



DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 144, 146, 147, 148, 153, 154, 155, 156, and 158

[CMS-9949-F]

RIN 0938-AS02

Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule addresses various requirements applicable to health insurance issuers, Affordable Insurance Exchanges (“Exchanges”), Navigators, non-Navigator assistance personnel, and other entities under the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act). Specifically, the rule establishes standards related to product discontinuation and renewal, quality reporting, non-discrimination standards, minimum certification standards and responsibilities of qualified health plan (QHP) issuers, the Small Business Health Options Program, and enforcement remedies in Federally-facilitated Exchanges. It also finalizes: a modification of HHS’s allocation of reinsurance collections if those collections do not meet our projections; certain changes to allowable administrative expenses in the risk corridors calculation; modifications to the way we calculate the annual limit on cost sharing so that we round this parameter down to the nearest \$50 increment; an approach to index the required contribution used to determine eligibility for an exemption from the shared responsibility payment under section 5000A of the Internal Revenue Code; grounds for imposing civil money

penalties on persons who provide false or fraudulent information to the Exchange and on persons who improperly use or disclose information; updated standards for the consumer assistance programs; standards related to the opt-out provisions for self-funded, non-Federal governmental plans and related to the individual market provisions under the Health Insurance Portability and Accountability Act of 1996 including excepted benefits; standards regarding how enrollees may request access to non-formulary drugs under exigent circumstances; amendments to Exchange appeals standards and coverage enrollment and termination standards; and time-limited adjustments to the standards relating to the medical loss ratio (MLR) program. The majority of the provisions in this rule are being finalized as proposed.

DATES: This rule is effective [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER] except for amendments to 45 CFR 155.705 which are effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION:

Electronic Access

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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)
AV	Actuarial Value
CAHPS®	Consumer Assessment of Healthcare Providers and Systems
CFR	Code of Federal Regulations
CMP	Civil Money Penalty
CMS	Centers for Medicare & Medicaid Services
CSR	Cost-Sharing Reductions
EHB	Essential Health Benefits
ERISA	Employee Retirement Income Security Act of 1974 (Pub. L. 93-406)
ESS	Enrollee Satisfaction Survey
FFE	Federally-facilitated Exchange
FF-SHOP	Federally-facilitated Small Business Health Options Program
HCC	Hierarchical Condition Category
HHS	United States Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191)
IRS	Internal Revenue Service
MLR	Medical Loss Ratio
NAIC	National Association of Insurance Commissioners
OMB	United States Office of Management and Budget

OPM	United States Office of Personnel Management
PHS Act	Public Health Service Act
PRA	Paperwork Reduction Act of 1995
QHP	Qualified health plan
QRS	Quality Rating System
SHOP	Small Business Health Options Program
The Code	Internal Revenue Code of 1986

I. Executive Summary

Since January 1, 2014, qualified individuals and small employers have been able to obtain private health insurance through Affordable Insurance Exchanges, or “Exchanges” (also known as Health Insurance Marketplaces, or “Marketplaces”).¹ The Exchanges provide competitive marketplaces where individuals and small employers can compare available private health insurance options on the basis of price, quality, and other factors. The Exchanges help enhance competition in the health insurance market, improve choice of affordable health insurance, and give small businesses the same purchasing power as large businesses.

Individuals who enroll in QHPs through individual market Exchanges may be eligible to receive premium tax credits to make health insurance purchased through an Exchange more affordable and cost-sharing reductions (CSRs) that lower out-of-pocket expenses for health care services. The premium tax credits, combined with the new insurance reforms, have significantly increased the number of individuals with health insurance coverage. The premium stabilization programs— risk adjustment, reinsurance, and risk corridors— protect against adverse selection in

¹ The word “Exchanges” refers to both State Exchanges, also called State-based Exchanges, and Federally-facilitated Exchanges (FEEs). In this final rule, we use the terms “State Exchange” or “FEE” when we are referring to a particular type of Exchange. When we refer to “FEEs,” we are also referring to State Partnership Exchanges, which are a form of FEEs.

the newly enrolled population. These programs, in combination with the MLR program and market reforms extending guaranteed availability (also known as guaranteed issue) protections, prohibiting the use of factors such as health status, medical history, gender, and industry of employment to set premium rates, will help to ensure that every American has access to high quality, affordable health insurance.

This final rule addresses various requirements applicable to health insurance issuers, Exchanges, Navigators, non-Navigator assistance personnel, and other entities under the Affordable Care Act. Specifically, the rule establishes standards related to product discontinuation and renewal, quality reporting, non-discrimination standards, minimum certification standards and responsibilities of QHP issuers, the Small Business Health Options Program (SHOP), and enforcement remedies in Federally-facilitated Exchanges (FTEs). It also finalizes: a modification of HHS's allocation of reinsurance collections if those collections do not meet our projections; certain changes to allowable administrative expenses in the risk corridors calculation; modifications to the way we calculate the annual limit on cost sharing so that we round this parameter down to the nearest \$50 increment; an approach to indexing the required contribution used to determine eligibility for an exemption from the shared responsibility payment under section 5000A of the Internal Revenue Code; grounds for imposing CMPs on persons who provide false or fraudulent information to the Exchange and on persons who improperly use or disclose information; updated standards for Exchange consumer assistance programs; standards related to the opt-out provisions for self-funded, non-Federal governmental plans and related to the individual market provisions under the Health Insurance Portability and Accountability Act of 1996 (HIPAA); amendments to Exchange appeals

standards and coverage enrollment and termination standards; and time-limited adjustments to the standards relating to the MLR program.

Product Discontinuance and Uniform Modification of Coverage Exceptions to Guaranteed Renewability Requirements: Under sections 2702 and 2703 of the Public Health Service Act (PHS Act), as added by the Affordable Care Act, health insurance issuers in the group and individual markets must guarantee the availability and renewability of coverage unless an exception applies. In this final rule, we establish criteria for determining when modifications made by an issuer to the health insurance coverage for a product would and would not constitute the discontinuation of an existing product and the creation of a new product. The same criteria would apply to determine whether the rate filing is subject to submission and review under 45 CFR Part 154. We also direct that issuers use standard consumer notices in a format designated by the Secretary when discontinuing or renewing a product in the group or individual market. Additionally, we clarify that the guaranteed availability and renewability requirements should not be construed to supersede other provisions of Federal law in certain circumstances.

Conforming Changes to Individual Market Provisions: Sections 2741 through 2744 of the PHS Act were added by HIPAA to improve the portability and continuity of coverage in the individual health insurance market. These provisions are implemented through regulations in 45 CFR Part 148. In this final rule, we amend the individual market provisions in Part 148 to reflect the amendments made by the Affordable Care Act. These amendments are for clarity only.

Fixed Indemnity Insurance in the Individual Market: Consistent with previously released guidance, we amend the criteria for fixed indemnity insurance to be treated as an excepted benefit in the individual health insurance market.² The amendments eliminate the requirement

² FAQs about Affordable Care Act Implementation (Part XVIII) and Mental Health Parity Implementation, Q11

that individual fixed indemnity insurance must pay on a per-period basis (as opposed to a per-service basis), and require on a prospective basis, among other things, that it be sold only to individuals who have other health coverage that is minimum essential coverage to be considered an excepted benefit.

HIPAA Opt-Out for Self-Funded, Non-Federal Governmental Plans: Prior to enactment of the Affordable Care Act, sponsors of self-funded, non-Federal governmental plans were permitted to elect to exempt those plans from (“opt out of”) certain provisions of title XXVII of the PHS Act. Consistent with previously released guidance, we finalize amendments to the non-Federal governmental plan regulations (45 CFR 146.180) to reflect the amendments made by the Affordable Care Act to these provisions, with clarifications specifying that, in the case of a plan sponsor submitting opt-out elections for more than one collectively bargained health plan, each such plan must be listed in the opt-out election, and in the case of a plan sponsor submitting opt-out elections for group health plans that are not subject to a collective bargaining agreement, the sponsor must submit separate election documents for each such plan.³

Essential Health Benefits (EHB) Prescription Drug Coverage: Under 45 CFR 156.122(c), a plan providing EHB must have procedures in place that allow an enrollee to request and gain access to a clinically appropriate drug not covered by the plan. In this final rule, we are revising paragraph (c) to require that the plan’s procedures include an expedited process for exigent circumstances that requires the health plan to make its coverage determination within

(January 9, 2014). Available at: <http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Affordable-Care-Act-implementation-faqs18.html> and <http://www.dol.gov/ebsa/faqs/faq-Affordable-Care-Act18.html>.

³ Amendments to the HIPAA opt-out provision (formerly section 2721(b)(2) of the Public Health Service Act) made by the Affordable Care Act (September 21, 2010). Available at: http://www.cms.gov/CCIIO/Resources/Files/Downloads/opt_out_memo.pdf.

no more than 24 hours after it receives the request and that requires the health plan to provide the drug for the duration of the exigency.

Premium Stabilization Programs: The Affordable Care Act establishes three premium stabilization programs—risk adjustment, reinsurance, and risk corridors—to protect against adverse selection. The Affordable Care Act directs that a permanent risk adjustment program be established in each State to mitigate the impacts of possible adverse selection and stabilize premiums in the individual and small group markets as and after insurance market reforms are implemented. The Affordable Care Act also directs that a transitional reinsurance program be established in each State to help stabilize premiums by helping to pay the cost of treating high-cost enrollees in the individual market from 2014 through 2016. The Affordable Care Act directs the Secretary to establish and administer a temporary risk corridors program. In this final rule, we modify and finalize our proposal to allocate contributions collected under that program in the event of a shortfall in collections. In that event, we will allocate reinsurance contributions first to the reinsurance payment pool, and second to administrative expenses and the U.S. Treasury. We also finalize the proposal, unchanged, to increase the ceiling on allowable administrative costs and the floor on profits by 2 percent in the risk corridors calculation to account for uncertainty and changes in the market prior to and during benefit year 2015.

Exchange Establishment and QHP Issuer Standards: The rule amends oversight standards regarding QHP decertification and CMPs. It also directs that QHP issuers provide enrollees with an annual notice of coverage changes. This rule creates a process for survey vendors to appeal an HHS decision not to approve its application to become an enrollee satisfaction survey (ESS) vendor, as well as standards for revoking HHS-approval of ESS vendors. Finally, it establishes standards for the ESS and quality rating system (QRS) related to

the display of such information by Exchanges and the submission of validated data by QHP issuers.

We align the start of employer election periods in FF-SHOPs for plan years beginning in 2015 with the start of open enrollment in the corresponding individual market Exchange for the 2015 benefit year and, in all SHOPs, eliminate the 30-day minimum time frames for the employer and employee annual election periods. We also allow State Insurance Commissioners the opportunity to recommend that, in 2015, a SHOP not provide employers with the option of selecting a level of coverage as described in section 1302(d)(1) of the Affordable Care Act and making all QHPs at that level of coverage available to their employees if the commissioner can adequately explain that it is his or her expert judgment, based on a documented assessment of the full landscape of the small group market in his or her State, that not implementing employee choice would be in the best interest of small employers and their employees and dependents, given the likelihood that implementing employee choice would cause issuers to price products and plans higher in 2015 due to the issuers' beliefs about adverse selection. We allow the opportunity for a person appealing a determination of SHOP eligibility to withdraw an appeal by telephone, if the appeals entity is capable of accepting telephonic signatures.

Civil Money Penalties for False Information or Improper Use of Information: The final rule specifies the grounds for imposing CMPs on persons who provide false or fraudulent information to the Exchange and on persons who use or disclose information in violation of section 1411(g) of the Affordable Care Act. The grounds for imposing a penalty include: negligent failure to provide correct information, knowing and willful provision of false or fraudulent information, and knowing and willful use or disclosure of information in violation of section 1411(g). This section specifies the factors used to determine the amount of the CMP to

be imposed against a person. The section also provides for the requirements for notices which must be provided to a person if HHS proposes to impose a CMP, and the processes a person may follow should the person wish to challenge HHS' determination that a CMP should be imposed, including a process pursuant to which a person may request a hearing before an administrative law judge. We also amend current privacy and security regulations at 45 CFR 155.260 to reference the new CMP provisions associated with knowingly and willfully using or disclosing information in violation of section 1411(g) of the Affordable Care Act.

Civil Money Penalties for Consumer Assistance Entities: The final rule provides that HHS may impose CMPs against Navigators, non-Navigator assistance personnel, certified application counselor designated organizations, and certified application counselors in FFEs, if these entities and/or individuals violate Federal requirements applicable to their activities.

Navigator, Non-Navigator Assistance Personnel, and Certified Application Counselor Program Standards: In this final rule, we specify certain types of State laws applicable to Navigators, non-Navigator assistance personnel, and certified application counselors that HHS considers to prevent the application of the provisions of title I of the Affordable Care Act within the meaning of section 1321(d) of the Affordable Care Act. We also make several changes to update the standards applicable to these consumer assistance entities and individuals, such as prohibiting them from specified marketing or solicitation activities. We require Navigators and non-Navigator assistance personnel to obtain authorization before accessing a consumer's personally identifiable information and to prohibit them from charging consumers for their services. We also require that certified application counselors be recertified on at least an annual basis, and prohibit certified application counselors and certified application counselor designated organizations from receiving consideration, directly or indirectly, from health insurance issuers

or stop loss insurance issuers in connection with the enrollment of consumers in QHPs or non-QHPs. We further provide that, in specific circumstances, certified application counselor designated organizations can serve targeted populations without violating the broad non-discrimination requirement related to Exchange functions.

Indexing of Cost-Sharing Requirements: Under §§156.130(a) and 156.130(b), the annual limitation on cost sharing and the annual limitation on deductibles in the small group market for years after 2014 are to be indexed by the premium adjustment percentage. We established our methodology for calculating the premium adjustment percentage in the 2015 Payment Notice. In this final rule, we provide for the annual limitation on cost sharing to be updated based on the premium adjustment percentage by rounding down to the nearest \$50 increment. We are eliminating the annual limit on deductibles for small group plans, consistent with the Protecting Access to Medicare Act of 2014 (Public Law No. 113-93), which was signed into law on April 1, 2014.

Required Contribution Percentage: Under section 5000A of the Code, an applicable individual must maintain minimum essential coverage for each month, qualify for an exemption, or make a shared responsibility payment. An individual may qualify for an exemption from the shared responsibility payment if the amount that he or she would be required to pay towards minimum essential coverage (required contribution) exceeds a particular percentage (the required contribution percentage) of his or her household income. Under section 5000A of the Code, the required contribution percentage for 2014 is 8 percent, and for each plan year beginning in a calendar year after 2014, the percentage, as determined by the Secretary of Health and Human Services (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 the same period. In the

preamble to this final rule, we establish a methodology for determining the percentage reflecting the excess of the rate of premium growth over the rate of income growth for plan years after 2014. We also establish a required contribution percentage for 2015 of 8.05 percent. For calendar years after 2015, the required contribution percentage will be published in the annual HHS notice of benefit and payment parameters.

Eligibility Appeals: The rule amends standards related to eligibility appeals provisions in subparts F and H of Part 155. To facilitate the efficient conclusion of an appeal at the request of the appellant, we amend the withdrawal procedure to permit withdrawals made via telephonic signature.

Minimum Essential Coverage: We clarify that entities other than plan sponsors (for example, issuers) can apply for their coverage to be recognized as minimum essential coverage, pursuant to the process outlined in 45 CFR 156.604 and guidance thereunder.

Medical Loss Ratio: The MLR program created pursuant to the Affordable Care Act generally requires issuers to rebate a portion of premiums if their MLR fails to meet the applicable MLR standard in a State and market for the applicable reporting year. An issuer's MLR is the ratio of claims plus quality improvement activities to premium revenue, with the premium adjusted by the amounts paid for taxes, licensing and regulatory fees, and the premium stabilization programs. On December 1, 2010, we published an interim final rule entitled "Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements under the Patient Protection and Affordable Care Act" (75 FR 74864), which established standards for the MLR program. Since then, we have made several revisions and technical corrections to those rules. In this final rule, we modify the timeframe for which issuers can include their ICD-10 conversion costs in their MLR calculation. We also modify the regulation to clarify how issuers

would calculate MLRs and rebates in States that require the individual and small group markets to be merged. We note that the standards for ICD-10 conversion costs and merged markets also apply to the risk corridors program. Further, we modify the regulation to account for the special circumstances of the issuers affected by the HHS transitional policy and the issuers impacted by systems challenges during the implementation of the Exchanges.

