pool coverage'' for purposes of the requirements established in 45 CFR part 154.

risk pool coverage products (including new or discontinued products) when any plan within a product in the individual or small group (or merged) market is subject to a rate increase, regardless of the size of the increase. This requirement was established, in part, to carry out the Secretary's responsibility, in conjunction with the States, under section 2794(b)(2)(A) of the PHS Act to monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange beginning in 2014. However, our experience with the rate review program has shown that premium increases cannot reasonably be monitored without evaluating the net effect on premiums, including the impact of rate decreases, plans with unchanged rates, and new plans' rates. We therefore propose to revise paragraphs (a) and (b) to address this gap in information.

We propose to revise paragraph (a)(1) to require health insurance issuers to submit the Unified Rate Review Template (also known as Part I of the Rate Filing Justification) for all single risk pool coverage products in the individual or small group (or merged) market, regardless of whether any plan within a product is subject to a rate increase. We note that most issuers offering single risk pool coverage already submit a Unified Rate Review Template because:

- A plan within the issuer's single risk pool has a rate increase;
- The issuer's State regulator requires submission of the Rate Filing Justification for all rates;
- The issuer is seeking to offer a QHP through a Federally-Facilitated or State Partnership Exchange; or
- The issuer chooses to use the Rate Filing Justification to satisfy the requirement to annually set an index rate.

We believe that requiring the submission of the Unified Rate Review Template, rather than requiring submission of a new document, will reduce administrative burden for issuers while providing the Secretary and the States with the information necessary to more effectively carry out their responsibilities to monitor premium increases inside and outside of Exchanges.

We propose to revise paragraph (a)(2) so that issuers must submit a Unified Rate Review Template and an Actuarial Memorandum (also known as Parts I and III of the Rate Filing Justification) when a plan within a product is subject to a rate increase. The Unified Rate Review Template and Actuarial Memorandum are submitted at the risk pool level, but the requirement to submit is based on increases at the plan level. This is the current policy but we are revising regulatory text for clarity.

We propose to revise paragraph (a)(3) to provide that all three parts of the Rate Filing Justification (that is, the Unified Rate Review Template, a written description justifying a rate increase, and the Actuarial Memorandum) must be filed when a plan within a product has a rate increase that is subject to review. The information is submitted at the risk pool level, but the requirement to submit is based on increases at the plan level. This is the current policy but we are revising regulatory text for clarity.

We also propose to revise paragraph (b) to provide that a Unified Rate Review Template, a written description justifying a rate increase, and rate filing documentation (commonly referred to as an Actuarial Memorandum) are part of a Rate Filing Justification. One or all of those parts of the Rate Filing Justification may be required by CMS and the State, depending on the change, if any, to plan rates. We also propose to remove and reserve paragraph (c), as it would be unnecessary in light of the proposed amendments to paragraphs (a) and (b).

These proposed amendments and clarifications will ensure that the rate review process is transparent regardless of whether coverage is included in the individual market or small group market single risk pool, and will allow HHS and the States to more effectively monitor premium increases for coverage offered through or outside of an Exchange. Furthermore, the proposed amendments and clarifications will introduce consistent submission requirements for all issuers of single risk pool coverage, regardless of whether the issuer is increasing, decreasing, or maintaining rates.

We also remind issuers of student health insurance plans to use the Rate Review Justification (RRJ) module of the Health Insurance Oversight System (HIOS) to submit the required rate filing information.[15] Even though we propose to amend § 147.145 in this rulemaking (see III.C.4. of this preamble) to extend the index rate setting methodology to student health insurance plans for plan years beginning on or after January 1, 2017, we do not propose to change the form or manner of submission of rate filing information under 45 CFR part 154 for such coverage. In States without Effective Rate Review programs, issuers would be required to submit Preliminary Justifications for all student health insurance plans with rate increases subject to review to CMS by the earlier of the date that the issuer files the Preliminary Justification with the State or a date prior to implementation of the rate increase. In the States where CMS enforces the Public Health Service Act requirements, as amended by the Affordable Care Act, issuers must submit rate filings for student health insurance plan coverage for (a) rate increases of 10 percent or more into the HIOS RRJ module; and (b) rate increases of less than 10 percent into the HIOS Document Collection Form Filing Module.

We propose to permit the Secretary to specify in guidance, as provided under § 154.220(b)(2), different submission deadlines for Rate Filing Justifications for single risk pool coverage plans versus non-single risk pool coverage plans.

In accordance with paragraph (h)(2), we intend to make public on an HHS Web site the information contained in parts I and III of each Rate Filing Justification that is not a trade secret or confidential commercial or financial information, as defined in HHS' Freedom of Information Act regulations, 45 CFR 5.65. We intend to disclose such information for all single risk pool coverage proposed rate increases (regardless of whether the increase is subject to review) and for all final rate increases. We note that we currently make such information available to the public for single risk pool coverage proposed rate increases subject to review and all final rates. The disclosure of information for all single risk pool coverage proposed rate increases, rather than only proposed rate increases subject to review, will provide the public with more comprehensive information and increase the transparency of the rate setting process.

c. Timing of Providing the Rate Filing Justification (§ 154.220)

Section 154.220 establishes time frames for required rate filing justifications. As previously discussed, we propose to collect a Unified Rate Review Template for all single risk pool coverage products in the individual or small group (or merged) market, regardless of whether any plan within a product is subject to a rate increase. We propose technical changes to the language in this section to align with this proposal to remove references to rate increases and clarify that the time frames listed pertain to all single risk

[15] See Rate Review Student Health Plans FAQ published on August 12, 2015. *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Rate_Review_Student_Health_Plans_FAQ_20150812_Final.pdf.*

pool coverage products with or without rate changes. Specifically, we propose to revise the introductory language to this section with accompanying edits to the language in paragraphs (b) and (b)(1).

d. Submission and Posting of Final Justifications for Unreasonable Rate Increases (§ 154.230)

We propose a technical change to paragraph (c)(2)(i). That paragraph currently includes a reference to § 154.215(i) but no such paragraph exists. We propose to fix the typographical error and change the cross reference to § 154.215(h).

e. CMS's Determinations of Effective Rate Review Programs (§ 154.301)

Section 154.301 sets forth criteria for evaluating whether a State has an Effective Rate Review Program in the individual and small group (or merged) markets. In the 2016 Payment Notice (80 FR 10783), we provided that the criteria for determining whether a State has an Effective Rate Review program includes making rate information available to the public at a uniform time (rather than on a rolling basis) for proposed rate increases subject to review and all final rate increases, including those not subject to review (as applicable) for single risk pool coverage in the relevant market segment and without regard to whether coverage is offered through an Exchange or outside of an Exchange. As this was the first year for these uniform posting requirements, and because the uniform timelines were published by CMS well into 2015, CMS understands that some States had significant challenges in meeting the specified timelines for rates filed for coverage beginning on or after January 1, 2016. For rates filed for coverage beginning on or after January 1, 2017, we intend to make a proposed timeline for release of rate information for single risk pool coverage available for comment from States and other stakeholders in December and finalize the timeline no later than March. We believe the comment process will allow States and other stakeholders to identify in advance any challenges that the timeline may pose and allow us to make adjustments as may be necessary to accommodate State-specific needs and other considerations. We also believe this process will better support States that seek to operate an Effective Rate Review program in compliance with these requirements for rates filed for coverage beginning on or after January 1, 2017.

We consider the posting of proposed rate increases that are subject to review and the posting of all final rate increases (including those not subject to review) for single risk pool coverage at a uniform time a criterion for a State retaining its designation as having an Effective Rate Review Program. We will continue to monitor States to ensure that single risk pool coverage rate filings are posted at a uniform time, in the relevant market segment and without regard to whether the coverage is offered through or outside of an Exchange, in accordance with these requirements and guidance issued by CMS.

F. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act

1. General Provisions

a. Definitions (§ 155.20)

In § 155.20, we propose to amend the definition of ''applicant'' for the small group market so that the term also includes an employer seeking eligibility to purchase coverage through a SHOP, without necessarily enrolling in that coverage themselves. The current definition of an applicant contemplates an employer, employee, or former employee seeking eligibility for enrollment in a QHP through the SHOP for himself or herself. For consistency with our existing regulations governing the SHOP application process at §§ 155.710 and 155.715 and for consistency with how the small group market typically works, we propose that the term applicant also include an employer who is seeking eligibility to purchase coverage through a SHOP, but who is not seeking to enroll in that coverage himself or herself.

We also propose to amend § 155.20 to add a definition for ''Federal platform agreement'' to apply to this part. We propose to define a Federal platform agreement to mean an agreement entered into by a State Exchange and HHS, under which the State Exchange elects to rely on the Federal platform to carry out select Exchange functions.

We also propose to modify the definitions of a ''small employer'' and ''large employer'' at § 155.20 to align with the Protecting Affordable Coverage for Employees Act (Pub. L. 114–60), which was recently enacted, as further described in the preamble for § 144.103. As described in that section of the preamble, consistent with section 1304(b) of the Affordable Care Act and section 2791(e) of the PHS Act, we propose to codify that in the case of an employer that was not in existence throughout the preceding calendar year, the determination of whether the employer is a large employer or a small employer be based on the average number of employees that it is reasonably expected the employer will employ on business days in the current calendar year. We do not propose to change the applicability of the counting methodology under 4980H(c)(2) of the Code to these definitions, but we propose to eliminate language about the timing of its applicability, which will no longer be relevant when this rule is finalized.

2. General Standards Related to the Establishment of an Exchange

a. Election To Operate an Exchange After 2014 (§ 155.106)

We propose to modify the timeframes for submission and approval of documentation specifying how an Exchange established by a State or a regional Exchange meets the Exchange approval standards (that is, the Exchange Blueprint). Based on our experience over the last two open enrollment periods, we believe the current Exchange Blueprint application deadlines for States intending to operate a State Exchange do not sufficiently balance the need to provide States with time to adequately prepare their Blueprint applications against the need to ensure HHS has sufficient time to accurately assess a State's progress and ability to timely build the necessary Exchange information technology. In our experience, the process for seeking approval to operate a State Exchange involves substantial technical assistance and collaboration between HHS and the State in developing plans to transition from one Exchange operational model and information technology infrastructure to another, including key milestones, deadlines, and contingency measures. Since the completion of some of these key milestones and deadlines would need to occur prior to the submission of the Blueprint application, we propose that we will make that technical assistance available and initiate the transition planning process following submission of a declaration letter from the State, as provided for in the Blueprint approval process. The declaration letter would serve as formal notification to HHS of a State's intent to pursue approval to operate a State Exchange, and will initiate coordination between the State and HHS on a transition plan. We would seek a declaration letter approximately 21 months prior to the beginning of the SBE's first annual enrollment and 9 months prior to the beginning of an SBE–FP's first annual open enrollment.

In § 155.106(a)(2), we propose to require States that are establishing a State Exchange (not including a State Exchange using the Federal platform for

select functions) to submit an Exchange Blueprint at least 15 months prior to the date the Exchange proposes to begin open enrollment as a State Exchange. We also propose in § 155.106(a)(3) to increase the time that the State must have in effect an approved or conditionally approved Exchange Blueprint from 6.5 months to 14 months prior to the date the Exchange proposes to begin open enrollment as a State Exchange. We recognize that in some situations the open enrollment period may not have been established when Blueprints are due. Therefore, we propose in paragraph (a)(5), if the open enrollment period for the year the State intends to begin operating an SBE has not been established, a State should assume open enrollment will begin on the same date as open enrollment is to begin for the year in which they are submitting the Blueprint.

We propose to revise paragraph (b) to clarify that HHS will operate the Exchange if a State Exchange ceases operations.

We propose to add a paragraph (c) to establish requirements for a State that elects to operate an SBE–FP. These States must submit an Exchange Blueprint (or submit an update to an existing approved Exchange Blueprint) at least 3 months prior to the date open enrollment is to begin for the State as an SBE–FP; and must have in effect an approved, or conditionally approved, Exchange Blueprint and operational readiness assessment at least 2 months prior to the date on which the Exchange proposes to begin open enrollment as an SBE–FP. If the State Exchange has a conditionally approved Exchange Blueprint application, we propose that it would not be required to submit a new Blueprint application, but must submit any significant changes to that application for HHS approval at least 3 months prior to the date on which the Exchange proposes to begin open enrollment as an SBE–FP. Upon receipt of approval or conditional approval of the Exchange Blueprint or amended Blueprint, and prior to the start of the open enrollment period, we propose that these States must execute a Federal platform agreement and be required to coordinate with HHS on a transition plan.

Lastly, we want to be clear that we are only proposing changes to the timelines for submission of the Blueprint application. We are not otherwise proposing any modifications to the information and documents that States must submit as part of the actual Exchange Blueprint application.

We seek comment on these proposals.

b. Additional Required Benefits (§ 155.170)

Section 1311(d)(3)(B) of the Affordable Care Act permits a State, at its option, to require QHPs to cover benefits in addition to the essential health benefits, but requires a State to make payments, either to the individual enrollee or to the issuer on behalf of the enrollee, to defray the cost of these additional State-required benefits. In the 2016 Payment Notice, we instructed States to select a new EHB base-benchmark plan to take effect beginning for the 2017 plan year. The final EHB base-benchmark plans selected as a result of this process have been made publicly available.[16]

Section 1311(d)(3)(B) of the Affordable Care Act refers to situations in which the State requires QHPs to cover benefits. That section is not specific to State statutes and we have interpreted that section to apply not only in cases of legislative action but also in cases of State regulation, guidance, or other State action. Therefore, we propose to reword § 155.170(a)(2) to make clear that a benefit required by the State through action taking place on or before December 31, 2011 is considered an EHB.

In the EHB Rule (78 FR 12837 through 12838), we discussed § 155.170(a)(2), which implements section 1311(d)(3)(B) of the Affordable Care Act. In our discussion of that provision, we provided that ''State-required benefits enacted on or before December 31, 2011 (even if not effective until a later date) may be considered EHB, which would obviate the requirement for the State to defray costs for these State-required benefits.'' This policy continues to apply. Therefore, benefits required by a State through action taking place after December 31, 2011 that directly apply to the QHPs are not considered EHB (unless enactment is directly attributable to State compliance with Federal requirements, as discussed below).

Although benefits requirements enacted by States after December 31, 2011 that directly apply to the QHP and that were not enacted for purposes of compliance with Federal requirements are not considered EHB,[17] the base-benchmark plan might cover some of those non-EHB. Nonetheless, issuers must treat those benefits as they would other non-EHB, such as those identified in § 156.115(d) [18] and the State must defray the cost. We propose to codify this interpretation in § 155.170(a)(2). We seek comment on this proposal.

At § 155.170(a)(3), we currently require the Exchange to identify which additional State-required benefits, if any, are in excess of EHB. We propose to amend paragraph (a)(3) to designate the State, rather than the Exchange, as the entity that identifies which State-required benefits are not EHB. We propose this change because we believe insurance regulators are generally more familiar with State-required benefits. We believe each State should determine the appropriate State entity best suited to identify newly required benefits. Additionally, for consistency of terminology, we propose to amend paragraph (a)(3) to replace the reference to ''in excess of EHB'' to ''in addition to EHB.''

In current § 155.170(c)(2)(iii), we require QHP issuers to quantify the cost attributable to each additional State-required benefit and report their calculations to the Exchange. We also propose to designate the State as the entity that receives issuer calculations in paragraph (c)(2)(iii). Since the State is required by statute to remit a payment to an enrollee or issuer, we believe the calculation should be sent directly to the State rather than to the Exchange. We seek comment on this proposal.

The 2016 Payment Notice specified that a State may need to supplement habilitative services if the base-benchmark plan does not cover such services. If a State supplements the base-benchmark plan, there is no requirement to defray the cost of the benefits added through supplementation, as long as the State imposes the requirement to comply with the Affordable Care Act or another Federal requirement. Examples of such Federal requirements include: Requirements to provide benefits and services in each of the 10 categories of EHB; requirements to cover preventive services; requirements to comply with the Mental Health Parity and Addiction Equity Act; and the removal of discriminatory age limits from existing benefits.

In some States, the base-benchmark plan may be a large group (non-Medicaid HMO) or State employee plan. We have received questions regarding State-required benefits that are

[16] Available at *https://downloads.cms.gov/cciio/FinalListofBMPs_15_10_21.pdf*.

[17] The 2016 Payment Notice provides that States are not expected to defray the cost of State-required benefits enacted on or after January 1, 2012 that were required in order to comply with new Federal requirements. (80 FR 10749, 10813 (Feb. 27, 2015)).

[18] An issuer of a plan offering EHB may not include routine non-pediatric dental services, routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, or non-medically necessary orthodontia as EHB.

embedded in those large group (non-Medicaid HMO) base-benchmark plans. As stated earlier in this section, if the State-required benefit in question was required by State action after December 31, 2011, applies directly to the QHP, and was not enacted for purposes of compliance with Federal requirements, the benefit is not considered EHB, even if the benefit is embedded in the base-benchmark plan. However, a benefit required only in the large group market and reflected in a large group base-benchmark plan is not an EHB for QHPs offered in the individual or small group markets because such a benefit requirement does not apply directly to those plans, and to the extent it is included in the base-benchmark plan, it may be ''substituted'' for, in accordance with § 156.115(b). Therefore, the State would not have to defray the cost of individual and small group market QHPs covering State-required benefits that are required in the large group market only. (However, to the extent the State permits large group plans to be sold as QHPs through the State's Exchange, the State would have to defray the cost of the large group QHPs covering the mandated benefit.) We note that plans subject to the EHB requirements offered in the individual and small group markets in those States would have to be substantially equal to the base-benchmark plan, and therefore may cover the State-required benefit as EHB since it is embedded in the base-benchmark plan. In such a case, the benefit is an EHB because it is covered by the base-benchmark plan, but the cost of coverage by individual and small group QHPs does not have to be defrayed, because the State-required benefit does not apply directly to those QHPs.

Some States have imposed new benefit requirements only on individual and small group plans that are not QHPs such that only individual and small group plans sold outside the Exchange must cover the State-required benefit. We note that a QHP generally may be sold outside the Exchanges in which case it would be subject to the new benefit requirements. States are cautioned, however, that imposing different benefit mandates depending on a plan's status as a QHP or because it is sold through the Exchange may violate section 1252 of the Affordable Care Act. Under this section, State standards or requirements implementing, or related to, standards or requirements in title I of the Act must be applied uniformly within a given insurance market. Thus, if a State requires that non-QHPs in the individual or small group market provide any benefits, under section 1252, the State must require QHPs sold through the Exchange to provide those same benefits, and consistent with our earlier stated policy at § 155.170(a)(2), States would generally be required to defray the cost of QHPs providing the required benefits if they were required through State action taking place after December 31, 2011.

As noted earlier, the Protecting Affordable Coverage for Employees Act, enacted in October 2015, amended the definitions of small employer and large employer in section 1304(b) of the Affordable Care Act and section 2791(e) of the PHS Act such that a small employer is generally [19] an employer with 1–50 employees, with the option for States to expand the definition of small employer to 1–100 employees.[20] We have proposed amendments to § 144.103 to reflect these statutory amendments.

Several States have enacted benefit requirements that would apply to small group insurance plans offered to employers with 51–100 employees, but not to employers with 1–50 employees. This may arise because the State-required benefit was designed to apply only in the large group market when the large group market included employers with more than 50 employees, but the State has since then availed itself of the option to define a ''small employer'' as an employer with 1–100 employees.

Section 2702 of the PHS Act and § 147.104 generally require an issuer to offer all approved products to any individual or employer in the market for which the product was approved and to accept any individual or employer that applies for any approved product in a given market. If a State elects to expand the definition of small employer so that it covers employers with 1–100 employees, all products approved for sale in the small group market (defined by the State as 1–100 employees) generally must be offered to employers with 1–100 employees. This effectively means that existing State benefits mandates that apply to insurance coverage sold to employers with 51–100 employees would then effectively also apply to all products sold to employers with 1–100 employees. As long as the benefit was required by State action taken on or before December 31, 2011, the expansion of coverage would not trigger the requirement to defray, because the expansion was required to comply with Federal guaranteed availability laws. If a State does not opt to expand the definition of small employer to 1–100 employees, then any State-required benefits applicable in the large group market (including to employers with 51–100 employees) would continue to not apply in the small group market. If a State-required benefit was imposed by State action taking place January 1, 2012 or later, then defrayal generally would be required.

3. General Functions of an Exchange

a. Functions of an Exchange (§ 155.200)

We propose to amend § 155.200(a) to include reference to subpart M, which establishes oversight and program integrity standards for State Exchanges, and subpart O, which establishes quality reporting standards for Exchanges. These subparts were not originally incorporated into this paragraph because they were finalized after § 155.200(a) was finalized. We propose incorporating them now because we view them as providing important safeguards for consumers.

We also propose to amend § 155.200 by adding a paragraph (f) to address SBE–FPs. This arrangement is intended to permit a State Exchange to leverage existing Federal assets and operations by relying on HHS services for performing certain Exchange functions, particularly eligibility and enrollment functions. The SBE–FP would also rely on HHS to perform certain consumer call center functions and casework processes, and maintain related information technology infrastructure. The SBE–FP would retain responsibility for plan management functions, subject to certain rules requiring the SBE–FP to require its QHP issuers to comply with certain FFE standards governing QHPs and issuers (as proposed in § 155.200(f)(2) of this proposed rule), and consumer support functions, subject to FFE rules governing consumer assistance functions.

Under § 155.200(f)(1), we propose that a State may receive approval or conditional approval to operate an SBE–FP under proposed § 155.106(c) and meet its obligations under § 155.200(a)

[19] Prior to enactment of the Protecting Affordable Coverage for Employees Act, small employer was defined to mean, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. In case of plan years beginning before January 1, 2016, a State was able to elect to define small employer by substituting ''50 employees'' for ''100 employees''. For ease of reference with regard to this section, we will refer to employers as having 1–50 or 1–100 employees.

[20] States that elect to extend the small employer definition were requested to notify CMS of their election by October 30, 2015 at *marketreform@cms.hhs.gov*.

by entering into a Federal platform agreement with HHS. In the Federal platform agreement, an SBE–FP would indicate its decision to rely on HHS for services related to the individual market Exchange, the SHOP Exchange, or both the individual market and SHOP Exchanges. The Federal platform agreement would specify the Federal services on which the State Exchange relies, the user fee that HHS will collect from issuers in that SBE–FP for the Federal services (as specified at § 156.50(c)(2)), and other mutual obligations relating to the arrangement, including obligations for the transfer of data. We intend to release the Federal platform agreement at a later date. We note that at this point the Federal services on which SBE–FPs may rely will come as an entire package. That is, HHS will not at this time offer a ''menu'' of Federal services from which an SBE–FP may select some but not other services on the Federal platform. However, we will explore the feasibility of doing so in the future.

The Federal platform agreement would also specify expectations between the State and HHS across various operational areas.

Although the SBE–FPs would retain primary, formal responsibility for overseeing QHPs and issuers, we propose under § 155.200(f)(2) to require an SBE–FP to establish and oversee certain requirements for its QHPs and QHP issuers that are no less strict than the requirements that apply to QHPs and QHP issuers on an FFE. We propose these requirements to include the existing and proposed standards under the following sections: § 156.122(d)(2) (the requirement for QHPs to make available published up-to-date, accurate, and complete formulary drug list on its Web site in a format and at times determined by HHS); § 156.230 (network adequacy standards); § 156.235 (essential community providers standards); § 156.298 (meaningful difference standards); § 156.330 (changes of ownership of issuers requirement); § 156.340(a)(4) (QHP issuer compliance and compliance of delegated and downstream entities requirements); § 156.705 (maintenance of records standard), § 156.715 (compliance reviews standard); and § 156.1010 (casework standards).

Applying the changes of ownership issuers' requirement to SBE–FPs will help fulfill the Federal platform's need for data and technical consistency. It will ensure that HHS maintains the most accurate and updated information to present to consumers through its branded platform, HealthCare.gov. HHS must be able to monitor and provide regulatory oversight over change in control situations. Change in control has a significant operational impact on the Federal platform and requires the expenditure of considerable technical resources to effectuate the change throughout the multiple systems that constitute the Federal platform.

Applying the formulary drug list, network adequacy, meaningful difference, and essential community providers standards will ensure that all QHPs on HealthCare.gov meet a consistent minimum standard and that consumers obtaining coverage as a result of applying through Healthcare.gov are guaranteed plans that meet these minimum standards. For example, all QHP issuers must meet a ''reasonable access'' network adequacy standard, but FFE issuers must meet additional network adequacy standards. It is important to HHS that shoppers at HealthCare.gov do not enroll in plans that fail to meet these minimum standards, so we propose that SBE–FPs that wish to rely on the HealthCare.gov platform require its issuers to meet these minimum standards as well, since their consumers are obtaining the coverage through HealthCare.gov. SBE–FPs may exceed these minimum standards to the extent they do not present display problems on HealthCare.gov. Although the SBE–FPs are legally distinct from FFEs, this difference will not always be apparent to Healthcare.gov consumers. Not having these standards apply may lead to consumer confusion and dilution of consumer goodwill with respect to the plans available on HealthCare.gov. The States would conduct QHP certification reviews for these standards.

Applying the QHP issuer compliance and compliance of delegated or downstream entities requirement at § 156.340(a)(4), which involves the maintenance of records standards of § 156.705 and the compliance reviews for QHP issuers standards of § 156.715, will ensure that the SBE–FP has authority at least as strong as that possessed by HHS to enforce compliance with these standards and will ensure that the SBE–FP and HHS are able to access all records upon request from the issuers in the SBE–FPs.

Applying the casework standards at § 156.1010 will ensure that the SBE–FP and HHS can respond to problems about which they both bear responsibility. Since SBE–FPs must use the Health Insurance Casework System (HICS) for handling consumer casework and meeting casework resolution timeframes, the SBE–FP would not be overseeing casework processes. However, as with all other Exchange types, State Departments of Insurance will still handle appropriate consumer complaints related to issuers in their States. For cases that are Exchange-related, or those in which the consumer has chosen to contact the Exchange even after contacting the appropriate Department of Insurance, HHS would oversee the routing and resolution of casework. HHS' intent is to work collaboratively with the SBE–FP, similar to how HHS works with SPMs.

Finally, we propose under § 155.200(f)(3) that HHS will work with SBE–FPs to enforce the FFE standards listed under § 155.200(f)(2) directly against SBE–FP issuers or plans, when the SBE–FP is not substantially enforcing one or more of these requirements. In that circumstance, we propose that HHS would have the authority to suppress a plan under § 156.815. This will ensure that consumers shopping for coverage on HealthCare.gov have access to plans that are in compliance with the FFE standards with which SBE–FP issuers must comply as a condition of offering QHPs through a State Exchange on the Federal platform.

We intend to work closely and collaboratively with SBE–FPs, and believe that our collaboration with States that currently use the Federal platform with respect to enforcement matters has been close and effective. We seek comments on all aspects of this proposal.

b. Consumer Assistance Tools and Programs of an Exchange (§ 155.205)

We propose two amendments to § 155.205 to address functions of an SBE–FP. First, because an SBE–FP relies on HHS to carry out call center functions, we propose to amend § 155.205(a) to exempt an SBE–FP from the requirement to operate a toll-free call center, and instead provide that an SBE–FP must at a minimum operate a toll-free telephone hotline to respond to requests for assistance to consumers in their State, in accordance with section 1311(d)(4)(B) of the Affordable Care Act. We seek comments on this proposal.

Secondly, we propose to amend § 155.205(b) by adding paragraph (b)(7) to provide that an SBE–FP must, at a minimum, operate an informational Internet Web site through which consumers can also be directed to HealthCare.gov, in accordance with section 1311(d)(4)(C) of the Affordable Care Act. We seek comments on this proposal.

c. Standards Applicable to Navigators under §§ 155.210 and 155.215; Standards Applicable to Consumer Assistance Tools and Programs of an Exchange under § 155.205(d) and (e); and Standards Applicable to Non-Navigator Assistance Personnel in an FFE and to Non-Navigator Assistance Personnel Funded through an Exchange Establishment Grant (§§ 155.205, 155.210 and 155.215)

We have previously established a range of consumer assistance programs to help consumers apply for and enroll in QHPs and insurance affordability programs through the Exchange. These consumer assistance programs include the Navigator program described at section 1311(d)(4)(K) and (i) of the Affordable Care Act and § 155.210. Among other duties, section 1311(i)(3) of the Affordable Care Act requires Navigators to conduct public education activities to raise awareness of the availability of QHPs; to distribute fair and impartial information concerning enrollment in QHPs and the availability of Exchange financial assistance under the Affordable Care Act; to facilitate enrollment in QHPs; and to provide referrals to certain State agencies for any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under such plan or coverage.

We have also established under § 155.205(d) and (e) that each Exchange must provide consumer assistance, outreach, and education functions. These must include a Navigator program and can include a non-Navigator assistance personnel program.

We propose to amend § 155.210(e) by adding a new paragraph (e)(8) that would require Navigators in all Exchanges to provide targeted assistance to serve underserved and/or vulnerable populations within the Exchange service area. Section 155.210(b)(2)(i) already requires Navigators to have expertise in the needs of underserved and vulnerable populations. We believe that also requiring Navigators to provide targeted assistance to underserved and vulnerable populations is critical to improving access to health care for communities that often experience a disproportionate burden of disease. In keeping with the spirit of section 1311(i)(3)(A) of the Affordable Care Act, which directs that Navigator entities must conduct public education activities to raise awareness about the availability of QHPs, we believe that Navigators should focus their outreach and enrollment assistance efforts on harder-to-reach populations and the remaining uninsured, to build increased awareness of the coverage options available through the Exchange and to help new consumers find affordable health coverage that meets their needs.

Because the characteristics of underserved and vulnerable populations may vary over time and from region to region, we do not propose to define and identify these populations for all Exchanges. Instead, we propose to permit each Exchange to define and identify the underserved and vulnerable populations in its service area, and to update these definitions as necessary. This could include an Exchange allowing its Navigator grantees to propose, for the Exchange's approval (for example, in their grant applications), which communities to target. In Federally-facilitated Exchanges, we would identify populations as vulnerable or underserved through our Navigator Funding Opportunity Announcements, and would give FFE Navigator grant applicants an opportunity to propose additional communities to target during the grant application process. Vulnerable or underserved populations might include, for example, populations that are disproportionately without access to coverage or care, or are at a greater risk for poor health outcomes. We propose that these would be the primary criteria used to identify such populations within the FFEs. Members of these populations could be identified by age groups, demographics, disease, geography, or other characteristics as defined or approved by the Exchange. We believe reaching vulnerable or underserved populations is important to increasing awareness among the remaining uninsured of the coverage options available through the Exchange, helping new consumers find affordable coverage that meets their needs, and narrowing health disparities. In Federally-facilitated Exchanges, our proposal would apply beginning with the application process for Navigator grants awarded in 2018.

We seek comment on all aspects of this proposal, including on how Exchanges, including the FFEs, should identify vulnerable or underserved populations in their service areas, and on the appropriate process and timeframes under which these populations would be identified. Additionally, although we have not proposed to extend this requirement to certified application counselors and non-Navigator assistance personnel subject to § 155.215, we encourage certified application counselors and non-Navigator assistance personnel to prioritize reaching and assisting the vulnerable and underserved populations identified by the Exchange in their communities, and we recognize that many of these assisters already focus their efforts on such populations.

We note that Navigators would not exclusively be serving these target populations, since all Navigators are required to assist any consumer seeking assistance. As we have explained in prior rulemakings, we interpret Navigators' duty to provide fair and impartial information and services under § 155.210(e)(2) to require that all Navigators should have the ability to help any individual who seeks assistance, even if that consumer is not a member of the community or group the Navigator intends to target (see 78 FR 20589; 78 FR 42830; 79 FR 30270; 79 FR 30278).

In § 155.210, we propose to add paragraph (e)(9) to specify that Navigators in all Exchanges would be required to help consumers with certain other types of assistance, including post-enrollment assistance. This proposal is designed to ensure that consumers would have access to skilled assistance beyond applying for and enrolling in health coverage, including, for example, assistance with the process of filing Exchange eligibility appeals or with applying through the Exchange for exemptions from the individual shared responsibility payment, providing basic information about reconciliation of premium tax credits, and understanding basic concepts related to using health coverage. Section 1311(i)(3)(D) of the Affordable Care Act and § 155.210(e)(4) already expressly require Navigators to provide post-enrollment assistance by referring consumers with complaints, questions, or grievances about their coverage to appropriate State agencies. This suggests that Congress anticipated that consumers would need assistance beyond the application and enrollment process, and that Navigators would maintain relationships with consumers and be a source of such assistance.

Consistent with the requirements under section 1311(i)(3)(B) and (C) of the Affordable Care Act that Navigators distribute fair and impartial information concerning enrollment in QHPs and facilitate enrollment in QHPs, and pursuant to the Secretary's authority under section 1321(a)(1)(A) of the Affordable Care Act, we propose at § 155.210(e)(9)(i) to require Navigators in all Exchanges to help consumers with the process of filing appeals of Exchange eligibility determinations. We are not proposing to establish a duty for Navigators to represent a consumer in an appeal, sign an appeal request, or file an appeal on the consumer's behalf. We believe that helping consumers

understand Exchange appeal rights when they have received an adverse eligibility determination, and assisting them with the process of completing and submitting appeal forms, would help to facilitate enrollment and would help consumers obtain fair and impartial information about enrollment, including information about available exemptions from the individual shared responsibility payment that would help consumers decide whether or not to enroll in coverage. We would interpret this proposal to include helping consumers file appeals of eligibility determinations made by an Exchange (including SHOP Exchanges) related to enrollment in a QHP, special enrollment periods, exemptions from the individual shared responsibility payment that are granted by the Exchange, participation as an employer in a SHOP, and any insurance affordability program, including eligibility determinations for Exchange financial assistance, Medicaid, the Children's Health Insurance Program (CHIP), and Basic Health Programs.

We also propose at § 155.210(e)(9)(ii) to require that Navigators in all Exchanges help consumers understand and apply for exemptions from the individual shared responsibility payment that are granted by the Exchange. We believe that it would be consistent with the Secretary's rulemaking authority under section 1321(a)(1)(A) of the Affordable Care Act to require Navigators to provide assistance with exemptions that the Exchange must grant under section 1311(d)(4)(H) of the Affordable Care Act. Additionally, we believe that this proposal is consistent with Navigators' duty under section 1311(i)(3)(B) of the Affordable Care Act to distribute fair and impartial information concerning enrollment in QHPs, since impartial information concerning the availability of exemptions from the individual shared responsibility payment would help consumers make informed decisions about whether or not to enroll in coverage.

This assistance with Exchange-granted exemptions would include informing consumers about the requirement to maintain minimum essential coverage and the individual shared responsibility payment; helping consumers fill out and submit Exchange-granted exemption applications and obtain any necessary forms prior to or after applying for the exemption; explaining what the exemption certificate number is and how to use it; and helping consumers understand and use the Exchange tool to find bronze plan premiums. This duty would also include explaining the general purpose of Internal Revenue Service (IRS) Form 8965 to consumers, consistent with IRS published guidance on the topic, and explaining how to access this form and related tax information on irs.gov.

Navigators may not provide tax assistance or interpret tax rules within their capacity as Exchange Navigators, and this proposal would not require Navigators to help consumers apply for exemptions claimed through the tax filing process. We would interpret this proposal, however, to require helping consumers generally understand the availability of exemptions claimed through the tax filing process and how to obtain them. This interpretation would help ensure that Navigators share information about the full scope of possible exemptions while not providing actual tax assistance or tax advice. We request comment on whether we should require that, prior to providing this assistance and information, Navigators provide consumers with a disclaimer stating that they are not acting as tax advisers and cannot provide tax advice within their capacity as Exchange Navigators. We seek comment on whether such a disclaimer would help avoid consumer misunderstandings and detrimental reliance on Navigator advice, or whether it might be unnecessary, impractical, or cause consumer confusion.

We also seek comment on whether a Navigator's duty to provide assistance with filing exemption applications under proposed § 155.210(e)(9)(ii) and filing appeals of exemption application denials under proposed § 155.210(e)(9)(i) should be limited, for example, to consumers who have applied for or have been denied coverage or financial assistance, or whether another limitation should apply. We are cognizant of the resource limitations that Navigators and their funding agencies may face, and do not want to reduce the assistance available to consumers seeking coverage, as opposed to those who only seek to avoid the individual shared responsibility penalty. At the same time, we recognize that consumers may be unable to access coverage for a wide variety of reasons, including their financial circumstances, coverage gaps, and other personal or systemic obstacles, and want to be sure that experienced help is available so that these consumers are fully aware of and can access their exemptions options. We seek comment on these issues.

In addition, we propose at § 155.210(e)(9)(iii) to require Navigators to help consumers with the Exchange-related components of the premium tax credit reconciliation process, such as by ensuring they have access to their Forms 1095–A and receive general, high-level information about the purpose of this form that is consistent with published IRS guidance on the topic. This proposal stems from the requirement under section 1311(i)(3)(B) of the Affordable Care Act that Navigators distribute fair and impartial information concerning the availability of the premium tax credits under section 36B of the Code. Consumers who receive advance payments of the premium tax credit may need help with a variety of issues related to reconciliation. Navigators would be required to help consumers obtain IRS Forms 1095–A and 8962, and the instructions for both, and to provide general information, consistent with applicable IRS guidance, about the significance of the forms. Navigators would also be required to help consumers understand (1) how to report errors on the Form 1095–A; (2) how to find silver plan premiums using the Exchange tool; and (3) the difference between advance payments of the premium tax credit and the premium tax credit and the potential implications for enrollment and re-enrollment of not filing a tax return and reconciling any advance payments of the premium tax credit that were paid on consumers' behalf.

As noted above, Navigators may not provide tax assistance or advice, or interpret tax rules and forms within their capacity as Exchange Navigators, but their expertise related to the consumer-facing aspects of the Exchange, including eligibility and enrollment rules and procedures, uniquely qualifies them to help consumers understand and obtain information from the Exchange that is necessary to the premium tax credit reconciliation process. Because this proposal would include a requirement that Navigators provide consumers with information and assistance understanding the availability of IRS resources, Navigators would be expected to familiarize themselves with the availability of materials on irs.gov, including the Form 8962 instructions, IRS Publication 974 Premium Tax Credit, and relevant FAQs, and to refer consumers with questions about tax law to those resources or to other resources, such as free tax return preparation assistance from the Volunteer Income Tax Assistance or Tax Counseling for the Elderly programs. Again, we request comment on whether we should require that, prior to providing this information and assistance, Navigators provide

consumers with a disclaimer stating that they are not acting as tax advisers and cannot provide tax advice within their capacity as Exchange Navigators.

To help ensure consumers have seamless access to Exchange-related tax information beyond the basic information that Navigators can provide, we propose at 155.210(e)(9)(v) that Navigators be required to refer consumers to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice related to consumer questions about the Exchange application and enrollment process, exemptions from the requirement to maintain minimum essential coverage and the individual shared responsibility payment, and premium tax credit reconciliation.

We interpret the Navigator duties to facilitate enrollment in QHPs in section 1311(i)(3)(C) of the Affordable Care Act, to distribute fair and impartial information concerning enrollment in QHPs under section 1311(i)(3)(B) of the Affordable Care Act, and to conduct public education activities to raise awareness about the availability of QHPs in section 1311(i)(3)(A) of the Affordable Care Act to include helping consumers understand the kinds of decisions they will need to make in selecting coverage, and how to use their coverage after they are enrolled. We have previously stated that one overall purpose of consumer assistance programs is to help consumers become fully informed and health literate. (See 79 FR 30276.) To improve consumers' health literacy related to coverage generally, and to ensure that individual consumers are able to use their coverage meaningfully, we propose at § 155.210(e)(9)(iv) to require Navigators in all Exchanges to help consumers understand basic concepts related to health coverage and how to use it. These activities could be supported through the use of existing resources such as the HHS ''*From Coverage to Care*'' initiative, which we encourage Navigators to review, and which are now available in multiple languages at *https://marketplace.cms.gov/c2c*. This proposal would improve consumers' access to health coverage information not just when selecting a plan, but also when using their coverage. For example, Navigators could help consumers understand (1) key terms used in health coverage materials, such as ''deductible'' and ''coinsurance,'' and how they relate to the consumer's health plan; (2) the cost and care differences between a visit to the emergency department and a visit to a primary care provider under the coverage options available to the consumer; (3) how to identify in-network providers to make and prepare for an appointment with a provider; (4) how the consumer's coverage addresses steps that often are taken after an appointment with a provider, such as making a follow-up appointment and filling a prescription; and (5) the right to coverage of certain preventive health services without cost sharing. We anticipate that this assistance would vary depending on each consumer's needs and goals. We invite comment on whether we should provide additional specificity for Navigators related to this proposed duty to help consumers understand and use their coverage, and if so, which additional topics should be included.

We note that under § 155.215(b)(2), Navigators in FFEs must already be trained on the tax implications of enrollment decisions, the individual responsibility to have health coverage, eligibility appeals, and rights and processes for QHP appeals and grievances. To ensure that Navigators in all States receive training in every area for which there would be a corresponding Navigator duty, we propose to require all Exchanges, including State Exchanges, to provide training that would prepare Navigators for the additional areas of responsibility proposed in this rulemaking. In proposed § 155.210(b)(2)(v) through (viii), therefore, we would require Exchanges to develop and disseminate training standards to be met by all entities and individuals carrying out Navigator functions to ensure expertise in: The process of filing appeals of Exchange eligibility determinations; general concepts regarding exemptions from the requirement to maintain minimum essential coverage and the individual shared responsibility payment, including the application process for exemptions granted through the Exchange, and IRS resources on exemptions; the Exchange-related components of the premium tax credit reconciliation process and IRS resources on this process; and basic concepts related to health coverage and how to use it.

We note that providing assistance with certain other post-enrollment issues already falls within the scope of existing required Navigator duties. We interpret the requirement to facilitate enrollment in a QHP under section 1311(i)(3)(C) of the Affordable Care Act, and the requirement at § 155.210(e)(2) to provide information that assists consumers with submitting the eligibility application, to include assistance with updating an application for coverage through an Exchange, including reporting changes in circumstances and assisting with submitting information for eligibility redeterminations.

Additionally, Navigators are already permitted, but not required, to help with a variety of other post-enrollment issues. For example, we interpret the requirements in § 155.210(e)(1) and (2) that Navigators conduct public education activities to raise awareness about the Exchange and provide fair and impartial information about the application and plan selection process to mean that Navigators may educate consumers about their rights with respect to coverage available through an Exchange, such as nondiscrimination protections, prohibitions on preexisting condition exclusions, and preventive services available without cost-sharing. We also interpret these requirements, together with the requirement in section 1311(i)(3)(B) of the Affordable Care Act that Navigators distribute fair and impartial information concerning enrollment in QHPs, and the availability of Exchange financial assistance, to mean that Navigators may assist consumers with questions about paying premiums for coverage or insurance affordability programs enrolled in through an Exchange. Finally, we interpret the requirement in section 1311(i)(3)(D) of the Affordable Care Act and § 155.210(e)(4) to provide referrals for certain post-enrollment issues to mean that Navigators may help consumers obtain assistance with coverage claims denials. We request comments on whether we should make any of the above interpretations explicit in the regulation and whether there are additional post-enrollment duties required or permitted by these provisions that should be made explicit as either required or simply permitted (but not required) duties, as well as whether there are other forms of post-enrollment assistance that Exchanges should require Navigators to provide, commensurate with their general legal authority, but which are not already specifically required under our regulations.

Although we have not proposed to extend any of the requirements under proposed § 155.210(e)(8) or (9) to non-Navigator assistance personnel subject to § 155.215, we note that the requirement to provide information that assists consumers with submitting the eligibility application under § 155.210(e)(2), which would include helping consumers report changes in circumstances and submit information for eligibility redeterminations, also applies to certain non-Navigator assistance personnel through § 155.215(a)(2)(i). We also note that

under § 155.215, the training requirements for these non-Navigator assistance personnel are the same as for Navigators in States with an FFE.

We have also not proposed to extend any of these requirements to certified application counselors. However, nothing prevents non-Navigator assistance personnel or certified application counselors from helping with activities that are consistent with their existing regulatory duties. We request comments on whether we should extend these proposed requirements to help with post-enrollment and other activities to these assisters.

We propose to amend §§ 155.205(d) and 155.215(b)(1)(i) to specify that any individual or entity carrying out consumer assistance functions under § 155.205(d) and (e) or § 155.210, in both State Exchanges and FFEs, would be required to complete training prior to performing any assister duties, including before conducting outreach and education activities, as well as before providing application and enrollment assistance. Section 155.215(b), which establishes training standards for Navigators and non-Navigator assistance personnel in FFEs and for non-Navigator assistance personnel funded through Exchange Establishment grants under section 1311(a) of the Affordable Care Act, requires that these assisters must obtain certification by the Exchange prior to carrying out any consumer assistance functions under § 155.205(d) and (e) or § 155.210. We also propose to amend § 155.215(b)(1)(i) to specify that the consumer assistance functions referenced in that provision would include outreach and education activities. In addition, we propose to amend § 155.205(d) to specify that training would have to be completed not only before providing the assistance described in that paragraph, but also before conducting the outreach and education activities specified in paragraph (e). These proposals would require that Navigators, non-Navigator assistance personnel subject to § 155.215, and other entities and persons providing consumer assistance under § 155.205(d) and consumer outreach and education activities under § 155.205(e), complete training prior to carrying out any consumer assistance functions, including outreach and education activities.

We note that nothing in the Exchange regulations prohibits individuals or organizations from conducting outreach about Exchanges and providing application and enrollment assistance without being trained and certified as Navigators, non-Navigator assistance personnel, certified application counselors, or other kinds of Exchange-approved assisters. However, this proposal would ensure that individuals and organizations do not perform any Exchange outreach and education activities or application and enrollment assistance while identifying as or holding themselves out to the public as Navigators, non-Navigator assistance personnel, or certified application counselors, prior to completing Exchange requirements, including training and certification. This proposal would also help ensure that Navigators and non-Navigator assistance personnel are providing accurate information when performing outreach and education activities.

Section 155.210(d)(6) currently prohibits Navigators from providing to an applicant or potential enrollee any gifts unless they are of nominal value; or any promotional items that market or promote the products or services of a third party, when those promotional items are being used as an inducement for enrollment. Through a cross-reference to § 155.210(d) in § 155.215(a)(2)(i) and a parallel provision in § 155.225(g)(4), this prohibition also applies to non-Navigator assistance personnel subject to § 155.215, and to certified application counselors.

We have received questions indicating that there is general confusion about when gifts and promotional items can be provided to applicants and potential enrollees. To reduce this confusion, we propose to amend §§ 155.210(d)(6) and 155.225(g)(4) to specify that gifts of any value (including third-party promotional items of any value) should never be provided to applicants or potential enrollees as an inducement for enrollment. We also propose to specify that gifts that are not provided as an inducement for enrollment may be provided to applicants and potential enrollees if they do not exceed nominal value.[21] This proposed nominal value restriction would apply both to each individual gift and to the cumulative value of multiple gifts, including promotional items, which are provided by these types of assisters to an applicant or potential enrollee. We further propose that the nominal value restriction on the cumulative value of multiple gifts would only apply to single encounters between the assister and an individual applicant or potential enrollee, and not to multiple encounters, so that assisters would not have to collect PII as a means of tracking the number and value of gifts provided to an individual consumer across multiple encounters, such as all encounters in a single calendar year or enrollment season. Since we anticipate that gifts or promotional items of a nominal value, such as pens, magnets or keychains, could be provided to consumers at outreach and education events or at other forums attended by members of the general public, we do not want to establish a nominal value restriction that would be difficult or burdensome for assisters to enforce, or that would require the unnecessary collection of PII from consumers. We would consider a single outreach or educational event to be a ''single encounter''; that is, assisters would not be permitted to provide multiple gifts to the same consumer at the same outreach event if the cumulative value of those gifts exceeded nominal value. We seek comments on all aspects of this proposal, including whether the nominal value restriction should apply to a single encounter with an individual consumer, as proposed, or whether a longer timeframe, such as all encounters with an individual consumer in a calendar year, in an enrollment season, or in total, would be preferable.

Finally, to simplify the rule, we propose to define ''gifts,'' for purposes of §§ 155.210(d)(6) and 155.225(g)(4), to include gift items, gift cards, cash cards or cash, as well as promotional items that market or promote the products or services of a third party. We further propose to amend language in §§ 155.210(d)(6) and 155.225(g)(4) that currently provides that gifts, gift cards, or cash may exceed nominal value for the purpose of providing reimbursement for legitimate expenses incurred by a consumer in an effort to receive Exchange application assistance, such as travel or postage expenses. We propose to amend this language to indicate that the reimbursement of legitimate expenses, such as travel or postage expenses, when incurred by a consumer in an effort to receive Exchange application assistance, would not be considered a gift, and therefore, would not be subject to the proposed restrictions on providing gifts.

Our proposal seeks to strike a balance between permitting these types of assisters to provide small gifts and promotional items as part of creative outreach and education strategies, while ensuring that gifts, including promotional items, are never provided to applicants and potential enrollees to

[21] We have previously defined ''nominal value'' as a cash value of $15 or less, or an item worth $15 or less, based on the retail purchase price of the item, regardless of the actual cost. (79 FR 15831 and 79 FR 30283).

induce enrollment. We believe this outright prohibition on providing gifts and promotional items, of any value, to induce enrollment, is consistent with the duties of these assisters to provide information and services to consumers in a fair, accurate, and impartial manner, including clarifying the distinctions among health coverage options, and helping consumers make informed decisions during the health coverage selection process. We believe it would be inconsistent with these duties for an assister to try to influence the consumer's decision about whether to enroll in coverage by providing them with a gift to induce enrollment.

In addition, the duty of these assisters to provide information and services in a fair, accurate and impartial manner would make it inappropriate for them to engage in activities that give the appearance that they are endorsing, promoting, or marketing the products or services of third party business interests when performing their authorized activities and services. At the same time, we believe that any appearance that these assisters are endorsing, promoting, or marketing the products or services of a third party, is substantially mitigated if the items are only of nominal value and not provided to induce enrollment, since it is unlikely that gifts of a nominal value will influence a consumer's health coverage selection and enrollment decisions. We also recognize that providing gifts, including promotional items, of a nominal value may help to attract applicants and potential enrollees to engage in a discussion with these assisters during an outreach event and encourage consumers to consider seeking Exchange application assistance. For these reasons, we do not want to entirely prohibit these types of assisters from using gifts and promotional items as part of their outreach efforts.

Finally, we note that existing regulations under § 155.210(d)(7) already prohibit the use of Exchange funds to purchase gifts or gift cards, or promotional items that market or promote the products or services of a third party, that would be provided to any applicant or potential enrollee. We do not propose to amend this provision.

We request comments on all aspects of our proposals.

d. Ability of States To Permit Agents and Brokers To Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs (§ 155.220)

Section 1312(e) of the Affordable Care Act directs the Secretary to establish procedures under which a State may permit agents and brokers to enroll qualified individuals and qualified employers in QHPs through an Exchange, and to assist individuals in applying for financial assistance for QHPs sold through an Exchange. Under § 155.220, we established procedures to support the States' ability to permit agents and brokers to assist individuals, employers or employees with enrollment in QHPs offered through an Exchange, subject to applicable Federal and State requirements.

At § 155.220(c), we established parameters for enrollment of qualified individuals through an Exchange with the assistance of an agent or broker. At § 155.220(c)(1), we established that an agent or broker who assists with enrollment through the Exchange must ensure completion of an eligibility verification and enrollment application through the Exchange Web site as described § 155.405. In § 155.220(c)(3), we established the standards that apply when a Web site of an agent or broker is used to complete the QHP selection.

As described at § 155.220(d), an agent or broker that enrolls qualified individuals through an Exchange, or assists individuals in applying for Exchange financial assistance, must comply with the terms of a general agreement with the Exchange, as well as register with the Exchange and receive training in the range of QHP options and insurance affordability programs. In addition, all agents and brokers must execute the applicable privacy and security agreement required by § 155.260(b) to provide assistance with enrollment through the Exchange.

In § 155.220(g), we established standards under which HHS may terminate an agent's or broker's general agreement with the FFEs for cause. We established that HHS may pursue termination with notice of an agent's or broker's agreement with the FFEs if, in HHS's determination, a specific finding of noncompliance or pattern of noncompliance is sufficiently severe. As established, the termination for cause of the general agreement with notice means that after a 30-day opportunity to resolve the matter, HHS would take necessary steps to prohibit an agent or broker from assisting or enrolling individuals in a QHP offered through an FFE, or a web-broker's ability to securely exchange information with HHS, if the matter is not resolved to the satisfaction of HHS. As of the date of termination, an agent or broker would no longer be registered with the FFEs and would not be able to assist with enrollment through the FFEs or exchange information with HHS. Certain obligations of the agent or broker would survive that termination, including the duty to protect and maintain the privacy and security of personally identifiable information (PII) it has created, collected, accessed, or acquired through its relationship with the FFEs. We established that an agent or broker may be considered noncompliant if HHS finds that the agent or broker violated: (a) Any standard specified under § 155.220; (b) any term or condition of its agreement with the FFEs required under paragraph (d) of this section, or if, the agent's or broker's FFE privacy and security agreements under § 155.260(b) are terminated; (c) any applicable State law; or (d) any other applicable Federal law.

In § 155.220(h), we established a one-level process through which an agent or broker may request reconsideration of HHS's decision to terminate for cause an agreement required under § 155.220(d). We established that an agent or broker must submit a request for reconsideration to the HHS reconsideration entity within 30 calendar days of the date of the written termination notice from HHS. We established that the HHS reconsideration entity would provide the agent or broker with a written reconsideration decision within 30 calendar days of the date it receives the request for reconsideration. This decision constitutes HHS's final determination.

i. New Exchange Standards for Web-Brokers

As specified at § 155.220(c)(1), an agent or broker who assists with an enrollment through the Exchange must ensure that the applicant completes an eligibility verification and enrollment application through the Exchange Internet Web site. Under this standard, agents and brokers that use a non-Exchange Web site to assist consumers in the QHP selection and enrollment process (''direct enrollment'' through a ''web-broker'') must redirect an applicant to go directly to the Exchange Web site to complete the application and receive an eligibility determination. HHS is considering an option under which an applicant could remain on the web-broker's Web site to complete the application and enroll in coverage, and the web-broker's Web site can obtain eligibility information from the Exchange to support the consumer in selecting and enrolling in a QHP with Exchange financial assistance. The intent is to have this information exchange occur through an Exchange-approved web service as described below, enhancing the direct enrollment

process. This option would provide Exchanges offering direct enrollment and web-brokers more operational flexibility to expand front-end, consumer-facing channels for enrollment through a seamless consumer experience.

HHS solicits comments related to the current consumer experience with web-brokers and the potential integration of the streamlined eligibility application if a non-FFE Web site is used for the entire process. We request comment on how much flexibility a web-broker should have relative to the consumer experience on its Web site, using the direct enrollment channel, to provide an end-to-end eligibility and enrollment experience. We propose that web-brokers be required to use the FFE single streamlined application without deviation from the language of the application questions and the sequence of information required for an eligibility determination or redetermination. This will ensure that the information gathered when an applicant completes an application on the Exchange Web site will also be collected to send to the Exchange for an eligibility determination or redetermination that is accurate and consistent across any channel used for enrollment. We seek comment on this standard. HHS is also considering how to ensure that consumers understand that they are applying for Exchange coverage, such as through specific branding or wording requirements if a non-FFE front-end Web site is used for the entire application and enrollment process, and we seek comment on this as well.

Accordingly, we propose to revise § 155.220(c)(1) to ensure that an applicant who initiates enrollment directly with the web-broker for enrollment through the Exchange receives an eligibility determination for coverage through the Exchange Web site or through an Exchange-approved web service via the FFE single streamline application. This maintains the role of the Exchange in determining eligibility. We propose to adopt similar changes to the standards for the use of QHP issuer Web sites under § 156.265(b)(2)(ii). Please see section III.G.4.c for this accompanying preamble discussion. We seek comment on this proposal.

We are also soliciting comments about the current agent and broker provisions in § 155.220 as applied to web-brokers. We are interested in feedback on consumer and agent/broker experiences with enrollment through web-brokers, any concerns with privacy and security of the information transmitted through web-brokers by expanding direct enrollment to incorporate the FFE single streamlined application, and suggestions for improvements in the future, such as increased monitoring and oversight activities. For example HHS is considering expanding audits, requiring additional information display requirements (such as the lowest cost plan at each metal level) beyond those outlined in § 155.220(c)(3) to ensure that consumers understand basic information about cost and availability of qualified health plans, and requiring HHS approval of alternative enrollment pathway processes. Additional requirements to safeguard consumer information or enhancements to improve the consumer and web-broker experience are also being considered. These may include establishing more robust privacy and security requirements, requiring adoption of cyber security best practices, additional web-broker reporting requirements and specificity as to the collection and use of consumer information. We note that the current oversight provisions for the general agreement, registration, training, termination, and reconsideration in § 155.220(d) through (h), as well as the changes in paragraphs (f), (g), (j), and (k) proposed below, would apply to web-brokers.

ii. New Standards for Termination of Agent and Broker Agreements With the FFEs

We propose to amend existing paragraph (g)(2)(ii) that an agent or broker may be determined noncompliant if HHS finds that the agent or broker violated any term or condition of the agreement with the FFEs required under paragraph (d) of this section, or any term or condition of an agreement with the FFEs required under § 155.260(b).

We propose to add paragraph (g)(5) to § 155.220(g) to address suspension or termination of an agent's or broker's agreements with the FFEs in cases involving potential fraud or abusive conduct. These cases would include cases in which there is an allegation of potential fraud or abusive conduct that HHS finds to be credible; or any report of potential fraud or abusive conduct made by a State or Federal agency or law enforcement. We propose to add this paragraph to give HHS authority to act quickly to terminate access to HHS systems in these instances to prevent further harm to consumers and to support the efficient and effective administration of the FFEs.

We propose in § 155.220(g)(5)(i)(A) that if HHS reasonably suspects that an agent or broker may have engaged in fraud or abusive conduct using PII of Exchange applicants or enrollees, or in connection with an Exchange enrollment or application, HHS may suspend the agent's or broker's agreement and accompanying registration with the FFEs for up to 90 calendar days, with the suspension effective as of the date of the notice to the agent or broker. This would apply whether the activity or conduct in question was committed directly by the agent or broker, or through a third party who acts at the direction of or on behalf of the agent or broker. This immediate and temporary suspension would prohibit the agent or broker from assisting with or facilitating enrollment in coverage in a manner that constitutes enrollment through the FFEs, including enrollment through the FFE Application Programming Interface, while the investigation is conducted during this 90-day period. Immediate suspension is critical in these circumstances to stop additional potentially fraudulent enrollments through the FFE during the period of investigation. Although the agent or broker would not be provided with advance notice, we propose under § 155.220(g)(5)(i)(B) that the agent or broker may submit evidence to HHS to rebut the allegation during this 90-day period. If HHS determines that the agent or broker satisfactorily addresses the concerns at issue, HHS would lift the temporary suspension and notify the agent or broker. We further propose under § 155.220(g)(5)(i)(B) that failure to submit information during this 90-day period may result in termination of the agreement for cause effective immediately under § 155.220(g)(5)(ii).

We propose in § 155.220(g)(5)(ii) that if HHS reasonably confirms the credibility of an allegation that an agent or broker engaged in fraud or abusive conduct using personally identifiable information of Exchange enrollees or applicants, or in connection with an Exchange enrollment or application, or is notified by a State or law enforcement authority of the State or law enforcement authority's finding or determination of fraud or behavior that would constitute abusive conduct in such a circumstance, HHS will notify the agent or broker and terminate, immediately and permanently, the agent's or broker's agreements with the FFEs for cause. In contrast to termination for other violations listed in § 155.220(g), we propose that following an HHS reasonable confirmation of such an allegation or such a State or law enforcement notification, termination would occur without 30 days' advance notice and would be effective upon the date of the termination notice. An agent or broker who engages in fraud or

abusive conduct may pose immediate harm to consumers and to HHS's ability to properly administer the FFEs. Under this scenario, following the reasonable confirmation by HHS (that is, the FFE) of fraud or abusive conduct, HHS would notify the agent or broker of HHS's termination action. We note that we would coordinate with OIG and other State and Federal agencies (including law enforcement) as appropriate when investigating these situations. Similar to any termination for cause described in paragraph (g)(1), any termination notice would include information on the agent's or broker's right to seek reconsideration as described in § 155.220(h). HHS currently works with States and local law enforcement to investigate and resolve suspected incidents of fraud. We note that termination proposed in § 155.220(g) only applies to the FFE agreement described in paragraph (d) of this section, and the agreements required under § 155.260(b)(2). While States remain the primary oversight authority for agents and brokers, HHS reserves the right to take any other permissible enforcement or remedial action against an agent or broker for violation of Federal requirements.

In § 155.220(g)(5)(iii), we propose that during the 90-day suspension period, as well as following the termination of the FFE agreements for cause, the agent or broker would not be registered with the FFEs, or be permitted to assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees through an FFE, or assist individuals in applying for Exchange financial assistance for QHPs. However, consistent with the FFE agreement described in § 155.260(b)(2), the agent or broker must continue to protect any PII accessed during the term of the agreement with the FFEs. Section 155.260(g) includes penalties for failure to continue protecting PII as described in the § 155.260(b)(2) agreement. For consistency with these proposed termination standards, we propose corresponding updates to paragraph (g)(4). We also propose to amend existing paragraph (f)(4) to remove the reference to paragraph (g) for further alignment of these regulatory provisions.

We solicit comment on all aspects of these proposals, including: The appropriate length of time for the temporary suspension period under § 155.220(g)(5)(i); whether we should provide authority for HHS to suspend an agent's or broker's agreements with the FFEs for cause for conduct other than potential fraud or abusive conduct; and whether we should include a provision permitting HHS to immediately terminate (that is, without the advance 30-day notice currently provided under § 155.220(g)(3)) an agent's or broker's agreements with the FFEs for cause for suspected conduct other than fraud or abusive conduct. We are also considering whether the notice requirements captured in § 155.220(f)(3)(i) that currently apply to agent or broker initiated terminations should also be extended to terminations for cause under § 155.220(g), including these proposed grounds for termination for cause under § 155.220(g)(5). In addition, see § 155.430 below for a discussion of proposals related to retroactive termination of coverage for consumers affected by potential fraudulent activity by a third party related to enrollment through the FFEs.

iii. FFE Standards of Conduct for Agents and Brokers

We propose adding a paragraph § 155.220(j) to establish standards of conduct for agents and brokers that assist consumers to enroll in coverage through the FFEs to protect consumers and ensure the proper administration of the FFEs. We are proposing these standards of conduct to protect against agent and broker conduct that is harmful towards consumers, or prevents the efficient operation of the FFEs. In § 155.220(j)(1)(i) through (iii), we propose to capture as part of these standards of conduct the requirements that an agent or broker that assists with or facilitates enrollment of qualified individuals, qualified employers, or qualified employees through an FFE, or assists individuals in applying for Exchange financial assistance for QHPs sold through the FFEs, must (i) have executed the required agreement under § 155.260(b)(2); (ii) be registered with the FFEs as described in paragraph (d)(1) of this section; and (iii) comply with the FFE standards of conduct proposed in this paragraph. We note that signing of the FFE agreement as well as all required registration steps must be completed prior to assisting with or facilitating enrollment of qualified individuals, qualified employers, or qualified employees through an FFE, or assisting individuals in applying for Exchange financial assistance for QHPs sold through the FFEs.

In § 155.220(j)(2), we propose to capture as part of the standards of conduct the requirements that the agents and brokers described in paragraph (j)(1) must: (i) Provide consumers with correct information, without omission of material fact, regarding the FFEs, QHPs (including SADPs [22]) offered through the FFEs, and insurance affordability programs, and refrain from marketing or conduct that is misleading or coercive, or discriminates based on race, color, national origin, disability, age, sex, gender identity, or sexual orientation; (ii) provide the FFEs with correct information under section 1411(b) of the Affordable Care Act; (iii) obtain the consent of the individual, employer, or employee prior to assisting with or facilitating enrollment in coverage through an FFE, or assisting with the application for financial assistance for QHPs sold through the FFEs; (iv) protect consumer PII in accordance with § 155.260(b)(3) and the agreement described in § 155.260(b)(2); and (v) comply with all applicable Federal and State laws and regulations. We note that these proposed standards for conduct extend to naming of businesses and Web sites associated with agents, brokers or web-brokers, and that use of ''Exchange,'' ''Marketplace,'' or other words in a name or URL that would reasonably cause confusion with a Federal program or Web site may be considered misleading under paragraph (j)(1)(i).

In § 155.220(j)(3), we propose that an agent or broker will be considered to be in compliance with the standard of conduct requirements to provide consumers and the FFEs with correct information if HHS determines that there was a reasonable cause for any failure to provide correct information and that the agent or broker acted in good faith.

We further propose that violation of these standards of conduct may result in termination for cause of the agent's or broker's agreements with the FFEs as described in paragraph § 155.220(g) or the imposition of other penalties authorized by law. We will continue to coordinate our enforcement activities with States, other Federal agencies, and local and Federal law enforcement, and anticipate imposing penalties (beyond the termination of the FFE agreements) only in instances where States do not or are unable to act.

We expect that States will continue to license and monitor agents and brokers, and will continue to have primary responsibility to oversee and regulate all

[22] As detailed in the Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers; Final Rule and Interim Final Rule (77 FR 18310, 18315) (March 27, 2012), with some limited exceptions, SADPs are considered a type of QHP. We expect agents, brokers, and web-brokers registered with the FFEs to comply with applicable rules and requirements in connection with SADPs, just as they must comply with those rules in connection with medical QHPs.

agents and brokers, both inside and outside of the Exchanges. All State laws and regulations related to agents and brokers, including State requirements related to appointments, contractual relationships with issuers, and licensing and marketing requirements, will continue to apply. To avoid duplication of oversight activities related to agents and brokers assisting with enrollment through an FFE, we propose that HHS will continue to focus its oversight activities primarily on ensuring that agents and brokers assisting with enrollment through an FFE meet the standards outlined in § 155.220. In particular, HHS plans to focus on protecting the privacy and security of PII of applicants and enrollees through the FFEs, as well as the misuse of such PII, to the extent this is not already covered under existing State or Federal efforts. We will continue to collaborate with State regulators to resolve cases of potential misconduct and to further develop standard operating procedures for the FFEs that will be critical to HHS oversight of agents and brokers registered to assist with enrollment through the FFEs.

iv. Penalties Other Than Termination of the Agreements With the FFEs

In § 155.220(k), we propose penalties for agents and brokers registered with the FFEs other than termination of the agreements with the FFEs. In § 155.220(k)(1), we propose that if HHS determines that an agent or broker fails to comply with the requirements of § 155.220, he or she may be denied the right to enter into an agreement with the FFEs in future years, and may be subject to CMPs as described in § 155.285 if the violation involved the provision of false or fraudulent information to an Exchange or the improper use or disclosure of information. In § 155.220(k)(2), we propose that the denial of the right to enter into an agreement with the FFEs in future years would be subject to 30 calendar days' advance notice and the reconsideration process established in § 155.220(h). The imposition of CMPs for the provision of false or fraudulent information to an Exchange or the improper use of disclosure of information would be subject to the advance notice and appeals process described in § 155.285.

We are also proposing a denial of the right to enter into future agreements with the FFEs in cases where an agent or broker has not completed FFE registration requirements, and not entered into the required agreements with the FFEs, but has enrolled qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through an FFE, or assisted individual market consumers with submission of applications for Exchange financial assistance through an FFE and has sought compensation based on the enrollment through the FFEs in his or her capacity as an agent or broker. We note that § 155.285 applies to agents and brokers, and we propose to specify here that agents and brokers may also be subject to CMPs as described in § 155.285 for noncompliance if the violation involved the provision of false or fraudulent information to an Exchange or the improper use or disclosure of information. We seek comment on these additional proposed penalties, including the length of time for which the prohibition on entering into an agreement with the FFEs would apply in these cases.

We intend to continue to collaborate with State regulators to further develop standard operating procedures for an FFE that will be critical to HHS's oversight of agents and brokers registered to assist with enrollment through an FFE and to ensure the efficient and effective administration of the FFEs. We encourage comment on the information required to carry out these activities, and on any definitions, timeframes, or procedures described in our proposed amendments to § 155.220.

v. Agents and Brokers Assisting Consumers With Enrollment in Coverage Through SBE–FPs

We propose adding § 155.220(l) to provide that an agent or broker who enrolls qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through an SBE–FP, or assists individual market consumers with submission of applications for Exchange financial assistance through an SBE–FP must comply with all applicable FFE standards in § 155.220. We believe it is important to extend the FFE standards in § 155.220 to agents and brokers who assist with enrollments through an SBE–FP due to the HHS's role in operating the FFE infrastructure and the accompanying access that this provides to HHS data systems. We also propose that agents and brokers in SBE–FP States would be able to satisfy the requirement for training in § 155.220(d)(2) by taking FFE training offered by a vendor as described in § 155.222.

e. Standards for HHS-Approved Vendors of FFE Training for Agents and Brokers (§ 155.222)

At § 155.222, we previously established a process for HHS to approve vendors to offer training and information verification services through which State licensed agents and brokers could complete the training requirements necessary to assist consumers seeking coverage through the FFEs. As part of an approved training and information verification program, we stated that the vendor must require agents and brokers to successfully complete identity proofing, provide identifying information, and successfully complete the required curriculum. Further, we established that no vendor training program would be recognized unless it included an information verification component under which the vendor confirms the identity and applicable State licensure of the person who is credited with successful completion of the training program.

We propose eliminating the § 155.222 requirement that vendors perform information verification functions, including State licensure verification and identity proofing. Section 155.220(e) requires an agent or broker that enrolls qualified individuals through the Exchange or assists with the submission of applications for financial assistance through an Exchange to comply with applicable State law, which includes requirements related to operating as an insurance producer, such as licensure. We expect that QHP issuers will adhere to the § 156.340(a)(3) requirement to ensure their delegated and downstream entities, which include affiliated agents and brokers, comply with the standards of § 155.220 with respect to assisting with enrollments in QHPs, including the requirement to comply with applicable State law. The FFE will continue to provide identity proofing services to facilitate the registration of agents or brokers as required by § 155.220(d)(1). We propose these changes to avoid duplication of efforts. If QHP issuers are ensuring that their affiliated agents and brokers are complying with State law, such as licensure, it is not necessary for vendors to do so as well. Consistent with this proposal, we propose amending § 155.222(a)(1) to provide that a vendor must be approved by HHS, and remove the reference to information verification. We also propose in § 155.222(a)(2) to remove the requirements that vendors must require agents and brokers to provide proof of valid State licensure.

Consistent with these changes proposed for § 155.222(a), we propose amending § 155.222(b)(1) through (5) and (d) to remove standards for information verification, identity proofing, verification of agents' and brokers' valid State licensure, and all

related standards that support these functions. We propose to eliminate the requirements in paragraphs (b)(1)(i) through (ii) to submit an application demonstrating prior experience with verification of State licensure and identity proofing; instead, we propose to combine into paragraph (b)(1) the existing requirements to demonstrate prior experience with online training and technical support for a large customer base. In paragraph (b)(2), we propose to eliminate the requirement to adhere to HHS specifications for content, format, and delivery of information verification; separately, in (b)(2), we propose to include SBE–FP States in the requirement to offer continuing education units (CEUs) in five FFE States. In paragraph (b)(3), we propose to eliminate the requirement that vendors collect, store, and share with HHS all data from agent and broker users of the vendor's training; instead we propose that vendors would only be required to collect, store and share with HHS FFE training completion data. In paragraph (b)(4), we propose to amend the standards for the agreement that vendors must execute with HHS, to eliminate the requirement that vendors implement information verification processes. We propose amending § 155.222(b)(5) and (d) to remove references to information verification. We solicit comment on the proposals to eliminate these requirements related to information verification.

We propose adding a paragraph (b)(6) to require vendors to provide technical support to agent and broker users of the vendor's FFE training as specified by HHS. Currently, paragraph (b)(1) requires vendors to demonstrate prior experience with providing technical support to a large customer base. We propose adding this requirement to specify that a vendor must provide tier-one help desk support to assist agents and broker accessing the vendor's FFE training platform from the CMS Enterprise Portal. Tier-one support includes, for any inquiry received by the vendor's help desk, intake, initial response, and resolution of inquiry through a scripted response or re-routing to another help desk. The scope of inquiries that must be answered through scripted response will be provided by HHS in guidance. We seek comments on the requirement that a vendor must provide technical assistance as specified by HHS to agent and broker users of the vendor's FFE training.

We note that HHS has the authority to require approved vendors to provide technical support, as well as FFE training, in accordance with HHS guidelines and in a manner and format that complies with Section 508 of the Rehabilitation Act of 1973. The World Wide Web Consortium's Web Content Accessibility Guidelines (WCAG) 2.0 Level AA standards is an alternative that we propose would also be considered an acceptable national standard for Web site accessibility. For more information see, the WCAG Web site at *http://www.w3.org/TR/WCAG20/*.

f. Standards Applicable to Certified Application Counselors (§ 155.225)

This proposed rule would also require certified application counselor organizations to report performance data to an Exchange, in order to improve the ability of each Exchange to monitor the work of the organizations it has designated as certified application counselor organizations. In accordance with the Secretary's authority under section 1321(a)(1)(A) of the Affordable Care Act to establish standards related to the operation of Exchanges, we propose to amend § 155.225(b)(1) to provide that certified application counselor designated organizations must, as a condition of their designation as certified application counselor organizations by the Exchange, provide the Exchange with information and data related to the number and performance of the organization's certified application counselors, and about the consumer assistance being provided by the organization's certified application counselors, upon request, in the form and manner specified by the Exchange.

Section 155.225(b)(1)(ii) already requires certified application counselor designated organizations to maintain a registration process and method to track the performance of certified application counselors, but it does not specify the type of performance information that must be tracked, nor does it require that information to be provided to the Exchange.