II. Background

A. Legislative 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 final rule, we refer to the two statutes collectively as the “Affordable Care Act.”

The Affordable Care Act reorganizes, amends, and adds to the provisions of title XXVII of the PHS Act relating to group health plans and health insurance issuers in the group and individual markets.

Section 1201 of the Affordable Care Act added sections 2702 and 2703 of the PHS Act. Section 2702 of the PHS Act generally requires an issuer that offers health insurance coverage in the individual or group market in a State to offer coverage to and accept every individual or employer in the State that applies for such coverage. Section 2703 of the PHS Act generally requires an issuer to renew or continue in force coverage in the group or individual market at the option of the plan sponsor or the individual.

Prior to enactment of the Affordable Care Act, HIPAA amended the PHS Act to improve access to individual health insurance coverage for certain eligible individuals who previously had

group coverage, and to guarantee the renewability of all coverage in the individual market.

These reforms were added as sections 2741 through 2744 of the PHS Act.

HIPAA also added PHS Act provisions permitting sponsors of self-funded, non-Federal governmental plans to elect to exempt those plans from (“opt out of”) certain provisions of title XXVII of the PHS Act. This election was authorized under section 2721(b)(2) of the PHS Act, which is now designated as section 2722(a)(2) of the PHS Act by the Affordable Care Act.

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 consumers if they do not achieve specified MLRs.

Sections 2722 and 2763 of the PHS Act, as implemented in 45 CFR 146.145(b) and 148.220, provide that the requirements of parts A and B of title XXVII of the PHS Act shall not apply to any individual coverage or any group health plan (or group health insurance coverage) in relation to its provision of excepted benefits. Excepted benefits are described in section 2791(c) of the PHS Act. One category of excepted benefits, called “noncoordinated excepted benefits,” includes coverage for only a specified disease or illness, and hospital indemnity or other fixed indemnity insurance. Benefits in this category are excepted only if they meet certain conditions specified in the statute and regulations.

Section 1302(b) requires the Secretary to define EHB, including prescription drugs.

Section 1302(c) of the Affordable Care Act establishes an annual limitation on cost sharing for 2014, and provides that this limitation is to be increased for each year after 2014 by the percentage by which the average per capita premium for health insurance coverage in the United States for the preceding year exceeds the average per capita premium for 2013. Under section 1302(c), this limitation is to be rounded to the next lowest multiple of \$50.

Section 1311(b) of the Affordable Care Act provides that each State has the opportunity to establish an Exchange that: (1) facilitates the purchase of insurance coverage by qualified individuals through QHPs; (2) provides for the establishment of a SHOP designed to assist qualified employers in the enrollment of their qualified employees in QHPs; and (3) meets other requirements specified in the Affordable Care Act.

Section 1311(c)(3) of the Affordable Care Act requires the Secretary to develop a rating system to rate QHPs offered through an Exchange on the basis of quality and price. Section 1311(c)(4) of the Affordable Care Act directs the Secretary to establish an ESS system that would evaluate the level of enrollee satisfaction of members in QHPs offered through an Exchange, for each QHP with more than 500 enrollees in the previous year. Sections 1311(c)(3) and 1311(c)(4) of the Affordable Care Act further require an Exchange to provide information to individuals and employers from the rating and ESS systems on the Exchange's website. We have already promulgated regulations in 45 CFR 155.200(d) that direct Exchanges to oversee implementation of ESSs and ratings of health care quality and outcomes, and 45 CFR 156.200(b)(5)⁴ that directs QHP issuers that participate in Exchanges to report health care quality and outcomes information and to implement an ESS consistent with the Affordable Care Act.

Sections 1311(d)(4)(K) and 1311(i) of the Affordable Care Act direct all Exchanges to establish a Navigator program.

Section 1312(a)(2) of the Affordable Care Act provides that a qualified employer may provide support for coverage of employees under a QHP by selecting any level of coverage under section 1302(d) to be made available to employees through a SHOP. Section 1312(a)(2)

⁴ Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers; Final Rule, 77 FR 18310 (Mar. 27, 2012) (to be codified at 45 CFR parts 155, 156, & 157).

further provides that employees of an employer who makes such an election may choose to enroll in a QHP that offers coverage at that level.

Section 1321(a) of the Affordable Care Act provides 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. Section 1321(a)(2) requires the Secretary to engage in consultation to ensure balanced representation among interested parties.

Section 1321 of the Affordable Care Act provides for State flexibility in the operation and enforcement of Exchanges and related requirements. Section 1321(d) provides that nothing in title I of the Affordable Care Act shall be construed to preempt any State law that does not prevent the application of title I of the Affordable Care Act. Section 1311(k) specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations promulgated by the Secretary.

Section 1321(c)(1) requires the Secretary of HHS (referred to throughout this rule as the Secretary) to establish and operate an FFE within States that either: (1) Did not elect to establish an Exchange; or (2) as determined by the Secretary, did not have any required Exchange operational by January 1, 2014.

Section 1321(c)(2) of the Affordable Care Act provides that the provisions of section 2723(b) of the PHS Act⁵ shall apply to the enforcement under section 1321(c)(1) of requirements

⁵ Section 1321(c) of the Affordable Care Act erroneously cites to section 2736(b) of the PHS Act instead of 2723(b) of the PHS Act. This was clearly a typographical error, and we have interpreted section 1321(c) of the Affordable Care Act to incorporate section 2723(b) of the PHS Act.

of section 1321(a)(1), without regard to any limitation on the application of those provisions to group health plans. 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, in the Secretary's determination, a State fails to substantially enforce these provisions.

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 from 2014 through 2016. Section 1342 of the Affordable Care Act directs the Secretary to establish a temporary risk corridors program that provides for the sharing in gains or losses resulting from inaccurate rate setting from 2014 through 2016 between the Federal government and certain participating health plans. Section 1343 of the Affordable Care Act establishes a permanent risk adjustment program that provides for payments to health insurance issuers that attract higher-risk populations, such as those with chronic conditions, and charges issuers that attract lower-risk populations thereby reducing incentives for issuers to avoid higher-risk enrollees.

Section 1411(f)(1) of the Affordable Care Act provides that the Secretary, in consultation with the Secretary of the Treasury, the Secretary of Homeland Security, and the Commissioner of Social Security, shall establish procedures by which the Secretary or one of such other Federal officers hears and makes decisions with respect to appeals of any determination under subsection (e) and redetermines eligibility on a periodic basis in appropriate circumstances. Section 1411(f)(2) of the Affordable Care Act provides that the Secretary shall establish a separate appeals process for employers who are notified under section 1411(e)(4)(C) of the Affordable Care Act that the employer may be liable for a tax imposed by section 4980H of the Internal

Revenue Code of 1986 (the Code) with respect to an employee because of a determination that the employer does not provide minimum essential coverage through an employer-sponsored plan or that the employer does provide that coverage but it is not affordable coverage with respect to an employee.

Section 1411(h) of the Affordable Care Act sets forth CMPs to which any person may be subject if that person provides inaccurate information as part of an Exchange application or improperly uses or discloses an applicant's information.

Section 1501(b) of the Affordable Care Act added section 5000A to the Code. That section, as amended by the TRICARE Affirmation Act of 2010 (PL 111–159, 124 Stat. 1123) and Public Law 111–173 (124 Stat. 1215), requires nonexempt individuals to either maintain minimum essential coverage or make a shared responsibility payment for each month beginning in 2014. It also describes categories of individuals who may qualify for an exemption from the individual shared responsibility payment. Section 1311(d)(4)(H) of the Affordable Care Act specifies that the Exchange will, subject to section 1411 of the Affordable Care Act, grant certifications of exemption from the individual shared responsibility payment specified in section 5000A of the Code. Standards relating to these provisions were established in IRS regulations titled, “Shared Responsibility Payment for Not Maintaining Minimum Essential Coverage Final Rule,” published in the August 30, 2013 **Federal Register** (78 FR 53646) and HHS regulations titled, “Exchange Functions: Eligibility for Exemptions; Miscellaneous Minimum Essential Coverage Provisions Final Rule,” published in the July 1, 2013 **Federal Register** (78 FR 39494).

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. HHS has held a number of

listening sessions with consumers, providers, employers, health plans, the actuarial community, and State representatives to gather public input. HHS 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, technical health care quality measurement experts, health care survey development experts, and meetings with Tribal leaders and representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties. In addition, HHS received public comment on various notices published in the **Federal Register** relating to health care quality in the Exchanges,⁶ enrollee experience measures and domains,⁷ and the QRS, which provided valuable feedback on quality reporting and quality rating requirements.⁸ We considered all of the public input as we developed the policies in this final rule.

C. Structure of Final Rule

The regulations outlined in this final rule will be codified in 45 CFR parts 144, 146, 147, 148, 153, 154, 155, 156, and 158. Part 144 outlines requirements relating to health insurance coverage. Part 146 outlines the group health insurance market requirements of the PHS Act added by HIPAA and other statutes, including opt-out provisions for sponsors of self-funded, non-Federal governmental plans. Part 147 outlines health insurance reform requirements for the group and individual markets added by the Affordable Care Act, including standards related to guaranteed availability and guaranteed renewability of coverage. Part 148 outlines the individual health insurance market requirements of the PHS Act added by HIPAA and other statutes,

⁶ Request for Information Regarding Health Care Quality for Exchanges: <http://www.gpo.gov/fdsys/pkg/FR-2012-11-27/pdf/2012-28473.pdf>.

⁷ Request for Domains, Instruments, and Measures for Development of a Standardized Instrument for Use in Public Reporting of Enrollee Satisfaction With Their Qualified Health Plan and Exchange: <http://www.gpo.gov/fdsys/pkg/FR-2012-06-21/html/2012-15162.htm>.

⁸ Patient Protection and Affordable Care Act; Exchanges and Qualified Health Plans, Quality Rating System (QRS) Framework, Measures and Methodology; Notice with Comment, 78 FR 69418 (Nov. 19, 2013).

including standards related to guaranteed availability with respect to certain eligible individuals and guaranteed renewability for all individuals. Part 153 outlines standards related to the reinsurance and risk corridors programs. Part 154 outlines standards related to the disclosure and review of rate increases. Part 155 outlines standards related to the operations and functions of an Exchange, including standards related to non-discrimination, accessibility, and enforcement remedies; standards applicable to the consumer assistance functions performed by Navigators, non-Navigator assistance personnel, and certified application counselors; standards related to eligibility appeals; standards related to exemptions; standards related to quality reporting; and standards related to SHOP. Part 156 outlines health insurance issuer responsibilities, including EHB prescription drug standards; the methodology for calculating the annual limit on cost-sharing for years after 2014; minimum certification standards; standards for recognition of certain types of coverage as minimum essential coverage; quality standards for QHPs; and other QHP issuer responsibilities. Part 158 outlines standards related to the MLR program, including standards related to treatment of ICD-10 conversion costs, standards related to adjustments for issuers affected by the HHS transitional policy and issuers that incurred costs due to the technical issues during the implementation of the Exchanges, and standards related to MLR reporting and rebate calculations in States with merged individual and small group markets.

III. Provisions of the Proposed Regulations and Analysis and Responses to Public Comments

The proposed rule titled, “Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond,” was published in the **Federal Register** on March 21, 2014 (79 FR 15808), with comment period ending April 21, 2014 (referred to in this preamble as the “proposed rule”). In total, we received approximately 220 comments on the

proposed rule. Comments represented a wide variety of stakeholders, including but not limited to States, tribes, tribal organizations, health plans, consumer groups, employer groups, healthcare providers, industry experts, and members of the public.

Some comments were general public comments on the Affordable Care Act and the government's role in health care, but not specific to the proposed rule. We have not addressed such comments, and others that are not directly related to the proposed rule, because they are outside the scope of this final rule.

In this final rule, we provide a summary of each proposed provision, a summary of and responses to the public comments received, and the provisions we are finalizing.

Comment: Some commenters were concerned that the 30-day comment period did not provided sufficient opportunity for public review and comment on the proposed rule. One commenter stated that the proposed rule included many distinct policy issues, each of which should be addressed in separate rulemaking.

Response: HHS provided a 30-day comment period, which is consistent with the Administrative Procedure Act and the policy established by the Assistant Secretary for Administration (ASA) and the Office of Management and Budget (OMB). Additionally, HHS discussed nearly all of the proposed policies in the preamble to the HHS Notice of Benefit and Payment Parameters for 2015 final rule published on March 11, 2014 (79 FR 13744).⁹ HHS believes that interested stakeholders had adequate opportunity to provide comment on the policies established in this final rule.

A. Part 144 – Requirements Relating to Health Insurance Coverage

Definitions of Product and Plan (§144.103)

⁹ Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2015, 79 FR 13744 (March 11, 2014).

See the discussion in section III.C.1.b, “Product Discontinuance and Uniform Modification of Coverage Exceptions to Guaranteed Renewability Requirements.”

B. Part 146—Requirements for the Group Health Insurance Market

1. HIPAA Opt-Out Provisions for Plan Sponsors of Self-Funded, Non-Federal Governmental Plans (§146.180)

We proposed to codify the requirement that self-funded, non-Federal governmental plans may no longer elect to be exempt from (“opt out of”) requirements of title XXVII of the PHS Act related to limitations on preexisting condition exclusion periods; requirements for special enrollment periods; and prohibitions on health status discrimination. Self-funded, non-Federal governmental plans may, however, continue to opt-out of requirements related to benefits for newborns and mothers; parity in mental health and substance use disorder benefits; required coverage for reconstructive surgery following mastectomies; and coverage of dependent students on a medically necessary leave of absence.

We also proposed to streamline the submission process by requiring that opt-out elections be submitted electronically in a format specified by the Secretary in guidance. We solicited comment on these proposals, including ways to improve the electronic submission process.

The proposed rule provided a special effective date for self-funded, non-Federal governmental plans maintained pursuant to a collective bargaining agreement ratified before March 23, 2010 (the date of enactment of the Affordable Care Act) that had opted out of the requirement categories which are no longer available for exemption. These collectively bargained plans may continue to be exempt from the requirements until the first plan year following the expiration of such agreement.

The effect of the Affordable Care Act amendments on the HIPAA opt-out provisions was discussed in previous CMS guidance released on September 21, 2010.¹⁰

We noted that under the current regulations, plan sponsors of collectively bargained plans may submit one opt-out election for all group health plans subject to the same collective bargaining agreement. We solicited comment on whether the plan sponsor in such circumstances should be required to list all plans subject to the agreement. We also solicited comment on whether a single opt-out submission should be permitted in the case of multiple group health plans not subject to collective bargaining.

Comment: One commenter supported a requirement that plan sponsors of collectively bargained plans must list in their opt-out election all group health plans subject to the collective bargaining agreement.

Response: We establish this requirement in new paragraph (b)(1)(ix) of §146.180. Sponsors of group health plans not subject to collective bargaining will continue to be required to file a separate election for each group health plan.

We solicited comments on whether the regulation should be modified to allow plan sponsors of multiple group health plans not subject to collective bargaining to submit one election for all of its group health plans. We did not receive any comments on this issue; accordingly, we are adding regulation text to clarify the current requirement that a separate election must be filed for each group health plan not subject to collective bargaining.

We will continue to accept opt-out elections via U.S. Mail or facsimile until December 31, 2014. During this time, opt-out elections will continue to be accepted by mail to: Centers for

¹⁰ Amendments to the HIPAA opt-out provision (formerly section 2721(b)(2) of the Public Health Service Act) made by the Affordable Care Act (September 21, 2010). Available at: http://www.cms.gov/CCIIO/Resources/Files/Downloads/opt_out_memo.pdf.

Medicare & Medicaid Services (CMS), Center for Consumer Information and Insurance Oversight (CCIIO), Attn: HIPAA Opt-Out, 200 Independence Avenue, SW, Room 733H-02, Washington, DC 20201. Elections may also continue to be submitted via facsimile at 301-492-4462. For elections submitted via U.S. mail, CMS will continue to use the postmark on the envelope in which the election is submitted to determine that the election is timely filed. If the latest filing date falls on a Saturday, Sunday, or a State or Federal holiday, CMS accepts a postmark or a fax on the next business day. Questions regarding the opt-out process can be submitted to CMS at HIPAAOptOut@cms.hhs.gov. CMS's Center for Consumer Information and Insurance Oversight makes publicly available on its website a list of self-funded, non-Federal governmental plans that have submitted an opt-out election and the PHS Act provisions subject to the election.¹¹

Summary of Regulatory Changes

We are finalizing the revisions proposed in §146.180 of the proposed rule, with the following modifications. In paragraph (b), we add paragraph (b)(1)(ix) to state that, in the case of plan sponsor submitting one opt-out election for multiple group health plans subject to the same collective bargaining agreement, the opt-out election must list each group health plan subject to the agreement. Also in paragraph (b), we add paragraph (b)(1)(x) to state that, in the case of a plan sponsor submitting more than one opt-out election for plans that are not collectively bargained, a separate opt-out election must be submitted for each such plan. In paragraph (c)(3), we delete the special rule for timely filing with respect to opt out elections submitted by U.S. mail, and instead specify a special rule for timely filing that applies to

¹¹ See List of HIPAA Opt-Out Elections for Self-Funded Non-Federal Governmental Plans. Available at: <http://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/hipaa-optout-nfegp-list-05-06-2014.pdf>.

electronic filings. The special rule indicates that, if the latest filing date falls on a Saturday, Sunday, or a State or Federal holiday, CMS accepts filings submitted the next business day.

C. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

Guaranteed Availability and Guaranteed Renewability of Coverage (§§147.104 and 147.106)

a. No Effect on Other Laws

We proposed that nothing in the guaranteed availability requirements should be construed to require an issuer to offer coverage where other Federal laws operate to prohibit the issuance of such coverage. Similarly, we proposed that nothing in the guaranteed renewability requirements should be construed to require an issuer to renew or continue in force coverage for which continued eligibility would otherwise be prohibited under applicable Federal law. We offered several examples of statutory exceptions to the guaranteed availability and renewability requirements in the preamble to the proposed rule (78 FR 15815-6), and noted that only Federal law, not State law, can create such exceptions. We solicited comment on these clarifications, as well as other clarifications that may be helpful.

Additionally, we proposed a technical correction in §147.104(b)(1)(i) to delete duplicate regulatory text added in earlier rulemaking.¹² We also proposed other minor regulatory revisions in paragraph (b)(1)(i) for clarity.

Comment: Some commenters recommended the final rule enumerate all current Federal prohibitions on the sale of health insurance coverage that would create exceptions to the guaranteed availability and renewability requirements.

¹² Patient Protection and Affordable Care Act; Maximizing January 1, 2014 Coverage Opportunities, 78 FR 76212 (December 17, 2013).

Response: We believe it is neither appropriate nor practical to outline every specific exception to the guaranteed availability and renewability requirements and that a general rule of construction provides sufficient guidance to stakeholders.

Comment: One commenter sought clarification on situations where issuers offering coverage through an Exchange can sell coverage to individuals who are enrolled in Medicare and recommended that HHS add additional questions within the eligibility application to prevent individuals from receiving advance payments of the premium tax credit (APTC) who are also enrolled in Medicare.

Response: Section 1882(d)(3) of the Social Security Act (the “Medicare anti-duplication provision”) prohibits the sale of an individual market insurance policy that duplicates Medicare benefits to anyone known to be entitled to benefits under Part A (receiving free Part A) or enrolled in Part B or Premium Part A. This prohibition applies to individual health insurance coverage sold both through and outside an Exchange. This final rule clarifies that this prohibition creates an exception to the guaranteed availability provision where the prohibition would be violated by a sale.

While the Medicare anti-duplication provision prohibits the sale or issuance of a policy, it does not provide for discontinuance or non-renewal of a policy already issued, such as when an individual covered by an individual market policy becomes covered by Medicare. As stated in the individual market regulations at 45 CFR 148.122(b)(2), implementing the HIPAA guaranteed renewability provision, Medicare eligibility or entitlement is not a basis for non-renewal or termination of individual health insurance coverage. For ease of reference we are adding §147.106(g)(2) of this final rule, which repeats the regulatory language in §148.122(b)(2). We note, however, that nothing in the Medicare anti-duplication provision or the guaranteed

availability or renewability regulations prohibits an issuer from coordinating benefits under an individual health insurance policy with Medicare benefits in the case of a beneficiary. HHS will consider including questions in the FFE enrollment application to address this issue.

Summary of Regulatory Changes

We are finalizing the proposed provisions with the following modification. We add §147.106(g)(2) to restate the standard under the HIPAA guaranteed renewability regulations at §148.122(b)(2) that Medicare eligibility or entitlement is not a basis for non-renewal or termination of an individual's health insurance coverage in the individual market.

b. Product Discontinuance and Uniform Modification of Coverage Exceptions to Guaranteed Renewability Requirements

We proposed standards to define whether certain modifications to coverage constitute “uniform modifications” within the meaning of the PHS Act. These provisions were proposed in the guaranteed renewability regulations at 45 CFR 146.152, 147.106, and 148.122. Under the proposed rule, they would apply to issuers offering health insurance coverage in the group and individual markets, including both grandfathered and non-grandfathered health plans.

Specifically, we proposed that a modification made by an issuer solely pursuant to applicable Federal or State law would be considered a modification of the same product, and offered several examples of changes in response to Federal law that would constitute a modification of coverage.

We further proposed that if an issuer makes changes to the health insurance coverage for a product that are not pursuant to applicable Federal or State law, the modifications would also be considered a uniform modification of coverage if the resulting product meets all of the following criteria:

- The product is offered by the same health insurance issuer (within the meaning of section 2791(b)(2) of the PHS Act);
- The product is offered as the same product type (for example, preferred provider organization (PPO) or health maintenance organization (HMO));
- The product covers a majority of the same counties in its service area;
- The product has the same cost-sharing structure, except for variation in cost sharing solely related to changes in cost and utilization of medical care, or to maintain the same level of coverage described in sections 1302(d) and (e) of the Affordable Care Act (for example, bronze, silver, gold, platinum or catastrophic); and
- The product provides the same covered benefits, except for changes in benefits that cumulatively impact the rate for the product by no more than 2 percent (not including changes required by applicable Federal or State law).

These proposed criteria were intended to provide flexibility for issuers to make reasonable adjustments to coverage, while ensuring predictability and continuity for consumers and minimizing unnecessary terminations of coverage.

We proposed that States have flexibility to apply additional criteria that broaden the scope of what is considered a uniform modification, but that narrower State standards would be preempted.

We also proposed to add a provision in §147.106(e)(1) to restate the uniform modification of coverage provision for individual health insurance coverage under §148.122(g). This was proposed for ease of reference and to facilitate issuer compliance.

To provide clear information to consumers and help ensure they understand the changes and choices available to them in the individual and group markets, we proposed that issuers

provide standard notices in a form and manner prescribed by the Secretary when discontinuing or renewing coverage. Contemporaneously with the proposed rule, we released draft standard notices that issuers would be required to use in each of these situations, and requested public comment.¹³ In the standard notices guidance, we noted that States would have the option of developing State-required notices for issuers to use in place of the Federal notices, if approved by CMS. State notices approved for use could not be modified in any way by the issuer.

Finally, we stated that HHS or the applicable State will review rate increases for existing products that an issuer withdrew and attempted to re-file within a 12-month period as new products in order to avoid rate review as if they were simply renewed, if the changes to the discontinued product do not differ from the uniform modification criteria outlined above. We indicated that the same criteria set forth under the guaranteed renewability standards will be used to determine whether the re-filed product is considered to be the same “product” for purposes of determining whether the rate filing is subject to submission and review under 45 CFR Part 154. We requested comment on whether this clarification, or a reference to the uniform modification criteria, should be incorporated into the rate review regulations.

Comment: Some commenters recommended the proposed uniform modification of coverage provisions and standard notice requirements not apply in the large group market. They noted that large employers are sophisticated purchasers that typically negotiate customized products for their employees and that will receive little value from these protections. One commenter recommended the requirements not apply to grandfathered health plans, noting that

¹³ Standard Notices When Discontinuing or Renewing a Particular Product in the Group or Individual Market (March 14, 2014). Available at: <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/draft-discontinuance-renewal-notices-03-14-14.pdf>.

grandfathered plans are already, as part of the requirements related to maintaining grandfathered status, subject to restrictions on benefit changes that make the proposed provisions unnecessary.

Response: We recognize that purchasers in the large group market have greater leverage than those in the individual and small group markets. The guaranteed renewability statute contemplates these market differences by placing the requirement that modifications must be “consistent with State law and effective on a uniform basis” only on products in the individual and small group markets, but not on products in the large group market.¹⁴ For these reasons, we do not believe that the same interpretation, providing additional protection of renewability, is necessary in the large group market and are finalizing the regulation to apply only to coverage in the individual and small group markets.

We also note that, based on the statutory language requiring the changes to be “effective on a uniform basis,” we are adding regulation text explicitly stating that the interpretation of uniform modification provided for in this rule also requires that the modifications be made uniformly.

Because the guaranteed renewability statutes applicable to grandfathered individual market policies and group health insurance plans, PHS Act sections 2742 and 2712, respectively, use the same terms as the statute enacted under the Affordable Care Act at PHS Act section 2703, we decline to interpret the requirements differently for grandfathered plans. We note that in proposing to amend §146.152, we unintentionally proposed to replace paragraph (g) with the new paragraph regarding notice of renewal of coverage, rather than adding a new paragraph (h).

¹⁴ The PHS Act guaranteed renewability sections enacted under HIPAA, section 2712 for the group market and 2742 for the individual market, both include exceptions for uniform modifications of coverage. We recognize that PHS Act section 2703 excludes reference in some paragraphs to the individual market. However, we note that the provisions of PHS Act section 2742 still apply, and we believe that the uniform modification exception is still applicable in the individual market.

In this final rule, we correctly add the new paragraph as paragraph (h). Similarly, we note that in proposing to amend §148.122, we unintentionally proposed to replace paragraph (h) with the new paragraph regarding notice of renewal of coverage, rather than adding a new paragraph (i). In this final rule, we correctly add the new paragraph as paragraph (i).

Comment: The proposed rule provided that coverage modifications made “solely pursuant to applicable Federal or State law” would be considered a uniform modification of coverage. Some commenters requested clarification that references to Federal or State law also include Federal or State regulations or guidance. Another commenter urged HHS to allow issuers to increase out-of-pocket maximums based on annual index adjustments to the annual limitation on cost sharing without triggering a product discontinuance.

Response: The regulation text of the proposed rule specified that modifications made “solely pursuant to applicable Federal or State law” would be considered uniform modifications of coverage. We did not intend the word “law” to limit the scope of this provision to statutory requirements. Therefore, we are modifying the regulation text to explicitly state that, for coverage modifications to meet this standard, they must be made “solely pursuant to applicable Federal or State requirements.” Such requirements could be based on statutes, rules, regulations and any other applicable authority imposing binding requirements on issuers.

In response to the comment addressing the example we provided in the proposed rule of what would be considered “solely pursuant to applicable Federal or State law,” we also are adding language providing more detail on what constitutes a modification “made solely pursuant to applicable Federal and State requirements.” Specifically, the modification must be made within a reasonable time period after a Federal or State requirement is imposed or modified, and

it must also be directly related to the imposition or modification of a Federal or State requirement. For example, if State legislation newly requires a minimum level of benefits (for example, imposing a new minimum visit limit on specific benefits) reducing covered benefits to meet the minimum requirement would not be directly related to the new requirement because the lesser coverage of the benefit coverage was previously permissible, and the modification did not have to be made in order for the issuer to comply with the State law. Accordingly, the modification would not be considered to have been “made solely pursuant to” the new requirement. Such a modification would have to meet the other criteria in the final rule to be considered a uniform modification of coverage.

Comment: We received comments that requested clarification about whether and how the guaranteed renewability provisions apply to stand-alone dental plans (SADPs).

Response: Pursuant to §146.145(b)(3) and §148.220(b)(1), if an SADP is provided under a separate policy, certificate, or contract of insurance or is otherwise not an integral part of a group health plan, it would constitute excepted benefits and, therefore, generally would not be subject to the requirements of the PHS Act, including the guaranteed renewability requirements.

However, in the 2015 Letter to Issuers in the Federally-facilitated Marketplaces (2015 Letter to Issuers),¹⁵ we indicated that we will apply the guaranteed renewability standards to determine whether a plan offered in 2014 is the same plan for purposes of recertifying the plan for sale in 2015 through the Federally-facilitated Exchange, and that this standard would also apply to the determination of whether SADPs are being renewed for purposes of recertification. This does not in any way change the status of SADPs as excepted benefits. We are merely using

¹⁵ 2015 Letter to Issuers in the Federally-facilitated Marketplaces (March 14, 2014), available at: <http://www.cms.gov/CCHIO/Resources/Regulations-and-Guidance/Downloads/2015-final-issuer-letter-3-14-2014.pdf>.

the uniform modification standard for the purpose of identifying SADPs that can be recertified and renewed, rather than certified as different plans from those that were Exchange-certified in 2014.

In the 2015 Payment Notice, we established the national annual limit on cost sharing for the pediatric dental EHB when offered through an SADP of \$350 for one covered child and \$700 for two or more covered children. We acknowledge that, given the change to the annual limit on cost sharing, SADP issuers may need to modify the cost sharing of their currently certified plans in order to meet the annual limit established for implementation in 2015.

We interpret any uniform cost-sharing changes made to conform to the new national annual limit on cost sharing as meeting the uniform modification standard, because these modifications would meet the requirements under §147.106(e)(2) of this final rule, which provides that, “modifications made uniformly and solely pursuant to applicable Federal or State requirements are considered a uniform modification of coverage.” We further note that the general applicability of the annual limitation on cost sharing, if applied to all plans, would affect all consumers.

Therefore, we would consider an SADP that is uniformly modified to reduce its annual limitation on cost sharing pursuant to the change in regulations to meet the standards in paragraph (e)(2) as being a renewal with a uniform modification of the same plan for the purposes of recertification.

Comment: Several commenters urged HHS to more clearly distinguish whether the proposed uniform modification provisions would be applied to “products” or “plans.” Commenters explained that if our proposed rule were interpreted to apply to modifications made at the plan level, issuers would be forced to discontinue all plans associated with a product in

order to make any plan-level changes (such as creating identical new plans to reflect network pricing)—causing significant market disruption and many unnecessary terminations of coverage for existing enrollees.

Response: We interpret the guaranteed renewability provisions of section 2703 of the PHS Act to apply at the product-level. This statute, which closely resembles the guaranteed renewability statutes enacted under HIPAA, uses the terms “health insurance coverage,” which, as defined at section 2791 of the PHS Act, means “benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise and including items and services paid for as medical care) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or health maintenance organization contract offered by a health insurance issuer.” We interpret the references to “health insurance coverage” throughout section 2703 of the PHS Act to mean what is referred to in the commercial health insurance context as a health insurance “product.”

To clarify the application of these provisions in response to the above comments, we are codifying definitions of “product” and “plan” for purposes of this rule. Because similar language and concepts apply in the guaranteed availability statutes and regulations, we will apply these definitions to those regulations as well, by codifying the definitions at §144.103. These definitions are adopted largely from the Web portal and the rate review regulations.