The proposed requirement would give Exchanges valuable information to aid in their oversight of certified application counselor programs, and would help improve Exchanges' understanding of the scope of consumer assistance being provided in the Exchange service area. The proposed requirement would also improve the consumer assistance functions of the Exchange in other significant ways, for example, by providing information that could help an Exchange focus its outreach and education efforts, target its recruitment of certified application counselor organizations, and identify the need for increased technical assistance and support for certified application counselor organizations.

Under this proposal, Exchanges could establish reporting standards as they determine appropriate based on their own specific needs and objectives. In States with FFEs, HHS proposes that it would begin collecting information and data from certified application counselor designated organizations on a monthly basis beginning in January 2017. We propose that the kind of information and data that the FFEs would require from these organizations will include, at a minimum, data regarding the number of individuals who have been certified by the organization; the total number of consumers who received application and enrollment assistance from the organization; and of that number, the number of consumers who received assistance applying for and selecting a QHP, enrolling in a QHP, or applying for Medicaid or CHIP. We anticipate that the monthly reports submitted to the FFEs would provide information and data from the preceding month, and would be submitted electronically, through HIOS or another electronic submission vehicle. We also expect that some of the data that FFEs would require from certified application counselor designated organizations would be similar to what is collected from Navigator grantees in the FFEs.[23] We do not expect this information collection to include consumers' PII. HHS recognizes the importance of certified application counselors, and we intend that any FFE information collection would be straightforward and place little additional burden on certified application counselor organizations.

We request comments on this proposal, on the scope of information and data that Exchanges should collect, and on HHS's specific proposals for collecting information and data from certified application counselor organizations in the FFEs, including the proposed scope and timing of reports by these organizations to the FFEs.

As discussed earlier in this preamble in a parallel proposal to amend § 155.210(d)(6), we propose to amend § 155.225(g)(4), which prohibits certified application counselors in all Exchanges from providing certain kinds of gifts and promotional items to an applicant or potential enrollee. For the

[23] The data collection requirements for FFE Navigator grantees in 2015–2016 are specified in the Information Collection Request (OMB control number 0938–1215) under the Cooperative Agreement to Support Navigators in Federally-facilitated and State Partnership Exchanges (see the PRA package associated with 80 FR 36810). *http://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201507-0938-001.*

same reasons discussed above, we propose to amend § 155.225(g)(4) consistent with our proposed amendments to § 155.210(d)(6).

We seek comment on all aspects of this proposal

g. Privacy and Security of Personally Identifiable Information (§ 155.260)

Section 155.260(a)(1) refers to insurance affordability programs, as defined in § 155.20. We propose to make a technical correction to this paragraph so that § 155.300, which contains the definition of insurance affordability programs, is referenced instead.

h. Oversight and Monitoring of Privacy and Security Requirements (§ 155.280)

Section 155.280(a) permits HHS to oversee and monitor the FFEs and non-Exchange entities associated with FFEs to ensure compliance with the privacy and security standards established and implemented by an FFE under § 155.260. Section 155.280(a) also provides authority for HHS to monitor State Exchanges for compliance with the privacy and security standards established and implemented by the State Exchanges under § 155.260. We propose amending paragraph (a) to permit HHS to also oversee and monitor SBE–FPs' compliance with the privacy and security standards established and implemented by an FFE under § 155.260.

4. Exchange Functions in the Individual Market: Eligibility Determinations for Exchange Participation and Insurance Affordability Programs

a. Options for Conducting Eligibility Determinations (§ 155.302)

We propose to amend § 155.302(a) by adding an option for an SBE–FP to satisfy the requirement of conducting eligibility determinations by relying on HHS to carry out eligibility determination activity and other requirements within subpart D, through a Federal platform agreement. We seek comments on this proposal.

b. Eligibility Process (§ 155.310(h))

We propose to amend § 155.310(h) related to the requirement that the Exchange must notify an employer that an employee has been determined eligible for Exchange financial assistance upon such determination. This notice serves two main purposes. First, it informs an employer that it may be liable for the payment assessed under section 4980H of the Code because one of the employer's employees was determined eligible for Exchange financial assistance.[24] Second, it may reduce an employee's tax liability because in the event an employer prevails in an employer appeal described in § 155.555, the Exchange will redetermine the employee's eligibility (including for Exchange financial assistance) or notify the employee of the requirement to report changes in eligibility, as discussed in the preamble section III.F.6.g of this proposed rule. Currently under § 155.310(h), the Exchange is directed to notify an employer that an employee has been determined eligible for Exchange financial assistance. We propose to revise this requirement so that the Exchange must notify an employer that an employee has been determined eligible for Exchange financial assistance only if the employee has also enrolled in a QHP through the Exchange. For purposes of this provision, an employee is determined eligible for cost-sharing reductions when the employee is determined eligible for cost-sharing reductions based on income in accordance with § 155.305(g) or § 155.350(a).

We believe this change better reflects the statutory requirement to send employer notices and will reduce confusion among employers and employees. The relevant statutes that address the employer notice requirement contemplate that employer notices will be provided for enrolled individuals who have been determined eligible for Exchange financial assistance. Sections 4980H(a)(2) and (b)(1)(B) of the Code provide that an assessable payment may be imposed on an employer if at least one full-time employee is certified as *having enrolled* in a QHP for which Exchange financial assistance is allowed or paid for the employee.

In the case of an employee who has been determined eligible for Exchange financial assistance but has not enrolled in a QHP, it would be inaccurate and confusing to send a notice under § 155.310(h) because the employer receiving the notice would not be liable for a payment assessed under section 4980H of the Code if its employee does not enroll in a QHP through the Exchange (even if the employee could have received Exchange financial assistance if the employee had enrolled in a QHP). Futhermore, because sections 36B(b)(1) and (c)(2)(A) of the Code provide that a premium tax credit amount may not be allowed for any month in which, as of the first day of the month a tax filer (or the tax filer's spouse or tax dependent) was not enrolled in a QHP through the Exchange, a notice under § 155.310(h) serves no purpose in protecting an employer from potential tax liability under section 4980H or an employee from tax liability under section 36B when the employee has been determined eligible for Exchange financial assistance but has not enrolled in a QHP through the Exchange. We also propose to revise paragraph (h)(2) so that a notice sent in accordance with § 155.310(h) must indicate that an employee has been determined eligible for Exchange financial assistance and has enrolled in a QHP through the Exchange.

Additionally, for purposes of operational efficiency with regard to the timing of the employer notification required under paragraph (h), we propose that the Exchange may choose to either (a) notify employers on an employee-by-employee basis as eligibility determinations are made for Exchange financial assistance and enrollment in a QHP through the Exchange, or (b) notify employers for groups of employees who are determined eligible for Exchange financial assistance and enroll in a QHP through the Exchange. Under both options, the Exchange must notify employers within a reasonable timeframe following any month an employee was determined eligible for either form of Exchange financial assistance and enrolled in a QHP, with the goal to notify employers as soon as possible to provide the greatest benefit to enrollees. We seek comment on these proposals.

c. Verification Process Related to Eligibility for Insurance Affordability Programs (§ 155.320)

We propose to revise § 155.320(c)(3)(vi) to allow the Exchange to establish a reasonable threshold at which the Exchange must follow the alternate verification process for decreases in the annual household income between the applicant's

[24] Only certain employers (called applicable large employers) are subject to the employer shared responsibility provisions under section 4980H of the Code. In general, applicable large employers must either offer minimum essential coverage that is ''affordable'' and that provides ''minimum value'' to their full-time employees (and their dependents), or make an employer shared responsibility payment to the IRS if at least one full-time employee receives the premium tax credit under section 36B of the Code. For more information on which employers are subject the employer shared responsibility provisions and under what circumstances an applicable large employer will be subject to a payment (and how the payments are calculated), see *Shared Responsibility for Employers Regarding Health Coverage; Final Rule,* 79 FR 8544 (Feb. 12, 2014).). Liability for the employer shared responsibility payment is determined independently by the IRS. More information on the IRS process can be found at *www.irs.gov*.

attestation of projected annual household income and the annual income computed in accordance with § 155.320(c)(3)(ii)(A). The reasonable threshold would be subject to approval by HHS. Current regulations require the Exchange to follow the alternate verification process under § 155.320(c)(3)(vi) if either (1) the attested annual household income submitted by the consumer is more than 10 percent less than income data received from trusted data sources, or (2) if no data is available from trusted data sources. We recognize that many consumers have difficulty projecting their annual household income and complying with the verification requirements. Annual household income may fluctuate year to year and throughout the year, making it difficult for consumers to project their income for the year ahead. Income data from trusted data sources can be up to 2 years old. In addition, consumers with lower incomes have a smaller margin for error in dollar terms under the current percentage-based threshold. We recognize that the current threshold of 10 percent may not be adequate to allow for normal variation in a consumer's annual household income, and may be too sensitive a threshold in terms of triggering the alternate verification process. Accordingly, we propose that the Exchange may set a reasonable threshold for when an applicant enters the alternate verification process in cases where the applicant's attestation of projected annual household income is lower than income data received from trusted data sources. A reasonable standard would allow for a realistic variation in a consumer's projected annual household income for the year for which they are seeking coverage from previous years' income data received from trusted data sources and may be defined in terms of a percentage, or a percentage and a fixed dollar amount (for example, the greater of 20 percent or $5,000). A threshold set less than 10 percent would not be a reasonable standard since it would not allow for small projected reductions in income from a previous year. HHS will provide additional guidance on what constitutes a reasonable threshold. This proposal would allow the Exchange to establish a threshold that effectively maintains program integrity, while minimizing burdens to consumers to the extent possible. It would also allow the Exchange to make adjustments in future years as more data becomes available. We seek comment on this proposal.

In § 155.320(d), we make certain proposals related to alternative processes relating to verification of enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan.

In paragraph (d)(3), we propose to redesignate paragraph (d)(3)(i) as (d)(3)(ii) and redesignate paragraph (d)(3)(ii) as (d)(3)(i). To preserve the accuracy of the redesignated paragraph (d)(3)(ii), we propose to update the cross-reference to paragraph (d)(3)(ii) with (d)(3)(i), and paragraph (d)(3)(iii) with (d)(4)(i), discussed below. We also propose to remove paragraph (d)(3)(iii), which requires the Exchange to select a statistically significant random sample of applicants for whom the Exchange does not have data as specified in paragraphs (d)(2)(i) through (iii) and take steps to contact any employer identified on the application for the applicant and the members of his or her household to verify whether the applicant is enrolled in an eligible employer-sponsored plan or is eligible for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested. This process is referred to as ''sampling.'' We propose to modify this requirement, and describe that proposal in our discussion of proposed paragraph (d)(4) below. We believe these amendments to paragraph (d)(3) will organize and simplify the regulatory text.

We propose to add paragraph (d)(4) concerning a survey of verification procedures. In paragraph (d)(4), we propose that the Exchange must follow the procedures described in paragraph (d)(4)(i) or, in the alternative, for benefit years 2016 and 2017, the Exchange may follow the procedures specified in paragraph (d)(4)(ii), for any benefit year for which it does not reasonably expect to obtain sufficient verification data as described in paragraphs (d)(2)(i) through (iii). For the purposes of this section, the Exchange reasonably expects to obtain sufficient verification data for any benefit year when, for the benefit year, the Exchange is able to obtain data about enrollment in and eligibility for qualifying coverage in an eligible employer-sponsored plan from at least one electronic data source that is available to the Exchange and has been approved by HHS, based on evidence showing that the data source is sufficiently current, accurate, and minimizes administrative burden, as described in paragraph (d)(2)(i).

In paragraph (d)(4)(i), we propose that the Exchange may conduct sampling. This paragraph is substantially the same as current paragraph (d)(3)(iii), with three differences. First, we propose to remove the absolute requirement to conduct sampling, and for benefit years 2016 and 2017, allow the Exchange to implement an alternate process approved by HHS. This proposal and rationale is described in more detail in the discussion of paragraph (d)(4)(ii), below. Second, we propose to remove the language that currently appears in paragraph (d)(3)(iv) since the relief it provided only applied to eligibility determinations that were effective before January 1, 2015. Third, we propose to replace two internal cross-references to paragraph (d)(3)(iii) with appropriate cross-references to paragraph (d)(4)(i).

We propose moving the sampling requirement from paragraph (d)(3) and adding it to new paragraph (d)(4) to more accurately reflect the role of the sampling process. Paragraph (d)(3) contains standards for ''[v]erification procedures'' applicable to all applicants for Exchange financial assistance. The sampling process, however, does not involve verification of eligibility information for all applicants, and is primarily intended to serve as a way for the Exchange to gain insight into whether consumers provide accurate information on the application regarding their enrollment in and eligibility for qualifying coverage in an eligible employer-sponsored plan and the effectiveness of an Exchange's verification of such information.

In paragraph (d)(4)(ii), we propose to permit an Exchange the option to implement an alternate process approved by HHS for the benefit years 2016 and 2017. We believe this option will provide Exchanges with needed flexibility as verification processes are refined and employer databases compiled over the next several years, to improve long-term verification programs. We seek comment on these proposals.

d. Medicare Notices

Over the course of the first two years of Exchange operations, we have realized the importance of providing notification to enrollees in coverage through the Exchange of their potential eligibility for Medicare. We recognize the importance of a smooth transition to Medicare coverage, and seek comment on whether and how to implement a notification that an enrollee may have become eligible for Medicare. For example, for enrollees in an FFE, we are considering ''pop up'' text on HealthCare.gov for individuals who are going to turn 65 during the benefit year. We seek comment on this and other ways to promote smooth coverage transitions.

5. Exchange Functions in the Individual Market: Enrollment in Qualified Health Plans

a. Annual Eligibility Redetermination (§ 155.335(j))

In the Patient Protection and Affordable Care Act; Annual Eligibility Redeterminations for Exchange Participation and Insurance Affordability Programs; Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges final rule (79 FR 52994, 53000 (Sept. 5, 2014)), we established a renewal and re-enrollment hierarchy at § 155.335(j) to minimize potential enrollment disruptions. To further minimize potential disruptions of enrollee eligibility for cost-sharing reductions, we propose to amend § 155.335(j)(1) to create a new re-enrollment hierarchy for all enrollees in a silver-level QHP that is no longer available for re-enrollment. Specifically, if such an enrollee's current silver-level QHP is not available and the enrollee's current product no longer includes a silver-level QHP available through the Exchange, the enrollee's coverage would be renewed in a silver-level QHP in the product offered by the same issuer that is the most similar to the enrollee's current product, rather than in a plan one metal level higher or lower than his or current silver-level QHP, but within the same product. Transitioning enrollees in this manner is an operationally efficient way of maintaining continuity for enrollees eligible for cost-sharing reductions, and, because the benchmark plans for establishing the amount of the premium tax credit for which an eligible taxpayer is eligible is a silver-level plan, continued enrollment in a silver-level plan, as opposed to enrollment in a plan at a different metal level but in the same product is likely to be more consumer protective. We request comment on this proposal, including the best means of determining which product is most similar to the enrollee's current product. We also seek comment on whether the hierarchy should permit a QHP enrollee to be automatically re-enrolled into a plan not available through an Exchange, and under what circumstances such a re-enrollment should occur.

In the 2016 Payment Notice proposed rule, we also noted that we are exploring a change to the re-enrollment hierarchy at § 155.335(j), which currently prioritizes re-enrollment with the same issuer in the same or a similar plan. As we discussed in that rulemaking, many consumers place a high value on low premiums when selecting a plan, and the approach we were exploring would recognize that plans that have competitively priced premiums in one year may not continue to be the most competitively priced in subsequent years. As a result, default enrollment in the same or similar plan may sometimes encourage consumers to remain in plans that are significantly more expensive than the lowest cost plans available to the enrollee.

We are considering an approach under which an enrollee in an FFE would be offered a choice of re-enrollment hierarchies at the time of initial enrollment, and could thereby opt into being re-enrolled by default for the subsequent year into a low-cost plan, rather than his or her current plan or the plan specified in the current re-enrollment hierarchy. The alternative enrollment hierarchy could be triggered if the enrollee's current plan's premium increased from the prior year, or increased relative to the premium of other similar plans (such as plans of the same metal tier), by more than a threshold amount, such as 5 percent or 10 percent. For example, in those conditions, the enrollee would be placed into a QHP of the same metal level with the lowest premium in the enrollee's service area, or perhaps one of three such QHPs with the lowest premiums, by random allocation or another appropriate allocation process. As is the case under the existing approach, a consumer would retain the option to take action to enroll in a different plan during open enrollment if he or she wished to do so.

We received a number of comments regarding the discussion in the 2016 Payment Notice proposed rule. Some commenters supported the approach generally. Other commenters stated that the approach does not give adequate deference to the plan an enrollee has selected during open enrollment, or to the impact of cost sharing. A number of commenters had concerns that consumers may not realize that opting into a default enrollment hierarchy based on low-cost premiums may result in other significant changes to their coverage, and emphasized the importance of education by the Exchanges with respect to this re-enrollment hierarchy. We received a few alternative ideas for re-enrollment hierarchies, including basing re-enrollment on factors consumers identify as most important to them, or basing re-enrollment on the consumer's original choice of premium. Similarly, one commenter suggested implementing this approach only for those consumers currently enrolled in the lowest-cost or second-lowest cost silver plan.

Continuing the discussion in the 2016 Payment Notice, we are requesting further comment on this concept to update our policy in the final rule. In particular, we are interested in understanding how to ensure that consumers understand the increased risk of being re-enrolled automatically in a plan with a significantly different provider network, benefits, cost-sharing structure, or service area. We seek comment on the timing and form of the notice related to plan re-enrollment that the Federally-facilitated Exchange would provide to consumers opting in to such an enrollment hierarchy. We seek comment on whether hierarchies that considered factors other than metal level or premiums, such as plan type (for example, HMO versus PPO) or network breadth could help to reduce the risk that consumers are re-enrolled automatically into a plan that does not suit their needs. We are interested in comments on what premium growth in the current plan (or what growth relative to other similar plans) would trigger re-enrollment into a low-cost plan, and how to determine which enrollees get assigned to which plans, for example if enrollees are allocated among one of the three lowest cost QHPs of the metal level in the enrollee's service area. We seek comment on how best to deal with the risk of providing small plans with excess enrollment, in order to avoid destabilizing such plans with a deluge of new enrollments. As we did last year, we seek comment on how these types of default re-enrollment procedures have functioned in other programs and settings, and what lessons can be drawn from those experiences. Finally, we seek comment on the appropriate timeframe for implementing such an alternative hierarchy.

b. Enrollment of Qualified Individuals into QHPs (§ 155.400)

i. Rules for First Month's Premium Payments for Individuals Enrolling With Regular, Special, and Retroactive Coverage Effective Dates.

We propose to amend § 155.400(e) related to the payment of the first month's premium (that is, binder payments), including deadlines, to codify previously released guidance in section 8.2 of the updated Federally-facilitated Marketplace and Federally-facilitated Small Business Health Options Program Enrollment Manual,[25] that specified our interpretation of these requirements. Specifically, we propose to amend § 155.400(e)(1)(i) and (ii) to

[25] Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Updated_ENR_Manual.pdf.*

provide that, for prospective coverage, the binder payment must consist of the first month's premium. To provide added flexibility for issuers, we also would add to the rule to specify that the deadline for a binder payment related to prospective coverage with a prospective special effective date, would have to be no earlier than the coverage effective date and no later than 30 calendar days from the date the issuer receives the enrollment transaction or the coverage effective date, whichever is later. This would align the requirement for enrollments with prospective special effective dates with the requirement for enrollments with regular effective dates. We propose to add § 155.400(e)(1)(iii) to reflect our interpretation, intended to limit the risk that issuers would provide retroactive coverage without receiving sufficient premium payments from enrollees, that applicants requesting coverage being effectuated under retroactive effective dates, such as coverage in accordance with a special enrollment period or a successful eligibility appeal, must pay a binder payment that consists of all premium due (meaning the premium for all months of retroactive coverage). If the applicant pays only the premium for one month of coverage, we propose that the issuer would be required to enroll the applicant in prospective coverage in accordance with regular effective dates. We also propose to specify that the deadline for payment of all premium due must be no earlier than 30 calendar days from the date the issuer receives the enrollment transaction or notification of the enrollment. This change to the binder payment rules is intended to allow issuers flexibility to set a reasonable deadline for enrollees to submit payment of retroactive premium, the total amount of which may consist of payment for several months of coverage.

Based on our experience implementing the grace period provisions under our previous rulemaking, particularly in cases involving advance payments of the premium tax credit, that require full payments of amounts due to avoid being put in a grace period and to avoid termination of enrollment, we have identified the need for additional flexibility for issuers to establish reasonable policies regarding premium collection that would allow issuers to collect a minimal amount of premium less than that which is owed without necessarily triggering the consequences for non-payment of premiums. For example, in the Exchange Establishment Rule, we established that enrollees receiving advance payments of the premium tax credit have to pay full payments of all outstanding premiums owed in order to avoid entering a grace period or having their coverage terminated. In response to requests from issuers, we propose to add flexibility to this rule to allow issuers the option to adopt a premium payment threshold policy to avoid situations in which an enrollee who owes only a de minimis amount of premium has his or her enrollment terminated for non-payment of premiums.

Accordingly, at new § 155.400(g), we propose to codify a provision related to premium payment threshold policies, thereby allowing additional issuer flexibility regarding when amounts collected will be considered to satisfy the obligation to pay amounts due, so long as issuers implement such a policy uniformly and without regard to health status and that the premium payment threshold adopted is reasonable. This would allow issuers flexibility to effectuate an enrollment, not to place an enrollee in a grace period for failure to pay 100 percent of the amount due, or not to terminate enrollments after exhaustion of the applicable grace period for enrollees who owe only a small amount of premium within the threshold.

We seek comment on these proposals.

ii. Reliance on HHS To Carry Out Enrollment and Related Functions.

We also propose to amend § 155.400 by adding a new paragraph (h) to reflect that SBE–FPs must rely on HHS to implement the functions related to eligibility and enrollment within subpart E, through the Federal platform agreement. This reflects that eligibility and enrollment functions must be performed together in the FFE, and that neither function can be performed separately by an SBE–FPs at this time. We seek comments on this proposal.

c. Annual Open Enrollment Period (§ 155.410)

In § 155.410, we propose to amend paragraph (e), which provides the dates for the annual open enrollment period in which qualified individuals and enrollees may apply for or change coverage in a QHP. We propose to amend paragraph (e)(2) to define the open enrollment period for coverage year 2017, which would be November 1 through January 31. We also propose to amend the annual open enrollment period coverage effective date provisions in paragraphs (f)(2)(i) through (iii) to include the coverage effective dates for 2017.

We propose this time period and these coverage effective dates to remain consistent with the 2016 open enrollment period. This time frame will continue to partially overlap with the annual open enrollment period for Medicare and most employer offerings, which will benefit consumers by facilitating smooth transitions between coverage and creating process efficiencies for issuers handling enrollments and re-enrollments during the same period. We seek comments on this proposal.

We are also considering defining the open enrollment period for coverage year 2018, and seek comment on what that period should be. For example, we could incrementally shift to an earlier open enrollment period, while maintaining the same duration, such that the open enrollment period for benefit year 2018 would run from October 15, 2017 through January 15, 2018. Alternatively, we could shift to an earlier open enrollment period and shorten its duration simultaneously, such that the open enrollment period would run from October 15, 2017 through December 15, 2017. We note that open enrollment periods for health coverage typically end before the end of the year prior to the benefit year to promote full-year coverage. However, in the short run, as eligible consumers are learning about their options and the individual shared responsibility requirement and newly insured consumers are learning how to re-enroll into coverage for the next benefit year, we note that there is value in a longer open enrollment period. We would also face significant operational limitations in moving the beginning of the open enrollment period to an earlier time. However, if we do not shift the beginning of the open enrollment period to an earlier date, ending the period before the end of the year would result in a shorter open enrollment period. We seek comment on the length, start, and end of the open enrollment period for 2018 and subsequent years.

d. Special Enrollment Periods (§ 155.420)

Special enrollment periods are available to consumers under a variety of circumstances as described in § 155.420. We seek comment and any available data on existing special enrollment periods.

In addition, we have heard concerns that these special enrollment periods may be subject to abuse. We seek comment regarding this, and data, if available. Elsewhere in this document, we propose an amendment to § 155.430(b)(2)(vi) that would allow the

Exchange to initiate cancellation or retroactive termination of an enrollee's enrollment, after a determination has been made that the enrollment was due to fraudulent activity. We believe this proposal would provide us with an important tool for addressing potential gaming of these rules.

e. Termination of Coverage (§ 155.430)

Under our current rules, § 155.430(b)(1) requires an Exchange to permit an enrollee to cancel or terminate his or her coverage in a QHP following appropriate notice to the Exchange or the QHP issuer. We propose to add paragraph (b)(1)(iv) to allow an enrollee to retroactively cancel or terminate his or her enrollment in a QHP through the Exchange in the limited circumstances set forth below. For enrollees whose enrollment or continued enrollment in a QHP resulted from an error, misconduct, or fraud committed by an entity other than the enrollee, we aim to increase flexibility under the regulations to permit such enrollees to avoid the consequences of that entity's actions by canceling the QHP coverage. To this end, we propose to redesignate current paragraph (b)(2)(vi) as (b)(2)(vii) and add a new paragraph (b)(2)(vi) to permit the Exchange to cancel an enrollee's enrollment in a QHP under certain circumstances. This rule would permit cancellations of fraudulent enrollments that the Exchange discovers, even if the enrollee is never aware of the enrollment.

New paragraph (b)(1)(iv)(A) would provide that the enrollee would be permitted to retroactively terminate his or her coverage or enrollment if he or she demonstrates to the Exchange that he or she attempted to terminate his or her coverage or enrollment and experienced a technical error that did not allow the enrollee to effectuate termination of his or her coverage or enrollment through the Exchange. Such an enrollee would have 60 days after he or she discovered the technical error to request retroactive termination. This aligns with our standard 60-day window for special enrollment periods.

We propose a new paragraph (d)(9), which would provide that the retroactive termination date under paragraph (b)(1)(iv)(A) would be no sooner than 14 days after the earliest date that the enrollee could demonstrate that he or she contacted the Exchange to terminate his or her coverage or enrollment through the Exchange, unless the issuer agrees to an earlier effective date as set forth in § 155.430(d)(2)(iii). This 14-day window aligns with the regulation on voluntary, enrollee-initiated prospective terminations.

We propose in paragraph (b)(1)(iv)(B) to provide for cancellation for an enrollee who demonstrates to the Exchange that his or her enrollment in a QHP through the Exchange was unintentional, inadvertent, or erroneous and was the result of the error or misconduct of an officer, employee, or agent of the Exchange or HHS, its instrumentalities, or a non-Exchange entity providing enrollment assistance or conducting enrollment activities. Such an enrollee would have 60 days from the point he or she discovered the unintentional, inadvertent, or erroneous enrollment to request cancellation, to align with our standard 60-day special enrollment period window. In determining whether an enrollee has demonstrated to the Exchange that his or her enrollment meets the criteria for cancellation under this paragraph, the Exchange would examine the totality of the circumstances surrounding the enrollment, such as whether the enrollee was enrolled in other minimum essential coverage at the time of his or her QHP enrollment and whether he or she submitted claims for services rendered to the QHP. These factors would serve to indicate the intentions of the enrollee and whether the enrollment really was undesired and would be weighed in making a determination whether a cancellation is warranted. This approach offers a broad and fair analysis of the enrollee's intentions and balances the interests and protection of consumers with the interests of issuers. For example, we believe that, without additional evidence to the contrary, one reasonably could assume that an enrollee who was enrolled in other minimum essential coverage at the time of his or her QHP enrollment and who submitted no claims to that QHP likely did not intend to enroll in such QHP. Conversely, claims submitted by an enrollee to the QHP would weigh against the enrollee's request for cancellation because, barring contrary evidence, the Exchange would view submittal of such claims to constitute a ratification of the enrollee's contract with the QHP issuer, even if the enrollee did not intend to enroll in QHP coverage. We seek comment on what other factors are indicative of an enrollee's bona fide intent and can limit ''gaming,'' and should be considered in this analysis.

In paragraph (b)(1)(iv)(C), we propose to allow cancellations for enrollees who are enrolled in a QHP without their knowledge or consent due to the fraudulent activity of any third party, including third parties who have no connection with the Exchange. Such an enrollee would have 60 days from the point at which he or she discovered the fraudulent enrollment to request cancellation, to align with our standard 60-day special enrollment period window.

New paragraph (d)(10) would provide that for cancellation or retroactive terminations granted in accordance with paragraphs (b)(1)(iv)(B) and (C), the cancellation or termination date would be the original coverage effective date or a later date, as determined appropriate by the Exchange, based on the circumstances of the cancellation or termination.

Under our current rules, § 155.430(b)(2) allows the Exchange to initiate termination of an enrollee's coverage or enrollment in a QHP through the Exchange, and permits a QHP issuer to terminate such coverage or enrollment in certain circumstances. Amended paragraph (b)(2)(ii)(A) reflects the change to § 156.270(d) and (g) that gives an enrollee who, upon failing to timely pay premium, is receiving advance payments of the premium tax credit (APTC), a three-month grace period. The changes to § 156.270 are described in section ''Termination of Coverage or Enrollment for Qualified Individuals'' of the preamble.

We propose in new paragraph (b)(2)(vi) that the Exchange could cancel an enrollee's enrollment that the Exchange determines was due to fraudulent activity, including fraudulent activity by a third party with no connection with the Exchange.

New paragraph (d)(11) would provide that for cancellations granted in accordance with paragraph (b)(2)(vi), the cancellation date would be the original coverage effective date. The Exchange only would send the cancellation transaction following reasonable notice to the enrollee (recognizing that where no contact information is available that notice may be impossible or impracticable).

Our current guidance recognizes that at some point, the Exchange must discontinue the ability for enrollees to retroactively adjust coverage for the preceding coverage year. To this end, we are considering codifying a deadline for requesting cancellations or retroactive terminations. We seek comment on these proposals.

6. Appeals of Eligibility Determinations for Exchange Participation and Insurance Affordability Programs

a. General Eligibility Appeals Requirements (§ 155.505)

In § 155.505, we make certain proposals related to the general

eligibility appeals requirements. Currently, paragraph (b)(1) of this section states that an applicant or enrollee has the right to appeal an eligibility determination made in accordance with subpart D. This right includes the right to appeal determinations of eligibility for QHP enrollment periods, such as special enrollment periods. To clarify the scope of applicants' and enrollee's right to appeal, we are proposing to add paragraph (b)(1)(iii) which would more explicitly state that applicants and enrollees have the right to appeal a determination of eligibility for an enrollment period. This change would apply to appeals provided by the HHS appeals entity and a State Exchange appeals entity.

Similarly, we propose new paragraph (b)(5) to clarify that applicants and enrollees have the right to appeal a decision issued by the State Exchange appeals entity. Section 155.520(c) already provides that an appellant who disagrees with a decision of a State Exchange appeals entity may request an appeal to the HHS appeals entity within 30 days of the notice of appeal decision. New paragraph (b)(5) would clarify applicants' and enrollees' existing right to appeal any decision issued by a State Exchange appeals entity in accordance with § 155.545(b), in addition their right to appeal a denial of a request to vacate a dismissal made by a State Exchange appeals entity, as described in § 155.505(b)(4).

Finally, in paragraph (b)(4), we propose to correct a typographical error by replacing the word ''or'' with the word ''of,'' and to replace ''pursuant to'' with ''under,'' so the last clause of the paragraph would read, ''. . . made under paragraph (c)(2)(i) of this section. . .''. We seek comment on these proposals.

b. Appeals Coordination (§ 155.510)

We propose to revise § 155.510(a)(1) to give the appeals entity and agencies administering insurance affordability programs more flexibility in obtaining documentation and information from appellants. To minimize burden on appellants, § 155.510(a)(1) currently prohibits the appeals entity or agency administering insurance affordability programs from asking an appellant to provide information or documentation that the appellant already provided. However, when such information or documentation is not available to the appeals entity or agency, this provision may also prevent the appeals entity or agency from obtaining information that is necessary to properly adjudicate the appellant's appeal. As a result, the appeals entity is deprived of documentation that could support a decision favorable to the appellant.

Accordingly, we propose to revise paragraph (a)(1) to allow the appeals entity, the Exchange, or the agency administering insurance affordability programs to request information or documentation from the appellant that the appellant already has provided if the agency does not have access to such information or documentation and cannot reasonably obtain it. We believe this revision balances the need to minimize the burden on the appellant as well as the need to ensure that all information necessary for the appellant's appeal is available to the appeals entity, Exchange, or agency administering the insurance affordability program, which ultimately will inure to the appellant's benefit by helping to ensure a correct appeal decision and eligibility determination. We seek comment on this proposal.

c. Appeal Requests (§ 155.520)

We propose to add paragraph (d)(2)(i)(D), concerning appellants whose appeal request is determined invalid for failure to request an appeal by the date determined in paragraph (b) or (c) of this section. Currently, when an appellant's request is invalid because it is untimely, it is not possible for the appellant to cure the defect as contemplated under § 155.520(d)(2)(i)(C). Therefore, the appeals entity dismisses the appeal in accordance with § 155.530(a)(3). If the appellant makes a written request within 30 days of the date of the notice of dismissal showing good cause why the dismissal should be vacated, the appeals entity must vacate the dismissal in accordance with § 155.530(d). Accordingly, an appellant who shows good cause why his or her appeal should proceed even though the appeal request was untimely (for example, an appellant who was unable to submit a timely appeal request because he or she was hospitalized with a serious condition) currently may proceed with an appeal, but the process is circuitous.

This proposed addition of (d)(2)(i)(D) would require the appeals entity to notify an appellant that, in the event the appeal request is invalid because it was not timely submitted, the appeal request may be considered valid if the applicant or enrollee demonstrates within a reasonable timeframe determined by the appeals entity that failure to timely submit was due to exceptional circumstances and should not preclude the appeal. This would allow the appellant to demonstrate before the appeal is dismissed that failure to submit a timely appeal request was due to exceptional circumstances constituting good cause why the appeal should proceed, which would minimize burden on the appellant as well as administrative burden on the appeals entity.

The appeals entity may determine what constitutes an exceptional circumstance that should not preclude an appeal notwithstanding the appellant's failure to timely submit an appeal request. An appeals entity may, for instance, find that circumstances making timely submission impossible constitute an exceptional circumstance. A weather emergency, such as a blizzard, a hurricane or a tornado, may cause power outages making it impossible to prepare, mail, or fax appeal requests to the appeals entity. Similarly, such disasters may cause consumers to lose access to the documents they need to complete and submit appeal requests. Likewise, if a consumer suffers a catastrophic medical event and is consequently unable to submit an appeal request on time, the appeals entity may determine that this constitutes an exceptional circumstance under the proposed exception.

The appeals entity may also determine what is considered a reasonable timeframe for an appellant to demonstrate an exceptional circumstance. For example, if an appellant was unable to send an appeal request on time due to a snow storm and power outage and sent the request four months after the snow storm and power outage had been resolved, the appeals entity may find that the appellant experienced an exceptional circumstance as contemplated by this proposed rule, but that the appellant waited an unreasonable amount of time to demonstrate it. Without such flexibility for the appeals entity, appellants who experienced an exceptional circumstance would have an unlimited amount of time to request that the appeals entity consider their appeal. We seek comment on this proposal.

d. Dismissals (§ 155.530)

We propose to revise § 155.530(a)(4) to allow an appeal to continue when an appellant dies if the executor, administrator, or other duly authorized representative of the estate requests to continue the appeal. We seek comment on this proposal.

e. Informal Resolution and Hearing Requirements (§ 155.535)

In § 155.535, we propose amendments to the informal resolution and notice of hearing requirements. In § 155.535(a),

we propose a change to clarify that the requirements of the informal resolution process described in paragraphs (a)(1) through (4) apply to both the HHS appeals entity and a State Exchange appeals entity.

In § 155.535(b), we propose providing two exceptions to the requirement that the appeals entity must send written notice to the appellant of the date, time, and location or format of the hearing no later than 15 days prior to the hearing date. In paragraph (b)(1), we propose an exception when an appellant requests an earlier hearing date. Currently, the 15-day notice requirement prevents an appellant from selecting a hearing date within 15 days even if such a date is available and desired by the appellant. In paragraph (b)(2), we propose an exception to the notice requirement under paragraph (b) when a hearing date sooner than 15 days is necessary to process an expedited appeal, as described in § 155.540(a), and the appeals entity and appellant have mutually agreed to the date, time, and location or format of the hearing. If finalized, this amendment would create efficiency for the appeals process as a whole and create a more agreeable experience for the appellant. In addition, it would allow for an earlier hearing when there is an immediate need for a health service. We seek comment on these proposals.

f. Appeal Decisions (§ 155.545)

We propose several changes to § 155.545. In paragraph (b)(1), we propose to remove the third appearance of the word ''of'' to correct a typographical error. We also propose to revise paragraph (c)(1)(i) to include cross references to § 155.330(f)(4) and (5), which discuss effective dates for certain special enrollment periods described in § 155.420. This change aligns with our proposed change § 155.505(b) to clarify that applicants and enrollees have the right to appeal a determination of eligibility for an enrollment period.

Finally, we propose to revise § 155.545(c)(1)(ii) so that the coverage effective date for eligible appellants requesting a retroactive appeal decision effective date is the coverage effective date that the appellant did receive or would have received if the appellant had enrolled in coverage under the incorrect eligibility determination that is the subject of the appeal. This is consistent with the coverage effective dates consumers receive in comparable situations when given the option for retroactive coverage, such as in the case of certain special enrollment periods. We seek comment on this proposal.

g. Employer Appeals Process (§ 155.555)

We also propose to amend § 155.555(l) to give the Exchange more operational flexibility in implementing an employer appeal decision. Currently under § 155.555(l), when an employer appeal decision affects an employee's eligibility, the Exchange is directed to redetermine the employee's eligibility and the eligibility of the employee's household members, if applicable. An employer's appeal decision may affect an employee's eligibility when the employer prevails in the appeal by establishing that it does offer the employee employer-sponsored coverage that meets the minimum value standard and is affordable for the employee, and the HHS appeals entity therefore finds that the employee is not eligible for Exchange financial assistance.

We propose to amend § 155.555(l) by revising paragraph (l) and adding paragraphs (l)(1) and (2). Under proposed paragraph (l), after receipt of the notice under paragraph (k)(3) of this section, the Exchange must follow the requirements in either paragraph (l)(1) or (2) if the appeal decision affects the employee's eligibility. Under proposed paragraph (l)(1), the Exchange must promptly redetermine the employee's eligibility and the eligibility of the employee's household members, if applicable, in accordance with the standards specified in § 155.305, as currently provided in paragraph (l). Under proposed paragraph (l)(2), the Exchange must promptly notify the employee of the requirement to report changes in eligibility as described in § 155.330(b)(1). The FFE intends to implement the latter procedure to give employees the opportunity to report any additional changes in their eligibility information to help ensure the most accurate redetermination of eligibility for insurance affordability programs. We believe this amendment will also give the Exchange greater operational flexibility.

Additionally, we propose to make a technical correction to § 155.555(e)(1) by removing the cross-reference to paragraph (d)(3) of this section, which does not exist, and replacing it with paragraph (d)(1)(iii). We seek comment on these proposals.

7. Exchange Functions in the Individual Market: Eligibility Determinations for Exemptions

a. Eligibility Standards for Exemptions (§ 155.605)

We are proposing to clarify and streamline policies related to exemptions and are proposing to amend § 155.605 to reflect those changes. The proposed changes will simplify and streamline the process for members of health care sharing ministries, members of Indian tribes, and incarcerated individuals by directing consumers solely to the tax filing process to claim these exemptions. To claim one of these exemptions on a tax return, the individual needs only to file IRS Form 8965, *Health Coverage Exemptions,* with his or her tax return. Presently, the Exchange process requires that an application be submitted to the Exchange, and the Exchange review, process, and respond to the application. If the individual does not complete the Exchange application with all required information, the individual will be asked to submit the missing information before the application can be processed. The follow-up steps may result in a significant delay to the individual's application if he or she does not submit the information on a timely basis. Further, the Exchange may only grant certain exemptions on a retrospective basis so that the individual may need to submit multiple applications throughout the year. Finally, the Exchange may not grant exemptions for members of health care sharing ministries and individuals who were incarcerated for the previous year if the individual requests the exemption after December 31 of the previous year. This adds confusion when many individuals are preparing their tax returns, assessing their exemption eligibility and discovering that they can apply with the Exchange. Corresponding requirements do not exist in the tax return process; consumers simply claim the exemption on IRS Form 8965 when filing the tax return. Therefore, we propose that the Exchange would no longer make eligibility determinations for exemptions based on membership in a health care sharing ministry, membership in an Indian tribe, or incarceration status, and therefore propose to delete paragraphs (d) through (f). We propose to redesignate paragraph (g) as paragraph (d).

We also propose to add a new paragraph (e), under which we propose that certain exemptions authorized under Section 5000(A) of the Internal Revenue Code may be claimed during the tax filing process without obtaining an exemption certificate number (ECN) from the Exchange. In previous guidance, we identified these exemptions and provided that they may be claimed on a tax return without obtaining an ECN.[26] The IRS has also

[26] HHS Centers for Medicare & Medicaid Services, Shared Responsibility Guidance-Filing Threshold

Continued

published guidance identifying these exemptions, and allowing eligible individuals to claim the exemption without first obtaining an ECN.[27] These proposed regulations codify our prior guidance.

An ECN is not required for an exemption that can be claimed on a tax return. Rather, an individual can simply list the appropriate code to claim the exemption per the instructions to Form 8965. The varying requirements between the IRS and the Exchange exemption processes may cause confusion for applicants. Further, we intend to permit individuals who have already been granted an ECN from the Exchange on a continuing basis (such as for members of Federally recognized tribes or individuals eligible for services through an Indian health care provider) to use their ECN on their Federal income tax return to claim this exemption until such time that they no longer are eligible for this exemption. An individual will be able to obtain information about his or her ECN after the Exchange ceases processing tribal membership exemptions. We also propose a clarifying amendment to § 155.605(b) to remove the cross-reference to paragraphs (f)(2) and (g) and replace it with paragraphs (c)(2) and (d). We seek comment on all aspects of this proposal.

We propose to redesignate § 155.605(g), which discusses hardship exemptions, as § 155.605(d), and reorganize and revise the newly redesignated paragraph (d). In newly redesignated § 155.605(d)(1), we propose to limit the amount of time a general hardship exemption may cover to the remainder of the calendar year from the date the hardship commenced plus the next calendar year, plus the month before the hardship began. We believe that such a maximum period for the hardship exemption provides the individual with a sufficient period of time during which he or she will be covered by the exemption, and sufficient time for the individual to recover from the hardship. We propose that an individual would need to submit a new hardship exemption application to the Exchange to request subsequent hardship exemptions on the same basis, however the Exchange may use the proof of hardship submitted with the previous application as long as it is within 3 years of an individual's initial application for the hardship exemption. We propose that individuals would not be required to submit additional proof within 3 years of their initial application because we believe that this proof would be sufficiently current to support an additional exemption application. We seek comment on this proposal, in particular with respect to the timeframes—both the maximum timeframe for the length of the hardship exemption, and the 3-year timeline for submission of new supporting evidence.

Next, we propose to revise newly redesignated § 155.605(d)(2) to set out specific examples of events and circumstances that qualify an individual for a hardship exemption under the umbrella of the general set of events and circumstances described under newly redesignated § 155.605(d)(1). We note that these specific proposed criteria are not intended to limit the Exchange's ability to determine individuals' eligibility for a hardship exemption based on other criteria provided through guidance, covering a specified duration, such as the exemption available to individuals enrolled in CHIP Buy-In plans in 2014. The specific illustrative criteria we propose to add are:

- Homelessness;
- Eviction or facing eviction or foreclosure;
- Received a shut-off notice from a utility company;
- Experienced domestic violence;
- Experienced the death of a family member;
- Experienced a fire, flood or other nature or human-caused disaster that caused substantial damage to your property;
- Filed for bankruptcy;
- Experienced unexpected increases in necessary expenses due to caring for an ill, disabled or aging family member;
- Seeking categorical Medicaid eligibility under section 1902(f) of the Social Security Act (the Act) for ''209(b)'' States (codified at § 435.121);
- Seeking Medicaid coverage provided to medically needy individuals under section 1902(a)(10(C) of the Act that is not included as government-sponsored minimum essential coverage under IRS regulations and not recognized as MEC by the Secretary of HHS in accordance with the CMS State Health Official (SHO) Letter #14–002;
- Enrolled in Medicaid coverage provided to a pregnant woman that is not included as government-sponsored minimum essential coverage under IRS regulations and not recognized as minimum essential coverage by the Secretary of HHS in accordance with CMS SHO #14–002;
- Enrolled in CHIP coverage provided to an unborn child that includes comprehensive prenatal care for the pregnant mother; or
- As a result of an eligibility appeals decision the individual is eligible for enrollment in a qualified health plan through the Exchange, lower costs on the individual's monthly premiums or CSRs for a time period when the individual was not enrolled in a QHP through the Exchange. These criteria were previously laid out in Exchange guidance, and capture many of the reasons why an individual has requested a hardship exemption to date. We seek comment on this proposal.

We propose to revise newly redesignated paragraph (d)(3) to require that a hardship event or circumstance must have occurred within 3 years from the date of the individual's hardship application submitted to the Exchange. This proposed paragraph is in line with the requirement that an Exchange may only accept an application for a hardship exemption up to 3 calendar years after the month or months during which the applicant attests that the hardship occurred under § 155.610(h). The same hardship event or circumstance may qualify an individual for two ECNs that cover a period of 4 years total.

For example, assume an individual experiences a hardship event in January 2015 and submits a hardship application to the Exchange in February 2015. If the individual otherwise qualifies for the exemption, the individual may be granted an ECN spanning December 2014 through December 2016. If the individual submits a second hardship application in January 2017 noting that the exemption is requested for the same event covered by the original ECN that occurred in January 2015, the individual may be granted a second ECN that extends through December 2018.

Next, consider an individual who experiences a hardship event in January 2015 and submits a hardship application to the Exchange in January 2018. The individual is eligible for a hardship exemption from December 2014 through December 2016, and the individual may request a second ECN to cover through December 2018.

Finally, consider an individual who experiences a hardship event in January 2015 and submits a hardship application to the Exchange in January 2019. The individual is not eligible for an exemption for the January 2015 event because it happened more than 3 years from the date of the individual's exemption application. However, if the individual can show the Exchange that

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Hardship Exemption (Sept. 18, 2014), available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Filing-Threshold-Exemption-Guidance-9–18–14.pdf*.

[27] Notice 2014–76, 2014–50 I.R.B. 946 (December 8, 2014), available at *https://www.irs.gov/pub/irs-irbs/irb14–50.pdf*.

the event continued or a new hardship qualifying event occurred anytime from January 2016 to January 2019, the individual would be eligible for a hardship exemption. We seek comment on this proposal and on whether 3 years is the appropriate length of time, or whether a shorter period is warranted.

In addition, we propose to amend newly redesignated § 155.605(d)(5), which provides an exemption for a calendar year to an individual who has been determined ineligible for Medicaid for one or more months during a benefit year solely as a result of a State not implementing section 2001(a) of the Affordable Care Act. We propose to remove the requirement to obtain an eligibility determination from the individual's appropriate State Medicaid office. Instead, we propose that this exemption be made available to an individual who would be determined ineligible for Medicaid for one or more months during a benefit year solely as a result of a State not implementing section 2001(a) of the Affordable Care Act. By removing the requirement to obtain a Medicaid determination, we believe that we are reducing State administrative costs and are alleviating a significant burden on individuals who do not request this exemption until the previous calendar year has passed and are therefore unable to obtain a Medicaid determination for the previous year. We anticipate that this proposed change will simplify the process for filing an exemption application with the Exchange. We seek comment on this proposal.

Finally, we propose § 155.605(e)(4) to allow individuals to claim the exemption described in section F of I.R.S. Notice 2014–76 (Dec. 8, 2014), relating to certain individuals who reside in a State that did not expand Medicaid eligibility, on their Federal income tax return without first obtaining an ECN from the Exchange. We propose to allow this exemption to be claimed beginning for the 2015 tax year so that there is no gap in the ability for consumers to claim this exemption on a tax return.

b. Required Contribution Percentage (§ 155.605(e)(3))

Under section 5000A of the Code, an individual must have minimum essential coverage for each month, qualify for an exemption, or make a shared responsibility payment with his or her Federal income tax return. Under section 5000A(e)(1) of the Code, an individual is exempt if the amount that he or she would be required to pay for minimum essential coverage (the required contribution) exceeds a particular percentage (the required contribution percentage) of his or her actual household income for a taxable year. In addition, under § 155.605(g)(2) (redesignated as § 155.605(d)(2)), an individual is exempt if his or her required contribution exceeds the required contribution percentage of his or her projected household income for a year. Finally, under § 155.605(g)(5) (redesignated as § 155.605(d)(5)), certain employed individuals are exempt if, on an individual basis, the cost of individual coverage is less than the required contribution percentage, but the aggregate cost of individual coverage through employers exceeds the required contribution percentage, and no family coverage is available through an employer at a cost less than the required contribution percentage.

Section 5000A established the 2014 required contribution percentage at 8 percent. For plan years after 2014, section 5000A(e)(1)(D) of the Code and 26 CFR 1.5000A–3(e)(2)(ii) provide that the required contribution percentage is the percentage determined by the Secretary that reflects the excess of the rate of premium growth between the preceding calendar year and 2013, over the rate of income growth for that period.

In the 2015 Market Standards Rule (79 FR 30302), we established a methodology for determining the excess of the rate of premium growth over the rate of income growth for plan years after 2014. We also said future adjustments would be published annually in the HHS notice of benefit and payment parameters.

Under the HHS methodology, the rate of premium growth over the rate of income growth for a particular calendar year is the quotient of (x) 1 plus the rate of premium growth between the preceding calendar year and 2013, carried out to ten significant digits, divided by (y) 1 plus the rate of income growth between the preceding calendar year and 2013, carried out to ten significant digits.[28]

As the measure of premium growth for a calendar year, we established in the 2015 Market Standards Rule that we would use the premium adjustment percentage. The premium adjustment percentage is based on projections of average per enrollee employer-sponsored insurance premiums from the National Health Expenditure Accounts (NHEA), which are calculated by the CMS Office of the Actuary. [29] In § 156.130 of this proposed rule, we propose the 2017 premium adjustment percentage of 1.1325256291 (or about 13.3 percent) over the period from 2013 to 2016. This reflects an increase of about 5.1 percent for 2015–2016.

As the measure of income growth for a calendar year, we established in the 2015 Market Standards Rule that we would use per capita Gross Domestic Product (GDP), using the projections of per capita GDP used for the NHEA, which is calculated by the Office of the Actuary.

However, as noted in the 2015 Market Standards Rule (79 FR 30304), we stated that we would consider alternative measures of income and premium growth should projections of those measures become available. As part of its projections of National Health Expenditures, the Office of the Actuary published projections of personal income (PI) for the first time in September 2014 and subsequently in July 2015. As a result, we are considering substituting this new measure of per capita PI for per capita GDP in the calculation for the required contribution percentage. We believe per capita PI better aligns with the statutory intent of measuring the income of an individual than per capita GDP. The projections of PI published by the Office of the Actuary are consistent with the measure published by the Bureau of Economic Analysis, which reflects income received by individuals from all sources, including income from participation in production. Specifically, it includes compensation of employees (received), supplements to wages and salaries, proprietors' income with adjustments for inventory valuation and capital consumption, personal income receipts on assets, rental income, and personal current transfer receipts, less contributions for government social insurance.

The Office of the Actuary's PI projection is generated using the University of Maryland's Long Term Inter-industry Forecasting Tool. The Long Term Inter-industry Forecasting Tool model is a macro-economic model that is based on the historical relationships that exist between PI growth, GDP growth, and changes in other macro-economic variables. For instance, the correlation between PI and GDP is influenced by fluctuations in

[28] We also defined the required contribution percentage at § 155.600(a) to mean the product of 8 percent and the rate of premium growth over the rate of income growth for the calendar year, rounded to the nearest one-hundredth of one percent.

[29] For any given year the premium adjustment percentage is the percentage (if any) by which the most recent NHEA projection of per enrollee employer-sponsored insurance premiums for the current year exceeds the most recent NHEA projection of per enrollee employer-sponsored insurance premiums for 2013.

taxes and government transfer payments, depreciation of capital stock, and retained earnings and transfer payments of private business.[30] Estimates of GDP in the NHE projections reflect economic assumptions from the 2015 Medicare Trustees Report and are updated to incorporate the latest available consensus data from the monthly Blue Chip Economic Indicators. These same economic assumptions are used for producing projections of PI and employer-sponsored insurance premiums, so using this estimate will generate an internally consistent estimate of the growth in premiums relative to growth in income. We welcome comments on whether to substitute per capita PI for per capita GDP in the calculation to establish the rate of income growth for the required contribution percentage.

We will continue to consider other changes to the measures of income per capita and premium growth as additional information becomes available and as we gain experience with the current measures, and seek comment on other indices that we should develop or consider. For example, we have considered a measure of per capita personal income that does not include government transfers such as social security, Medicare, and Medicaid. We welcome comments on whether we should seek to develop such a measure of income, and whether we should use this or another alternative measure to establish the rate of income growth for the required contribution percentage.

Since updating the required contribution percentage for 2017 requires calculating the cumulative difference between premium growth and income growth between the preceding calendar year and 2013, we propose to replace per capita GDP with per capita PI for all years beginning in 2013 and then calculate cumulative income growth through 2016. We propose this retrospective approach as it allows for consistency across all years with the most recent data available. We note that potential future changes based on new data that are not available for 2013 may be made on a prospective basis.

Under this proposal, using the NHEA data, the rate of income growth for 2017 is the percentage (if any) by which the most recent projection of per capita PI for the preceding calendar year ($49,875 for 2016) exceeds the per capita PI for 2013, ($44,925), carried out to ten significant digits. The total rate of income growth for the 3-year period from 2013–2016 is estimated to be 1.1101836394 (or about 11.0 percent). This reflects an increase of about 2.68 percent for 2015–2016.

Thus, using the proposed 2017 premium adjustment percentage, the excess of the rate of premium growth over the rate of income growth for 2013–2016 is 1.1325256291/1.1101836394, or 1.0201245892. This results in a required contribution percentage for 2017 of 8.00*1.0201245892, or 8.16 percent, when rounded to the nearest one-hundredth of one percent, an increase of 0.37 percentage points from 2016. The required contribution percentage is also used for 36B(b)(3)(A) and (c)(2)(C).

c. Eligibility Process for Exemptions (§ 155.610)

In § 155.610, we propose to delete a cross-reference and add a paragraph about the handling of incomplete exemption applications received by the Exchange.

First, we propose to strike the cross-reference to paragraph (f) in § 155.610(h)(1) as we propose elsewhere in this proposed rule that the Exchange will no longer process exemption applications related to membership in an Indian tribe.

Second, we propose to add new paragraph § 155.610(k) regarding how the Exchange will handle incomplete exemption applications submitted to the Exchange. We propose that the Exchange will handle incomplete exemption applications similarly to how it handles incomplete health coverage applications under § 155.310(k). Specifically, when the Exchange receives an application that does not contain sufficient information to make an eligibility determination, the Exchange will: (1) Provide notice to the applicant indicating that information necessary to complete an eligibility determination is missing, specifying the missing information, and providing instructions on how to provide the missing information; (2) provide the applicant with a period of no less than 10 and no more than 90 days starting from the date on which the notice is sent to the applicant to provide the information needed to complete the application to the Exchange; and (3) if the Exchange does not receive the requested information, the Exchange will notify the applicant that the Exchange will not process the application and will provide appeal rights to the applicant. We seek comment on this proposal.

d. Verification Process Related to Eligibility for Exemptions (§ 155.615)

In § 155.615, we propose deletions related to exemptions that we are proposing elsewhere in this proposed rule to remove from the Exchange exemption eligibility determination process, and an addition to align with newly added paragraphs pertaining to a general hardship exemption.

First, we propose conforming edits to delete § 155.615(c), (d), (e), and (f)(3) in accordance with our proposal to remove the option to obtain an ECN from the Exchange for certain exemptions.

Next, we propose to add paragraph § 155.615(c)(2) to align with the 3-year time frame requirement proposed in § 155.605(d)(3). We propose that if the hardship-qualifying event or circumstance in § 155.605(d)(1) began more than 3 years from the date the exemption application was submitted, and if the event or circumstance continued beyond the initial 3-year period, the Exchange must verify the applicant continued to experience the hardship to which he or she is attesting during a period that is within 3 years from the date of the exemption application submitted under § 155.605(d)(1). We believe that this requirement places minimum burden on the applicant while ensuring that the Exchange appropriately meets the requirements in paragraph (c)(1) of this section under the proposed 3-year time frame in § 155.605(d)(3). We seek comment on this proposal.

e. Options for Conducting Eligibility Determinations for Exemptions (§ 155.625)

We propose to amend § 155.625(a)(2) and (b) to remove the deadline after which a State Exchange was to be required to process exemption applications for residents of the State by the start of open enrollment for 2016, and to permit an Exchange to adopt an exemption eligibility determination made by HHS indefinitely. Based on HHS's operation of this service to date, we have determined that the HHS exemption option is an efficient process for State Exchanges that has minimized confusion for consumers. This proposed rule follows an FAQ published on July 28, 2015 in which HHS stated that it will not take any enforcement action against State Exchanges that continue to use the HHS service for exemptions beyond the start of open enrollment for 2016. Therefore, we propose to delete paragraphs (b)(1), (2) and (3). We seek comment on this proposal.

[30] Projections of PI and GDP are available from Table 1 at: Centers for Medicare & Medicaid Services. National Health Expenditure Data: Projected. *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.*

8. Exchange Functions: Small Business Health Options Program (SHOP)

a. Functions of a SHOP (§ 155.705)

Sections 155.705(b)(2) and (3) set forth regulations related to employer choice in SHOPs. We are proposing to add new paragraphs (b)(3)(viii) and (ix) to specify that the FF–SHOPs would provide additional options for employer choice for plan years beginning on or after January 1, 2017.

For plan years beginning in 2015, employers offering coverage in certain FF–SHOP States have two options for providing coverage: they can offer a single plan or they can offer ''horizontal'' choice, in which an employer selects a single actuarial value coverage level and makes all plans at that coverage level available to the qualified employees. These same two options are available to participating employers in all FF–SHOP States for plan years beginning on or after January 1, 2016. For plan years beginning on or after January 1, 2017, we propose to add paragraphs (b)(3)(viii) and (ix) to this section to add an additional employer choice option available to consumers participating in FF–SHOPs. We are proposing to add a ''vertical choice'' option for QHPs and SADPs under which employers will be able to offer qualified employees a choice of all plans across all available levels of coverage from a single issuer, for plan years beginning on or after January 1, 2017. We anticipate that this ''vertical choice'' option would be appealing to employers because it gives employees greater flexibility across coverage levels, and that it may encourage more issuers to participate in SHOPs because issuers would be able to offer all of their plans to employees. Issuers may also prefer this option because it minimizes the risk of adverse selection by limiting choices to their own plans. By offering multiple plans to an employer, the issuer may be more likely to enroll a greater share of the employer's group than if multiple issuers offering coverage in a single coverage level were vying for members of the group. By doing so, the issuer would be likely to enroll a more diverse risk pool from the employer's group, minimizing the risk of adverse selection. We note that existing SHOP regulations at § 155.705(b)(3)(i)(B) and (b)(3)(ii)(B) provide State-based SHOPs with the flexibility to provide employers with vertical choice or other options for providing employer choice in addition to ''horizontal'' choice, and these amendments would not affect State-based SHOPs' flexibility in this regard.

We are also seeking comment on whether the FF–SHOPs should make other employer choice options available. For example, we are considering allowing participating employers to select an actuarial value level of coverage, after which employees could choose from plans available at that level and at the level above it. We also seek comment on whether to give the State in which the FF–SHOP is operating an opportunity to recommend whether the FF–SHOP in that State should implement any additional model of employer choice. Under this approach, a State regulatory agency, such as the State Department of Insurance, could submit a letter to the Secretary with a recommendation for the employer choice models that should be offered in their State, based on the additional models of employer choice the FF–SHOP has made available. The FF–SHOP would then evaluate the State's recommendation and determine whether to make the additional models of employer choice available in the State. In all States, the FF–SHOPs would continue to give employers the option of offering a single QHP (or SADP) as well as the option of offering a choice of all QHPs (or SADPs) at a single actuarial value level of coverage, and States would not be given an opportunity to recommend that these options not be implemented in their State.

We also propose adding a new § 155.705(b)(3)(x) to provide that the employer choice models that would be available for SBE–FPs utilizing the Federal platform for SHOP enrollment functions would be the ones that are available through the FF–SHOP platform, because employer choice is an integral part of the FF–SHOP platform's enrollment functionality and system build. If we finalize an approach under which States with an FF–SHOP would be given an opportunity to recommend whether the FF–SHOP in that State should implement any additional models of employer choice that would ultimately be finalized as a result of these proposals, the same opportunity would be made available to a State with an SBE–FP.

We propose to amend paragraph (b)(4)(ii)(B) to specify the timeline under which qualified employers in a FF–SHOP must make initial premium payments. Specifically, we are proposing to add paragraph (b)(4)(ii)(B)(*1*) to specify that in the FF-SHOPs, payment for the group's first month of coverage must be received by the premium aggregation services vendor on or before the 20th day of the month prior to the month that coverage begins. This means electronic payments must be completed or the premium aggregation services vendor must have receipt of any hard copy check on or before the 20th day of the month prior to the month that coverage would begin. HHS currently advises employers participating in FF–SHOPs to submit initial premium payments electronically by the 15th of the month prior to the coverage effective date to ensure that there is sufficient time for the payment to be cleared. Selecting the 20th of the month provides sufficient time to cancel coverage prior to the effective date. Under this proposal, if an initial premium payment is not received by the premium aggregation services vendor on or before the 20th day of the month prior to the month that coverage would begin, coverage would not be effectuated. If this happens, the employer could apply to purchase coverage that would be effective at the beginning of another month during the year, as coverage would not have been effectuated. The group would not need to submit a new application, but would need to select a new coverage effective date. Therefore, the grace period and reinstatement opportunities under § 155.735(c)(2) that are provided to groups that do not make timely payments after coverage has taken effect are not relevant in this context, and we are proposing amendments to the introductory language of § 155.735(c)(2) to reflect this.

In circumstances where an FF–SHOPs would be retroactively effectuating coverage for qualified employer groups, the FF–SHOP would need to receive payment prior to effectuating coverage. We seek comment on the timing of when premium payment must be received by an FF–SHOP when coverage is effectuated retroactively. We are considering a policy under which payments for the first month's coverage and all months of the retroactive coverage would have to be received and processed no later than 30 days after the event that triggers the eligibility for retroactive coverage. We believe 30 days would provide sufficient time for groups to make these payments.

In paragraph (b)(4)(ii)(C)(*2*) of this section, we propose to correct a cross reference to § 155.705(b)(4)(ii)(B)(*1*) that should have been updated to cross-reference § 155.705(b)(4)(ii)(C)(*1*) when § 155.705(b)(4)(ii)(A) was added in the 2016 Payment Notice.

We also propose amendments to § 155.705(b)(11)(ii), which governs employer contributions to premiums in FF–SHOPs and applies to both medical and dental plans. Section 155.705(b)(11)(ii) currently states that the FF–SHOP ''must use'' the reference plan contribution methodology

currently set forth at § 155.705(b)(11)(ii). We propose to amend this provision to provide for FF–SHOPs to use a ''fixed contribution methodology,'' in addition to the reference plan methodology set forth in the current regulation. The amendments would specify that when an employer decides to offer a single plan to qualified employees, the employer would be required to use the fixed contribution methodology. Specifically, when offering a single plan, the employer would contribute a fixed percentage of the plan's premium for each qualified employee, and (if applicable) for each dependent of a qualified employee. This policy for employers offering a single plan is consistent with what was described in the preamble to the Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Small Business Health Options Program rulemaking (78 FR 33233), in which we explained that when a choice of plans is not available to the employee, the single QHP offered by the employer would be the reference plan under the reference plan methodology described in the current regulation. See 78 FR 33236. While the proposed methodology would be consistent with our interpretation of the current regulation in circumstances where a choice of plans is not offered, we are proposing to codify how the contribution methodology would be handled operationally in those circumstances. Additionally, we propose to permit employers to choose between the reference plan contribution methodology set forth in the current regulation and the proposed fixed contribution methodology when offering a choice of plans. When offering a choice of plans, an employer opting for the fixed percentage contribution methodology would contribute a fixed percentage of the premiums across all plans in which any qualified employee and, if applicable, any dependent of a qualified employee, is enrolled. The dollar amount of the fixed percentage contribution would vary from enrollee to enrollee based on their age and the plan they choose. We believe that offering these two employer contribution methodologies to employers offering a choice of plans would provide employers with flexibility to contribute to their qualified employees' plans in a manner that is appropriate for the group. We are also proposing to add language to § 155.705(b)(11)(ii) explaining that a tobacco surcharge, if applicable, would be added to the monthly premium after the employer contribution is applied to the premium so that the financial impact of the surcharge is borne by the tobacco user, as opposed to being shared with the employer or other enrollees. We also propose to streamline the discussion of the reference plan contribution methodology described in § 155.705(b)(11)(ii), and propose removing § 155.705(b)(11)(ii)(D) because the FF–SHOPs are currently not able to support basing employer contributions on calculated composite premiums.

We seek comment on these proposals.

b. Eligibility Determination Process for SHOP (§ 155.715)

We propose to amend § 155.715(g)(1), which sets forth what a SHOP must do if a qualified employer withdraws from the SHOP, to distinguish between terminations of enrollment and terminations of coverage. This regulation currently provides that, if an employer ceases to purchase coverage through a SHOP, the SHOP must ensure that each QHP terminates the coverage of the qualified employee who is enrolled in the QHP through the SHOP. Consistent with guaranteed availability and guaranteed renewability, coverage purchased through a SHOP might in many circumstances continue outside a SHOP in a manner no longer considered to be enrollment through the SHOP. Therefore, we propose to specify that the termination described in this paragraph would be a termination of the employer group's enrollment through the SHOP, rather than a termination of the group's coverage. For example, in many circumstances, an employer may offer to continue the same coverage outside of the SHOP, in which case the issuer should not terminate the coverage.

We seek comment on this proposal.

c. Enrollment Periods Under SHOP (§ 155.725)

Section 155.725(c) discusses the annual employer election period. We are proposing to delete paragraph (c)(1) because it is outdated, redesignate current paragraph (c)(2) as (c) introductory text and redesignate the remaining paragraphs to reflect the new structure of paragraph (c).

We propose to redesignate § 155.725(e) as § 155.725(e)(1) and add paragraph (e)(2). To provide adequate time for qualified employees in FF–SHOPs to make coverage selections during their annual open enrollment period, we propose adding paragraph (e)(2) to specify that qualified employers in the FF–SHOP must provide qualified employees an annual open enrollment period of at least one week. This proposed amendment, like all of § 155.725(e), would apply only with respect to renewals.

We are also proposing amendments to § 155.725(h)(2) to specify that the event that triggers a group's coverage effective date in a FF–SHOP is not the plan selections of the individual enrollees, but the employer's submission of all plan selections for the group (which we call the group enrollment), and to allow employers to opt for a coverage effective date later than the standard dates provided for under the rule. The proposed amendments would permit qualified employers to set enrollment periods for their qualified employees that could include plan selections both before and after the 15th of a month, and would also permit employers to select a coverage effective date later than the standard dates provided for under the rule. Employers would be able to select a coverage effective date up to 2 months in advance, provided that small group market rates are available for the quarter in which the employer would like coverage to take effect. This would allow employers to maximize their enrollment periods so that they could begin the SHOP enrollment process as soon as small group market rates are available for the quarter in which they would like coverage to take effect. Under the proposed amendments, if an employer submits its group enrollment by the 15th day of any month, the FF–SHOP would ensure a coverage effective date of the first day of the following month, unless the employer opts for a later effective date for which rates are available. If an employer submits its group enrollment between the 16th day of the month and the last day of the month, we propose that the FF–SHOP must ensure a coverage effective date of the first day of the second following month, unless the employer opts for a later effective date for which rates are available.

We propose to amend § 155.725(i)(1), which currently provides that if a qualified employee enrolled in a QHP through a SHOP remains eligible for coverage, that qualified employee will remain in the QHP selected the previous year, unless certain exceptions apply. We propose to provide that a SHOP be permitted to, but need not, provide for auto-renewals of qualified employees, and also propose to revise the language of the provision for consistency with our interpretation of guaranteed renewability. If a SHOP does not provide for auto-renewals for qualified employees, qualified employees would have to review and provide a response to the employer's renewal offer of coverage. If auto-renewal is available,

qualified employees need not take any action to continue in the prior year's coverage through the SHOP. We are proposing this amendment to reflect current operational capabilities in the FF–SHOPs.

Additionally, we propose to amend paragraph (j)(2)(i) of this section to remove a reference to § 155.420(d)(10), which was deleted in the 2016 Payment Notice. We also propose to amend the paragraph to specify that there would not be a SHOP special enrollment period when a qualified employee or dependent of a qualified employee experiences an event described in § 155.420(d)(1)(ii), which provides for a special enrollment period for individuals enrolled in a non-calendar-year group health plan.

We seek comment on these proposals.

d. Termination of SHOP Enrollment or Coverage (§ 155.735)

For the reasons discussed above in the preamble discussion of our proposed amendments to § 155.705(b)(4), we are proposing to modify the introductory language of § 155.735(c)(2) to specify that the provisions related to termination of employer group health coverage for non-payment of premiums in FF–SHOPs under paragraph (c)(2) would not apply to premium payments for the first month of coverage.

We are also proposing amendments to § 155.735(d). Under existing regulations at § 155.735(d)(2), terminations of FF–SHOP coverage or enrollment are effective on the last day of the month in which the FF–SHOP receives notice for enrollees that change from one QHP to another during the employer's annual open enrollment period or during a special enrollment period. We propose that if an enrollee changes from one QHP to another during the annual open enrollment period or during a special enrollment period, the last day of coverage would be the day before the effective date of coverage in the enrollee's new QHP. We believe that this would prevent any instances of double coverage as well as avoid a gap in coverage.

We also propose to require at § 155.735(d)(2)(iii) that the FF–SHOPs send advance notices to qualified employees before their dependents age off of their plan. This notice would be sent 90 days in advance of the date when the child dependent enrollee is no longer eligible for coverage under the plan the employer purchased through the FF–SHOP because he or she has reached the maximum child dependent age for the plan. The notice would include information about the plan the dependent is currently enrolled in, the date the dependent would age off the plan, and information about next steps. In the FF–SHOPs, consistent with current § 155.735(d)(2) and proposed § 155.735(d)(2)(i), a dependent aging off of the plan loses eligibility for dependent coverage at the end of the month of the dependent's 26th birthday or at the end of the month in which the issuer has set the maximum dependent age limit (but in some cases might have the option to keep the coverage for a period of time after that date under applicable continuation coverage laws). This notice is intended to be a courtesy notice as enrollees would still receive a termination notice when their coverage through the SHOP is terminating.

e. SHOP Employer and Employee Eligibility Appeals Requirements (§ 155.740)

In § 155.740, we make certain proposals relating to SHOP appeals. We propose to amend paragraphs (c)(2) and (d)(2) to provide that employers and employees may file an appeal not only if a SHOP fails to provide an eligibility determination in a timely manner but also if a SHOP fails to provide timely notice of an eligibility determination, in accordance with § 155.715(e) and (f). We propose these amendments in order to better align the SHOP appeals provisions with individual market Exchange appeals. We note that the FF–SHOPs provide the notice of eligibility automatically when an application is submitted. For the FF–SHOPs, the date of eligibility determination and eligibility notice are generally the same date.

We also propose to amend paragraph (l)(3) to allow employers and employees who successfully appeal a denial of SHOP eligibility to select whether the effective date of coverage or enrollment through the SHOP under their appeal decision will be retroactive to the effective date of coverage or enrollment through the SHOP that the employer or employee would have had if they had correctly been determined eligible, or prospective from the first day of the month following the date of the notice of the appeal decision. The current version of paragraph (l)(3) requires all SHOP appeal decisions to be retroactive to the date the incorrect eligibility determination was made. This proposed change would grant employers and employees added flexibility regarding the effective date of coverage or enrollment through the SHOP under their appeal decision and would be better aligned with current and proposed policy for individual market Exchange appeals. For example, an employer or employee would have flexibility under this proposal to opt for a prospective effective date because he or she did not want to pay retrospective premiums. We also propose to revise paragraph (l)(3) to specify that if eligibility is denied under an appeal decision, the effective date of the coverage or enrollment through the SHOP under the appeal decision would be the first day of the month following the date of the notice of the appeal decision. We seek comment on these proposals.

9. Exchange Functions: Certification of Qualified Health Plans

a. Certification Standards for QHPs (§ 155.1000)

In the first few years of FFE operations, HHS has generally used an ''open market'' approach to QHP certification, accepting plans that met the minimum QHP certification criteria. As the new QHP market developed, it has been valuable to maintain predictability for issuers, and that remains an important consideration. For example, elsewhere in this rulemaking, we propose codifying and making transparent standards related to network adequacy. At the same time we are exploring the most useful tools to ensure that QHPs offer consumers a quality product. In this section, we seek comment on a means of improving product value by using the authority to deny certification to QHP applications.

1. Denial of Certification

Section 1311(e)(1)(B) of the Affordable Care Act states that Exchanges may certify a health plan as a QHP if ''(A) such health plan meets the requirements for certification as promulgated by the Secretary . . . and (B) the Exchange determines that making available such health plan through such Exchange is in the interests of qualified individuals and qualified employers.'' Section 1311(e)(1)(B) thereby affords Exchanges the discretion to deny certification of QHPs that meet minimum QHP certification standards, but are not ultimately in the interests of qualified individuals and qualified employers. We interpret the ''interest'' standard to mean QHPs should provide quality coverage to consumers to meet the Affordable Care Act's goals.

Section 155.1000 provides Exchanges with broad discretion to certify health plans that otherwise meet the QHP certification standards specified in part 156. HHS will continue to focus denials of certification in the FFEs based on the ''interest of the qualified individuals and qualified employers'' standard to

cases involving the integrity of the FFEs and the plans offered through them. Examples of issues that could result in non-certification of a plan include concerns related to an issuer's material non-compliance with applicable requirements, an issuer's financial insolvency, or data errors related to QHP applications and data submissions. Under this approach, HHS could consider an assessment of past performance, including with respect to oversight concerns raised through compliance reviews and consumer complaints received and the frequency and extent of any data submission errors. HHS would adopt a measured approach in exercising this authority that would take into consideration several factors, including available market competition and the availability of operational resources.

As we consider this approach, we anticipate seeking more specific comment. We seek comment on this proposal generally, and on these and any other factors HHS should consider when evaluating QHPs to determine if they meet the interests of consumers and businesses. HHS would also ensure any future policy changes do not interfere with State activities. We seek comments, specifically from States and other stakeholders, on this aspect of the proposal.

We note that the OPM has the sole discretion for contracting with multi-State plans and as such retains the authority to selectively contract with multi-State plans.

G. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

1. Standardized Options

a. Standardized Option Definition (§ 156.20)

The Affordable Care Act gives Exchanges considerable flexibility in certification and oversight of QHPs. An excessive number of health plan options makes consumers less likely to make any plan selection, more likely to make a selection that does not match their health needs, and more likely to make a selection that leaves them less satisfied. In studies of consumer behavior in Medicare Part D, Medicare Advantage, and Medigap, a choice of 15 or fewer plans was associated with higher enrollment rates, while a choice of 30 or more plans led to a decline in enrollment rates.[31] In 2015, across the 37 Exchanges using the HealthCare.gov platform, the number of health plan choices available per county varied from 2 to 54 plans at the bronze level, 2 to 73 plans at the silver level, and 1 to 43 plans at the gold level.[32] Our experience in the first two open enrollment periods suggests that many consumers, particularly those with a high number of health plan options, find the large variety of cost-sharing structures available on the Exchanges difficult to navigate.

We believe that standardized options will provide these consumers the opportunity to make simpler comparisons of plans offered by different issuers within a metal level. Consumers will be able to focus their decision making on the providers in the plan networks, premiums, benefits, and quality, and will not be required to make complex tradeoffs among cost-sharing differences among a large number of plans. Taken together, standardized options, EHB, AV, and QHP certification standards can significantly simplify consumers' ability to compare plans and make informed choices.

To simplify the consumer plan selection process, HHS is proposing to establish ''standardized options'' in the individual market FFEs. These plans would have standardized cost sharing for a key set of EHB that comprise a large percentage of the total allowable costs for an average enrollee. We propose that issuers would not be required to offer standardized options in 2017 and would retain the flexibility to offer non-standardized plans, but we are considering ways that standardized options, when certified by an FFE, could be displayed on HealthCare.gov in a manner that makes it easier for consumers to find and identify them, including distinguishing them from non-standardized plans.

We propose cost-sharing structures for standardized options at the bronze, silver (and associated silver cost-sharing reduction plan variations), and gold levels of coverage. At § 156.20, we propose adding a definition for standardized option. A standardized option would be defined as a QHP with a standardized cost-sharing structure specified by HHS and that is offered for sale through an individual market FFE (see Table 9 for proposed models). We envision standardized options to include a single provider tier, a fixed in-network deductible, a fixed annual limitation on cost sharing, and standardized copayments and coinsurance for a key set of EHB that comprise a large percentage of the total allowable costs for an average enrollee. We seek comment on this proposal.

b. Standardized Option Design Principles

We have designed one bronze standardized option, one silver standardized option, one standardized option for each silver CSR plan variation, and one gold standardized option. We are not proposing a platinum standardized option because only a small proportion of QHP issuers in the FFEs offered platinum plans in 2015. Silver plans are the most common and popular plans in the FFEs.[33] As such, we encourage issuers to offer at least one standardized option at the silver level of coverage (along with the associated standardized silver CSR plan variations) to simplify the consumer shopping experience for the greatest number of enrollees. We intend to propose standardized option changes annually. We seek comment on these proposals.

c. General Features of the Standardized Options

To minimize market disruption, we have designed the standardized options to be as similar as possible to the most popular 2015 FFE QHPs (based on enrollment), and we have sought a cost-sharing structure that would generally not raise premiums. In arriving at these standardized option designs, we also consulted the standardized option designs offered in the SBEs that have provided standardized plans since the 2014 plan year (California, Connecticut, Massachusetts, New York, Oregon, and Vermont).

i. Drug Formularies

We propose that standardized options have the four drug tiers currently utilized in our consumer-facing applications at this time—generic, preferred brand, non-preferred brand, and specialty drug tiers. However, we propose to allow issuers to offer additional lower-cost tiers if desired. Slightly more than half (56 percent) of the proposed 2016 FFE QHPs have more than four drug tiers. We seek comment on this design element.

[31] Chao Zhou and Yuting Zhang, ''The Vast Majority Of Medicare Part D Beneficiaries Still Don't Choose The Cheapest Plans That Meet Their Medication Needs.'' *Health Affairs,* 31, no.10 (2012):2259–2265.

[32] The average number of plans available per county in 2015 were: 12 bronze plans, 15 silver plans, and 9 gold plans. Available at: *https://www.cms.gov/cciio/resources/data-resources/marketplace-puf.html.*

[33] In 2015, across the FFEs, there were a total of: 263 catastrophic, 1864 bronze, 2500 silver, 1774 gold, and 551 platinum plans. Available at: *https://www.cms.gov/cciio/resources/data-resources/marketplace-puf.html.*

ii. Provider Tiers

We propose that standardized options have no more than one in-network provider tier. Varying cost sharing by provider tier affects the actuarial value of a plan, making it difficult to standardize a cost-sharing structure. Further, only 14 percent of FFE enrollees are currently enrolled in QHPs with more than one in-network tier, and only 6 percent of enrollees are covered by an issuer that does not offer a single-tier plan in addition to a multi-tier plan in the same county. We seek comment on this design element.

iii. Deductible-Exempt Services

In designing the standardized options, we seek to exempt from the deductible certain routine services, such as primary care, specialist visits (at the silver and gold metal levels), and generic drugs, to ensure that access to coverage translates into access to care for routine and chronic conditions and that enrollees receive some up-front value for their premium dollars. Again, in terms of this feature, we designed the standardized options to be as similar as possible to the most popular 2015 FFE QHPs (based on enrollment). Among those 2015 FFE QHPs, over 85 percent of silver plan enrollees and over 50 percent of bronze plan enrollees selected plans that cover certain services prior to application of the deductible. (The figure for gold plan enrollees was over 90 percent. However, many gold plans have a $0 deductible, for which the concept of deductible-exempt services would not be meaningful.) Primary care and generic drugs are the services most likely to be covered without a deductible at all three metal levels. Other services that are also likely to be covered prior to the deductible, particularly by silver and gold plans, include specialist visits and mental/behavioral health and substance use disorder outpatient services. We seek comment on this design element.

iv. Copayment vs. Coinsurance

We sought to balance consumer preference for copayments over coinsurance with the potential impact on premiums. Research shows that consumers often prefer copayments to coinsurance because the former are more transparent and make it easier for consumers to predict their out-of-pocket costs. On the other hand, setting fixed copayments on a national level could lead to disparate premium effects due to regional and issuer-specific cost differences. We seek comment on this design element.

d. Specific Standardized Option Designs

The proposed 2017 bronze standardized option closely resembles a catastrophic plan, with a few key exceptions. The plan has a $6,650 deductible, an annual limitation on cost sharing equal to the maximum allowable annual limitation on cost sharing for 2017 (proposed to be $7,150), and 50 percent coinsurance. Primary care visits (for the first three visits) and mental health/substance use outpatient services are exempt from the deductible, and have a copayment of $45. Generic drugs are also exempt from the deductible and have a copayment of $35. Note that for all standardized options, cost-sharing rules for preventive services under § 147.130 apply (we do not list this benefit category in Table 9).

The proposed 2017 silver standardized option has a $3,500 deductible, an annual limitation on cost sharing equal to the maximum allowable annual limitation on sharing for 2017, and a 20 percent enrollee coinsurance rate. Primary care visits, mental health/substance use outpatient services, specialist visits, urgent care visits, and all drug benefits are exempt from the deductible, and all of the deductible-exempt benefits have copayments instead of co-insurance, except for specialty drugs, which are subject to a 40 percent coinsurance rate. Emergency room services are subject to the deductible, with a $400 copayment applicable after the deductible.

The proposed 2017 silver cost-sharing reduction standardized options reduce all cost sharing parameters successively to meet the 73 percent, 87 percent, and 94 percent AV requirements. Where possible, the cost-sharing reduction standardized options and the non-cost-sharing reduction standardized silver option maintain similar differentials between the cost sharing for certain benefits like primary care and specialty visits.

The proposed 2017 gold standardized option has a $1,250 deductible, a $4,750 annual limitation on cost sharing, and a 20 percent enrollee coinsurance rate. Primary care visits, mental health and substance use outpatient services, specialist visits, urgent care visits, and all drug benefits are not subject to the deductible. All of the benefits not subject to the deductible have copayments except for specialty drugs. We seek comment on these designs, in particular with respect to whether particular cost-sharing elements, such as deductibles or copayments for particular services, should be modified.

TABLE 9—PROPOSED 2017 STANDARDIZED OPTIONS

	Bronze	Silver	Silver 73% actuarial value variation	Silver 87% actuarial value variation	Silver 94% actuarial value variation	Gold
Actuarial Value (%)	61.8	71.00	73.55	87.47	94.3	79.98.
Deductible	$6,650	$3,500	$3,000	$700	$250	$1,250.
Annual Limitation on Cost Sharing.	$7,150	$7,150	$5,700	$2,000	$1,250	$4,750.
Emergency Room Services.	50%	$400 (copay applies only after deductible.	$300 (copay applies only after deductible).	$150 (copay applies only after deductible).	$100 (copay applies only after deductible).	$250 (copay applies only after deductible).
Urgent Care	50%	$75 (*)	$75 (*)	$40 (*)	$25 (*)	$65 (*).
Inpatient Hospital Services.	50%	20%	20%	20%	5%	20%.
Primary Care Visit	$45 (* first 3 visits, then subject to deductible and 50% coinsurance).	$30 (*)	$30 (*)	$10 (*)	$5 (*)	$20 (*).
Specialist Visit	50%	$65 (*)	$65 (*)	$25 (*)	$15 (*)	$50 (*).
Mental Health/Substance Use Disorder Outpatient Services.	$45 (*)	$30 (*)	$30 (*)	$10 (*)	$5 (*)	$20 (*).

TABLE 9—PROPOSED 2017 STANDARDIZED OPTIONS—Continued

	Bronze	Silver	Silver 73% actuarial value variation	Silver 87% actuarial value variation	Silver 94% actuarial value variation	Gold
Imaging (CT/PET Scans, MRIs).	50%	20%	20%	20%	5%	20%.
Rehabilitative Speech Therapy.	50%	20%	20%	20%	5%	20%.
Rehabilitative OT/PT	50%	20%	20%	20%	5%	20%.
Laboratory Services	50%	20%	20%	20%	5%	20%.
X-rays	50%	20%	20%	20%	5%	20%.
Skilled Nursing Facility.	50%	20%	20%	20%	5%	20%.
Outpatient Facility Fee.	50%	20%	20%	20%	5%	20%.
Outpatient Surgery Physician/Surgical.	50%	20%	20%	20%	5%	20%.
Generic Drugs	$35 (*)	$10 (*)	$10 (*)	$5 (*)	$3 (*)	$10 (*).
Preferred Brand Drugs.	50%	$50 (*)	$50 (*)	$25 (*)	$5 (*)	$30 (*).
Non-Preferred Brand Drugs.	50%	$100 (*)	$100 (*)	$50 (*)	$10 (*)	$75 (*).
Specialty Drugs	50%	40% (*)	40% (*)	30% (*)	25% (*)	30% (*).

(*) = not subject to the deductible.

We propose that an issuer may offer multiple plans through an FFE for each standardized option within a service area when the plans are meaningfully different, such as offering an HMO standardized option and a PPO standardized option at a certain metal level. We seek comment on this proposal.

To reduce operational complexity, we do not propose to vary the standardized options by State or region. Instead, we propose one set of standardized options for all FFEs, including those in which States perform plan management functions. We recognize that some States regulate the level of cost sharing applied to certain benefits, such as emergency room services and specialty drugs. We invite comment from States and other stakeholders on the proposed standardized options, and how they may interact with State-specific cost-sharing laws or regulations, as well as any potential options for incorporating State cost-sharing requirements into the standardized option framework.

We do not propose to limit the number of non-standardized options that an issuer may offer through an FFE; however, meaningful difference standards at § 156.298 and other QHP certification standards still apply. There is currently no such cap on the number of plans that an issuer offering a QHP through an FFE can offer, or on the number of issuers that can offer coverage at each metal level in an FFE. In this proposed rule, we do not propose to limit the total number of QHPs that may be sold through an FFE in a rating area or county. However, we may consider limiting the number of plan options in future plan years, to further simplify the health plan shopping experience for consumers. We seek comment as to whether we should limit the number of non-standardized options an issuer may offer through an FFE in future years.

We are considering making modifications to our consumer-facing plan comparison features to readily allow consumers to identify standardized options, and seek comment on how we should do so. We intend to conduct consumer testing to help us make this determination. We also anticipate providing information to explain the standardized option concept to consumers. We expect to provide information about specific design features through issuer testing of plan data and other fora. We seek comment on these proposals, including whether there should be a requirement on QHP issuers or web-brokers to differentially display standardized options when a non-FFE Web site is used to facilitate enrollment in an FFE. Multi-State plan issuers may use the standardized options noted above. OPM, at its discretion, may design additional standardized options applicable only to multi-State plan issuers, though we would not display these OPM options in a differential manner in order to preserve consistency in the standardized options identified on the FFE.

2. FFE User Fee for the 2017 Benefit Year (§ 156.50)

Section 1311(d)(5)(A) of the Affordable Care Act permits an Exchange to charge assessments or user fees on participating health insurance issuers as a means of generating funding to support its operations. In addition, 31 U.S.C. 9701 permits a Federal agency to establish a charge for a service provided by the agency. If a State does not elect to operate an Exchange or does not have an approved Exchange, section 1321(c)(1) of the Affordable Care Act directs HHS to operate an Exchange within the State. Accordingly, at § 156.50(c), we specify that a participating issuer offering a plan through an FFE must remit a user fee to HHS each month that is equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for FFEs for the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through an FFE.

OMB Circular No. A–25R establishes Federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. As in benefit years 2014 to 2016, issuers seeking to participate in an FFE in benefit year 2017 will receive two special benefits not available to the general public: (1) The certification of their plans as QHPs; and (2) the ability to sell health insurance coverage through an FFE to individuals determined eligible for enrollment in a QHP. These special benefits are provided to participating issuers through the following Federal activities

in connection with the operation of FFEs:

- Provision of consumer assistance tools.
- Consumer outreach and education.
- Management of a Navigator program.
- Regulation of agents and brokers.
- Eligibility determinations.
- Enrollment processes.
- Certification processes for QHPs (including ongoing compliance verification, recertification and decertification).
- Administration of a SHOP Exchange.

OMB Circular No. A–25R further states that user fee charges should generally be set at a level so that they are sufficient to recover the full cost to the Federal government of providing the service when the government is acting in its capacity as sovereign (as is the case when HHS operates an FFE). Accordingly, we propose to set the 2017 user fee rate for all participating FFE issuers at 3.5 percent. This user fee rate assessed on FFE issuers is the same as the 2014 to 2016 user fee rate. In addition, we intend to seek an exception from OMB Circular No. A–25R, which requires that the user fee charge be sufficient to recover the full cost to the Federal government of providing the special benefit. We seek this exception to ensure that the FFE can support many of the goals of the Affordable Care Act, including improving the health of the population, reducing health care costs, and providing access to health coverage, in cases where user fee collections do not cover the full cost of the special benefit. We seek comments on this proposal.

Additionally, we have proposed under §§ 155.106(c) and 155.200(f) to allow State Exchanges to enter into a Federal platform agreement with HHS so that the State Exchange may rely on the Federal platform for certain Exchange functions to enhance efficiency and coordination between State and Federal programs, and to leverage the systems established by the FFE to perform certain Exchange functions. We propose in § 156.50(c)(2) to charge SBE–FP issuers a user fee for the services and benefits to the issuers provided by HHS. For 2017, these functions will include the Federal Exchange information technology and call center infrastructure used in connection with eligibility determinations for enrollment in QHPs and other applicable State health subsidy programs, as defined at section 1413(e) of the Affordable Care Act and enrollment in QHPs under § 155.400. As previously discussed, OMB Circular No. A–25R establishes Federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. If our proposals under §§ 155.106(c) and 155.200(f) are finalized, issuers seeking to participate in an SBE–FP in benefit year 2017 will receive special benefits not available to the general public: The ability to sell health insurance coverage through a State Exchange that realizes efficiencies by relying on the Federal platform to enroll individuals determined eligible for enrollment in a QHP, including individuals who may be eligible for insurance affordability programs that may support premiums paid to issuers offering plans through the State Exchange by way of the Federal platform (HealthCare.gov), and the ability to sell health insurance coverage to small employers eligible to purchase QHPs for its employees through a SHOP exchange. Other services that will be provided to issuers offering plans through State Exchanges on the Federal platform include the Federal Exchange information technology and call center infrastructure used in connection with eligibility determinations for enrollment in QHPs and other applicable State health subsidy programs. We propose to charge issuers offering QHPs through an SBE–FP a user fee rate of 3.0 percent of the monthly premium charged by the issuer for each policy under a plan offered through an SBE–FP. This fee will recover funding to support FFE operations incurred by the Federal government associated with providing the services described above.

The proposed user fee rate was calculated based on the proportion of FFE costs that are associated with the FFE information technology infrastructure, the consumer call center, and eligibility and enrollment services, and allocating a share of those costs to issuers in the relevant SBE–FPs. A significant portion of expenditures for FFE services are associated with the information technology, call center infrastructure, and personnel who conduct eligibility determinations for enrollment in QHPs and other applicable State health subsidy programs as defined at section 1413(e) of the Affordable Care Act, and who perform the functions set forth in § 155.400 to facilitate enrollment in QHPs. We intend to review the costs incurred to provide these special benefits each year, and revise the user fee rate for issuers in SBE–FPs accordingly in the annual HHS notice of benefit and payment parameters. Additional guidance on user fee collection processes will be provided in the future.

While a user fee rate of 3.0 percent is reflective of HHS's actual costs, we recognize that States that are currently using the Federal platform may find the abrupt change of the proposed user fee in 2017 challenging for their health insurance markets. Therefore, HHS is also considering reducing for the 2017 benefit year the user fee rate by one half or one third (that is, to 1.5 or 2.0 percent) for the issuers in State Exchanges utilizing the Federal platform, to provide these States additional time to integrate this user fee rate. In future years, issuers in SBE–FPs would be charged the full user fee rate for SBE–FPs to cover their full share of costs incurred by the FFE for those services. We seek comment on this proposal and this possible reduction.

Additionally, to ease administrative burdens on issuers and States, at the request of SBE–FPs, pursuant to the authority under the Intergovernmental Cooperation Act of 1968 (IGCA), HHS will seek to offer States the option to have HHS collect an additional user fee from issuers at a rate specified by the State to cover costs incurred by the State-based Exchange for the functions the State retains. If HHS grants requests to provide such services, States may be required to reimburse HHS any additional costs that are associated with HHS's provision of such service. This coordination between the State and Federal programs will reduce administrative burden on issuers as well as the SBEs–FP.

3. Single Risk Pool (§ 156.80)

In the small group market, an issuer may update rates on a quarterly basis, provided that any changes to rates have effective dates of January 1, April 1, July 1, or October 1. In the preamble to the second Program Integrity Rule (78 FR 65067), we explained that any new rates set by an issuer would apply for new or renewing coverage on or after the rate effective date, and would apply for the entire the plan year. We propose to codify this policy in § 156.80(d)(3)(ii), and to make non-substantive changes to the wording of that paragraph, including to delete an outdated reference to when quarterly rate changes could first be implemented.

For all issuers, we also reiterate that § 156.80(d)(2) permits a health insurance issuer to vary the plan-adjusted index rate for a particular plan from its market-wide index rate adjusting only for the explicitly stated factors. Any plan level adjustment not

specifically stated, including adjusting for morbidity of plan enrollees, is not permissible.

4. Essential Health Benefits Package

a. Prescription Drug Benefits (§ 156.122)

Current § 156.122(c) requires plans providing EHB to have procedures in place that allow an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request and gain access to clinically appropriate drugs not covered by the plan. Such procedures must include a process to request an expedited review based on exigent circumstances. Under the expedited process, the issuer must make its coverage determination no later than 24 hours after it receives the request. This requirement, commonly referred to as the ''exceptions process,'' applies to drugs that are not included on the plan's formulary drug list. For plan years beginning in 2016, these processes must also include certain processes and timeframes for the standard review process, and have an external review process if the internal review request is denied. The costs of the non-formulary drug provided through the exceptions process count towards the annual limitation on cost sharing and AV of the plan.

As discussed in the 2016 Payment Notice (80 FR 10750), the exceptions process established in this section is distinct from the coverage appeals process established under § 147.136. Specifically, the drug exceptions process applies to drugs that are not included on the plan's formulary drug list, while the coverage appeals regulations apply if an enrollee receives an adverse benefit determination for a drug that is included on the plan's formulary drug list. Because these two processes serve different purposes, we believe they are not duplicative and we do not propose to change these definitions. However, we also clarified in the 2016 Payment Notice that ''nothing under this policy (§ 156.122(c)) precludes a State from requiring stricter standards in this area.''

Since finalizing the rule, we have received additional comment regarding States' coverage appeals laws and regulations and non-formulary drugs. For example, if a State is subjecting non-formulary drugs to the standards under § 147.136 as opposed to § 156.122(c), the State's coverage appeals laws or regulations would provide the enrollee with a different process for review, and as a result a different process for obtaining coverage of the non-formulary drug. Specifically, § 147.136 has separate requirements for its external review process. Also, § 147.136(b)(ii)(G) allows for a secondary level of internal review before the final internal review determination for group plans. Therefore, if the State is subjecting non-formulary drugs to § 147.136 and the issuers are also required to comply § 156.122(c), the issuer may have to satisfy two standards for non-formulary drugs.

We are considering amending the rule to establish that a plan, in a State that has coverage appeals laws or regulations that are more stringent than or are in conflict with our exceptions process under § 156.122(c), and that include reviews for non-formulary drugs, satisfies § 156.122(c) if it complies with the State's coverage appeals laws or regulations. The purpose of § 156.122(c) is to ensure that an enrollee has the ability to request and gain access to clinically appropriate drugs not covered by the plan. Regardless of whether a State's coverage appeals laws or regulations are satisfying § 156.122(c) or if the issuer is meeting § 156.122(c) through its exception process, we would expect that an enrollee would retain the ability to request and gain access to clinically appropriate drugs not covered by the plan. Therefore, we solicit comments on the scope of application of State appeals laws or regulations that are allowing determinations for non-formulary drugs for this purpose, especially under medical necessity provisions and whether these provisions would allow the enrollee the ability to request and gain access to clinically appropriate drugs not covered by the plan in all cases through a State's coverage appeals laws or regulations. As the State is the primary enforcer of the EHB requirements, the State would determine whether its coverage appeals laws or regulations would satisfy § 156.122(c) and therefore, would allow the issuers in the State to defer to the States' coverage laws or regulations. We note that we consider multi-State plans that comply with OPM's coverage appeals requirements to satisfy § 156.122(c), and we are considering codifying this interpretation.

We are also considering amending the process at § 156.122(c) to allow for a second level of internal review. For example, we are considering using the same timelines as the first level of internal review, 72 hours for the standard review request and 24 hours for the expedited review request. We seek comments on all of these proposals.

Lastly, opioid abuse has become a public health crisis in recent years. In 2013, nearly 2 million Americans abused prescription painkillers, and each day, nearly 7,000 people receive emergency department care for misusing these drugs. We recognize that medication-assisted treatments for substance use disorders might not be available to all consumers as an essential health benefit. Therefore, we seek comment on whether the substance use disorder requirement in essential health benefits needs additional clarification with regard to medication-assisted treatment for opioid addiction.

b. Premium Adjustment Percentage (§ 156.130)

Section 1302(c)(4) of the Affordable Care Act directs the Secretary to determine an annual premium adjustment percentage, which is used to set the rate of increase for three parameters detailed in the Affordable Care Act: The maximum annual limitation on cost sharing (defined at § 156.130(a)), the required contribution percentage by individuals for minimum essential coverage the Secretary may use to determine eligibility for hardship exemptions under section 5000A of the Code, and the assessable payment amounts under section 4980H(a) and (b) of the Code. Section 156.130(e) provides that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013, and that this percentage will be published annually in the HHS notice of benefit and payment parameters.

Under the methodology established in the 2015 Payment Notice and amended in the 2015 Market Standards Rule for estimating average per capita premium for purposes of calculating the premium adjustment percentage, the premium adjustment percentage is calculated based on the projections of average per enrollee employer-sponsored insurance premiums from the NHEA, which is calculated by the Office of the Actuary. Accordingly, using the employer-sponsored insurance data, the premium adjustment percentage for 2017 is the percentage (if any) by which the most recent NHEA projection of per enrollee employer-sponsored insurance premiums for 2016 ($6,076) exceeds the most recent NHEA projection of per enrollee employer-sponsored insurance premiums for 2013 ($5,365).[34] Using

[34] *See https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf*, *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology2012.pdf* and

this formula, the proposed premium adjustment percentage for 2017 is 13.25256291 percent. We note that the 2013 premium used for this calculation has been updated to reflect the latest NHEA data. Based on the proposed 2017 premium adjustment percentage, we propose the following cost-sharing parameters for calendar year 2017.

Maximum Annual Limitation on Cost Sharing for Calendar Year 2017. Under § 156.130(a)(2), for the 2017 calendar year, cost sharing for self-only coverage may not exceed the dollar limit for calendar year 2014 increased by an amount equal to the product of that amount and the premium adjustment percentage for 2017, and for other than self-only coverage, the limit is twice the dollar limit for self-only coverage. Under § 156.130(d), these amounts must be rounded down to the next lowest multiple of 50. Using the premium adjustment percentage of 13.25256291 percent for 2017 we established above, and the 2014 maximum annual limitation on cost sharing of $6,350 for self-only coverage, which was published by the IRS on May 2, 2013,[35] we propose that the 2017 maximum annual limitation on cost sharing would be $7,150 for self-only coverage and $14,300 for other than self-only coverage.

c. Reduced Maximum Annual Limitation on Cost Sharing (§ 156.130)

Sections 1402(a) through (c) of the Affordable Care Act direct issuers to reduce cost sharing for EHBs for eligible individuals enrolled in a silver level QHP. In the 2014 Payment Notice, we established standards related to the provision of these cost-sharing reductions. Specifically, in 45 CFR part 156, subpart E, we specified that QHP issuers must provide cost-sharing reductions by developing plan variations, which are separate cost-sharing structures for each eligibility category that change how the cost sharing required under the QHP is to be shared between the enrollee and the Federal government. At § 156.420(a), we detailed the structure of these plan variations and specified that QHP issuers must ensure that each silver plan variation has an annual limitation on cost sharing no greater than the applicable reduced maximum annual limitation on cost sharing specified in the annual HHS notice of benefit and payment parameters. Although the amount of the reduction in the maximum annual limitation on cost sharing is specified in section 1402(c)(1)(A) of the Affordable Care Act, section 1402(c)(1)(B)(ii) of the Affordable Care Act states that the Secretary may adjust the cost-sharing limits to ensure that the resulting limits do not cause the AVs of the health plans to exceed the levels specified in section 1402(c)(1)(B)(i) of the Affordable Care Act (that is, 73 percent, 87 percent, or 94 percent, depending on the income of the enrollee). Accordingly, we propose to use a method we established in the 2014 Payment Notice for determining the appropriate reductions in the maximum annual limitation on cost sharing for cost-sharing plan variations. As we proposed above, the 2017 maximum annual limitation on cost sharing would be $7,150 for self-only coverage and $14,300 for other than self-only group coverage. We analyzed the effect on AV of the reductions in the maximum annual limitation on cost sharing described in the statute to determine whether to adjust the reductions so that the AV of a silver plan variation will not exceed the AV specified in the statute. Below, we describe our analysis for the 2017 benefit year and our proposed results.

Consistent with our analysis in the 2014, 2015, and 2016 Payment Notices, we developed three test silver level QHPs, and analyzed the impact on AV of the reductions described in the Affordable Care Act to the estimated 2017 maximum annual limitation on cost sharing for self-only coverage ($7,150). The test plan designs are based on data collected for 2016 plan year QHP certification to ensure that they represent a range of plan designs that we expect issuers to offer at the silver level of coverage through the Exchanges. For 2017, the test silver level QHPs included a PPO with typical cost-sharing structure ($7,150 annual limitation on cost sharing, $2,175 deductible, and 20 percent in-network coinsurance rate), a PPO with a lower annual limitation on cost sharing ($4,800 annual limitation on cost sharing, $2,775 deductible, and 20 percent in-network coinsurance rate), and an HMO ($7,150 annual limitation on cost sharing, $3,000 deductible, 20 percent in-network coinsurance rate, and the following services with copayments that are not subject to the deductible or coinsurance: $500 inpatient stay per day, $350 emergency department visit, $25 primary care office visit, and $50 specialist office visit). All three test QHPs meet the AV requirements for silver level health plans.

We then entered these test plans into the proposed 2017 AV Calculator developed by HHS and observed how the reductions in the maximum annual limitation on cost sharing specified in the Affordable Care Act affected the AVs of the plans. We found that the reduction in the maximum annual limitation on cost sharing specified in the Affordable Care Act for enrollees with a household income between 100 and 150 percent of the Federal poverty line (FPL) (⅔ reduction in the maximum annual limitation on cost sharing), and 150 and 200 percent of the FPL (⅔ reduction), would not cause the AV of any of the model QHPs to exceed the statutorily specified AV level (94 and 87 percent, respectively). In contrast, the reduction in the maximum annual limitation on cost sharing specified in the Affordable Care Act for enrollees with a household income between 200 and 250 percent of FPL (½ reduction), would cause the AVs of two of the test QHPs to exceed the specified AV level of 73 percent. As a result, we propose that the maximum annual limitation on cost sharing for enrollees in the 2017 benefit year with a household income between 200 and 250 percent of FPL be reduced by approximately ⅕, rather than ½. We further propose that the maximum annual limitation on cost sharing for enrollees with a household income between 100 and 200 percent of the FPL be reduced by approximately ⅔, as specified in the statute, and as shown in Table 10. These proposed reductions in the maximum annual limitation on cost sharing should adequately account for unique plan designs that may not be captured by our three model QHPs. We also note that selecting a reduction for the maximum annual limitation on cost sharing that is less than the reduction specified in the statute would not reduce the benefit afforded to enrollees in aggregate because QHP issuers are required to further reduce their annual limitation on cost sharing, or reduce other types of cost sharing, if the required reduction does not cause the AV of the QHP to meet the specified level. We welcome comment on this analysis and the proposed reductions in the maximum annual limitation on cost sharing for 2017.

We note that for 2017, as described in § 156.135(d), States are permitted to

Table 17 (located in the NHE Projections 2014–2024—Tables link) found here *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html* in *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2012.pdf* for additional information.

[35] *See http://www.irs.gov/pub/irs-drop/rp-13-25.pdf.*

submit for approval by HHS State-specific data sets for use as the standard population to calculate AV. No State submitted a data set by the September 1 deadline.

TABLE 10—REDUCTIONS IN MAXIMUM ANNUAL LIMITATION ON COST SHARING FOR 2017

Eligibility category	Reduced maximum annual limitation on cost sharing for self-only coverage for 2017	Reduced maximum annual limitation on cost sharing for other than self-only coverage for 2017
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i) (that is, 100–150 percent of FPL)	$2,350	$4,700
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(ii) (that is, 150–200 percent of FPL)	2,350	4,700
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(iii) (that is, 200–250 percent of FPL)	5,700	11,400

d. AV Calculation for Determining Level of Coverage (§ 156.135)

Section 2707(a) of the PHS Act and section 1302 of the Affordable Care Act direct issuers of non-grandfathered health insurance in the individual and small group markets, including QHPs, to ensure that plans meet a level of coverage specified in section 1302(d)(1) of the Affordable Care Act and codified at § 156.140(b). On February 25, 2013, HHS published the EHB Rule (78 FR 12833) implementing section 1302(d) of the Affordable Care Act that required that, to determine the level of coverage for a given metal tier level, the calculation of AV be based upon the provision of EHB to a standard population. Section 156.135(a) establishes that AV is generally to be calculated using the AV Calculator developed and made available by HHS for a given benefit year. In the 2015 Payment Notice (79 FR 13743), we established at § 156.135(g) provisions for updating the AV Calculator in future plan years and provided an overview of how we would consider each of these updates and our approach towards making these updates.

As discussed in the 2015 Payment Notice, we recognize the importance of balancing the interests of ensuring that the AV Calculator accurately reflects the current market and that changes to the AV Calculator minimize disruption to current plan designs through keeping AVs stable. In considering updates to the AV Calculator under the factors established under § 156.135(g), we found the need for greater flexibility than provided for under current regulations to better ensure updates to the AV Calculator achieve these objectives.

For example, in the preamble of the 2015 Payment Notice, we established our methodology for developing the trend factor. We stated that ''when updating the trending factor in the AV Calculator, we will use two sources of data, one to reflect the individual market and one to reflect the small group market, to develop a single trend factor that could be applied to the AV Calculator.'' [36] However, in considering options for updating the trend factor annually under this policy, we found that this policy unduly limits our options. For instance, costs for specific services, such as specialty drugs, are currently increasing at a significantly different rate than other medical services. Trending costs based on each service type could capture those different rates of cost growth more accurately and better ensure that the trend adjustments in the AV Calculator reflect the actual market.

We propose to revise § 156.135(g) to allow for additional flexibility in our approach and options for updating of the AV Calculator in the future. We propose that HHS will update the AV Calculator annually for material changes that may include costs, plan designs, the standard population, developments in the function and operation of the AV Calculator and other actuarially relevant factors. Specifically, we would not be required to make each of these changes each year, but we could include these types of material changes in our annual updating of the AV Calculator. Under this proposed policy, we will continue to make updates to the AV Calculator, as we have in previous years, including updates to the trend factor, algorithms changes and user interface changes. We will also update the claim data and demographic distribution being used in the AV Calculator as needed and continue to update the AV Calculator's annual limitation on cost sharing based on a projected estimate to allow for compliance with § 156.130(a). The major difference under the proposed § 156.135(g) will be that the methodology, data sources, and trigger for making updates in the AV Calculator would be more flexible than the current § 156.135(g). For instance, we propose that specific timelines and materiality thresholds for updating the continuance tables to reflect more current enrollment and claims data will no longer be specified by the regulation. This will allow us more options in considering approaches to making changes in the AV Calculator, particularly as the health insurance market and the AV Calculator evolve, new methodological approaches are developed, and new data becomes available. In developing the annual updates to the AV Calculator, we will continue to take into consideration stakeholder feedback on needed changes to the AV Calculator (through *actuarialvalue@cms.hhs.gov*) and to publicly release a draft version of the AV Calculator and the AV Calculator Methodology for comment before releasing the final AV Calculator. We also understand the importance for issuers and States to have time to use the final version of the AV Calculator to develop and adjust plan designs and we hope that by providing the additional flexibility under proposed § 156.135(g), we will have more options that could allow us to release the AV Calculator sooner. We solicit comments on the proposed § 156.135(g).

e. Application to Stand-Alone Dental Plans Inside the Exchange (§ 156.150)

In § 156.150, we propose revisions to increase the annual limitation on cost sharing for SADPs. In the 2015 Payment Notice, we established that the annual limitation on cost sharing for an SADP covering the pediatric dental EHB under

[36] 79 FR 13811. Col 1. [March 11, 2014].

§ 155.1065 in any Exchange may not exceed $350 for one covered child and $700 for two or more covered children.

To make adjustments to the annual limitation on cost sharing in subsequent years to keep pace with inflation, we propose in paragraph (a)(1) that for a plan year beginning after 2016, the dollar limit applicable to a SADP for one covered child be increased by an amount equal to the product of that amount and the quotient of consumer price index for dental services for the year 2 years prior to the benefit year, divided by the consumer price index for dental services for 2016. In paragraph (a)(2), we propose that the dollar limit for two or more covered children be twice the dollar limit for one child described in paragraph (a)(1) of this section.

We considered using the premium adjustment percentage defined in § 156.130(e), but ultimately decided that the dental CPI would be a more appropriate adjuster for the annual limitation on cost sharing as it is based on dental services. The annual limitation on cost sharing should increase over time to keep pace with inflation and moderate potential increases in premium. This is similar to the approach for medical QHPs. We seek comment on whether the premium adjustment percentage defined in § 156.130(e) should be used instead. We would propose and finalize the annual increase to the dental annual limitation on cost sharing in the annual Payment Notice.

In paragraph (c), we propose to define the dental CPI, which is a sub-component of the U.S. Department of Labor's Bureau of Labor Statistics Consumer Price Index specific to dental services. We would use the annual dental CPI published by the Department of Labor.

In paragraph (d), we propose that increases in the annual dollar limits for one child that do not result in a multiple of $25 will be rounded down, to the next lowest multiple of $25. We believe this provision will result in stability in SADPs, making changes in annual limits that are based on round figures in moderate increments.

We seek comment on these proposals.

5. Qualified Health Plan Minimum Certification Standards

a. Network Adequacy Standards (§ 156.230)

At § 156.230, we established the minimum criteria for network adequacy that health and dental plan issuers must meet to be certified as QHPs, including SADPs, in accordance with the Secretary's authority in section 1311(c)(1)(B) of the Affordable Care Act. Section 156.230(a)(2) requires all issuers to maintain a network that is sufficient in number and types of providers to assure that all services will be accessible without unreasonable delay. Section 156.230(b) sets forth standards for access to provider directories requiring issuers to publish an up-to-date, accurate, and complete provider directory for plan years beginning on or after January 1, 2016 and § 156.230(c) requires QHPs in the FFE to make this provider directory data available on its Web site in an HHS specified format and also submit this information to HHS in a format and manner and at times determined by HHS.

i. State Selection of Minimum Network Adequacy Standards

The National Association of Insurance Commissioners' (NAIC's) Network Adequacy Model Review Subgroup has been doing significant work in the area of network adequacy, which includes work towards development of a Network Adequacy Model Act that States could adopt in whole or in part. We will continue to monitor the NAIC work and look forward to partnering with States and the NAIC in developing and promulgating network adequacy protections. In the interest of furthering this work, we are proposing standards related to network adequacy below, but will take into consideration the NAIC's final recommendation as we assess these policies.

In recognition of the traditional roles States have in developing and enforcing network adequacy standards, we propose that FFEs would rely on State reviews for network adequacy in States in which an FFE is operating, provided that HHS determines that the State uses an acceptable quantifiable network adequacy metric commonly used in the health insurance industry to measure network adequacy, approved by HHS.

We anticipate that HHS would determine that a State's network adequacy assessment methodology meets the standard above if the State selects one or more standards from a list of metrics provided by HHS and applies them prospectively to the QHP issuers in the State. HHS intends to detail the specific criteria and process for meeting the standard in each annual Letter to Issuers, but we anticipate including at least the following metrics:

- Prospective time and distance standards at least as stringent as the FFE standard.
- Prospective minimum provider-covered person ratios for the specialties with the highest utilization rate for its State.

HHS would discuss with States their selection in advance of the start of the certification cycle to determine whether the State's network adequacy standard would be acceptable under the standard above. We would thereafter notify issuers via subregulatory guidance whether the State standards or Federal default standards apply.

If HHS determines that a State's nework adequacy standard is acceptable under the standard above, the State would certify to the FFE which plans meet the network adequacy standard, and the FFE in that State would rely on the State's review for purposes of determining whether a QHP meets the requirements under § 156.230(a)(2), although those issuers would still be required to submit to HHS provider data, attest to the HHS network adequacy certification requirements, and meet other applicable HHS standards, including the other standards under § 156.230.

We welcome comments on this proposal, including suggestions for additional State network adequacy methodologies that the FFEs could rely on, and other factors we might consider.

In States that do not review for network adequacy, or do not select a standard as described above, the FFE would conduct an independent review under a Federal default standard. We propose the Federal default standard at § 156.230(d) to be a time and distance standard. For the certification cycle for plan years beginning in 2017, we anticipate evaluating the QHP issuer networks under this standard based on the numbers and types of providers, in addition to their general geographic location. In particular, we propose to calculate a time and distance standard at the county level. We are considering using standards similar to those used in Medicare Advantage, utilizing the National Provider Identifier database, and focusing on the specialties that enrollees most generally use. HHS is also carefully considering other network standards, including those of individual States, accrediting entities, and Federal health care programs, as it develops the time and distance standards for the FFEs. We solicit comments on whether these proposed standards are appropriate. We also seek comment specifically on whether they are appropriate for SADPs, and, if not, what standards for SADPs would be more appropriate, and the basis for any deviation.

The county-specific time and distance parameters that plans will be required to meet, including specifications for

specific provider and facility types, would be detailed annually in conjunction with the Letter to Issuers.

We also propose that issuers that are unable to meet the specified standards would be able to submit a justification to account for any variances, and that the FFE would review the justification to determine whether the variance is reasonable based on circumstances, such as the availability of providers and variables reflected in local patterns of care.

It is not our intent in establishing these default standards to prohibit certification of plans with narrow networks or otherwise impede innovation in plan design. Instead, we intend to establish a minimum floor consistent with the levels generally maintained in the market today, so that generally a very small number of plans would be idenfitied as having networks deemed inadequate. The Federal default standard would provide issuers with more transparency regarding our certification processes and will be designed and implemented to achieve results similar to those yielded by the reviews conducted by the FFEs in prior certification cycles. We believe this will promote predictability for issuers in the course of certification. We note that multi-State plan options will be considered to meet the network adequacy requirements under § 156.230(a)(2) if they meet network adequacy standards established by OPM.

We seek comments on this proposal, including how we might develop time and distance standards appropriate for the FFEs, the use of Medicare Advantage or other standards and other factors we should examine in measuring network adequacy, and suggestions of other models we might consider.

ii. Additional Network Adequacy Standards

We also propose other additional network-related standards under § 156.230(e) and (f).

In the new § 156.230(e)(1), we propose to require QHP issuers in all FFEs to notify enrollees about a discontinuation in their network coverage of a contracted provider. We believe that it is important for enrollees to be notified of changes to the network on a timely basis. Consumers need accurate information about which providers are in-network to ensure that they can optimize their health insurance coverage and make cost effective choices. Therefore, we propose that a QHP in an FFE be required to make a good faith effort to provide written notice of a discontinued provider, 30 days prior to the effective date of the change or otherwise as soon as practicable, to all enrollees who are patients seen on a regular basis by the provider or receive primary care from the provider whose contract is being discontinued, irrespective of whether the contract is being discontinued due to a termination for cause or without cause, or due to a non-renewal. We propose that a discontinued provider includes cases of where the provider is being removed and where the provider is leaving the network. We solicit comments on this proposed provision, including the timeframe for notification and whether separate timeframe requirements are needed for primary care providers versus other types of providers that a patient sees on a regular basis. We also solicit comments on an appropriate definition of ''regular basis,'' or whether the implementation of that phrase should be left to the good faith interpretation of the issuer. For instance, we considered whether we should define regular basis if the enrollee has seen the provider within the last 3 months, 6 months or 12 months. To satisfy this requirement, we expect the issuer to try to work with the provider to obtain the list of affected patients or to use their claims data system to identify enrollees who see the affected providers. As part of the notice, we encourage issuers to notify the enrollee of other comparable in-network providers in the enrollee's service area, provide information on how an enrollee could access the plan's continuity of care coverage, and encourage the enrollee to contact the plan with any questions.

In developing the proposed notification standard under § 156.230(e)(1), we considered Medicaid Managed Care and Medicare Advantage's notification requirements and considered the work by the NAIC's Network Adequacy Model Review Subgroup. For instance, Medicare Advantage's notification requirements are similar to the proposed § 156.230(e)(1), and require that the Medicare Advantage organization make a good faith effort to provide written notice of a termination of a contracted provider at least 30 calendar days before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating, irrespective of whether the termination was for cause or without cause. Medicare Advantage also requires that when a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must be notified.[37] Medicaid Managed Care, on the other hand, requires the Managed Care Organization, the Prepaid Inpatient Health Plan, and, when appropriate, the Prepaid Ambulatory Health Plan or Primary Care Case Manager, to make a good faith effort to give written notice of termination of a contracted provider, within 15 days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a regular basis by the terminated provider.[38] We seek comments on other standards for notifying enrollees about their network coverage in cases of discontinuation, including States' standards and whether exceptions should be allowed for States' that already require notification to enrollees when a provider leaves the network.

We are also proposing in § 156.230(e)(2) a provision for QHP issuers in all FFEs to ensure continuity of care for enrollees in cases where a provider is terminated without cause. Specifically, we propose to require the issuer, in cases where the provider is terminated without cause, to allow an enrollee in active treatment to continue treatment until the treatment is complete or for 90 days, whichever is shorter, at in-network cost-sharing rates. Additionally, in proposed paragraph (e)(2), we propose a definition of active treatment as meaning: (1) An ongoing course of treatment for a life-threatening condition; (2) an ongoing course of treatment for a serious acute condition; (3) the second or third trimester of pregnancy; or (4) an ongoing course of treatment for a health condition for which a treating physician or health care provider attests that discontinuing care by that physician or health care provider would worsen the condition or interfere with anticipated outcomes. Under the proposed definition of active treatment, an ongoing course of treatment would include treatments for mental health and substance use disorders that fall within the proposed definition. For the purposes of the active treatment definition, we propose to interpret a life-threatening condition as a disease or condition for which likelihood of death is probable unless the course of the disease or condition is interrupted; and a serious acute condition as a disease or condition requiring complex on-going care which the covered person is currently receiving, such as chemotherapy, post-operative visits, or radiation therapy. Finally, under paragraph (e)(2)(ii), we

[37] 42 CFR 422.111(e).

[38] 42 CFR 438.10(f)(5).

propose that any decisions made for a request for continuity of care be subject to the health benefit plan's internal and external grievance and appeal processes in accordance with applicable State or Federal law or regulations. We solicit comments on this proposed section of the regulation, including the definitions of ''active treatment,'' ''life-threatening condition,'' and ''serious acute condition'' and whether exceptions should be allowed for States' standards that already require coverage of continuity of care for enrollees. We also solicit comments about whether enrollees in their second or third trimester of pregnancy should be allowed to extend obstetric care through the postpartum period, which could require the continuity of care standard to extend beyond 90 days. If these enrollees were allowed to extend obstetric care through the postpartum period, we solicit comment on the definition of the postpartum period, such as for 6 weeks after birth, and whether the allowance of care through the postpartum period should apply for broader types of care than for obstetric care. We also solicit comments on proposed § 156.230(e)(1) and (2) on the distinction between a termination with or without cause versus when a provider leaves the network because the provider's contract is non-renewed. Specifically, we solicit comments on whether § 156.230(e)(2) should incorporate cases where the provider's contract is non-renewed or whether we should consider a non-renewal of the provider's contract as a termination without cause under § 156.230(e)(1) and (2). Lastly, we seek comments about what other possible provisions may be needed to protect an enrollee when a provider contract is terminated and can be implemented with limited burden on issuers.

In general, our network adequacy rules for QHPs require that a network plan maintain a network sufficient to assure that all services will be accessible without unreasonable delay. However, there may be occasions when an enrollee obtains an EHB outside the QHP's network because the enrollee unknowingly receives out-of-network care. An enrollee may have made reasonable efforts to stay within the QHP's network when obtaining an EHB service, but then unknowingly received care from an out-of-network provider in an in-network setting (for example, an anesthesiologist or pathologist). To address these circumstances, we propose to add a new § 156.230(f).

In that paragraph, we propose to require, notwithstanding § 156.130(c) of the subpart, for a network to be deemed adequate, each QHP that uses a provider network must count cost sharing paid by an enrollee for an EHB provided by an out-of-network provider in an in-network setting under certain circumstances towards the enrollee's annual limitation on cost sharing. That is, if an enrollee received an EHB in an in-network setting, such as an in-network hospital, but as part of the provision of the EHB the enrollee was charged out-of-network cost-sharing for an EHB provided by an out-of-network provider (such as anesthesiology or pathology services, for example), that cost-sharing would apply towards the annual limitation on cost-sharing. The enrollee could still be responsible for out-of-network cost sharing, and balance billing, for other benefits received from an out-of-network provider at any time, but not for cost sharing for a covered EHB provided in-network or out-of-network in a circumstance described in this paragraph after the annual limitation is met.

Alternatively, the plan could provide a written notice to the enrollee at least 10 business days before the provision of the benefit that additional costs may be incurred for EHB provided by an out-of-network provider in an in-network setting, including balance billing charges, unless such costs are prohibited under State law, and that any additional charges may not count toward the in-network annual limitation on cost sharing. Such notice could be provided during preauthorization. If the plan provides such notice, this rule would not require the plan to apply the out-of-network cost sharing towards the enrollee's annual limit on cost sharing or to be responsible for covering out-of-network cost sharing above the annual limit. This alternative would not be available if fewer than 10 business days' notice is provided, including in cases where that amount of time is not available (for example, in urgent but non-emergency care situations).

We believe that this proposal balances financial protection for consumers against surprise out-of-network cost sharing, while maintaining the larger part of the QHP's cost-sharing structure. The 10 business days' advance notice provision is intended to allow the enrollee to arrange for an in-network provider to provide the EHB; we solicit comments on whether this time frame should be shorter or longer. We would expect the issuer would provide this notification to the enrollee at the time it notifies the provider with any pre-authorization documents. The issuer would also be permitted to send a ''form'' document—that is, one that is not customized to the particular situation at issue—but it could not rely on a blanket notification through its Web site or provided at enrollment, for example. We seek comment on this proposal and if we should instead require the issuer to provide customized information to the consumer including information on potential in-network providers.

We acknowledge that some States and issuers may offer consumers in these scenarios protections which go beyond what we are proposing here for QHPs. Several States have enacted laws that similarly provide consumers financial protection from the high out-of-pocket expenditures associated with receiving out-of-network care. States, relying on their authority to regulate both providers and issuers, generally impose requirements on both, whereas our proposal focuses on QHP issuers. States have generally included in their laws mechanisms to address the level of reimbursement an issuer must pay an out-of-network provider. For example, States have required payment of all charges, set the rate at a percentage of a fee schedule, and set forth a process through which providers and issuers must resolve disputes about charges. Some States have also prohibited balance billing consumers for certain out-of-network services, ranging from only emergency services to any covered service. This proposal is not intended to preempt any State laws that would be more consumer protective. We note that this proposal would apply to QHPs in all Exchanges. We seek comment on these proposals.

We are also soliciting comments regarding other network adequacy standards that may be appropriate to apply to QHPs in an FFE in future years, including standards included in the work being done by the NAIC's Network Adequacy Model Review Subgroup. One policy we are considering is whether a QHP in an FFE should have a network resilience policy for disaster preparedness. Network resilience refers to the provider network's capacity to withstand and recover from natural or man-made disasters that may threaten enrollees' continuous access to quality care. Disasters may negatively impact an issuer's network and can result in delay in services. Therefore, issuers who have a network resilience policy will be better prepared to ensure that their network can provide reasonable access under adverse circumstances. Some examples of appropriate network resilience policies might include business continuity planning, consideration of temporary policy changes in the event of a disaster, and/or disclosure or communication plans.

We solicit comments on this possible future policy and the examples provided, including thoughts on what type of policy would be reasonable and operationally feasible.

In addition, certain States measure network adequacy based on enrollee wait times for scheduled appointments. As a result, we are interested in comments on the variation in wait times depending on the type of provider, such as for primary care or non-primary care services. Additionally, we also solicit comments as to whether we should add a wait time standard as an option under the proposed permissible State standards mentioned in this preamble, or if we should apply a broad wait time standard across QHPs in the FFEs.

We are also soliciting comments on whether an issuer should be required to survey all of its contracted providers on a regular basis to determine if a sufficient number of network providers are accepting new patients. Additionally, we solicit comments on transparency of issuers' standards for selecting and tiering of participating providers for QHPs in an FFE and whether issuers should be required to make available their selecting and tiering criteria for review and approval by HHS and the State upon request. We are proposing § 156.230(e) as a requirement for QHPs in the FFEs and § 156.230(f) as a requirement for QHPs in all Exchanges. However, we solicit comments on whether these provisions should apply to all QHPs or only QHPs in the FFEs. We also solicit comments on applying § 156.230(e) and (f) to SADPs and whether other standards should be provided for these provisions for stand-alone dental plans. We note that § 156.230(f) applies to cost sharing incurred in connection with EHB, and, of dental benefits, only pediatric dental is EHB.

In addition to the policies above, we are also considering providing on HealthCare.gov a rating of each QHP's relative network coverage. This rating or classification could be made available to a consumer when making a plan selection. We believe that such a rating would help an enrollee select the plan that best meets his or her needs, and we anticipate that this analysis would compare the breadth of the QHP network at the plan level as compared to the breadth of the other plan networks for plans available in the same geographic area.

We anticipate analyzing the QHP network by calculating the number of specific providers that are accessible within specified time and distance standards. We would then classify the QHP networks into three categories. We are considering performing the calculation based on the provider information submitted by all QHP issuers in the existing network adequacy FFE QHP certification template, but comments on potential additional data collections are welcome.

This network breadth rating would allow an enrollee to better understand plans' design, and, like other consumer tools, could help improve plan satisfaction. We anticipate providing additional details about how we would classify networks in the Letter to Issuers and in the QHP certification instructions, and solicit comments on what types of methods should be used to identify each network's breadth, what specific specialties should be included in the analysis, what sorts of adjustments should be made to address provider shortages, and other possible data sources to obtain information about available providers in the area. We welcome comments on the best way to make this information available to consumers, and any other comments related to this topic.

b. Essential Community Providers (§ 156.235)

On June 5, 2015, we proposed through a Paperwork Reduction Act notice a provider petition process to update the ECP list against which issuer compliance with the ECP standard is measured. We expect that this data collection for the 2017 benefit year should be completed by the end of 2015, although HHS will provide additional opportunities for ECPs to submit provider data to HHS for benefit years beyond 2017. If the degree of provider participation in this data collection effort through the ECP petition allows HHS to assemble a more complete listing of ECPs, we believe the proposals described below would strengthen the ECP standard.

We propose that, for the 2017 QHP certification cycle, HHS will continue to credit a health plan seeking certification to be offered through an FFE with multiple providers at a single location counting as a single ECP toward both the available ECPs in the plan's service area and the issuer's satisfaction of the ECP participation standard. For QHP certification cycles beginning with the 2018 benefit year, we solicit public comment on crediting issuers for multiple contracted full-time equivalent (FTE) practitioners at a single location, up to the number of available FTE practitioners reported to HHS by the ECP facility through the provider petition process and published on the HHS ECP list. HHS would apply this credit in the numerator of an issuer's percentage satisfaction of the general ECP standard described in paragraphs (a)(1) and (2) of this section. The denominator of an issuer's percentage satisfaction of the ECP standard would reflect the number of available FTE practitioners reported to HHS by each ECP facility that appears on the HHS ECP list located in the issuer's plan service area. Once we have collected this FTE practitioner data through the provider petition process, we believe that crediting an issuer for multiple contracted FTE practitioners at a single location would more accurately reflect the issuer's ECP participation in its network. Therefore, we propose for QHP certification cycles beginning with the 2018 benefit year to revise § 156.235(a)(2)(i) to credit an issuer for multiple contracted FTE practitioners at a single location, up to the number of available FTE practitioners reported to HHS by the ECP facility and reflected on the HHS ECP list, toward the issuer's satisfaction of the ECP participation standard.

In the final 2016 Payment Notice, we stated that we would consider disaggregating certain ECP categories to ensure better access to a wider variety of health care services. However, our analysis of the available ECPs in each of the additional categories considered for disaggregation (that is, children's hospitals, rural health clinics, free-standing cancer centers, community mental health centers, and hemophilia treatment centers) does not support further ECP category disaggregation at this time. We believe there are too few ECPs within each of these additional categories appearing on our HHS ECP list to afford issuers sufficient flexibility in their contracting. We may revisit this consideration in the future and encourage QHP issuers to include in their networks these additional providers to best meet the needs of the populations they serve.

For the same reasons described for our proposal to revise § 156.235(a)(2)(i), we propose in § 156.235(b)(2)(i) that issuers that qualify for the alternate ECP standard described in § 156.235(a)(5) that seek certification to be offered through an FFE (or SBE–FP) be credited for multiple contracted FTE practitioners at a single location toward the issuer's satisfaction of the alternate ECP standard described in paragraphs (b)(1) and (2) of this section, beginning with the 2018 benefit year. We propose that for the 2017 benefit year, HHS will continue to credit an issuer that qualifies for the alternate ECP standard and is seeking certification to be offered through an FFE with multiple providers at a single location counting as a single

ECP toward both the available ECPs in the plan's service area and the issuer's satisfaction of the ECP participation standard. We seek comment on these proposals.

c. Enrollment Process for Qualified Individuals (§ 156.265)

Under § 156.265(b)(2), if an applicant initiates enrollment directly with the QHP issuer for enrollment through the Exchange (direct enrollment through an issuer), the QHP issuer must redirect an applicant to go directly to the Exchange Web site to complete the application and receive an eligibility determination. HHS is considering options under which an applicant could remain on the QHP issuer's Web site to complete the application and enroll in coverage, and the QHP issuer's Web site can obtain eligibility information from the Exchange in order to support the consumer in selecting and enrolling in a QHP with Exchange financial assistance. The intent is to have this information exchange occur through an Exchange-approved web service, as described in § 155.220, enhancing the current direct enrollment process. This option would provide Exchanges offering direct enrollment and QHP issuers more operational flexibility to expand front-end, consumer-facing channels for enrollment through a more seamless consumer experience.

For a discussion of the options we are considering in the direct enrollment scenario, see the discussion regarding direct enrollment by web-brokers in our discussion of changes to § 155.220. We seek comment on these options, and whether standards should differ for a web-broker compared to a QHP issuer, and how to maintain privacy and security.

Accordingly, we propose to revise § 156.265(b)(2)(ii) to ensure that an applicant who initiates enrollment directly with the QHP issuer for enrollment through the Exchange receives an eligibility determination for coverage through the Exchange through the Exchange Web site or through an Exchange-approved web service via the FFE single streamline application. This maintains the role of the Exchange in determining eligibility. We seek comment on this proposal.

d. Termination of Coverage or Enrollment for Qualified Individuals (§ 156.270)

We propose to amend § 156.270(d) to specify that a QHP issuer must provide a 3-month grace period to an enrollee who, upon failing to timely pay his or her premiums, is receiving advance payments of the premium tax credit. Because we believe that changing the length of an enrollee's grace period during the middle of such a grace period would be confusing to enrollees and could result in otherwise avoidable terminations for failure to pay premium, enrollees receiving APTC who enter a grace period for failing to timely pay premiums and who lose their eligibility for APTC during the grace period would be able to complete the remaining portion of the grace period as though the loss of eligibility for APTC did not occur. The proposed amendment to § 156.270(d) also eliminates language limiting the 3-month grace period for enrollees who are receiving APTC to only those enrollees who made a payment during the benefit year. This would permit enrollees renewing coverage that does not require a binder payment who fail to pay January premiums in full (or fail to pay within an issuer's premium payment threshold policy, if applicable) to receive the full grace period of 3 months. This change would align more closely with our interpretation of the interaction between grace periods, guaranteed availability and renewability, and the binder payment requirement, that a binder payment is not necessary when an enrollee enrolls, either actively or passively, in a plan within the same insurance product, and would prevent enrollees who re-enroll in the same plan or product from unfairly losing their right to a grace period because they do not make a payment for January coverage. Finally, we propose to codify with regard to the grace period standards our policy described in the preamble for § 155.400 of this part that if an enrollee receiving advance payments of the premium tax credit can satisfy the requirement to pay all outstanding premiums, or if the enrollee satisfies an issuer's premium payment threshold implemented under § 155.400(g), if applicable, the QHP issuer must not terminate for non-payment of premium the enrollee's enrollment through the Exchange. This change to the rule would reflect the extension of the premium threshold policy to enrollees who are in a grace period for non-payment of premium.

e. Additional Standards Specific to SHOP (§ 156.285)

Sections 155.720(g) and 156.285(c)(5) currently provide that SHOPs and QHP issuers must reconcile enrollment information on no less than a monthly basis. We propose to amend § 156.285(c)(5) to specify additional details about how a QHP issuer offering a QHP through a FF–SHOP should reconcile enrollment files with the FF–SHOP. Specifically, the proposed amendments would provide that the issuer must send enrollment reconciliation files on at least a monthly basis according to a process and timeline established by the FF–SHOP, and in a file format specified by the FF–SHOP.

We are also proposing to delete § 156.285(d)(2) consistent with our interpretation of guaranteed availability and renewability. If a qualified employer withdraws from a SHOP, the SHOP, not the issuer, should terminate the group's enrollment through the SHOP, and coverage might in many circumstances continue outside the SHOP.

f. Meaningful Difference Standard for Qualified Health Plans in the Federally-Facilitated Exchanges (§ 156.298)

At § 156.298, we propose modifications to the meaningful difference standard for QHPs in the FFEs. We propose to remove the criterion in paragraph (b)(5) that otherwise identical plans would be considered meaningfully different on the basis of one QHP being health savings account eligible. A QHP's health savings account eligibility is a cost-sharing status that may be assessed by examining the QHP's cost sharing, which is included at paragraph (b)(1). This criterion is therefore redundant.

We also propose to delete ''self-only'' and ''non-self-only'' from paragraph (b)(6). Self-only (that is, individual) plans do not allow any dependent relationships, while non-self-only (that is, enrollee group) plans allow at least one dependent relationship type. An individual can enroll in individual and enrollee group plans. The allowance of dependents is the only difference between two plans if they are identified as individual or enrollee group only. We have determined that these statuses alone are not indicative of meaningful differences among QHPs. We will maintain the ''child-only'' versus non-child-only status. We further propose to redesignate paragraph (b)(6) as paragraph (b)(5) and add the word ''or'' to paragraph (b)(4). We seek comment on the proposed changes.

g. Other Considerations

We remind issuers that certain other Federal civil rights laws impose non-discrimination requirements. Issuers that receive Federal financial assistance, including in connection with offering a QHP on an Exchange, are subject to Title VI of the Civil Rights Act of 1964, the Age Discrimination Act of 1975, section 504 of the Rehabilitation Act of 1973, and section 1557 of the Affordable

Care Act. The Office for Civil Rights (OCR), which enforces these statutes, published a notice of proposed rulemaking on September 9, 2015 (80 FR 54172) on the requirements of section 1557. Issuers that intend to seek certification of one or more QHPs are directed to that proposed rule and to *http://www.hhs.gov/ocr/civilrights* for additional information.

We also seek to foster market-driven programs that can improve the management of costs and care. We note that innovative issuer, provider, and local programs or strategies may be successful in promoting and managing care, potentially resulting in better health outcomes and lower rates while creating important differentiation opportunities for market participants. We seek comment on ways in which we can facilitate such innovation, and in particular on whether there are regulations or policies in place that we should modify in order to foster this innovation.

6. Standards for Qualified Health Plan Issuers on Federally-Facilitated Exchanges and State-Based Exchanges on the Federal Platform

To make it operationally feasible for a State-based Exchange to rely on the Federal platform for eligibility and enrollment functions, issuers and plans offered on the SBE–FP must comply with rules, as interpreted and implemented in policy and guidance related to the Federal eligibility and enrollment infrastructure. These would be the same requirements related to eligibility and enrollment that are applicable to QHP issuers and plans on FFEs. For example, SBE–FP special enrollment periods must be administered within the guidelines of the FFE special enrollment periods, as it is not possible at this time for the FFE to accommodate State customization in policy or operations, such as State-specific SEPs, application questions, display elements in plan compare, or data analysis. Additionally, if the FFE is to perform eligibility and enrollment functions, the FFE would also need to provide for certain consumer tools (plan compare, premium estimator, second-lowest cost silver plan tool, etc.) to support those functions. Thus, the FFE would need SBE–FP QHP plan data by the dates specified in the annual Letter to Issuers to provide for enough time for adequate testing and loading of the data into the various consumer tools the FFE offers. Issuers must also comply with certain FFE enrollment policies and operations (for example, premium payment and grace period rules, effective date logic, acceptable transaction codes, and reconciliation rules) for the FFE to successfully process 834 transactions with issuers and minimize any data discrepancies for reconciliation.

Therefore, we propose to add § 156.350 to address eligibility and enrollment standards for QHP issuers participating on an SBE–FP. In paragraph (a) of new § 156.350, we would require QHP issuers participating in an SBE–FP to comply with HHS regulations, and guidance related to the eligibility and enrollment functions for which the State-based Exchange relies on the Federal platform. For example, those issuers would be required to comply with operational standards in the Federally-facilitated Marketplace and Federally-facilitated Small Business Health Options Program Enrollment Manual. We provide in paragraph (a) a list of provisions with which QHP issuers participating in an SBE–FP would be required to comply. These provisions relate to eligibility and enrollment functions directly, or are critical to enabling HHS to assess compliance with eligibility and enrollment functions. For example, we would require QHP issuers to comply with the requirements regarding compliance reviews of QHP issuers to the extent relating directly to applicable eligibility and enrollment functions. Without this requirement, we would be severely limited in our ability to determine whether an issuer is complying with the requirements related directly to the Federal platform's eligibility and enrollment functions. In paragraph (b), we propose to permit these issuers to directly enroll applicants in a manner that is considered to be through the Exchange, under § 156.1230, just as QHP issuers on FFEs are permitted.

In paragraph (c), we propose that if an SBE–FP does not substantially enforce the eligibility and enrollment standards described in paragraph (a), then HHS may enforce against the issuer or plan using the enforcement remedies and processes described in subpart I of part 156. We also propose that the administrative review process in subpart J of part 156 would apply to enforcement actions taken against QHP issuers or plans under proposed § 156.350. Because timely compliance with paragraph (a) is vital to the smooth functioning of the Federal platform and because the Federal platform would apply a uniform compliance and enforcement regime for reasons of efficiency and speed, we believe it is appropriate that HHS have this authority in this circumstance.

Because this proposal would insert a section applicable to SBE–FPs in subpart D, which currently describes only standards for QHP issuers on the FFEs, we propose to amend the title of subpart D to read Standards for Qualified Health Plan Issuers on Federally-Facilitated Exchange and State-Based Exchanges on the Federal Platform.

We seek comment on this proposal.

7. Enforcement Remedies in Federally-Facilitated Exchanges (§§ 156.800, 156.805, 156.810, and 156.815)

We propose to revise paragraph § 156.805(d). We believe paragraph (d) provides insufficient information on the effect of appealing a CMP. In the interest of aligning our CMP and decertification regulations, we propose to rename paragraph (d) ''Request for hearing.'' Next, we propose to revise paragraph (d)(1) to state affirmatively the issuer's right to file a request for hearing on the assessment of a CMP. Finally, we propose to add paragraph (d)(2), stating that the request for hearing will suspend the assessment of CMP until a final administrative decision on the appeal. A similar provision exists in the decertification regulation at § 156.810.

We propose to amend § 156.810 by revising paragraph (e) to present the appeal rights of QHP issuers and the impact of an appeal more clearly. Specifically, we propose to provide for the issuer's appeal right in paragraph (e). Then in paragraph (e)(1) and its paragraphs, we propose to explain how an appeal will affect the effective date of a decertification depending on whether the decertification is standard or expedited.

Previously, we finalized § 156.800(c), in which we stated that sanctions will not be imposed on a QHP issuer on an FFE if it has made good faith efforts to comply with applicable requirements for calendar years 2014 and 2015. We are not proposing to extend this policy. Starting in the 2016 calendar year and beyond, sanctions may be imposed if a QHP issuer on an FFE fails to comply with applicable standards, even if the QHP issuer has made good faith efforts to comply with these requirements.

Section 156.810 contains bases for decertification of a QHP. One of the bases for decertification, § 156.810(a)(5), authorizes decertification if a QHP issuer is hindering the efficient and effective operation of a Federally-facilitated Exchange. We interpret the efficient and effective operation of the FFEs to include displaying plans that will provide coverage to enrollees who purchase coverage under that plan. Where an issuer has informed HHS that

it cannot continue to provide coverage under a QHP, HHS will interpret this information to mean that the efficient and effective operation of the FFE will be hindered because it will incorrectly display plans on the FFE platform. In such a case, HHS may take all necessary steps to suppress and/or decertify the QHP.

We propose to add new bases for decertification to § 156.810 to address situations where a QHP issuer is the subject of a pending or existing State enforcement action, including a consent order, or where HHS has reasonably determined that an issuer lacks the funds to continue providing coverage to its consumers for the remainder of the plan year. Under its obligation to determine that making a plan available on the FFEs is in the interest of qualified individuals and employers, HHS is proposing to adopt these decertification bases as a consumer protection measure.

We welcome comments on these proposals.

8. Quality Standards

a. Patient Safety Standards for QHP Issuers (§ 156.1110)

In § 156.1110, we established the first phase of patient safety standards, beginning on January 1, 2015, for QHP issuers to verify that certain contracted hospitals meet Medicare Hospital Conditions of Participation requirements regarding a quality assessment and performance improvement program and a discharge planning process. We propose to strengthen QHP patient safety standards in accordance with section 1311(h) of the Affordable Care Act for plan years beginning on or after January 1, 2017. In addition to hospital requirements to meet certain quality and patient safety standards delineated in the Medicare Conditions of Participation, HHS has engaged with several initiatives such as the Patient Safety Organization (PSO) program, Hospital Engagement Networks and the Quality Improvement Organizations, to broaden the national impact on reducing patient harm. By leveraging the successful work already being done at national, regional, and local hospital systems for health care quality improvement and harm reduction, we believe that alignment of the QHP issuer standards with effective patient safety interventions will achieve greater impact. Therefore, we propose amending § 156.1110 to capture the current patient safety standards that continue to apply for plan years beginning before January 1, 2017 in new paragraph (a)(1). We also propose to add new paragraph (a)(2)(i)(A) to specify that for plan years beginning on or after January 1, 2017, a QHP issuer that contracts with a hospital with greater than 50 beds must verify that the hospital uses a patient safety evaluation system as defined in 42 CFR 3.20. The patient safety evaluation system is defined in the PHS Act as the collection, management, or analysis of information for reporting to or by a Patient Safety Organization.[39] We propose in § 156.1110(a)(2)(i)(B) to require that a QHP issuer that contracts with a hospital with greater than 50 beds must ensure that the hospital implemented a comprehensive person-centered discharge program to improve care coordination and health care quality for each patient. We believe that use of a data-driven approach, analytic feedback, and shared learning to advance patient safety, such as working with a PSO, are essential to implementing meaningful interventions to improve patient health care quality.

In accordance with the flexibility provided to the Secretary under section 1311(h)(2) of the Affordable Care Act to establish reasonable exceptions to the QHP issuer patient safety requirements, we propose in § 156.1110(a)(2)(ii), that the hospital may implement evidence-based initiatives to reduce all cause preventable harm,[40] prevent hospital readmission, improve care coordination and improve health care quality through the collection, management and analysis of patient safety events by a means other than reporting of such information to or by a PSO. For example, a QHP issuer may comply with the proposed patient safety standards if the applicable QHP issuer-contracted hospital participates through the Partnership for Patients initiative as part of a Hospital Engagement Network.[41] We believe this would allow for flexibility and promote alignment for hospitals that already engage in effective national, State, public and private patient safety programs. Although hospital patient safety programs are diverse, we believe that promoting a common goal of preventing the risk of patient harm in an effective, sustainable way is important. We also believe it is important to recognize the core components of a hospital patient safety program, including development of comprehensive patient safety systems to identify, report and analyze data; tracking of process and outcome measures; encouraging a culture of safety with leadership and health care provider support and expertise; and engaging patients and families in quality improvement and action plans. Over time, as PSO activities continue to expand in scope, maturity and effectiveness to advance efforts to ensure patient safety, we anticipate continuing to reassess the reasonable exceptions to the QHP issuer patient safety requirements outlined in § 156.1110(a)(2)(ii). We expect that QHP-issuer contracted hospitals with more than 50 beds will contract with a PSO and implement a comprehensive person-centered discharge program to improve care coordination and health care quality for each patient. HHS will continue to monitor the status of the PSO program and other patient safety initiatives and will develop additional requirements or guidance, if needed, to support effective patient safety strategies and harmonization of evidence-based standards and requirements under § 156.1110.

In addition, HHS strongly supports hospital tracking of patient safety events using the Agency for Healthcare Research and Quality Common Formats,[42] which are a useful tool for a hospital regardless of what patient safety interventions are implemented for ongoing, data-driven quality assessment. The Agency for Healthcare Research and Quality anticipates releasing version 2.0 of the Common Formats for Event Reporting—Hospitals, which would define a systematic process for reporting adverse events, near misses and unsafe conditions, and allow a hospital to report harm from all causes. We believe that use of Common Formats, and aligning with existing HHS recommendations for hospitals,[43] is integral whether a hospital chooses to work with a PSO to comply with the proposed requirement in § 156.1110(a)(2)(i) or implements the alternative approach under the reasonable exception provision as proposed in § 156.1110(a)(2)(ii).

We believe these proposed amendments to QHP issuer patient safety requirements would support these common aspects and goal, and also align with the established

[39] *See,* 42 U.S.C. 299b–21(6); and *http://www.pso.ahrq.gov/regulations/fnlrule01.pdf.*

[40] All cause preventable harm or all adverse events-any event during the care process that results in harm to a patient, regardless of cause (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-19.pdf*).

[41] *http://partnershipforpatients.cms.gov/about-the-partnership/aboutthepartnershipforpatients.html.*

[42] *https://www.pso.ahrq.gov/common.*

[43] *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-19.pdf.*

requirements in § 156.1130 for a QHP quality improvement strategy, specifically the outlined quality improvement strategy topic areas from section 1311(g) of the Affordable Care Act, including implementation of activities to prevent hospital readmissions and implementation of activities to improve patient safety and reduce medical errors.