Under this final rule, for purposes of guaranteed availability and guaranteed renewability, the term “product” means a discrete package of health insurance coverage benefits that a health insurance issuer offers using a particular product network type (for example, health maintenance organization (HMO), preferred provider organization (PPO), exclusive provider organization (EPO), point of service (POS), or indemnity) within a service area. This term generally reflects

the definition of “health insurance coverage” in the PHS Act, which primarily refers to a specific contract of covered benefits, rather than a specific level of cost-sharing imposed.¹⁶

For purposes of guaranteed availability and guaranteed renewability, the term “plan” means, with respect to an issuer and a product, the pairing of the health insurance coverage benefits under the product with a particular level of coverage (as described in sections 1302(d) and (e) of the Affordable Care Act) and service area. The combination of all plans within a product constitutes the total product that must be made available under guaranteed availability and renewed under guaranteed renewability to anyone in the service area of the plan in question, while the combined service areas of all plans constitute the service area of the product. If a product, or a plan under a product, does not have a defined service area, then the service area is the entire State in which the product is offered. To avoid any confusion, we also will change the reference to “termination of plan” to “termination of product” at §146.152.(b)(4), §147.106(b)(4), and §148.122(c)(3), and make a technical grammatical correction to §146.152.(b)(4) and §148.122(c)(3). This technical correction changes an “and” to an “or,” because an issuer is only required to comply with one and not both of the referenced paragraphs.

Under these definitions, an issuer must guarantee availability and guarantee renewability at the option of the plan sponsor or individual of the particular product that they purchased in the group or individual market, including each of the plans available in the sponsor or individuals service area that are part of all the plans that comprise the product at the time of renewal. The product discontinuance and uniform modification exceptions to guaranteed renewability also apply at the product level. An issuer may discontinue offering a particular product in a market only if the issuer uniformly withdraws the product from that market. Similarly, an issuer may

¹⁶ See PHS Act section 2791(b)(1).

modify the health insurance coverage for a product if the issuer ensures the modification is effective uniformly for all plans within that product. Issuers have flexibility, however, to make modifications at the plan level or to discontinue plans within a product consistent with the provisions of (e)(2) or (3).

As further described in subsequent responses to comments in this section, we are clarifying how three of the proposed criteria—related to cost-sharing, benefits, and service area—apply primarily at the plan level rather than the product level.

Comment: A few commenters sought clarification about the changes that could be made under the criterion related to product type. Two commenters raised particular questions about changes with respect to combined product arrangements, such as adding a point of service (POS) option to a health maintenance organization (HMO) product or removing an exclusive provider organization (EPO) benefit from a preferred provider organization (PPO) product. One commenter recommended that restrictions on product type be limited to situations when a product transitions to or from an HMO.

Response: While an issuer may offer particular benefits within a product using various network options, HHS believes most products generally are based on a single primary network type. For example, an HMO product with a POS option is nonetheless an HMO product, and a PPO product with an EPO benefit is nonetheless a PPO product. Accordingly, a product will not cease to be offered as the same product type solely because it adds or removes certain secondary network options. We believe referring to “product network type” more accurately conveys the intent of this requirement and make that revision in the final rule. We also provide the examples of HMO, PPO, EPO, POS and indemnity as product network types in the definition of “product” in §144.103 of this final rule.

Comment: Regarding the proposed service area criterion, a number of commenters recommended focusing only on service area reductions, rather than expansions. One commenter expressed concern about discriminatory service areas and suggested HHS establish standards to prevent issuers from dropping coverage in areas that are expected to have higher health risk. Two commenters noted that, in many States, product service areas are not filed with the State insurance department, presenting challenges for State regulators to administer requirements related to service areas.

Response: Under the proposed rule, for modifications to be considered uniform modifications of coverage, a product must continue to cover a majority of the same counties in its service area. This standard prevents significant reductions in a product's service area; however, service area expansions of any degree would satisfy this standard, provided that a majority of the original product service area remains covered. We acknowledge the concerns but believe the standard established in this final rule balances consumers' interest in coverage stability and issuers' interest in flexibility to appropriately manage their provider networks. We note that, since 1996, the HIPAA guaranteed renewability provisions (sections 2712(b)(5) and 2742(b)(4) of the PHS Act, as codified prior to enactment of the Affordable Care Act) have allowed issuers to non-renew or discontinue coverage under a network plan if there is no longer any enrollee in connection with the plan who lives, resides, or works within the service area of issuer (or in the area for which the issuer is authorized to do business).

In response to these comments, we are finalizing the rule so that the provision now requires that, "The product continues to cover a majority of the same service area" to be considered a uniform modification of coverage. We are making this change in recognition that a service area can be based on units other than counties, consistent with §147.102(b)(3), which

indicates that geographical rating areas can be based on counties, zip codes, or metropolitan statistical areas.

Comment: Many commenters requested clarification about the extent of changes that could be made to a plan's cost-sharing structure. Some commenters interpreted the provision as limiting changes in the type of cost-sharing used (for example, a co-payment versus coinsurance) and recommended that issuers be allowed to revise specific cost-sharing amounts (for example, based on historical or anticipated utilization of a particular benefit). Other commenters requested flexibility to modify cost sharing as long as the plan maintains the same metal level, meaning the same actuarial value metal tier (or catastrophic coverage).

Response: As stated above, we interpret the guaranteed renewability provisions of section 2703 of the PHS Act to apply at the product-level. But, in accordance with our definitions of "product" and "plan," we note that cost-sharing applies at the plan level. Similar to the proposed rule, this final rule provides that, for a modification to be considered a uniform modification of coverage, each plan within the product must continue to have the same cost-sharing structure as before the modification, except for any variation in cost sharing solely related to changes in cost and utilization of medical care (medical inflation or demand for services based on inflationary increases in the cost of medical care), or to the extent that changes are necessary to maintain the same level of coverage (that is, bronze, silver, gold, platinum, or catastrophic). This provision is intended to establish basic parameters around cost sharing modifications to protect consumers from extreme changes in deductibles, copayments, coinsurance, while preserving issuer flexibility to make reasonable and customary adjustments from year to year. Further, States have flexibility to permit broader changes to cost sharing within the uniform modification provisions, as discussed below. We do not adopt the suggestion

to allow all types of changes to cost sharing within a metal level, since this could be subject to manipulation and potential abuse. HHS will monitor compliance with this provision and may issue future guidance if necessary.

Comment: The proposed rule provided that one of the criteria for uniform modification is that the product provides the same covered benefits, except for changes in benefits that cumulatively impact the rate for the product by no more than 2 percent (not including changes required by applicable Federal or State law). Some commenters sought clarification that benefit changes could either increase or decrease the rate by 2 percentage points without exceeding the 2 percent rate variation threshold. One commenter asked whether issuers could adjust for medical inflation when making this assessment. Other commenters requested clarification whether the provision includes both benefit enhancements and reductions. Some commenters requested clarification that benefit changes in response to Federal or State requirements, such as the addition of the pediatric dental benefit and State-mandated benefits, are excluded from the 2 percent rate variation threshold. One commenter recommended applying a separate rate change threshold to each EHB category and providing States and Exchanges the discretion to override benefit modifications that have the potential to substantially harm the consumer.

Response: While benefit changes occur at the product level, consumers are affected by plan-adjusted index rates based on those changes. We believe that benefit changes that affect the rate for any plan within a product by more than 2 percent, regardless of whether they increase or decrease the rate, are significant to the consumer and should therefore constitute a new product offering. Therefore, in accordance with our definitions of “product” and “plan” for purposes of this rule and in response to these comments, we are finalizing the rule to state that, to be a uniform modification under this part of the rule, changes that cumulatively impact the plan-

adjusted index rate for any plan within the product must be within an allowable variation of +/- 2 percentage points. This provision applies only to changes in covered benefits, not cost sharing. It includes changes both to EHB and non-EHB benefits covered under the plan, as well as increases or decreases in covered benefits. However, rate changes that are directly attributable to compliance with applicable Federal or State legal requirements concerning covered benefits (such as those related to the requirement to provide EHB) are excluded for purposes of determining the cumulative rate impact.

Comment: Several commenters favored auto-enrollment of individuals whose product is discontinued, where issuers would “map” enrollees to another product offered by that issuer that most closely resembles the individuals’ previous product. The commenters indicated this practice is common in the commercial market and Medicare Advantage and promotes continuity of coverage.

Response: Nothing in this final rule prevents an issuer from auto-enrolling individuals whose product is being discontinued into another available product offered by that issuer, as long as the issuer meets all of the requirements for product discontinuance under the guaranteed renewability regulations. This includes providing at least 90 days’ notice of the discontinuation in writing and offering each individual the option to purchase, on a guaranteed availability basis, any other coverage offered by the issuer.

There are some instances in which an individual may lose coverage under his or her particular plan but not under the product. For example, an issuer may decide to no longer offer a particular plan within a product or to modify a plan’s service area within a product such that the plan no longer covers certain individuals. If these plan-level changes do not give rise to a product-level discontinuance under this final rule, the product remains guaranteed renewable at

the option of the plan sponsor or individual, as long as other plans within that product cover their service area. Again, nothing in this rule prevents an issuer from re-enrolling individuals into another plan that covers their service area under the same product in which the individuals are enrolled. HHS expects that issuers would re-enroll individuals in a new plan providing the same metal level of coverage as their previous plan within the same product. If a plan at that metal level is not available, HHS expects that issuers will re-enroll individuals in a plan that is most similar in metal level to the individual's previous plan under the same product for that service area.

We note that this does not address the operations of an Exchange, which may specify additional standards and processes for product termination, termination of enrollment, and re-enrollment in QHPs through an Exchange.

Comment: Several commenters expressed support for using the uniform modification standards to determine whether a rate filing for a product that is discontinued and another product re-filed the following year is subject to submission and review under 45 CFR Part 154, noting that this is an important protection to prevent gaming of the rate review requirements. Some commenters specifically recommended the clarification be incorporated into the rate review regulations.

Response: In response to comments, we have amended the definition of "product" in §154.102 to provide that the term includes any product that is discontinued and newly filed within a 12-month period in a market within a State that meets the standards of §147.106(e)(2) or (3) (relating to uniform modification of coverage).

Comment: Many commenters supported the flexibility in the proposed rule for States to broaden, but not narrow, the scope of what is considered a uniform modification of coverage.

Some commenters sought clarification about the meaning of “broaden” in this context. Other commenters recommended that State laws that prevent issuers from discontinuing or uniformly modifying coverage be expressly preempted by the Federal standards.

Response: After further consideration of this issue, we have determined not to finalize the ability of States to apply additional criteria that broaden the scope of what would be considered a uniform modification in connection with some of the criteria provided for in this rule, because the characteristics of a product defined in those criteria are so integral to the product that they cannot be altered without fundamentally changing the health insurance coverage for that product. These include the criteria that a product must continue to be offered by the same issuer (paragraph (c)(3)(i)), maintain the same product network type (paragraph (c)(3)(ii)), and provide, subject to specific exceptions, the same covered benefits (paragraph (c)(3)(v)). Modifications that result in a product that does not meet these criteria will not constitute a uniform modification under this final rule. This final rule does, however, continue to provide States flexibility to broaden the definition of uniform modification of coverage based on the criteria related to service area and cost-sharing structure. Thus, States could designate a lower threshold for meeting the service area standard than the requirement to continue to cover at least a majority of the same service area standard established in this final rule for which a product must maintain the same service area, or permit greater changes to a plan’s cost-sharing structure, and still permit the changes to be considered a uniform modification under this final rule. We reiterate our statement from the preamble to the final rule published on February 27, 2013 under section 2703 of the PHS Act (78 FR 13419) that a State standard or requirement that prohibits an issuer from uniformly modifying coverage in accordance with this final rule would prevent the application of a Federal requirement and therefore be preempted.

Comment: Some commenters supported the proposal to require standard consumer notices when issuers discontinue or renew coverage. Other commenters felt the notices were overly prescriptive and advocated for issuer flexibility to modify the notices. For example, commenters suggested HHS provide model notice language or specify minimum content requirements. Many commenters requested issuers have the ability to customize the notices in order to provide specific information to help consumers make informed purchase decisions, such as information about premiums, a description of benefit changes, and the policy year and enrollment deadlines. Some commenters recommended eliminating the renewal notice requirement altogether. Other commenters argued that States are in the best position to regulate on product discontinuance and renewal and suggested that notice requirements be left to the States.

Response: While we acknowledge the advantages of tailored consumer communications, and recognize the importance of State involvement, the final rule adopts the proposed language that notices be provided in a form and manner specified by the Secretary. We plan to address the notices in future guidance and intend to address the use of State-specific notices at that point in time.

Comment: Several commenters recommended that notices be sent only to the group or individual market policyholder, arguing that it would be administratively burdensome for issuers and confusing for employees and dependents to receive information about product renewal and discontinuation when they are not the primary decision makers.

Response: The final rule maintains the requirement that discontinuation notices must be provided to all enrollees under the plan or coverage. Section 2703(c)(1) of the PHS Act requires an issuer that elects to discontinue offering a particular product to provide at least 90 days' notice

of the discontinuation in writing to each plan sponsor or individual provided that particular product and to “all participants and beneficiaries covered under such coverage.” We note that an issuer may satisfy this requirement by providing the notice only to the subscriber.

By contrast, renewal notices are not required to be provided to participants, beneficiaries, or enrollees. Both the proposed rule and this final rule make clear that notices of renewal must only be provided to the plan sponsor (for example, employer) in the small group market or the individual market policyholder in the individual market.

Comment: Several commenters recommended that renewal notices be sent prior to the beginning of the open enrollment period, rather than 90 days before the end of the plan or policy year, to better align with the options and schedule of the Exchange.

Response: The statute and regulations establish a 90-day notice requirement only for product discontinuation. In the final rule, we have added in §148.122(i) a requirement that renewal notices be delivered at least 60 calendar days before the date of renewal of the coverage for grandfathered products in the individual market and, in §147.106(f)(2) and §146.152(h), for all products in the small group market. For non-grandfathered products in the individual market, in response to the commenters’ request to coordinate the notices with enrollment in the Exchange, we are requiring in §147.106(f)(1) the renewal notices be delivered before the first day of the annual open enrollment period. We believe this provides sufficient advance notice for consumers in non-grandfathered individual policies to review other options for coverage. Since the small group market has continuous year-round open enrollment, the 60 day advanced notice of renewal provides sufficient notice to employers. Many grandfathered policies in the individual market have non-calendar policy years that do not line up with the annual open

enrollment period in the individual market. Accordingly, the 60 day advanced notice requirement is more appropriate for these policies.

Comment: Some commenters noted that the Federal notices will duplicate renewal notices developed by issuers, States, and Exchanges, and emphasized the need for coordination to prevent consumer confusion.

Response: We agree and encourage issuers, States, and Exchanges to coordinate enrollee communications to the extent possible.

Summary of Regulatory Changes

We are finalizing the uniform modification provisions proposed in §147.106 of the proposed rule with the following modifications and made corresponding changes in §146.152 and §148.122. We are adding regulation text explicitly stating that the interpretation of uniform modification provided for in this rule also requires that the modifications be made uniformly. We add language amending and clarifying the term “pursuant to applicable Federal and State law”; replace “product type” with “product network type”; and to specify that the product must continue to cover at least a majority of the same service area, and delete the reference to “counties.” We only finalize the ability of States to apply additional criteria that broaden the scope of what would be considered a uniform modification in connection with the criteria involving service area and cost-sharing structure. We clarify that the criteria related to cost-sharing and covered benefits apply at the plan-level. We do not finalize the interpretation of uniform modification or the corresponding renewal notice requirements with respect to issuers in the large group market, only with respect to issuers offering coverage in the individual and small group markets.

We also are adding definitions of “product” and “plan” at §144.103; changing the reference to “termination of plan” to “termination of product” at §146.152(b)(4), §147.106(b)(4), and §148.122(c)(3); and are amending the definition of “product” in the rate review regulations to reflect the interpretation of uniform modification, as applied in the rate review context.