We propose in § 156.1110(b) to amend the documentation requirement to specify that, for plan years beginning on or after January 1, 2017, a QHP issuer to collect information from each of its contracted hospitals with greater than 50 beds to demonstrate that those hospitals meet the patient safety standards required in paragraph (a)(2) of this section. Such information could include a copy of the current agreement to partner with a PSO, a Hospital Engagement Network, or a Quality Improvement Organization. The documentation should reflect implementation of PSO activities, such as PSOs and hospitals working together to collect, report and analyze patient safety events, and implementation of a comprehensive person-centered hospital discharge program to demonstrate compliance with the proposed requirements in § 156.1110(a)(2)(i); or implementation of other patient safety initiatives to reduce all cause preventable harm, prevent hospital readmission, improve care coordination and improve health care quality through the collection, management and analysis of patient safety events to demonstrate compliance with the reasonable exception provision proposed to be captured in § 156.1110(a)(2)(ii). We also propose to remove paragraph (d) from section § 156.1110 because it is no longer needed given the clarifying proposed effective date language within paragraphs (a) and (b). We clarify that, at this time, HHS does not intend to amend the number of hospital beds threshold authorized by section 1311(h)(3) of the Affordable Care Act and does not intend to begin implementing the provisions in section 1311(h)(1)(B) regarding non-hospital health care providers.

We seek comment on the proposed amendments to paragraphs (a) and (b), and the proposed deletion of paragraph (d). We seek comment specifically on the proposals to require that a QHP issuer that contracts with a hospital with greater than 50 beds must verify that the hospital uses a patient safety evaluation system and implements a comprehensive person-centered discharge program to improve care coordination and health care quality for each patient. We also seek comment on the reasonable exception provision under which the QHP issuer-contracted hospital with greater than 50 beds may implement evidence-based initiatives other than working with a PSO to reduce all cause preventable harm, prevent hospital readmission, improve care coordination and improve health care quality through the collection, management and analysis of patient safety events. We are considering providing that QHP issuers must ensure that their contracted hospitals as described in section 1311(h) are standardizing reporting of patient safety events with the use of the Agency for Healthcare Research and Quality Common Formats, and we seek comment regarding this potential requirement. We seek comment on the types of information, such as hospital agreements with PSOs, HENs or QIOs, that may be submitted to a QHP issuer to comply with the proposed standard in § 156.1110(b)(2). We also seek comment on the proposed documentation standard, including the burden and costs, to require a QHP issuer to track information and demonstrate compliance with meeting the new patient safety standards described in paragraph (a)(2).

9. Qualified Health Plan Issuer Responsibilities

a. Payment and Collections Processes (§ 156.1215)

In the 2015 Payment Notice, HHS established a monthly payment and collections cycle for insurance affordability programs, user fees, and premium stabilization programs. In 2017, as discussed elsewhere in this document, we are proposing to charge issuers in State-based Exchanges that utilize the Federal platform for eligibility and enrollment services a user fee for the use of the platform. To streamline our payment and collections process, we propose that, for 2017 and later years, for purposes of the netting process, the reference to FFE user fees in § 156.1215(b) would be interpreted to include any fees for issuers in State-based Exchanges using the Federal platform, as well as user fees that HHS collects on behalf of the State-based Exchange using the Federal platform.

In the 2015 Payment Notice, we established in § 156.1215(c) that any amount owed to the Federal government by an issuer and its affiliates is the basis for calculating a debt owed to the Federal government. Similarly, we propose that, for 2015 and later years, for purposes of calculating the debt owed to the Federal government, we would interpret the reference to FFE user fees to include any fees for issuers in State-based Exchanges using the Federal platform, as well as user fees that HHS collects on behalf of the State-based Exchange using the Federal platform.

We solicit comments on these proposals, including whether the current regulations should be amended to reflect this interpretation.

b. Administrative Appeals (§ 156.1220)

In the 2015 Payment Notice (79 FR 13818), we established an administrative appeals process for issuers. We established a three-tiered appeals process: a request for reconsideration under § 156.1220(a); a request for an informal hearing before a CMS hearing officer under § 156.1220(b); and a request for review by the Administrator of CMS under § 156.1220(c). We note that should we finalize our proposal around SBE–FPs, we would interpret this administrative appeals process to apply to user fee payments that we collect from SBE–FP QHP issuers that offer plans on an SBE–FP.

Under § 156.1220(a), an issuer may only file a request for reconsideration based on the following: a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error. For example, an issuer may file a request for reconsideration that challenges the assessment of a default risk adjustment charge if the issuer believes the default charge was assessed because HHS incorrectly applied its methodology regarding data quantity and data sufficiency standards; however, the issuer may not file a request for reconsideration to challenge the methodology itself. We note that we are seeking comment on the proposed requirements related to the data quantity and data sufficiency methodology for the reinsurance and risk adjustments programs elsewhere in this proposed rule. We also clarify that an issuer may not file a request for reconsideration regarding issues arising from the issuer's failure to load complete and accurate data to its dedicated distributed data environment within the data submission window. Errors by the issuer are not appealable.

We seek to clarify these grounds for appeal for the risk adjustment and reinsurance programs, as follows. In line with our proposal to delete § 153.710(d), we propose to make conforming amendments to modify § 156.1220 to remove cross-references to the interim discrepancy reporting process. Under § 156.1220(a)(4)(ii), a reconsideration relating to risk adjustment or

reinsurance may only be requested if, to the extent the issue could have been previously identified by the issuer to HHS under the final discrepancy reporting process proposed to be redesignated at § 153.710(d)(2), it was so identified and remains unresolved. As proposed to be redesignated, § 153.710(d)(2) states that an issuer must identify to HHS any discrepancies it identified in the final distributed data environment reports. We clarify that issuers may identify issues during the discrepancy reporting process under newly designated § 153.710(d)(2) that are not subject to appeal; issuers may identify issues that are not processing errors by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical errors. We clarify that, in contrast, an issuer may only request a reconsideration of unresolved issues that were identified under the final discrepancy reporting process proposed to be redesignated at § 153.710(d)(2), if contesting a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error. The existence of an unresolved discrepancy is not alone a sufficient basis on which to request a reconsideration.

We also seek to clarify the grounds for appeal for the risk corridors program. An issuer may not file a request for reconsideration to challenge the standards for the risk corridors program, including those established in §§ 153.500 through 153.540 and in guidance issued by HHS. In addition, appeals related to data for programs other than risk corridors covered in § 156.1220(a) cannot be grounds for risk corridors appeals.

We also propose to shorten the deadline for filing a request for reconsideration in § 156.1220(a)(3) from 60 to 30 calendar days. This proposal will permit HHS to resolve administrative appeals, calculate final payments and charges, and make payments in a more expedited manner. Additionally, we propose to clarify that an issuer must pay the full amount owed to HHS as set forth in the applicable notification, even if the issuer files a request for reconsideration under § 156.1220. Failure to pay an amount owed will result in interest accruing after the applicable payment deadline. Therefore, if an appeal is unsuccessful, and the issuer has not already remitted the charge amount owed, the issuer would owe the debt plus the interest, and administrative fees which accrue from delayed payment. If an appeal is successful, HHS will refund the amount paid in accordance with the final appeal decision.

Therefore, we propose that the request for reconsideration must be filed in accordance with the following timeframes: (i) For the premium tax credit and cost-sharing reduction portions of the advance payments, or FFE user fee charges, within 30 calendar days after the date of the final reconsideration notification specifying the aggregate amount of such advance payments or user fees for the applicable benefit year; (ii) for a risk adjustment payment or charge, including an assessment of risk adjustment user fees, within 30 calendar days of the date of the notification under § 153.310(e); (iii) for a reinsurance payment, within 30 calendar days of the date of the notification provided under § 153.240(b)(1)(ii); (iv) for a default risk adjustment charge, within 30 calendar days of the date of the notification of such charge; (v) for reconciliation of the cost-sharing reduction portion of the advance payments, within 30 calendar days of the date of the notification of such payment or charge; and (vi) for a risk corridors payment or charge, within 30 calendar days of the date of the notification of such payment or charge for the purposes of § 153.510(d). We propose to clarify that the last submission of data to which the issuer has attested serves as the notification for purposes of § 153.510(d). We seek comment on this proposal.

c. Third Party Payment of Qualified Health Plan Premiums (§ 156.1250)

On March 19, 2014, we published in the **Federal Register** an interim final rule (IFR) with comment period titled, Patient Protection and Affordable Care Act; Third Party Payment of Qualified Health Plan Premiums (79 FR 15240). The IFR requires individual market QHP issuers, including SADP issuers, to accept premium and cost-sharing payments made on behalf of enrollees by: The Ryan White HIV/AIDS Program; other Federal and State government programs that provide premium and cost sharing support for specific individuals; and Indian tribes, tribal organizations, and urban Indian organizations. The IFR applies the requirements at § 156.1250 to all individual market QHPs and SADPs, regardless of whether they are offered through an FFE, an SBE, or outside of an Exchange.

The IFR also amended § 156.805 to ensure that § 156.1250 could be enforced. Specifically, the IFR amended § 156.805(a)(1) to: Provide that § 156.805 targets violations of issuer standards and requirements of part 153 that are applicable to issuers; clarify that substantial non-compliance with any Exchange standard or requirement applicable to issuers in the FFE is grounds for imposing CMPs; and explicitly reference part 156 to clarify that substantial non-compliance with the Exchange standards applicable to issuers offering QHPs in the FFEs under part 156, including new § 156.1250, may be a basis for the imposition of CMPs under § 156.805.

Prior to publishing the IFR, HHS issued two ''Frequently Asked Questions'' documents regarding premium and cost-sharing payments made by third parties on behalf of QHP enrollees. In an FAQ issued on November 4, 2013 (the November FAQ), HHS encouraged QHP issuers not to accept third-party payments made on behalf of enrollees by hospitals, other healthcare providers, and other commercial entities due to concerns that such practices could skew the insurance risk pool and create an uneven field in the Exchanges.[44] On February 7, 2014, HHS issued another FAQ (the February FAQ) clarifying that the November FAQ did not apply to third party premium and cost-sharing payments made on behalf of enrollees by Indian tribes, tribal organizations, and urban Indian organizations; State and Federal government programs (such as the Ryan White HIV/AIDS Program); or private, not-for-profit foundations that base eligibility on financial status, do not consider enrollees' health status, and provide assistance for an entire year.[45] In the February FAQ, HHS affirmatively encouraged QHP issuers to accept such payments given that Federal or State law or policy specifically envisions third party payment of premium and cost-sharing amounts by these entities.

We received 174 comments in response to the March 19, 2014 IFR. The comments ranged from general support of or opposition to the IFR's provisions to very specific questions or comments. Based on these comments, we propose to make some modifications to the policy finalized in the IFR.

Several commenters requested that final regulations clarify that ''Federal and State government programs'' include programs administered by a State's political sub-divisions (for example, counties and municipalities). Several other commenters expressed confusion regarding the definition of

[44] *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-qa-11-04-2013.pdf.*

[45] *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-payments-of-premiums-for-qualified-health-plans-in-the-marketplaces-2-7-14.pdf.*

''State and Federal government programs,'' particularly in the case where an entity is both a (Federal or State) government program as well as a health care provider. These commenters expressed concern that § 156.1250 does not make a distinction between government programs (such as Ryan White HIV/AIDS programs) and programs that involve Federal grantees receiving considerable public funding. Other commenters expressed concern that the category of Federal and State government programs is too broad, and does not provide adequate notice of which payments must be accepted.

We propose to amend § 156.1250 to clarify that a Federal or State government program includes programs of the political subdivisions of the State, namely counties and municipalities, which we refer to as ''local governments.'' Including this clarification in regulations will ensure that States have the flexibility to distribute care and Exchange financial assistance to their vulnerable populations through local governments, consistent with their statutory and regulatory authority.

In terms of the distinction between programs sponsored and operated by the government (such as the Ryan White HIV/AIDS programs) and programs that involve Federal grantees that receive considerable public funding, we acknowledge that programs such as the Ryan White HIV/AIDS program operate by working with cities, States, and local community-based organizations to provide services in line with their statutory authority. Sections 2604(c)(3)(F), 2612(c)(3)(F), and 2651(c)(3)(F) of the PHS Act authorize Ryan White HIV/AIDS program grantees and sub-grantees to use program funds for premium and cost-sharing assistance. These grantees and sub-grantees must provide the assistance through third-party payments as they are prohibited from making payments directly to patients. Though many Ryan White HIV/AIDS program grantees are State and local governments, not all are; similarly, many of the State and local government grantees administer funds through sub-grantees that are not government entities. We propose to distinguish government programs from government grantees such that the requirement at § 156.1250 applies to government programs, but not necessarily to entities that are government grantees, unless specifically authorized and funded by the Federal, State, or local government program to make the payments on behalf of the program, consistent with the government programs' statutory and regulatory authority to provide premium and cost-sharing assistance through grants and grantees. In other words, if such Federal, State, and local governments are authorized to administer their premium and cost-sharing assistance through grantees or sub-grantees, the payments may not be rejected on the grounds that they did not come directly from the government programs. In such cases, the source of the Exchange financial assistance is the government program, and administration or distribution of that assistance through grants and grantees is authorized under statute or regulation. We seek comment on this proposal and also on whether final regulations should list out the specific entities that qualify as government programs for purposes of this provision.

We also propose to require entities that make third party payments of premiums under this section to notify HHS, in a format and timeline specified in guidance. We propose that the notification must reflect the entity's intent to make payments of premiums under this section and the number of consumers for whom it intends to make payments. We seek comment on this requirement, and on what information entities should provide as part of this notification.

We also propose to clarify that while issuers offering individual market QHPs, including SADPs, generally do not collect cost-sharing payments, they are required to accept third party cost-sharing payments on behalf of enrollees in circumstances where the issuer or the issuer's downstream entity accepts cost-sharing payments from plan enrollees. Although generally cost-sharing payments are made to providers, rather than to issuers, there are certain contractual circumstances where an issuer's non-provider downstream entity engages in activities on behalf of the issuer, including the collection of cost-sharing payments. For example, an issuer's pharmacy benefits manager may collect cost-sharing payments from the issuer's plan enrollees for prescription drugs. We propose to clarify that in such situations, the rules at § 156.1250 regarding third-party payments would apply to cost sharing. We seek comment on these proposals.

We received a number of comments requesting that final regulations require issuers to accept third-party payments from not-for-profit, charitable organizations. Several comments stated that requiring QHP issuers to accept third party payments from Ryan White HIV/AIDS programs but not from other disease-specific programs is unfair to those individuals with other diseases or conditions. Several other commenters expressed that many not-for-profit foundations and charitable organizations offer premium and cost-sharing assistance to individuals based on both financial status and diagnosis of a particular condition or disease.

We are considering whether we should expand the list of entities from whom issuers are required to accept payment under § 156.1250 to include not-for-profit charitable organizations organizations in future years. If we did include not-for-profit charitable organizations, we would intend to include guardrails intended to minimize risk pool impacts, such as limiting assistance to individuals not eligible for other MEC and requiring assistance until the end of the calendar year. In making this determination, we intend to carefully review data provided by entities currently making third party premium payments and data related to the overall risk pool to better understand the impact of these payments.

d. Other Notices (§ 156.1256)

We propose to add a new § 156.1256, which would add a requirement for issuers, in the case of a plan or benefit display error included in § 155.420(d)(4), to notify their enrollees within 30 calendar days after the error is identified, if directed to do so by the FFE. We believe that enrollees should be made aware of any error that may have impacted their QHP selection and enrollment and any associated monthly or annual costs. Therefore, we are proposing a requirement for issuers to notify their enrollees of such error, should such error occur, as well as the availability of a special enrollment period, under § 155.420(d)(4), for the enrollee to select a different QHP, if desired. We seek comment on this proposal.

H. Part 158—Issuer Use of Premium Revenue: Reporting and Rebate Requirements

1. Definitions (§ 158.103)

To ensure consistency in the definitions of ''large employer'' and ''small employer'' between the MLR regulation and the market reform requirements, and to reflect the recent amendments to section 2791(e) of the PHS Act and section 1304(b) of the Affordable Care Act that were made by the Protecting Affordable Coverage for Employees Act (Pub. L. 114–60), we propose to revise the regulatory definitions of ''large employer'' and ''small employer'' in § 158.103 to cross-

reference the definitions of those terms in § 144.103.

2. Reporting of Incurred Claims (§§ 158.103 and 158.140(a))

The MLR December 1, 2010 interim final rule (75 FR 74864) and the May 16, 2012 technical corrections thereto (77 FR 28788) direct issuers to report incurred claims with a 3-month run-out period, and define unpaid claim reserves to mean reserves and liabilities established to account for claims that were incurred during the MLR reporting year but had not been paid within 3 months of the end of the MLR reporting year. The run-out period improves the accuracy of reported incurred claims by using the actual claims payments that take place during the run-out period, instead of the estimated claims liabilities and reserves, in the calculation of claims incurred in the reporting year.

Prior to the 2014 MLR reporting year, the deadline for submitting MLR reports to the Secretary was June 1 of the year following the reporting year. The 2014 Payment Notice (78 FR 15410) moved the reporting deadline from June 1 to July 31 of the year following the reporting year to accommodate inclusion of the transitional reinsurance and risk adjustment amounts, which HHS generally publishes by June 30, in the MLR and risk corridors calculations.

Because the MLR reporting deadline applicable to the 2014 and later reporting years occurs later in the year, the incurred claims valuation can also occur later in the year. Therefore, we propose to amend the definition of unpaid claims reserves in § 158.103 and the requirements for reporting incurred claims in § 158.140(a) to utilize a 6-month, rather than a 3-month run-out period beginning with the 2015 reporting year. This proposed amendment would require incurred claims to be calculated as of June 30, rather than March 31, of the year following the reporting year. We note that this approach is consistent with the proposal outlined in section III.D.3.a. of this preamble regarding the treatment of incurred but not received claims for the risk corridors program. We seek comment on this proposal.

Finally, we are inviting comment on whether we should modify the treatment of a health insurance issuer's investments in fraud prevention activities for MLR reporting purposes in the final rule. We are considering amending the MLR regulation to permit the counting of a health insurance issuer's investments in fraud prevention activities among those expenses attributable to incurred claims. We solicit comments on this approach, including whether safeguards against potential abuse should be included (for example, an upper limit on this allowance, such as a percentage based on the ratio of issuers' fraud reduction expenses reported under § 158.140(b)(iv) and issuers' earned premium as defined in § 158.130); whether we should collect fraud prevention activity expense data as an informational item on the MLR Annual Reporting Form before amending the regulation; as well as on potential alternative treatment of these expenses for MLR reporting or rebate calculation purposes. We seek comment on this issue from all stakeholders, and specific actual data, if available, including with respect to the additional incentives that would result for health plan investments of this sort.

IV. 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. This proposed rule contains information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 11. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) 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.

We are soliciting public comment on each of these issues for the following sections of this proposed rule that contain ICRs. We generally used data from the Bureau of Labor Statistics to derive average labor costs (including a 35 percent increase for fringe benefits and overhead) for estimating the burden associated with the ICRs.[46]

[46] See May 2014 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates at *http://www.bls.gov/oes/current/oes_nat.htm.*

A. ICRs Regarding Submission of Risk Corridors Data (§ 153.530)

We are proposing to amend the risk corridors program requirements at § 153.530 to require issuers to true-up claims liabilities and reserves used to determine the allowable costs reported for the preceding benefit year to reflect the actual claims payments made through June 30 of the year following the benefit year. Although this proposal would require issuers to submit data indicating the difference between their incurred liability estimated as of March 31 and June 30, we believe that issuers will be recording these amounts as part of their normal business practices, and that there will be no new data elements and no additional burden as a result of this proposal. Therefore, in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), we believe the burden associated with this requirement would be exempt as it associated with a usual and customary business practice.

B. ICRs Regarding Submission of Rate Filing Justification (§ 154.215)

This proposed rule would require health insurance issuers to submit a Unified Rate Review Template for all single risk pool coverage regardless of whether there is a plan within a product that experiences a rate increase. The existing information collection requirement is approved under OMB Control Number 0938–1141. This includes the unified rate review template and instructions for rate filing documentation that issuers currently use to submit rate information to HHS for rate increases of any size for single risk pool coverage and rate increases that meet or exceed the subject to review threshold for non-single risk pool coverage. As detailed in the accompanying preamble discussion, we believe most issuers already report this information. Therefore, we do not expect issuers to incur a burden associated with this proposed regulation. Prior to the deadline for the submission of rate information to CMS for rates for single risk pool coverage effective on or after January 1, 2017, HHS intends to solicit public comment on and seek OMB approval for revisions to the information collection template and instructions approved under OMB Control Number 0938–1141.

C. ICRs Regarding Election To Operate an Exchange After 2014 (§ 155.106)

This proposed rule would modify the dates for application submission and approval for States seeking to operate an SBE, and have an approved or

conditionally-approved Exchange Blueprint application and operational readiness assessment. HHS does not propose modifying the documents that States already must submit as part of the required Exchange Blueprint application. Therefore, HHS does not anticipate any additional impact to the administrative burden associated with the proposed regulatory changes to § 155.106. HHS proposes utilizing the existing PRA package approved under OMB Control Number 0938–1172 for the Exchange Blueprint application.

D. ICRs Regarding Standards for Certified Application Counselors (§ 155.225(b)(1)(iii))

Section 155.225(b)(1)(ii) requires certified application counselor designated organizations to maintain a registration process and methodology to track the performance of certified application counselors. This proposed rule would add a new § 155.225(b)(1)(iii) requiring certified application counselor designated organizations to provide the Exchange with information and data regarding the performance of the organization's certified application counselors, and the consumer assistance they provide. Although the current requirement at § 155.225(b)(1)(ii) does not specify the type of performance information that must be tracked, or require that the information be provided to the Exchange, we expect that certified application counselor designated organizations already have a tracking process in place to collect performance information from individual certified application counselors, and that individual certified application counselors are already recording and submitting this required information to their organization. Therefore, we expect this proposal to have minimal impact on individual certified application counselors and on certified application counselor designated organizations.

The proposed § 155.225(b)(1)(iii) would add a new burden of compiling the performance information and submitting it to the Exchanges. In States with FFEs, HHS anticipates that, beginning in January 2017, it would collect three performance data points each month from certified application counselor designated organizations: The number of individuals who have been certified by the organization; the total number of consumers who received application and enrollment assistance from the organization; and of that number, the number of consumers who received assistance applying for and selecting a QHP, enrolling in a QHP, or applying for Medicaid or CHIP. We anticipate that this data would be reported to FFEs electronically, through HIOS or another electronic submission vehicle. For the purpose of estimating costs and burdens, we assume that State Exchanges will collect the same information with the same frequency, although our proposal gives Exchanges the flexibility to determine which data to collect and the form and manner of the collection. We estimate that certified application counselor designated organizations will have a mid-level health policy analyst prepare the reports and a senior manager will review each monthly report. HHS expects that a mid-level health policy analyst (at an hourly wage rate of $40.64) will spend 2 hours each month to provide the required monthly submissions and a senior manager (at an hourly wage rate of $91.31) will spend $^{3}/_{\text{fxsp0;8}}$ hour to review the submissions. Therefore, we estimate each monthly report will require 2.375 hours and a cost burden of $115.52 per month per organization, or 28.50 hours with a cost (12 monthly reports) of $1,386.25 annually per certified application counselor designated organization. Nationwide, we estimate there are 5,000 certified application counselor designated organizations, resulting in an annual cost burden of $6,931,200 and 142,500 hours for certified application counselor designated organizations.

Under proposed § 155.225(b)(1)(iii), if an Exchange requests these certified application counselor reports, the Exchange would also need to review the reports. We assume that all Exchanges will require monthly reports and will utilize in-house staff to review them. We assume that an employee earning a wage that is equivalent to a mid-level GS–11 employee would review monthly report submissions from certified application counselor designated organizations.[47] We estimate that a mid-level employee (at an hourly wage rate of $43.13) will spend 10 minutes reviewing each monthly report for a cost burden of approximately $7.19 per monthly report per certified application counselor designated organization. For State Exchanges, we estimate that there are 1,500 certified application counselor designated organizations resulting in a cost burden of 3,000 hours and approximately $129,390 annually. Costs to the FFEs are estimated separately in the Regulatory Impact Analysis section of this proposed rule.

[47] Federal wage rates are available at *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2015/GS_h.pdf.*

E. ICRs Regarding Network Adequacy Standards (§ 156.230(e) and (f))

Proposed § 156.230(e) would require that QHP issuers make a good faith effort to provide written notice of discontinuation of a provider 30 days prior to the effective date of the change or otherwise as soon as practicable, to enrollees who are patients seen on a regular basis by the provider or who receive primary care from the provider whose contract is being discontinued, irrespective of whether the contract is being discontinued due to a termination for cause or without cause, or due to a non-renewal. This is a third-party disclosure requirement. We estimate that a total of 475 issuers participate in the FFE and would be required to comply with the proposed standard. We propose an estimate of 5 percent of providers discontinue contracts per year and that an issuer in the FFE covers 7,500 National Provider Identifiers, which means that we estimate an issuer would have 375 provider discontinuations in a year. For each provider discontinuation, we propose an estimate that it will take a database administrator 30 minutes for data analysis to produce the list of affected enrollees at $55.37 an hour and an administrative assistant 30 minutes to develop the notification and send the notification to the affected enrollees, at $29.93 an hour. The total costs per an issuer would be $15,993.75. The total annual costs estimate would be $7,597,031. Because we are already collecting information regarding network classifications as part of the existing QHP certification process, we do not believe that this proposal described in the preamble will result in additional information collection requirements for issuers.

Proposed § 156.230(f) would require QHP issuers to provide a notice to enrollees of the possibility of out-of-network charges from an out-of-network provider in an in-network setting at least 10 business days prior to the benefit being provided to avoid counting the out-of-network costs against to the annual limitation on cost sharing. This provision would apply to all QHPs, which includes 575 issuers. We estimate it would take an issuer's mid-level health policy analyst (at an hourly wage rate of $54.87) approximately 6 minutes to create a notification and send the proposed information. We estimate that approximately 2 notices would be sent for every 100 enrollees. Assuming approximately 9 million enrollees in QHPs 2017, we estimate QHPs would send approximately 180,000 total

notices, for a total hours of 18,000, with a total cost of $987,660.

F. ICR Regarding Monthly SHOP Enrollment Reconciliation Files Submitted by Issuers (156.285(c)(5))

Proposed amendments to § 156.285(c)(5) would specify that issuers in a Federally-facilitated SHOP would send monthly enrollment reconciliation files to the SHOP according to a process, timeline and file format established by the FF–SHOP. CMS anticipates that it would require FF–SHOP issuers to submit a standard file with specific data elements and submit their files in a process set out by the SHOP, no less frequently than on a monthly basis.

Issuers of QHPs available through the SHOP are already required under the current version of § 156.285(c)(5) ''to reconcile enrollment files with the SHOP at least monthly.'' Therefore, we expect this proposal to have minimal impact on SHOP issuers.

G. ICR Regarding Patient Safety Standards (§ 156.1110)

In § 156.1110(a)(2), we propose that for plan years beginning on or after January 1, 2017, a QHP issuer that contracts with a hospital with greater than 50 beds must verify that the hospital uses a patient safety evaluation system and implements a mechanism for comprehensive person-centered hospital discharge to improve care coordination and health care quality for each patient. We also propose in § 156.1100(a)(2)(ii) to establish reasonable exceptions to these new QHP issuer patient safety requirements such that the hospital may implement evidence-based initiatives to reduce all cause preventable harm, prevent hospital readmission, improve care coordination and improve health care quality through the collection, management and analysis of patient safety events (rather than requiring reporting of such information to or by a Patient Safety Organization). The burden estimate associated with the information collection, recordkeeping, and disclosure requirements to demonstrate compliance with these standards includes the time and effort required for QHP issuers to maintain and submit to the applicable Exchanges, documentation including but not limited to, hospital agreements to partner with a Patient Safety Organization, a Hospital Engagement Network, or a Quality Improvement Organization that demonstrate that each of its contracted hospitals with greater than 50 beds meets the patient safety standards required in § 156.1110(a)(2) for plan years beginning on or after January 1, 2017. QHP issuers may not already be collecting such network provider information; therefore, we estimate the cost and burden to collect this administrative information as follows: For a total of 600 QHP issuers, offering 15 plans as potential QHPs, we estimate each issuer would require one senior manager an average of 3 hours to collect and maintain the hospital agreements or other information necessary to demonstrate compliance as required in § 156.1110(a)(2) for their QHPs offered on Exchanges for plan years beginning on or after January 1, 2017. For a senior manager (at an hourly wage rate of $91.31), we estimate the total annual cost for a QHP issuer to be $273.93. Therefore, we estimate a total annual burden of 1,800 hours, resulting in an annual cost of $164,358.

H. ICR Regarding Third Party Payment of Qualified Health Plan Premiums (§ 156.1250)

We are proposing to require entities that make third party payments of premiums under this section to notify HHS, in a format and timeline specified in guidance. We expect that the notification would reflect the entity's intent to make payments of premiums under this section and the number of consumers for whom it intends to make payments. We estimate it would take approximately four hours to analyze the number of consumers the entity intends to make payments of premiums on behalf of, draft a notification and send the proposed information by a mid-level health policy analyst (at an hourly wage rate of $54.87). Assuming 500 entities exist that make third party payments and each would send one notice, we estimate a total burden of 2,000 hours resulting in an annual cost of $109,740.

I. ICRs Regarding Other Notices (§ 156.1256)

We are proposing to add a new section at § 156.1256 to require that, in the event of a plan or benefit display error, QHP issuers notify their enrollees within 30 calendar days after the error is identified, both of the plan or benefit display error and of the opportunity to enroll in a new QHP under a special enrollment period at § 155.420(d)(4), if directed to do so by the FFE. This provision would apply to all QHPs in the FFEs, which includes 475 issuers. We estimate it would take approximately 30 minutes to amend a form notice, add SEP language provided by the FFE, and send the proposed information by an issuer's mid-level health policy analyst (at an hourly wage rate of $54.87). We estimate that approximately 4 percent of enrollees would receive such a notice. Assuming approximately 7 million FFE enrollees, we estimate QHPs in the FFEs would send approximately 280,000 total notices, for a total hours of 140,000, with a total cost of $7,681,800.

However, although this proposal would require issuers to send notices for the specified situation, sending these notices is already part of normal issuer business practices and issuers are already working with the FFE to include language in their notices about special enrollment periods, as applicable and appropriate. Therefore, there will be no additional information required by issuers and no new administrative burden as a result of this proposal. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), we believe the burden associated with this requirement would be exempt as it associated with a usual and customary business practice.

TABLE 11—ANNUAL REPORTING, RECORDKEEPING AND DISCLOSURE BURDEN

Regulation section	OMB Control number	Number of respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 155.225(b)(1)(iii)—certified application counselor organizations.	0938–1172	5,000	60,000	2.375	142,500	48.64	6,931,200	6,931,200
§ 155.225(b)(1)(iii)—State Exchange	0938–1172	1,500	1,500	0.167	3,000	43.13	129,390	129,390
§ 156.230(e)	0938–NEW	475	178,125	1	375	42.65	7,597,031	7,597,031
§ 156.230(f)	0938–NEW	575	180,000	0.1	18,000	54.87	987,660	987,660
§ 156.1110	0938–1249	600	9,000	0.2	1,800	91.31	164,358	164,358
§ 156.1250	0938–NEW	500	500	4	2,000	54.87	109,740	109,740
§ 156.1256	0938–NEW	475	280,000	0.5	140,000	54.87	7,681,800	7,681,800

TABLE 11—ANNUAL REPORTING, RECORDKEEPING AND DISCLOSURE BURDEN—Continued

Regulation section	OMB Control number	Number of respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
Total		6,100			334,675		23,601,179	23,601,179

Note: 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 11.

Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection requirements. These requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at *http://www.cms.hhs.gov/PaperworkReductionActof1995*; email your request, including your address, phone number, OMB control number, and CMS document identifier, to *Paperwork@cms.hhs.gov*; or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you comment on these information collection and recordkeeping requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule. Please include ''CMS–9937–P,'' the ICR's OMB control number, and the CMS document ID number in your comment.

PRA-specific comments must be received by February 1, 2016.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

This rule proposes standards related to the premium stabilization programs (risk adjustment, reinsurance, and risk corridors) for the 2017 benefit year, as well as certain modifications to these programs that will protect issuers from the potential effects of adverse selection and protect consumers from increases in premiums due to issuer uncertainty. The Premium Stabilization Rule and previous Payment Notices provided detail on the implementation of these programs, including the specific parameters for the 2014, 2015, and 2016 benefit years applicable to these programs. This rule proposes additional standards related to essential health benefits, meaningful access in the Exchange, consumer assistance tools and programs of an Exchange, Navigators, non-Navigator assistance personnel, agents and brokers registered with the Federally-facilitated Exchange, certified application counselors, cost-sharing parameters and cost-sharing reduction notices, essential community providers, qualified health plans, network adequacy, stand-alone dental plans, acceptance of third-party payments by QHP issuers, patient safety standards for issuers of qualified health plans participating in Exchanges, guaranteed availability and guaranteed renewability, minimum essential coverage, the rate review program, the medical loss ratio program, the Small Business Health Options Program, and FFE user fees.

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 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any 1 year).

OMB has determined that this proposed rule is ''economically significant'' within the meaning of section 3(f)(1) of Executive Order 12866, because it is likely to have an annual effect of $100 million in any 1 year. Accordingly, we have prepared an RIA that presents the costs and benefits of this proposed rule.

Although it is difficult to discuss the wide-ranging effects of these provisions in isolation, the overarching goal of the premium stabilization, market standards, and Exchange-related provisions and policies in the Affordable Care Act is to make affordable health insurance available to individuals who do not have access to affordable employer-sponsored coverage. The provisions within this proposed rule are integral to the goal of expanding coverage. For example, the premium stabilization programs help prevent risk selection and decrease the risk of financial loss that health insurance issuers might otherwise expect in 2017 and Exchange financial assistance assists low- and moderate-income consumers and American Indians/Alaska Natives in purchasing health insurance. The combined impacts of these provisions affect the private sector, issuers, and consumers, through increased access to health care services including preventive services, decreased uncompensated care, lower premiums, establishment of the next phase of patient safety standards, and increased plan transparency. Through the reduction in financial uncertainty for issuers and increased affordability for consumers, these provisions are expected to increase access to affordable health coverage.

HHS anticipates that the provisions of this proposed rule will help further the Department's goal of ensuring that all consumers have access to quality and affordable health care and are able to make informed choices, that Exchanges operate smoothly, that premium stabilization programs work as intended, that SHOPs are provided flexibility, and that employers and consumers are protected from fraudulent and criminal activities.

Affected entities such as QHP issuers would incur costs to comply with the proposed provisions, including administrative costs related to notices, new patient safety requirements, training and recertification requirements, and establishing a larger provider network. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

In accordance with OMB Circular A–4, Table 12 depicts an accounting statement summarizing HHS's assessment of the benefits, costs, and transfers associated with this regulatory action.

This proposed rule implements standards for programs that will have numerous effects, including providing consumers with affordable health insurance coverage, reducing the impact of adverse selection, and stabilizing premiums in the individual and small group health insurance markets and in an Exchange. We are unable to quantify certain benefits of this proposed rule—such as improved health outcomes and longevity due to continuous quality improvement, improved patient safety and increased insurance enrollment—and certain costs—such as the cost of providing additional medical services to newly-enrolled individuals. The effects in Table 12 reflect qualitative impacts and estimated direct monetary costs and transfers resulting from the provisions of this proposed rule for health insurance issuers. The annualized monetized costs described in Table 12 reflect direct administrative costs to health insurance issuers as a result of the proposed provisions, and include administrative costs related to notices, new patient safety requirements, and training and recertification requirements that are estimated in the Collection of Information section of this proposed rule. The annual monetized transfers described in Table 12 include costs associated with FFE user fees, the risk adjustment user fee paid to HHS by issuers, changes in the overall transfer amount for the risk corridors program for fiscal years 2017 through 2018, and an increase in MLR rebates to consumers. We are proposing to collect a total of $52 million in risk adjustment user fees or $1.80 per enrollee per year from risk adjustment issuers, which is slightly more than the $50 million generated in benefit year 2016 when we established a $1.75 per-enrollee-per-year risk adjustment user fee amount. As in 2016, the risk adjustment user fee contract costs for 2017 include additional costs for risk adjustment data validation; however, we expect increased enrollment in 2017 HHS risk adjustment covered plans, which decreases the per enrollee amount. Also, the increase in FFE user fee collections is the result of expected growth in enrollment in the FFEs rather than an increase in the user fee rate, which at 3.5 percent remains the same from 2016 to 2017. Beginning in 2017, we are also proposing to charge a user fee for SBEs that utilize the Federal platform for eligibility and enrollment services. This user fee rate would be set at 3.0 percent for benefit year 2017.

TABLE 12—ACCOUNTING TABLE

Benefits:

Qualitative:

- Increased enrollment in the individual market leading to improved access to health care for the previously uninsured, especially individuals with medical conditions, which will result in improved health and protection from the risk of catastrophic medical expenditures.
- Continuous quality improvement among QHP issuers to reduce patient harm and improve health outcomes at lower costs.
- More informed Exchanges QHP certification decisions.
- Increased coverage options for small businesses and employees with minimal adverse selection.

Costs:	Estimate	Year dollar	Discount rate (percent)	Period covered
Annualized Monetized ($/year)	$23.91	2015	7	2016–2020
	23.91	2015	3	2016–2020

Quantitative:

- Costs incurred by issuers to comply with provisions in the proposed rule.

Transfers:	Estimate	Year dollar	Discount rate (percent)	Period covered
Annualized Monetized ($/year)	$21.73	2015	7	2016–2020
	21.84	2015	3	2016–2020

- Transfers reflect an additional $2 million annual cost of risk adjustment user fees (the total risk adjustment user fee amount for 2015 was $50 million), which are transfers from health insurance issuers to the Federal government. Transfers also reflect an additional $31 million in rebates from entities subject to medical loss ratio (MLR) requirements to consumers, an increase of $105 million in the amount of user fees collected from State-based Exchanges that use the Federal platform for eligibility and enrollment, which are transfers from issuers to the Federal government, and a total decrease of $112 million in the amount of risk corridors transfers between issuers of qualified health plans (QHPs).
- Unquantified: Lower premium rates in the individual market due to the improved risk profile of the insured, competition, and pooling.

This RIA expands upon the impact analyses of previous rules and utilizes the Congressional Budget Office's (CBO) analysis of the Affordable Care Act's impact on Federal spending, revenue collection, and insurance enrollment. The Affordable Care Act ends the temporary risk corridors program and, in this rulemaking, we propose to end the transitional reinsurance program after the benefit year 2016. Therefore, the costs associated with those programs are not included in Tables 12 or 13 for fiscal years 2019–2020. Table 13 summarizes the effects of the risk adjustment program on the Federal budget from fiscal years 2016 through 2020, with the additional, societal effects of this proposed rule discussed in this RIA. We do not expect the provisions of this proposed rule to

significantly alter CBO's estimates of the budget impact of the premium stabilization programs that are described in Table 13. We estimate that the proposal to true up claims liabilities and reserves used to determine allowable costs for the risk corridors program will reduce the overall risk corridors transfer amount by $112 million in each of fiscal years 2017 and 2018. We note that transfers associated with the risk adjustment and reinsurance programs were previously estimated in the Premium Stabilization Rule; therefore, to avoid double-counting, we do not include them in the accounting statement for this proposed rule (Table 12).

In addition to utilizing CBO projections, HHS conducted an internal analysis of the effects of its regulations on enrollment and premiums. Based on these internal analyses, we anticipate that the quantitative effects of the provisions proposed in this rule are consistent with our previous estimates in the 2016 Payment Notice for the impacts associated with the advance payments of cost-sharing reductions and premium tax credits, the premium stabilization programs, and FFE user fee requirements.

TABLE 13—ESTIMATED FEDERAL GOVERNMENT OUTLAYS AND RECEIPTS FOR THE RISK ADJUSTMENT, REINSURANCE, AND RISK CORRIDORS PROGRAMS FROM FISCAL YEAR 2016–2020

[In billions of dollars]

Year	2016	2017	2018	2019	2020	2016–2020
Risk Adjustment, Reinsurance, and Risk Corridors Program Payments	16.5	19.5	13	15	16	80
Risk Adjustment, Reinsurance, and Risk Corridors Program Collections*	15.5	18.5	13	15	16	78

Note 1: Risk adjustment program payments and receipts lag by one quarter. Receipt will fully offset payments over time.

Note 2: The CBO score reflects an additional $2 million in collections in FY 2015 that are outlayed in the FY 2016–FY 2020 timeframe. CBO does not expect a shortfall in these programs.

Source: Congressional Budget Office. Insurance Coverage Provisions of the Affordable Care Act—CBO's March 2015 Baseline Table *https://www.cbo.gov/sites/default/files/cbofiles/attachments/43900-2015-03-ACAtables.pdf.*

1. Fair Health Insurance Premiums

The proposed regulations would permit an additional principal business address to be identified for a small employer that is within the service area of an issuer's network plan, in instances where the issuer is rating based on geography and the employer's principal business address is not within that service area. This would ensure that the network plan can be appropriately rated for sale to the group policyholder, benefitting both issuers and employers.

2. Guaranteed Availability

This proposed rule would codify certain exceptions to guaranteed availability. Because we believe this codification is consistent with current industry practice under current standards, we do not believe this change will have a material impact on issuers or enrollees.

2. Student Health Insurance Coverage

This proposed rule would subject student health insurance coverage to the index rating methodology under the single risk pool regulation, but specify that issuers may establish one or more separate risk pools for each institution of higher education, provided they are based on a bona fide school-related classification and not related to health status. The proposed rule would also eliminate the requirement that issuers of student health insurance coverage provide coverage comprised of the specific metal levels, and instead require such issuers to provide insurance policies that provide at least 60 percent AV. This would provide flexibility for colleges and universities to offer student health insurance plans that are more generous than the standard metal levels. This would affect an estimated 41 issuers that offer student health insurance coverage nationwide and approximately 1.3 million students and dependents enrolled in such plans.[48]

3. Risk Adjustment

The risk adjustment program is a permanent program created by the Affordable Care Act that transfers funds from lower risk, non-grandfathered plans to higher risk, non-grandfathered plans in the individual and small group markets, inside and outside the Exchanges. We established standards for the administration of the risk adjustment program, in subparts D and G of part 45 of the CFR.

A State approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf. As described in the 2014, 2015, and 2016 Payment Notices, if HHS operates risk adjustment on behalf of a State, it will fund its risk adjustment program operations by assessing a risk adjustment user fee on issuers of risk adjustment covered plans. For the 2017 benefit year, we estimate that the total cost for HHS to operate the risk adjustment program on behalf of States for 2017 will be approximately $52 million, slightly more than in 2016, and that the risk adjustment user fee would be approximately $1.80 per enrollee per year. This user fee reflects both increased contract costs to support the risk adjustment data validation process in 2017 and an expected increase in enrollment in risk adjustment covered QHPs.

4. Risk Corridors

The Federally operated temporary risk corridors program ends in benefit year 2016 as required by statute. Because risk corridors charges are collected in the year following the applicable benefit year, and risk corridors payments lag receipt of collections by one quarter, we estimate that risk corridors transfers will continue through fiscal year 2018. We are proposing that for the 2015 and later benefit years, the issuer must true up claims liabilities and reserves used to determine the allowable costs reported for the preceding benefit year to reflect the actual claims payments made through June 30 of the year following the benefit year. This proposed amendment would provide for a more accurate risk corridors calculation by substituting actual experience in place of estimates. Some issuers overestimate their claims and liabilities, while others underestimate them. Based on the 2014 MLR and risk corridors data, we estimate that this proposed amendment will result in a combined total reduction of approximately $315 million in risk corridors payments or increase in risk

[48] Source: Data from Medical Loss Ratio submissions for 2013 reporting year.

corridors charges for some issuers; and a combined total increase of approximately $203 million in risk corridors payments or decrease in risk corridors charges for other issuers. The estimated net impact of the proposed amendment would thus be a reduction of approximately $112 million in total transfers between issuers.

5. Rate Review

In § 154.215, we propose to amend the criteria for submission of the Unified Rate Review Template for single risk pool coverage to HHS. We estimated the burden associated with the rate filing process in the Supporting Statement approved under OMB Control Number 0938–1141. We intend to revise the information collection currently approved under OMB Control Number 0938–1141 to clarify instructions related to completing the template for single risk pool coverage that has a rate decrease, no rate change and for new plans.

6. Additional Required Benefits

In § 155.170, we propose to amend the requirement for coverage of benefits in addition to the essential health benefits. Specifically, we propose to reword § 155.170(a)(2) to make clear that a benefit required by the State through action taking place on or before December 31, 2011 is considered an EHB and one required by the State through action taking place after December 31, 2011 is considered in addition to EHB. As we see this as a clarification, we do not anticipate an additional burden on States or issuers. At § 155.170(a)(3), we currently require the Exchange to identify which additional State-required benefits, if any, are in excess of EHB. We propose to amend paragraph (a)(3) to designate the State, rather than the Exchange, as the entity that identifies which State-required benefits are not EHB. Because Exchanges have generally been relying upon State Departments of Insurance in determining what constitutes an essential health benefit, we do not anticipate any additional burden to States because of this modification.

7. Standards for Navigators and Certain Non-Navigator Assistance Personnel

This proposed rule would amend some of the standards for consumer assistance functions under § 155.205(d) and (e), as well as for the activities of Navigators and non-Navigator assistance personnel subject to § 155.215. The proposed changes include ensuring consumers have access to skilled assistance with Exchange-related issues beyond applying for and enrolling in coverage. Such post enrollment and other assistance would include assisting consumers with applying for exemptions from the individual shared responsibility payment that are granted through the Exchange, with the process of filing Exchange appeals, and with understanding basic concepts related to health coverage and how to use it. The proposed rule would also require Navigators to provide targeted assistance to serve underserved and/or vulnerable populations, as identified by each Exchange. Our proposals would also specify that any individual or entity carrying out consumer assistance functions under § 155.205(d) and (e) or § 155.210 must complete training prior to performing any assister duties, including conducting outreach and education activities.

Our proposal to amend §§ 155.205(d) and 155.215(b)(1)(i) related to completing training for Navigators and certain non-Navigator assistance personnel only applies to the timing of the training and does not have any impact on the training itself. Therefore, it would not affect the burden or cost for entities already subject to training requirements. Because under existing § 155.215(b)(2), Navigators in FFEs must already be trained on the tax implications of enrollment decisions, the individual responsibility to have health coverage, eligibility appeals, and rights and processes for QHP appeals and grievances, we expect our amendments to § 155.210(b)(2)(v) through (viii) to have minimal impact on FFE training. If any SBEs do not already provide training on these topics, we expect they would incur minimal costs in developing and implementing this training. Our proposal requiring Navigators to serve underserved and vulnerable populations will have an increased benefit for consumers, especially hard to reach populations. All costs associated with reaching these consumers in FFEs would be considered allowable costs that would be covered by the Navigator grants for the FFEs and that may be drawn down as the grantee incurs such costs. Additionally, § 155.210(b)(2)(i) already requires Navigators in all States to receive training on serving underserved and vulnerable populations.

8. Certified Application Counselors

This proposed rule would require certified application counselor organizations to submit data and information to the Exchanges regarding the performance of their certified application counselors and the consumer assistance they provide, upon request, in a form and manner specified by the Exchange. Under proposed § 155.225(b)(1)(iii), if an Exchange requests these certified application counselor reports, the Exchange would also need to review them. We assume that all Exchanges will require monthly reports and will utilize in-house staff to review them. We assume that an employee earning a wage that is equivalent to a mid-level GS–11 employee would review monthly report submissions from certified application counselor designated organizations.[49] We estimate that a mid-level employee (at an hourly wage rate of $43.13) will spend 10 minutes reviewing each monthly report for a cost burden of approximately $7.19 per monthly report per certified application counselor designated organization. We estimate the costs of this proposal for State Exchanges in the Collection of Information Requirements section of this proposed rule. For the FFEs, we estimate there are 3,500 certified application counselor designated organizations, resulting in a total annual burden for FFEs of 7,000 hours, at a cost of $301,910.

9. SHOP

The SHOP facilitates the enrollment of eligible employees of small employers into small group health insurance plans. A qualitative analysis of the costs and benefits of establishing a SHOP was included in the RIA published in conjunction with the Exchange Establishment Rule.[50]

The proposed § 155.735(d)(2)(iii) would require the FF–SHOPs to send qualified employees a notice notifying them that their child dependent(s) are no longer eligible for dependent child coverage under their plan because of age. The notice would be sent 90 days in advance of the date when the dependent enrollee loses eligibility for dependent coverage. We estimate the Federally-facilitated SHOPs will spend roughly 35 hours annually, per State, to prepare the notice, for a total cost of $1,775, per State, to design and implement the notices proposed under § 155.735(d)(2)(iii). We estimate that there will be approximately 32 States operating under the Federally-facilitated SHOPs and all will be subject to this requirement. Therefore, we estimate a total annual cost of $58,575 for the FF–SHOPs as a result of this requirement.

[49] Federal wage rates are available at *http://www.opm.gov/policy-data-oversight/pay-leave/salries-wages/salary-tables/pdf/2015/GS_h.pdf.*

[50] Available at: *http://cciio.cms.gov/resources/files/Files2/03162012/hie3r-ria-032012.pdf.*

10. Standardized Options

In assessing the burden associated with implementing standardized options, as described in § 156.20, we assessed the potential impact on premiums established by QHP issuers in the FFEs. Due to the many complex factors that issuers consider when setting premiums, it is impossible to fully predict how each QHP issuer would price a standardized option prior to HHS sharing the standardized option with stakeholders and soliciting feedback. We anticipate that an issuer will price a standardized option based on how similar or different the standardized option is to the issuer's current shelf (plan offerings). Because of the large variation across the country, we expect that how standardized options will be priced will vary by issuer and by State. We do not anticipate that it will significantly affect 2017 plan premiums. We expect that issuers will offer standardized options at a given metal level if the standardized options are similar to their existing plans and can be priced competitively.

The premium impact on issuers' non-standard plan offerings is difficult to estimate.

Among the six State Exchanges that standardized plans and required standardized options to be offered by QHP issuers in 2014, two (California and New York) that attempted to conduct premium impact analysis found that introduction of the requirement on issuers to offer standardized options was associated with a negligible or downward impact on premiums. However, these SBEs found it was difficult to isolate the effects of plan standardization on premiums given the many changes that occurred in the insurance market in 2014 (including the uptake in individual market enrollment, the movement to narrow networks, and active purchasing and rate negotiation in California).

Again, we note that there is a great deal of uncertainty in how this policy will affect Exchanges due to several considerations:

- While we propose to standardize cost-sharing on key essential health benefits, there are a wide range of other benefit design parameters that we will not standardize. It is not clear how this differentiation will manifest among plans or affect consumer choice.
- There is also wide geographic variation in health care markets, including with respect to prices, plan designs, and provider networks. As such, we anticipate that the take-up of standardized options and their impacts on consumers will vary in different locations across the country.

11. User Fees

To support the operation of FFEs, we require in § 156.50(c) that a participating issuer offering a plan through an FFE must remit a user fee to HHS each month equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through an FFE. In this proposed rule, for the 2017 benefit year, we propose a monthly FFE user fee rate equal to 3.5 percent and, for a State-based Exchange that relies on the Federal platform, 3.0 percent of the monthly premium. For the user fee charges assessed on issuers in the FFE and State-based Exchanges using the Federal platform, we intend to seek an exception to OMB Circular No. A–25R, which requires that the user fee charge be sufficient to recover the full cost to the Federal government of providing the special benefit. We seek this exception to ensure that the FFE can support many of the goals of the Affordable Care Act, including improving the health of the population, reducing health care costs, and providing access to health coverage as advanced by § 156.50(d).

12. Actuarial Value

The proposed § 156.135(g) changes current § 156.135(g) to allow for additional flexibility in our approach and options for updating of the AV Calculator in the future. Issuers may incur minor administrative costs associated with altering cost-sharing parameters of their plan designs to ensure compliance with AV requirements when utilizing the AV calculator from year-to-year. These requirements are established in the EHB Rule. Since issuers have extensive experience in offering products with various levels of cost sharing and since these modifications are expected to be relatively minor for most issuers, HHS expects that the process for computing AV with the AV Calculator will not demand many additional resources.

13. Network Adequacy

In § 156.230(f), we propose to require QHPs in the FFEs to count certain out-of-network cost sharing towards the in-network annual limitation on cost sharing for enrollees who receive EHB from an out-of-network provider at an in-network setting. The premium impact will vary based on existing State laws. It is difficult to estimate a nationwide effect with precision. We seek comment on the impact of this policy.

14. Provisions Related to Cost Sharing

The Affordable Care Act provides for the reduction or elimination of cost sharing for certain eligible individuals enrolled in QHPs offered through the Exchanges. This assistance will help many low- and moderate-income individuals and families obtain health insurance—for many people, cost sharing is a barrier to obtaining needed health care.[51]

We set forth in this proposed rule the reductions in the maximum annual limitation on cost sharing for silver plan variations. Consistent with our analysis in previous Payment Notices, we developed three model silver level QHPs and analyzed the impact on their AVs of the reductions described in the Affordable Care Act to the estimated 2017 maximum annual limitation on cost sharing for self only coverage ($7,150). We do not believe these changes will result in a significant economic impact. Therefore, we do not believe the provisions related to cost-sharing reductions in this proposed rule will have an impact on the program established by and described in the 2015 and 2016 Payment Notices.

We also proposed the premium adjustment percentage for the 2017 benefit year. Section 156.130(e) provides that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013. The annual premium adjustment percentage sets the rate of increase for three parameters detailed in the Affordable Care Act: The annual limitation on cost sharing (defined at § 156.130(a)), the required contribution percentage by individuals for minimum essential coverage the Secretary may use to determine eligibility for hardship exemptions under section 5000A of the Code, and the assessable payments under sections 4980H(a) and 4980H(b). We believe that the proposed 2017 premium adjustment percentage of 13.25256291 percent is well within the parameters used in the modeling of the Affordable Care Act, and we do not expect that these

[51] Brook, Robert H., John E. Ware, William H. Rogers, Emmett B. Keeler, Allyson Ross Davies, Cathy D. Sherbourne, George A. Goldberg, Kathleen N. Lohr, Patricia Camp and Joseph P. Newhouse. *The Effect of Coinsurance on the Health of Adults: Results from the RAND Health Insurance Experiment.* Santa Monica, CA: RAND Corporation, 1984. Available at: *http://www.rand.org/pubs/reports/R3055*.

proposed provisions will alter CBO's March 2015 baseline estimates of the budget impact.

15. Stand-Alone Dental Plans

In § 156.150, we propose increasing the annual limitation on cost sharing for stand-alone dental plans being certified by the Exchanges. We believe that the benefit of increasing the annual limit on cost sharing is that issuers would be able to offer consumers SADPs that provide preventive care without any cost sharing, similar to what is generally offered by SADPs in the large group market. This proposal may also decrease the likelihood of premium increases.

16. Meaningful Difference

In § 156.298, we propose to remove health savings account eligibility and the individual coverage or enrollment group coverage criteria as options for meeting the meaningful difference standard. As we believe the health savings account eligibility criterion to overlap with cost-sharing criterion (that is, we believe that a plan that meets the meaningful difference standard for health savings account eligibility would also meet the standard under the cost-sharing criterion), we do not believe that removing this criterion will have any impact on issuers. Additionally, our records indicate that no self-only coverage plans were reviewed for meaningful difference in 2015 and none are offered for 2016 Open Enrollment. As such, we estimate that the impact of this proposed change is negligible.

17. Patient Safety Standards

The proposed next phase of patient safety standards requires QHP issuers participating in Exchanges to track hospital participation agreements with PSOs or other evidence-based patient safety initiatives. We believe this proposed requirement to verify that hospitals with greater than 50 beds use a patient safety evaluation tool and implement a comprehensive person-centered hospital discharge program would encourage continuous quality improvement among QHP issuers by strengthening system-wide efforts to reduce patient harm in a measurable way, improve health outcomes at lower costs, allow for flexibility and innovation in patient safety interventions and practices, and encourage meaningful health care quality improvements. We discuss the administrative costs associated with submitting this information in the Collection of Information section of this proposed rule.

18. Acceptance of Certain Third Party Payments

On March 19, 2014, we published in the **Federal Register** an interim final rule (IFR) with comment period titled, Patient Protection and Affordable Care Act; Third Party Payment of Qualified Health Plan Premiums (79 FR 15240). In § 156.1250, we propose to refine this rule to require individual market QHPs and SADPs to accept premium payments made by certain third parties. This rule proposes to clarify the circumstances in which individual market QHPs and SADPs must accept payments made by Ryan White HIV/AIDS program; Federal and State government programs that provide premium and cost sharing support for specific individuals; and Indian tribes, tribal organizations, and urban Indian organizations. We do not believe these actions would impose any significant new costs on issuers because we assume that most issuers already accept such payments under our interim final rule.

19. Medical Loss Ratio

In this proposed rule, we propose to amend the definition of unpaid claims reserves in § 158.103 and the requirements for reporting incurred claims in § 158.140(a) to utilize a 6-month, rather than a 3-month, run-out period beginning with the 2015 reporting year. This proposed amendment would require incurred claims to be calculated as of June 30, rather than March 31, of the year following the reporting year. This proposed amendment would provide for a more accurate MLR and risk corridors calculation by reducing reliance on estimates. Some issuers overestimate their claims and liabilities, while others underestimate them. We estimate that this proposed provision would increase rebate payments from issuers to consumers by a net total of approximately $12 million.

In addition, we are proposing to amend the risk corridors program requirements at § 153.530 to require issuers to true-up claims liabilities and reserves used to determine the allowable costs reported for the preceding benefit year to reflect the actual claims payments made through June 30 of the year following the benefit year. We estimate the impact of this proposal on the risk corridors program elsewhere in this RIA. Because risk corridors payments and charges are a component of the MLR and rebate calculation, the impact of this proposed provision on risk corridors payments and charges will affect MLR rebates to consumers. We estimate that this proposed provision would increase rebate payments from issuers to consumers by an estimated net total of $19 million for the 2015 MLR reporting year.

D. Regulatory Alternatives Considered

In developing the policies contained in this proposed rule, we considered numerous alternatives to the presented proposals. Below we discuss the key regulatory alternatives that we considered.

Regarding the 2017 required contribution percentage, which establishes the threshold for spending on minimum essential health care required for an affordability exemption from the individual responsibility requirement, we considered continuing to use the per capita gross domestic product as the measure of income growth. However, a new measure of income growth, per capita personal income, became available for the first time last year as part of the National Health Expenditure's projections, and includes not only participation in production but also transfer payments. We believe that this broader measure of personal income more accurately reflects individual income than GDP per capita.

For proposed § 155.200(f), we considered a number of alternatives. We considered not codifying the SBE–FP model, and winding down use of the Federal platform by SBEs. This would have forced SBEs to find a way to perform all required Exchange eligibility and enrollment functions themselves, including the implementation of an Exchange technology platform, or else convert to FFEs. We made the proposal we did because we believe that it is technically feasible and will permit a number of SBEs to access the Federal government's greater economies of scale. We also considered a more customized option, under which an SBE would be permitted to select from a menu of Federal services. While we are considering providing more flexibility to SBE–FPs in the future, at this point we do not have the operational ability to permit that level of customization. Finally, we considered alternatives under which issuers and other delegated and downstream entities in States with SBE–FPs would not be required to meet FFE standards, or HHS would not participate in enforcement against issuers violating those FFE rules. As discussed in this proposed rule, we believe that applying Federal standards to issuers and their downstream entities for SBE–FPs helps promote consistent minimum standards associated with HealthCare.gov.

Regarding the exemptions program, we considered maintaining the option under which individuals can receive certification of certain exemptions from the Exchange, rather than transitioning the process for obtaining those exemption types fully to the IRS. However, we believe that this approach contributes to confusion and unnecessarily creates additional hurdles for individuals claiming these exemptions. We also considered whether to cede other exemption types to the IRS, in addition to the exemptions for Indian status, members of health care sharing ministries, and incarceration. However, to minimize potential consumer confusion, we opted only to streamline the exemptions process and not to expand the scope of exemptions that the IRS may grant.

We propose issuing hardship exemptions when a consumer shows their hardship is ongoing at the time of application. Hardship exemptions are issued for months within the current calendar year plus the next, plus the months before and after the hardship ends. When consumers approach the Exchange near the end of the calendar year, we typically can only grant them a hardship exemption for a few months. We believe the current approach may not give consumers sufficient time to seek coverage before their hardship exemption expires, and therefore proposed extending the length of the hardship exemption. Many enrollees eligible for a hardship exemption are currently facing significant life disruptions, and may need more time to find coverage.

For employer choice in the FF–SHOPs, we considered offering an additional employer choice option that would permit an employer to select an actuarial value level of coverage, after which employees could choose from plans available at that level and at the level above it. Recognizing that small group market dynamics differ by State, we decided to seek comment on, but not propose this option at this time. We also considered requiring all SHOPs to offer these additional employer choice options, but instead opted to maintain State-based SHOPs' flexibility under the current regulations, so that States can decide whether implementing additional employer choice options would be in the best interest of small group market consumers in their State.

We considered requiring QHP issuers to offer standardized options as a condition of participation in the FFEs. However, we believe that markets and Exchanges may be at different stages of readiness for standardized options, and that the cost-sharing structure that HHS specifies may not be well tailored for all States. Similarly, we believe that some issuers may have difficulty offering standardized options in the short run because of operational constraints.

In developing proposed § 156.230, we considered waiting for the NAIC's workgroup to complete its work on drafting a revised model act on network adequacy and not proposing changes to the network adequacy standard for 2017. As discussed in the preamble of the final rule for the HHS Notice of Benefit and Payment Parameters for 2016 (80 FR 10750), HHS had planned to await the results of the NAIC's workgroup to develop a revised model act before proposing significant changes to network adequacy policy. However, since the NAIC workgroup has not completed its work, we have decided to proceed with proposing some concepts from the draft versions of the NAIC model act to strengthen network adequacy requirements, particularly for QHPs being offered in the FFEs. We propose these requirements to ensure certain consumer protections and standards are being provided to enrollees in 2017. As an alternative, we also considered proposing more concepts from the NAIC's drafts of the model act in the area of network adequacy, such as requiring issuers to submit for review and approval an access plan and establishing requirements for what the access plan must include. However, we are cognizant of the burden on issuers to implement many policy changes in one year, especially when these changes affect issuers' QHP certification applications. Therefore, we will continue to monitor the NAIC's workgroup efforts to develop a model act on network adequacy, and will consider whether additional standards will be needed in future years.

In § 156.230(f), regarding QHP enrollees in the FFE who receive an EHB from an out-of-network provider in an in-network setting, we considered an alternative under which all cost sharing, regardless of notification, would count towards the in-network annual limitation on cost sharing, or to accrue at in-network rates. However, we recognize that the issuer often has a limited ability to control the use of out-of-network providers, and are wary of the impact of such a policy on premiums.

In § 156.1110, we considered maintaining the current approach of aligning with Medicare hospital Conditions of Participation standards and not establishing further regulations at this time for QHP issuers to collect information, such as hospital participation agreements with PSOs, to comply with new patient safety standards for plan years beginning on or after January 1, 2017. However, we decided to propose the policy in this proposed rule because we believe that strengthening patient safety standards and aligning with current, effective patient safety interventions will achieve greater impact for consumers, in terms of health care quality improvement and harm reduction, resulting in higher quality QHPs being offered in the Exchanges. Additionally, we considered proposing an approach that did not include establishing reasonable exceptions to the requirements for a QHP issuer that contracts with a hospital with greater than 50 beds to utilize a patient safety evaluation system and implement a mechanism for comprehensive person-centered hospital discharges, as described in section 1311(h)(1) of the Affordable Care Act. However, we determined that it is important to support national patient safety efforts, promote evidence-based patient safety interventions and allow for flexibility, innovation, and minimal burden for issuers and hospitals.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act, (5 U.S.C. 601, *et seq.*), requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of ''small entity.'' HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

In this proposed rule, we propose standards for the risk adjustment, reinsurance, and risk corridors programs, which are intended to stabilize premiums as insurance market reforms are implemented and Exchanges facilitate increased enrollment. Because we believe that insurance firms offering comprehensive health insurance policies generally exceed the size thresholds for ''small entities'' established by the SBA, we do not believe that an initial regulatory

flexibility analysis is required for such firms.

For purposes of the RFA, we expect the following types of entities to be affected by this proposed rule:

- Health insurance issuers.
- Group health plans.

We believe that health insurance issuers and group health plans would be classified under the North American Industry Classification System code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $38.5 million or less would be considered small entities for these North American Industry Classification System codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be $32.5 million or less.

In this proposed rule, we proposed standards for employers that choose to participate in a SHOP Exchange. The SHOPs are limited by statute to employers with at least one but not more than 50 employees, unless a State opts to provide that employers with from 1 to 100 employees are ''small employers.'' For this reason, we expect that many employers who would be affected by the proposals would meet the SBA standard for small entities. We do not believe that the proposals impose requirements on employers offering health insurance through a SHOP that are more restrictive than the current requirements on small businesses offering employer sponsored insurance. We believe the processes that we have established constitute the minimum amount of requirements necessary to implement the SHOP program and accomplish our policy goals, and that no appropriate regulatory alternatives could be developed to further lessen the compliance burden.

We believe that a substantial number of sponsors of self-insured group health plans could qualify as ''small entities.'' This proposed rule provides HHS with the authority to audit these entities. However, we do not believe that the burden of these audits is likely to reflect more than 3 to 5 percent of such an entity's revenues.

Some of the entities that voluntarily act as Navigators and non-Navigator assistance personnel subject to § 155.215, or as designated certified application counselor organizations, might be small entities and could incur costs to comply with the provisions of this proposed rule. It should be noted that HHS, in its role as the operator of the FFEs, does not impose any fees on these entities for participating in their respective programs, nor are there fees for taking the Federally required training or completing continuing education or recertification in FFEs. The cost burden related to our proposals about reaching vulnerable and underserved populations and providing post-enrollment and other assistance would apply to Navigators in all Exchanges. The costs associated with these proposals would generally be considered an allowable cost that would be covered by the Navigator grants for the FFEs, and these grant funds may be drawn down as the grantee incurs such costs. Depending upon applicable State law and how States with State Exchanges implement their Navigator grant programs, the same might be true in those States. Though it is very likely that many costs associated with these proposals would be covered by affected entities' and individuals' funding sources, HHS cannot guarantee that all such costs would be covered because of the possibility of budget limitations applicable to the FFEs in any given period, and because there may be variations in how State Exchanges implement their Navigator grant programs.

The costs related to the proposed reporting requirement for designated certified application counselor organizations would be borne by those organizations, which do not receive funding from Exchanges for these services. The costs incurred by designated certified application counselor organizations for the reporting of performance metrics are expected to be low.

Based on data from MLR annual report submissions for the 2014 MLR reporting year, approximately 118 out of 525 issuers of health insurance coverage nationwide had total premium revenue of $38.5 million or less. This estimate may overstate the actual number of small health insurance companies that may be affected, since almost 80 percent of these small companies belong to larger holding groups, and many if not all of these small companies are likely to have non-health lines of business that would result in their revenues exceeding $38.5 million. Only seven of these 118 potentially small entities, all of them part of larger holding groups, are estimated to experience an increase or decrease in the rebate amount under the proposed amendments to the MLR provisions of this proposed rule in part 158, including one entity that did not owe a rebate for the 2014 reporting year. Two additional entities may experience a small (less than 2.5 percent) change in their risk corridors payments and charges under the MLR provisions of this proposed rule. Based on data from the 2014 MLR and risk corridors annual report submissions, 20 of these 118 potentially small entities had risk corridors payments or charges for the 2014 benefit year. Only one of these entities is estimated to experience a decrease in its risk corridors payment under the proposed provisions in § 153.530(b)(2)(iv), with no impact on its rebate liability. Therefore, we do not expect the proposed provisions of this rule to affect a substantial number of small entities.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a proposed rule that includes any Federal mandate that may result in expenditures in any 1 year by a State, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold is approximately $144 million. Although we have not been able to quantify all costs, the combined administrative cost and user fee impact on State, local, or Tribal governments and the private sector may be above the threshold. Earlier portions of this RIA constitute our UMRA analysis.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. Because States have flexibility in designing their Exchange and Exchange-related programs, State decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment or reinsurance program. For States electing to operate an Exchange, risk adjustment or reinsurance program, much of the initial cost of creating these programs will be funded by Exchange Planning and Establishment Grants. After establishment, Exchanges will be financially self-sustaining, with revenue sources at the discretion of the State. Current State Exchanges charge user fees to issuers.

In HHS's view, while this proposed rule would not impose substantial direct requirement costs on State and local governments, this regulation has Federalism implications due to direct effects on the distribution of power and responsibilities among the State and Federal governments relating to

determining standards relating to health insurance that is offered in the individual and small group markets. For example, our proposal permitting a State to elect to utilize the Federal platform for enrollment and eligibility services may make certain SBEs more economically feasible, providing more options for States seeking to exercise the right to establish and operate n Exchange. However, HHS anticipates that the Federalism implications (if any) are substantially mitigated because under the statute, States have choices regarding the structure and governance of their Exchanges and risk adjustment and reinsurance programs. Additionally, the Affordable Care Act does not require States to establish these programs; if a State elects not to establish any of these programs or is not approved to do so, HHS must establish and operate the programs in that State.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the States, HHS has engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with State insurance officials on an individual basis.

While developing this proposed rule, HHS has attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide access to Affordable Insurance Exchanges for consumers in every State. By doing so, it is HHS's view that we have complied with the requirements of Executive Order 13132.

States will continue to license, monitor, and regulate agents and brokers, both inside and outside of Exchanges. All State laws related to agents and brokers, including State laws related to appointments, contractual relationships with issuers, licensing, marketing, conduct, and fraud will continue to apply.

H. Congressional Review Act

This proposed rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, *et seq.*), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to Congress and the Comptroller for review.

List of Subjects

45 CFR Parts 144, 146, and 147

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 153

Administrative practice and procedure, Health care, Health insurance, Health records, Organization and functions (Government agencies), Reporting and recordkeeping requirements.

45 CFR Part 154

Administrative practice and procedure, Claims, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Health care, Health insurance, Reporting and recordkeeping requirements, State and local governments.

45 CFR Part 156

Administrative practice and procedure, Advertising, American Indian/Alaska Natives, Conflict of interest, Consumer protection, Cost-sharing reductions, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Individuals with disabilities, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 45 CFR parts 144, 146, 147, 150, 153, 154, 155, 156, and 158 as set forth below.

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

■ 1. The authority citation for part 144 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act, 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92.

■ 2. Section 144.103 is amended by revising paragraph (1) of the definition of ''Excepted benefits'' and revising the definitions of ''Large employer'' and ''Small employer'' to read as follows:

§ 144.103 Definitions.

* * * * *

Excepted benefits * * *

(1) Group market provisions in 45 CFR part 146, subpart D, is defined in 45 CFR 146.145(b); and

* * * * *

Large employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 51 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. A State may elect to define large employer by substituting ''101 employees'' for ''51 employees.'' In the case of an employer that was not in existence throughout the preceding calendar year, the determination of whether the employer is a large employer is based on the average number of employees that it is reasonably expected the employer will employ on business days in the current calendar year.

* * * * *

Small employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 50 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. A State may elect to define small employer by substituting ''100 employees'' for ''50 employees.'' In the case of an employer that was not in existence throughout the preceding calendar year, the determination of whether the employer is a small employer is based on the average number of employees that it is reasonably expected the employer will employ on business days in the current calendar year.

* * * * *

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

■ 3. The authority citation for part 146 continues to read as follows:

Authority: Secs. 2702 through 2705, 2711 through 2723, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300gg–92).

■ 4. Section 146.150 is amended by—

■ a. In paragraph (a) introductory text, removing the reference ''paragraphs (c)

through (f)'' and adding in its place the reference ''paragraphs (c) through (g)''.

■ b. Adding paragraph (g).

The addition reads as follows:

§ 146.150 Guaranteed availability of coverage for employers in the small group market.

* * * * *

(g) *Exception for discontinuing a particular product or all coverage.* (1) If an issuer decides to discontinue offering a particular product or all coverage in the small group market in accordance with § 146.152, the issuer may between the time of providing the relevant notice and discontinuing the coverage —

(i) Deny health insurance coverage in that product when the exception to guaranteed renewability of coverage related to discontinuing the particular product under § 146.152(c) applies.

(ii) Deny health insurance coverage in the small group market when the exception to guaranteed renewability of coverage related to discontinuing all coverage under § 146.152(d) applies.

(2) An issuer that denies coverage under this paragraph (g) must apply paragraph (g)(1) of this section uniformly to all small employers in the State consistent with applicable State law and without regard to the claims experience or any health-status related factor relating to those employers and their employees (or their respective dependents).

(3) Nothing in this paragraph (g) relieves an issuer of its obligations with respect to existing policyholders, such as enrolling dependents under an applicable special enrollment period.

* * * * *

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

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

Authority: Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 6. Section 147.102 is amended by revising paragraph (a)(1)(ii) to read as follows:

§ 147.102 Fair health insurance premiums.

(a) * * *

(1) * * *

(ii) Rating area, as established in accordance with paragraph (b) of this section. For purposes of this paragraph (a), rating area is determined—

(A) In the individual market, using the primary policyholder's address.

(B) In the small group market, using the group policyholder's principal business address. For purposes of this paragraph, principal business address means the principal business address registered with the State or, if a principal business address is not registered with the State, or is registered solely for purposes of service of process and is not a substantial worksite for the employer's business, the business address within the State where the greatest number of employees of such employer works. If, for a network plan, the group policyholder's principal business address is not within the service area of such plan, and the policyholder has employees who live, reside, or work within the service area, the principal business address for purposes of the network plan is deemed to be the business address within the plan's service area where the greatest number of employees work as of the beginning of the plan year. If there is no such business address, the principal business address for purposes of the network plan is deemed to be an address within the rating area selected by the employer that reasonably reflects where the greatest number of employees within the plan's service area live or reside as of the beginning of the plan year.

* * * * *

■ 7. Section 147.104 is amended by—

■ a. In paragraph (a), removing the reference ''paragraphs (b) through (d)'' and adding in its place the reference ''paragraphs (b) thorugh (e)''.

■ b. Redesignating paragraphs (e) through (i) as paragraphs (f) through (j), respectively.

■ c. Adding paragraph (e).

The addition reads as follows:

§ 147.104 Guaranteed availability of coverage.

* * * * *

(e) *Exception for discontinuing a particular product or all coverage.* (1) If an issuer decides to discontinue offering a particular product or all coverage in the large group, small group, or individual market in accordance with § 147.106, the issuer may between the time of providing the relevant notice and discontinuing the coverage—

(i) Deny health insurance coverage in that product when the exception to guaranteed renewability of coverage related to discontinuing the particular product under § 147.106(c) applies.

(ii) Deny health insurance coverage in that market when the exception to guaranteed renewability of coverage related to discontinuing all coverage under § 147.106(d) applies.

(2) An issuer that denies coverage under this paragraph (e) must apply paragraph (e)(1) of this section uniformly to all employers or individuals in the large group, small group, or individual market, as applicable, in the State consistent with applicable State law and without regard to the claims experience or any health-status related factor relating to those individuals or employers and their employees (or their respective dependents).

(3) Nothing in this paragraph (e) relieves an issuer from any of its obligations with respect to existing policyholders, such as enrolling dependents under an applicable special enrollment period.

* * * * *

■ 8. Section 147.145 is amended by revising paragraph (b)(3) and adding paragraph (b)(4) to read as follows:

§ 147.145 Student health insurance coverage.

* * * * *

(b) * * *

(3) *Single risk pool.* For plan years beginning on or after January 1, 2017, student health insurance coverage is subject to the index rating provisions of § 156.80(d) of this subchapter. For purposes of the preceding sentence, a health insurance issuer that offers student health insurance coverage may establish one or more separate risk pools for each institution of higher education, if the distinction between or among groups of students (or dependents of students) who form the risk pool is based on a bona fide school-related classification and not based on a health factor as described in § 146.121 of this subchapter.

(4) *Levels of coverage.* The requirement to provide a specific level of coverage described in section 1302(d) of the Affordable Care Act does not apply to student health insurance coverage for plan years beginning on or after January 1, 2017. However, the benefits provided by such coverage must provide at least 60 percent actuarial value, as certified by a member of the American Academy of Actuaries using generally accepted actuarial principles.

* * * * *

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

■ 9. The authority citation for part 153 continues to read as follows:

Authority: Secs. 1311, 1321, 1341–1343, Pub. L. 111–148, 24 Stat. 119.

■ 10. Section 153.405 is amended by revising paragraph (i) to read as follows:

§ 153.405 Calculation of reinsurance contributions.

* * * * *

(i) *Audits.* HHS or its designee may audit a contributing entity to assess its compliance with the requirements of this subpart. HHS or its designee may audit a third party administrator, administrative services-only contractor, or other third party who assists a contributing entity with its obligations under this subpart to assess compliance with the requirements of this subpart. A contributing entity that chooses to use a third party administrator, administrative services-only contractor, or other third party to assist with its obligations under this subpart must ensure that the third party administrator, administrative services-only contractor, or other third party cooperate with any audit under this section.

■ 11. Section 153.510 is amended by adding paragraph (g) to read as follows:

§ 153.510 Risk corridors establishment and payment methodology.

* * * * *

(g) *Adjustment to risk corridors payments and charges.* If an issuer reported a certified estimate of 2014 cost-sharing reductions on its 2014 MLR and Risk Corridors Annual Reporting Form that is lower than the actual value of cost-sharing reductions calculated under § 156.430(c) of this subchapter for the 2014 benefit year, HHS will make an adjustment to the amount of the issuer's 2015 benefit year risk corridors payment or charge measured by the full difference between the certified estimate of 2014 cost-sharing reductions reported and the actual value of cost-sharing reductions provided as calculated under § 156.430(c) for the 2014 benefit year.

■ 12. Section 153.530 is amended by revising paragraphs (b)(2)(ii) and (iii) and adding paragraph (b)(2)(iv) to read as follows:

§ 153.530 Risk corridors data requirements.

* * * * *

(b) * * *

(2) * * *

(ii) Any reinsurance payments received by the issuer for the non-grandfathered health plans under the transitional reinsurance program established under subpart C of this part;

(iii) A cost-sharing reduction amount equal to the amount of cost-sharing reductions for the benefit year as calculated under § 156.430(c) of this subchapter, to the extent not reimbursed to the provider furnishing the item or service.

(iv) For the 2015 and later benefit years, any difference between—

(A) The sum of unpaid claims reserves and claims incurred but not reported, as set forth in §§ 158.103 and 158.140(a)(2) and (3) of this subchapter, that were reported on the MLR and Risk Corridors Annual Reporting Form for the year preceding the benefit year; and

(B) The actual claims incurred during the year preceding the benefit year and paid between the valuation date of the unpaid claims reserves and liabilities described above and June 30 of the year following the benefit year.

* * * * *

■ 13. Section 153.710 is amended by—

■ a. Removing paragraph (d).

■ b. Redesignating paragraphs (e) and (f) as paragraphs (d) and (e), respectively.

■ c. Revising newly redesignated paragraph (e).

■ d. Adding paragraph (f).

■ e. Revising paragraphs (g) introductory text, (g)(1) introductory text, (g)(1)(iii) and (iv), and (g)(2).

■ f. Adding paragraph (g)(3).

The revisions and additions read as follows:

§ 153.710 Data requirements.

* * * * *

(e) *Unresolved discrepancies.* If a discrepancy first identified in a final dedicated distributed data environment report in accordance with paragraph (d)(2) of this section remains unresolved after the issuance of the notification of risk adjustment payments and charges or reinsurance payments under § 153.310(e) or § 153.240(b)(1)(ii), respectively, an issuer of a risk adjustment covered plan or reinsurance-eligible plan may make a request for reconsideration regarding such discrepancy under the process set forth in § 156.1220(a) of this subchapter.

(f) *Data sufficiency.* If an issuer of a risk adjustment covered plan fails to provide sufficient required data, such that HHS cannot apply the applicable methodology to calculate the risk adjustment payment transfer amount for the risk adjustment covered plan in a timely or appropriate fashion, then HHS will assess a default risk adjustment charge under § 153.740(b). A default charge will be assessed under this paragraph no later than the date of the notification provided by HHS under § 153.310(e). If an issuer of a reinsurance eligible plan fails to provide data sufficient for HHS to calculate reinsurance payments, the issuer will forfeit reinsurance payments for claims it fails to submit.

(1) *Data quantity.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan must provide, in a format and on a timeline specified by HHS, data on its total enrollment and claims counts by market, which HHS may use in evaluating whether the issuer provided access in the dedicated distributed data environment to a sufficient quantity of data to meet reinsurance and risk adjustment data requirements.

(2) *Data quality.* If, following the deadline for submission of data specified in § 153.730, HHS identifies an anomaly that would cause the data that a risk adjustment covered plan or a reinsurance-eligible plan made available through a dedicated data environment to fail HHS's data quality thresholds, the issuer may, within 10 calendar days of receiving notification of the anomaly, submit an explanation of the anomaly for HHS to consider in determining whether the issuer met the reinsurance and risk adjustment data requirements.

(g) *Risk corridors and MLR reporting.* Except as provided in paragraph (g)(3) of this section:

(1) Notwithstanding any discrepancy report made under paragraph (d)(2) of this section, or any request for reconsideration under § 156.1220(a) of this subchapter with respect to any risk adjustment payment or charge, including an assessment of risk adjustment user fees; reinsurance payment; cost-sharing reduction payment or charge; or risk corridors payment or charge, unless the dispute has been resolved, an issuer must report, for purposes of the risk corridors and MLR programs:

* * * * *

(iii) A cost-sharing reduction amount equal to the actual amount of cost-sharing reductions for the benefit year as calculated under § 156.430(c) of this subchapter, to the extent not reimbursed to the provider furnishing the item or service; and

(iv) For medical loss ratio reporting only, the risk corridors payment to be made or charge assessed by HHS under § 153.510.

(2) An issuer must report any adjustment made or approved by HHS for any risk adjustment payment or charge, including an assessment of risk adjustment user fees; any reinsurance payment; any cost-sharing reduction payment or charge; or any risk corridors payment or charge; where such adjustment has not be accounted for in a prior MLR and Risk Corridor Annual Reporting Form, in the MLR and Risk Corridors Annual Reporting Form for the following reporting year.

(3) In cases where HHS reasonably determines that the reporting instructions in paragraph (g)(1) or (2) of this section would lead to unfair or

misleading financial reporting, issuers must mitigate or correct their data submissions in a form and manner to be specified by HHS.

PART 154—HEALTH INSURANCE ISSUER RATE INCREASES: DISCLOSURE AND REVIEW REQUIREMENTS

■ 14. The authority citation for part 154 continues to read as follows:

Authority: Section 2794 of the Public Health Service Act (42 U.S.C. 300gg–94).

■ 15. Section 154.200 is amended by revising paragraph (c)(2) to read as follows:

§ 154.200 Rate increases subject to review.

* * * * *

(c) * * *

(2) For rates filed for single risk pool coverage beginning on or after January 1, 2017, the average increase, including premium rating factors described in § 147.102 of this subchapter, for all enrollees weighted by premium volume for any plan within the product meets or exceeds the applicable threshold.

* * * * *

■ 16. Section 154.215 is amended by revising paragraphs (a) and (b) introductory text and removing and reserving paragraph (c) to read as follows:

§ 154.215 Submission of rate filing justification.

(a) A health insurance issuer must submit to CMS and to the applicable State (if the State accepts such submissions) the information specified below on a form and in a manner prescribed by the Secretary.

(1) For all single risk pool coverage products, including new and discontinuing products, the Unified Rate Review Template, as described in paragraph (d) of this section;

(2) For each single risk pool coverage product that includes a plan that is subject to a rate increase, regardless of the size of the increase, the Unified Rate Review Template and Actuarial Memorandum, as described in paragraph (f) of this section;

(3) For each single risk pool coverage product that includes a plan with a rate increase that is subject to review under § 154.210, all parts of the Rate Filing Justification, as described in paragraph (b) of this section

(b) A Rate Filing Justification includes one or more of the following:

* * * * *

(c) [Reserved]

* * * * *

■ 17. Section 154.220 is amended by revising the introductory text and paragraphs (b) introductory text and (b)(1) to read as follows:

§ 154.220 Timing of providing the rate filing justification.

A health insurance issuer must submit applicable sections of the Rate Filing Justification for all single risk pool coverage in the individual or small group market, as follows:

* * * * *

(b) For coverage effective on or after January 1, 2017, by the earlier of the following:

(1) The date by which the State requires submission of a rate filing; or

* * * * *

■ 18. Section 154.230 is amended by revising paragraph (c)(2)(i) to read as follows:

§ 154.230 Submission and posting of Final Justifications for unreasonable rate increases.

* * * * *

(c) * * *

(2) * * *

(i) The information made available to the public by CMS and described in § 154.215(h).

* * * * *

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 19. The authority citation for part 155 continues to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301, 1302, 1303, 1304, 1311, 1312, 1313, 1321, 1322, 1331, 1332, 1334, 1402, 1411, 1412, 1413, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083).

■ 20. Section 155.20 is amended by—

■ a. In the definition of ''Applicant'', revising paragraph (2).

■ b. Adding the definition of ''Federal platform agreement'' in alphabetical order.

■ c. Revising the definitions of ''Large employer'' and ''Small employer''.

The addition and revisions read as follows:

§ 155.20 Definitions.

* * * * *

Applicant * * *

(2) For SHOP:

(i) An employer seeking eligibility to purchase coverage through the SHOP; or

(ii) An employer, employee, or a former employee seeking eligibility for enrollment in a QHP through the SHOP for himself or herself and, if the qualified employer offers dependent coverage through the SHOP, seeking eligibility to enroll his or her dependents in a QHP through the SHOP.

* * * * *

Federal platform agreement means an agreement between a State Exchange and HHS under which a State Exchange elects to rely on the Federal platform to carry out select Exchange functions.

* * * * *

Large employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 51 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. In the case of an employer that was not in existence throughout the preceding calendar year, the determination of whether the employer is a large employer is based on the average number of employees that it is reasonably expected the employer will employ on business days in the current calendar year. A State may elect to define large employer by substituting ''101 employees'' for ''51 employees.'' The number of employees must be determined using the method set forth in section 4980H(c)(2) of the Code.

* * * * *

Small employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least one but not more than 50 employees on business days during the preceding calendar year and who employs at least one employee on the first day of the plan year. In the case of an employer that was not in existence throughout the preceding calendar year, the determination of whether the employer is a small employer is based on the average number of employees that it is reasonably expected the employer will employ on business days in the current calendar year. A State may elect to define small employer by substituting ''100 employees'' for ''50 employees.'' The number of employees must be determined using the method set forth in section 4980H(c)(2) of the Code.

* * * * *

■ 21. Section 155.106 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(2) and (3), and (b) introductory text.

■ b. Adding paragraphs (a)(4), (a)(5), and (c).

The revisions and additions read as follows:

§ 155.106 Election to operate an Exchange after 2014.

(a) *Election to operate an Exchange.* Except as provided in paragraph (c) of this section, a State electing to seek approval of its Exchange must:

* * * * *

(2) Submit an Exchange Blueprint application for HHS approval at least 15 months prior to the date on which the Exchange proposes to begin open enrollment as a State Exchange;

(3) Have in effect an approved, or conditionally approved, Exchange Blueprint and operational readiness assessment at least 14 months prior to the date on which the Exchange proposes to begin open enrollment as a State Exchange;

(4) Develop a plan jointly with HHS to facilitate the transition to a State Exchange; and

(5) If the open enrollment period for the year the State intends to begin operating an SBE has not been established, this deadline must be calculated based on the date open enrollment began or will begin in the year in which the State is submitting the Blueprint application.

(b) *Transition process for State Exchanges that cease operations.* If a State intends to cease operation of its Exchange, HHS will operate the Exchange on behalf of the State. Therefore, a State that intends to cease operations of its Exchange must:

* * * * *

(c) *Process for State Exchanges that seek to utilize the Federal platform for select functions.* A State seeking approval as a State Exchange utilizing the Federal platform to support select functions through a Federal platform agreement under § 155.200(f) must:

(1) If the State Exchange does not have a conditionally approved Exchange Blueprint application, submit one for HHS approval at least 3 months prior to the date on which the Exchange proposes to begin open enrollment as an SBE–FP;

(2) If the State Exchange has a conditionally approved Exchange Blueprint application, submit any significant changes to that application for HHS approval, in accordance with § 155.105(e), at least 3 months prior to the date on which the Exchange proposes to begin open enrollment as an SBE–FP;

(3) Have in effect an approved, or conditionally approved, Exchange Blueprint and operational readiness assessment at least 2 months prior to the date on which the Exchange proposes to begin open enrollment as an SBE–FP, in accordance with HHS rules, as a State Exchange utilizing the Federal platform;

(4) Upon approval, or conditional approval, of the Exchange Blueprint, execute a Federal platform agreement prior to the start of the open enrollment period for which the State Exchange desires to begin utilizing the Federal platform; and

(5) Coordinate with HHS on a transition plan to be developed jointly between HHS and the State.

■ 22. Section 155.170 is amended by revising paragraphs (a)(2), (a)(3), and (c)(2)(iii) to read as follows:

§ 155.170 Additional required benefits.

(a) * * *

(2) A benefit required by State action taking place on or before December 31, 2011 is considered an EHB. A benefit required by State action taking place on or after January 1, 2012, other than for purposes of compliance with Federal requirements, is considered in addition to the essential health benefits.

(3) The State will identify which State-required benefits are in addition to the EHB.

* * * * *

(c) * * *

(2) * * *

(iii) Reported to the State.

■ 23. Section 155.200 is amended by revising paragraph (a) and adding paragraph (f) to read as follows:

§ 155.200 Functions of an Exchange.

(a) *General requirements.* An Exchange must perform the functions described in this subpart and in subparts D, E, F, G, H, K, M, and O of this part unless the State is approved to operate only a SHOP by HHS under § 155.100(a)(2), in which case the Exchange operated by the State must perform the functions described in subpart H of this part and all applicable provisions of other subparts referenced in that subpart. In a State that is approved to operate only a SHOP, the individual market Exchange operated by HHS in that State will perform the functions described in this subpart and in subparts D, E, F, G, K, M, and O of this part.

* * * * *

(f) *Requirements for State Exchanges on the Federal platform.* (1) A State that receives approval or conditional approval to operate a State Exchange on the Federal platform under § 155.106(c) may meet its obligations under paragraph (a) of this section by relying on Federal services that the Federal government agrees to provide under a Federal platform agreement.

(2) A State Exchange on the Federal platform must establish and oversee requirements for its issuers that are no less strict than the following requirements that are applied to Federally-facilitated Exchange issuers:

(i) Data submission requirements under § 156.122(d)(2) of this subchapter;

(ii) Network adequacy standards under § 156.230 of this subchapter;

(iii) Essential community providers standards under § 156.235 of this subchapter;

(iv) Meaningful difference standards under § 156.298 of this subchapter;

(v) Changes of ownership of issuers requirements under § 156.330 of this subchapter;

(vi) QHP issuer compliance and compliance of delegated or downstream entities requirements under § 156.340(a)(4) of this subchapter; and

(vii) Casework requirements under § 156.1010 of this subchapter.

(3) If a State is not substantially enforcing any requirement listed under § 155.200(f)(2) of this subchapter with respect to a QHP issuer or plan in a State-based Exchange on the Federal platform, HHS may enforce that requirement directly against the issuer or plan by means of plan suppression under § 156.815 of this subchapter.

■ 24. Section 155.205 is amended by—

■ a. Revising paragraphs (a) and (d)(1).

■ b. Adding paragraph (b)(7).

The addition and revisions read as follows:

§ 155.205 Consumer assistance tools and programs of an Exchange.

(a) *Call center.* The Exchange must provide for operation of a toll-free call center that addresses the needs of consumers requesting assistance and meets the requirements outlined in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section, unless it enters into a Federal platform agreement through which it relies on HHS to carry out call center functions, in which case the Exchange must provide at a minimum a toll-free telephone hotline to respond to requests for assistance.

(b) * * *

(7) A State-based Exchange on the Federal platform must at a minimum maintain an informational Internet Web site.

* * * * *

(d) * * *

(1) The Exchange must have a consumer assistance function that meets the standards in paragraph (c) of this section, including the Navigator program described in § 155.210. Any individual providing such consumer assistance must be trained regarding QHP options, insurance affordability programs, eligibility, and benefits rules and regulations governing all insurance affordability programs operated in the State, as implemented in the State, prior

to providing such assistance or the outreach and education activities specified in paragraph (e) of this section.

* * * * *

■ 25. Section 155.210 is amended by—
■ a. Revising paragraphs (b)(2)(iii) and (iv).
■ b. Adding paragraphs (b)(2)(v), (vi), (vii), and (viii).
■ c. Revising paragraph (d)(6).
■ d. In paragraph (e)(7), removing the period at the end of the paragraph and adding a semicolon in its place.
■ e. Adding paragraphs (e)(8) and (9).

The revisions and additions read as follows:

§ 155.210 Navigator program standards.

* * * * *

(b) * * *

(2) * * *

(iii) The range of QHP options and insurance affordability programs;

(iv) The privacy and security standards applicable under § 155.260;

(v) The process of filing Exchange eligibility appeals;

(vi) General concepts regarding exemptions from the requirement to maintain minimum essential coverage and from the individual shared responsibility payment, including the application process for exemptions granted through the Exchange, and IRS resources on exemptions;

(vii) The Exchange-related components of the premium tax credit reconciliation process and IRS resources on this process; and

(viii) Basic concepts related to health coverage and how to use it.

* * * * *

(d) * * *

(6) Provide to an applicant or potential enrollee gifts of any value as an inducement for enrollment. The value of gifts provided to applicants and potential enrollees for purposes other than as an inducement for enrollment must not exceed nominal value, either individually or in the aggregate, when provided to that individual during a single encounter. For purposes of this paragraph (d)(6), the term gifts includes gift items, gift cards, cash cards, cash, and promotional items that market or promote the products or services of a third party, but does not include the reimbursement of legitimate expenses incurred by a consumer in an effort to receive Exchange application assistance, such as travel or postage expenses.

* * * * *

(e) * * *

(8) Provide targeted assistance to serve underserved or vulnerable populations, as identified by the Exchange, within the Exchange service area.

(i) In a Federally-facilitated Exchange, this paragraph (e)(8) will apply beginning with the Navigator grant application process for Navigator grants awarded in 2018. The Federally-facilitated Exchange will identify populations as vulnerable or underserved that are disproportionately without access to coverage or care, or that are at a greater risk for poor health outcomes, in the funding opportunity announcement for its Navigator grants, and applicants for those grants will have an opportunity to propose additional vulnerable or underserved populations in their applications for the Federally-facilitated Exchange's approval.

(ii) [Reserved]

(9) Provide information and assistance with—

(i) The process of filing Exchange eligibility appeals;

(ii) Understanding and applying for exemptions from the individual shared responsibility requirement that are granted through the Exchange, understanding the availability of exemptions from the requirement to maintain minimum essential coverage and from the individual shared responsibility payment that are claimed through the tax filing process and how to apply for them, and understanding the availability of IRS resources on this topic;

(iii) Understanding the Exchange-related components of the premium tax credit reconciliation process, and the availability of IRS resources on this process;

(iv) Understanding basic concepts related to health coverage and how to use it; and

(v) Referrals to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice related to consumer questions about the Exchange application and enrollment process, exemptions from the requirement to maintain minimum essential coverage and from the individual shared responsibility requirement, and premium tax credit reconciliations.

* * * * *

■ 26. Section 155.215 is amended by revising paragraph (b)(1)(i) to read as follows:

§ 155.215 Standards applicable to Navigators and Non-Navigator Assistance Personnel carrying out consumer assistance functions under §§ 155.205(d) and (e) and 155.210 in a Federally-facilitated Exchange and to Non-Navigator Assistance Personnel funded through an Exchange Establishment Grant.

* * * * *

(b) * * *

(1) * * *

(i) Obtain certification by the Exchange prior to carrying out any consumer assistance functions or outreach and education activities under § 155.205(d) and (e) or § 155.210;

* * * * *

■ 27. Section 155.220 is amended by—
■ a. Revising paragraph (c)(1), (f)(4), (g)(2)(ii), (g)(3), and (g)(4);
■ b. Adding paragraphs (g)(5), (j), (k), and (l).

The revisions and additions read as follows:

§ 155.220 Ability of States to permit agents and brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(c) * * *

(1) The agent or broker ensures the applicant's completion of an eligibility verification and enrollment application through the Exchange Internet Web site or an Exchange approved web service using the FFE single streamline application;

* * * * *

(f) * * *

(4) When termination of the agreement between the agent or broker and the Exchange under paragraph (d) of this section becomes effective under paragraph (f) of this section, the agent or broker will no longer be registered with the Federally-facilitated Exchanges, or be permitted to assist with or facilitate enrollment of qualified individuals, qualified employers or qualified employees in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or be permitted to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs. The agent's or broker's agreement with the Exchange under § 155.260(b) will also be terminated through the termination for cause process set forth in that agreement. The agent or broker must continue to protect any personally identifiable information accessed during the term of either of these agreements with the Federally-facilitated Exchange.

(g) * * *

(2) * * *

(ii) Any term or condition of the agreement with the Federally-facilitated

Exchange required under paragraph (d) of this section, or any term or condition of the agreement with the Federally-facilitated Exchange required under § 155.260(b);

* * * * *

(3) HHS will notify the agent or broker of the specific finding of noncompliance or pattern of noncompliance made under paragraph (g)(1) of this section, and after 30 days from the date of the notice, may terminate the agreement for cause if the matter is not resolved to the satisfaction of HHS.

(4) After the period in paragraph (g)(3) of this section has elapsed and the agreement under paragraph (d) of this section is terminated, the agent or broker will no longer be registered with the Federally-facilitated Exchanges, or be permitted to assist with or facilitate enrollment of a qualified individual, qualified employer, or qualified employee in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or be permitted to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs. The agent's or broker's agreement with the Exchange under § 155.260(b) will also be terminated through the process set forth in that agreement. The agent or broker must continue to protect any personally identifiable information accessed during the term of either of these agreements with a Federally-facilitated Exchange.

(5) In cases involving potential fraud or abusive conduct—

(i)(A) If HHS reasonably suspects that an agent or broker may have engaged in fraud or abusive conduct using personally identifiable information of an Exchange enrollee or applicant, or in connection with an Exchange enrollment or application, HHS may temporarily suspend the agent's or broker's agreements required under paragraph (d) of this section and under § 155.260(b) for up to 90 calendar days. The suspension will be effective starting on the date of the notice that HHS sends to the agent or broker advising of the suspension under this paragraph (g)(5)(i).

(B) The agent or broker may submit evidence in a form and manner to be specified by HHS, to rebut the allegation during this 90-day period. If the agent or broker fails to submit such evidence during the suspension period, HHS may terminate the agent's or broker's agreements required under paragraph (d) of this section and under § 155.260(b) for cause under paragraph (g)(5)(ii) of this section.

(ii) If HHS reasonably confirms the credibility of an allegation that an agent or broker engaged in fraud or abusive conduct (or is notified by a State or law enforcement authority of the State or law enforcement authority's finding or determination of fraud or behavior that would constitute abusive conduct) using personally identifiable information of Exchange enrollees or applicants, or in connection with an Exchange enrollment or application, HHS will terminate the agent's or broker's agreements required under paragraph (d) of this section and under § 155.260(b) for cause. The termination will be effective starting on the date of the notice that HHS sends to the agent or broker advising of the termination of the agreements under this paragraph (g)(5)(ii).

(iii) During the suspension period under paragraph (g)(5)(i) of this section and following termination of the agreements under paragraph (g)(5)(ii) of this section, the agent or broker will not be registered with the Federally-facilitated Exchanges, or be permitted to assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or be permitted to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs. In the case of termination under paragraph (g)(5)(ii) of this section, the agent's or broker's agreement with the Exchange under § 155.260(b) will also be terminated as of the date of the notice. The agent or broker must continue to protect any personally identifiable information accessed during the term of either of these agreements with a Federally-facilitated Exchange.

* * * * *

(j) *Federally-facilitated Exchange standards of conduct.* (1) An agent or broker that assists with or facilitates enrollment of qualified individuals, qualified employers, or qualified employees, in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or assists individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs sold through a Federally-facilitated Exchange, must—

(i) Have executed the required agreement under paragraph § 155.260(b);

(ii) Be registered with the Federally-facilitated Exchanges under paragraph (d)(1) of this section; and

(iii) Comply with the standards of conduct in paragraph (j)(2) of this section.

(2) Standards of conduct. An individual or entity described in paragraph (j)(1) of this section must—

(i) Provide consumers with correct information, without omission of material fact, regarding the Federally-facilitated Exchanges, QHPs offered through the Federally-facilitated Exchanges, and insurance affordability programs, and refrain from marketing or conduct that is misleading or coercive, or discriminates based on race, color, national origin, disability, age, sex, gender identity, or sexual orientation;

(ii) Provide the Federally-facilitated Exchanges with correct information under section 1411(b) of the Affordable Care Act;

(iii) Obtain the consent of the individual, employer, or employee prior to assisting with or facilitating enrollment through a Federally-facilitated Exchange, or assisting the individual in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs;

(iv) Protect consumer personally identifiable information according to § 155.260(b)(3) and the agreement described in § 155.260(b)(2); and

(v) Comply with all applicable Federal and State laws and regulations.

(3) An agent or broker will be considered to be in compliance with paragraphs (j)(2)(i) and (ii) of this section if HHS determines that there was a reasonable cause for the failure to provide correct information and that the agent or broker acted in good faith.

(k) *Penalties other than termination of the agreement with the Federally-facilitated Exchanges.* (1) If HHS determines that an agent or broker has failed to comply with the requirements of this section, in addition to any other available remedies, that agent or broker—

(i) May be denied the right to enter into agreements with the Federally-facilitated Exchanges in future years; and

(ii) May be subject to civil money penalties as described in § 155.285.

(2) HHS will notify the agent or broker of the proposed imposition of penalties under paragraph (k)(1)(i) of this section and, after 30 calendar days from the date of the notice, may impose the penalty if the agent or broker has not requested a reconsideration under paragraph (h) of this section. The proposed imposition of penalties under paragraph (k)(1)(ii) of this section will follow the process outlined under § 155.285.

(l) *Application to State-Based Exchanges using a Federal platform.* An agent or broker who enrolls qualified individuals, qualified employers, or

qualified employees in coverage in a manner that constitutes enrollment through an State-Based Exchange using a Federal platform, or assists individual market consumers with submission of applications for advance payments of the premium tax credit and cost-sharing reductions through an State-Based Exchange using a Federal platform must comply with all applicable Federally-facilitated Exchange standards in this section.

■ 28. Section 155.222 is amended by—

■ a. Revising the section heading.

■ b. Revising paragraphs (a)(1), (a)(2), (b)(1) through (5), and (d).

■ c. Adding paragraph (b)(6).

The revisions and addition read as follows:

§ 155.222 Standards for HHS-approved vendors of Federally-facilitated Exchange training for agents and brokers.

(a) * * *

(1) A vendor must be approved by HHS, in a form and manner to be determined by HHS, to have its training program recognized for agents and brokers assisting with or facilitating enrollment in individual market or SHOP coverage through the Federally-facilitated Exchanges consistent with § 155.220.

(2) As part of the training program, the vendor must require agents and brokers to provide identifying information and successfully complete the required curriculum.

* * * * *

(b) * * *

(1) Submit a complete and accurate application by the deadline established by HHS, which includes demonstration of prior experience with successfully conducting online training, as well as providing technical support to a large customer base.

(2) Adhere to HHS specifications for content, format, and delivery of training, which includes offering continuing education units (CEUs) for at least five States in which a Federally-facilitated Exchange or State-Based Exchange using a Federal platform is operating.

(3) Collect, store, and share with HHS training completion data from agent and broker users of the vendor's training in a manner, format, and frequency specified by HHS, and protect all data from agent and broker users of the vendor's training in accordance with applicable privacy and security requirements.

(4) Execute an agreement with HHS, in a form and manner to be determined by HHS, which requires the vendor to comply with applicable HHS guidelines for implementing the training and interfacing with HHS data systems, and the use of all data collected.

(5) Permit any individual who holds a valid State license or equivalent State authority to sell health insurance products to access the vendor's training.

(6) Provide technical support to agent and broker users of the vendor's training as specified by HHS.

* * * * *

(d) *Monitoring.* HHS may periodically monitor and audit vendors approved under this subpart, and their records related to the training functions described in this section, to ensure ongoing compliance with the standards in paragraph (b) of this section. If HHS determines that an HHS-approved vendor is not in compliance with the standards required in paragraph (b) of this section, the vendor may be removed from the approved list described in paragraph (c) of this section and may be required by HHS to cease performing the training functions described under this subpart.

* * * * *

■ 29. Section 155.225 is amended by adding paragraph (b)(1)(iii) and revising paragraph (g)(4) to read as follows:

§ 155.225 Certified application counselors.

* * * * *

(b) * * *

(1) * * *

(iii) Provides data and information to the Exchange regarding the number and performance of its certified application counselors and regarding the consumer assistance provided by its certified application counselors, upon request, in the form and manner specified by the Exchange. Beginning in January 2017, in a Federally-facilitated Exchange, organizations designated by the Exchange must submit monthly reports that include, at a minimum, data regarding the number of individuals who have been certified by the organization; the total number of consumers who received application and enrollment assistance from the organization; and of that number, the number of consumers who received assistance in applying for and selecting a QHP, enrolling in a QHP, or applying for Medicaid or CHIP.

* * * * *

(g) * * *

(4) Provide to an applicant or potential enrollee gifts of any value as an inducement for enrollment. The value of gifts provided to applicants and potential enrollees for purposes other than as an inducement for enrollment must not exceed nominal value, either individually or in the aggregate, when provided to that individual during a single encounter. For purposes of this paragraph (g)(4), the term gifts includes gift items, gift cards, cash cards, cash, and promotional items that market or promote the products or services of a third party, but does not include the reimbursement of legitimate expenses incurred by a consumer in an effort to receive Exchange application assistance, such as travel or postage expenses.

* * * * *

■ 30. Section 155.260 is amended by revising paragraph (a)(1) introductory text to read as follows:

§ 155.260 Privacy and security of personally identifiable information.

(a) * * *

(1) Where the Exchange creates or collects personally identifiable information for the purposes of determining eligibility for enrollment in a qualified health plan; determining eligibility for other insurance affordability programs, as defined in § 155.300; or determining eligibility for exemptions from the individual responsibility provisions in section 5000A of the Code, the Exchange may only use or disclose such personally identifiable information to the extent such information is necessary:

* * * * *

■ 31. Section 155.280 is amended by revising paragraph (a) to read as follows:

§ 155.280 Oversight and monitoring of privacy and security requirements.

(a) *General.* HHS will oversee and monitor the Federally-facilitated Exchanges, State-based Exchanges on the Federal platform, and non-Exchange entities required to comply with the privacy and security standards established and implemented by a Federally-facilitated Exchange pursuant to § 155.260 for compliance with those standards. HHS will oversee and monitor State Exchanges for compliance with the standards State Exchanges establish and implement pursuant to § 155.260. State Exchanges will oversee and monitor non-Exchange entities required to comply with the privacy and security standards established and implemented by a State Exchange in accordance to § 155.260.

* * * * *

■ 32. Section 155.302 is amended by revising paragraph (a)(1) to read as follows:

§ 155.302 Options for conducting eligibility determinations.

(a) * * *

(1) Directly, through contracting arrangements in accordance with § 155.110(a), or as a State-based Exchange on the Federal platform through a Federal platform agreement under which HHS carries out eligibility

determinations and other requirements contained within this subpart; or

* * * * *

■ 33. Section 155.310 is amended by revising paragraphs (h) introductory text and (h)(2) to read as follows:

§ 155.310 Eligibility process.

* * * * *

(h) *Notice of an employee's receipt of advance payments of the premium tax credit and cost-sharing reductions to an employer.* The Exchange must notify an employer that an employee has been determined eligible for advance payments of the premium tax credit and cost-sharing reductions and has enrolled in a qualified health plan through the Exchange within a reasonable timeframe following a determination that the employee is eligible for advance payments of the premium tax credit and cost-sharing reductions in accordance with § 155.305(g) or § 155.350(a) and enrollment by the employee in a qualified health plan through the Exchange. Such notice must:

* * * * *

(2) Indicate that the employee has been determined eligible advance payments of the premium tax credit and cost-sharing reductions and has enrolled in a qualified health plan through the Exchange;

* * * * *

■ 34. Section 155.320 is amended by—

■ a. Revising paragraphs (c)(3)(vi) and (d)(3).

■ b. Adding paragraph (d)(4).

The revisions and addition read as follows:

§ 155.320 Verification process related to eligibility for insurance affordability programs.

* * * * *

(c) * * *

(3) * * *

(vi) *Alternate verification process for decreases in annual household income estimates and for situations in which tax return data is unavailable.* If a tax filer qualifies for an alternate verification process based on the requirements specified in paragraph (c)(3)(iv) of this section and the applicant's attestation to projected annual household income, as described in paragraph (c)(3)(ii)(B) of this section, is more than a reasonable threshold below the annual household income computed in accordance with paragraph (c)(3)(ii)(A) of this section, or if data described in paragraph (c)(1)(i) of this section is unavailable, the Exchange must attempt to verify the applicant's attestation of the tax filer's projected annual household income by following the procedures specified in paragraph (c)(3)(vi)(A) through (G) of this section. For the purposes of this paragraph (c)(3)(vi), a reasonable threshold is established by the Exchange in guidance and approved by HHS, but must not be less than10 percent, and can also include a threshold dollar amount. The Exchange's threshold is subject to approval by HHS.

* * * * *

(d) * * *

(3) *Verification procedures.* (i) If an applicant's attestation is not reasonably compatible with the information obtained by the Exchange as specified in paragraphs (d)(2)(i) through (iii) of this section, other information provided by the application filer, or other information in the records of the Exchange, the Exchange must follow the procedures specified in § 155.315(f).

(ii) Except as specified in paragraph (d)(3)(i) or (d)(4)(i) of this section, the Exchange must accept an applicant's attestation regarding the verification specified in paragraph (d) of this section without further verification.

(4) *Alternate procedures.* For any benefit year for which it does not reasonably expect to obtain sufficient verification data as described in paragraphs (d)(2)(i) through (iii) of this section, the Exchange must follow the procedures specified in paragraph (d)(4)(i) of this section or, for benefit years 2016 and 2017, the Exchange may follow the procedures specified in paragraph (d)(4)(ii) of this section. For purposes of this paragraph (d)(4), the Exchange reasonably expects to obtain sufficient verification data for any benefit year when, for the benefit year, the Exchange is able to obtain data about enrollment in and eligibility for qualifying coverage in an eligible employer-sponsored plan from at least one electronic data source that is available to the Exchange and that has been approved by HHS, based on evidence showing that the data source is sufficiently current, accurate, and minimizes administrative burden, as described under paragraph (d)(2)(i) of this section.

(i) Select a statistically significant random sample of applicants for whom the Exchange does not have any of the information specified in paragraphs (d)(2)(i) through (iii) of this section and—

(A) Provide notice to the applicant indicating that the Exchange will be contacting any employer identified on the application for the applicant and the members of his or her household, as defined in 26 CFR 1.36B–1(d), to verify whether the applicant is enrolled in an eligible employer-sponsored plan or is eligible for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested;

(B) Proceed with all other elements of the eligibility determination using the applicant's attestation, and provide eligibility for enrollment in a QHP to the extent that an applicant is otherwise qualified;

(C) Ensure that advance payments of the premium tax credit and cost-sharing reductions are provided on behalf of an applicant who is otherwise qualified for such payments and reductions, as described in § 155.305, if the tax filer attests to the Exchange that he or she understands that any advance payments of the premium tax credit paid on his or her behalf are subject to reconciliation;

(D) Make reasonable attempts to contact any employer identified on the application for the applicant and the members of his or her household, as defined in 26 CFR 1.36B–1(d), to verify whether the applicant is enrolled in an eligible employer-sponsored plan or is eligible for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested;

(E) If the Exchange receives any information from an employer relevant to the applicant's enrollment in an eligible employer-sponsored plan or eligibility for qualifying coverage in an eligible employer-sponsored plan, the Exchange must determine the applicant's eligibility based on such information and in accordance with the effective dates specified in § 155.330(f), and if such information changes his or her eligibility determination, notify the applicant and his or her employer or employers of such determination in accordance with the notice requirements specified in § 155.310(g) and (h);

(F) If, after a period of 90 days from the date on which the notice described in paragraph (d)(4)(i)(A) of this section is sent to the applicant, the Exchange is unable to obtain the necessary information from an employer, the Exchange must determine the applicant's eligibility based on his or her attestation regarding coverage provided by that employer.

(G) To carry out the process described in paragraph (d)(4)(i) of this section, the Exchange must only disclose an individual's information to an employer to the extent necessary for the employer to identify the employee.

(ii) Establish an alternative process approved by HHS.

* * * * *

■ 35. Section 155.335 is amended by revising paragraph (j) to read as follows:

§ 155.335 Annual eligibility redetermination.

* * * * *

(j) *Re-enrollment.* If an enrollee remains eligible for enrollment in a QHP through the Exchange upon annual redetermination and—

(1) QHPs under the product under which the QHP in which he or she is enrolled remain available through the Exchange for renewal, consistent with § 147.106 of this subchapter, such enrollee will have his or her enrollment through the Exchange in a QHP under that product renewed, unless he or she terminates coverage, including termination of coverage in connection with voluntarily selecting a different QHP, in accordance with § 155.430. The Exchange will ensure that re-enrollment in coverage under this paragraph (j)(1) occurs under the same product (except as provided in paragraph (j)(1)(iii)(A) of this section) in which the enrollee was enrolled, as follows:

(i) The enrollee's coverage will be renewed in the same plan as the enrollee's current QHP, unless the current QHP is not available through the Exchange.

(ii) If the enrollee's current QHP is not available through the Exchange, the enrollee's coverage will be renewed in a QHP at the same metal level as the enrollee's current QHP within the same product.

(iii) If the enrollee's current QHP is not available through the Exchange and the enrollee's product no longer includes a QHP at the same metal level as the enrollee's current QHP and—

(A) The enrollee's current QHP is a silver level plan, the enrollee will be re-enrolled in a silver level QHP under a different product offered by the same QHP issuer that is most similar to the enrollee's current product. If no such silver level QHP is available for enrollment through the Exchange, the enrollee's coverage will be renewed in a QHP that is one metal level higher or lower than the enrollee's current QHP under the same product;

(B) The enrollee's current QHP is not a silver level plan, the enrollee's coverage will be renewed in a QHP that is one metal level higher or lower than the enrollee's current QHP under the same product; or

(iv) If the enrollee's current QHP is not available through the Exchange and the enrollee's product no longer includes a QHP that is at the same metal level as, or one metal level higher or lower than the enrollee's current QHP, the enrollee's coverage will be renewed in any other QHP offered under the product in which the enrollee's current QHP is offered in which the enrollee is eligible to enroll.

(2) No plans under the product under which the QHP in which he or she is enrolled are available through the Exchange for renewal, consistent with § 147.106 of this subchapter, such enrollee may be enrolled in a QHP under a different product offered by the same QHP issuer, to the extent permitted by applicable State law, unless he or she terminates coverage, including termination of coverage in connection with voluntarily selecting a different QHP, in accordance with § 155.430. The Exchange will ensure that re-enrollment in coverage under this paragraph (j)(2) occurs as follows:

(i) The enrollee will be re-enrolled in a QHP at the same metal level as the enrollee's current QHP in the product offered by the same issuer that is the most similar to the enrollee's current product;

(ii) If the issuer does not offer another QHP at the same metal level as the enrollee's current QHP, the enrollee will be re-enrolled in a QHP that is one metal level higher or lower than the enrollee's current QHP in the product offered by the same issuer through the Exchange that is the most similar to the enrollee's current product; or

(iii) If the issuer does not offer another QHP through the Exchange at the same metal level as, or one metal level higher or lower than the enrollee's current QHP, the enrollee will be re-enrolled in any other QHP offered by the same issuer in which the enrollee is eligible to enroll.

* * * * *

■ 36. Section 155.400 is amended by revising paragraph (e) and adding paragraphs (g) and (h) to read as follows:

§ 155.400 Enrollment of qualified individuals into QHPs.

* * * * *

(e) *Premium payment.* Exchanges may, and the Federally-facilitated Exchange will, require payment of a binder payment to effectuate an enrollment or to add coverage retroactively to an already effectuated enrollment. Exchanges may, and the Federally-facilitated Exchange will, establish a standard policy for setting premium payment deadlines:

(1) In a Federally-facilitated Exchange:

(i) For prospective coverage to be effectuated under regular coverage effective dates, as provided for in §§ 155.410(f) and 155.420(b)(1), the binder payment must consist of the first month's premium, and the deadline for making the binder payment must be no earlier than the coverage effective date, and no later than 30 calendar days from the coverage effective date;

(ii) For prospective coverage to be effectuated under special effective dates, as provided for in § 155.420(b)(2), the binder payment must consist of the first month's premium, and the deadline for making the binder payment must be no earlier than the coverage effective date and no later than 30 calendar days from the date the issuer receives the enrollment transaction or the coverage effective date, whichever is later.

(iii) For coverage to be effectuated under retroactive effective dates, as provided for in § 155.420(b)(2), the binder payment must consist of the premium due for all months of retroactive coverage through the first prospective month of coverage, and, the deadline for making the binder payment must be no earlier than 30 calendar days from the date the issuer receives the enrollment transaction. If only the premium for one month of coverage is paid, only prospective coverage should be effectuated, in accordance with regular effective dates.

(2) [Reserved]

* * * * *

(g) *Premium payment threshold.* Exchanges may, and the Federally-facilitated Exchange will, allow issuers to implement, a premium payment threshold policy under which issuers can consider enrollees to have paid all amounts due if the enrollees pay an amount sufficient to maintain a percentage of total premium paid out of the total premium owed equal to or greater than a level prescribed by the issuer, provided that the level is reasonable and that the level and the policy are applied in a uniform manner to all enrollees. If an applicant or enrollee satisfies the premium payment threshold policy, the issuer may:

(1) Effectuate an enrollment based on payment of the binder payment under paragraph (e) of this section.

(2) Avoid triggering a grace period for non-payment of premium, as described by § 156.270(d) of this subchapter or a grace period governed by State rules.

(3) Avoid terminating the enrollment for non-payment of premium as, described by §§ 156.270(g) of this subchapter and 155.430(b)(2)(ii)(A) and(B).

(h) *Requirements.* A State Exchange may rely on HHS to carry out the requirements of this section and other requirements contained within this subpart E through a Federal platform agreement.

■ 37. Section 155.410 is amended by revising paragraphs (e)(2) and (f)(2) to read as follows:

§ 155.410 Initial and annual open enrollment periods.

* * * * *

(e) * * *

(2) For the benefit years beginning on January 1, 2016 and on January 1, 2017, the annual open enrollment period begins on November 1 of the calendar year preceding the benefit year, and extends through January 31 of the benefit year.

(f) * * *

(2) For the benefit years beginning on January 1, 2016 and on January 1, 2017, the Exchange must ensure that coverage is effective—

(i) January 1 for QHP selections received by the Exchange on or before December 15 of the calendar year preceding the benefit year.

(ii) February 1 for QHP selections received by the Exchange from December 16 of the calendar year preceding the benefit year through January 15 of the benefit year.

(iii) March 1 for QHP selections received by the Exchange from January 16 through January 31 of the benefit year.

* * * * *

■ 38. Section 155.430 is amended by—

■ a. Adding paragraph (b)(1)(iv).

■ b. Revising paragraphs (b)(2)(ii)(A).

■ c. Redesignating paragraph (b)(2)(vi) as paragraph (b)(2)(vii).

■ d. Adding paragraphs (b)(2)(vi) and (d)(9), (10), and (11)

The additions and revision read as follows:

§ 155.430 Termination of Exchange enrollment or coverage.

* * * * *

(b) * * *

(1) * * *

(iv) The Exchange must permit an enrollee to retroactively terminate or cancel his or her coverage or enrollment in a QHP in the following circumstances:

(A) The enrollee demonstrates to the Exchange that he or she attempted to terminate his or her coverage or enrollment in a QHP and experienced a technical error that did not allow the enrollee to terminate his or her coverage or enrollment through the Exchange, and requests retroactive termination within 60 days after he or she discovered the technical error.

(B) The enrollee demonstrates to the Exchange that his or her enrollment in a QHP through the Exchange was unintentional, inadvertent, or erroneous and was the result of the error or misconduct of an officer, employee, or agent of the Exchange or HHS, its instrumentalities, or a non-Exchange entity providing enrollment assistance or conducting enrollment activities. Such enrollee must request cancellation within 60 days of discovering the unintentional, inadvertent, or erroneous enrollment. For purposes of this paragraph (b)(1)(iv)(B), misconduct includes the failure to comply with applicable standards under this part, part 156 of this subchapter, or other applicable Federal or State requirements as determined by the Exchange.

(C) The enrollee was enrolled in a QHP without his or her knowledge or consent due to the fraudulent activity of any third party, including third parties who have no connection with the Exchange, and requests cancellation within 60 days of discovering of the fraudulent enrollment.

(2) * * *

(ii) * * *

(A) The exhaustion of the 3-month grace period, as described in § 156.270(d) and (g) of this subchapter, required for enrollees, who when first failing to timely pay premiums, are receiving advance payments of the premium tax credit;

* * * * *

(vi) The enrollee was enrolled in a QHP due to fraudulent activity, including fraudulent activity by a third party with no connection with the Exchange.

* * * * *

(d) * * *

(9) In case of a retroactive termination in accordance with paragraph (b)(1)(iv)(A) of this section, the termination date will be no sooner than 14 days after the date that the enrollee can demonstrate he or she contacted the Exchange to terminate his or her coverage or enrollment through the Exchange, unless the issuer agrees to an earlier effective date as set forth in paragraph (d)(2)(iii) of this section.

(10) In case of a retroactive cancellation or termination in accordance with paragraph (b)(1)(iv)(B) or (C) of this section, the cancellation date or termination date will be the original coverage effective date or a later date, as determined appropriate by the Exchange, based on the circumstances of the cancellation or termination.

(11) In the case of cancellation in accordance with paragraph (b)(2)(vi) of this section, the Exchange may cancel the enrollee's enrollment upon its determination that the enrollment was performed fraudulently and following reasonable notice to the enrollee (where possible). The termination date will be the original coverage effective date.

* * * * *

■ 39. Section 155.505 is amended by adding paragraphs (b)(1)(iii) and (b)(5) and revising paragraph (b)(4) to read as follows:

§ 155.505 General eligibility appeals requirements.

* * * * *

(b) * * *

(1) * * *

(iii) A determination of eligibility for an enrollment period, made in accordance with § 155.305(b);

* * * * *

(4) A denial of a request to vacate dismissal made by a State Exchange appeals entity in accordance with § 155.530(d)(2), made under paragraph (c)(2)(i) of this section; and

(5) An appeal decision issued by a State Exchange appeals entity in accordance with § 155.545(b), consistent with § 155.520(c).

* * * * *

■ 40. Section 155.510 is amended by revising paragraph (a)(1) to read as follows:

§ 155.510 Appeals coordination.

(a) * * *

(1) Minimize burden on appellants, including not asking the appellant to provide duplicative information or documentation that he or she already provided to an agency administering an insurance affordability program or eligibility appeals process, unless the appeals entity, Exchange, or agency does not have access to the information or documentation and cannot reasonably obtain it;

* * * * *

■ 41. Section 155.520 is amended by adding paragraph (d)(2)(i)(D) to read as follows:

§ 155.520 Appeal requests.

* * * * *

(d) * * *

(2) * * *

(i) * * *

(D) That, in the event the appeal request is not valid due to failure to submit by the date determined under paragraph (b) or (c) of this section, as applicable, the appeal request may be considered valid if the applicant or enrollee sufficiently demonstrates within a reasonable timeframe determined by the appeals entity that failure to timely submit was due to exceptional circumstances and should not preclude the appeal.

* * * * *

■ 42. Section 155.530 is amended by revising paragraph (a)(4) to read as follows:

§ 155.530 Dismissals.

(a) * * *

(4) Dies while the appeal is pending, except if the executor, administrator, or

other duly authorized representative of the estate requests to continue the appeal.

* * * * *

■ 43. Section 155.535 is amended by revising paragraphs (a) introductory text and (b) to read as follows:

§ 155.535 Informal resolution and hearing requirements.

(a) *Informal resolution.* The HHS appeals process will provide an opportunity for informal resolution and a hearing in accordance with the requirements of this section. A State Exchange appeals entity may also provide an informal resolution process prior to a hearing. Any information resolution process must meet the following requirements:

* * * * *

(b) *Notice of hearing.* When a hearing is scheduled, the appeals entity must send written notice to the appellant of the date, time, and location or format of the hearing no later than 15 days prior to the hearing date unless—

(1) The appellant requests an earlier hearing date; or

(2) A hearing date sooner than 15 days is necessary to process an expedited appeal, as described in § 155.540(a), and the appeals entity has contacted the appellant to schedule a hearing on a mutually agreed upon date, time, and location or format.

* * * * *

■ 44. Section 155.545 is amended by revising paragraphs (b)(1) and (c)(1)(i) and (ii) to read as follows:

§ 155.545 Appeal decisions.

* * * * *

(b) * * *

(1) Must issue written notice of the appeal decision to the appellant within 90 days of the date an appeal request under § 155.520(b) or (c) is received, as administratively feasible.

* * * * *

(c) * * *

(1) * * *

(i) Prospectively, on the first day of the month following the date of the notice of appeal decision, or consistent with § 155.330(f)(2), (3), (4), or (5), if applicable; or

(ii) Retroactively, to the coverage effective date the appellant did receive or would have received if the appellant had enrolled in coverage under the incorrect eligibility determination that is the subject of the appeal, at the option of the appellant.

* * * * *

■ 45. Section 155.555 is amended by revising paragraphs (e)(1) introductory text and (l) to read as follows:

§ 155.555 Employer appeals process.

* * * * *

(e) * * *

(1) Upon receipt of a valid appeal request under this section, or upon receipt of the notice under paragraph (d)(1)(iii) of this section, the Exchange must promptly transmit via secure electronic interface to the appeals entity—

* * * * *

(l) *Implementation of the appeal decision.* After receipt of the notice under paragraph (k)(3) of this section, if the appeal decision affects the employee's eligibility, the Exchange must promptly:

(1) Redetermine the employee's eligibility and the eligibility of the employee's household members, if applicable, in accordance with the standards specified in § 155.305; or

(2) Notify the employee of the requirement to report changes in eligibility as described in § 155.330(b)(1).

* * * * *

■ 46. Section 155.605 is amended by:

■ a. In paragraph (b), removing the reference ''paragraphs (c)(2), (f)(2), and (g) of this section'' and adding in its place the reference ''paragraphs (c)(2) and (d) of this section'';

■ b. Removing paragraphs (d), (e) and (f);

■ c. Redesignating paragraph (g) as paragraph (d);

■ d. Revising newly redesignated paragraph (d); and

■ c. Adding paragraph (e).

The revision and addition read as follows:

§ 155.605 Eligibility standards for exemptions.

* * * * *

(d) *Hardship*—(1) *General.* The Exchange must grant a hardship exemption to an applicant eligible for an exemption for at least the month before, the month or months during which, and the month after a specific event or circumstance, if the Exchange determines that the applicant has suffered a hardship in relation to his or her ability to obtain coverage because they experienced one or more of the events or circumstances listed in paragraph (d)(1)(i) through (iii) or (d)(2) of this section. Notwithstanding the length of the hardship, any hardship exemption granted pursuant to this paragraph (d) may be granted for a maximum period that is not to exceed the month before the event or circumstance and the remainder of the calendar year during which the hardship commenced, plus the next calendar year.

(i) He or she experienced financial or domestic circumstances, including an unexpected natural or human-caused event, such that he or she had a significant, unexpected increase in essential expenses that prevented him or her from obtaining coverage under a qualified health plan;

(ii) The expense of purchasing a qualified health plan would have caused him or her to experience serious deprivation of food, shelter, clothing or other necessities; or

(iii) He or she has experienced other circumstances that prevented him or her from obtaining coverage under a qualified health plan.

(2) Examples of events and circumstances for which the Exchange must grant a hardship exemption to an applicant based on paragraph (d)(1) of this section include:

(i) Individuals that the Exchange determines are homeless.

(ii) Individuals who have been evicted or facing eviction or foreclosure.

(iii) Individuals who have received a shut-off notice from a utility company.

(iv) Individuals who have experienced domestic violence.

(v) Individuals who have experienced the death of a family member.

(vi) Individuals who have experienced a fire, flood or other nature or human-caused disaster that caused substantial damage to your property.

(vii) Individuals who have filed for bankruptcy.

(viii) Individuals who had medical bills which resulted in substantial debt

(ix) Individuals who experienced unexpected increases in necessary expenses due to caring for an ill, disabled or aging family member.

(x) Individuals who are seeking categorical Medicaid eligibility under section 1902(f) of the Act for ''209(b)'' States (codified at 42 CFR 435.121).

(xi) Individuals who are seeking Medicaid coverage provided to medically needy individuals under section 1902(a)(10)(C) of the Social Security Act 42 U.S.C. 1396(a)(10)(C) that is not recognized as government-sponsored minimum essential coverage (MEC) under IRS regulations or HHS regulations or guidance.

(xii) Individuals who are enrolled in Medicaid coverage provided to a pregnant women that is not recognized as government-sponsored MEC under IRS regulations or HHS regulations or guidance.

(xiii) Individuals who are enrolled in CHIP coverage provided to an unborn child that includes comprehensive prenatal care for the pregnant mother.

(xiv) Individuals who are eligible for enrollment in a qualified health plan

(QHP) through the Exchange, lower costs on the individual's monthly premiums or cost-sharing reductions for a time period when the individual was not enrolled in a QHP through the Exchange as a result of an eligibility appeals decision.

(3) The hardship event or circumstance described under paragraph (d)(1) or (2) of this section must have occurred within 3 years of the date the applicant submits an application to the Exchange under § 155.610, except in the case of applicants who are or who were homeless or experienced domestic violence.

(i) The date of submission of an application means the date of receipt of the application by the Exchange via the channels available for the submission of an application, as described in § 155.610(d) or the date the application was signed by the submitter.

(ii) [Reserved]

(4) *Lack of affordable coverage based on projected income.* The Exchange must determine an applicant eligible for an exemption for a month or months during which he or she, or another individual the applicant attests will be included in the applicant's family, as defined in 26 CFR 1.36B–1(d), is unable to afford coverage in accordance with the standards specified in section 5000A(e)(1) of the Code, provided that—

(i) Eligibility for this exemption is based on projected annual household income;

(ii) An eligible employer-sponsored plan is only considered under paragraphs (d)(4)(iii) and (iv) of this section if it meets the minimum value standard described in § 156.145 of this subchapter.

(iii) For an individual who is eligible to purchase coverage under an eligible employer-sponsored plan, the Exchange determines the required contribution for coverage such that—

(A) An individual who uses tobacco is treated as not earning any premium incentive related to participation in a wellness program designed to prevent or reduce tobacco use that is offered by an eligible employer-sponsored plan;

(B) Wellness incentives offered by an eligible employer-sponsored plan that do not relate to tobacco use are treated as not earned;

(C) In the case of an employee who is eligible to purchase coverage under an eligible employer-sponsored plan sponsored by the employee's employer, the required contribution is the portion of the annual premium that the employee would pay (whether through salary reduction or otherwise) for the lowest cost self-only coverage.

(D) In the case of an individual who is eligible to purchase coverage under an eligible employer-sponsored plan as a member of the employee's family, as defined in 26 CFR 1.36B–1(d), the required contribution is the portion of the annual premium that the employee would pay (whether through salary reduction or otherwise) for the lowest cost family coverage that would cover the employee and all other individuals who are included in the employee's family who have not otherwise been granted an exemption through the Exchange.

(iv) For an individual who is ineligible to purchase coverage under an eligible employer-sponsored plan, the Exchange determines the required contribution for coverage in accordance with section 5000A(e)(1)(B)(ii) of the Code, inclusive of all members of the family, as defined in 26 CFR 1.36B–1(d), who have not otherwise been granted an exemption through the Exchange and who are not treated as eligible to purchase coverage under an eligible employer-sponsored plan, in accordance with paragraph (d)(4)(ii) of this section; and

(v) The applicant applies for this exemption prior to the last date on which he or she could enroll in a QHP through the Exchange for the month or months of a calendar year for which the exemption is requested.

(vi) The Exchange must make an exemption in this category available prospectively, and provide it for all remaining months in a coverage year, notwithstanding any change in an individual's circumstances.

(5) *Ineligible for Medicaid based on a State's decision not to expand.* The Exchange must determine an applicant eligible for an exemption for a calendar year if he or she would be determined ineligible for Medicaid for one or more months during the benefit year solely as a result of a State not implementing section 2001(a) of the Affordable Care Act.

(e) *Eligibility for an exemption through the IRS.* Hardship exemptions in this paragraph can be claimed on a Federal income tax return without obtaining an exemption certificate number. The IRS may allow an individual to claim the hardship exemptions described in this paragraph (e) without requiring an exemption certificate number from the Exchange.

(1) *Filing threshold.* The IRS may allow an applicant to claim an exemption specified in HHS Guidance published September 18, 2014, entitled, Shared Responsibility Guidance—Filing Threshold Hardship Exemption,'' and in IRS Notice 2014–76, section B.

(2) *Self-only coverage in an eligible employer-sponsored plan.* The IRS may allow an applicant to claim an exemption specified in HHS Guidance published November 21, 2014, entitled, ''Guidance on Hardship Exemptions for Persons Meeting Certain Criteria,'' and in IRS Notice 2014–76, section A.

(3) *Eligible for services through an Indian health care provider.* The IRS may allow an applicant to claim the exemption specified in HHS Guidance published September 18, 2014, entitled, ''Shared Responsibility Guidance—Exemption for Individuals Eligible for Services through an Indian Health Care Provider,'' and in IRS Notice 2014–76, section E.

(4) *Ineligible for Medicaid based on a State's decision not to expand.* The IRS may allow an applicant to claim the exemption specified in HHS Guidance published November 21, 2014, entitled, ''Guidance on Hardship Exemptions for Persons Meeting Certain Criteria,'' and in IRS Notice 2014–76, section F.

■ 47. Section 155.610 is amended by revising paragraph (h)(1) and adding paragraph (k) to read as follows:

§ 155.610 Eligibility process for exemptions.

* * * * *

(h) * * *

(1) Except for the exemptions described in § 155.605(c) and (d), after December 31 of a given calendar year, the Exchange may decline to accept an application for an exemption that is available retrospectively for months for such calendar year, and must provide information to individuals regarding how to claim an exemption through the tax filing process.

* * * * *

(k) *Incomplete application.* (1) If an applicant submits an application that does not include sufficient information for the Exchange to conduct a determination for eligibility of an exemption the Exchange must—

(i) Provide notice to the applicant indicating that information necessary to complete an eligibility determination is missing, specifying the missing information, and providing instructions on how to provide the missing information; and

(ii) Provide the applicant with a period of no less than 10 and no more than 90 days, in the reasonable discretion of the Exchange, from the date on which the notice described in paragraph (k)(1) of this section is sent to the applicant to provide the information needed to complete the application to the Exchange; and

(iii) Not proceed with the applicant's eligibility determination during the

period described in paragraph (k)(2) of this section.

(2) If the Exchange does not receive the requested information within the time allotted in paragraph (k)(1)(ii) of this section, the Exchange must notify the applicant in writing that the Exchange cannot process the application and provide appeal rights to the applicant.

■ 48. Section 155.615 is amended by-

■ a. Removing paragraphs (c), (d), and (e).

■ b. Redesignating paragraphs (f), (g), (h), (i), (j), and (k) as paragraphs (c), (d), (e), (f), (g), and (h), respectively.

■ c. Revising newly redesignated paragraph (c)(1).

■ d. Removing newly redesignated paragraph (c)(3).

■ e. Further redesignating newly redesignated paragraph (c)(2) as paragraph (c)(3).

■ f. Adding paragraph (c)(2).

The revision and addition read as follows:

§ 155.615 Verification process related to eligibility for exemptions.

* * * * *

(c) *Verification related to exemption for hardship*—(1) *In general.* For any applicant who requests an exemption based on hardship, except for the hardship exemptions described in § 155.605(d)(3), the Exchange must verify whether he or she has experienced the hardship to which he or she is attesting.

(2) *Hardship.* If the hardship-qualifying event or circumstance in § 155.605(d)(1) began more than 3 years prior to the date the exemption application was submitted, as specified in § 155.605(d)(3)(i), and the event or circumstance continued beyond the initial 3-year period, the Exchange must verify the applicant continued to experience the hardship to which he or she is attesting during a period that is within 3 years from the date of the exemption application submitted under § 155.605(d)(1).

* * * * *

■ 49. Section 155.625 is amended by revising paragraphs (a)(2) and (b) to read as follows:

§ 155.625 Options for conducting eligibility determinations for exemptions.

(a) * * *

(2) By use of the HHS service under paragraph (b) of this section.

(b) *Use of HHS service.* Notwithstanding the requirements of this subpart, the Exchange may adopt an exemption eligibility determination made by HHS.

■ 50. Section 155.705 is amended by:

■ a. Adding paragraphs (b)(3)(viii), (ix), and (x).

■ b. In paragraph (b)(4)(ii)(B), removing the semicolon and adding a colon in its place.

■ c. Adding paragraph (b)(4)(ii)(B)(*1*) and adding and reserving paragraph (b)(4)(ii)(B)(*2*).

■ d. Revising paragraphs (b)(4)(ii)(C)(*2*) and (b)(11)(ii)(A), (B), and (C).

■ e. Removing paragraphs (b)(11)(ii)(D) and (E).

The revisions and additions read as follows:

§ 155.705 Functions of a SHOP.

* * * * *

(b) * * *

(3) * * *

(viii) For plan years beginning on or after January 1, 2017, a Federally-facilitated SHOP will provide a qualified employer a choice of three methods to make QHPs available to qualified employees and their dependents:

(A) The employer may choose a level of coverage as described in paragraph (b)(2) of this section;

(B) The employer may choose a single QHP; or

(C) The employer may offer its qualified employees a choice of all QHPs offered through a Federally-facilitated SHOP by a single issuer across all available levels of coverage, as described in section 1302(d)(1) of the Affordable Care Act and implemented in § 156.140(b) of this subchapter.

(ix) For plan years beginning on or after January 1, 2017, a Federally-facilitated SHOP will provide a qualified employer a choice of three methods to make stand-alone dental plans available to qualified employees and their dependents:

(A) The employer may choose to make available a single stand-alone dental plan;

(B) The employer may choose to make available all stand-alone dental plans offered through a Federally-facilitated SHOP at a level of coverage as described in § 156.150(b)(2) of this subchapter; or

(C) The employer may offer its qualified employees a choice of all plans offered through a Federally-facilitated SHOP by a single issuer across all available levels of coverage, as described in § 156.150(b)(2) of this subchapter.

(x) States operating as a State-based Exchange utilizing the Federal platform for SHOP enrollment functions will have the same employer choice models available as States with a Federally-facilitated SHOP.

(4) * * *

(ii) * * *

(B) * * *

(*1*) In a Federally-facilitated SHOP, payment for the group's first month of coverage must be received by the premium aggregation services vendor on or before the 20th day of the month prior to the month that coverage begins.

(*2*) [Reserved]

(C) * * *

(*2*) The number of days for which coverage is being provided in the month described in paragraph (b)(4)(ii)(C)(*1*) of this section.

* * * * *

(11) * * *

(ii) * * *

(A) When the employer offers a single plan to qualified employees, the employer must use a fixed contribution methodology under which the employer contributes a fixed percentage of the plan's premium for each qualified employee and, if applicable, for each dependent of a qualified employee. A tobacco surcharge, if applicable, will be applied after the employer's contribution is applied to the premium.

(B) When the employer offers a choice of plans to qualified employees, the employer may use a fixed contribution methodology or a reference plan contribution methodology. Under the fixed contribution methodology, the employer contributes a fixed percentage of the premiums for each qualified employee and, if applicable, for each dependent of a qualified employee, across all plans in which any qualified employee, and, if applicable, any dependent of a qualified employee, is enrolled. Under the reference plan contribution methodology, the employer will select a plan from within the level of coverage offered as described in paragraphs (b)(2) and (3) of this section to serve as a reference plan on which contributions will be based, and then will define a percentage contribution toward premiums under the reference plan; the resulting contribution amounts under the reference plan will be applied toward any plan in which a qualified employee or, if applicable, any dependent of a qualified employee, is enrolled, up to the lesser of the contribution amount or the total amount of any premium for the selected plan before application of a tobacco surcharge, if applicable. A tobacco surcharge, if applicable, will be applied after the employer's contribution is applied to the premium.

(C) The employer will define a percentage contribution toward premiums for employee-only coverage and, if dependent coverage is offered, a percentage contribution toward premiums for dependent coverage. To

the extent permitted by other applicable law, for plan years beginning on or after January 1, 2015, a Federally-facilitated SHOP may permit an employer to define a different percentage contribution for full-time employees from the percentage contribution it defines for non-full-time employees, and it may permit an employer to define a different percentage contribution for dependent coverage for full-time employees from the percentage contribution it defines for dependent coverage for non-full-time employees.

* * * * *

■ 51. Section 155.715 is amended by revising paragraph (g)(1) to read as follows:

§ 155.715 Eligibility determination process for SHOP.

* * * * *

(g) * * *

(1) Each QHP terminates the enrollment through the SHOP of the employer's enrollees enrolled in a QHP through the SHOP; and

* * * * *

■ 52. Section 155.725 is amended by revising paragraphs (c), (e), (h)(2), (i)(1) introductory text, and (j)(2)(i) to read as follows:

§ 155.725 Enrollment periods under SHOP.

* * * * *

(c) *Annual employer election period.* The SHOP must provide qualified employers with a standard election period prior to the completion of the employer's plan year and before the annual employee open enrollment period, in which the qualified employer may change its participation in the SHOP for the next plan year, including—

(1) The method by which the qualified employer makes QHPs available to qualified employees pursuant to § 155.705(b)(2) and (3);

(2) The employer contribution towards the premium cost of coverage;

(3) The level of coverage offered to qualified employees as described in § 155.705(b)(2) and (3); and

(4) The QHP or QHPs offered to qualified employees in accordance with § 155.705.

* * * * *

(e) *Annual employee open enrollment period.* (1) The SHOP must establish a standardized annual open enrollment period for qualified employees prior to the completion of the applicable qualified employer's plan year and after that employer's annual election period.

(2) Qualified employers in a Federally-facilitated SHOP must provide qualified employees with an annual open enrollment period of at least one week.

* * * * *

(h) * * *

(2) For a group enrollment received by the Federally-facilitated SHOP from a qualified employer at the time of an initial group enrollment or renewal:

(i) Between the first and fifteenth day of any month, the Federally-facilitated SHOP must ensure a coverage effective date of the first day of the following month unless the employer opts for a later effective date within a quarter for which small group market rates are available.

(ii) Between the 16th and last day of any month, the Federally-facilitated SHOP must ensure a coverage effective date of the first day of the second following month unless the employer opts for a later effective date within a quarter for which small group market rates are available.

* * * * *

(i) * * *

(1) If a qualified employee enrolled in a QHP through the SHOP remains eligible for enrollment through the SHOP in coverage offered by the same qualified employer, the SHOP may provide for a process under which the employee will remain in the QHP selected the previous year, unless—

* * * * *

(j) * * *

(2) * * *

(i) Experiences an event described in § 155.420(d)(1) (other than paragraph (d)(1)(ii)), or experiences an event described in § 155.420(d)(2), (4), (5), (7), (8), or (9);

* * * * *

■ 53. Section 155.735 is amended by revising paragraphs (c)(2) introductory text and (d)(2) to read as follows:

§ 155.735 Termination of SHOP enrollment or coverage.

* * * * *

(c) * * *

(2) In an FF–SHOP, for premium payments other than payments for the first month of coverage—

* * * * *

(d) * * *

(2) In the FF–SHOP, termination is effective:

(i) In the case of a termination in accordance with paragraphs (d)(1)(i), (ii), (iii), and (v) of this section, termination is effective on the last day of the month in which the Federally-facilitated SHOP receives notice of the event described in paragraph (d)(1)(i), (ii), (iii), or (v) of this section.

(ii) In the case of a termination in accordance with paragraph (d)(1)(iv) of this section, the last day of coverage in an enrollee's prior QHP is the day before the effective date of coverage in his or her new QHP, including for any retroactive enrollments effectuated under § 155.420(b)(2).

(iii) The FF–SHOP will send qualified employees a notice notifying them in advance of a child dependent's loss of eligibility for dependent child coverage under their plan because of age. The notice will be sent 90 days in advance of the date when the dependent enrollee would lose eligibility for dependent child coverage. The enrollee will also receive a separate termination notice when coverage is terminated, under § 155.735(g).

* * * * *

■ 54. Section 155.740 is amended by revising paragraphs (c)(2), (d)(2), and (l)(3) to read as follows:

§ 155.740 SHOP employer and employee eligibility appeals requirements.

* * * * *

(c) * * *

(2) A failure by the SHOP to provide a timely eligibility determination or a timely notice of an eligibility determination in accordance with § 155.715(e).

(d) * * *

(2) A failure by the SHOP to provide a timely eligibility determination or a timely notice of an eligibility determination in accordance with § 155.715(f).

* * * * *

(l) * * *

(3) Be effective as follows:

(i) If an employer is found eligible under the decision, then at the employer's option, the effective date of coverage or enrollment through the SHOP under the decision can either be made retroactive to the effective date of coverage or enrollment through the SHOP that the employer would have had if the employer had been correctly determined eligible, or prospective to the first day of the month following the date of the notice of the appeal decision.

(ii) If an employee is found eligible under the decision, then at the employee's option, the effective date of coverage or enrollment through the SHOP under the decision can either be made effective retroactive to the effective date of coverage or enrollment through the SHOP that the employee would have had if the employee had been correctly determined eligible, or prospective to the first day of the month following the date of the notice of the appeal decision.

(iii) If the employer or employee is found ineligible under the decision, then the decision is effective on the first

day of the month following the date of the notice of the appeal decision.

* * * * *

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 55. The authority citation for part 156 continues to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301–1304, 1311–1313, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

■ 56. Section 156.20 is amended by adding a definition of ''Standardized option'' in alphabetical order to read as follows:

§ 156.20 Definitions.

* * * * *

Standardized option means a QHP with a standardized cost-sharing structure specified by HHS and that is offered for sale through an individual market Federally-facilitated Exchange.

■ 57. Section 156.50 amended by revising paragraph (c) to read as follows:

§ 156.50 Financial support.

* * * * *

(c) *Requirement for Federally-facilitated Exchange user fee.* (1) To support the functions of Federally-facilitated Exchanges, a participating issuer offering a plan through a Federally-facilitated Exchange must remit a user fee to HHS each month, in the time frame and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for Federally-facilitated Exchanges for the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through a Federally-facilitated Exchange.

(2) To support the functions of State-based Exchanges on the Federal platform, a participating issuer offering a plan through a State-based Exchange that elects to utilize the Federal Exchange platform for certain Exchange functions described in § 155.200 of this subchapter, as specified in a Federal platform agreement, must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the sum of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for State-based Exchanges that use the Federal platform for the applicable benefit year plus any additional user fee rate that HHS will collect on behalf of the Sate-based Exchange, multiplied by the monthly premium charged by the issuer for each policy under the plan where enrollment is through the State-based Exchange on the Federal platform.