D. Part 148—Requirements for the Individual Health Insurance Market

1. Conforming Changes to Individual Market Regulations (§§148.101 through 148.128)

We proposed conforming revisions to the individual market provisions contained in 45 CFR Part 148 to remove provisions that are superseded by the prohibition on preexisting condition exclusions under new section 2704 of the PHS Act, added by the Affordable Care Act.¹⁷ We proposed these amendments generally apply when the final rule becomes effective. Under our proposal, however, the requirement to issue certificates of creditable coverage would continue to apply until December 31, 2014. This would allow individuals to continue to offset a preexisting condition exclusion that could potentially be imposed by a group health plan with a plan year from December 31, 2013 to December 30, 2014. We indicated that these amendments were for clarity only and that they were consistent with amendments to the group market provisions and with previous CMS guidance.¹⁸ We solicited comment on these proposals.

¹⁷ The Affordable Care Act adds section 715(a)(1) of ERISA and section 9815(a)(1) of the Code to incorporate the provisions of part A of title XXVII of the PHS Act, including section 2704 of the PHS Act, into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. PHS Act section 2704 applies to grandfathered and non-grandfathered group health plans and group health insurance coverage, and non-grandfathered individual health insurance coverage. It does not apply to grandfathered individual health insurance coverage. For more information on grandfathered health plans, see section 1251 of the Affordable Care Act and its implementing regulations at 26 CFR 54.9815-1251T, 29 CFR 2590.715-1251, and 45 CFR 147.140.

¹⁸ See Ninety-Day Waiting Period Limitation and Technical Amendments to Certain Health Coverage Requirements Under the Affordable Care Act, 78 FR 10296 (February 24, 2014). See also Questions and Answers Related to Health Insurance Market Rules, Q2. Available at: http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/qa_hmr.html.

Comment: Two commenters stated that certificates of creditable coverage might continue to be needed in limited circumstances after 2014, such as when a dependent is added to a grandfathered individual health insurance plan, which is not subject to the prohibition on preexisting condition exclusions. The commenters recommended that certificates be required to be provided upon request after December 31, 2014.

Response: While certain plans in the individual market, such as grandfathered health plans that are individual health insurance coverage and transitional individual market plans, may impose preexisting condition exclusions after 2014, such plans are not required to give credit for prior coverage against a preexisting condition exclusion period. Accordingly, there are no circumstances in which a certificate of creditable coverage will be relevant after December 30, 2014.

Summary of Regulatory Changes

We are finalizing the amendments proposed in §§148.101 through 148.128 of the proposed rule without change.

2. Fixed Indemnity Insurance in the Individual Health Insurance Market (§148.220)

As indicated in previous CMS guidance, which described our intended approach, we proposed to amend the criteria for fixed indemnity insurance to be treated as an excepted benefit in the individual health insurance market. Excepted benefits are exempt from many of the requirements of title XXVII of the PHS Act.

Specifically, under the proposed rule, individual fixed indemnity policies would be considered an excepted benefit if the benefits are provided under a separate policy, certificate, or contract of insurance and all of the following criteria are met: (1) The benefits are provided only to individuals who have other health coverage that is minimum essential coverage within the

meaning of section 5000A(f) of the Code; (2) there is no coordination between the provision of benefits and an exclusion of benefits under any other health coverage; (3) the benefits are paid in a fixed dollar amount per day of hospitalization or illness or per service (for example, \$100/day or \$50/visit) regardless of the amount of expenses incurred and without regard to the amount of benefits provided with respect to the event or service under any other health coverage; and (4) a notice is displayed prominently in the plan materials in at least 14-point type that has the following language: “THIS IS A SUPPLEMENT TO HEALTH INSURANCE AND IS NOT A SUBSTITUTE FOR MAJOR MEDICAL COVERAGE. LACK OF MAJOR MEDICAL COVERAGE (OR OTHER MINIMUM ESSENTIAL COVERAGE) MAY RESULT IN AN ADDITIONAL PAYMENT WITH YOUR TAXES.”

This proposal was intended to prevent disruption and address stakeholder concerns that many fixed indemnity insurance policies marketed today in the individual market do not qualify as excepted under the regulations at §148.220(b)(3) and, as further described in a frequently asked question (FAQ) published on January 24, 2013, because they pay on a per-service rather than a per-period basis.¹⁹ We solicited comment on this approach, including comments on the proposed notice language.

We explained that, to meet the standard that fixed indemnity insurance must be sold only to individuals who have other health coverage that is minimum essential coverage, the issuer would have to be “reasonably assured” that an individual purchasing a fixed indemnity policy has minimum essential coverage. We sought comment on the extent of verification issuers may need for reasonable assurance, including the possibility of consumer self-attestation. We also

¹⁹ See FAQs about Affordable Care Act Implementation (Part XI), Q7, available at <http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Affordable-Care-Act-implementation-faqs11.html> and <http://www.dol.gov/ebsa/faqs/faq-Affordable-Care-Act11.html>.

sought comment on whether the “other health coverage that is minimum essential coverage” standard was sufficient protection or if another standard may be appropriate (for example, requiring that fixed indemnity insurance be sold to individuals with other health coverage that meets the EHB requirements).

We noted that under a safe harbor approach established by the Departments of HHS, Labor, and the Treasury (the Departments) for supplemental health insurance coverage to be considered an excepted benefit, the supplemental coverage must be issued by an entity that does not provide the primary coverage under the plan.²⁰ We indicated that we were considering adopting a similar standard for individual fixed indemnity insurance to qualify as excepted and sought comment.

Finally, we indicated that, in our view, most fixed indemnity products offered in the individual market today would largely satisfy these proposed criteria. We solicited comment, nonetheless, on how the proposal might affect existing market arrangements. We also solicited comment on whether applying the provisions for policy years beginning on or after January 1, 2015 would provide a sufficient transition period, and whether keeping the current regulatory criteria in place on a permanent or temporary basis could help to alleviate any potential market disruption.

Comment: Several commenters questioned HHS’s legal authority to impose the requirement that fixed indemnity insurance must be sold as supplement to minimum essential coverage in order to be an excepted benefit. They noted that Congress created another category

²⁰ See CMS Insurance Standards Bulletin 08-01 (available at http://www.cms.gov/CCIIO/Resources/Files/Downloads/hipaa_08_01_508.pdf); the Department of Labor's Employee Benefits Security Administration's Field Assistance Bulletin No. 2007-04 (available at <http://www.dol.gov/ebsa/pdf/fab2007-4.pdf>); and Internal Revenue Service Notice 2008-23 (available at http://www.irs.gov/irb/2008-07_IRB/ar09.html).

of excepted benefits for supplemental coverage. Some commenters indicated that imposing the supplemental requirement was an encroachment of States' regulatory authority since States have the primary authority to regulate excepted benefits. One commenter stated that the proposal contravenes the holding of the Supreme Court that the government cannot compel individuals to engage in economic activity. One commenter stated that the requirement that fixed indemnity insurance be sold only as supplemental coverage to minimum essential coverage should be removed, and that Federal and State regulators, along with consumer and carrier representatives, should work together to develop requirements that will protect consumers and also retain coverage options.

Response: We do not agree with these comments. As with all excepted benefits, what the coverage provides, rather than how it is labelled, is determinative of whether it is treated as excepted benefits. Accordingly, we have developed standards for when coverage would be considered exempt from the requirements of the Affordable Care Act and other provisions in Title XXVII of the PHS Act. In so doing, we have not encroached on State's regulatory authority to regulate excepted benefits. Under this final rule, States will continue to have primary enforcement authority over such benefits, using the Federal definition as a floor, consistent with the overall framework for implementing Title XXVII of the PHS Act. We note that the statutory category which includes fixed indemnity coverage as an excepted benefit conditions its status on the coverage being "independent, noncoordinated" benefits, presuming the existence of other coverage. For purposes of the individual market, we are clarifying that there must be such other coverage, and that the other coverage in question must be minimum essential coverage. Additionally, requiring that fixed indemnity insurance in the individual market must be sold as supplemental to minimum essential coverage in order to be an excepted benefit does not compel

any individual to purchase minimum essential coverage or otherwise engage in any economic activity. We will continue to work in partnership with States, along with consumer and issuer representatives, as we always have, to develop and fine-tune approaches to all Affordable Care Act provisions, including revisiting any aspect of these fixed indemnity provisions, as appropriate and necessary.

Comment: One commenter made the general assertion that the purpose of the excepted benefits provisions in the Affordable Care Act was not to indicate that the types of coverage listed as excepted benefits are excepted from the provisions of the Affordable Care Act, but to allow a health plan to include such categories of coverage under a health plan without having to conform this coverage (that is, the excepted benefits) to the provisions of the Affordable Care Act that apply to the health plan.

Response: Section 2722 of the PHS Act (42 U.S.C. 300gg-21) reads in relevant part in subparagraph (c)(2): “The requirements of subparts 1 and 2 shall not apply to any individual coverage or any group health plan (or group health insurance coverage) in relation to its provision of excepted benefits described in section 2791(c)(3) of this title.” We believe this statutory language is clear that the excepted benefits provisions apply to any individual coverage that meets the definition of any of the excepted benefits listed in section 2791(c)(3), including, but not limited to, hospital and other fixed indemnity policies. (We also believe that subparagraphs 2722(b), (c)(1), and (c)(3) are similarly clear that the excepted benefits provisions apply to any individual coverage in relation to its provision of any of the excepted benefits listed therein. In this final rule, we are making a relatively minor change to the introductory text (changing “individual health insurance coverage” to “individual coverage”), to bring it into conformance with the wording of the statute.

Comment: One commenter asserted that, because coverage provided as an excepted benefit can only be provided in relation to a health plan, proposed section 148.220(b)(4)(i), which states that fixed indemnity insurance is an excepted benefit only if, among other criteria, the individual has minimum essential coverage, is superfluous.

Response: We disagree that the statute and current regulations already provided that fixed indemnity coverage (or any other excepted benefit listed in the statute) is only an excepted benefit if provided in relation to another health plan (although as noted above, this is implicit).

Comment: While one commenter agreed with the inclusion of §148.220(b)(4)(ii) and (iii) as requirements in order for fixed-indemnity policies to qualify as excepted benefits, several commenters believed it would be beneficial to add in subparagraph (b)(4)(ii), a requirement that benefits may not be reduced on account of funds received from any other source. The commenter asserted that, in order to qualify as excepted benefits, a fixed indemnity policy should pay without regard to any other sources of payment.

Response: We do not believe such a requirement would be necessary. Subparagraph (b)(4)(ii) is intended to address the statutory provision in the PHS Act at section 2791(c)(3) that hospital indemnity or other fixed indemnity insurance is an excepted benefit if the benefits are offered as independent, noncoordinated benefits. In this context, we interpret “noncoordinated” as meaning noncoordinated with other coverage, as opposed to noncoordinated with other sources of financial support, such as friends or family members.

Comment: One commenter questioned whether it is the intent of HHS to regulate, and through such regulation prohibit, the sale of fixed indemnity policies on a stand-alone basis.

Response: It is not the intent of HHS to regulate or prohibit the sale of fixed-indemnity policies on a stand-alone basis. Rather, the fixed indemnity insurance provisions set forth the

circumstances under which such a policy would or would not qualify as excepted benefits. In the preamble to the proposed regulation, we mentioned that this proposal for determining whether fixed indemnity policies are excepted benefits is consistent with previously released guidance describing our intended approach.

Comment: One commenter argued that it would not make sense to require purchasers of fixed-indemnity coverage to have minimum essential coverage in order for the fixed indemnity coverage to be an excepted benefit, when there is no such requirement for other types of coverage to be an excepted benefit.

Response: As noted in the preamble to the proposed regulation, we proposed that fixed indemnity policies in the individual market be permitted to pay on a per-medical-service basis, to accommodate the concerns of several stakeholders. In order to accommodate those concerns in a reasonable way, we are requiring that individuals who purchase fixed-indemnity policies in the individual market have other minimum essential coverage in order for the fixed indemnity policy to be an excepted benefit. Because we are not expanding the definition of any other type of excepted benefit as we are here, we do not believe it is necessary to impose new conditions on other categories of excepted benefits that the purchaser have other minimum essential coverage.

Comment: The majority of commenters supported the disclosure requirement in order to inform consumers of the nature and extent of fixed indemnity insurance coverage. One commenter recommended that the notice requirement be expanded to indicate that the consumer has been advised on the difference between major medical coverage and fixed indemnity insurance and has been informed on how to acquire major medical coverage from the carrier. Another commenter stated that the last line of the HHS proposed disclosure notice could easily mislead consumers and cause them to think supplemental coverage is somehow tied to the tax

provisions of the individual shared responsibility payment, and recommended that it be replaced with this line: “This policy does not provide the minimum essential coverage that individuals may be required to have under the Affordable Care Act.” One commenter requested clarification that the requirement that the notice be displayed in plan materials does not specifically require the notice be inserted in the filed contract forms. Several commenters recommended that the disclosure language be consumer tested. One commenter objected to a Federal prescription of specific wording.

Response: We believe the proposed content of the notice is sufficient to meet its objectives. To ensure that the objectives are met, we believe the standardized language is necessary. With respect to where the notice is displayed, we believe, for policies issued after January 1, 2015, the most appropriate place is in the application for coverage, as this is the most likely document in which a purchaser of fixed indemnity coverage would actually see the notice. Therefore, in this final rule, we are requiring that the notice be displayed in the application. As described below, policies issued before January 1, 2015 are not required to come into compliance with the notice requirements until the first renewal on or after January 1, 2015. For policies issued before January 1, 2015, we believe it would be appropriate for the notice to be delivered shortly before the first renewal date occurring on or after January 1, 2015, but we defer to State law on the timing. In an effort to minimize industry burden, we are not requiring that fixed indemnity insurers, in order for the coverage to be an excepted benefit, insert the notice in filed contract forms or into any other specific document.

Comment: Many commenters opined that an attestation would be sufficient but others suggested that issuers be required to request documentation from the consumer verifying that they have minimum essential coverage. One commenter requested that the attestation be

required upon renewal of the fixed indemnity coverage, noting that individuals could lose their minimum essential coverage after the initial attestation. Another commenter recommended that the attestation be expanded to have the consumer attest that the difference between major medical coverage and fixed indemnity insurance had been explained to them and had been informed on how to purchase major medical coverage.

Response: Although methods in addition to attestation might help ensure that individuals have and maintain minimum essential coverage, we seek to balance this objective against the burden of verification. Therefore, this final rule requires that the purchaser of fixed indemnity coverage attest that he or she has minimum essential coverage, but does not require any further documentation. In this final rule, this is a one-time attestation upon issuance of the policy that does not have to be re-performed upon renewal of the policy or any other time. For policies issued before January 1, 2015, we believe it would be appropriate for the one-time attestation to be collected from the policyholder shortly before the first renewal occurring on or after October 1, 2016, but we defer to State law on the timing. We do not believe it is necessary that the attestation be expanded to have consumers attest that the difference between major medical coverage and fixed indemnity insurance had been explained to them and they had been notified about how to purchase major medical coverage.

Comment: We proposed that individuals must have minimum essential coverage in order to be sold fixed indemnity insurance coverage but solicited comments on whether that was sufficient protection. As an alternative standard, we sought comment on whether individuals could be required to have a policy that provided all of the EHB. Many commenters opined that the requirement to have minimum essential coverage is sufficient protection. One commenter noted that minimum essential coverage is a defined term in the Affordable Care Act and can be

applied nationally. Other commenters felt that the protection should be expanded to require individuals to have coverage that complied with the EHB requirement in order to be sold fixed indemnity insurance.

Response: We believe it is appropriate and sufficient to require that fixed indemnity insurance be sold as supplemental to minimum essential coverage, in order to be an excepted benefit. As having minimum essential coverage is generally the standard for determining whether an individual complies with the shared responsibility provision, we believe it is also the appropriate standard for this purpose.

Comment: One commenter requested clarification that fixed indemnity insurance can pay in a combination of per day *and* per service amounts, in addition to being able to pay per day *or* per service amounts.

Response: We believe such a clarification would be helpful, and have changed “or” to “and/or” in this final rule. As part of this clarification, we are revising the phrase “per day of hospitalization or illness” so it reads “per period of hospitalization or illness.” This clarification makes this provision of the individual market rule, consistent with the corresponding provision in the group market rule on hospital and fixed indemnity policies.