* * * * *

■ 58. Section 156.80 is amended by revising paragraph (d)(3)(ii) to read as follows:

§ 156.80 Single risk pool.

* * * * *

(d) * * *

(3) * * *

(ii) A health insurance issuer in the small group market (not including a merged market) may establish index rates and make the marketwide adjustments under paragraph (d)(1) of this section, and make the plan-level adjustments under paragraph (d)(2) of this section, no more frequently than quarterly. Any changes to rates must have effective dates of January 1, April 1, July 1, or October 1. Such rates may only apply to coverage issued or renewed on or after the rate effective date and will apply for the entire plan year of the group health plan.

* * * * *

■ 59. Section 156.135 is amended by revising paragraph (g) to read as follows:

§ 156.135 AV calculation for determining level of coverage.

* * * * *

(g) *Updates to the AV Calculator.* HHS will update the AV Calculator annually for material changes that may include costs, plan designs, the standard population, developments in the function and operation of the AV Calculator and other actuarially relevant factors.

■ 60. Section 156.150 is amended by adding paragraphs (a)(1) and (2), (c), and (d) to read as follows:

§ 156.150 Application to stand-alone dental plans inside the Exchange.

(a) * * *

(1) For plan years beginning after 2016, for one covered child—the dollar limit applicable to a stand-alone dental plan for one covered child specified in this paragraph (a) increased by an amount equal to the product of that amount and the quotient of consumer price index for dental services for the year 2 years prior to the benefit year, divided by the consumer price index for dental services for 2016.

(2) For plan years after 2016, for two or more covered children—twice the dollar limit for one child described in paragraph (a)(1) of this section.

* * * * *

(c) *Consumer price index for dental services defined.* The consumer price index for dental services is a sub-component of the US Department of Labor's Bureau of Labor Statistics Consumer Price Index specific to dental services.

(d) *Increments of cost sharing increases.* Any increase in the annual dollar limits described in paragraph (a)(1) of this section that does not result in a multiple of 25 dollars will be rounded down, to the next lowest multiple of 25 dollars.

■ 61. Section 156.230 is amended by adding (d), (e), and (f) to read as follows.

§ 156.230 Network adequacy standards.

* * * * *

(d) *Minimum threshold.* A QHP in a Federally-facilitated Exchange meets the standard under paragraph (a)(2) of this section if its network is determined adequate under the following standards:

(1) In a State that implements an acceptable quantifiable network adequacy metric commonly used in the health insurance industry to measure network adequacy, under that metric; or

(2) In any other State, under the Federal time and distance standard, based on minimum number of providers and average time and distance to those providers. QHPs that cannot meet the time and distance standard established by HHS may satisfy this requirement by reasonably justifying variances from this standard based on such factors as the availability of providers and variables reflected in local patterns of care.

(e) *Provider transitions.* A QHP issuer in a Federally-facilitated Exchange must—

(1) Make a good faith effort to provide written notice of discontinuation of a provider 30 days prior to the effective date of the change or otherwise as soon as practicable, to enrollees who are patients seen on a regular basis by the provider or who receive primary care from the provider whose contract is being discontinued, irrespective of whether the contract is being discontinued due to a termination for cause or without cause, or due to a non-renewal;

(2) In cases where a provider is terminated without cause, allow an enrollee in active treatment to continue treatment until the treatment is complete or for 90 days, whichever is shorter, at in-network cost-sharing rates.

(i) For the purposes of paragraph (e)(2) of this section, active treatment means:

(A) An ongoing course of treatment for a life-threatening condition;

(B) An ongoing course of treatment for a serious acute condition;

(C) The second or third trimester of pregnancy; or

(D) An ongoing course of treatment for a health condition for which a treating physician or health care provider attests that discontinuing care by that physician or health care provider would worsen the condition or interfere with anticipated outcomes.

(ii) Any decisions made for a request for continuity of care under paragraph (e)(2) of this section must be subject to the health benefit plan's internal and external grievance and appeal processes in accordance with applicable State or Federal law or regulations.

(f) *Out-of-network cost sharing.* Notwithstanding § 156.130(c), for a network to be deemed adequate, each QHP that uses a provider network must:

(1) Count the cost sharing paid by an enrollee for an essential health benefit provided by an out-of-network provider in an in-network setting towards the enrollee's annual limitation on cost sharing; or

(2) Provide a written notice to the enrollee at least ten business days before the provision of the benefit that additional costs may be incurred for an essential health benefit provided by an out-of-network provider in an in-network setting, including balance billing charges, unless such costs are prohibited under State law, and that any additional charges may not count toward the in-network annual limitation on cost sharing.

■ 62. Section 156.235, as amended on February 27, 2015 (80 FR 10873), is further amended by revising paragraphs (a)(2)(i) and (b)(2)(i) to read as follows:

§ 156.235 Essential community providers.

(a) * * *

(2) * * *

(i) The network includes as participating practitioners at least a minimum percentage, as specified by HHS, of available essential community providers in each plan's service area. For plan years beginning prior to January 1, 2018, multiple providers at a single location will count as a single essential community provider toward both the available essential community provider s in the plan's service area and the issuer's satisfaction of the essential community provider participation standard. For plan years beginning on or after January 1, 2018, multiple contracted or employed full-time equivalent practitioners at a single location will count toward both the available essential community providers in the plan's service area and the issuer's satisfaction of the essential community provider participation standard; and

* * * * *

(b) * * *

(2) * * *

(i) The number of its providers that are located in Health Professional Shortage Areas or five-digit zip codes in which 30 percent or more of the population falls below 200 percent of the Federal Poverty Line satisfies a minimum percentage, specified by HHS, of available essential community provider in the plan's service area. For plan years beginning prior to January 1, 2018, multiple providers at a single location will count as a single essential community provider toward both the available essential community providers in the plan's service area and the issuer's satisfaction of the essential community provider participation standard. For plan years beginning on or after January 1, 2018, multiple contracted or employed full-time equivalent practitioners at a single location will count toward both the available essential community providers in the plan's service area and the satisfaction of the essential community provider participation standard; and

* * * * *

■ 63. Section 156.265 is amended by revising paragraph (b)(2)(ii) to read as follows:

§ 156.265 Enrollment process for qualified individuals.

* * * * *

(b) * * *

(2) * * *

(ii) Ensure the applicant received an eligibility determination for coverage through the Exchange through the Exchange Internet Web site or an Exchange approved web service using the FFE single streamline application.

* * * * *

■ 64. Section 156.270 is amended by revising paragraphs (d) introductory text and (g) to read as follows:

§ 156.270 Termination of coverage or enrollment for qualified individuals.

* * * * *

(d) *Grace period for recipients of advance payments of the premium tax credit.* A QHP issuer must provide a grace period of 3 months for an enrollee, who when failing to timely pay premiums, is receiving advance payments of the premium tax credit. During the grace period, the QHP issuer must:

* * * * *

(g) *Exhaustion of grace period.* If an enrollee receiving advance payments of the premium tax credit exhausts the 3-month grace period in paragraph (d) of this section without paying all outstanding premiums, subject to a premium payment threshold implemented under § 155.400(g) of this subchapter, if applicable, the QHP issuer must terminate the enrollee's enrollment through the Exchange on the effective date described in § 155.430(d)(4) of this subchapter, provided that the QHP issuer meets the notice requirement specified in paragraph (b) of this section.

* * * * *

■ 65. Section 156.285 is amended by revising paragraph (c)(5) and removing and reserving paragraph (d)(2) to read as follows:

§ 156.285 Additional standards specific to SHOP

* * * * *

(c) * * *

(5) In a Federally-facilitated SHOP, must send enrollment reconciliation files on at least a monthly basis according to a process, timeline, and file format established by the Federally-facilitated SHOP;

* * * * *

(d) * * *

(2) [Reserved]

* * * * *

■ 66. Section 156.298 is amended by—

■ a. Revising paragraph (b)(4).

■ b. Removing paragraph (b)(5).

■ c. Redesignating paragraph (b)(6) as paragraph (b)(5).

■ d. Revising newly redesignated paragraph (b)(5).

The revision reads as follows:

§ 156.298 Meaningful difference standard for Qualified Health Plans in the Federally-facilitated Exchanges.

* * * * *

(b) * * *

(4) Plan type; or

(5) Child-only versus non Child-only plan offerings.

* * * * *

■ 67. The heading of subpart D is revised to read as follows:

Subpart D—Standards for Qualified Health Plan Issuers on Federally-Facilitated Exchanges and State-Based Exchanges on the Federal Platform

■ 68. Section 156.350 is added to subpart D to read as follows:

§ 156.350 Eligibility and enrollment standards for Qualified Health Plan issuers on State-based Exchanges on the Federal platform.

(a) In order to participate in a State-based Exchange on the Federal platform,

a QHP issuer must comply with HHS regulations, and guidance pertaining to issuer eligibility and enrollment functions as if the issuer were an issuer of a QHP on a Federally-facilitated Exchange. These requirements include—

(1) Section 156.285(a)(4)(ii) regarding the premiums for plans offered on the SHOP;

(2) Section 156.285(c)(8)(iii) regarding enrollment process for SHOP; and

(3) Section 156.715 regarding compliance reviews of QHP issuers, to the extent relating directly to applicable eligibility and enrollment functions.

(b) HHS will permit issuers of QHPs in each State-based Exchange on the Federal platform to directly enroll applicants in a manner that is considered to be through the Exchange, as if the issuers were issuers of QHPs on Federally-facilitated Exchanges under § 156.1230(a), to the extent permitted by applicable State law.

(c) If the State-based Exchange on the Federal platform does not substantially enforce a requirement in paragraph (a) of this section against the issuer or plan, then HHS may do so, in accordance with the enforcement remedies in subpart I of this part, subject to the administrative review process in subpart J of this part.

■ 69. Section 156.805 is amended by revising paragraph (d) to read as follows:

§ 156.805 Bases and process for imposing civil money penalties in Federally-facilitated Exchanges.

* * * * *

(d) *Request for hearing.* (1) An issuer may appeal the assessment of a civil money penalty under this section by filing a request for hearing under an applicable administrative hearing process.

(2) If an issuer files a request for hearing under this paragraph (d), the assessment of a civil money penalty will not occur prior to the issuance of the final administrative decision in the appeal.

* * * * *

■ 70. Section 156.810 is amended by revising paragraphs (a)(12) and (13) and (e) and adding paragraphs (a)(14) and (15) to read as follows:

§ 156.810 Bases and process for decertification of a QHP offered by an issuer through a Federally-facilitated Exchange.

(a) * * *

(12) The QHP issuer substantially fails to meet the requirements related to the cases forwarded to QHP issuers under subpart K of this part;

(13) The QHP issuer substantially fails to meet the requirements related to the offering of a QHP under subpart M of this part;

(14) The QHP issuer offering the QHP is the subject of a pending, ongoing, or final State regulatory or enforcement action or determination that relates to the issuer offering QHPs in the Federally-facilitated Exchanges; or

(15) HHS reasonably believes that the QHP issuer lacks the financial viability to provide coverage under its QHPs until the end of the plan year.

* * * * *

(e) *Request for hearing.* An issuer may appeal the decertification of a QHP offered by that issuer under paragraph (c) or (d) of this section by filing a request for hearing under an applicable administrative hearing process.

(1) If an issuer files a request for hearing under this paragraph (e):

(i) If the decertification is under paragraph (b)(1) of this section, the decertification will not take effect prior to the issuance of the final administrative decision in the appeal, notwithstanding the effective date specified in paragraph (b)(1) of this section.

(ii) If the decertification is under paragraph (b)(2) of this section, the decertification will be effective on the date specified in the notice of decertification, but the certification of the QHP may be reinstated immediately upon issuance of a final administrative decision that the QHP should not be decertified.

(2) [Reserved]

■ 71. Section § 156.1110 is amended by revising paragraphs (a) and (b) and removing paragraph (d) to read as follows:

§ 156.1110 Establishment of patient safety standards for QHP issuers.

(a) *Patient safety standards.* A QHP issuer that contracts with a hospital with greater than 50 beds must verify that the hospital, as defined in section 1861(e) of the Act:

(1) For plan years beginning before January 1, 2017, is Medicare-certified or has been issued a Medicaid-only CMS Certification Number (CCN) and is subject to the Medicare Hospital Conditions of Participation requirements for—

(i) A quality assessment and performance improvement program as specified in 42 CFR 482.21; and

(ii) Discharge planning as specified in 42 CFR 482.43.

(2) For plan years beginning on or after January 1, 2017—

(i)(A) Utilizes a patient safety evaluation system as defined in 42 CFR 3.20; and

(B) Implements a mechanism for comprehensive person-centered hospital discharge to improve care coordination and health care quality for each patient; or

(ii) Implements evidence-based initiatives to reduce all cause preventable harm, prevent hospital readmission, improve care coordination and improve health care quality through the collection, management and analysis of patient safety events.

(3) A QHP issuer must ensure that each of its QHPs meets the patient safety standards in accordance with this section.

(b) *Documentation.* A QHP issuer must collect:

(1) For plan years beginning before January 1, 2017, the CCN from each of its contracted hospitals with greater than 50 beds, to demonstrate that those hospitals meet patient safety standards required in paragraph (a)(1) of this section; and

(2) For plan years beginning on or after January 1, 2017, information, from each of its contracted hospitals with greater than 50 beds, to demonstrate that those hospitals meet patient safety standards required in paragraph (a)(2) of this section.

* * * * *

■ 72. Section 156.1220 is amended by revising paragraphs (a)(3) and (a)(4)(ii) to read as follows:

§ 156.1220 Administrative appeals.

(a) * * *

(3) *Time for filing a request for reconsideration.* The request for reconsideration must be filed in accordance with the following timeframes:

(i) For advance payments of the premium tax credit, advance payments of cost-sharing reductions, or Federally-facilitated Exchange user fee charges, within 30 calendar days after the date of the final reconsideration notification specifying the aggregate amount of advance payments of the premium tax credit, advance payments of cost-sharing reductions, and Federally-facilitated Exchange user fees for the applicable benefit year;

(ii) For a risk adjustment payment or charge, including an assessment of risk adjustment user fees, within 30 calendar days of the date of the notification under § 153.310(e) of this subchapter;

(iii) For a reinsurance payment, within 30 calendar days of the date of the notification under § 153.240(b)(1)(ii) of this subchapter;

(iv) For a default risk adjustment charge, within 30 calendar days of the date of the notification of the default risk adjustment charge;

(v) For reconciliation of cost-sharing reductions, within 30 calendar days of the date of the notification of the cost-sharing reduction reconciliation payment or charge; and

(vi) For a risk corridors payment or charge, within 30 calendar days of the date of the notification under § 153.510(d) of this subchapter.

(4) * * *

(ii) Notwithstanding paragraph (a)(1) of this section, a reconsideration with respect to a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error may be requested only if, to the extent the issue could have been previously identified by the issuer to HHS under § 153.710(d)(2) of this subchapter, it was so identified and remains unresolved.

* * * * *

■ 73. Section 156.1250 is revised to read as follows:

§ 156.1250 Acceptance of certain third party payments.

(a) Issuers offering individual market QHPs, including stand-alone dental plans, and their downstream entities, must accept premium and cost-sharing payments from the following third-party entities on behalf of plan enrollees:

(1) A Ryan White HIV/AIDS Program under title XXVI of the Public Health Service Act;

(2) An Indian tribe, tribal organization, or urban Indian organization; and

(3) A local, State, or Federal government program, including a grantee directed by a government program to make payments on its behalf consistent with the program's statutory authority.

(b) An entity making third party payments of premiums under paragraph (a) of this section must notify HHS of its intent to do so, and the expected number of consumers for which it will do so, in a format and timeline established by HHS.

■ 74. Section 156.1256 is added to subpart M to read as follows:

§ 156.1256 Other notices.

As directed by the FFE, health insurance issuer that is offering QHP coverage through an FFE must notify its enrollees of material plan or benefit display errors and the enrollees' eligibility for a special enrollment period, included in § 155.420(d)(4) of this subchapter, within 30 calendar days after the error is identified.

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 75. The authority citation for part 158 continues to read as follows:

Authority: Section 2718 of the Public Health Service Act (42 U.S.C. 300gg-18), as amended.

■ 76. Section 158.103 is amended by revising the definitions of ''Large Employer'', ''Small Employer'', and ''Unpaid claim reserves'' to read as follows:

§ 158.103 Definitions.

* * * * *

Large Employer has the meaning given the term in § 144.103 of this subchapter.

* * * * *

Small Employer has the meaning given the term in § 144.103 of this subchapter.

* * * * *

Unpaid claim reserves means reserves and liabilities established to account for claims that were incurred during the MLR reporting year but had not been paid within 6 months of the end of the MLR reporting year.

■ 77. Section 158.140 is amended by revising paragraph (a) introductory text to read as follows:

§ 158.140 Reimbursement for clinical services provided to enrollees.

(a) *General requirements.* The report required in § 158.110 must include direct claims paid to or received by providers, including under capitation contracts with physicians, whose services are covered by the policy for clinical services or supplies covered by the policy. In addition, the report must include claim reserves associated with claims incurred during the MLR reporting year, the change in contract reserves, reserves for contingent benefits and the medical claim portion of lawsuits, and any incurred experience rating refunds. Reimbursement for clinical services, as defined in this section, is referred to as ''incurred claims.'' All components of and adjustments to incurred claims, with the exception of contract reserves, must be calculated based on claims incurred only during the MLR reporting year and paid through June 30th of the following year. Contract reserves must be calculated as of December 31st of the applicable year.

* * * * *

Dated: October 23, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: November 17, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015–29884 Filed 11–20–15; 4:15 pm]

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Part III

Department of Agriculture

Food Safety and Inspection Service

9 CFR Parts 300, 441, 530, et al.
Mandatory Inspection of Fish of the Order Siluriformes and Products Derived From Such Fish; Final Rule

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 300, 441, 530, 531, 532, 533, 534, 537, 539, 540, 541, 544, 548, 550, 552, 555, 557, 559, 560, and 561

[Docket No. FSIS–2008–0031]

RIN 0583–AD36

Mandatory Inspection of Fish of the Order Siluriformes and Products Derived From Such Fish

AGENCY: Food Safety and Inspection Service.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending its regulations to establish a mandatory inspection program for fish of the order Siluriformes and products derived from these fish. These final regulations implement the provisions of the 2008 and 2014 Farm Bills, which amended the Federal Meat Inspection Act, mandating FSIS inspection of Siluriformes.

DATES: *Effective Date:* March 1, 2016.

On the effective date (March 1, 2016), Siluriformes fish and fish products are under FSIS jurisdiction. By March 1, 2016, foreign countries seeking to continue exporting Siluriformes fish and fish products to the United States during the transitional period are required to submit lists of establishments (with the establishment name and number) that currently export and will continue to export Siluriformes fish and fish products to the United States. Foreign countries are also required to submit documentation showing that they currently have laws or other legal measures in place that provide authority to regulate the growing and processing of fish for human food and to assure compliance with the Food and Drug Administration's (FDA) regulatory requirements in 21 CFR part 123, Fish and Fishery Products.

Transitional Period (transition to complete implementation): Beginning on March 1, 2016 and continuing until September 1, 2017, FSIS will conduct inspection and exercise broad enforcement discretion in domestic establishments that slaughter or slaughter and process and distribute Siluriformes fish and fish products. Foreign countries seeking to continue to export Siluriformes fish and fish products to the United States after the transitional period has expired are required to submit to FSIS by September 1, 2017 adequate documentation showing the equivalence of their Siluriformes inspection systems with that of the United States. Foreign countries submitting such documentation by the deadline are permitted to continue exporting Siluriformes fish and fish products to the United States while FSIS undertakes an evaluation as to equivalency.

Date of Full Enforcement (September 1, 2017): FSIS will fully enforce these regulations in domestic Siluriformes fish products and fish processing establishments. Foreign countries seeking to continue exporting Siluriformes fish and fish products to the United States upon full enforcement are required to submit their documentation showing equivalence by this date.

FOR FURTHER INFORMATION CONTACT: Daniel Engeljohn, Assistant Administrator, Office of Policy and Program Development, FSIS, U.S. Department of Agriculture, 1400 Independence Avenue SW., Washington, DC 20250–3700, (202) 205–0495.

SUPPLEMENTARY INFORMATION:

Executive Summary

The 2008 Farm Bill amended the Federal Meat Inspection Act (FMIA), to make ''catfish'' a species amenable to the FMIA and, therefore, subject to FSIS inspection. In addition, the 2008 Farm Bill gave FSIS the authority to define the term ''catfish.''

On February 24, 2011, FSIS published a proposed rule that outlined a mandatory catfish inspection program and presented two options for defining ''catfish'': One option was to define catfish narrowly as those fish belonging to the family Ictaluridae. The other option was a broader definition, all fish of the order Siluriformes (76 FR 10434). FSIS sought public comments on the scope of the definition in the proposed rule. The Agency proposed regulatory requirements for mandatory catfish inspection that were adapted from the meat inspection regulations.

The 2014 Farm Bill, enacted on February 7, 2014, amended the FMIA to remove the term ''catfish'' and to make ''all fish of the order Siluriformes'' subject to FSIS jurisdiction and inspection. As a result, FSIS inspection of Siluriformes is mandated by law. This final rule adopts all the regulatory requirements outlined in the February 2011 proposal, with the following changes:

- The term ''catfish'' defined in proposed 9 CFR part 531 and used throughout the proposed regulatory text, is replaced in this final rule by the term ''fish of the order Siluriformes,'' ''Siluriformes fish,'' or simply ''fish,'' understood to mean, for purposes of the final regulations, any fish of the order Siluriformes.
- The retail store exemption includes, as an exempt retail operation, the slaughter of fish at retail stores or restaurants for consumers who purchase the fish at those facilities, and in accordance with the consumers' request.
- Fish with unusual gross deformities caused by disease or chemical contamination (rather than merely with gross deformities) are not to be used for human food (9 CFR 539.1(d)).
- The labeling regulations (9 CFR 541.7) permit the use of the term ''catfish'' only on labels of fish classified within the family Ictaluridae, consistent with provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 321d (a) and 343(t)). Fish of the order Siluriformes, from families other than Ictaluridae, must be labeled with an appropriate common or usual name.
- The labeling regulations (9 CFR 541.7) require packages of Siluriformes fish and fish products that are not ready-to-eat to bear safe-handling instructions to include ''fish'' in the rationale statement, *i.e.,* ''This product was prepared from inspected and passed fish, ''and in the labeling statements, *i.e.,* ''Keep raw fish from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw fish.''
- The labeling regulations (9 CFR 541.7) to clarify that the labeling of fish covered commodities sold by a retailer bear country of origin and method of production information, in compliance with the requirements in 7 CFR part 60, subpart A, Country of Origin Labeling for Fish and Shellfish.
- The import inspection regulations for Siluriformes fish and fish products (9 CFR part 557) to make them consistent with the September 19, 2014, rule amending the FSIS regulations for imported meat, poultry, and egg products (79 FR 56220).
- The regulations include provisions for State-Federal, Federal-State Cooperate Agreements; State Designations (9 CFR part 560) and authorize coordination with States that have fish inspection programs to select certain establishments to participate in an interstate shipment program. These changes reference regulations that took effect after the proposed rule on catfish inspection was published. The regulations incorporate requirements for establishments to maintain written recall plans (9 CFR 532.2) and to notify the FSIS District Office of any adulterated or misbranded product that

the establishment has received or shipped in commerce (9 CFR 537.3). These changes reference regulations that took effect after the proposed rule on catfish inspection was published.

• The regulations on official marks and devices for identifying inspected-and-passed fish and fish products (9 CFR 541.2(d)) require whole, gutted fish carcasses to bear the official inspection legend or to be properly packaged in an immediate container marked with the official inspection legend, as well as all other required labeling features.

• The preamble discussion explains that the net weight for ice-glazed fish is determined on a rigid-state basis, as provided in the National Institute of Standards and Technology (NIST) Handbook 133, ''Checking the Net Contents of Packaged Goods.''

• The regulatory requirements in this final rule will be effective 90 days after its publication. FSIS will implement the regulatory requirements during an 18-month timeframe.

• In addition, during the 18-month transitional period, foreign countries are to begin submitting to FSIS documentation demonstrating the equivalency of their inspection systems for Siluriformes fish and fish products.

The annualized cost to the Siluriformes fish domestic industry is $326.55 thousand.[1] This would be an additional annualized average net direct cost to this domestic fish industry of about $0.0008 per pound of processed Siluriformes fish and Siluriformes products. For comparison, the average price received by domestic processors for domestic catfish (of the order Siluriformes) products was considerably greater at $3.04 per pound, in 2013. Furthermore, the additional annualized average direct cost to FSIS is $2,604.4 thousand. On the other hand, the decreased annualized average direct cost to FDA and to the U.S. Department of Commerce's (USDC) National Oceanic and Atmospheric Administration (NOAA)/National Marine Fisheries Service (NMFS) is $1,490 thousand because of this final rule. The net difference of these annualized average direct costs to these three Federal government agencies is $1,114.40 thousand. Therefore, the annualized (at 7 percent) average net direct cost to the Siluriformes fish domestic industry and to the three affected Federal government agencies is $1,440.95 thousand.

[1] Annualized present value of average costs is at a 7 percent discount rate over 10 years.

TABLE 1—PROJECTED SUMMARY ADDITIONAL ANNUALIZED AVERAGE NET DIRECT COSTS (DOMESTIC) OF THE FINAL RULE

Affected sectors of the domestic economy	Additional annualized cost, over 10 years, discounted $thousands	
	7 percent	3 percent
Siluriformes Fish Industry	$326.55	$317.78
Federal Government Agencies	1,114.40	1,097.22
Total	1,440.95	1,414.99

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Background

I. 2008 Farm Bill

The Food, Conservation, and Energy Act of 2008 (Pub. L. 110–246, Section 10016(b)), known as the 2008 Farm Bill, amended the Federal Meat Inspection Act (FMIA) to provide that ''catfish, as defined by the Secretary,'' is an amenable species (21 U.S.C. 601 (w)(2)). Therefore, the 2008 Farm Bill placed catfish and catfish products under FSIS jurisdiction and inspection. The 2008 Farm Bill also added 21 U.S.C. 625, which provides that the sections of the FMIA dealing with ante-mortem and post-mortem inspection and humane slaughter (21 U.S.C. 603 and 604), inspection of carcasses and parts before their entry into establishments or further-processing departments (21 U.S.C. 605), and exemptions from inspection for custom and farm slaughter and processing and other exemptions (21 U.S.C. 623) do not apply to catfish. In addition, the 2008 Farm Bill revised 21 U.S.C. 606, which requires the appointment of inspectors to examine and inspect all meat food products prepared for commerce and provided that the examination and inspection of meat food products derived from catfish are to take into account the conditions under which catfish are raised and transported to processing establishments (21 U.S.C. 606(a) and (b)).

II. 2011 Proposed Rule

On February 24, 2011, FSIS published the proposed rule, ''*Mandatory Inspection of Catfish and Catfish Products,''* (76 FR 10434). The regulations proposed to implement the provisions of the 2008 Farm Bill. The proposed rule's comment period closed on June 24, 2011, 90 days after its publication.

In May 2011, FSIS held two public meetings, in Washington, DC, and Stoneville, MS, to discuss the proposed rule. At those meetings, FSIS provided an overview of the proposed rule and provided the public with an opportunity to comment on the proposed regulation. Transcripts of the public meeting are available on the FSIS Web site at *http://www.fsis.usda.gov/wps/wcm/connect/eefd3e0d-ea69-4c75-b1ac-ea4df9d133e4/Transcripts_05242011_Catfish_meeting.pdf?MOD=AJPERES* and *http://www.fsis.usda.gov/wps/wcm/connect/ddb209ab-6aa3-4953-9514-70a8532d3348/Transcripts_05262011_Catfish_meeting.pdf?MOD=AJPERES.*

III. 2014 Farm Bill

On February 7, 2014, the Agricultural Act of 2014 (Pub. L. 113–79, Sec. 12106), known as the 2014 Farm Bill, amended Section 1(w) of the FMIA to remove the phrase ''catfish, as defined by the Secretary,'' and replace it with ''all fish of the order Siluriformes,'' thus including these fish among the amenable species under FSIS jurisdiction and inspection (21 U.S.C. 601(w)(2)). The 2014 Farm Bill also amended the 2008 Farm Bill instructing FSIS, in consultation with the Food and Drug Administration (FDA), to issue final regulations to carry out the amendments in a manner that ensures no duplication in inspection activities. In addition, the 2014 Farm Bill instructed FSIS to execute a Memorandum of Understanding (MOU) with FDA to improve interagency cooperation and to maximize the effectiveness of personnel and resources by ensuring that inspections are not duplicative, and that any information from the examination, testing, and inspections is considered in making risk-based determinations, including the establishment of inspection priorities. The MOU between FSIS and FDA was signed on April 30, 2014, and can be found on the FSIS Web site at *http://www.fsis.usda.gov/wps/portal/informational/aboutfsis/food-safety-agencies/mou.*

This final rule issues regulations in response to the 2014 Farm Bill mandate. In addition, this final rule includes a summary of the major issues raised by comments to the 2011 proposed rule and FSIS's responses to the comments, including changes made to the proposed regulations in response to comments.

IV. Use of the Terms ''Catfish'' and ''Fish'' in Preamble Discussion

For purposes of convenience, the preamble discussion in this final rule will use the terms ''catfish'' and ''catfish products'' where appropriate when discussing and referencing the 2011 Proposed Rule, since those terms were used in the proposal. The preamble discussion of the final rule amendments will use the terms ''fish of the order Siluriformes'', ''Siluriformes fish,'' or ''fish.''

V. Scientific Classification (Taxonomy) of the Catfishes

As discussed in the proposed rule (76 FR 10435), in the taxonomy of the fishes, fish of the order Siluriformes include the Ictaluridae, the North American catfish, to which family belong the fork-tailed channel catfish (*Ictalurus punctatus*) and blue catfish (*I. furcatus*), the principal United States farm-raised species, and the flathead catfish (*Pylodictis olivaris*). Other species in the United States that are in the Ictaluridae family are the white catfish (*Ameiurus catus,* synonym *I. catus*), and the black, brown, and yellow bullhead (*A. melas,* syn. *I. melas, A. nebulosus,* syn. *I. nebulosus,* and *A. natalis,* syn.*I. natalis*). Also among the Siluriformes are the air-breathing catfishes of the Clariidae family, to which belongs *Clarias fuscus,* a species raised in the United States on a small scale in Hawaii.

Another family of Siluriformes, the Pangasiidae, the so-called ''giant catfishes,''[2] includes the aquaculture species basa (*Pangasius bocourti*) and tra or swai (*Pangasius hypophthalmus;* syn., *Pangasius sutchi*), raised principally in Southeast Asia for domestic consumption and export. Other Siluriformes fish species raised in Asia include the hybrid *Clarias macrocephalus* and North American channel catfish (*I. punctatus*) that are raised for export to the United States.

VI. Current Inspection of Domestic and Imported Fish

As discussed in the proposed rule, U.S. catfish processors, exporters, and importers have been subject to the U.S. Food and Drug Administration's (FDA) seafood Hazard Analysis Critical Control Point (HACCP) regulations (21 CFR 123) and to other requirements under the Food, Drug, and Cosmetic (FD&C) Act (76 FR 10437). FDA's regulations on current good manufacturing practices (cGMPs, at 21 CFR 110) and on recordkeeping and registration requirements (21 CFR part 1, subparts H and J) also apply to those establishments.

For imported fish and fishery products, FDA requires the importer to either: (1) Obtain fish or fish products from a country that has an active memorandum of understanding with FDA that covers the product and documents the equivalence or compliance of the foreign inspection system with that of the United States, or (2) have and implement written verification procedures for ensuring fish and fish products offered for import into the United States were processed in accordance with FDA regulations in 21 CFR part 123 (21 CFR 123.12).

In addition to the FDA regulations, some United States catfish processing establishments contract for voluntary, fee-for-service inspection and certification programs administered by the Department of Commerce's National Marine Fisheries Service (NMFS) under the Agricultural Marketing Act (7 U.S.C. 1622, 1624) and implementing

[2] Integrated Taxonomic Information System (ITIS) report on ''Siluriformes.'' At *http://www.itis.gov.*

regulations (50 CFR part 260). NMFS administers three levels of seafood inspection programs under authority of the Agricultural Marketing Act (7 U.S.C. 1622, 1624) and regulations implementing that act (50 CFR part 260). The three levels are: (1) A resident inspection program, which provides inspection to qualifying establishments; (2) an integrated quality assurance program, under which an establishment operates an NMFS-approved quality assurance system and assists NMFS personnel in carrying out U.S. grading or specification regulations; and (3) a HACCP-Quality Management Program (QMP), under which the establishment's quality assurance program is enhanced to meet the ISO 9001 quality management standards.

VII. Public Health Considerations: Potential Chemical and Microbiological Contaminants

As discussed in the proposed rule, because catfish of domestic or foreign origin may be exposed to chemical and microbiological contaminants, FSIS considered the food safety issues that might be presented by catfish in planning its regulatory approach (76 FR 10438).

In the Hazard Identification section of its risk assessment, *Assessment of the Potential Change in Human Health Risk Associated with Applying Inspection to Fish of the Order Siluriformes,* the Agency discussed the three main classes of chemical residues identified in some domestic and foreign catfish—heavy metals, pesticides, and antimicrobials and the adverse health effects that have been associated with those chemicals. The assessment also summarized the results of FSIS, Agriculture Marketing Service (AMS) and FDA testing of the fish for these residues (76 FR 10438). The test results showed that, while catfish may not frequently harbor residues of illegal drugs or violative concentrations of other chemicals, the potential exists for such contamination. For example, 9% and 2% of imported catfish tested for malachite green and gentian violet, respectively, tested positive for those banned chemicals. Because some shipments of imported catfish have been found with residues of drugs that FDA has banned and that are unsafe, FSIS proposed to conduct regular residue sampling, as it does for imported meat products, to ensure the safety of imported catfish products (9 CFR 557.6(a)(3)).

For microbial pathogens in catfish, the hazard identification component of the FSIS catfish risk assessment [3] identified certain microorganisms as higher-priority. The prioritization was based on association with catfish-related outbreaks and on the severity of resultant illness. The microorganisms identified included *Salmonella, Listeria monocytogenes,* and Enterotoxigenic *E. coli* (76 FR 10439).

FSIS conducted an assessment of the potential risk to human health from consumption of fish of the order Siluriformes, using the example of *Salmonella* contamination. The Agency was particularly interested in *Salmonella* because the bacteria are the most frequently reported cause of foodborne illness in the United States. From a public health perspective, even a small decrease in the percentage of an illness that affects a large number of people can have a substantial effect of decreasing illness, and thus, improve public health. According to the Centers for Disease Control and Prevention (CDC), salmonellosis causes an estimated 1.4 million cases of foodborne illness and more than 400 deaths annually in the United States.[4] In addition, CDC lists catfish as the vehicle in at least one outbreak of human salmonellosis may have been related to catfish consumption.[5] *Salmonella* is a useful model because its presence provides an indication of the sanitary conditions under which food is produced and, if considering illnesses rather than raw product, the way it is prepared. In addition, an approach that produces a reduction in *Salmonella* through improved process control can be effective in controlling for the presence of other microbial pathogens.[6]

FSIS invited all interested stakeholders to submit additional data and scientific evidence specific to catfish food safety. USDA also sought public comment on the evidence regarding the public health benefits and cost-effectiveness to be achieved with the proposed program (76 FR 10440). FSIS received comments on these issues and its responses are included in Comments and Responses (Section XI), below.

The FSIS risk assessment has been modified to move the hazard identification section to the body of the risk assessment document. In addition, an Addendum has been added to the risk assessment, which: (1) Summarizes potentially relevant research studies published since the draft risk assessment was conducted; (2) provides an update from CDC's outbreak database, stating that it does not indicate that any additional outbreaks have occurred recently; and (3) updates data on the results of analyses of pesticides from the Agricultural Marketing Service's Pesticide Data Program. The updated risk assessment (December 2014) is posted on the FSIS Web site at: *http://www.fsis.usda.gov/wps/wcm/connect/63387be5-ca8e-442d-b047-f031f29a8a47/Silurifomes-RA.pdf?MOD=AJPERES*

VIII. Summary of Proposed and Final Regulatory Requirements

FSIS proposed regulatory requirements for the inspection of catfish and catfish products adapted from the appropriate meat inspection regulations that prevent the transportation, sale, offer for sale or transportation, or receipt for transportation, in commerce, of adulterated or misbranded products (21 U.S.C. 602, 610, 621). Because there are differences between fish and ''meat'' (cattle, sheep, swine, goats, horses, mules or other equines), FSIS proposed some separate regulations for catfish establishments and products. In many cases, FSIS proposed to reference the existing regulations for meat and meat food products as applying to catfish.

A. Organization of Inspection Operations

In general, the proposed regulations paralleled the sequence of operations from the harvesting and delivery of the fish to the processing plant, through the in-plant operations, to transportation in commerce, specifying export and import requirements where appropriate.

After outlining the district-level supervision of the inspection in proposed 9 CFR 530.2, FSIS made it clear in proposed 9 CFR 530.3, that, as provided in 9 CFR 300.6, persons that are subject to the FMIA, as specifically the catfish inspection provisions, are to grant authorized Agency or Department personnel access to establishments that process catfish and to other establishments in industries related to

[3] U.S. Department of Agriculture. Food Safety and Inspection Service. Office of Public Health Science. December 2010. Draft Risk Assessment of the Potential Human Health Effect of Applying Continuous Inspection to Catfish. Washington, DC (as referenced in the proposed rule).

[4] Scallan, *et al.* Emerging Infectious Diseases, Vol. 17, No. 1. January 2011.

[5] U.S. Department of Agriculture. Food Safety and Inspection Service. Office of Public Health Science. December 2010. Draft Risk Assessment of the Potential Human Health Effect of Applying Continuous Inspection to Catfish. Washington, DC (as referenced in the proposed rule).

[6] Food Safety and Inspection Service. 2006. Review of the Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems Final Rule pursuant to Section 610 of the Regulatory Flexibility Act, as Amended. Available at: *http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2007-0022P/610_Report_PR_HACCP.pdf.*

the catfish processing industry (for example, fish farms, fish hatcheries, fish feed mills, live-fish catchers/loaders and haulers, distributors, and brokers) (76 FR 10440).

FSIS did not make any changes in the final regulations to the inspection operations provisions or to the access Agency or Department personnel have to establishments.

B. Definitions

In proposed 9 CFR part 531, FSIS used the same definitions for the catfish inspection regulations as the meat inspection regulations (9 CFR 301.2). The Agency proposed to add definitions for ''catfish,'' ''catfish byproduct,'' ''catfish food product,'' ''catfish product,'' ''farm-raised,'' and some other terms (76 FR 10441). The ante-mortem inspection, post-mortem inspection, and humane slaughter provisions of the amended FMIA do not apply to catfish, therefore, the Agency did not propose definitions for slaughtering methods. FSIS specifically requested comment on whether the term ''slaughter'' should be defined.

The Agency received comments on some of the proposed regulatory definitions but, as explained in the Comments and Responses (Section XI) below, determined that it was not necessary to make changes to these definitions. The Agency received numerous comments on the ''catfish'' species definition. However, as provided by the 2014 Farm Bill, FSIS has jurisdiction over all fish of the order Siluriformes. In this final rule, 9 CFR part 531 has been amended to delete the term ''catfish,'' and its definition, and replace it with ''fish,'' defined as ''any fish of the order Siluriformes, whether live or dead.''

C. Establishments Requiring Inspection; Grant and Approval of Inspection

In proposed 9 CFR part 532, FSIS identified the classes of catfish establishments that require inspection and outlined the requirements to qualify for a grant of inspection and the application procedures. FSIS also cross-referenced 9 CFR parts 305 and 306, on the assignment of establishment numbers and the assignment and authorities of FSIS personnel.

As discussed in the proposed rule, the amended FMIA did not provide an exemption from inspection for custom catfish slaughter and processing facilities. FSIS did however, propose to provide an exemption for retail stores and restaurants in proposed 9 CFR 532.3 (under 21 U.S.C. 661(c)(2), that parallels 9 CFR 303.1(d) and (e). FSIS also proposed exemptions for individual household (single-sale) purchases and non-household consumers based on the poultry exemptions in 9 CFR 381.10. FSIS solicited comment on the limits on retail sales to household or non-household consumers.

In proposed 9 CFR 532.4, the Agency asserted Federal pre-emption of State or local authority with respect to premises, facilities, and operations at an official establishment and with respect to labeling, packaging, and ingredient requirements in proposed 9 CFR 532.4.

In addition, the Agency proposed in 9 CFR 532.5 to exempt from inspection articles that do not contain a minimum amount of catfish (3 percent raw or 2 percent cooked catfish) or are historically not regarded by consumers as products of the catfish food products industry.

FSIS received a comment on the proposed limits on retail sales, discussed in Comments and Responses (Section XI) below. The Agency did not make any changes to the purchase quantity limits in the final regulations. However, in response to a comment on exemptions, the Agency has added language (in 9 CFR 532.3) defining as an exempt retail operation, the slaughter, by the operator of a retail store or restaurant, of live fish purchased by a consumer at the retail store or restaurant for the consumer and at the consumer's instructions.

D. Facility Requirements for Inspection

In proposed 9 CFR part 533, FSIS set forth facility requirements for catfish processing establishments. The regulations proposed requirements for office space and furnishings for program employees, sufficient lighting for the proper conduct of inspection, facilities for performing inspection, receptacles for diseased carcasses and parts, and materials for cleansing and disinfecting hands, for sterilizing instruments used in handling diseased carcasses, and for cleaning and sanitizing floors and other articles or places contaminated by diseased carcasses. FSIS also proposed that establishments have to provide adequate facilities for the receipt and inspection of catfish and catfish products. The final regulations are consistent with those proposed.

Under this final rule, FSIS will approve operating schedules for fish establishments (9 CFR 533.5) just as it does for official meat establishments. FSIS received comments on schedule of operations and addressed the comments in the Comments and Responses (Section XI), below. The final regulations are consistent with those proposed.

E. Pre-Harvest and Transport To Processing Establishment

In proposed 9 CFR part 534, FSIS outlined the pre-harvest standards to be applied to catfish to ensure that the environmental conditions and source waters in which the catfish are grown will not render them unfit for food. FSIS also proposed general standards for the transportation of catfish to the processing plant. As discussed below, FSIS received comments on pre-harvest and transport issues and is clarifying comments raised in the responses to comments section below. However, the final provisions are consistent with those proposed.

F. Sanitation and Hazard Analysis and Critical Control Point (HACCP) System Requirements for Processing Facilities

In proposed 9 CFR part 537, FSIS proposed to require that any official establishment that prepares or processes catfish or catfish products for human food comply with all of the sanitation requirements in 9 CFR part 416 and the HACCP requirements in 9 CFR part 417. In this final rule, FSIS is adopting 9 CFR part 537, which requires Siluriformes fish establishments to comply with the HACCP and sanitation requirements.

G. Mandatory Dispositions; Performance Standards Respecting Physical, Chemical, or Biological Contaminants

In proposed 9 CFR part 539, FSIS listed the diseases or other conditions that would lead to condemnation of catfish carcasses or parts affected upon inspection. FSIS requested comment on the extent to which infection should result in condemnation and on whether there are other conditions found in catfish that require such disposition. FSIS received general comments to the effect that diseases should not automatically render catfish adulterated as discussed in Comments and Responses (Section XI) below. FSIS has not changed the proposed regulations in response to these comments. However, in section 539, for greater precision than in the proposed rule, FSIS is stating that ''unusual gross deformities caused by disease or chemical contamination'' may not be used for human food.

H. Handling and Disposal of Condemned and Inedible Materials

In 9 CFR part 540, FSIS proposed to require that a processor prevent catfish that have died otherwise than by slaughter from entering the official establishment. FSIS explained (in proposed 9 CFR 540.1(b)) that the establishment would have to maintain physical separation between slaughtered catfish and those that died otherwise

than by slaughter to prevent commingling of edible and inedible product (76 FR 10444). In addition, FSIS explained that all condemned or otherwise inedible catfish parts would have to be conveyed from the official premises for further disposition at a rendering plant or other facility that handles inedible products. FSIS received some comments on these requirements, as discussed in Comments and Responses (Section XI) below; however, the Agency did not change the proposed provisions in response to the comments.

I. Marks, Marking, and Labeling of Products and Containers

1. Official Marks and Devices

FSIS proposed to use certain official marks, devices, and certificates for the purpose of identifying inspected and passed catfish and catfish products and their status (9 CFR 541.1 through 541.5).

The Agency proposed in 9 CFR 541.2(a) to provide for an official inspection legend containing the number of the official establishment, and that the form of the official inspection legend will be that for meat products (9 CFR 312.2(b)(1)), or another form that the Agency would prescribe. FSIS requested comments and suggestions on alternative forms. There were no comments on the form of the official inspection legend. Therefore, the Agency is requiring 9 CFR 541.1 that the official inspection legend for fish and fish products be in the form of the meat products inspection legend (9 CFR 312.12) or another form determined by the Administrator to provide flexibility for future innovations in marking of product.

FSIS proposed to require that whole, gutted catfish carcasses, inspected and passed at an official establishment and intended for sale as whole, gutted catfish, be marked or labeled with the official inspection legend containing the number of the establishment at the time of inspection (9 CFR 541.2(d)). The Agency requested comment on whether the marking is necessary, the form of the mark that would be satisfactory, and how the mark should be applied. FSIS received comments that applying the mark of inspection to all carcasses of whole, gutted fish may be impractical because of the size of the product. As discussed in the Comments and Responses (Section XI) below, the Agency recognizes that it may be impractical to physically apply the inspection legend to whole, gutted fish carcasses. Therefore, in this final rule, 9 CFR 541.2(d) provides that whole, gutted fish carcasses that have been inspected and passed at an official establishment, and that are intended for sale as whole, gutted catfish, must be stamped with the official inspection legend or properly packaged in an immediate container labeled with the official inspection legend, as well as all other required labeling features.

All other official marks and devices labeling regulations (9 CFR 541.1 through 541.5) are finalized without change.

2. Labeling Requirements; Prior Approval of Labeling

The Agency proposed (9 CFR 541.7) to apply to catfish and catfish products many of the general meat labeling and label approval requirements in 9 CFR part 317, subpart A. The proposed labeling regulations govern labels and labeling, safe-handling labeling, abbreviations of official marks, labeling approval, generically approved labeling, the use of approved labels, the labeling of products for foreign commerce, prohibited practices, the reuse of official inspection marks, filling of containers, relabeling of products, the storage and distribution of labels, and the requirements for packaging materials. In the proposed rule, the Agency specifically noted that processors of catfish and catfish products will be able to use generically approved labeling if it meets the generic labeling requirements in 9 CFR 317.5 (76 FR 10445).

As discussed in the Comments and Responses (Section XI) below, the final provisions in 9 CFR 541.7 include a paragraph (c), which modifies the safe handling instructions to make the rationale statement read, ''This product was prepared from inspected and passed fish,'' and the labeling statements read, ''Keep raw fish from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw fish.''

In addition, on November 7, 2013, FSIS published the final rule, ''Prior Label Approval System: Generic Label Approval'' (78 FR 66826). In that final rule, the Agency consolidated the meat and poultry label approval regulations into a new part, 9 CFR part 412, Label Approval. Therefore, in this final rule, 9 CFR 541.7 includes a paragraph (g) that references 9 CFR 412 for label approval.

This rule adopts the other proposed labeling and label approval regulations in 9 CFR 541.7 without change.

3. Prevention of False or Misleading Labeling Practices

In the preamble of the proposed rule (76 FR 10445), FSIS explained that under its regulations, no product or any of its wrappers, packaging, or other containers may bear any false or misleading marking, label, or other labeling, and no statement, work picture, design, or device that conveys any false impression or gives any false indication of origin or quality or that is otherwise false or misleading may appear in any marking or other labeling. In addition, no product may be enclosed wholly or partly in any wrapper, packaging, or other container that is made, formed, or filled in a manner that would make it misleading (9 CFR 317.8).

The Agency explained that to prevent the misuse of labeling, FSIS enforces regulations controlling the conditions under which product may be relabeled at a location other than an official establishment (9 CFR 317.12). The Agency also regulates the conditions under which labels, wrappers, or containers bearing official marks may be transported from one official establishment to another official establishment (9 CFR 317.13). FSIS proposed that all these requirements, which apply to meat and meat food products, would apply to catfish and catfish products under the proposed rule (9 CFR 541.7(a)).

In the preamble discussion on preventing false or misleading labeling practices, the Agency stated that, after a fish is processed, it is a major challenge for regulators and industry to visually identify the species of fish (76 FR 10445). Because of the interest of the catfish products industry and consumers in ensuring that product labeling correctly represents the actual species of fish in the product, FSIS was considering various technological means to verify catfish species. The Agency requested comment and suggestions on species verification methods that the Agency might use.

The Agency received several comments on the methods of speciation and country of origin labeling. The responses to these comments are discussed in the Comments and Responses (Section XI) below. This rule finalizes the prevention of false or misleading labeling regulations in 9 CFR 541.7(a) (consistent with 9 CFR 317.8, 317.12, and 317.13 specifically) and adds 9 CFR 541.7(b) to correct the reference to the AMS regulations for the country of origin labeling for fish (7 CFR, part 60, subpart A).

In addition, under the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 321d (a)), the term ''catfish'' may only be considered to be a common or usual name (or part thereof) for fish classified within the family Ictaluridae; and only labeling or advertising for fish

classified within that family may include the term ''catfish.'' Also, a food is misbranded if it purports to be or is represented as catfish, unless it is fish classified within the family Ictaluridae (21 U.S.C. 343(t)). Therefore, in this final rule, FSIS has revised proposed 9 CFR 541.7 to require that the term ''catfish'' be used only on labels and in labeling of fish within the family Ictaluridae and the products of those fish.

The Agency is also requiring in 9 CFR 541.7 that fish and fish products in all other families in the order Siluriformes be labeled with appropriate common or usual names. Domestic and foreign fish establishments should consult FDA's ''Guidance for Industry: The Seafood List—FDA's Guide to Acceptable Market Names for Seafood Sold in Interstate Commerce,'' for appropriate common or usual names (*http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/seafood/ucm113260.htm*.

4. Net Weight and Retained Water

As discussed in the preamble, FSIS's labeling regulations on net weight of meat products incorporates by reference the National Institute of Standards and Technology's (NIST) Handbook 133 (76 FR 10445). The Agency also explained that the net weight of catfish presents a specific challenge because of the frequent and varying use of ice-glazing to preserve the freshness of the product (76 FR 10445). The Agency proposed that packages of fresh or fresh-frozen catfish or parts must be labeled to reflect 100-percent net weight after thawing (9 CFR 541.7(b)(1)).

To regulate the net weight for raw catfish products, FSIS proposed in 9 CFR 541.7(b) to apply the requirements for control of retained water from processing in raw meat and poultry products through 9 CFR part 441. Retained water—water remaining in raw product after it undergoes immersion chilling or a similar process—would not be permitted unless the official establishment could show that the retained water is an unavoidable consequence of the process (9 CFR 441.10(a)). The establishment would have to label its product to state the maximum percentage of retained water.

In response to comment, discussed further in Comments and Responses (Section XI) below, the Agency is clarifying that, according to NIST Handbook 133 net weight test procedures for ice-glazed fish products are ''deglazed'' by placing the product under a gentle spray of cold water, and the product should remain rigid. However, as proposed, the NIST Handbook 133, net weight test procedures for frozen or fresh-frozen fish are determined on a thawed basis. The proposed net weight and retained water labeling regulations in 9 CFR 541.7 are adopted without change.

5. Nutrition Labeling Requirements

In 9 CFR 541.7(c), the Agency proposed, under the FMIA (21 U.S.C. 601(n)(1), 621) to apply the nutrition labeling requirements to catfish and catfish products that are not raw, single-ingredient products. The Agency received no comments on this provision, and it is adopted as proposed.

J. Food Ingredients Permitted

FSIS proposed in 9 CFR part 544 to apply to catfish products the requirements in 9 CFR part 424 prohibiting a product from bearing or containing any food ingredient that would render it adulterated or misbranded.

As discussed in the proposed rule, FSIS will make determinations on the safety and suitability of uses of food ingredients for Siluriformes products in consultation with FDA, as it does for all food ingredients (76 FR 10446). FSIS compiles safe and suitable uses, including limits and conditions of use, of food ingredients in these products and makes the information available in an instruction to its inspection force in FSIS Directive 7120.1. This directive is regularly updated and published on the Agency's Web site at: *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives/7000-series*. This final rule adopts the requirement as proposed.

K. Ready-to-Eat and Canned Fish Products: Control of Listeria monocytogenes

As discussed in the proposed rule (76 FR 10446), ready-to-eat (RTE) catfish products, such as smoked catfish, would have to comply with appropriate performance standards if they are not to be considered adulterated under the FMIA (21 U.S.C. 601(m)). FSIS proposed to make post-lethality-exposed catfish products subject to the requirements in 9 CFR part 430 (proposed 9 CFR 548.6). An RTE catfish product would be considered adulterated if it contains *L. monocytogenes,* or if it comes into direct contact with a food-contact surface that is contaminated with *L. monocytogenes* because it is likely to be consumed without further processing, such as cooking. The Agency is adopting this provision as proposed.

L. Canned Products

As discussed in the proposed rule, FSIS is not aware of any canned catfish products processed in the U.S., but canned catfish soups are imported into this country (76 FR 10446). FSIS proposed (9 CFR 548.6) that any domestic canned catfish products that an official establishment manufactures will be subject to requirements similar to those for canning and canned meat products (9 CFR 318.300–318.311). As explained in the proposed rule, imported canned catfish products would have to be prepared under requirements that are equivalent to those applying to domestic products. FSIS is adopting this provision as proposed.

M. Accredited Laboratories

FSIS proposed that catfish processing establishments, like other official establishments, may use a non-Federal analytical laboratory that meets the accreditation requirements in 9 CFR 439 instead of an FSIS laboratory to analyze official regulatory samples (proposed 9 CFR 548.9). The Agency is adopting proposed 9 CFR 548.9 as final, without changes.

N. Standards of Identity and Composition

In the preamble to the proposed rule, FSIS requested comment on whether the Agency should promulgate any standards of identity or composition for catfish products (76 FR 10446). The Agency received comments on catfish standards of identity, as discussed in Comments and Responses (Section XI) below, but is not promulgating standards of identity or composition in this final rule.

O. Exports

The Agency proposed (9 CFR part 552) to adopt requirements for exported catfish and catfish products that are similar to those that apply to meat articles by cross-referencing the provision of 9 CFR part 322. There are no changes to the proposed regulations in this final rule.

P. Transportation in Commerce

FSIS proposed in 9 CFR 555.1 to require that any catfish product capable of use as human food that is to be transported in commerce be properly handled and maintained to ensure that it is not adulterated and is properly marked and labeled. As discussed in the proposed rule, a transport conveyance intended to carry catfish products would be subject to FSIS inspection to determine its sanitary condition (76 FR 10447). FSIS also explained that

products on an insanitary vehicle would have to be removed and either handled in accordance with the regulations on mandatory dispositions or on the handling of condemned and inedible materials (9 CFR part 539 or part 540).

The Agency also discussed that it had tentatively determined that other regulations on the transportation of meat and meat food products (in 9 CFR part 325) are appropriate for the transportation of catfish products (9 CFR 555.3–555.8). The proposed regulations addressed the transportation of unmarked inspected product under FSIS affixed-seal; product that may have become adulterated in transit or storage; inedible products; the filing of original certificates for unmarked inspected products; and the unloading of any catfish product from an officially sealed conveyance or loading after the conveyance has left the official establishment. The Agency is adopting these proposed regulations as final.

Q. Imported Products

As FSIS discussed in the proposed rule, under the FMIA, the provisions of the act governing imports apply to catfish and catfish products (76 FR 10447). FSIS proposed to apply the requirements for the inspection of imported meat products to imported catfish products (9 CFR part 557, referencing 9 CFR part 327). Under the proposed rule and final rule, FSIS would have to find that the system of fish inspection maintained by any foreign country, with respect to establishments preparing products in such country for export to the United States, insures compliance of the establishments and their products with requirements equivalent to the inspection and other requirements of the FMIA and the regulations that implement it in the United States. When the Agency determines that a foreign country's inspection system for fish is equivalent to that operated by FSIS, the Agency would publish a proposed rule to list the country in the regulations as eligible to export Siluriformes fish and fish products to the U.S., and would provide an opportunity for public comment. Should the Agency decide to list the country's system as equivalent, FSIS would respond to comments in the final rule and list the name of the country in the regulations (9 CFR 557.2(b)). FSIS is adopting these proposed requirements as final, except for terminology changes to reflect that they apply to fish in the order Siluriformes.

On September 19, 2014, FSIS published a final rule (79 FR 56220) amending its regulations for imported meat, poultry, and egg products to provide, among other things, for use of the Agency's electronic Public Health Information System (PHIS) import component. In addition to providing for the PHIS import component, the final rule deleted overly prescriptive formatting and narrative requirements for foreign establishments and inspection certificates, required additional information on the certificates, and made the requirements the same for imported meat, poultry, and egg products. The regulations in 9 CFR part 557 adopted by this final rule on Siluriformes inspection reflect the amendments to accommodate the use of PHIS.

R. Demonstrating Equivalence of Foreign Systems

FSIS proposed that countries will need to demonstrate that their inspection systems are equivalent to the U.S. system in the following respects:

(1) *Program administration.* Under proposed 9 CFR 557.2 (referencing 9 CFR 327.2) the foreign program for catfish would have to be staffed in a way that will ensure uniform enforcement of the laws and regulations. Ultimate control and supervision must rest with the national government (9 CFR 327.2(a)(2)(i)(B)). Qualified, competent inspection personnel must be employed in the food safety system (9 CFR 327.2(a)(2)(i)(C)). National inspection officials would have to have the authority to enforce requisite laws and regulations and certify or refuse to certify products intended for export (9 CFR 327.2(a)(2)(i)(D)). There would have to be adequate administrative and technical support and inspection, sanitation, quality, species verification, residue standards, and other regulatory requirements that are equivalent to those of the United States (9 CFR 327.2(a)(2)(i)(E)–(G)). FSIS is adopting these requirements as proposed.

(2) *Legal authority and requirements governing catfish and catfish products inspection.* Under proposed 9 CFR 557.3, to be considered eligible to export catfish products to the United States, foreign countries would have to enforce laws and regulations that address the conditions under which catfish are raised and transported to the processing establishment (9 CFR 327.2(a)(2)(ii)(I)). In countries where catfish producers use floating cages on rivers and ''raceway ponds'' that are filled and emptied by the continuous flow of water from nearby rivers, under the proposed rule, the water quality, residue, and other standards would have to be equivalent to those applying to catfish raised in the United States.

Also, under the proposed rule, eligible foreign countries would have to establish standards for, and maintain official supervision of, preparation and processing of product to ensure that adulterated or misbranded product is not prepared for export to the United States (9 CFR 327.2(a)(ii)(D)). A single standard of inspection and sanitation would need to be maintained throughout all certified establishments (9 CFR 327.2(a)(ii)(E)). The country's requirements would need to address sanitary handling of product and provide for official controls over condemned material; a HACCP system equivalent to that set forth in 9 CFR part 417; and other applicable controls under the FMIA or implementing regulations (9 CFR 327.2(a)(ii)(F)–(I)).

(3) *Document evaluation and system review.* Under the proposed rule, foreign countries seeking eligibility to export catfish and catfish products into the United States (9 CFR 557.2(a)) would also have to present to FSIS copies of laws, regulations, and other information pertaining to their system of catfish product inspection, just as countries now do when they seek eligibility to export products of other species amenable to the FMIA. FSIS estimates that it would take approximately 3 months per submission to evaluate this documentation. FSIS would determine eligibility on the basis of a study of these documents and an on-site visit to the country of the system in operation by FSIS. FSIS would also conduct periodic reviews of foreign catfish products inspection systems to determine their continued eligibility (9 CFR 327.2(a)(3)).

(4) *Maintenance of standards.* In addition, countries that FSIS eventually determines to be eligible to export catfish and catfish products into the United States would have to provide for periodic visits to certified establishments to ensure that U.S. requirements are being met and for written reports on the supervisory visits (proposed 9 CFR 557.2, under 21 U.S.C. 620). The reports would have to be available to FSIS. The foreign program would have to conduct random sampling of catfish tissues and the testing of the tissues for residues identified by FSIS or by the foreign inspection authority as potential contaminants, in accordance with sampling and analytical techniques approved by FSIS (9 CFR 327.2(a)(2)(iv)(C)). The residue testing would have to be conducted on samples from catfish intended for export to the United States.

Once FSIS has determined that countries maintain equivalent

inspection systems, only certified foreign catfish establishments, that is, establishments that foreign program officials have certified as complying with the requirements equivalent to United States requirements, would be eligible to export their catfish products to the United States. If FSIS found that a foreign establishment is not in compliance with United States requirements for imported products, FSIS would terminate the eligibility of the establishment. FSIS would provide reasonable notice to the foreign government of the proposed termination of eligibility, unless delay in notification could result in the importation of adulterated or misbranded product (9 CFR 327.2(a)(3)).

This final rule adopts these proposed regulations without change. However, to provide foreign countries with adequate time to transition to the final regulations, on the date that the rule becomes effective, March 1, 2016, foreign countries seeking to continue exporting Siluriformes fish and fish products to the United States during the 18-month transitional period are permitted to do so, provided they submit (1) the list of establishments (with the establishment name and number) currently exporting Siluriformes fish and fish products to the United States and (2) adequate documentation demonstrating that the foreign country currently has laws or other legal measures in place that provide authority to regulate the growing and processing of fish for human food and to assure compliance with the Food and Drug Administration's (FDA) regulatory requirements in 21 CFR part 123, Fish and Fishery Products, which include requirements for good manufacturing practices, Hazard analysis and Hazard Analysis Critical Control Point (HACCP) plans, and sanitation control procedures. This initial documentation will not be used to establish equivalency.

By the end of the 18-month transitional period, foreign countries seeking equivalency must submit documentation showing that they have systems for inspection of Siluriformes fish and fish products equivalent to FSIS's system. A country can continue to export fish products to the United States after the 18-month transitional period, if the country has submitted its documentation on equivalency by the start of full enforcement of this rule, September 1, 2017. See Section XII., ''FSIS Implemention,'' for more details.

S. Marking and Labeling of Imported Products

The proposed regulations (9 CFR 557.14 and 557.15) reference the meat regulations (9 CFR 327.14 and 327.15) requiring the marking and labeling of immediate and outside containers of imported catfish and catfish products. There are no changes to these proposed regulations in this final rule.

IX. Proposed Regulations Under Other FMIA Subchapters

A. Rules of Practice; Reference to Rules of Practice

FSIS proposed to apply its rules of practice (9 CFR part 500) in enforcing the proposed catfish inspection regulations (proposed 9 CFR 561.1). Also, FSIS proposed to provide establishments with an opportunity for presentation of views (proposed 9 CFR 561.2, referencing 9 CFR part 335) before reporting violations to the Department of Justice for criminal prosecution. The procedure to be followed in a case relating to catfish and catfish products inspection would be the same as that followed in a case relating to meat and meat food products inspection. FSIS uses its rules of practice for enforcement processes that may lead to such actions as withholding (refusing to allow the mark of inspection to be applied to product) or suspension (withdrawing inspection program employees from a facility) of inspection. There are no changes to the proposed regulations in this final rule.

B. Detention, and Seizure and Condemnation

1. Detention

FSIS proposed to exercise its detention authority under the FMIA upon finding that catfish or catfish products in commerce are adulterated, misbranded, or otherwise in violation of the Act or regulatory requirements (proposed 9 CFR 559.1, referencing 9 CFR 329.1–329.6). This final rule adopts these proposed regulations without change.

2. Seizure and Condemnation

FSIS proposed to apply the provisions for seizure and condemnation in the meat regulations (9 CFR 329.7–329.9) to catfish (proposed 9 CFR 559.2). The regulations also address criminal offenses addressed in Sections 22 and 405 of the FMIA (21 U.S.C. 622, 675), such as bribery of Program employees, receipt of gifts by Program employees, and assaults on, or other interference with, Program employees while engaged in, or on account of, the performance of their official duties under the Act. There are no changes to the proposed regulations in this final rule.

X. Records Required To Be Kept

In proposed 9 CFR part 550, FSIS proposed to require persons and firms involved in processing, buying and selling, or rendering catfish or catfish products to keep records on their activities respecting catfish sold, transported, or offered for sale or transport, in commerce. The records they would be required to keep include sales records or invoices, shippers' certificates and required permits, records of seal numbers used in the sealed transport of inedible products, guaranties provided by suppliers of packaging materials, canning records as required by 9 CFR part 318, subpart G, nutrition labeling records, and records of all labeling, along with the formulation and processing procedures. In addition, the Agency proposed that persons and firms covered by the recordkeeping requirements would have to register with the FSIS Administrator, and asked for comment on a proposed time frame for completing this registration (76 FR 10449).

FSIS also stated that it would require each official establishment to provide accurate information to FSIS employees so that they could report on the amount of products prepared or handled in the establishment, and on sanitation, microbiological testing, and other aspects of the establishment's operations (76 FR 10449). The Agency proposed that the operator of each establishment report quarterly on the number of pounds of catfish processed. The report has to be filed within 15 days after the end of each quarter. The establishment operator would also have to file other reports as FSIS might require from time to time under the FMIA (9 CFR 550.6).

In addition, FSIS proposed to require that a consignee who refuses to accept delivery of a product bearing the mark of inspection because it is adulterated or misbranded notify the Inspector-in-Charge of the kind, quantity, source, and present location of the product (9 CFR 550.7).

There are no changes to the proposed regulations in this final rule.

XI. Comments and Responses

FSIS received approximately 4,335 comments on the proposed rule. About 4,000 of the comments were form letters submitted as part of a write-in campaign initiated by a consumer advocacy organization. FSIS also received a separate petition signed by 41 private citizens, and a joint submission from 16 food and agricultural organizations and

companies. Almost all of the remaining comments were from private citizens; domestic and foreign catfish farmers; trade groups and associations representing the catfish and seafood industry (processing, manufacturing, storage, and distribution); the catfish processing industry; consumer advocacy groups; members of U.S. Congress; foreign government ministries of agriculture and rural development; foreign chambers of commerce; trade associations representing retail and restaurant industries; aquaculture industry advocacy associations; public policy organizations; U.S. State and county officials; aquaculture scientists; members of academia; restaurant consortiums; a foreign government; an organization of U.S. regulatory officials; and a small business advocacy association. The Agency's responses to comments on major issues concerning the proposed rule are discussed below.

A. General Opposition

Comment: Some comments opposed the transfer of jurisdiction over catfish and catfish products to FSIS for a variety of reasons. The comments generally expressed the concern that the proposal was unnecessary, wasteful, unjustified, or redundant. Several commenters stated that both FDA and FSIS will regulate the same product. Many commenters also stated that FDA's current regulatory approach ensures the safety of domestically produced and imported seafood products, and that the catfish industry has a demonstrated track record of food safety.

Response: Under the 2008 Farm Bill, FSIS was required to develop regulations, in consultation with FDA, to implement FSIS inspection of ''catfish,'' as defined by its regulations. Under the 2014 Farm Bill, which amended the 2008 Farm Bill, all fish of the order Siluriformes are amenable species under the jurisdiction of FSIS. The 2014 Farm Bill requires FSIS to develop final regulations in consultation with FDA. FSIS consulted FDA during development of these final regulations. The legislation also requires FSIS and FDA to execute a Memorandum of Understanding (MOU) to improve interagency cooperation on food safety and fraud prevention and to maximize the effectiveness of limited personnel and resources. FDA and FSIS have agreed on this MOU. It is posted at *http://www.fsis.usda.gov/wps/portal/informational/aboutfsis/food-safety-agencies/mou*.

B. The Definition of Catfish

Comments: Many comments representing domestic groups, individuals, and numerous comments from members of the U.S. Congress, urged FSIS to define catfish as all species in the order Siluriformes, the broader definition. The commenters stated that the broader definition affords the greatest food safety protection for the entire ''catfish'' category of seafood; it is consistent with the science of taxonomy; and it would include all imported catfish.

Foreign governments, foreign ministries of agriculture, foreign catfish farmers, and foreign industries supported defining catfish as only fish of the Ictaluridae family, stating that this definition is the current FDA regulatory definition, adopted by Congress in the 2002 Farm Bill (21 U.S.C. 321d (a)), and that it would provide consistency and eliminate confusion among seafood exporters.

Response: The 2014 Farm Bill settled this issue. It amended the FMIA to give FSIS jurisdiction over all establishments that slaughter or process ''all fish of the order Siluriformes.'' Many Siluriformes fish species are produced in foreign countries and are exported to the United States. To be eligible to be imported into the U.S., these products will have to be produced under inspection systems equivalent to the U.S. system and will be subject to reinspection in the U.S.

For labeling or advertising purposes, the FD&C Act provides that the term ''catfish'' can only be used in labeling of fish classified within the family Ictaluridae. By removing the term ''catfish'' from the FMIA and using the term ''certain fish'' in its stead, Congress left FSIS free to use the FD&C Act's definition of ''catfish.'' Therefore, in this final rule, FSIS is modifying the labeling regulations that it proposed to permit the use of the term ''catfish'' only on labels of fish from the Ictaluridae family. Siluriformes fish, which includes families in addition to Ictaluridae, will need to be labeled with the appropriate common or usual name.

C. Risk Assessment

Comments: Many comments asked for additional evidence to support the shift in jurisdiction for catfish and catfish products from FDA to FSIS. The comments also stated that the products of aquaculture are rarely involved in outbreaks of salmonellosis. Comments from a foreign government, a foreign country's chamber of commerce, members of the seafood industry, and trade policy organizations asked FSIS to explain how the proposed rule was consistent with its World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (the ''SPS Agreement'') obligations. A domestic catfish processor expressed the need for a risk assessment associated with chemical contamination of catfish aquaculture based on the constantly changing quality of river water.

Response: It is important to note that the risk assessment was not conducted ''to support the shift in jurisdiction for catfish and catfish products from FDA to FSIS.'' FSIS conducted a quantitative food safety risk assessment, in accordance with national and international guidelines, that included all four components of a standard risk assessment: (1) Hazard Identification, (2) Exposure Assessment, (3) Hazard Characterization, and (4) Risk Characterization. FSIS thoroughly reviewed the scientific literature and garnered input from scientists from other Federal agencies and academia in performing the Hazard Identification portion of the risk assessment. The risk assessment was also independently peer-reviewed in accordance with the Office of Management and Budget's Peer Review Guidelines, as required under the Information Quality Act (Pub. L. 106–554). The purpose of the risk assessment was to provide predictions of the public health benefits (*e.g.,* reduction in foodborne illnesses) that might accompany the implementation of a mandatory inspection system. The risk assessment identified *Salmonella* as a hazard of primary concern because: (1) It is the foodborne pathogen associated with catfish (McCoy et. al., *Journal of Food Protection* 74(3):500–16, 2011); (2) there was more available data for assessing the risk of human illnesses associated with *Salmonella* and assessing the effectiveness of an FSIS regulatory strategy for this hazard; (3) its occurrence in domestic catfish processing facilities and retail catfish is documented; (4) its presence in catfish imported to the United States is documented; and (5) CDC identifies catfish as the vehicle associated with a 1991 outbreak of *Salmonella hadar.*

The estimates for human salmonellosis cases associated with catfish consumed in the United States (under current inspection programs) were supported by an FSIS Risk Assessment and Analytics Staff independent analysis (''attribution analysis'') on the basis of epidemiological data.[7] [8] The Centers for

[7] U.S. Centers for Disease Control and Prevention (CDC). (June 2009) Foodborne Disease Outbreak

Continued

Disease Control and Prevention (CDC) concurred with FSIS' findings and stated that FSIS may even have underestimated the number of human salmonellosis cases attributed to catfish by not considering outbreaks attributed to ''finfish,'' that may have been ''catfish.''

FSIS requirements are consistent with the WTO SPS Agreement on the Application of Sanitary and Phytosanitary Measures. Under the articles of the SPS Agreement, a measure can be taken when it is necessary to protect against a public health hazard and there is scientific support for the measure.

Chemical contamination hazards are important to catfish food safety and FSIS anticipates generating chemical contamination data once it begins its inspection program. Any risks identified through FSIS's surveillance will be addressed to ensure food safety.

D. Cost and Benefits Analysis

Comments: Several comments questioned FSIS's ''break-even'' analysis in light of the fact that, historically, so few salmonellosis illnesses have been associated with the consumption of contaminated catfish. A member of academia, however, stated that the benefits of implementing this rule would be far greater than those estimated because the calculations did not include the long-term public health benefits of preventing imported product contaminated with chemical residues, such as malachite green, from entering the United States. Other comments stated that the incremental cost increases associated with the rule would negatively affect the marketability of catfish and catfish products.

Response: By focusing solely on *Salmonella* in the risk assessment and the subsequent break-even analysis, FSIS took a conservative approach to estimating the number of illnesses prevented needed to offset costs of implementing this rule. It is possible that the process steps needed to reduce *Salmonella* on fish will also result in the reduction of other pathogenic microorganisms, such as *E. coli* (enterohemorrhagic, Shigatoxigenic, enterotoxigenic, and enteropathogenic strains), *Listeria monocytogenes,* and *Clostridium botulinum* on raw and ready-to-eat (RTE) fish.

Comment: Several comments questioned FSIS's relatively high Agency cost to implement and maintain the proposed mandatory catfish inspection program.

Response: In the final rule costs analysis, FSIS lowered its estimated additional net direct costs to implement and continue the mandatory inspection of fish and fish products. These costs are lower than preliminary Regulatory Impact Analysis (RIA) estimates because the domestic fish industry is now more consolidated, contracted, and concentrated and will require fewer additional FSIS resources for inspection. Furthermore, the FSIS Office of Field Operations was recently consolidated and now we will use more of the existing OFO staff (with minimal new hires and relocations) in patrol assignments for the processing-only establishments. This recent consolidation transitioned the Office of Catfish Inspection Programs (OCIP) to OFO. Thus, this transition would eliminate permanent staff positions (such as for managers, supervisors, inspection program personnel, and technical staff) that would have been dedicated to the OCIP, as discussed in the PRIA (scenario 1) of the published Proposed Rule. The Agency cost estimate is in the full RIA of the final rule, in the Appendix material (FRIA Appendix A).