Comment: One commenter indicated that it should be clear that the fixed indemnity insurance provisions apply to individual products as defined in the PHS Act regardless of whether the products are filed as group products under State law. The commenter noted that there can be conflicting definitions of group and individual products under State and Federal law.

Response: The PHS Act defines individual market in terms of health insurance (that is, not in terms of excepted benefits), and defines individual health insurance coverage. Nonetheless, our intention is that §148.220 applies to excepted benefits sold in the “individual

market” as that term is defined in §144.103, absent the reference to “health insurance.” This would preempt any State law that classifies an individual product as a “group” product (for example, individual products sold through associations).

Comment: Several commenters stated that fixed indemnity insurers should be permitted to sell policies to certain categories of individuals other than those who have minimum essential coverage, such as healthy and young or middle aged individuals with moderate income who cannot afford high-deductible coverage under the Affordable Care Act, but can afford a limited indemnity plan, those who qualify for a hardship exemption from the individual shared responsibility payment, and those who feel they cannot afford the price of minimum essential coverage offered to their dependents through an employer’s health plan. These commenters asserted that eliminating a valid and possibly affordable option to provide these individuals with a source of assistance during a medical emergency is of concern. Several commenters believe the requirement to have minimum essential coverage will cause negative consequences for individuals living in States where the Medicaid expansion was not adopted, and who earn too much money to qualify for Medicaid but not enough to qualify for exchange subsidies, and to undocumented residents who are neither eligible for subsidies nor eligible to access the exchanges to acquire minimum essential coverage. Finally, one commenter observed that, according to the code at 26 U.S.C. 5000(A)(f)(4), residents of U.S. territories shall be “treated as having minimum essential coverage.” Therefore, the commenter asked that we clarify in the final rule that fixed indemnity insurance sold to residents of the U.S. territories are treated as having minimum essential coverage, for purposes of the requirement that fixed indemnity insurance must be sold to individuals who have minimum essential coverage in order for the fixed indemnity coverage to be an excepted benefit.

Response: While we do not agree that fixed indemnity insurers should be permitted to sell policies to every category of individuals who do not have minimum essential coverage, we accept the commenter's suggestion that those who are treated as having minimum essential coverage due to their status as residents of U.S. territories should be able to purchase fixed indemnity insurance without actually having minimum essential coverage. We believe it is consistent with the nature of Code section 5000A(f)(4)(B), to treat such individuals similarly to individuals who actually have minimum essential coverage, for purposes of whether a fixed indemnity insurer may sell them a policy without losing excepted benefits status. Therefore, we have incorporated this provision into this final rule. We believe that expanding this principle any further to other populations would erode the objective of attempting to ensure that as many individuals as possible enroll in minimum essential coverage. We also note that individuals who have hardship exemptions to the shared responsibility payment are permitted under Federal law to purchase a catastrophic plan, which typically provides economical health insurance benefits.

Comment: Several commenters stated that as an alternative to the proposed requirement that fixed indemnity coverage be sold only to individuals who have minimum essential coverage in order for the fixed indemnity coverage to be an excepted benefit, fixed indemnity insurance should be considered excepted benefits if offered, marketed, and sold as supplemental insurance.

Response: We do not believe that merely offering, marketing, and selling fixed indemnity policies as supplemental benefits, will effectively address the confusion about these policies that many consumers have, or will effectively contribute to the Affordable Care Act's goal of maximizing the number of individuals who have comprehensive, major medical coverage.

Comment: One commenter was concerned that “transitional policies,” that is, policies that do not conform with certain Affordable Care Act requirements first applicable in 2014, but continue to be renewed for policy years ending on or before October 1, 2016 as a result of CMS’ March 5, 2014 bulletin on Extension of Transitional Policy through October 1, 2016, might not constitute minimum essential coverage.

Response: Such transitional policies are small employer or individual market policies that constitute minimum essential coverage.

Comment: We sought comment on whether to add a requirement that a fixed indemnity policy must be issued by a different issuer than minimum essential coverage, in order for the fixed indemnity insurance to be an excepted benefit. Several commenters supported adding such a requirement, stating that doing so would be an appropriate interpretation of the requirement that fixed indemnity insurance be independent. Other commenters did not agree that this requirement be added. One such commenter did not believe that the problem of an issuer of major medical coverage carving out benefits for the purpose of selling an enrollee a fixed indemnity plan, exists in the commenter’s local area, while others stated that, under the Affordable Care Act requirements, issuers offering major medical coverage in the individual and small group markets must include essential health benefits in their major medical coverage.

Response: We agree with the commenters that such a requirement might harm consumers by limiting their choice of fixed indemnity issuers. Thus, we are not including such a requirement in this final rule. However, we remind commenters that section 2791(c)(3) of the Public Health Service Act, which prohibits fixed indemnity policies from coordinating with other coverage, would still apply.

Comment: One commenter did not object to the proposed provisions taking effect for policy years beginning on or after January 1, 2015. Several commenters stated that the proposed provisions should apply to coverage issued on or after July 1, 2015, rather than coverage issued on or after January 1, 2015. One commenter stated that the provisions should apply to policies issued after December 31, 2015. One commenter noted that a January 1, 2015 date is unrealistic in light of the time needed for filing new products and applications, as well as the workload on State Insurance Departments in the coming months as they review filings and rates for insurance products to be sold in 2015.

Response: In order to provide sufficient time for such insurers to prepare to meet the new minimum essential coverage and notice requirements, these two new requirements will apply to policies first issued on or after January 1, 2015. The notice requirement will also apply to existing policies starting with policy years beginning on or after January 1, 2015. Prior to that date, upon the final rule taking effect, the other criteria in section 148.220 will replace the existing regulatory criteria (as interpreted in our January 24, 2013 FAQ) for fixed indemnity insurance to be an excepted benefit.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §148.220 of the proposed rule with the following modifications. In the introductory text, we clarify that the requirements of parts 146 and 147 do not apply to “any individual coverage” (as opposed to individual health insurance coverage) that meet the relevant requirements of that section, consistent with statutory language. In paragraph (b)(4)(i), we indicate that the fixed indemnity benefits must be provided only to individuals who attest, in their application, that they have other health coverage that is minimum essential coverage, or that they are treated as having minimum essential coverage based on their

status as a bona fide resident of any possession of the United States pursuant to Code section 5000A(f)(4)(B). In paragraph (b)(4)(iii), we clarify that the fixed indemnity benefit must be paid in a fixed dollar amount per period of hospitalization or illness “and/or” per service. In §148.220(b)(4)(iv), we clarify that the notice to fixed indemnity policyholders must be displayed in the application. In new paragraph (b)(4)(v), we state that the requirement of paragraph (b)(4)(iv) applies to all hospital or other fixed indemnity insurance policy years beginning on or after January 1, 2015 and the requirement of paragraph (b)(4)(i) applies to hospital or other fixed indemnity insurance policies issued on or after January 1, 2015, and to hospital or other fixed indemnity policies issued before that date, upon their first renewal occurring on or after October 1, 2016.

E. Part 153—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment under the Affordable Care Act

As noted in the proposed rule, both the reinsurance and risk adjustment programs are subject to the fiscal year 2015 sequestration. The risk adjustment and reinsurance programs will be sequestered at a rate of 7.3 percent in fiscal year 2015. The Federal government’s 2015 fiscal year begins on October 1, 2014. HHS, in coordination with the OMB, has determined that, pursuant to section 256(k)(6) of the Balanced Budget and Emergency Deficit Control Act of 1985 as amended, and the underlying authority for these programs, funds that are sequestered in fiscal year 2015 from the reinsurance and risk adjustment programs will become available for payment to issuers in fiscal year 2016 without further Congressional action. Should Congress fail to enact deficit reduction that replaces 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.

Comment: Several commenters asked that HHS clarify the details regarding the payment of sequestered funds, particularly for risk adjustment. One commenter suggested that reinsurance payments that might have otherwise been sequestered be made by prioritizing collections for reinsurance payments over collections for the U.S. Treasury. One commenter noted that a short delay in risk adjustment and reinsurance payments would not pose major problems for issuers.

Response: As we stated in the proposed rule, we aim to make payments of sequestered fiscal year 2015 funds for the reinsurance and risk adjustment programs as soon as practicable in fiscal year 2016, which begins on October 1, 2015. We note that we cannot sequester amounts from reinsurance collections for the U.S. Treasury because the U.S. Treasury collections are not budgetary resources. Therefore, they are not subject to sequestration and do not affect HHS's required reductions under the sequestration law. We will provide further clarification regarding how the amount of sequestered funds will be calculated and paid in future guidance.

1. Provisions and Parameters for the Permanent Risk Adjustment Program

We have received input from commenters suggesting that the coefficients in our risk adjustment models may not fully capture the relative actuarial risk of certain hierarchical condition categories (HCCs), in part because those conditions may be subject to changing therapies and higher trends in medical inflation. Although some inaccuracy in our coefficients is inevitable due to lags in the data, we believe that we will be able to mitigate this problem if we recalculate, on an annual basis, the weights assigned to the various HCCs and demographic factors in our risk adjustment models using the most recent data available, even in the years where we do not fully recalibrate the models. We intend to propose such a reweighting in the HHS notice of benefit and payment parameters for 2016, and we will consider having those

updated coefficients apply also for the 2015 benefit year. These adjusted models would be subject to public notice and comment.

2. 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 and the 2015 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 and 2015 benefit years. In this final rule, we finalize our allocation proposal, with one modification, so that, in the event of a shortfall in our collections, reinsurance contributions will first be allocated to the reinsurance payment pool, and second to administrative expenses and the U.S. Treasury.

In the 2014 Payment Notice and the 2015 Payment Notice, we provided that, if total contributions collected for 2014 and 2015 exceed \$12.02 billion and \$8.025 billion, respectively, we would allocate \$2 billion to the U.S. Treasury, \$20.3 or \$25.4 million, as applicable, to administrative expenses, and all remaining contributions for reinsurance payments, thus prioritizing excess contributions towards reinsurance payments. Due to the uncertainty in our estimates of reinsurance contributions to be collected, and to help assure that the reinsurance payment pool is sufficient to provide the premium stabilization benefits intended by the statute, we proposed to adopt a similar prioritization in the event that reinsurance collections fall short of our estimates. Specifically, we proposed that, if collections fall short of our estimates for a particular benefit year, we would allocate contributions that are collected first to the reinsurance payment pool and administrative expenses, until our targets for reinsurance payments and

administrative expenses are met. Once those targets are met, the remaining contributions collected for that benefit year would be allocated toward the U.S. Treasury.

We sought comment on this proposal, including our legal authority to implement a prioritization of reinsurance contributions to reinsurance payments over payments to the U.S. Treasury.

Comment: Several commenters supported our allocation proposal with respect to reinsurance collections if they fell short of our estimates for a particular benefit year. The commenters stated that the proposed allocation would further the premium stabilization effects of the program and provide more certainty that reinsurance payments will be fully funded. One commenter stated that section 1341 of the Affordable Care Act provides HHS with the discretion to allocate reinsurance contributions as HHS determines appropriate to carry out the goals of the statute and that the use of contributions first for reinsurance payments furthers the program's goal of stabilizing premiums. This commenter noted that section 1341 of the Affordable Care Act imposes few requirements on the expenditure of reinsurance contributions, stating that the statute does not specify that payments must be made to issuers and to the U.S. Treasury simultaneously, or that the U.S. Treasury must receive its full funding before reinsurance pool payments are made. Additionally, the commenter stated that section 1341 is silent on how reinsurance contributions are to be distributed if there are insufficient collections to satisfy the statutory obligations, providing HHS with flexibility to interpret and implement the statute and to decide the priority, method, and timing of the allocation of contributions. One commenter asked that we allocate contributions first to reinsurance payments and administrative expenses, and then roll over any excess funds for the subsequent benefit year, postponing the allocation of any contributions to the U.S. Treasury until the end of the reinsurance program. Some commenters

suggested that under the revised allocation policy administrative expenses should have the same priority as payments to U.S. Treasury.

Response: Section 1341 of the Affordable Care Act directs that a transitional reinsurance program be established in each State for a three-year period to reduce premiums and to ensure market stability for enrollees in the individual market as the new consumer protections and market reforms are implemented in 2014. The statute does not, however, prescribe how HHS should approach the distribution of reinsurance contributions if insufficient amounts are collected to fully fund all three components of the program (that is, reinsurance payments, administrative expenses, and payments to the U.S. Treasury). We agree that HHS has discretion to implement the program to determine the priority, method, and timing for the allocation of reinsurance contributions collected. Section 1341(b)(3)(B)(iii) uses mandatory language with respect to the collection of amounts for the reinsurance payment pool and states that the total contribution amounts “shall . . . equal \$10,000,000,000” for 2014 and specific, lesser amounts for 2015 and 2016. Thus, the statute explicitly directs the Secretary to collect these amounts for the reinsurance payment pool (based on the best estimates of the NAIC). On the other hand, the statute uses more permissive language in sections 1341(b)(3)(B)(ii) and (iv) with respect to the collection of amounts for administrative expenses and payments for the U.S. Treasury (that is, “can” and “reflects”, respectively). We believe that this language, as well as language directing that amounts collected pursuant to section 1341(b)(3)(B)(iv) be collected “in addition to the aggregate contribution amounts under clause (iii),” as well as the general authority granted to the Secretary under section 1341(b)(3)(A) to design the method for determining the contribution amount toward reinsurance payments, gives the Secretary discretion to prioritize the collections for the reinsurance program. We also believe that it is significant that prioritizing the allocation

of reinsurance contributions to the reinsurance payment pool furthers the statutory goals for this program by bringing more certainty to the individual market and helping moderate future premium increases.

We are therefore finalizing our proposal, with one modification – we will not allocate reinsurance collections to administrative expenses or the U.S. Treasury until the reinsurance payment pool for a benefit year is funded. Thus, if our reinsurance collections fall short of our estimates for a particular benefit year, we will allocate reinsurance contributions collected first to the reinsurance payment pool, with any remaining amounts being then allocated to administrative expenses and the U.S. Treasury, on a pro rata basis. For example, as described in Table 1, for the 2014 benefit year, reinsurance contributions will go first to the reinsurance payment pool, up to \$10 billion, and any additional contributions collected will be allocated to administrative expenses and the U.S. Treasury, on a pro rata basis, up to the total \$12.02 billion.

Table 1: Proportion of Reinsurance Contributions Collected under the Uniform Reinsurance Contribution Rate for the 2014 Benefit Year for Reinsurance Payments, Payments to the U.S. Treasury, and Administrative Expenses

Proportion or amount for:	If total contribution collections under the 2014 uniform reinsurance contribution rate are less than or equal to \$10 billion	If total contribution collections under the 2014 uniform reinsurance contribution rate are more than \$10 billion, but less than or equal to \$12.02 billion	If total contribution collections under the 2014 uniform reinsurance contribution rate are more than \$12.02 billion
Reinsurance payments	Total collections	\$10 billion	Total collections less \$2.02 billion (U.S. Treasury and administrative expenses)
Payments to the U.S. Treasury	\$0	99.0 percent of the total collections less \$10 billion (\$2 billion/\$2.02 billion)	\$2 billion
Administrative	\$0	1.0 percent of the total	\$20.3 million

expenses		collections less \$10 billion (\$20.3 billion/\$2.02 billion)	
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Similarly, for the 2015 benefit year, in the event of a shortfall in our collections, reinsurance contributions will go first to the reinsurance payment pool, up to \$6 billion, and any additional contributions collected will be allocated to administrative expenses and the U.S. Treasury on a pro rata basis, up to the total \$8.025 billion.