Comment: A domestic catfish processor claimed that transferring catfish inspection to FSIS would give processors of all other non-FSIS inspected seafood an unfair cost advantage.

Response: FSIS projects in its regulatory impact analysis that the final rule would increase domestic product average net direct cost of aggregate processed fish and fish food products by $0.0008 per pound. According to the USDA, National Agricultural Statistics Service (NASS), the average price received by domestic processors for domestic catfish products was $3.04 per pound in 2013. Thus, FSIS's projected additional net direct cost to the domestic fish processing industry is relatively small when compared to the average domestic price received.

Comment: A domestic catfish processor claimed that transferring catfish inspection to FSIS would increase catfish processor's costs. The processor stated that the initial cost to house inspectors and for the industry to conduct laboratory analysis sufficiently rigorous to ensure compliance with FSIS requirements may be significant. In addition, the processor stated that the testing for drugs with sufficient rigor would likely cost several thousand dollars per year.

Response: FSIS projected an additional average net direct cost of $0.0008 per pound of aggregated processed fish and fish products to the domestic processors. This additional average net direct cost includes expected capital costs including additional office space for inspectors. Furthermore, the Agency projected additional establishment testing costs for required validation and verification of HACCP processing plans at official establishments. FSIS found on site visits that many domestic processors already have available office space for inspectors. Furthermore, many of these domestic processors already test their fish and fish products for microorganisms and drugs, according to the FDA 2011 Report. Thus, some domestic processors would have little to no additional costs for inspector office space or for microbe and drug testing. The aggregate direct cost FSIS projects for the domestic activities is an annualized $326.55 thousand.[9]

Comment: A domestic seafood distributor stated that the proposed rule regulatory impact analysis underestimated the number of catfish processors in the U.S. A public policy organization stated that the data presented in the regulatory impact analysis were not properly attributed to a source, that no specific market failure or major health problem was identified, and that the theory behind the assertions was not articulated. The commenter further added that the regulatory impact analysis calculates a salmonellosis illness baseline without considering whether poultry processors used voluntary (fee-for-service) inspection services at the time, and that the numbers cannot be compared to the catfish industry.

Response: The commenter provided no estimate of the number of affected catfish processors in the United States. In the proposed rule, FSIS used data from its research and site visits to project the number of affected domestic processors and distributors. The proposed rule regulatory impact analysis (RIA) data sources are in footnotes, tables, a list of references, and exhibits. In the final rule analysis, FSIS used the best available data from the Food and Drug Administration (FDA); National Oceanic and Atmospheric Administration (NOAA)/National Marine Fisheries Service (NMFS); import records of the U.S. Department of Homeland Security (DHS/CBP); and

Surveillance Data. Atlanta, GA. Retrieved from *http://www.cdc.gov/foodsafety/fdoss/index.html.*

[8] Mead, P.S., Slutsker, L., Dietz, V., McCaig, L.F., Bresee, J.S., Shapiro, C., Griffin, P.M., & Tauxe, R.V. (1999). Food-Related Illness and Death in the United States. Emerging Infectious Diseases, 5,607–625.

[9] Annualized present value of average costs is at a 7 percent discount rate over 10 years.

Dun and Bradstreet, and updated the presentation of summary data and its sources.

As for the market failure, FSIS finds foodborne illness to be potentially consistent with an informational market failure; specifically, the market for food may be characterized by an asymmetry in which producers know more than consumers about the microbiologic status and chemical residue status of the foods they prepare and consume.

While the proposed rule employed a risk assessment in its PRIA, the final rule employs a break-even analysis in its RIA. The break-even analysis was calculated using catfish data and did not incorporate findings from the risk assessment.

Comment: A trade association stated that the proposed rule would deprive seafood processors of imported products that they need and would subject them to duplicative and costly regulation.

Response: The 2014 Farm Bill amendments of the FMIA give FSIS jurisdiction over all Siluriformes fish and fish products, including Siluriformes fish and fish products imported from other countries. Through its planned outreach to affected entities, FSIS will address the continued importation of those fish species and will conduct records reviews and audits to verify that all countries that import those fish species to the U.S. maintain inspections systems and requirements that are equivalent to those of FSIS. See sections Q. *Imported Products* and R. *Demonstrating Equivalence of Foreign Systems* for additional discussion of how FSIS will evaluate the equivalence of these countries and conduct rulemaking to list these countries in the regulations.

To prevent duplicative and costly regulation, the 2014 Farm Bill also instructed FSIS to execute a MOU with FDA to maximize the effectiveness of limited personnel and by ensuring that inspections of shipments and processing facilities are not duplicative, and that any information resulting from examination, testing, and inspections is considered in making risk-based determinations, including the establishment of inspection priorities.

E. Trade Barriers and Agreements

Comments: A comment stated that the proposed rule violated the World Trade Organization (WTO) National Treatment Principle, which states that imported and locally-produced goods should be treated equally once they enter the market. Another comment stated that the proposal violated the WTO agreement on Technical Barriers to Trade because it may be considered a disguised restriction on international trade. Some comments stated that the United States could be subjected to WTO-sanctioned tariffs if the rule is found by the WTO dispute settlement body to be noncompliant with its WTO obligations. A comment from a foreign government stated that it had been exporting catfish to the U.S. for many years under a food and feed safety agreement protocol with FDA, and that it hoped that the protocol would continue.

Response: As with all other products FSIS regulates under the FMIA, this final rule would ensure that equivalent regulatory standards are applied to imported and domestic fish of the order Siluriformes. Therefore, this rule is not a violation of WTO National Treatment Principles. Imported products must be produced under an inspection system equivalent to the domestic system.

F. Equivalency and Implementation

Comment: Many domestic catfish farmers and processors and private citizens endorsed the concept of an exporting country's food safety system being held to equivalent standards that are applied to domestic production. A trade association strongly opposed phasing in the requirements because the phase-in jeopardizes the health and safety of consumers and is unnecessary because there has been ample time to comply. An aquaculture industry advocacy association stated that no catfish imports should enter the United States until the foreign system overseeing them is determined to be equivalent. The same association and a member of academia stated that requirements for domestic and foreign entities should have the same effective date. A foreign agricultural ministry requested that FSIS commit to a timeframe for equivalence determinations. Some commenters recommended possible timeframes for implementation.

Response: The Agency has given the implementation of this final rule careful consideration and has outlined the Agency's implementation strategy in Section XII. Under this implementation plan, FSIS will begin implementing inspection of domestic Siluriformes producers and inspection of imported Siluriformes product at the same time, 90 days after the publication of this final rule. Siluriformes fish and fish products exported to the U.S. will be subject to species and residue testing. Also, at the start of implementation, 90 days after the publication of this final rule, foreign countries will have to submit written documentation identifying a list of establishments (with the establishment name and number) that currently export and will continue to export Siluriformes fish and Siluriformes fish products to the U.S., and demonstrating that they have laws or other legal measures in place that provide authority to regulate the growing and processing of fish for human food and to assure compliance with FDA's regulatory requirements. In addition, during the 18-month transitional period, foreign countries seeking to continue importing into the United States Siluriformes and products derived from these fish after the expiration of the transitional period are encouraged to start submitting their documentation demonstrating the equivalency of their Siluriformes fish and fish products inspection systems. In any event, such documentation must be submitted by the end of the transitional period.

G. Facilities Requirements and Schedule of Operations

Comment: A domestic seafood processor stated that the proposed requirement (9 CFR 533.1) for separation of inspected and non-inspected facilities would make it impossible for them to operate because of a lack of space, resulting in huge hardship.

Response: Consistent with meat regulations in 9 CFR 305.2(a), FSIS generally considers a separation in time or space between inspected and non-inspected facilities to be sufficient, under certain conditions, to meet the requirement for separation of facilities. Therefore, common areas for inspected and uninspected operations may be used if the inspected product is acceptably maintained and protected to prevent product adulteration.

Comment: A trade association suggested that the proposed phrase ''docks and receiving room'' (9 CFR 533.4(f)) be replaced with ''existing plant receiving area'' because it would be cost prohibitive to retrofit existing fish processing plant designs to meet the meat and poultry plant models.

Response: Consistent with the meat regulations in 9 CFR 307.2, 9 CFR 533.4 requires the official Siluriformes establishment to provide docks and receiving rooms, designated by the operator of the official establishment, in consultation with the FSIS frontline supervisor, for the receipt and inspection of Siluriformes, Siluriformes products, and other products. These spaces are necessary to facilitate unloading and staging of products and to minimize the potential for cross-contamination that may occur through these activities. FSIS does not believe there is a meaningful distinction

between ''docks and receiving rooms'' and ''plant receiving area'' and is not modifying the regulatory language in this final rule. The Agency does not anticipate that catfish plant designs will need to be significantly modified to comply with the regulations that contain this language.

Comment: A trade association and a domestic processor asserted that the consistent work schedules and two weeks advance notice for schedule changes requirements, as proposed, will pose undue hardship on the catfish industry. The comments explained that operational hours necessarily fluctuate according to seasonal peaks, availability of fish, size of fish harvested, and other factors.

Response: As proposed, the final regulations for a fish establishment's schedule of operations (9 CFR 533.5) cross-reference the meat regulations (9 CFR 307.4) that define a shift and the basic workweek and require each official establishment to submit a work schedule to their District Manager for approval. In addition, each official establishment will be required to maintain a consistent work schedule. Deviations from the work schedule must be submitted to the District Manager at least two weeks in advance. Establishments may also request overtime inspection, if needed; however, seasonal demands can only be met as resources allow. Consistent work schedules and prior notification for schedule changes are necessary to ensure that the Agency can maintain an inspector presence during establishment operations. However, the Agency does not want to pose undue hardships on establishments, and District Managers will take into consideration any work schedule change request.

H. Definitions

1. ''Adulterated''

Comment: A domestic processor specifically requested that FSIS delete the phrase '' . . . an animal which has died otherwise than by slaughter,'' paragraph (5) under the proposed ''adulterated'' definition (9 CFR 531.1). In addition, a trade association suggested FSIS use the definition of ''adulterated'' to mean any food safety hazard as defined in 21 CFR part 123.

Response: As discussed in the proposed rule (76 FR 10441), the FMIA defines as adulterated a food product that is, in whole or in part, the product of an animal that has died otherwise than by slaughter (21 U.S.C.601(m)(5)), and the proposed ''adulterated'' definition in 9 CFR 531.1 is the same as the definition in the meat regulations (9 CFR 301.2). FSIS continues to view fish that died under circumstances other than the controlled circumstances of commercial fish harvesting and processing as adulterated under this provision of the FMIA and unacceptable for food. In cases where dead, dying, diseased, or otherwise unfit fish are in commerce, it may be necessary for the Agency to apply the detention, seizure, and condemnation provisions of the Act (21 U.S.C. 672, 673).

2. ''Slaughter'' and ''Slaughterhouse''

Comments: Several comments suggested various definitions of the term ''slaughter.'' A consumer advocacy group urged FSIS to provide a clear definition of slaughter that listed various acceptable methods of slaughter. A domestic processor suggested that ''slaughter'' be defined as ''when the head is removed for processing.'' A trade association stated that the catfish industry recognizes that slaughter, under controlled conditions, occurs at the de-header machine within the processing facility.

An organization of regulatory officials recommended that FSIS define ''slaughterhouse'' to include locations where catfish may have died under conditions other than the controlled circumstances of commercial processing. This comment further added that a definition for ''slaughterhouse'' should also include locations where ''wild-caught'' catfish are processed.

Response: After considering the comments, FSIS has concluded that the definition of ''slaughter'' as intentional killing under controlled conditions (9 CFR 531.1) is applicable to various slaughter methods, and it is not necessary to list all of the various methods in the regulations. In addition, the Agency does not see value in defining the term ''slaughterhouse,'' as the definition includes the phrase ''under controlled conditions.'' FSIS would consider fish that died under circumstances other than the controlled circumstances of commercial fish harvesting and processing to be adulterated under the FMIA and unacceptable for food, *e.g.,* a fish that fell onto the pavement in the delivery area of a processing plant and lay there until it died would not be acceptable for human food.

3. ''Farm-Raised'' and ''Wild-Caught''

Comment: A trade association suggested that the proposed definition for ''farm-raised'' (9 CFR 531.1) be amended to require the control of enclosed bodies of water to prevent contamination. A domestic processor asked that the proposed definition be amended to include ''raised in an enclosed environment of a clean, private, controlled water source.''

A comment from a foreign government described the proposed definition for ''farm-raised'' as unreasonable because it does not consider the diversity of raising methods (*e.g.,* breeding in pools and floating cages) and is inconsistent with ''the actual growth situation of catfish'' in their country. The foreign country stated that the floating cage method is the general method used in their country, as well as other foreign countries.

A member of academia stated that ''wild-caught'' catfish should be subjected to the same provisions of the rule as ''farm-raised'' catfish, including the testing requirements of the fish and water. A consumer advocacy group urged FSIS to require catfish establishments to segregate ''wild-caught'' fish from ''farm-raised'' fish during slaughter and processing. In addition, an aquaculture scientist stated that freshwater aquaculture needs an inspection and food safety system that differs from marine ''wild-caught'' seafood because hazards, their sources, and interventions differ significantly.

Response: Proposed 9 CFR part 534 outlines the pre-harvest standards that FSIS will require to ensure that the environmental conditions and source waters in which the fish are grown will not render the fish unfit for food. These regulations require that fish harvested for human food, whether wild-caught or farm-raised, must not have lived under conditions that would render them unsound, unwholesome, unhealthful, or otherwise unfit for human food (9 CFR 534.1) so the fish would not be ''adulterated'' as the term is defined in 21 U.S.C. 601(m)(3) in the FMIA. The definition of ''farm-raised'' in 9 CFR 531.1 of the regulations is intended to cover a variety of fish-raising methods, including methods that involve raising the fish in pools and floating cages.

Although the domestic fish growing process primarily utilizes fish-raising ponds, FSIS recognizes that wild-caught fish may be commercially processed. 9 CFR 534.2 states that farmers of fish should monitor the water in which the fish are raised for the presence of suspended solids, organic matter, nutrients, heavy metals, pesticides, fertilizers, and chemicals that may contaminate fish. FSIS will inspect wild-caught and farm-raised fish processed in official establishments and test them for metals, dyes, pesticides, and animal drug residues. The Agency does not see the need for requiring the segregation of ''farm-raised'' and ''wild-

caught'' fish as they are processed in an official establishment.

Comment: A consumer advocacy group requested that the manner by which the animal was raised, ''farm-raised'' or ''wild-caught,'' be required on the label. A similar comment requested that ''wild-caught'' fish be labeled as such to distinguish them from ''farm-raised'' fish.

Response: FSIS is authorized under the FMIA to regulate the marking, labeling, and packaging of all Siluriformes products in commerce (21 U.S.C. 607). However, there is no statutory obligation to label fish with the raising claims ''farm-raised,'' or ''wild-caught.'' Establishments may choose to voluntarily label their finished product with such raising claims, if the claims are not false or misleading. Such claims for fish would not require FSIS approval as required by 9 CFR 412.1(c)(3) and 541.7(g).

As discussed below, the final rule (9 CFR 541.7(b)) requires that country of origin statements on the label of any covered commodity (fish, including fillets, steaks, nuggets, and any other flesh) sold by a retailer must comply with the AMS regulations (7 CFR 60.200 and 60.300). For these products, the AMS regulations require method of production information (wild or farm-raised).

I. Labeling

1. Mark of Inspection

Comment: Several domestic processors, a consumer advocacy group, and an organization of regulatory officials recommended that the Federal mark of inspection be similar to the current brand for meat, poultry, and egg products. Another comment requested that the official inspection legend for catfish be unique in design and applied only to all finished packaging and in-process transfer containers. One comment favored assigning a number to each catfish establishment. Several comments noted that it may be impractical to stamp all carcasses of whole, gutted fish due to the size of the product and suggested alternative measures be considered, such as branding shipping containers, affixing inspection tags to lots, or marking invoices that accompany any shipments.

Response: Because all fish of the order Siluriformes are amenable species under the FMIA, FSIS will require the same inspection legend for those products as it does meat products (9 CFR 312.2, reproduced in 9 CFR 541.2, respectively). This inspection legend includes the number of the establishment. FSIS recognizes that it may be impractical to physically apply the inspection legend to whole, gutted, fish carcasses. Therefore, whole, gutted fish carcasses that have been inspected and passed at an official establishment, and that are intended for sale as whole, gutted fish may be stamped with the official inspection legend *or* properly packaged in an immediate container and then labeled with the official inspection legend, as well as with all other required labeling features (9 CFR 317.2). For all other Siluriformes fish products, the inspection legend will be required on the immediate container.

2. Species Identification and Prevention of False or Misleading Labeling Practices

Comment: One comment stated that FSIS should choose a rapid, accurate, and inexpensive method for catfish species identification. Another comment stated that FSIS should choose a method that provides accuracy at the species level. One comment stated that catfish products should be identified according to the species of fish throughout processing regardless of the final packing step location.

Response: FSIS will determine fish speciation by appropriately validated methods which are published in the Chemistry Laboratory Guidebook on the FSIS Web site at *http://www.fsis.usda.gov/Science/Chemistry_Lab_Guidebook/index.asp*. The methods chosen by FSIS are state-of-the-art and appropriate for their purpose in determining fish species identification.

The fish labeling regulations (9 CFR 541.7, cross-referencing part 317, subpart A) require the name of the product on the label (9 CFR 317.2(c)(1)). Product leaving an official Federal establishment for distribution in commerce for further processing would have to be properly identified with all applicable mandatory labeling features, including a product name. It would typically bear a statement of limited use, *e.g.,* ''for further processing'' to limit distribution to another official Federal establishment. Because the product is intended for further processing, and not for retail sale, some labeling features would not be required because they would meet an existing exemption, *e.g.,* nutrition labeling (317.400 (a)(3)), safe handling instructions (9 CFR 317.2(l)(4), and net weight (317.2(h)(1).

Under the FD&C Act (21 U.S.C. 321d (a)), the term ''catfish'' is considered to be a common or usual name (or part thereof) only for fish classified within the family Ictaluridae; and labeling or advertising only for fish classified within that family may include the term ''catfish.'' Species of Ictaluridae include, among others, *Ictalurus punctatus, I. furcatus,* and *Pylodictis olivaris,* which may be identified as ''channel catfish,'' ''blue catfish,'' and ''flat-head catfish,'' on the labeling, if it is not false or misleading (9 CFR 541.7, cross-referencing part 317, subpart A, 9 CFR 317.8). Through fish speciation sampling and testing, FSIS will routinely verify that product is accurately labeled and not misbranded at official establishments and at import reinspection facilities.

3. Standards of Identity

Comment: A domestic processor requested that all catfish products (as examples, formed nuggets, patties, cakes, gumbo) should contain at least 51 percent or more catfish.

Response: Product standards are intended to ensure that products sold under particular names have the characteristics expected by consumers. FSIS will, if necessary and appropriate, apply any of the existing meat regulatory standards in 9 CFR part 319- that may be applicable, *e.g.,* ''meat stew'' (9 CFR 319.304) to fish products. A mixture of Ictaluridae and other Siluriformes could be labeled with an accurate and truthful descriptive name identifying the Ictaluridae (catfish) and other species of the Siluriformes, *e.g.,* ''Catfish and Basa.''

As stated in the preamble of the proposed rule, there are few further-processed fish products produced domestically (76 FR 10446), and FSIS is not aware of any fish standard-of-identity issues that require rulemaking. However, as provided in 9 CFR part 392, any person can petition the Agency to issue a regulation for a standard of identity.

4. Percent Approved Substances

Comment: A trade association asked that the percentage of sodium tripolyphosphate, where allowed in catfish products (generally 0.5 percent by weight of the finished product), be explicitly addressed in the regulations to ensure that there is a uniform standard for domestic and foreign products.

Response: 9 CFR 544 states that no fish product may bear or contain any food ingredient that would render it adulterated or misbranded or that is not approved in 9 CFR part 424 of subchapter E. 9 CFR 424.21 lists food ingredients that are approved for use in the preparation of meat products if they are used for the purposes indicated, within the limit of the amounts stated, and under other conditions specified. FSIS will apply the purpose and amount of any food ingredients to fish products,

if appropriate, and in consultation with FDA. The purpose and amount of sodium tripolyphosphate listed in the table for meat food products that would be applicable to fish products is 0.5 percent in the meat food product to decrease the amount of cooked out juices.

5. Net Weight and Retained Water

Comment: An aquaculture industry advocacy group stated that the net weight of Individually Quick Frozen (IQF) fish is not determined on a ''thawed'' basis, as suggested in proposed 9 CFR 541.7(b)(1). The commenter stated that while it is correct that the deglazed net weight must be 100 percent of the stated net weight, the procedure to determine this weight, as found in the NIST Handbook 133, does not thaw the product but only requires the removal of the outer layer of ice, and that the product is maintained in a frozen state. Additionally, the commenter stated that the net weight for IQF seafood is determined on a frozen basis.

A domestic seafood distributor requested additional clarification on the section related to product moisture content and labeling because the proposed language is unclear on how to measure and label products that have undergone any kind of further processing. A foreign country's chamber of commerce stated that it would be impractical and serve no legitimate end to require catfish processors to calculate how much retained water is included in the production process.

Response: NIST Handbook 133 net weight test procedures for the ice-glazed catfish products state that the products are ''deglazed'' by placing the product under a gentle spray of cold water, and that the product should remain rigid (Section 2.6.2.2). FSIS will follow this procedure for determining net-weight compliance for ice-glazed fish. However, the NIST Handbook 133 test procedure for Encased-in-Ice Product Only (Section 2.6.1.2), which includes frozen catfish, including IQF catfish, is to thaw the product before weighing.

As explained in the proposed rule, the Agency proposed requirements for the control of retained water in catfish (76 FR 10445). FSIS will not permit retained water—water remaining in raw product after it undergoes immersion chilling or a similar process— in the packaged product unless the official establishment is able to show, with data collected under a written protocol, that the retained water is an unavoidable consequence of the process used to meet applicable food safety requirements (9 CFR 441.10(a)). To determine the amount of water retained in the product retained from a chilling process, an establishment may use physical water pick-up tests, weighing the product before the chilling process, and again just prior to final packaging and labeling. This is necessary because the amount of water retained in the product in excess of naturally occurring moisture must be prominently declared on the label.

6. Safe Handling Instructions

Comment: A comment suggested that, to avoid confusion, one of the statements required within the safe handling instructions (9 CFR 541.7, cross-referencing part 317, subpart A), ''This product was prepared from inspected and passed meat and/or poultry,'' be modified to include the word ''catfish'' along with ''meat and/or poultry.''

Response: FSIS agrees that a safe handling statement referencing ''meat and/or poultry'' may potentially confuse consumers. Therefore, in this final rule, FSIS has modified the proposed codified language (9 CFR 541.7(a)) to require that the safe handling instructions rationale statement read, ''This product was prepared from inspected and passed fish,'' and the labeling statements read, ''Keep raw fish from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw fish.''

7. Country of Origin Labeling

Comment: Several private citizens, trade groups, and domestic processors requested that FSIS require that the country in which the catfish was hatched and raised, as well as processed, appear on the finished product label.

Response: All shipping containers and immediate containers, as defined in 9 CFR 301.2, containing meat, including fish, imported into the United States for human consumption, must bear the name of the country of origin (9 CFR 327.14, 327.15; 9 CFR 557.14, 557.15).

The proposed labeling regulations (9 CFR 541.7, cross-referencing 9 CFR, part 317, subpart A) require that catfish and catfish products be labeled in accordance with the Agricultural Marketing Service (AMS) country of origin notification labeling regulations in 7 CFR, part 65, subpart A (9 CFR 317.8(b)(40)). The AMS regulations require that covered commodities (as defined in 7 CFR 60.105) sold by a retailer, whether individually, in a bulk bin, display case, carton, crate, barrel, cluster, or consumer package contain country of origin and method of production information (wild or farm-raised) (7 CFR 60.200 and 60.300). The proposed rule cross-referenced AMS' Country of Origin Labeling (COOL) requirements for meat commodities. In this final rule, the Agency is correcting the regulatory text, by adding a paragraph to 9 CFR 541.7, to cite 7 CFR part 60, subpart A, ''Country of Origin Labeling for Fish and Shellfish.'' Establishments are not required to label their fish products with country of origin labeling. However, if an establishment chooses to place a label on a Siluriformes fish or fish product covered commodity with a country of origin statement, it must comply with the AMS regulations. Labels with country of origin claims can be generically approved, *i.e.,* the labels can be prior-approved by the Agency without submitting such labels to FSIS for sketch approval (9 CFR 412.2). Generic label approval requires that all mandatory label features be in conformance with FSIS regulations.

J. Pre-Harvest and Transport Conditions

Comment: FSIS received several comments requesting that the final rule include performance standards for pre-harvest environmental and water conditions and transportation. A trade association stated that an FSIS monitoring program for water quality is unnecessary, and that water quality should be tested on a periodic basis, perhaps annually. Another trade association requested that any performance standards that the Agency develops should be clearly spelled out with adequate explanation for regulated parties to fully understand the new requirements.

Response: The general pre-harvest requirements in 9 CFR part 534, require that fish harvested for use as human food must have grown and have lived under conditions that will not render them unsound, unwholesome, unhealthful, or otherwise unfit for human food. 9 CFR 534.2 requires that farmers of catfish monitor the water in which the fish are raised for suspended solids, organic matter, nutrients, heavy metals, antimicrobials, pesticides, fertilizers, and industrial chemicals that may contaminate the fish. FSIS will collect samples of feed, fish, and pond water on a case-by-case basis, for cause, i.e, if FSIS finds residues or diseases in tissue at slaughter. Establishments will be required address the hazards associated with ''wild-caught'' fish as part of their HACCP plans (9 CFR 417.2), and FSIS will verify that they carry out this monitoring.

In addition, 9 CFR 534.4 requires that vats or other containers transporting fish

must be maintained in a sanitary condition, and that sufficient water and sufficient oxygen must be provided to the vats that hold the fish to ensure that the fish are delivered to the processing establishment not adulterated.

Comment: Several commenters stated that the regulations must address the quality of water used in transport vehicles. One trade association stated that proposed 9 CFR 534.4 should be amended to include the phrase, ''. . . sufficient unpolluted and uncontaminated water and sufficient oxygen or aeration must be provided to the vats. . . .''

Response: FSIS agrees with the comments but finds that no changes are necessary in response to the comments. In point of fact, the proposed regulations provided for the transport conditions the comments seek. Thus, the final regulation requires that sufficient water and oxygen be provided, and that vats or other containers be maintained in a sanitary condition, which includes the water in the vats (9 CFR 534.4). In addition, the regulations require that fish harvested for use as human food have been grown and have lived under conditions that will not render them or the products made from them unsound, unwholesome, unhealthful, or otherwise unfit for human food (9 CFR 534.1).

Comment: A trade association and several domestic processors stated that it is not uncommon for live fish to come in contact with dead, dying, or diseased catfish during transport.

Response: FSIS recognizes that live fish may, on occasion, come in contact with dead, dying, or diseased fish during transport. However, incidental contact during transport with dead, dying, or diseased fish would not automatically render an otherwise healthy fish adulterated. Under 9 CFR 548.2, adopted as proposed in this final rule, the establishment is required to prevent unsound, unhealthful, unwholesome, or otherwise unfit ingredients from being used in the preparation of products. 9 CFR 534.4 states that any fish that are dead, dying, diseased, or contaminated with substances that may adulterate catfish products are subject to condemnation at the official fish processing establishment. In cases where dead, dying, diseased, or otherwise unfit fish have entered commerce, it may be necessary for the Agency to apply the detention, seizure, and condemnation provisions of the Act (21 U.S.C. 672, 673).

K. Pathogen Reduction and Tolerances for Animal Drugs

Comment: FSIS received several comments requesting that the final rule include performance standards for pathogen reduction.

Response: In the preamble of the proposed rule (76 FR 10444), FSIS stated that it planned to implement a pathogen reduction program for catfish that would be similar to that for other classes of raw product subject to the FMIA. After completing a study to determine the national baseline prevalence and levels of *Salmonella* on raw catfish, FSIS will conduct regular testing in processing establishments for the purpose of measuring industry performance against the baseline. If, after observing the industry's performance, the Agency determines the need for performance standards, it will publish the planned standards in the **Federal Register**, for public comment.

Comment: Several comments suggested that the Agency stipulate ''zero tolerance'' for malachite green, crystal violet, enrofloxacin, ciprofloxacin, and other antimicrobials prohibited for use in the U.S. One comment requested that FSIS add regulatory requirements for appropriate disposition of catfish and lots of catfish found positive for these substances. Another comment asked that FSIS specify that only antibiotics approved for use in U.S farm-raised catfish be permitted for use in all catfish products sold in the United States, foreign or domestic.

Response: The Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) have statutory authority for establishing antibiotic and other animal drug tolerances for meat, including fish. FSIS works with the EPA and the FDA to control drug, pesticide, and contaminant residues including antibiotics in meat products, including fish, by testing animal tissues to verify that tolerance levels are not violated. Fish or fish products and lots of fish containing violative residues of the drugs or other chemicals including those the commenters listed would be considered adulterated and subject to condemnation (9 CFR 539.2).

L. Limits for Retail Quantities

Comment: A domestic processor stated that a retail purchase is generally less than 30 pounds, and non-household consumers would purchase 60 pounds or more. An organization of regulatory officials remarked that the retail purchase limits stated in the proposal seemed reasonable, although difficult to verify.

Response: FSIS is providing an exemption for retail stores and restaurants (9 CFR 532.3, paralleling 9 CFR 303.1(d) and (e)), using the poultry exemption regulations set out in 9 CFR 381.10 as a model. The final regulations provide a limit of 75 lbs. (single-sale) for an individual household purchase of fish to be considered a retail purchase; the corresponding limit for a non-household consumer would be 150 lb. Historically, these limits have been accepted as realistic, and, therefore, FSIS is not changing the limits in this final rule.

M. Hard Copy Information

Comment: A domestic food processor requested that FSIS simplify and minimize the collection and transfer of hard copy information.

Response: FSIS is taking steps to minimize the use of hard copy. Inspection assignments in the fish inspection program will be incorporated into FSIS's computerized PHIS, as appropriate. Establishments have access to PHIS. The Application for Federal Inspection (FSIS Form 5200–2) and the Application for Label Approval and Instructions (FSIS Form 7234.1) are available in fillable Portable Document Format (PDF) on the FSIS Web site. The electronic Label Submission and Approval System (LSAS) is also available to fish establishments that do not or cannot have their labels generically approved.

FSIS will provide for the electronic submission of information that it collects from entities that will come under its fish inspection regulations, where applicable. The Agency will continue to work to enhance its capacity for the electronic collection of information.

N. Other Comments

1. Exemptions and Periodic Auditing

Comment: A small domestic catfish processor requested that establishments that process less than 10,000 lb. of catfish products per week be exempted from the day-to-day FSIS mandatory inspection requirements. Additionally, the comment deemed a periodic audit system more appropriate for small scale operations than a mandatory inspection system. A similar comment suggested that the size of the catfish farm be taken into consideration when determining which farms are to be inspected.

Response: The FMIA does not provide an exemption for fish processors that produce less than a specified amount of product. In addition, the exemptions for

custom and farm slaughter and processing or other exemptions do not apply to fish (21 U.S.C. 623). The FMIA provides for the examination and inspection of conditions under which fish are raised. This requirement applies to all farms that supply fish to Federal establishments, regardless of the size of the farm.

However, as discussed in Section XII, ''FSIS Implementation,'' through its 18-month transitional period, the Agency is providing establishments ample time to prepare and comply with the final regulations. In addition, during the 18-month transitional period, the Agency will exercise broad enforcement discretion, focusing particularly on preventing adulterated or misbranded Siluriformes fish and fish products from entering commerce. After the 18-month transitional period, FSIS will fully enforce all of the final regulations.

2. Use of Program Seals

Comment: Some domestic processors and a trade association claimed that requiring a program employee to affix a seal to any means of conveyance will cause processors undue hardship, especially if program employees are unavailable during shipping times. Commenters contend that it is unnecessary and impractical to require the sealing of trucks, since the boxes of product inside the truck are inspected and sealed and are delivered to multiple locations.

Response: A means of conveyance (*e.g.,* a truck) transporting inspected and passed fish products and bearing the official inspection legend (9 CFR 541.2; 9 CFR 325.5) is not required to be sealed by FSIS. The requirement for sealing railroad cars, motortrucks, or other means of conveyance applies when inspected and passed fish products are being transported from one official establishment to another, and the products are ''unmarked'', *i.e.,* they do not contain the official mark of inspection. Shipping inspected and passed, and properly marked, product does not require FSIS inspection and typically occurs outside the hours of inspection. FSIS did not change these provisions because establishments have flexibility in timing the application of seals to shipments.

O. Cooperation With States

Comment: An organization of regulatory officials requested that FSIS develop cooperative agreements with States for the inspection of catfish and catfish products.

Response: Under 9 CFR 560.1, FSIS may cooperate with any State in developing and administering a fish inspection program that has requirements that are ''at least equal to'' the requirements of the FSIS inspection program. When resources allow, FSIS will enter into new State-Federal Cooperative Agreements under which the Agency will cooperate with, and provide assistance to, States carrying out inspection programs for fish and fish products that are to be sold intra-State. In addition, selected fish establishments in States that have and continue to maintain an ''at least equal to'' State meat inspection program will be eligible to ship their fish products across State lines and export them to foreign countries. In this final rule, FSIS is amending 9 CFR part 560 to include a paragraph specifically referencing 9 CFR 321.3, for the Cooperation of States for the Interstate Shipment of Carcasses, Parts of Carcasses, Meat, and Meat Food Products.

P. Outreach and Training

Comment: A trade association representing the storage industry asked that FSIS initiate substantial industry outreach to ensure regulated parties fully understand any new requirements and the phased-in implementation.

Response: FSIS intends to develop necessary outreach materials and hold sessions to inform and educate fish establishment owners and operators of the regulatory requirements contained in the final rule. The timing of the 18-month transitional period is based in part on the need to ensure that domestic as well as foreign regulated parties understand FSIS's requirements. The implementation strategy is discussed in Section XII, and implementation information will also be posted on the FSIS Web site.

XII. FSIS Implementation

FSIS proposed a four-phase approach to implementing the catfish inspection rule, but did not provide timeframes for implementation (76 FR 10452). The final rule provides an effective date, 90 days after its publication, and an 18-month transitional period until the regulations are fully enforced.

FSIS has given careful consideration in determining the nature of the inspection coverage that it will provide during the 18-month transitional period and once the rule is fully effective. In the proposed rule, FSIS used the term ''continuous inspection,'' but did not define what this would mean. The Egg Products Inspection Act uses the term ''continuous inspection'' (21 U.S.C. 1034(a)), and FSIS has interpreted it to mean that the Agency must have an inspector at an egg products plant whenever the plant is processing eggs. FSIS does not believe that Congress intended FSIS to provide this level of inspection coverage in establishments that slaughter and slaughter and process fish. Congress provided for inspection of fish in Section 606 of the FMIA (21 U.S.C. 606(b)). FSIS's longstanding and well-known interpretation of Section 606 is that it only requires inspection once per shift. If Congress had intended something different, it is reasonable to presume that it would have put the provision for inspection of fish in a different section. Second, the 2014 Farm Bill Joint Explanatory Statement of the Committee Conference'' [10] states: ''There exists scientific evidence that demonstrates that the use of substances such as malachite green, nitrofurans, fluoroquinolones, and gentian violet during the stages of production can result in continued presence in edible Siluriformes products. The managers believe that continuous inspection of farm-raised species is a legitimate tool to address concerns.'' In this statement, it is pretty clear that Congress was using ''continuous'' in its ordinary meaning of uninterrupted. Congress was saying that the FSIS model of performing inspection on an ongoing basis of once per shift is more consistent with the type of inspection necessary than the FDA model of sporadic inspection (once per year or more). Thus, FSIS believes that it will be providing the coverage that Congress intended and that it is not necessary to use ''continuous'' in the regulations.

Following its interpretation of the language in the Farm Bills, the 2014 Farm Bill Joint Explanatory Statement of the Committee of Conference and the FMIA, FSIS will, at the start of implementation, assign inspection program personnel to be present during all hours of operation on a daily basis at domestic establishments that slaughter and slaughter and process Siluriformes fish and fish products. At the start of implementation, FSIS will assign inspection program personnel to conduct inspection at processing-only facilities at least quarterly.

At the end of the 18-month transitional period, inspection program personnel will continue to be assigned to conduct inspection during all hours of operation at slaughter and slaughter and processing establishments for some period of time. Based on FSIS's findings during and after the transitional period, it may adjust inspection frequency in slaughter and slaughter and processing establishments in the future. FSIS will establish criteria it will follow in

[10] *http://docs.house.gov/billsthisweek/20140127/CRPT-113hrpt-HR2642-SOM.pdf.*

determining how inspection will be adjusted at these establishments and will make these criteria available to the public. At the end of the 18-month transitional period, inspection program personnel will be assigned at least once per day per shift at processing only establishments.

During initial implementation, FSIS will provide domestic Siluriformes fish and fish products establishments with guidance to ensure that they understand the new requirements. During the 18-month transitional period, if FSIS finds that an establishment has produced adulterated product (*e.g.,* product that contains a violative residue or other adulterant or has been produced under insanitary conditions that result in direct product contamination) or has misbranded product by labeling it ''Catfish'' when the product does not contain fish of the family Ictaluridae or intentionally over-declaring the net weight, FSIS will prevent the product from going into commerce or will take action to ensure that it is removed from commerce. If FSIS finds any other noncompliance with these regulations, FSIS will document its finding and work with the establishment to address the problem in a timely manner.

FSIS will conduct sampling and testing of Siluriformes fish and fish products for species and residues to ensure that product is not adulterated or misbranded. FSIS has developed a testing program that currently includes the capacity to test for malachite green, nitrofurans, veterinary drug residues (including some floroquinolones), gentian violet, metals, and pesticides(See Table 2, below). Also during the first 18 months, as noted in the Comment and Responses (Section XI), FSIS plans to commence collection of *Salmonella* data to determine the national baseline prevalence and levels of *Salmonella* on raw Siluriformes fish.

TABLE 2—PROJECTED FSIS FISH SAMPLING PLAN

Samples per year	Type of sample	Tests at eastern laboratory	Tests at western laboratory
100 (at each laboratory).	Domestic	*Salmonella,* Speciation, Metals, Dyes, and Veterinary Drug Residures (MRM).	*Salmonella,* Pesticides, Veterinary Drug Residues (MRM), and Nitrofurans.
50 (at each laboratory)	Import	*Salmonella,* Speciation, Metals, Dyes, and Veterinary Drug Residues (MRM).	Pesticides and Nitrofurans.

By the effective date of this final rule, March 1, 2016, foreign countries with establishments that are exporting Siluriformes fish and fish products to the United States, and that wish to continue to do so, are required to submit written documentation identifying a list of establishments (with the establishment name and number) that currently export and will continue to export Siluriformes fish and Siluriformes fish products. Foreign countries must also provide written documentation to demonstrate that they currently have laws or other legal measures in place that provide authority to regulate the growing and processing of fish for human food, and to assure compliance with FDA's good manufacturing practices, Hazard analysis and Hazard Analysis and Critical Control Point (HACCP) plans, sanitation control procedures, and other regulatory requirements in 21 CFR part 123, Fish and Fishery Products. This initial documentation will not be evaluated to determine the equivalency of the foreign country's inspection system to that of the United States, but to establish that the Siluriformes fish and fish products exported to the United States are produced under a foreign country's authority and meet FDA's regulatory requirements. A foreign country may provide FSIS with any of the following written documentation:

—pursuant to 21 CFR 123.12(a)(2)(ii)(B), copies of foreign inspection continuing or lot-by-lot certificates that the imported fish products are or were processed in accordance with requirements in 21 CFR part 123; or

—pursuant to 21 CFR 123.12(a)(1), an active memorandum of understanding (MOU) or similar agreement between the foreign country and FDA that covers Siluriformes fish or fish products and documents the equivalence or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the current situation between the signing parties, and is functioning and enforceable in its entirety; or

—an active memorandum of understanding (MOU) or similar agreement between the foreign country and FDA that covers the food safety of its products; or

—a checklist of the country's regulatory control system, procedures, to demonstrate the competent authority's control and ability to enforce a HACCP-based control program; or

—a side-by-side comparison of the country's or each processor's HACCP program with 21 CFR part 123; or

—a side-by-side comparison of the country's or each processor's sanitation program with FDA's GMP for sanitation at 21 CFR part 110; or

—for canned fish, a comparison of the country's or each processor's low-acid canned food and acidified food program with FDA's (at 21 CFR parts 108, 113, and 114); or

—a third-party certification of the country's or each processor's compliance with FDA requirements; or

—data and information that foreign countries submitted in response to any FDA Import Alert.

The initial documentation can be submitted to: Food Safety and Inspection Service, OPPD/International Equivalence Staff, 1400 Independence Avenue SW., Room 2145, South Building, Washington, DC 20250–3700.

After a foreign country submits its documentation, FSIS will evaluate its acceptability and notify the foreign country if any clarifications or additional documentation are necessary. For additional information and guidance on the initial documentation requirements, foreign countries are encouraged to contact FSIS's, Office of Policy and Program Development's International Equivalence Staff at the address above, by phone (202) 720–0082, by Fax: (202) 720–7990, or Email: *InternationalEquivalence@fsis.usda.gov*.

Starting on the effective date of the rule, March 1, 2016, or within a reasonable amount of time thereafter, FSIS will maintain a list on its Web site of foreign countries that have provided the list of establishments and met the initial documentation requirement. During the 18-month transitional period, Siluriformes fish and fish products exported to the United States from foreign counties that have not met the initial documentation requirement will be refused entry. If, during the transitional period, a foreign country wants to add establishments to its list,

it must notify FSIS using the contact information above. The foreign country should explain the circumstances behind adding the establishment and provide assurances that the facility conducts sanitary operations and produces wholesome product. FSIS will make determinations on adding establishments on a case-by-case basis, taking into account the information submitted.

FSIS will recognize the initial documentation foreign countries submit, until full enforcement of the rule, at the end of the 18-month transitional period, September 1, 2017, or FSIS determines whether the foreign inspection systems are equivalent to that of the United States, whichever occurs first. Foreign countries seeking to continue exporting Siluriformes fish and fish products to the United States after the 18-month transitional period, September 1, 2017, are advised to start submitting their documentation showing that they have an equivalent inspection system as soon as possible during the transitional period. The FSIS equivalency process is described fully on the FSIS Web site at: *http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/equivalence*. In any event, foreign countries must submit this information no later than the date of full enforcement, at the end of the 18 month transitional period, September 1, 2017. If foreign countries have done so, they may continue to export until such time that FSIS makes a determination with respect to the equivalency documentation submitted by the foreign country, and FSIS's determination is negative (*i.e.,* FSIS determines that the foreign inspection systems are not equivalent to that of the United States). If FSIS determination is positive, trade can continue.

On the effective date, March 1, 2016, at each official import inspection establishment, imported Siluriformes fish and fish product shipments will be reinspected and subjected to species and residue testing on at least a quarterly basis. At the end of the 18-month transitional period, on the date of full enforcement (September 1, 2017), all imported Siluriformes fish and fish product shipments will be reinspected, just as all imported meat and poultry products from equivalent countries that export product to the United states are reinspected.

By the end of the 18-month transitional period, foreign countries must apply, under FSIS' regulations, for equivalency determinations. If a country does not initiate a request for equivalency and provide documentation showing its system is equivalent by the end of the 18-month transitional period, *i.e.,* the date of full enforcement, September 1, 2017, FSIS will refuse entry to Siluriformes fish and fish products exported from that country. When a foreign country initiates a request for equivalency and provides documentation during the 18-month transitional period, if additional information is required, FSIS will request that the foreign country respond or resubmit complete equivalence documentation within 90 day of receiving FSIS's request. If, after the 18-month transitional period, the foreign country has failed to respond to FSIS's request within 90 days of receiving the request, FSIS will refuse entry to Siluriformes fish and fish products exported from that country. Based on its review of the information and documentation that the country submits, FSIS will tentatively decide whether the foreign country's inspection system and requirements are equivalent to FSIS', and if so, will plan an on-site audit of the country's Siluriformes fish and fish products inspection system. If FSIS also tentatively finds the foreign country's inspection system equivalent based on the audit, FSIS will publish a proposed rule in the **Federal Register** announcing the results of the document review and on-site audit, proposing to add the country to its list of eligible exporting countries (9 CFR 557.2(b)). After analysis of public comments, FSIS will publish a final rule announcing its determination on the country's eligibility.

XIII. Executive Orders 12866 and 13563 and the Regulatory Flexibility Act

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated an ''economically significant'' regulatory action under section 3(f) of Executive Order (E.O.) 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget under E.O. 12866. The Regulatory Flexibility Act requires an assessment of the effects of the final rule on small entities. This assessment is in this Section XIII, part J., below.

FSIS is adopting, with changes, the preliminary regulatory impact analysis (PRIA) Scenario #1 alternative, published in the proposed rule, as the final regulatory impact analysis (FRIA) in this final rule. The changes to the PRIA are the result of the 2014 Agricultural Act amendments to the FMIA mandating that ''all fish of the order Siluriformes are amenable species,'' public comments, and updates that include more current costs, prices, fish consumption data, fish demand data, fish supply data, fish exports, fish imports, and the changing structure of the Siluriformes fish industry. These include:

- Updated baseline information to reflect changes in the industry.
- Updated costs and prices for the more current markets.
- Updated assessment of the potential public health benefits of the final rule, in the break-even analysis, to reflect a lower average direct cost of $2,423 (in 2010 dollars) for a clinical case of salmonellosis.[11]
- Updated FSIS implementation schedule (see section XII, above).

A. Need for the Rule

FSIS inspection of Siluriformes is mandated by law and non-discretionary.

B. Baseline

Mandatory inspection of Siluriformes fish and Siluriformes fish products is a new program for FSIS. Currently, FDA does require a Seafood HACCP plan[12] for establishments that process seafood, including Siluriformes fish and Siluriformes fish products. A Seafood HACCP plan requires covered establishments to have completed a hazard analysis, be able to take corrective actions, conduct on-going verification activities, review records, conduct training, and establish and implement sanitation control procedures. In the preamble of the proposed rule and the PRIA, Table 2, FSIS provided an overview comparison of the FSIS, FDA and USDC/NMFS/NOAA inspection system requirements.

In establishments that request inspection services under the

[11] The FSIS estimate for the average cost of salmonellosis illnesses ($2,423 per case—2010 dollars) was developed using the USDA, ERS Foodborne Illness Costs Calculator: *Salmonella* (June 2011). FSIS updated the ERS calculator to include Scallan case distribution for *Salmonella.* Scallan, E., Hoekstra, R., Angulo, F., *et al.* (2011). Foodborne Illness Acquired in the United States—Major Pathogens. Emerging Infectious Diseases, 17 (1), pp.7–15.

[12] More additional information, see the FDA Seafood HACCP regulations and guidance at *http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006764.htm.*

Agricultural Marketing Act of 1946, USDC/NOAA/NMFS routinely inspects domestic seafood, including Siluriformes fish and Siluriformes fish products, on a fee-for-service basis. On average, domestic Siluriformes fish establishments' contract with NMFS for that service annually for an annual cost of $1,340.00 thousand. See the NMFS.gov Web site for more information on that service. However, neither FDA nor USDC/NOAA/NMFS inspects Siluriformes fish production facilities (fish farms); or transporters of live Siluriformes fish. Also, the USDC/NOAA/NMFS does not inspect commercial feed mills that manufacture fish feed products or rations for Siluriformes fish farms.

C. Catfish Consumption and Prices

Data on Siluriformes supply and demand is limited. Recently, the U.S. Farm-Raised Catfish Industry 2013 Review and 2014 Outlook [13] provided industry statistics for the Siluriformes Industry:

- U.S. farm-raised catfish consumption of the order Siluriformes was 0.5 pounds per person in the 2012 ''Top 10'' fish and seafood consumption list for Americans, who consumed 14.6 pounds of fish and seafood per year in total. In 2004, catfish consumption was 1.1 pounds when total seafood consumption for Americans was 16.6 pounds. The U.S. catfish industry has been on a contracting course since a high mark in 2003 when 662 million pounds of round weight (*i.e.,* live weight) catfish were processed. In 2013, 334 million pounds were processed, up 33.4 million pounds (11 percent) from 300 million pounds processed in 2012; but a 50 percent decrease since the 2003 peak.
- In 2002 there were more than 2200 catfish operations with sales and distribution. By 2012, that number was down by nearly 50 percent to about 1200 operations (NASS). There were 624 domestic producers reported by NASS in January 2013 down from 718 in 2012 and down from more than 1800 in 1989. Low prices and prior years of reduced production and processing have led to hatchery operators reducing their number of fingerlings and broodstock in stock.
- Imports of frozen Siluriformes fish fillets increased by 44 million pounds (18 percent) to 281 million pounds in 2013; and imports now account for 75 percent of all U.S. sales of frozen Siluriformes fish fillet product.
- There were 71,725 acres of water in U.S. catfish production in January 2014, down 14 percent from 2013. Current production acreage for the top three catfish producing states, Alabama, Arkansas and Mississippi, was down 10,925 acres (15 percent) to 64,075 acres. There were 196,760 acres of water in U.S. catfish production in January 2002 (NASS).
- The average price received by domestic producers was $0.974 per pound in 2013, down $0.002 per pound from the 2012 average price of $0.976 per pound. In 2013 there was a $0.294 per pound difference between high (November, $1.113 per pound) and low (January, $0.819 per pound) pond bank prices received during the year.
- Domestic in-pond inventories of foodsize fish in January 2014 were down 10 percent from January 2013 levels. Stocker inventory was down 14 percent from January 2013 levels. Fingerling weight (and number) inventory was up 4 percent (and down 21 percent) from January 2013 levels. Broodfish pounds were up 5 percent.
- Domestic catfish feed prices (32 percent protein) in 2013 averaged $483/ton, up $14/ton (3 percent) over the 2012 average feed price of $469/ton. Of note, 2013 feed prices peaked in July ($494/ton) while the lowest feed price in 2013 occurred in November ($425/ton).
- The average wholesale price received by domestic catfish processors was $3.04 per pound in 2013, down $0.04 per pound from the 2012 average price of $3.08 per pound. In 2013 there was a $0.60 per pound difference between high (October, $3.36 per pound) and low (January, $2.76 per pound) prices received during the year.

For the affected United States domestic industry, FSIS projects that there are 624 operating Siluriformes fish farms and fish hatcheries; 18 establishments that slaughter and conduct primary processing of Siluriformes fish and Siluriformes fish products; and 200 establishments that are (1) further or secondary processors of only Siluriformes fish and Siluriformes fish products, (2) live-fish loaders/haulers/wholesalers of Siluriformes fish, (3) wholesalers/brokers/importers/exporters of Siluriformes fish and Siluriformes fish products, and (4) Siluriformes fish feed mills. In 2012 the number of catfish operations with sales and distribution numbered 1200. In 2013, the number of catfish operations with sales and distribution numbered 842. See Table 5, below, for details.

The Agency based those projections on the USDA National Agricultural Statistics Service (NASS) (2013–2014 Catfish Production Report); Food and Drug Administration (FDA) (2014); [14] the Dun and Bradstreet (DNB) business database (2014); import records of the U.S. Department of Homeland Security (DHS) Customs and Border Protection (CBP) (2009–2013); [15] and the U.S. Census Bureau Economic Census (2012).

D. Alternative Regulatory Approaches Considered

Initially, FSIS considered two basic regulatory approaches to Siluriformes fish and Siluriformes fish products inspection: (1) A more command-and-control approach, or (2) the Pathogen Reduction/Hazard Analysis and Critical Control Points Systems (PR/HACCP) approach the Agency adopted in 1996 (61 FR 38806; July 25, 1996). FSIS, however, rejected the command-and-control approach in 1996 with the adoption of the Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) Systems final rule (61 FR 38806; Jul. 25, 1996). Moreover, command-and-control approaches are generally disfavored, while less burdensome, more flexible approaches are generally preferred, under Executive Order 12866 and OMB Circular A–4.

For the final rule, the Agency is adopting for Siluriformes fish and Siluriformes fish products, as it has for meat and poultry products, the PR/HACCP approach to inspection which focuses on the verification of an establishment's food safety system, which consists of an establishment's HACCP plan, Sanitation SOPs, and prerequisite programs.

Further, FSIS considered two regulatory alternatives for the PR/HACCP approach:

1. The first alternative considered is the same as the final rule except the Agency implements this alternative with additional assignments of inspection program personnel (IPP) at fish ponds, fish hatcheries, fish feed mills, processing-only establishments, and for live-fish capturing/loading/transporting to the slaughter establishments. Under this alternative, FSIS would implement the regulation in a manner consistent with previous

[13] Hanson, T and D. Sites. ''2013 U.S. Catfish Database''. Fisheries and Allied Aquacultures Department Series No. 1. Alabama Agricultural Experiment Station. Auburn University. Auburn, Alabama. April 2014. Sources: USDA National Agricultural Statistics Service (NASS) and Mississippi Agricultural Statistics Service (MASS).

[14] Email correspondence between the U.S. Food and Drug Administration and the Food Safety and Inspection Service. February 26, 2014.

[15] U.S. Department of Homeland Security (DHS) Customs and Border Protection (CBP) import records of 2009 through 2013.

rulemaking proposals.[16] The additional cost of this alternative to the Agency would be as outlined in the published PRIA (scenario 1) of the Proposed Rule, and would add approximately $13 million annualized cost (7 percent interest over 10 years)) to the final rule. We would not expect additional potential benefits of increased FSIS inspection on reducing illnesses, beyond those additional potential benefits from the implementation of the final rule.

2. The second alternative considered is the same as the final rule except the Agency implements the final rule in three phases of 18 months for each phase, over a total of 4.5 years. Under this alternative, FSIS would implement the regulation in a manner consistent with previous rulemaking proposals.[17] Presumably that would limit the prevention of salmonellosis cases in the first three years relative to the first alternative.

That delay in implementation would have additional direct costs to the domestic industry of paying for contracted certification of fish and fish products for some of the affected facilities in order to meet stipulations in purchase contracts, such as with large grocery chains. The industry may be asked to initiate and maintain third-party inspection/auditing services (*e.g.,* USDC/NOAA/NMFS) for a period of time until FSIS IPP are deployed, and, therefore, accruing additional costs (*i.e.,* not accruing the projected cost-savings that would result from an earlier implementation of the final rule), such as for these third-party inspection/auditing services. The additional cost of this alternative to the industry and the Agency would be as outlined in the proposed rule (scenario 1), and would add approximately $0.03 million annualized cost (7 percent interest over 10 years) to the final rule. It may also delay the potential benefits of increased FSIS inspection and detection on reducing illnesses. An extended transitional period may reduce the expected minimal costs to foreign entities. Foreign producers do not need to gather and submit information to FSIS. Rather, at the beginning of the transitional period foreign governments that wish to continue exporting Siluriformes products to the United States will have to submit documentation showing that they are compliant with FDA requirements and a list of establishments that currently export Siluriformes products to this country. By the end of the transitional period, they will need to submit information to FSIS showing that they maintain an equivalent inspection system for such product. This transitional period will provide FSIS more time to work with these governments to provide guidance on what they need to submit. In addition, FSIS will have time to follow up with the country, if FSIS has questions or needs additional information. FSIS's efforts should lessen the possibility of trade disruptions, thereby minimizing the costs to foreign producers and any effects on the availability of product.

E. Expected Cost of the Final Rule

The final rule establishes all fish of the order Siluriformes as an amenable species. This is Scenario #1 in the proposed rule. The final rule, however, is to be implemented in 18 months, as outlined above in Section XII.

In the proposed rule, the Agency discussed that, since the domestic fish industry, including Siluriformes, must comply with the Food and Drug Administration's Seafood Hazard Analysis Critical Control Point (HACCP) and other regulatory requirements, and that some of the domestic establishments that slaughter fish of the order Siluriformes contract with the USDC/NOAA/NMFS for voluntary, fee-for-service inspection and certification program, the Agency thinks, from observations during site visits, that many of the domestic Siluriformes fish and Siluriformes fish products industry would be compliant with many of the proposed requirements.

FSIS projects that all domestic Siluriformes fish and Siluriformes fish products establishments will be in compliance with the requirements for Sanitation SOPs and HACCP according to the implementation schedule of the final rule. From discussions with industry experts in the Cooperative Extension Services and USDC/NOAA/NMFS, FSIS believes that a significant share of the domestic Siluriformes fish and Siluriformes fish products industry is compliant with many of the individual final rule measures.[18] Even though compliance rates for some HACCP-related activities may be relatively high, the performance of HACCP systems depends on how well all the elements—hazard analysis, monitoring of critical control points and critical limits, recordkeeping, process control testing, and verification—are being performed. In addition, the provisions of the final rule have additional costs to the domestic industry such as for meeting sanitation requirements (SSOP), new training, new labels[19] for Siluriformes fish and Siluriformes fish products, new government office space and equipment, new equipment and operating costs for live fish transportation/hauling, and for new reinspection at import establishments.

The details of projected additional direct costs to the domestic industry, including the annual cost-savings of reduced payments of inspection fees to USDC/NMFS because of the implementation of the final rule are available at: *http://www.fsis.usda.gov/wps/wcm/connect/63387be5-ca8e-442d-b047-f031f29a8a47/Silurifomes-RA.pdf?MOD=AJPERES.* A summary table of the costs is included in Table 3 (below). FSIS projects that the annualized cost to these domestic industries is $326.55 thousand, at a 7 percent discount over 10 years. The projected additional annualized cost to these domestic industries is $317.78 thousand, at a 3 percent discount over 10 years.

At a 7-percent discount rate over 10 years, the projected additional annualized average net direct cost of the final rule provisions to the Siluriformes fish and Siluriformes food products domestic supply-chain industries is $0.0008 ($326.55 thousand/388,000 thousand pounds) per pound of aggregate Siluriformes fish and Siluriformes fish food products processed, on average yearly, in 2011, 2012, and 2013 (the last 3-year average of domestic and imported Siluriformes fish products), according to the USDA National Agricultural Statistics Service (NASS),[20] [21] [22] and the import records of the U.S. Department of Homeland Security (DHS).[23] The additional average net direct cost of the provisions to the Siluriformes fish food products domestic industry compares to the

[16] ''Mandatory Inspection of Ratites and Squabs.'' May 7, 2001 (66 FR 22899).

[17] ''Mandatory Inspection of Ratites and Squabs.'' May 7, 2001 (66 FR 22899).

[18] For more information regarding the difference, see the Proposed Regulatory Impact Analysis, Table 2.

[19] FDA March 2011 Labeling Cost Model.

[20] Source: Catfish Processing Reports, NASS, USDA. 2011–2013.

[21] Hanson, T and D. Sites. ''2012 U.S. Catfish Database''. Fisheries and Allied Aquacultures Department Series No. 1. Alabama Agricultural Experiment Station. Auburn University. Auburn, Alabama. March 2013. Sources: USDA National Agricultural Statistics Service (NASS) and Mississippi Agricultural Statistics Service (MASS).

[22] Hanson, T and D. Sites. ''2013 U.S. Catfish Database''. Fisheries and Allied Aquacultures Department Series No. 1. Alabama Agricultural Experiment Station. Auburn University. Auburn, Alabama. April 2014. Sources: USDA National Agricultural Statistics Service (NASS) and Mississippi Agricultural Statistics Service (MASS).

[23] U.S. Department of Homeland Security (DHS) CBP import records of 2009 through 2013.

average price received by domestic processors for domestic aggregate catfish (of the order Siluriformes) food products that was $3.04 per pound, in 2013, according to the NASS publication (2013).

These additional regulatory costs compare to an estimated direct cost of about $0.01 per pound of meat and poultry associated with the Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) rule of 1996.[24]

TABLE 3—SUMMARY, PROJECTED ADDITIONAL AVERAGE DIRECT COSTS [a] [b] TO THE DOMESTIC INDUSTRY OF THE FINAL RULE MEASURES

New measure	One-time	Recurring (savings)	Annualized total costs (savings)	
			7 percent	3 percent
Industry Costs:				
Sanitation SOPs	.....	.....	$42,283	$42,122
HACCP Plans—Validation	.....	.....	160,435	156,512
Pre-Harvest Actions—for Producers	$0	$60,971	60,971	60,971
Pre-Harvest Actions—for Haulers	86,400	18,355	29,851	28,189
Labels	131,670	13,398	30,918	28,384
Government Office Space and Equipment	16,500	7,200	9,396	9,078
Re-inspection at Import Establishments	8,910	27,477	28,663	28,492
Other—Reduced Payments	0	(35,970)	(35,970)	(35,970)
Sub-Total Industries Costs	.....	.....	326,548	317,777
Agency Costs:				
Additional Costs to FSIS Inspection	.....	.....	2,604,402	2,587,217
Reduced Costs to FDA	.....	150,000	(150,000)	(150,000)
Reduced Costs to Commerce Dept NOAA NMFS	.....	(1,340,000)	(1,340,000)	(1,340,000)
Sub-Total Agency Additional Costs	.....	.....	1,114,402	1,097,217
Total Net Costs	.....	.....	1,440,949	1,414,995

[a] Numbers in the table are rounded. Therefore, a total may not equal the sum of its parts.

[b] Because the fish covered by this rulemaking present a new area of inspection for FSIS, there is a potential for the costs that the Agency is projecting to change during implementation. While FSIS believes that it can absorb at least some of the work for processing plants within existing patrol assignments, FSIS will not be able to completely validate this judgment until inspectors begin performing the inspections, and the agency is able to evaluate the workload that results. The Agency will not be able to make this final assessment until completion of the implementation phase.

F. Costs to Foreign Entities

1. Foreign Governments

In order for a foreign establishment to be eligible to export Siluriformes fish products to the United States, FSIS must first determine if the regulatory system under which the foreign establishment operates is equivalent to the United States regulatory system. FSIS used U.S. Customs and Border Protection entry data from the period of January 1, 2009 to December 31, 2013 [25] to assess the number of countries currently exporting Siluriformes products to the United States. During that time period, 35 countries exported Siluriformes products to the United States. Of those, 26 registered fewer than 15 entries into the United States during that same period. The remaining nine countries (Table AA) registered between 30 and 24,474 shipments.

TABLE AA—TOTAL NUMBER OF SHIPMENTS TO THE UNITED STATES, SELECT TRADING PARTNERS, CY 2009—2013

Country of origin	2009	2010	2011	2012	2013	Total # shipments
CAMBODIA	125	53	33	3	.....	214
CANADA	265	232	232	205	151	1,085
CHINA	538	434	269	200	353	1,794
INDONESIA	19	8	3	.....	.....	30
MALAYSIA	24	12	2	3	1	42
MEXICO	33	30	7	9	1	80
SPAIN	13	17	23	8	.....	61
THAILAND	349	204	89	44	48	734
VIETNAM	2,603	3,094	5,480	6,741	6,556	24,474

The cost to a country of maintaining an equivalent inspection system as a result of any incremental change to its existing regulatory framework is likely to be minimal for several reasons. First, several of the governments currently exporting to the United States maintain a meat or poultry inspection system equivalent to that of the United States

[24] M. Ollinger, V. Mueller. 2003. Managing for Safer Food: The Economics of Sanitation and Process Controls in Meat and Poultry Establishments. Agricultural Economics Report 817. Economics Research Service, U.S. Department of Agriculture. Washington, D.C.

[25] Customs and Border Protection, Data pulled for OPPD by OFO/Recall Management and Technical Analysis Staff on February 18, 2014.

and are therefore aware of FSIS requirements.[26] Second, many foreign governments maintain inspection systems similar to that required by the FSIS in order to have access to other markets, *e.g.* European Union [27] and Canadian markets.[28] Third, FSIS has outlined a plan for phased implementation to mitigate disruptions. Finally, FSIS and FDA have established a Memorandum of Understanding [29] to assist our trading partners with the transition.

2. Foreign Establishments

Due to limitations in the data, FSIS ability to estimate the number of manufacturers shipping Siluriformes products to the United States is limited. In order to assess the impact on foreign establishments, FSIS queried the U.S. Customs and Border Protection, FDA, and NOAA for data related to the number of manufacturers currently exporting Siluriformes products to the United States. Based on the previously cited U.S. Customs and Border Protection entry data, there are an estimated 314 manufactures from the nine countries mentioned above that export Siluriformes products to the United States.[30] However, it is unclear from the data source mentioned above if these manufacturers exclusively ship Siluriformes products. Based on a FDA report to Congress,[31] in 2008 there were approximately 14,900 foreign seafood firms registered to export product to the U.S. However, it is impossible to discern which of these firms deal with Siluriformes. While NOAA provided its December 2014 USDC Approved Establishments publication,[32] due to data limitations it is impossible to determine which, if any, of these facilities export Siluriformes products to the United States. Even so, because foreign producers are currently meeting FDA standards, FSIS assumes that all establishments will continue to export Siluriformes product to the United State through the recognition of their respective national inspection systems and that the incremental costs to these establishments associated with this rule will be minimal. In addition, FSIS considered potential costs associated with reinspection at import facilities and has determined that it is not expected to cause an increase in spoilage because of the time needed to conduct the reinspection. The product arrives and is kept frozen.

G. Associated Costs to U.S. Consumers

FSIS has assumed that the transitional costs to foreign governments and producers are minimal. However, the Agency has also considered the possibility that any costs to these entities could be passed along to consumers. A review of the demand and supply literatures for Siluriformes yields ambiguous results. To start, given the numerous substitutes for Siluriformes filets, U.S. consumer demand for Siluriformes is expected to be elastic,[33] indicating downward pressure on price. On the supply side, the United States International Trade Commission (USITC) determined the domestic supply of frozen Siluriformes filets to be elastic.[34] Thus, any increase in price would be outpaced by an increase in domestic supply. This relationship puts downward pressure on price. Both volume-sold and retail-price data for 2005–2010 indicate that tilapia, pollock, and whiting, are competitive substitutes for both domestic and foreign Siluriformes. Competition for market share between these substitutes is expected to put downward pressure on retail prices.[35] Further, because foreign producers derive a competitive advantage through charging low prices, they are disincentivized from increasing the price they seek.[36] On the supply side, the United States International Trade Commission (USITC) determined the domestic supply of frozen Siluriformes filets, a substitute for imported Siluriformes filets, to be elastic, indicating that domestic processors have the flexibility to response to a change in demand brought about by a change in imports.[37] As such, any increase in price of imported Siluriformes would be curtailed by an increase in domestic supply. All else held equal, higher elasticity of supply leads to a greater portion of regulatory costs being borne by consumers (in the form of price increases) than by producers (in the form of decreases in profit). However, the combination of elastic demand and elastic supply suggests that any regulatory cost burdens will be shared between consumers and producers. Elastic demand, the presence of many substitutes, and the fact that foreign suppliers depend on low market prices for competitive advantage indicate that domestic Siluriformes prices are not expected to increase, whereas elastic supply would offset this increase to an undetermined degree.

H. Expected Budgetary Impacts on FSIS and Other Government Agencies

For the Government agencies, Table 3 shows the expected budgetary impacts that are the additional annualized average direct costs to FSIS and the reduced annualized average direct costs (*i.e.,* a direct cost savings benefit) to FDA and the United States Department of Commerce's National Oceanic and Atmospheric Administration/National Marine Fisheries Service (USDC/NOAA/NMFS) with the implementation of the final rule.

The annualized cost to the Government Agencies is $1,114.40 thousand, at a 7 percent discount over 10 years. The projected annualized cost to the government is $1,097.22 thousand, at a 3 percent discount over 10 years.

I. Break-Even Analysis

1. Possible Health Benefits—Assessment Break-Even Analysis

FSIS conducted an assessment of the potential risk to human health of Siluriformes fish consumption, using the example of *Salmonella* spp.

[26] At present Canada, China, Mexico, and Spain have equivalent status for at least one FSIS regulated product.

[27] The EU has approved importation of fish products from Vietnam, China, Canada, Thailand, Mexico, Spain, Malaysia, and Indonesia. This approval was granted after each country and its competent authority were evaluated for meeting specific requirements including residue monitoring and *Salmonella* spp. controls.

[28] Canada Food Inspection Agency, Import Information By Jurisdiction, Retrieved from *http://www.inspection.gc.ca/food/fish-and-seafood/imports/by-jurisdiction/eng/1373433337535/1373433338754.*

[29] Memorandum of Understanding Between The Food Safety and Inspection Service United States Department of Agriculture And The Food and Drug Administration United States Department of Health and Human Services. Retrieved from *http://www.fsis.usda.gov/wps/wcm/connect/8675a5cb-7bca-4a8f-a563-7788adceb583/MOU-FSIS-FDA-Fish-Products.pdf?MOD=AJPERES.*

[30] Customs and Border Protection, Data pulled for OPPD by OFO/Recall Management and Technical Analysis Staff on February 18, 2014.

[31] FDA Report to Congress. 20 November 2008. The Secretary's Report to Congress on Enhanced Aquaculture and Seafood Inspection. *http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm150954.htm.*

[32] NOAA USDC Approved Establishments. December 2014. *http://www.seafood.nmfs.noaa.gov/pdfs/participants_list14.pdf.*

[33] USITC. Certain Frozen Fish Fillets from Vietnam. Investigation No. 731–TA–1012ITC, 2009. Retrieved from *http://www.usitc.gov/publications/701_731/pub4083.pdf.*

[34] Ibid.

[35] Dey, M.M., A.G. Rabbani, K. Singh, and C.R. Engle. 2014. Determinants of Retail Price and Sales Volume of Catfish Products in the United States: An Application of Retail Scanner Data, Aquaculture Economics & Management, 18:2, 120–148.

[36] Singh, K and M.M. Dey. 2011. International competitiveness of catfish in the U.S. market: A constant market share analysis. Aquaculture Economics & Management. 15:3, 214–229.

[37] USITC. Certain Frozen Fish Fillets from Vietnam. Investigation No. 731–TA–1012ITC, 2009. Retrieved from *http://www.usitc.gov/publications/701_731/pub4083.pdf.*

contamination. It focuses on exposure to *Salmonella* spp. because a broad hazard identification identified *Salmonella* spp. as one of the few potential hazards that there was sufficient data to assess in Siluriformes. The risk assessment provides different scenarios for the benefits that might result from an inspection system in Siluriformes similar to FSIS's inspection system for poultry.

In addition, FSIS is particularly interested in *Salmonella* spp. because, among foodborne pathogens in FSIS-regulated products, it is the most common cause of hospitalizations and fatalities, and therefore a serious concern in the United States.[38] We also note that there is evidence that at least one outbreak of human salmonellosis may have been related to Siluriformes consumption. FSIS acknowledges, however, that applying its empirical evidence describing the effectiveness of an FSIS inspection program for *Salmonella* spp. control in another regulated species (*i.e.,* poultry) carries with it significant limitations. Therefore, we use *Salmonella* spp. to present potential benefits in this break-even analysis, but we do not directly use the findings of the risk assessment to monetize the expected benefits of the FSIS Siluriformes inspection system.

Epidemiological evidence suggests that salmonellosis leads to both acute and chronic illnesses. The acute illness that accompanies salmonellosis generally causes gastrointestinal symptoms that can lead to lost productivity and medical expenses. In rare instances, salmonellosis may result in acute or chronic arthritis. Arthritis is characterized by limited mobility, pain and suffering, productivity losses, and medical expenditures. Finally, salmonellosis can result in death. The risk of death appears to be higher in the elderly, children, and people with compromised immune systems. FSIS has estimated the costs of these severity levels.

In summary, in Table 4 (below), for the final rule, FSIS projects the additional annualized average net direct cost to the domestic supply industry and the Government. The annualized cost to the industry and Government is $1,440.95 thousand, at a 7-percent discount rate over 10 years. At a 3-percent discount rate over 10 years, the annualized cost to the industry and Government is $1,414.99 thousand.

Applying the methodology of the USDA Economic Research Service (ERS) in projecting a monetary value for each case, FSIS uses an annualized average direct cost of $2,423 (in 2010 dollars) per new average case of salmonellosis.[39] Thus, under the final rule for all fish of the order Siluriformes, using the projected annualized cost of $1,440.95 thousand (at a 7 percent discount rate over 10 years), and the estimated average direct cost of an average case of salmonellosis of $2,423 (in 2010 dollars), if an average of 595 domestic cases were averted, the additional annualized average direct costs would be equal to the additional annualized average public health benefits (salmonellosis domestic cases averted) of the final rule. At a 3-percent discount rate over 10 years, using the projected annualized cost of $1,414.99 thousand and the average direct cost of an average case of salmonellosis of $2,423 (in 2010 dollars), if an average of about 584 cases were averted, the additional annualized average total net direct costs would be equal to the additional annualized average total public health benefits (salmonellosis illnesses averted) of the final rule. The assessment of the potential public health benefit of the final rule is from the FSIS Risk Assessment (December 2014). That illness estimate includes illnesses from consumption of both domestic and imported Siluriformes.

Because of data limitations, this RIA does not factor in the cost to foreign entities in a quantitative analysis. A qualitative analysis of market elasticities, foreign entities competitive advantages, and substitute goods, however, indicates that the cost to foreign entities is not expected to affect the break even analysis.

FSIS's primary cost estimate, used in the calculation above, includes zero costs to foreign establishments (and zero pass-through of foreign costs to U.S. consumers). If this estimate is correct, it is an indication that foreign establishments will not change their practices as a result of this rule, and thus there will be no health benefits to U.S. consumers of imported *Siluriformes;* in other words, all the illness avoidance in the break-even result would need to be associated with consumption of domestic *Siluriformes.* If the zero foreign cost assumption is incorrect, then the level of illness avoidance that would be necessary for the rule to break even would be higher—and potentially much higher—than the estimates shown in this section. Of course, once the program is implemented, FSIS will have better data on true illness avoidance and on potential reductions in chemical residue hazards.

There is another reason to believe the break-even level of illness avoidance is higher than shown here. The actions assessed in the cost analysis are mostly related to knowledge of potential hazards, rather than the actual addressing of the hazards (for example, by discarding bad fish or taking a corrective action when an establishment that is newly monitoring a critical control point detects a deviation from an established critical limit). The latter is necessary for achieving health benefits and thus there are either costs—specifically, the costs of addressing hazards—currently omitted from the break-even calculation or the rule will not achieve the previously-calculated break-even point due to yielding negligible benefits. There are also benefits to establishments and consumers that FSIS cannot quantify at this time. For example, we cannot quantify the gains in consumer confidence that may result from better quality product, more accurate labeling, or better control over pathogens or residues.

The assessment of the potential public health benefit of the final rule is from the FSIS Risk Assessment (December 2014). However, we note that under FSIS HACCP inspection as described in the risk assessment, *Salmonella* prevalence domestically has varied over time within meat and poultry product classes and among classes and establishment sizes. In a minority of cases, *Salmonella* prevalence has proved resistant to improvement. Therefore, the difference in *Salmonella* prevalence witnessed between the 1994–95 and 2007–08 microbiological baselines for broilers may not be indicative of the future trends in the microbiological quality of catfish, and substantial time and adaptations may be required before improvements are realized. However, even if the estimated public health benefits do not achieve

[38] CDC. CDC Estimates of foodborne illness in the United States. 2011. *http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html.*

Batz, M. B., S. Hoffmann, and J. G. Morris, Jr. 2012. Ranking the disease burden of 14 pathogens in food sources in the United States using attribution data from outbreak investigations and expert elicitation. Journal of Food Protection. V75. 7. P1278–1291 and Scharff, R. L. 2012. Economic burden from health losses due to foodborne illness in the United States. Journal of Food Protection. V75. 1. P123–131.

[39] FSIS assumes that the average cost of illness is $2,423 for a clinical case of salmonellosis, according to the USDA Economic Research Service (ERS) cost-calculator: The average direct cost of salmonellosis illnesses. ($2,423 per case in 2010 dollars) was developed using the USDA, ERS Foodborne Illness Costs Calculator: *Salmonella* (June 2011). FSIS updated the ERS calculator to include Scallan case distribution for salmonellosis. Scallan, E., Hoekstra, R., Angulo, F., *et al.* (2011). Foodborne Illness Acquired in the United States—Major Pathogens. *Emerging Infectious Diseases,* 17 (1), pp. 7–15.

the break-even point, FSIS inspection of Siluriformes is mandated by law and non-discretionary.

TABLE 4—PROJECTED SUMMARY ADDITIONAL ANNUALIZED AVERAGE NET DIRECT COSTS AND BREAK-EVEN ASSESSMENT

Affected sectors of the domestic economy	Additional annualized cost, over 10 years, discounted $thousands		Assessment of Salmonellosis illnesses reduced needed to break even on annualized costs, over 10 years and discounted—in cases averted annually	
	7 percent	3 percent	7 percent	3 percent
Siluriformes Fish Industry	$326.55	$317.78	135	131
Federal Government Agencies	1,114.40	1,097.22	460	453
Total	1,440.95	1,414.99	595	584

Footnotes: The FSIS estimate for the average cost of Salmonellosis illnesses ($2,423 per case—in 2010 dollars) was developed using the USDA, ERS Foodborne Illness Costs Calculator: *Salmonella* (June 2011). FSIS updated the ERS calculator to include Scallan case distribution for salmonellosis. Scallan, E., Hoekstra, R., Angulo, F., *et al.* (2011). Foodborne Illness Acquired in the United States—Major Pathogens. Emerging Infectious Diseases, 17 (1), pp. 7–15.

2. Health Benefits—Removing Adulterated Products From the Market

Furthermore, as outlined in the hazard analysis section of the FSIS risk assessment, there is the potential for hazardous chemicals to be present in Siluriformes. For example, in 2008, 9% of 150 and 2% of 53 imported catfish samples tested by FDA tested positive for malachite green and gentian violet, respectively. There is evidence that those chemical are mutagenic or carcinogenic, and FDA has banned the use of both of those chemicals as aquaculture drugs or pesticides. The FSIS National Residue Program will target chemical hazards (identified as hazards of concern in the hazard identification of the FSIS risk assessment) and conduct testing with the goal of removing adulterated products from the market. As a result, although the number of illnesses that could be avoided by removing Siluriformes adulterated with illegal or violative concentrations of chemicals could not be quantified—the fish consuming public may accrue additional unquantified public health benefits from the removal of those products from the market.

J. Regulatory Flexibility Act Assessment

The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601–602), the final rule will not have a significant impact on a substantial number of small entities in the United States.

For the 842 affected entities of the U.S. domestic industry, we project an average of 624 fish farms and fish hatcheries; 18 establishments that slaughter and conduct primary processing of Siluriformes fish and Siluriformes fish products; and 200 facilities that are for (1) further/secondary processing-only of Siluriformes fish and Siluriformes fish products, (2) live-fish loaders/haulers/wholesalers of Siluriformes fish, (3) wholesalers/brokers/importers/exporters of Siluriformes fish, and (4) Siluriformes fish feed mills.

We based this on USDA NASS statistics (2013), Food and Drug Administration (FDA) (2014), import records of the U.S. Department of Homeland Security (DHS) (2009–2013),[40] Dun and Bradstreet (DNB) business database (2014), and the United States Census Bureau Economic Census (2012). See Table 5 for the details. Most of these establishments or entities meet the Small Business Administration (SBA) size criteria for small businesses in the food manufacturing classification or other categories, in that they have 500 or fewer employees. The final rule would affect a substantial number of these small entities because the requirements would apply to all processing establishments in the Siluriformes fish and Siluriformes fish food processing industry that ship their products in interstate commerce and would to some extent pertain to fish-farming practices. As stated above in the cost section, the projected annualized cost to the domestic Siluriformes fish supply chain industries of the provisions of the final rule is $0.0008 per pound of aggregate processed Siluriformes fish and Siluriformes fish food products. The additional average direct cost per pound of the provisions to the Siluriformes fish and Siluriformes fish food products domestic industry compares to the average wholesale net price per pound received by domestic processors for frozen and fresh catfish food products that was $3.04 per pound, in 2013, according to the USDA, National Agricultural Statistical Service (NASS).[41]

Furthermore, this final rule will likely not have a significant effect on a substantial number of businesses that import Siluriformes fish and Siluriformes fish products. FSIS projects that those companies will continue to import quantities of Siluriformes fish and Siluriformes fish products. Nevertheless, for the final rule, imported Siluriformes fish and Siluriformes fish products will be required to be inspected under a foreign system that is equivalent to that of the United States and be processed at establishments that the foreign inspection authority has certified as complying with United States requirements.

[40] U.S. Department of Homeland Security (DHS) Custom and Border Protection (CBP) import records of 2009 through 2013.

[41] Wholesale price, gross value FOB plant. Source: Catfish Processing Reports, NASS, USDA. 2009–2013.

TABLE 5—PROJECTED NUMBER OF SILURIFORMES FISH AND SILURIFORMES FISH PRODUCTS ENTITIES IN THE DOMESTIC SUPPLY CHAIN

Siluriformes fish supply chain type (NAICS code *)	Number of establishments (FRIA)	Percent SBA small
Slaughter and Primary Processors—Food Manufacturing (311712)	18	78
Further/Secondary Processors-only—Food Manufacturing (311711)	10	100
Producers—Farms, Ponds & Fish Hatcheries (112511	624	100
Feed Mills (311119)	14	86
Loaders/Haulers(/Wholesalers)—Transporters Livestock Trucking (4842202)	11	100
(Product) Wholesalers or Brokers, Importers and Exporters (424460)	165	100
Total	842	

a. The Small Business Administration defines a small business in food manufacturing classification processing as an entity that is independently owned and operated, is organized for profit, is not dominant, and has 500 or fewer employees.

* North American Industry Classification System (NAICS) code, NAICS Association, 2002

Sources: National Agricultural Statistics Service (NASS) (2013), NASS Census of Agriculture 2014, US Food and Drug Administration (FDA) (2014), Dun and Bradstreet (DNB) (2014), US Census Bureau Economic Census (2012), Customs and Border Protection (CBP) import records of the U.S. Department of Homeland Security (DHS) (2009–2013), and catfish experts from the cooperative extension service and the catfish industry.

XIV. Paperwork Reduction Act

As provided by the 2014 Farm Bill (Section 12106(b)(3)), referencing Section 1601(c)(2), FSIS is exempt from filing an information collection request under the Paper Work Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*)

XV. E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601 *et seq.*) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

XVI. Executive Order 12988, Civil Justice Reform

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

XVII. Expected Environmental Impact

Each USDA agency is required to comply with 7 CFR part 1b of the Departmental regulations, which supplements the National Environmental Policy Act (NEPA) regulations published by the Council on Environmental Quality. Under these regulations, actions of certain USDA agencies and agency units are categorically excluded from the preparation of an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) unless the agency head determines that an action may have a significant environmental effect (7 CFR 1b.4(b)). FSIS is among the agencies categorically excluded from the preparation of an EA or EIS (7 CFR 1b.4(b)(6)).

Currently, fish establishments are required to meet all local, State, and Federal environmental requirements. Under this final rule, fish establishments will still be required to meet all local, State and Federal environmental requirements. Thus, FSIS has determined that this final rule will not have significant individual or cumulative effect on the human health environment. Therefore, this regulatory action is appropriately subject to the categorical exclusion from the preparation of an EA or EIS provided under 7 CFR 1b.4(b)(6) of the USDA regulations. In accordance with 7 CFR 1b.3(c), FSIS will continue to scrutinize its activities to determine continued eligibility for categorical exclusion.

XVIII. Executive Order 13175 Indian Tribal Governments

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

XIX. USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How to File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf*, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250–9410, Fax: (202) 690–7442, Email: *program.intake@usda.gov*.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

XX. Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: *http://www.fsis.usda.gov/federal-register*.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders.

The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *http://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

List of Subjects

9 CFR Part 300

Meat inspection.

9 CFR Part 441

Consumer protection standards, Meat and meat products, Poultry products, Fish and fish products.

9 CFR Part 530

Fish and fish products, Fish inspection.

9 CFR Part 531

Fish and fish products, Fish inspection.

9 CFR Part 532

Fish and fish products, Fish inspection, Reporting and recordkeeping requirements.

9 CFR Part 533

Fish and fish products, Fish inspection, Government employees.

9 CFR Part 534

Aquaculture, Fish and fish products, Fish inspection.

9 CFR Part 537

Fish and fish products, Fish inspection, Hazard Analysis and Critical Control Point (HACCP) Systems, Sanitation, Reporting and recordkeeping requirements.

9 CFR Part 539

Animal diseases, Fish and fish products, Fish inspection.

9 CFR Part 540

Fish and fish products, Fish inspection.

9 CFR Part 541

Fish and fish products, Fish inspection, Food labeling, Food packaging, Nutrition, Reporting and recordkeeping requirements, Signs and symbols.

9 CFR Part 544

Fish and fish products, Fish inspection, Food additives, Food packaging, Laboratories, Reporting and recordkeeping requirements.

9 CFR Part 548

Fish and fish products, Fish inspection, Food additives, Food packaging, Laboratories, Reporting and recordkeeping requirements, Signs and symbols.

9 CFR Part 550

Fish and fish products, Fish inspection, Reporting and recordkeeping requirements.

9 CFR Part 552

Fish and fish products, Fish inspection, Exports.

9 CFR Part 555

Fish and fish products, Fish inspection, Reporting and recordkeeping requirements, Transportation.

9 CFR Part 557

Fish and fish products, Fish inspection, Food labeling, Food packaging, Imports.

9 CFR Part 559

Fish and fish products, Fish inspection, Crime, Seizures and forfeitures.

9 CFR Part 560

Fish and fish products, Fish inspection, Intergovernmental relations.

9 CFR Part 561

Administrative practice and procedure, Fish and fish products, Fish inspection, Government employees.

For the reasons set forth in the preamble, 9 CFR chapter III is amended as follows:

Subchapter A—Agency Organization and Terminology; Mandatory Meat and Poultry Products Inspection and Voluntary Inspection and Certification

PART 300—AGENCY MISSION AND ORGANIZATION

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 21 U.S.C. 450–471, 601–695, 1031–1056; 7 U.S.C. 138–138i, 450, 1621–1627, 1901–1906; 7 CFR 2.7, 2.18, 2.53.

■ 2. Section 300.3(a) is revised as follows:

§ 300.3 FSIS organization.

(a) *General.* The organization of FSIS reflects the Agency's primary regulatory responsibilities: implementation of the FMIA, including fish of the order Siluriformes, the PPIA, and the EPIA. FSIS implements the inspection provisions of the FMIA, the PPIA, and the EPIA through its field structure.

* * * * *

SUBCHAPTER E—REGULATORY REQUIREMENTS UNDER THE FEDERAL MEAT INSPECTION ACT AND THE POULTRY PRODUCTS INSPECTION ACT

PART 441—CONSUMER PROTECTION STANDARDS: RAW PRODUCTS

■ 3. The authority citation for part 441 continues to read as follows:

Authority: 21 U.S.C. 451–470, 601–695; 7 U.S.C. 450, 1901–1906; 7 CFR 2.18, 2.53

■ 4. In § 441.10, remove the term ''Raw livestock and poultry'' and add in its place the term ''Raw livestock, poultry, and fish'' at the beginning of the first sentence of paragraph (a) and at the beginning of the first sentence of paragraph (b).

■ 5. A new Subchapter F, consisting of Parts 530 to 561, is added to Chapter III to read as follows:

Subchapter F—Mandatory Inspection of Fish of the Order Siluriformes and Products of Such Fish

Part

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PART 530—GENERAL REQUIREMENTS; DEFINITIONS

Sec.
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Authority: 7 U.S.C. 138f; 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 530.1 General.

(a) The regulations in this subchapter provide for the inspection of Siluriformes fish and fish products. The inspection and regulations are intended to prevent the sale, transportation, offer for sale or transportation, or receipt for transportation, in commerce of any fish or fish product that is capable of use as human food and is adulterated or misbranded at the time of the sale, transportation, offer for sale or transportation, or receipt for transportation.

(b) Fish as defined in this subchapter are amenable to the Act, including, as the Administrator may determine, to provisions of the Act in which other amenable species are named, except where the Act specifically excludes the provisions from applicability to fish.

§ 530.2 FSIS organization for inspection of fish and fish products.

The Food Safety and Inspection Service, U.S. Department of Agriculture, administers an inspection program for fish and fish products. The organization of FSIS and the principal offices of FSIS and their functions are described, and organizational terms defined, in 9 CFR part 300, subchapter A of this chapter. Section 300.3 lists the FSIS district offices and the geographic areas of the districts.

§ 530.3 Access to establishments.

The provisions of 9 CFR 300.6 apply to fish processing establishments and related industries as they do to other establishments subject to the FMIA.

PART 531—DEFINITIONS

Sec.
531.1 Definitions.

Authority: 7 U.S.C. 138f; 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 531.1 Definitions.

As used in this subchapter, unless otherwise required by the context, the following terms shall be construed, respectively, to mean:

Act. The Federal Meat Inspection Act, as amended, (34 Stat. 1260, as amended, 81 Stat. 584, 84 Stat. 438, 92 Stat. 1069, 106 Stat. 4499, 119 Stat. 2166, 122 Stat. 1369, 122 Stat. 2130, 21 U.S.C., sec. 601 *et seq.*).

Adulterated. This term applies to any carcass, part thereof, fish or fish food product under one or more of the following circumstances:

(1) If it bears or contains any such poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

(2)(i) If it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (other than one which is:

(A) A pesticide chemical in or on a raw agricultural commodity;

(B) A food additive; or

(C) A color additive which may, in the judgment of the Administrator, make such article unfit for human food;

(ii) If it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 408 of the Federal Food, Drug, and Cosmetic Act;

(iii) If it bears or contains any food additive which is unsafe within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act;

(iv) If it bears or contains any color additive which is unsafe within the meaning of section 706 of the Federal Food, Drug, and Cosmetic Act: Provided, That an article which is not deemed adulterated under paragraphs (2)(ii), (iii), or (iv) of this definition shall nevertheless be deemed adulterated if use of the pesticide chemical food additive, or color additive in or on such article is prohibited by the regulations in this subchapter in official establishments;

(3) If it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

(4) If it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(5) If it is, in whole or in part, the product of an animal which has died otherwise than by slaughter;

(6) If its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health;

(7) If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act;

(8) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefore; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

Amenable species. A species that is, and whose products are, subject to the Act and regulations promulgated under the Act, except as the Act may provide.

Animal food. Any article intended for use as food for dogs, cats, or other animals, derived wholly, or in part, from the carcass or parts or products of the carcass of any amenable species, except that the term animal food as used herein does not include:

(1) Processed dry animal food or

(2) Feeds for amenable species manufactured from processed by products of amenable species.

Applicant. Any person who requests inspection service, exemption, or other authorization under the regulations.

Biological residue. Any substance, including metabolites, remaining in fish at time of slaughter or in any of their tissues after slaughter as the result of treatment or exposure of the fish to a pesticide, organic or inorganic compound, hormone, hormone like substance, anthelmintic, or other therapeutic or prophylactic agent.

Capable of use as human food. This term applies to any carcass or part or product of a carcass of any fish unless it is denatured or otherwise identified as required by § 540.3 of this subchapter to deter its use as a human food, or it is naturally inedible by humans; *e.g.,* barbels or fins in their natural state.

Carcass. All parts, including viscera, of any slaughtered livestock.

Commerce. Commerce between any State, any Territory, or the District of Columbia, and any place outside thereof; or within any Territory not organized with a legislative body, or the District of Columbia.

Consumer package. Any container in which a fish product is enclosed for the purpose of display and sale to household consumers.

Container. Any box, can, tin, cloth, plastic, or any other receptacle, wrapper, or cover.

Dead fish. The body of a fish that has died otherwise than by slaughter.

Dying or diseased fish. Fish affected by any of the conditions for which the fish are required to be condemned under part 539 or other regulations in this subchapter.

Edible. Intended for use as human food.

Farm-raised. Grown under controlled conditions, within an enclosed space, as on a farm.

Federal Food, Drug, and Cosmetic Act. The Act so entitled, approved June 25, 1938 (52 Stat. 1040), and Acts amendatory thereof or supplementary thereto.

Firm. Any partnership, association, or other unincorporated business organization.

Fish. (1) For the purposes of this subchapter, any fish of the order Siluriformes, whether live or dead.

(2) The skeletal muscle tissue of fish. As applied to products of fish of the order Siluriformes, this term has a meaning comparable to that of ''meat'' in the meat inspection regulations (9 CFR 301.2).

Fish byproduct. Any fish part capable of use as human food, other than the skeletal muscle tissue, that has been derived from one or more fish.

Fish food product. Any article capable of use as human food that is made wholly or in part from any fish or part thereof; or any product that is made wholly or in part from any fish or part thereof, excepting those exempted from definition as a fish product by the Administrator in specific cases or by a regulation in this subchapter; upon a determination that they contain fish ingredients only in a relatively small proportion or historically have not been considered by consumers as products of the fish food industry, and provided that they comply with any requirements that are imposed in such cases or regulations as conditions of such exemptions to ensure that the fish meat or other portions of such carcasses contained in such articles are not adulterated, and that such articles are not represented as fish food products.

Fish product. Any fish or fish part; or any product that is made wholly or in part from any fish or fish part, except for those exempted from definition as a fish product by the Administrator in a regulation in this subchapter. Except where the context requires otherwise (*e.g.,* in part 540 of this subchapter), this term is limited to articles capable of use as human food.

Further processing. Smoking, cooking, canning, curing, refining, or rendering in an official establishment of product previously prepared in official establishments.

Immediate container. The receptacle or other covering in which any product is directly contained or wholly or partially enclosed.

Inedible. Adulterated, uninspected, or not intended for use as human food.

''Inspected and passed'' or ''U.S. Inspected and Passed'' or ''U.S. Inspected and Passed by Department of Agriculture'' (or any authorized abbreviation thereof). This term means that the product so identified has been inspected and passed under the regulations in this subchapter, and at the time it was inspected, passed, and identified, it was found to be not adulterated.

Label. A display of written, printed, or graphic matter upon the immediate container (not including package liners) of any article.

Labeling. All labels and other written, printed, or graphic matter:

(1) Upon any article or any of its containers or wrappers, or

(2) Accompanying such article.

Misbranded. This term applies to any carcass, part thereof, fish or fish food product under one or more of the following circumstances:

(1) If its labeling is false or misleading in any particular;

(2) If it is offered for sale under the name of another food;

(3) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word ''imitation'' and immediately thereafter, the name of the food imitated;

(4) If its container is so made, formed, or filled as to be misleading;

(5) If in a package or other container unless it bears a label showing:

(i) The name and place of business of the manufacturer, packer, or distributor; and

(ii) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; except as otherwise provided in part 317 of this subchapter with respect to the quantity of contents;

(6) If any word, statement, or other information required by or under authority of the Act to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(7) If it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by the regulations in part 319 of this subchapter unless:

(i) It conforms to such definition and standard, and

(ii) Its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;

(8) If it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by the regulations in part 319 of this subchapter, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(9) If it is not subject to the provisions of paragraph (7)(ii) of this definition unless its label bears:

(i) The common or usual name of the food, if any there be, and

(ii) In case it is fabricated from two or more ingredients, the common or usual name of each such ingredient, except as otherwise provided in part 317 of this subchapter;

(10) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as is required by the regulations in part 317 of this subchapter.

(11) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears a label stating that fact; except as otherwise provided by the regulations in part 317 of this subchapter; or

(12) If it fails to bear, directly thereon or on its containers, when required by the regulations in part 316 or 317 of this subchapter, the inspection legend and, unrestricted by any of the foregoing, such other information as the Administrator may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

Nonfood compound. Any substance proposed for use in official establishments, the intended use of which will not result, directly or indirectly, in the substance becoming a component or otherwise affecting the characteristics of fish food and fish products excluding labeling and packaging materials as covered in part 541 of this subchapter.

Official certificate. Any certificate prescribed by the regulations in this subchapter for issuance by an inspector

or other person performing official functions under the Act.

Official device. Any device prescribed by the regulations in part 312 of this subchapter for use in applying any official mark.

Official establishment. Any slaughtering, cutting, boning, fish product canning, curing, smoking, salting, packing, rendering, or similar establishment at which inspection is maintained under the regulations in this subchapter.

Official import inspection establishment. This term means any establishment, other than an official establishment as defined in this section, where inspections are authorized to be conducted as prescribed in part 557 of this subchapter.

Official inspection legend. Any symbol prescribed by the regulations in this subchapter showing that an article was inspected and passed in accordance with the Act.

Official mark. The official inspection legend or any other symbol prescribed by the regulations in this subchapter to identify the status of any article, fish, or fish product under the Act.

Packaging material. Any cloth, paper, plastic, metal, or other material used to form a container, wrapper, label, or cover for fish products.

Person. Any individual, firm, or corporation.

Pesticide chemical, food additive, color additive, raw agricultural commodity. These terms shall have the same meanings for purposes of the Act and the regulations in this subchapter as under the Federal, Drug, and Cosmetic Act.

Prepared. Slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.

Process authority. A person or organization with expert knowledge in fish production process control and relevant regulations. This definition does not apply to § 548.6 of this subchapter or to subpart G of part 318 of this chapter.

Process schedule. A written description of processing procedures, consisting of any number of specific, sequential operations directly under the control of the establishment employed in the manufacture of a specific product, including the control, monitoring, verification, validation, and corrective action activities associated with production. This definition does not apply to § 548.6 of this subchapter or to subpart G of part 318 of this chapter.

Producer. Any person engaged in the business of growing farm-raised fish.

Product. Any carcass, fish, fish product, or fish food product, capable of use as human food.

Program. The organizational unit within the Department having the responsibility for carrying out the provisions of the Act.

Program employee. Any inspector or other individual employed by the Department or any cooperating agency who is authorized by the Secretary to do any work or perform any duty in connection with the Program.

Slaughter. With respect to fish, intentional killing under controlled conditions.

State. Any State of the United States or the Commonwealth of Puerto Rico.

Territory. Guam, the Virgin Islands of the United States, American Samoa, and any other territory or possession of the United States.

U.S. Condemned. This term means that the fish, part, or product of fish so identified was inspected and found to be adulterated and is condemned.

U.S. Detained. This term applies to fish, fish products, and other articles which are held in official custody in accordance with section 402 of the Act (21 U.S.C. 672), pending disposal as provided in the same section 402.

U.S. Retained. This term means that the fish, part, or product of fish so identified is held for further examination by an inspector at an official establishment to determine its disposal.

United States. The States, the District of Columbia, and the Territories of the United States.

PART 532—REQUIREMENTS FOR INSPECTION

Sec.

Authority: 7 U.S.C. 138f; 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 532.1 Establishments requiring inspection; other inspection.

(a) No establishment may process or prepare fish, fish parts, or fish products capable of use as human food, or sell, transport, or offer for sale or transportation in commerce any of these articles without inspection under these regulations, except as expressly exempted in § 532.3.

(b) Inspection under the regulations is required at:

(1) Every establishment, except as provided in the regulation on exemption of retail operations (§ 532.3), in which any fish or fish products are wholly or in part, processed for transportation or sale in commerce, as articles intended for use as human food.

(2) Every establishment, except as provided in the regulation on exemption of retail operations (§ 532.3), within any State or organized territory which is designated pursuant to section 301 of the Act (21 U.S.C. 661), at which any fish or fish products are processed for use as human food solely for distribution within that State or territory.

(3) Except as provided in the regulation on exemption of retail operations (§ 532.3), every establishment designated by the administrator under section 301 of the Act (21 U.S.C. 661) as one producing adulterated fish products which would clearly endanger the public health.

(4) *Coverage of fish and fish products processed in official establishments.* All fish and fish products prepared in an official establishment must be inspected, handled, processed, marked, and labeled as required by the regulations.

(5) *Other inspection.* Periodic inspections may be made of:

(i) The records of all persons engaged in the business of hatching, feeding, growing, or transporting fish between premises where fish are bred, hatcheries, and premises where fish are grown, and from these premises to processing establishments.

(ii) Exempted retail establishments to determine that those establishments are operating in accordance with these regulations.

§ 532.2 Application for inspection; information to be furnished; grant or refusal of Inspection; conditions for receiving inspection; official numbers and inspection; assignment and authorities of Program employees.

(a) Application for inspection is as required by 9 CFR 304.1.

(b) Information to be furnished is as required by 9 CFR 304.2(a), (b), and (c)(1). Conditions for receiving inspection, including having written Sanitation SOPs, HACCP plans and written recall procedures, are as required by 9 CFR 304.3.

(c) Official numbers; inauguration of inspection; withdrawal of inspection; reports of violation. The requirements for assignment of official numbers,

inauguration of inspection, withdrawal of inspection, and reports of violations at fish processing establishments are as required by part 305 of this chapter for meat establishments.

(d) Assignment and authorities of program employees. The requirements concerning the assignment and authorities of Program employees at fish processing establishments are as required by parts 306 and 307 of this chapter with respect to Program employees at meat establishments.

§ 532.3 Exemption of retail operations.

(a) The exemption in 9 CFR 303.1(d) for operations of types traditionally and usually conducted at retail stores and restaurants applies with respect to fish products as it does with respect to products of other amenable species under the FMIA.

(b) The exemption also applies to the slaughtering of fish conducted at and by the operator of a retail store or restaurant, with respect to live fish purchased by a consumer at the retail store or restaurant, in accordance with the consumer's instructions.

(c) A retail quantity of fish or fish products sold to a household consumer is a normal retail quantity if it does not exceed 75 pounds and the quantity of fish or fish product sold by a retail supplier to a non-household consumer is a normal retail quantity if it does not exceed 150 pounds in the aggregate.

§ 532.4 Inspection at official establishments; relation to other authorities.

(a) Requirements within the scope of the Act with respect to premises, facilities, and operations of any official establishment that are in addition to or different than those made under this subchapter may not be imposed by any State or local jurisdiction except that the State or local jurisdiction may impose recordkeeping and other requirements within the scope of § 550.1 of this subchapter, if consistent with those requirements, with respect to the establishment.

(b) Labeling, packaging, or ingredient requirements in addition to or different than those made under this subchapter, the Federal Food, Drug, and Cosmetic Act and Fair Packaging and Labeling Act may not be imposed by any State or local jurisdiction with respect to any fish or fish products processed at any official establishment in accordance with the requirements under this subchapter and those Acts.

§ 532.5 Exemption from definition of fish product of certain human food products containing fish.

The following articles contain fish ingredients only in a relatively small proportion or historically have not been considered by consumers to be products of the fish food products industry. Therefore, the articles are exempted from the definition of ''fish product'' and the requirements of the Act and the regulations that apply to fish products, if they comply with the conditions specified in this section.

(a) Any human food product if:

(1) It contains less than 3 percent raw or 2 percent cooked fish;

(2) The fish ingredients used in the product were prepared under Federal inspection or were inspected under a foreign inspection system approved under § 557.2 of this subchapter and imported in compliance with the Act and the regulations;

(3) The immediate container of the product bears a label which shows the name of the product in accordance with this section; and

(4) The product is not represented as a fish product. The percentage of cooked fish ingredients must be computed on the basis of the moist, deboned, cooked fish in the ready-to-serve product when prepared according to the serving directions on the consumer package.

(b) A product exempted under this section will be deemed to be represented as a fish product if the term ''fish'' or a term representing a fish species that is covered by the definition of ''fish'' in part 531 of this subchapter is used in the product name of the product without appropriate qualification.

(c) A product exempted under this section is subject to the requirements of the Federal Food, Drug, and Cosmetic Act.

PART 533—SEPARATION OF ESTABLISHMENT; FACILITIES FOR INSPECTION; FACILITIES FOR PROGRAM EMPLOYEES; OTHER REQUIRED FACILITIES

Sec.

Authority: 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 533.1 Separation of establishments.

Each official establishment shall be separate and distinct from any unofficial establishment and from any other official establishment, except an establishment preparing products under the FMIA, the PPIA, or the EPIA, or under State fish inspection requirements and authorities that are deemed to be at least equal to those provided under the FMIA. Further, doorways, or other openings, may be permitted between establishments at the discretion of the Administrator and under such conditions as he may prescribe. An official establishment that is not separate and distinct from another official or unofficial establishment must ensure that no sanitary hazards are created by the lack of separation.

§ 533.2 [Reserved]

§ 533.3 Facilities for Program employees.

Office space, including necessary furnishings, light, heat, and janitor service, must be provided by official establishments, rent free, for the exclusive use for official purposes of the inspector and other Program employees assigned thereto. The space set aside for this purpose shall meet with approval of the District Manager or the frontline supervisor and must be conveniently located, properly ventilated, and provided with lockers suitable for the protection and storage of Program supplies and with facilities suitable for Program employees to change clothing if such facilities are deemed necessary by the frontline supervisor. At the discretion of the Administrator, small establishments requiring the services of less than one full-time inspector need not furnish facilities for Program employees as prescribed in this section, where adequate facilities exist in a nearby convenient location. Laundry service for inspectors' outer work clothing must be provided by each establishment.

§ 533.4 Other facilities and conditions to be provided.

When required by the District Manager or the frontline supervisor, each official establishment must provide the following facilities and conditions, and such others as may be found to be essential to efficient conduct of inspection and maintenance of sanitary conditions:

(a) Sufficient light to be adequate for the proper conduct of inspection;

(b) Tables, benches, and other equipment on which inspection is to be performed, of such design, material, and construction as to enable Program employees to conduct their inspection in a ready, efficient and clean manner;

(c) Receptacles for holding and handling diseased carcasses and parts, so constructed as to be readily cleaned and to be marked in a conspicuous manner with the phrase ''U.S. Condemned'' in letters not less than 2 inches high, and, when required by the frontline supervisor, to be equipped in a way that allows the receptacles to be locked or sealed;

(d) Adequate arrangements, including liquid soap and cleansers, for cleansing and disinfecting hands, for sterilizing all implements used in handling diseased carcasses, for cleaning and sanitizing floors, and such other articles and places as may be contaminated by diseased carcasses or otherwise;

(e) Adequate facilities, including denaturing materials, for the proper disposal of condemned articles in accordance with the regulations in this subchapter;

(f) Docks and receiving rooms, to be designated by the operator of the official establishment, with the frontline supervisor, for the receipt and inspection of fish, fish products, or other products.

(g) Suitable lockers in which brands bearing the official inspection legend and other official devices (excluding labels) can be stored. Official certificates shall be kept when not in use in suitable file cabinets. All such lockers and file cabinets shall be equipped for sealing or locking with locks or seals to be supplied by the Department. The keys of such locks shall not leave the custody of Program employees.

§ 533.5 Schedule of operations.

The requirements governing the schedule of operations for fish processing establishments are as required by 9 CFR 307.4 for meat establishments.

§ 533.6 Overtime and holiday inspection service.

The requirements governing overtime and holiday inspection service in 9 CFR 307.5 apply to fish processing establishments.

§ 533.7 Basis of billing for overtime and holiday services.

The requirements for billing and overtime and holiday inspection services are as required by 9 CFR 307.6.

PART 534—PRE-HARVEST STANDARDS AND TRANSPORTATION TO PROCESSING ESTABLISHMENT

Sec.

Authority: 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 534.1 General.

Fish that are harvested for use as human food must have grown and lived under conditions that will not render the fish or their products unsound, unwholesome, unhealthful, or otherwise unfit for human food.

§ 534.2 Water quality for food fish.

Farmers of fish should monitor the water in which the fish are raised for the presence of suspended solids, organic matter, nutrients, heavy metals, pesticides, fertilizers, and industrial chemicals that may contaminate fish. FSIS will collect samples of feed, fish, and water from producers, at intervals to be determined by the Administrator, for the purpose of verifying that fish are being raised under conditions that will yield safe, wholesome products.

§ 534.3 Standards for use of drugs in the raising of fish.

New animal drugs that are the subject of an approved new animal drug application (NADA) or abbreviated new animal drug application (ANADA) under section 512 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360b), or a conditional approval under section 571 of the Act (21 U.S.C. 360ccc), or an investigational exemption under section 512(j) of the Act (21 U.S.C. 360b(j)) may be used in the raising of fish. New animal drugs approved under section 512 of the Act may be used in an extra-label manner if such use complies with section 512(a)(4) of the Act and FDA regulations found at 21 CFR part 530.

§ 534.4 Transportation to processing plant.

A vehicle used to transport fish from a producer's premises to a processing establishment must be equipped with vats or other containers for holding the fish. The vats or other containers must be maintained in a sanitary condition. Sufficient water and sufficient oxygen must be provided to the vats that hold the fish to ensure that fish delivered to the processing establishment will not be adulterated. Any fish that are dead, dying, diseased, or contaminated with substances that may adulterate fish products are subject to condemnation at the official fish processing establishments.

PART 537—SANITATION REQUIREMENTS AND HAZARD ANALYSIS AND CRITICAL CONTROL POINTS SYSTEMS; NOTIFICATION REGARDING ADULTERATED OR MISBRANDED PRODUCTS

Sec.

Authority: 21 U.S.C. 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 537.1 Basic requirements.

(a)(1) Any official establishment that prepares or processes fish or fish products for human food must comply with the requirements contained in 9 CFR parts 416, Sanitation and 417, Hazard Analysis and Critical Control Point (HACCP) Systems, except as otherwise provided in this subchapter.

(2) For the purposes of 9 CFR part 416, Sanitation; 9 CFR part 417, Hazard Analysis and Critical Control Point (HACCP) Systems; and 9 CFR part 500, Rules of Practice, an ''official establishment'' or ''establishment'' includes a plant that prepares or processes fish or fish products.

§ 537.2 Hazard analysis and HACCP plan.

(a) A fish establishment's hazard analysis shall take into account the food safety hazards that can occur before, during, and after harvest.

(b) The failure of an establishment to develop and implement a hazard analysis and a HACCP plan that comply with this part or to operate in accordance with the requirements of 9 CFR Chapter III, Subchapter E, will render the products produced under these conditions adulterated.

§ 537.3 Notification.

Each official establishment must promptly notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded fish product received by or originating from the official establishment has entered commerce, in accordance with the requirements of 9 CFR part 418.

PART 539—MANDATORY DISPOSITIONS; PERFORMANCE STANDARDS RESPECTING PHYSICAL, CHEMICAL, OR BIOLOGICAL CONTAMINANTS

Sec.

Authority: 21 U.S.C. 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 539.1 Disposal of diseased or otherwise adulterated fish carcasses and parts or fish products.

(a)(1) Carcasses or parts of fish affected by abscesses or lesions, zoonotic and non-zoonotic parasites such as cestodes, or such parasites as digenean trematodes, metacercaria (*Bolbophorus* spp.), yellow grubs (*Clinostomum* spp.), or white grubs (Hysteromorpha spp.) are subject to condemnation unless properly disposed of by the establishment to prevent their use as human food.

(2) Fish affected by Heterophyid intestinal flukes or *Dictophymatidae* nematodes are subject to condemnation unless properly disposed of by the establishment.

(b) Fish affected by diseases, including columnaris (infection by Flavobacterium columnare/*Flexibacter columnaris*) and enteric septicemia of fish (ESC), are subject to condemnation unless properly disposed of by the establishment to prevent their use as human food.

(c) Fish carcasses or parts or fish products that are found to be in a state of spoilage or decomposition are subject to condemnation unless properly disposed of by the establishment to prevent their use as human food.

(d) Fish with unusual gross deformities caused by disease or chemical contamination may not be used for human food.

§ 539.2 Physical, chemical, or biological contaminants.

(a) Fish and fish products that are contaminated with physical matter are subject to official retention and condemnation.

(b) Antibiotic or other drug residues in fish tissues must be within applicable tolerances in 21 CFR part 556 or within an applicable import tolerance established under 21 U.S.C. 360b(a)(6).

(c) Pesticide residues in fish tissues must be within applicable tolerances in 40 CFR part 180.

(d) Fish or fish products containing violative concentrations of drugs or other chemicals are subject to condemnation.

PART 540—HANDLING AND DISPOSAL OF CONDEMNED AND OTHER INEDIBLE MATERIALS

Sec.

Authority: 21 U.S.C. 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 540.1 Dead fish.

(a) With the exception of dead fish that have died en route to an official establishment that have been received with live fish at the official establishment, and that are subject to sorting and disposal at the official establishment, no fish or part of the carcass of fish that died otherwise than by slaughter may be brought onto the premises of an official establishment without advance permission from the FSIS frontline supervisor.

(b) The official establishment shall maintain physical separation between slaughtered fish and the edible parts or products of slaughtered fish and any fish or parts of fish that have died otherwise than by slaughter. Fish or any parts of fish that have died otherwise than by slaughter shall be excluded from any room or compartment in which edible product is prepared, handled, or stored.

§ 540.2 Specimens for educational, research, and other nonfood purposes; permits.

The requirements of 9 CFR 314.9 apply to the handling and release of specimens of condemned or other inedible fish materials.

§ 540.3 Handling and disposal of condemned or other inedible materials.

Condemned or other inedible fish and fish parts shall be separated from edible fish. If not disposed of on the premises of the establishment, the condemned and inedible fish parts shall be conveyed from the official establishment for disposition at a rendering plant, an animal feed manufacturing establishment, or at another establishment for other non-food use. If not decharacterized by use of approved denaturants or colorings, the inedible materials shall be enclosed in containers that are conspicuously marked to indicate that the contents are condemned or otherwise inedible. The materials may be shipped under company or official seal to a rendering facility or for other inedible processing.

PART 541—MARKS, MARKING AND LABELING OF PRODUCTS AND CONTAINERS

Sec.

Authority: 21 U.S.C. 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 541.1 General.

The marks, devices, and certificates prescribed or referenced in this part are official marks, devices, and certificates for the purposes of the Act respecting fish and fish products. The marks, devices, and certificates shall be used only in accordance with the regulations in this part.

§ 541.2 Official marks and devices to identify inspected and passed fish and fish products.

(a)(1) The official inspection legend required by this part must be shown on all labels for inspected and passed fish and fish products and must be in the following form prescribed in 9 CFR 312.2(b)(1) for inspected and passed products of cattle, sheep, swine, and goats, or in another form to be prescribed by the Administrator, except that it need not be of the size illustrated, if it is of a sufficient size and color to be conspicuously displayed, and readily legible, and in the same proportions of letter size and boldness are maintained as illustrated:

(2) The official inspection legend shall contain the words ''U.S. Inspected and Passed'' or an abbreviation of those words approved by the Administrator.

(b) This official mark must be applied by mechanical means and must not be applied by a hand stamp.

(c)(1) The official inspection legend, or the approved abbreviation of the legend, must be printed on consumer packages and other immediate containers of inspected and passed fish products or on labels to be securely affixed to the containers of the products and may be printed or stenciled on the containers but must not be applied by rubber stamping.

(2) The official inspection legend may also be used for the purposes of marking shipping containers, band labels, and other articles with the approval of the Administrator.

(d) Whole gutted fish carcasses that have been inspected and passed in an official establishment and are intended for sale as whole gutted fish must be marked with the official inspection

legend or properly packaged in an immediate container labeled with the official inspection legend and all other required labeling features, that will ensure that the fish carcasses are identified as ''Inspected and Passed'' and will not become misbranded while in commerce. The official inspection legend used for this purpose must be in the form illustrated below or in another form determined by the Administrator:

§ 541.3 Official seals for transportation of products.

The official mark for use in sealing railroad cars, cargo containers, or other means of conveyance as prescribed in part 555 of this subchapter must be the inscription and serial number shown in 9 CFR 312.5 or another official mark approved by the Administrator. Any seal approved by the Administrator for applying the official mark is an official device for the purposes of the Act. The seal must be attached to the means of conveyance only by a Program employee, who shall also affix a ''Warning Tag'' (Form MP–408–3 or similar official form).

§ 541.4 Official export inspection marks, devices, and certificates.

(a) The official export inspection mark for fish required by part 552 of this subchapter must be in the same form as that specified in 9 CFR 312.8(a) or otherwise as prescribed by the Administrator.

(b) The official export certificate for fish and fish products required by part 552 must be in the same form as that prescribed for meat and meat food products in 9 CFR 312.8(b) or otherwise as prescribed by the Administrator.

§ 541.5 Official detention marks and devices.

The official mark for shipments of articles and fish detained under this subchapter is the designation ''U.S. Detained,'' and the official device for applying the mark is the official ''U.S. Detained'' tag (FSIS Form 8400–2) as prescribed in 9 CFR 329.2 or otherwise by the Administrator.

§ 541.7 Labels required; supervision of a Program employee.

(a) *General labeling requirements.* The requirements in part 317, subpart A, of this chapter, governing labels and labeling, safe-handling labeling, abbreviations of official marks, the use of approved labels, the labeling of products for foreign commerce, prohibited practices, the reuse of official inspection marks, filling of containers, relabeling of products, the storage and distribution of labels, and the requirements for packaging materials, apply to fish and fish products.

(b) A country of origin statement on the label of any fish ''covered commodity'' as defined in 7 CFR part 60, subpart A, that is sold by a ''retailer,'' as defined in 7 CFR 60.124, must comply with the requirements of 7 CFR 60.200 and 60.300.

(c) The safe handling instructions required on labels of fish and fish products specified in paragraph (a) of this section shall replace statements that include the terms ''meat'' and ''poultry'' with the following:

(1) In the rationale statement, ''This product was prepared from inspected and passed fish. Some food products may contain bacteria that could cause illness if the product is mishandled and cooked improperly. For your protection, follow these safe handling instructions.'' This statement shall be placed immediately after the heading and before the safe handling statements.

(2) In the labeling statements, ''Keep raw fish separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw fish. (A graphic illustration of soapy hands under a faucet shall be displayed next to statement.)''

(d)(1) Labels and labeling of fish in the order Siluriformes and the products of those fish must bear the appropriate common or usual names of the fish. For example, among fish in the family Pangasiidae, the labels and labeling for fish of the species *Pangasius bocourti* must bear the term ''basa''; for the species *Pangasius hypophthalmus* or *Pangasionodon hypophthalmus,* ''swai,'' ''tra,'' or ''sutchi.''

(2) The labels and labeling only of fish and fish products within the family Icataluridae may bear the term ''catfish.''

(e) The requirements in part 441 of this chapter, governing water retained from processing in raw meat and poultry, apply to retained water in fish. The requirements in part 442 of this chapter, governing quantity of contents labeling, the testing of scales, and the handling of product that is found to be out of compliance with net weight requirements, apply to fish and fish products.

(1) Packages of frozen or fresh-frozen fish carcasses or parts must be labeled to reflect 100-percent net weight after thawing. The de-glazed net weight must average 100 percent of the stated net weight of the frozen product when sampled and weighed according to the method prescribed in National Institute of Standards and Technology (NIST) Handbook 133 Chapter 2, Section 2.6.[1]

(2) [Reserved]

(f) *Nutrition labeling.* The requirements for nutrition labeling of meat and meat food products in part 317, subpart B, of this chapter, also apply to the labeling of fish and fish food products.

(g) *Label approval.* The requirements for the label approval of meat and meat food products in part 412 of this chapter, also apply to the labeling of fish and fish products.

PART 544—FOOD INGREDIENTS PERMITTED

Sec.

544.1 Use of food ingredients.

Authority: 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 544.1 Use of food ingredients.

(a) No fish product may bear or contain any food ingredient that would render it adulterated or misbranded or that is not approved in part 424 of this chapter, or in this part or elsewhere in this subchapter, or by the Administrator in specific cases.

(b) [Reserved]

PART 548—PREPARATION OF PRODUCTS

Sec.

548.1 Preparation of fish products.

548.2 Requirements concerning ingredients and other articles used in the preparation of fish products.

548.3 Samples of products, water, dyes, chemicals, etc. to be taken for examination.

548.4 [Reserved]

548.5 Ready-to-eat fish products.

548.6 Canning and canned products.

548.7 Use of new animal drugs.

548.8 Polluted water contamination at establishment.

548.9 Accreditation of non-Federal chemistry laboratories.

Authority: 7 U.S.C. 138f; 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 548.1 Preparation of fish products.

(a) All processes used in preparing any fish product in official establishments shall be subject to inspection by Program employees unless such preparation is conducted as

[1] U.S. Department of Commerce. NIST Handbook 133: Checking the Net Contents of Packaged Goods, 2013. Washington, DC.

or consists of operations that are exempted from inspection under 9 CFR 303.1. No fixtures or appliances, such as tables, trucks, trays, tanks, vats, machines, implements, cans, or containers of any kind, shall be used unless they are of such materials and construction as will not contaminate or otherwise adulterate the product and are clean and sanitary. All steps in the preparation of edible products shall be conducted carefully and with strict cleanliness in rooms or compartments separate from those used for inedible products.

(b) It shall be the responsibility of the operator of every official establishment to comply with the Act and the regulations in this subchapter. To carry out this responsibility effectively, the operator of the establishment shall institute appropriate measures to ensure the maintenance of the establishment and the preparation, marking, labeling, packaging and other handling of its products strictly in accordance with the sanitary and other requirements of this subchapter.

§ 548.2 Requirements concerning ingredients and other articles used in the preparation of fish products.

All ingredients and other articles used in the preparation of any fish product must be clean, sound, healthful, wholesome, and otherwise such as will not result in the product's being adulterated.

§ 548.3 Samples of products, water, dyes, chemicals, etc. to be taken for examination.

Samples of products, water, dyes, chemicals, preservatives, spices, or other articles in any official establishment shall be taken, without cost to the Program, for examination, as often as may be deemed necessary for the efficient conduct of the inspection.

§ 548.4 [Reserved]

§ 548.5 Ready-to-eat fish products.

Ready-to-eat fish products are subject to the requirements in part 430 of this chapter.

§ 548.6 Canning and canned products.

The requirements for canning and canned products in 9 CFR part 318, subpart G (§§ 318.300–318.311) apply to fish products that are canned.

§ 548.7 Use of new animal drugs.

Edible tissues of fish with residues exceeding tolerance levels specified in 21 CFR part 556 or established in an import tolerance under 21 U.S.C. 360b(a)(6) are adulterated within the meaning of section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act because they bear or contain a new animal drug that is unsafe within the meaning of section 512 of the Federal Food, Drug, and Cosmetic Act.

§ 548.8 Polluted water contamination at establishment

In the event that there is polluted water (including but not limited to flood water) in an official establishment, all products and ingredients for use in the preparation of the products that have been rendered adulterated by the water must be condemned. After the polluted water has receded from the establishment, the establishment must follow the cleaning and sanitizing procedures in § 318.4 of this chapter.

§ 548.9 Accreditation of non-Federal chemistry laboratories.

A non-Federal analytical laboratory that has met the requirements for accreditation specified in 9 CFR part 439 and hence, at an establishment's discretion, may be used in lieu of an FSIS laboratory for analyzing official regulatory samples. Payment for the analysis of regulatory samples is to be made by the establishment using the accredited laboratory.

PART 549—[RESERVED]

PART 550—RECORDS REQUIRED TO BE KEPT

Sec.

Authority: 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 550.1 Records required to be kept.

The requirements in 9 CFR 320.1 for records to be kept apply to persons that engage in businesses relating to fish and fish products as they do to persons that engage in businesses relating to the carcasses, parts, or products of other species amenable to the FMIA.

§ 550.2 Place of maintenance of records.

The requirements in 9 CFR 320.2 for the place where records are to be maintained apply in the keeping of records under this part.

§ 550.3 Record retention period.

The record retention requirements in 9 CFR 320.3 apply to records required to be kept under this part.

§ 550.4 Access to and inspection of records, facilities and inventory; copying and sampling.

The provisions of 9 CFR 320.4 apply to businesses dealing in fish and fish products.

§ 550.5 Registration.

The registration requirements in 9 CFR 320.5 apply to persons engaging in businesses, in or for commerce, relating to fish and fish products as they do to persons engaging in businesses relating to the carcasses, parts, and products, or any livestock, of other animal species that are amenable to the FMIA.

§ 550.6 Information and reports required from official establishment operators.

The information and reporting requirements in 9 CFR 320.6 for operators of official establishments apply with respect to fish and fish products as they do with respect to other species amenable to the FMIA.

§ 550.7 Reports by consignees of allegedly adulterated or misbranded products; sale or transportation as violations.

The requirements in 9 CFR 320.7 for reports by consignees of allegedly adulterated or misbranded products apply with respect to fish and fish products as they do with respect to products of other species amenable to the Act.

PART 552—EXPORTS

Sec.

Authority: 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 552.1 Affixing stamps and marking products for export; issuance of export certificates; clearance of vessels and transportation.

(a) The manner of affixing stamps and marking products for export is that prescribed in § 322.1(a) of this chapter.

(b) The requirements for the issuance of export certificates are as prescribed in § 322.2 of this chapter.

(c) The requirements for clearing vessels and other transportation vehicles are set out in § 322.4 of this chapter.

PART 555—TRANSPORTATION OF FISH PRODUCTS IN COMMERCE

Sec.

Authority: 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 555.1 Transportation of fish products.

(a) No person may sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any fish or fish product that is capable of being used as human food and is adulterated or fails to bear an official inspection legend or is otherwise misbranded at the time of such sale, transportation, offer or receipt, except otherwise provided in this paragraph or in part 557 of this subchapter.

(b) No person, engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, fish products capable of use as human food, or importing such articles, shall transport, offer for transportation, or receive for transportation, in commerce or in any State designated under § 560.3 of this subchapter, any fish product which is capable of use as human food and is not wrapped, packaged, or otherwise enclosed to prevent adulteration by airborne contaminants, unless the railroad car, truck, or other means of conveyance in which the product is contained or transported is completely enclosed with tight fitting doors or other covers for all openings. In all cases, the means of conveyance shall be reasonably free of foreign matter (such as dust, dirt, rust, or other articles or residues), and free of chemical residues, so that product placed therein will not become adulterated.

(c) Any cleaning compound, lye, soda solution, or other chemical used in cleaning the means of conveyance must be thoroughly removed from the means of conveyance prior to its use. Such means of conveyance onto which product is loaded, being loaded, or intended to be loaded, shall be subject to inspection by an inspector at any official establishment.

(d) The decision whether or not to inspect a means of conveyance in a specific case, and the type and extent of such inspection shall be at the Agency's discretion and shall be adequate to determine if fish product in such conveyance is, or when moved could become, adulterated.

(e) Circumstances of transport that can be reasonably anticipated shall be considered in making said determination. These include, but are not limited to, weather conditions, duration and distance of trip, nature of product covering, and effect of restowage at stops en route. Any means of conveyance found upon such inspection to be in such condition that fish product placed therein could become adulterated shall not be used until such condition which could cause adulteration is corrected.

Fish product placed in any means of conveyance that is found by the inspector to be in such condition that the fish product may have become adulterated shall be removed from the means of conveyance and handled in accordance with part 539 or § 540.3 of this subchapter.

§ 555.2 Fish product transported within the United States as part of export movement.

When any shipment of any fish product is offered to any carrier for transportation within the United States as a part of an export movement, the same certificate shall be required as if the shipment were destined to a point within the United States.

§ 555.3 Unmarked, inspected fish product transported under official seal between official establishments for further processing; certificate.

The requirements governing transportation of fish product that has been inspected and passed, but not so marked, from one official establishment to another official establishment are the same as those in § 325.5 of this chapter that apply to unmarked inspected meat products.

§ 555.4 Handling of fish products that may have become adulterated.

The provisions of § 325.10 of this chapter regarding the handling of products that may have become adulterated or misbranded apply to fish and fish products.

§ 555.5 Transportation of inedible fish product in commerce.

The provisions in § 325.11(e) of this chapter regarding the transportation of inedible livestock products apply to the transportation of inedible fish parts or products.

§ 555.6 Certificates.

The provisions in § 325.14 of this chapter regarding the filing of original certificates of unmarked inspected meat products delivered to carriers applies with respect to fish and fish products.

§ 555.7 Official seals; forms, use, and breaking.

The official seals required by this part are those prescribed in § 541.3 and § 312.5 of this chapter.

§ 555.8 Loading or unloading of fish products in sealed transport conveyances.

The requirements in 9 CFR 325.17 governing the unloading of any meat or meat food product from an officially sealed railroad car, truck, or other means of conveyance containing any unmarked product or loading any means of conveyance after the product leaves an official establishment are applicable to fish and fish products.

§ 555.9 Diverting of shipments

(a) Shipments of inspected and passed fish products that bear the inspection legend may be diverted from the original destination without a reinspection of the articles if the waybills, transfer bills, running slips, conductor's card, or other papers accompanying the shipments are marked, stamped, or have attached thereto signed statements in accordance with § 325.15 of this chapter.

(b) In case of a wreck or similar extraordinary emergency, the Department seals on a railroad car or other means of conveyance containing any inspected and passed product may be broken by the carrier, and if necessary, the articles may be reloaded into another means of conveyance, or the shipment may be diverted from the original destination, without another shipper's certificate; but in all such cases the carrier must immediately report the facts by telephone or telegraph to the District Manager in the area in which the emergency occurs. The report must include the following information:

(1) Nature of the emergency.

(2) Place where seals were broken.

(3) Original points of shipment and destination.

(4) Number and initial of the original car or truck.

(5) Number and initials of the car or truck into which the articles are reloaded.

(6) New destination of the shipment.

(7) Kind and amount of articles.

§ 555.10 Provisions inapplicable to specimens for laboratory examination, etc., or to naturally inedible articles.

The provisions of this part do not apply:

(a) To specimens of product sent to or by the Department of Agriculture or divisions thereof in Washington, DC, or elsewhere, for laboratory examination, exhibition purposes, or other official use;

(b) To material released for educational, research, and other nonfood purposes, as prescribed in § 540.2 of this subchapter;

(c) To tissues for use in preparing pharmaceutical, organotherapeutic, or technical products and not used for human food, as described in § 540.2 of this subchapter;

(d) To material or specimens of product for laboratory examination, research, or other nonhuman food purposes, when authorized by the Administrator, and under conditions prescribed by him in specific cases; and

(e) To articles that are naturally inedible by humans.

§ 555.11 Transportation and other transactions concerning dead, dying, or diseased fish, and fish or parts of fish that died otherwise than by slaughter.

No person engaged in the business of buying, selling, or transporting in commerce, or importing any dead, dying, or diseased fish or parts of fish that died otherwise than by slaughter shall:

(a) Sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any dead, dying, or diseased fish or parts of fish that died otherwise than by slaughter, unless the fish and parts are consigned and delivered, without avoidable delay, to establishments of animal food manufacturers, renderers, or collection stations that are registered as required by part 550 of this subchapter, or to official establishments that operate under Federal inspection, or to establishments that operate under a State or Territorial inspection system approved by FSIS as one that imposes requirements at least equal to the Federal requirements for purposes of section 301(c) of the Act;

(b) Buy in commerce or import any dead, dying, or diseased fish or parts of fish that died otherwise than by slaughter, unless he is an animal food manufacturer or renderer and is registered as required by part 550 of this subchapter, or is the operator of an establishment inspected as required by paragraph (a) of this section and such fish or parts of fish are to be delivered to establishments eligible to receive them under paragraph (a) of this section;

(c) Unload en route to any establishment eligible to receive them under paragraph (a) of this section, any dead, dying, or diseased fish or parts of fish that died otherwise than by slaughter, which are transported in commerce or imported by any such person: *Provided,* That any such dead, dying, or diseased fish, or parts of fish may be unloaded from a means of conveyance en route where necessary in case of a wreck or otherwise extraordinary emergency, and may be reloaded into another means of conveyance; but in all such cases, the carrier must immediately report the facts by telephone or other electrical or electronic means to the Office of Investigation, Enforcement and Audit, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

(d) Load into any means of conveyance containing any dead, dying, or diseased fish, or parts of fish that died otherwise than by slaughter, while in the course of importation or other transportation in commerce any fish or parts of fish not within the foregoing description or any other products or other commodities.

§ 555.12 Means of conveyance in which dead, dying, or diseased fish or parts of fish must be transported.

All vehicles and other means of conveyance used by persons subject to § 555.11 for transporting in commerce or importing, any dead, dying, or diseased fish or parts of fish that died otherwise by slaughter must be leak proof and so constructed and equipped as to permit thorough cleaning and sanitizing. The means of conveyance used in conveying the fish or parts of fish must be cleaned and disinfected before being used in the transportation of any product intended for use as human food. The cleaning procedure must include the complete removal from the means of conveyance of any fluid, parts, or product of dead, dying, or diseased fish and the thorough application of a disinfectant approved by the Administrator to the interior surfaces of the cargo space.

PART 557—IMPORTATION

Sec.

Authority: 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 557.1 Definitions; application of provisions.

(a) When used in this part, the following terms shall be construed to mean:

(1) *Import.* To bring within the territorial limits of the United States whether that arrival is accomplished by land, air, or water.

(2) *Offer for entry.* Presentation of the imported product by the importer to the Program for reinspection.

(3) *Entry.* The point at which imported product offered for entry receives reinspection and is marked with the official mark of inspection in accordance with § 557.26 of this subchapter.

(b) The provisions of this part shall apply to fish and fish products that are capable of use as human food. Compliance with the conditions for importation of products under this part does not excuse the need for compliance

with applicable requirements under other laws, including the provisions in part 94 of chapter I of this title.

§ 557.2 Eligibility of foreign countries for importation of fish and fish products into the United States.

(a) The requirements in 9 CFR 327.2(a)(1), (a)(2)(i), (a)(2)(ii)(C)–(I), (a)(2)(iii)–(iv), and (a)(3), for determining the acceptability of foreign meat inspection systems for the importation of meat and meat food products into the United States, apply in determining the acceptability of foreign fish inspection systems for the importation of fish and fish products into the United States. In determining the acceptability of these systems, the Agency will evaluate the manner in which they take into account the conditions under which fish are raised and transported to a processing establishment.

(b)(1) It has been determined that fish and fish products from the following countries covered by foreign inspection certificates of the country of origin as required by § 557.4, are eligible under the regulations in this subchapter for entry into the United States after inspection and marking as required by the applicable provisions of this part: (None listed as of December 2, 2015).

(2) Persons interested in having the most recent list of eligible countries and establishments may contact the Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

§ 557.3 No fish or fish product to be imported without compliance with applicable regulations.

No fish or fish product offered for importation from any foreign country shall be admitted into the United States if it is adulterated or misbranded or does not comply with all the requirements of this subchapter that would apply to it if it were a domestic product.

§ 557.4 Imported fish and fish products; foreign certificates required.

(a) Except as provided in § 557.16, each consignment containing any fish or fish products consigned to the United States from a foreign country must be accompanied by an electronic foreign inspection certificate or a paper foreign inspection certificate for fish and fish products. The certificate must have been issued by an official of the foreign government agency responsible for the inspection and certification.

(b) An official of the foreign government must certify that any fish or fish product described on any official certificate was produced in accordance with the regulatory requirements in § 557.2.

(c) The electronic foreign inspection certification must be in English, be transmitted directly to FSIS before the product's arrival at the official import inspection establishment, and be available to import inspection personnel.

(d) The paper foreign inspection certificate must accompany each consignment; be submitted to import inspection personnel at the official import inspection establishment; be in English; bear the official seal of the foreign government responsible for the inspection of the product, and the name, title, and signature of the official authorized to issue inspection certificates for products imported to the United States.

(e) The electronic foreign inspection certification and paper foreign inspection certificate must contain:

(1) The date;

(2) The foreign country of export and the producing foreign establishment number;

(3) The species used to produce the product and the source country and foreign establishment number, if the source materials originate from a country other than the exporting country;

(4) The product's description, including the process category, the product category, and the product group;

(5) The name and address of the importer or consignee;

(6) The name and address of the exporter or consignor;

(7) The number of units (pieces or containers) and the shipping or identification;

(8) The net weight of each lot;

(9) Any additional information the Administrator requests to determine whether the product is eligible to be imported into the United States.

§ 557.5 Importer to make application for inspection of fish and fish products for entry.

(a) Applicants must submit an import inspection application, to apply for the inspection of any product offered for entry. Applicants may apply for inspection using a paper or electronic application form.

(b) Import inspection applications for each consignment must be submitted, electronically or on paper, to FSIS in advance of the shipment's arrival at the official import establishment where the product will be reinspected, but no later than when the entry is filed with U.S. Customs and Border Protection.

(c) The provisions of this section do not apply to products that are exempted from inspection by §§ 557.16 and 557.17.

§ 557.6 Fish and fish products for importation; program inspection, time and place; application for approval of facilities as official import inspection establishment; refusal or withdrawal of approval; official numbers.

(a)(1) Except as provided in §§ 557.16 and 557.17, all fish and fish products offered for entry from any foreign country shall be reinspected by a Program inspector before they shall be allowed entry into the United States.

(2) Every lot of product shall routinely be given visual inspection by a Program import inspector for appearance and condition, and checked for certification and label compliance.

(3) The electronic inspection system will be consulted for reinspection instructions. The electronic inspection system will assign reinspection levels and procedures based on established sampling plans and established product and plant history.

(4) When the inspector deems it necessary, the inspector may sample and inspect lots not designated by the electronic system.

(b) Fish and fish products required by this part to be inspected must be inspected only at an official establishment or at an official import inspection establishment approved by the Administrator as provided in this section.

(c) Owners or operators of establishments, other than official establishments, who want to have import inspections made at their establishments, shall apply to the Administrator for approval of their establishments for such purpose. Application must be made on a form furnished by the Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, and must include all information called for by that form.

(d) Approval for Federal import inspection must be in accordance with §§ 304.1 and 304.2 of this chapter. Also, before approval is granted, the establishment must have developed written Sanitation Standard Operating Procedures in accordance with part 416 of this chapter.

(e) Owners or operators of establishments at which import inspections of product are to be made shall furnish adequate sanitary facilities and equipment for examination of such product. The requirements of §§ 307.1, 307.2(b), (d), (f), (h), (k), and (l) and 416.1 through 416.6 of this chapter shall

apply as conditions for approval of establishments as official import inspection establishments to the same extent and in the same manner as they apply with respect to official establishments.

(f) The Administrator is authorized to approve any establishment as an official import inspection establishment, provided that an application has been filed in accordance with the requirements of paragraphs (c) and (d) of this section and he determines that such establishment meets the requirements under paragraph (e) of this section. Any application for inspection under this section may be denied or refused in accordance with the rules of practice in part 500 of this chapter.

(g) Approval of an official import inspection establishment may be withdrawn in accordance with applicable rules of practice if it is determined that the sanitary conditions are such that the product is rendered adulterated, that such action is authorized by section 21(b) of the Federal Water Pollution Control Act, as amended (84 Stat. 91), or that the requirements of paragraph (e) of this section were not complied with. Approval may be withdrawn in accordance with section 401 of the Act and applicable rules of practice.

(h) A special official number shall be assigned to each official import inspection establishment. Such number shall be used to identify all products inspected and passed for entry at the establishment.

(i) A product examination must be made, as provided in paragraph (a) of this section, of a foreign fish or fish product, including defrosting if necessary to determine its condition. Inspection standards for foreign chilled fresh or frozen fresh fish shall be the same as those used for domestic fish or fish products. Samples may be collected at no cost to FSIS and submitted to an FSIS laboratory for analysis (See § 557.18).

(j) Imported canned products are required to be sound, healthful, properly labeled, wholesome, and otherwise not adulterated at the time the products are offered for importation into the United States. Provided other requirements of this part are met, the determination of the acceptability of the product and the condition of the containers shall be based on the results of an examination of a statistical sample drawn from the consignment as provided in paragraph (a) of this section. If the inspector determines, on the basis of the sample examination, that the product does not meet the requirements of the Act and regulations thereunder, the consignment shall be refused entry. However, a consignment rejected for container defects but otherwise acceptable may be reoffered for inspection under the following conditions:

(1) If the defective containers are not indicative of an unsafe and unstable product as determined by the Administrator;

(2) If the number and kinds of container defects found in the original sample do not exceed the limits specified for this purpose in FSIS guidelines; and

(3) If the defective containers in the consignment have been sorted out and exported or destroyed under the supervision of an inspector.

(k) Program inspectors or Customs officers at border or seaboard ports shall report the sealing of cars, trucks, or other means of conveyance, and the sealing or identification of containers of foreign product to Program personnel at points where such product is to be inspected.

(l) Representative samples of canned product designated by the Administrator in instructions to inspectors shall be incubated under supervision of such inspectors in accordance with § 318.309(d)(1)(ii), (d)(1)(iii), (d)(1)(iv)(c), (d)(1)(v), (d)(1)(vii) and (d)(1)(viii) of this chapter. The importer or his/her agent shall provide the necessary incubation facilities in accordance with § 318.309(d)(1)(i) of this chapter.

(m) Sampling plans and acceptance levels as prescribed in paragraphs (j) and (l) of this section may be obtained, upon request, from the Office of Field Operations, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

§ 557.7 Products for importation; movement prior to inspection; handling; bond; assistance.

The requirements in 9 CFR 327.7 respecting the movement or conveyance from any port, or delivery to the consignee, of any product required to be inspected under part 327, apply to fish and fish products.

§ 557.8 Import fish and fish products; equipment and means of conveyance used in handling to be maintained in sanitary condition.

Compartments of ocean vessels, railroad cars, and other means of conveyance transporting any fish or fish product to the United States, and all trucks, chutes, platforms, racks, tables, tools, utensils, and all other devices used in moving and handling any fish or fish product offered for importation into the United States, shall be maintained in a sanitary condition.

§ 557.9 [Reserved]

§ 557.10 Samples; inspection of consignments; refusal of entry; marking.

The provisions in 9 CFR 327.10 governing the taking of samples, the inspection of consignments, the refusal of entry, and the controlled pre-stamping of shipments of meat and meat food products apply with respect to fish and fish products.

§ 557.11 Receipts to importers for import fish product samples.

FSIS will issue to importers official receipts for samples of foreign products collected for laboratory analysis, as provided in § 327.11 of this chapter.

§ 557.12 Foreign canned or packaged fish and fish products bearing trade labels; sampling and inspection.

Foreign canned or packaged fish and fish products bearing on their immediate containers trade labels that have or have not been approved in accordance with the regulations in § 541.7 of this subchapter are to be sampled and inspected in the same manner as provided by § 327.12 of this chapter for foreign canned meat food products.

§ 557.13 Foreign fish and fish products offered for importation; reporting of findings to Customs.

Program inspectors are to report their findings as to any fish or fish products that have been inspected in accordance with this part in the same manner as that provided by § 327.13 of this chapter for meat products. Fish and fish products that are refused entry are to be handled in the same manner as provided by § 327.13 of this chapter for meat products that are refused entry. Import personnel will identify to the Port Director of U.S. Customs and Border Protection and the Importer of record any products refused entry into the United States.

§ 557.14 Marking of fish and fish products and labeling of immediate containers thereof for importation.

The regulations in 9 CFR 327.14 governing the marking of meat and meat food products and the labeling of immediate containers of those products for importation apply with respect to fish and fish products.

§ 557.15 Outside containers of foreign products; marking and labeling; application of official inspection legend.

The requirements in 9 CFR 327.15 governing the marking and labeling of outside containers of meat and meat

food products apply also with respect to fish and fish products.

§ 557.16 Small importations for importer's own consumption; requirements.

The exemption in 9 CFR 327.16 for small importations of meat or meat food products for the importer's own consumption applies with respect to fish or fish products.

§ 557.17 Returned U.S. inspected and marked fish and fish products.

U.S. inspected and passed and so marked fish products exported to and returned from foreign countries will be admitted into the United States without compliance with this part upon notification of and approval by the Assistant Administrator, Office of Field Operations, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, in specific cases.

§ 557.18 Fish or fish products offered for entry and entered to be handled and transported as domestic; exception.

The regulations in 9 CFR 327.18 governing the offer for entry into the United States of meat and meat food products apply with respect to fish and fish products. Products that fail to meet these regulatory requirements are subject to penalties as administered by the U.S. Port Director of Customs and Border Protection. Likewise, the products may be subject to detention and to being proceeded against as determined by the Administrator.

§ 557.19 Specimens for laboratory examination and similar purposes.

Importation of fish or fish product samples for trade show exhibition, laboratory examination, research, evaluative testing, trade show exhibition, or other scientific purposes are subject to the same conditions as imported meat or meat product specimens under § 327.19 of this chapter.

§ 557.20–557.23 [Reserved]

§ 557.24 Appeals; how made.

An appeal from a decision of any Program employee is to be made as provided by 9 CFR 327.24.

§ 557.25 Disposition procedures for fish and fish products condemned or ordered destroyed under import inspection.

Disposition procedures for condemned fish or fish products ordered destroyed under import inspection are as those for carcasses, parts, meat, and meat food products under 9 CFR 327.25.

§ 557.26 Official import inspection marks and devices.

The official inspection legend and other marks to be applied to imported fish and fish products are as required by 9 CFR 327.26 for meat food products prepared from cattle, sheep, swine, and goats.

PART 559—DETENTION, SEIZURE, CONDEMNATION

Sec.

Authority: 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 559.1 Fish and other articles subject to administrative detention.

The provisions of 9 CFR 329.1 through 329.5 governing the administrative detention of carcasses, parts, meat, and meat food products of livestock apply also with respect to the carcasses, parts, and products of fish.

§ 559.2 Articles or fish subject to judicial seizure and condemnation.

The provisions of 9 CFR 329.6 through 329.8 governing the judicial seizure and condemnation of carcasses, parts, meat, and meat food products of livestock apply also with respect to the carcasses, parts, and products of fish.

§ 559.3 Criminal offenses.

The criminal provisions of the Act apply with respect to the inspection of fish and fish products as they do with respect to the inspection of other food products subject to the Act.

PART 560—STATE-FEDERAL, FEDERAL-STATE COOPERATIVE AGREEMENTS; STATE DESIGNATIONS

Sec.

Authority: 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 560.1 Cooperation with States and Territories.

The provisions in § 321.1 of this chapter authorizing the Administrator to cooperate with any State (including Puerto Rico) or any organized Territory in developing and administering a meat inspection program for the State or Territory apply with respect to fish and fish products inspection.

§ 560.2 Cooperation of States in Federal programs.

Under the ''Talmadge-Aiken Act'' of September 28, 1962 (7 U.S.C. 450), the Administrator is authorized to utilize employees and facilities of any State in carrying out Federal functions under the FMIA, including functions relating to the inspection of fish and fish products. A cooperative program for this purpose is called a Federal-State program.

§ 560.3 Cooperation of States for the Interstate Shipment of Fish and Fish Products.

The provisions in § 321.3 authorizing the Administrator to coordinate with States that have meat inspection programs as provided in § 321.1 of this chapter to select certain establishments operating under these programs to participate in a cooperative program to ship products in interstate commerce apply with respect to fish and fish products inspection.

§ 560.4 Designation of States under the Federal Meat Inspection Act.

The requirements in part 331 of this chapter apply with respect to fish and fish products inspection, including:

(a) The requirements in 9 CFR 331.3 governing the designation of States for Federal inspection under section 301(c) of the Act (21 U.S.C. 661(c));

(b) The requirements in 9 CFR 331.5 governing the designation under section 301(c) of the Act of establishments whose operations would clearly endanger the public health; and

(c) The requirements in 9 CFR 331.6 governing the designation of States under section 205 of the Act.

PART 561—RULES OF PRACTICE

Sec.

Authority: 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 561.1 Rules of practice governing inspection actions.

The rules of practice in part 500 of this chapter, governing inspection actions taken by FSIS with respect to establishments and products, apply to actions taken with respect to fish slaughter, fish processing, fish, and fish products regulated under this subchapter.

§ 561.2 Rules of practice governing proceedings under the Federal Meat Inspection Act.

The procedures that the Agency must follow before reporting a violation of the Federal Meat Inspection Act for prosecution by the Department of Justice are given in part 335 of this chapter.

Done, at Washington, DC: November 18, 2015.

Alfred V. Almanza,

Acting Administrator.

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Recovery Improvements for Small Entities After Disaster Act of 2015 (Nov. 25, 2015; 129 Stat. 686)

H.R. 639/P.L. 114–89

Improving Regulatory Transparency for New Medical Therapies Act (Nov. 25, 2015; 129 Stat. 698)

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