Table 2: Proportion of Reinsurance Contributions Collected under the Uniform Reinsurance Contribution Rate for the 2015 Benefit Year for Reinsurance Payments, Payments to the U.S. Treasury, and Administrative Expenses

Proportion or amount for:	If total contribution collections under the 2015 uniform reinsurance contribution rate are less than or equal to \$6 billion	If total contribution collections under the 2015 uniform reinsurance contribution rate are more than \$6 billion, but less than or equal to \$8.025 billion	If total contribution collections under the 2015 uniform reinsurance contribution rate are more than \$8.025 billion
Reinsurance payments	Total collections	\$6 billion	Total collections less \$2.025 billion (U.S. Treasury and administrative expenses)
Payments to the U.S. Treasury	\$0	98.8 percent of the total collections less \$6 billion(\$2 billion /\$2.025 billion)	\$2 billion
Administrative expenses	\$0	1.2 percent of the total collections less \$6 billion(\$25.4 million/\$2.025 billion)	\$25.4 million

We note that, in the 2015 Payment Notice, we amended 45 CFR 153.405(c) to provide a bifurcated contribution collection schedule, under which contributing entities will submit reinsurance contributions via two payments. The first payment would have covered the

contribution amount allocated to reinsurance payments and administrative expenses; the second payment would have covered the contribution amount allocated to payments to the U.S. Treasury for the applicable benefit year. In light of our revised allocation policy, contributions collected in the second collection will now be allocated for reinsurance payments to the extent the first collection does not fully fund the reinsurance payment pool. Therefore, for example, for the 2014 benefit year, if the first collection resulted in a total collection of \$9 billion, contributions collected via the second collection up to \$1 billion would be allocated for reinsurance payments. As we noted in the 2014 Payment Notice (78 FR 15460), we have considered comments about deferring payments to the U.S. Treasury, but concluded that we have no authority to defer the collection of reinsurance contributions for those payments to the end of the program.

Comment: In the 2015 Payment Notice, we established the reinsurance payment parameters for 2015. For 2015, we established an attachment point of \$70,000, a reinsurance cap of \$250,000, and a target coinsurance rate of 50 percent. Several commenters on this rule urged us to increase the premium stabilization effects of reinsurance by lowering the 2015 attachment point.

Response: We intend to propose changes to the reinsurance parameters for 2015 generally consistent with these recommendations. Specifically, in the proposed 2016 Payment Notice, we intend to propose to lower the 2015 attachment point from \$70,000 to \$45,000. We may also propose to modify the target 2015 coinsurance rate based on estimates of roll-over of funding from 2014 and estimates of collections and payments for 2015. These proposals will be subject to notice and comment rulemaking.

Summary of Regulatory Changes

We are finalizing this provision as proposed, with one modification: if reinsurance collections fall short of our estimates for a particular benefit year, we will allocate the reinsurance collections for that benefit year first to the reinsurance payment pool, and second to administrative expenses and payments to the U.S. Treasury on a pro rata basis.

3. Provisions for the Temporary Risk Corridors Program (§153.500)

In the 2015 Payment Notice, we indicated that we would consider additional adjustments to the risk corridors program for benefit year 2015. We did so recognizing that issuers of QHPs could face administrative costs and risk pool uncertainties from a number of sources in 2015.

We believe those QHP issuers will face pricing uncertainties related to:

- Uncertainties in the number of renewals of plans that do not comply with 2014 market reforms and rating rules – States continue to weigh whether to permit transitional plans or whether to extend the transitional policy, and in States where those decisions have been publicized, the willingness of issuers in those States to continue to offer transitional plans remains unclear;
- The effects on the risk pool of the phase-out of high risk pools – this phase-out leads to uncertainty in the estimate of likely claims costs from these individuals;
- The greater difficulty and additional time it will take to fully assess the risk profile of 2014 enrollees given the six-month initial open enrollment period – issuers will have a shorter 2014 claims history on which to base modeling; and
- Uncertainty estimating the number of individuals in reinsurance-eligible plans, and the number of covered lives for which reinsurance contributions will be paid.

As we discussed in the proposed rule, because relevant data will be difficult to obtain in the near term, we believe these uncertainties will continue through the summer of 2014, while issuers are in the process of setting their rates for the 2015 benefit year.

We also recognized in the proposed rule that issuers of QHPs may face additional administrative costs in order to complete the transition into compliance with the 2014 market rules. In particular, issuers continue to face unanticipated infrastructure requirements around Exchanges in all States, including the distributed data collection methodology for risk adjustment and reinsurance.

Therefore, in the proposed rule, we proposed to implement a national adjustment to the risk corridors formula set forth in subpart F of part 153 for each of the individual and small group markets by increasing the ceiling on allowable administrative costs (currently set at 20 percent, plus the adjustment percentage, of after-tax premiums) by 2 percentage points. We also proposed to increase the profit margin floor in the risk corridors formula (currently set at 3 percent, plus the adjustment percentage, of after-tax premiums) by 2 percentage points. These increases to the profit floor and administrative cost ceiling in the risk corridors formula would increase a QHP issuer's risk corridors ratio if claims costs are unexpectedly high, thereby increasing risk corridors payments or decreasing risk corridors charges.

We proposed these increases for 2015 for QHP issuers in every State because we believed that many of these additional administrative costs and risk pool uncertainties will be faced by issuers in all States, not just States adopting the transitional policy. Finally, under our authority under section 2718(c) of the PHS Act, we proposed that the MLR formula not take into account any additional risk corridors payments resulting from this adjustment. We requested comment on all aspects of this proposal.

Comment: Several commenters supported our proposal to implement the proposed adjustment on a nationwide basis so that it would apply equally to QHP issuers in all States. No commenters suggested a regional or State-level approach.

Response: We are finalizing the adjustment as proposed, and will apply the adjustment on a nationwide basis.

Comment: One commenter stated its support of the proposed adjustment to raise the ceiling on administrative costs, but questioned the necessity of the proposed adjustment to profits.

Response: We believe that an upward adjustment to the profit floor is necessary to account for unanticipated risk pool effects related to State decisions to adopt the transitional policy, the phase-out of high risk pools, and the six-month initial enrollment period, which would not be reflected in an issuer's administrative costs.

Comment: A few commenters urged HHS to increase the magnitude of the proposed adjustment, and to extend the duration of the adjustment so that it would apply beyond the 2015 benefit year. One commenter believed that issuers could face significant operations and risk pool challenges for the 2015 benefit year, and recommended that HHS raise the ceiling on allowable administrative costs by 5 percentage points, instead of 2 percentage points, as proposed in the proposed rule. The commenters did not specifically indicate or estimate any additional or greater administrative costs or pricing uncertainties that would necessitate an increase beyond the proposed 2 percentage point increase. Several other commenters supported our proposal, stating that the 2 percentage point increase is reasonable to address additional administrative costs and operational uncertainties in the 2015 benefit year. One commenter

noted that the proposed adjustment would suitably help smaller issuers forced to amortize fixed additional administrative costs over a smaller operational base.

Response: We are finalizing the proposed 2 percentage point increase to the risk corridors allowable administrative cost ceiling and profit floor for benefit year 2015. Based on our internal estimates and the methodology used to determine the administrative cost adjustment to the MLR formula discussed elsewhere in this final rule, we believe that this 2 percentage point increase will suitably account for additional administrative costs and pricing uncertainties that QHP issuers will experience in benefit year 2015.

Comment: One commenter requested that we modify the risk corridors formula so that reinsurance payments are not deducted from allowable costs, in order to enhance the protections of the risk corridors program.

Response: Section 1342(c)(1)(B) of the Affordable Care Act states that allowable costs in the risk corridors calculation are to be reduced by risk adjustment and reinsurance payments received under sections 1341 and 1343. Therefore, we are maintaining the current definition of “allowable costs” for the risk corridors program.

Comment: A number of commenters expressed concern with HHS’s intention to implement the risk corridors program in a budget neutral manner, as described in the preamble to the proposed rule. These commenters were concerned that an approach that makes risk corridors payments only when sufficient risk corridors charges are received could result in reduced risk corridors payments to issuers. The commenters questioned how much the payment formula specified in the final rules for 2014 and 2015 may be relied upon in setting premiums, if payments might be reduced. Several commenters believed that an approach implementing the risk corridors program in a budget neutral manner was counter to the intent of Section 1342 of

the Affordable Care Act, which states that the Secretary of HHS will establish a risk corridors program that is similar to the Medicare Part D risk corridors program, which is not budget neutral. One commenter believed that implementing the risk corridors program in a budget neutral manner would result in issuers sharing in the gains and losses of other issuers, would unintentionally affect market dynamics, and could result in solvency problems for some issuers if risk corridors receipts are insufficient to fully fund risk corridors payments.

Response: We recognize the commenters' concerns. To provide greater clarity on how 2014 and 2015 payments will be made, we issued a bulletin on April 11, 2014, titled "Risk Corridors and Budget Neutrality," describing how we intend to administer risk corridors in a budget neutral way over the three-year life of the program, rather than annually. Specifically, if risk corridors collections in the first or second year are insufficient to make risk corridors payments as prescribed by the regulations, risk corridors collections received for the next year will first be used to pay off the payment reductions issuers experienced in the previous year in a proportional manner, up to the point where issuers are reimbursed in full for the previous year, and remaining funds will then be used to fund current year payments. If any risk corridors funds remain after prior and current year payment obligations have been met, they will be held to offset potential insufficiencies in risk corridors collections in the next year.

As we stated in the bulletin, we anticipate that risk corridors collections will be sufficient to pay for all risk corridors payments. That said, we appreciate that some commenters believe that there are uncertainties associated with rate setting, given their concerns that risk corridors collections may not be sufficient to fully fund risk corridors payments. In the unlikely event of a shortfall for the 2015 program year, HHS recognizes that the Affordable Care Act requires the

Secretary to make full payments to issuers. In that event, HHS will use other sources of funding for the risk corridors payments, subject to the availability of appropriations.

Comment: One commenter asked that HHS apply this adjustment to all States for benefit year 2014. The commenter believed that this adjustment was necessary for the 2014 benefit year because of changes in the composition of the risk pools that were not anticipated when rates for the 2014 benefit year were developed.

Response: In the 2015 Payment Notice, we implemented an adjustment to the risk corridors formula for the 2014 benefit year that would help to further mitigate any unexpected losses for issuers of plans subject to risk corridors attributable to the effects of the transitional policy. In States that adopt the transitional policy, this adjustment would increase a QHP issuer's risk corridors ratio and its risk corridors payment amount to help offset losses that might occur under the transitional policy as a result of increased claims costs and unanticipated changes in the risk pool that were not accounted for when setting 2014 premiums. For the reasons discussed in the 2015 Payment Notice, we believe that this adjustment will suitably offset any losses that QHP issuers may incur as a result of the transitional policy, and that no further risk corridors adjustments are necessary for the 2014 benefit year.

Comment: One commenter requested that HHS allow non-QHPs to participate in the risk corridors program, so that plans that comply with requirements of the Affordable Care Act could receive risk corridors protections that would help to ameliorate changes in the risk pool resulting from the transitional policy.

Response: We believe the risk corridors program is intended to share risk and stabilize premiums for QHPs (and certain substantially similar off-Exchange plans). Therefore, we decline to expand the participation criteria for this risk corridors adjustment. Data from all

individual and small group market plans that comply with the Affordable Care Act market reforms will be included in a QHP issuer's risk corridors calculation as described in 45 CFR part 153, subpart F. However, consistent with our existing regulations set forth in subpart F of part 153, any risk corridors payment or charge amount, including any adjusted payment or charge amount resulting from the adjustment implemented in this final rule or the 2015 Payment Notice, will be calculated for a QHP issuer in proportion to the premium revenue that the issuer receives from its QHPs, as defined in §153.500.

Comment: One commenter requested clarification about whether HHS intends to implement risk corridors budget neutrality on a national or a State level. The commenter believed that budget neutrality should be applied on an individual State level, because applying budget neutrality on a national level would add uncertainty to the rate setting process.

Response: The risk corridors program is a Federally administered program that applies uniformly to all States.

Summary of Regulatory Changes

We are finalizing our policy to increase the administrative cost ceiling and the profit margin floor by 2 percentage points, as proposed.

F. Part 154 – Health Insurance Issuer Rate Increases: Disclosure and Review Requirements

Definition of Product (§154.102)

See the discussion in section III.C.1.b, “Product Discontinuance and Uniform Modification of Coverage Exceptions to Guaranteed Renewability Requirements.”

G. Part 155—Exchange Establishment Standards and Other Related Standards under the Affordable Care Act

1. Subpart B—General Standards Related to the Establishment of the Exchange

Non-Interference with Federal Law and Non-Discrimination Standards (§155.120)

Under 45 CFR 155.120(c), States and Exchanges, when carrying out the requirements of Part 155, must comply with any applicable non-discrimination statutes, and must not discriminate on the basis of race, color, national origin, disability, age, sex, gender identity or sexual orientation. The non-discrimination provisions of §155.120(c) apply not just to the Exchanges themselves, but to Exchange contractors and all Exchange activities (including but not limited to marketing, outreach and enrollment), Navigators, non-Navigator assistance personnel, certified application counselors, and organizations designated to certify their staff and volunteers as certified application counselors (78 FR 42829). Under 45 CFR 155.105(f) this non-discrimination requirement applies to the FFEs.

In the proposed rule, we proposed creating a limited exception to these non-discrimination requirements for an organization receiving Federal funds to provide services to a defined population under the terms of Federal legal authorities (for example, a Ryan White HIV/AIDS Program or an Indian health provider) that participates in the certified application counselor program under 45 CFR 155.225, to permit that organization to limit its provision of certified application counselor services to the same defined population without violating the non-discrimination provisions in existing §155.120(c). The intent of this proposal was to allow such organizations to provide certified application counselor services and assist their defined populations in enrolling in health coverage offered through the Exchanges consistent with the Federal legal authorities under which such organizations operate.

To the extent that one of these organizations decides to take advantage of this exception, but is approached for certified application counselor services by an individual who is not included in the defined population that the organization serves, we proposed that the organization

must refer the individual to other Exchange-approved resources, such as the toll-free Exchange call center, a Navigator, non-Navigator assistance personnel, or another designated certified application counselor organization, that is able to provide assistance to the individual. However, to the extent that one of these organizations decides that it will not take advantage of this proposed exception, we proposed that the non-discrimination provisions in existing §155.120(c) would apply. Therefore, if an organization decides that it will provide certified application counselor services to individuals that are not included in the defined population that it serves, it must provide those services to all individuals consistent with the non-discrimination provisions in existing §155.120(c).

We also proposed to make a number of technical changes to existing §155.120(c) to accommodate this new limited exception.

Comment: Commenters generally supported the proposed exception to the non-discrimination standards to allow an organization receiving Federal funds to limit their provision of assister services to that population. Several commenters requested that HHS clarify that these organizations are prohibited from discriminating against individuals who are within their defined population that the organization serves under the terms of Federal legal authorities.

Response: With respect to the clarification requested from commenters, we are revising paragraph (c)(2) of §155.120 to clarify that organizations that limit their provision of certified application counselor services to a defined population under this exception must still comply with the non-discrimination provisions in paragraph (c)(1) with respect to the provision of these services to that defined population. For example, a Ryan White organization that participates in the certified application counselor program and limits its provision of certified application services to its target population under Federal legal authorities cannot discriminate among

members of that target population on the basis of race, color, national origin, disability, age, sex, or any of the other prohibited factor in 45 CFR 155.120(c) when providing those certified application counselor services.

We are also making technical revisions to §155.120(c) to clarify here that paragraph (1)(i) is included to highlight to organizations their obligations under other laws. Each organization needs to determine what other non-discrimination laws, which may be Federal or State laws, apply to them. We note that the reference to statutes incorporates regulatory requirements issued pursuant to statute. Paragraph (1)(ii), on the other hand, references the non-discrimination obligations that exist under this Rule.

Consistent with this technical revision, we have made a change to the text of §155.120(c) to clarify that the exception to the non-discrimination requirement at §155.120(c)(2) only applies in regard to the non-discrimination provisions created under this Rule. We cannot create exceptions in regard to requirements that exist under other laws.

Comment: One commenter recommended extending the exception to organizations that provide services to defined populations that speak languages other than English, regardless of receipt of Federal funds to provide services to these populations.

Response: We understand the desire for organizations interested in targeting specific populations to have flexibility to limit their provision of certified application counselor services to these populations. However, we believe it is appropriate to limit the exception to organizations that receive Federal funds to provide services to a defined population under Federal legal authorities because their beneficiaries are generally defined under Federal law. Although other organizations may choose to target the services they generally provide to specific populations, we do not believe it is appropriate to extend the exception in §155.120(c)(2) to these

organizations. If all organizations were allowed to target certified application counselor services to specific, defined populations, the situation could arise where a consumer may not be able to readily access certified application counselor services because the consumer is not a part of a target population being serviced through the organizations in their area.

Summary of Regulatory Changes

We are finalizing our proposals to make technical changes to §155.120(c) and add a new limited exception to the non-discriminations provision in §155.120(c). We are also further revising new §155.120(c)(2) to clarify that organizations that limit their provision of certified application counselor services to a defined population under this exception must still comply with the non-discrimination provisions in paragraph (c)(1)(ii) with respect to the provision of these services to that defined population.

2. Subpart C—General Functions of an Exchange

a. Civil Money Penalties for Violations of Applicable Exchange Standards by Consumer Assistance Entities in Federally-Facilitated Exchanges (§155.206)

In §155.206, as part of HHS's enforcement authority under section 1321(c)(2) of the Affordable Care Act, we proposed to provide for the imposition of CMPs on Navigators, non-Navigator assistance personnel, and certified application counselors and certified application counselor designated organizations in FFEs, including State Partnership Exchanges, that do not comply with applicable Federal requirements. We explained that this proposal was designed to deter these entities and individuals from failing to comply with the Federal requirements that apply to them, and to ensure that consumers interacting with the Exchange receive high-quality assistance and robust consumer protection. We noted that as a general principle, while HHS intends to assess CMPs when appropriate, consistent with this final rule, we also intend to

continue to work collaboratively with consumer assistance entities and personnel to prevent noncompliance issues and address any that arise before they reach the level where CMPs might be assessed.

The Secretary, under the authority of sections 1311(i) and 1321(a)(1) of the Affordable Care Act, has 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(i) of the Affordable Care Act and 45 CFR 155.210; the consumer assistance, outreach, and education functions authorized by section 1321(a)(1) of the Affordable Care Act and established at 45 CFR 155.205(d) and (e), which can include a non-Navigator assistance personnel program; and the certified application counselor program authorized by section 1321(a)(1) of the Affordable Care Act and set forth at 45 CFR 155.225. Under these authorities and the authority granted to the Secretary by section 1321(c)(1) of the Affordable Care Act, the FFE has implemented a Navigator and certified application counselor program in all States that did not elect to establish an Exchange, and has implemented a non-Navigator assistance program in some of those States through an enrollment assistance contract.

Under section 1321(c)(2) of the Affordable Care Act, the provisions of section 2723(b) of the PHS Act²¹ apply to the Secretary's enforcement, under section 1321(c)(1) of the Affordable Care Act, of the standards established by the Secretary under section 1321(a)(1) of the Affordable Care Act for meeting the requirements under title I of the Affordable Care Act, including the establishment and operation of Exchanges, without regard to any limitation on the

²¹ Section 1321(c)(2) of the Affordable Care Act erroneously cites to section 2736(b) of the PHS Act instead of 2723(b) of the PHS Act. This was clearly a typographical error, and we have therefore interpreted section 1321(c)(2) of the Affordable Care Act to incorporate section 2723(b) of the PHS Act.

application of the provisions of section 2723(b) of the PHS Act to group health plans. Section 2723(b) of the PHS Act provides the Secretary with authority to assess CMPs against health insurance issuers that fail to meet certain Federal requirements set forth in the PHS Act that apply to group health plans, in circumstances where, in the Secretary's determination, the State that regulates the issuer has failed to "substantially enforce" those requirements. We interpret the cross-reference to section 2723(b) of the PHS Act in section 1321(c)(2) of the Affordable Care Act as providing the Secretary with authority to assess CMPs to enforce requirements established under section 1321(a)(1) of the Affordable Care Act against any entity subject to those requirements, under circumstances where the Secretary is exercising her authority under section 1321(c)(1) of the Affordable Care Act. For purposes of this final rule, we would consider that any State that has not elected to establish an Exchange, and in which the Secretary has therefore had to establish and operate an Exchange under section 1321(c)(1), is not "substantially enforcing" the requirements related to Exchanges that the Secretary has established under section 1321(a)(1).

Accordingly, HHS has the authority under section 1321(c)(2) of the Affordable Care Act to assess CMPs against Navigators, non-Navigator assistance personnel, and certified application counselors and certified application counselor designated organizations in FFEs, including State Partnership Exchanges, for violations of the requirements of the Navigator, non-Navigator, and certified application counselor programs that the Secretary established under section 1321(a)(1) of the Affordable Care Act. This rule sets forth the circumstances under which the Secretary would exercise this authority, and is based on the enforcement scheme laid out in section 2723(b) of the PHS Act, and the implementing regulations at 45 CFR 150.301 *et seq.*

In §155.206(a), we proposed to establish the scope and purpose of the CMP provisions and explained when and against whom HHS would assess a CMP under this rule. At §155.206(a)(2), we proposed that HHS could permit an entity or individual to whom it has issued a notice of assessment of CMP to enter into a corrective action plan instead of paying the CMP. We specified that permitting an entity to enter into a corrective action plan would not limit HHS's authority to require payment of the assessed CMP if the corrective action plan is not followed. We explained that this approach would allow us not only to penalize violations if necessary, but also to prioritize working collaboratively with consumer assistance entities to ensure that improvements are made and future violations are prevented. We also explained that this approach would be consistent with the limitation on imposing CMPs that is set forth at PHS Act section 2723(b)(2)(C)(iii)(II).

We requested comments on whether we should provide for an expedited process through which HHS may assess and impose CMPs, if extenuating circumstances exist or if necessary to protect the public. We also considered implementing an approach that would give the HHS Office of Inspector General (OIG) concurrent authority with CMS to enforce violations under this section, and we requested comments on such an approach and how it might be structured.

In §155.206(b), we proposed that the individuals and entities who would be subject to HHS' enforcement authority under this proposal would include the following entities in FFEs, including in State Partnership Exchanges: Navigators, non-Navigator assistance personnel (also referred to as in-person assistance personnel) authorized under §155.205(d) and (e), and certified application counselors and organizations designated as certified application counselor organizations. We explained that we refer to these individuals and entities as "consumer assistance entities," but these CMPs could be assessed against both entities and individuals. We

requested comment on whether all of the individuals and entities listed in proposed §155.205(b) should be subject to CMPs, and on whether other entities and individuals should be added to that list.

In §155.206(c), we proposed the grounds on which HHS could assess CMPs on the entities and individuals specified in §155.206(b). Section 1321(c)(2) of the Affordable Care Act authorizes the Secretary to enforce the requirements of section 1321(a)(1) of the Affordable Care Act, which include the requirements established by the Secretary regarding Exchange consumer assistance functions. This statutory provision authorizes HHS to assess a CMP or, in lieu of a CMP, a corrective action plan against Navigators, non-Navigator assistance personnel, certified application counselors, and certified application counselor organizations in FFEs if HHS determines that these individuals or entities are not in compliance with the Exchange standards applicable to them. We proposed that these Exchange standards would include any applicable regulations implemented under title I of the Affordable Care Act, as interpreted through applicable HHS guidance, such as the regulations governing consumer assistance tools and programs of an Exchange at §155.205; those governing Navigators at §155.210 and Navigators in FFEs at §155.215; those governing certified application counselors at §155.225; and those under §155.215 governing non-Navigator assistance personnel in FFEs; as well as any applicable HHS guidance interpreting an existing regulatory or statutory provision.

We note that §155.285 of this final rule extends CMPs to consumer assistance entities who misuse or impermissibly disclose personally identifiable information in violation of section 1411 of the Affordable Care Act. Therefore, we have not addressed penalties for those actions here. That section also extends CMPs to anyone providing false or fraudulent information on an Exchange application. Consequently, some conduct by consumer assistance entities may warrant

CMPs under either §155.285 or §155.206, and in such cases we believe HHS has discretion to determine whether to assess a CMP under this regulation or under §155.285 of this subpart. However, we proposed in §155.206(c) that HHS would not assess a CMP under this section if a CMP has already been assessed for the same conduct under §155.285.

In §155.206(d), we proposed the basis for initiating an investigation of a potential violation. We proposed that HHS could initiate an investigation based on any information it receives indicating that a consumer assistance entity might be in noncompliance with applicable Exchange standards.

In §155.206(e), (f) and (g), we proposed the process that HHS would follow to investigate potential violations in order to determine whether the consumer assistance entity has engaged in noncompliance of applicable Exchange standards. Under §155.206(e), we proposed that if HHS learns of a potential violation through the means described in paragraph (d) in this section and determines that further investigation is warranted, HHS would provide written notice of its investigation to the consumer assistance entity. Such notice would describe the potential violation, provide 30 days from the date of the notice for the consumer assistance entity to respond and provide HHS with information and documents, including information and documents to refute an alleged violation, and would state that a CMP might be assessed if the consumer assistance entity fails to refute the allegations in HHS' determination.

In §155.206(f), we proposed a process for a consumer assistance entity to request an extension from HHS when the entity cannot prepare a response to HHS's notice of investigation within the 30 days provided in the notice. We proposed that if HHS granted the extension, the responsible entity would be required to respond to the notice of investigation within the time frame specified in HHS's letter granting the extension of time, and failure to respond within 30

days, or within the extended time frame, could result in HHS's imposition of the CMP that would apply based upon HHS's initial determination of a potential violation as set forth in the notice of investigation under §155.206(e).

In §155.206(g), we proposed that HHS could review and consider documents or information received or collected in accordance with paragraph (d)(1) of this section or provided by the consumer assistance entity in response to receiving a notice in accordance with paragraph (e)(2) of this section. We also proposed that HHS may conduct an independent investigation into the alleged violation, which may include site visits and interviews, if applicable, and may consider the results of this investigation in its determination.

In §155.206(h), we proposed the factors that HHS would use to determine the appropriate CMP amount, and to determine whether it would be appropriate to offer the entity or individual an opportunity to enter into a corrective action plan in place of the CMP. These proposed factors included HHS's assessment of the consumer assistance entity's previous or ongoing record of compliance; the gravity of the violation, as determined in part by the frequency of the violation and the financial harm incurred by a consumer; and the culpability of the consumer assistance entity, as determined, in part, by whether the entity received payment for committing the violation.

Section 2723(b)(2)(C)(i) of the PHS Act limits the amount of CMPs authorized under section 1321(c)(2) of the Affordable Care Act to \$100 for each day for each individual directly affected. Therefore in §155.206(i), we proposed that the maximum daily amount of penalty assessed for each violation would be \$100 for each day, for each consumer assistance entity, for each individual directly affected by the entity's non-compliance. We also proposed that, consistent with the approach under existing rules at 45 CFR 156.805(c), where HHS cannot

determine the number of individuals directly affected, HHS may reasonably estimate this number based on available information, such as data from an FFE Navigator grantee's quarterly or weekly report concerning the number of consumers assisted. We requested comment on whether we should implement a cap on the total penalty that could be assessed by HHS.

In proposed §155.206(j), we proposed that nothing in this section would limit HHS's authority to settle any issue or case described in the notice furnished in accordance with paragraph (e), or to compromise on any CMP provided for in this section.

Section 2723(b)(2)(C)(iii) of the PHS Act places certain limitations on CMPs authorized under section 1321(c)(2) of the Affordable Care Act, including the limitation that HHS will not assess a CMP where the entity did not know, or exercising reasonable diligence would not have known, of the violation. We proposed to implement these limitations in §155.206(k). We also proposed, based on the HIPAA enforcement structure at 45 CFR 150.341, that the burden is on the consumer assistance entity to establish that the circumstances triggering these limitations existed.

In §155.206(l), we proposed standards for notifying consumer assistance entities of the intent to assess a CMP, which notice would include an explanation of the entity's right to an appeal pursuant to the process set forth at 45 CFR Part 150, Subpart D, as provided in proposed §155.206(m). We sought comment on whether all aspects of that process should be applicable to appeals of these CMPs. Finally, in §155.205(n), we proposed that HHS may require payment of the proposed CMP if the consumer assistance entity does not timely request a hearing.

We also requested comment on whether other provisions of 45 CFR Part 150 should be adopted and made applicable to the proposed enforcement scheme, and whether a specific

limitations period should apply, and if so, what limitations period would be appropriate for violations of applicable Exchange standards by consumer assistance entities in FFEs.

Comment: We received many comments in support of the proposed CMP provisions under §155.206. Some commenters expressed appreciation that the proposed rule struck a balance between holding consumer assistance entities accountable and protecting the public from wrongdoing, on the one hand, while not being overly punitive, on the other. A few commenters were concerned that the threat of CMPs might discourage participation in the Navigator, non-Navigator assistance personnel, or certified application counselor programs. Some commenters expressed concern that CMPs for violations of consumer assistance entity requirements would be an extreme response to such noncompliance, and one commenter expressed the view that the imposition of financial responsibility on consumer assistance entities muddies the distinction between these entities and agents and brokers.

Response: We do not see similarities between these penalties and the licensing, errors and omissions coverage, or other financial responsibility requirements that States may impose on agents and brokers as a prerequisite to performing the duties of an agent or broker. Consumer assistance entities will have no required fees or payments under this section unless they violate the Federal requirements that apply to them as described in §155.206(c). On the other hand, States may require agents and brokers to pay licensing, errors and omissions coverage, or other financial responsibilities up front before acting as a licensed agent or broker. Any CMPs assessed under this provision would be penalties for noncompliance, aimed at discouraging and rectifying violations of Federal requirements by consumer assistance entities in the FFEs, rather than financial conditions of participation in the Navigator, non-Navigator assistance personnel, or certified application counselor programs for the FFEs. Additionally, we believe that many

aspects of the final rule help ensure that individuals and entities are not deterred from performing consumer assistance functions in good faith, while also serving to protect members of the public from potential wrongdoing by consumer assistance entities. For example, the rule requires HHS to make individualized inquiries into the nature and consequences of each violation, and provides consumer assistance entities being investigated with the opportunity to explain the reasons behind their conduct. Further, the rule provides HHS with the opportunity to work collaboratively with entities by entering into a corrective action plan in lieu of paying a CMP, and HHS will continue to assist entities with avoiding and informally resolving any violations.

Comment: A number of commenters recommended that HHS extend the CMP provisions to cover consumer assistance entities operating in State Exchanges, work in conjunction with State Exchanges when implementing this section, or require State Exchanges to implement similar provisions. Some commenters appeared to suggest that HHS should have the ability to assess CMPs against consumer assistance entities in State Exchanges where the State fails to substantially enforce the Federal standards applicable to consumer assistance entities.

Response: Given the nature of the relationship between HHS and consumer assistance entities in FFEs, including the existence of formal agreements or grants between HHS and the FFE consumer assistance entities subject to these CMPs, and HHS's responsibility for providing training, technical assistance, and support to consumer assistance entities in FFEs, we believe that HHS is in the best position to exercise primary enforcement authority for Federal requirements that apply to consumer assistance entities in FFEs, including State Partnership Exchanges. At this time, we are not extending the CMP provisions under §155.206 to apply to consumer assistance entities working in State Exchanges. We will instead look to each State

Exchange to exercise its authority to enforce any Federal requirements applicable to these assistance programs in the State Exchange. We may take additional action in the future.

Comment: Some commenters believed that the proposed grounds for assessing CMPs in proposed §155.206(c) would not permit CMPs for violations of State Partnership Exchange rules where those rules differ from FFE rules.

Response: The CMP provisions under §155.206 are directed at consumer assistance entities that violate Federal requirements for assisters in FFEs, including assisters in State Partnership Exchanges. Under current §155.210(c)(1)(iii), as well as provisions finalized in this rulemaking at §155.215(f) and §155.225(d)(8), the consumer assistance entities subject to those regulations must meet any State licensing, certification, or other standards prescribed by the State, if applicable, so long as such standards do not prevent the application of the provisions of title I of the Affordable Care Act. Although HHS has authority under these provisions to enforce State requirements applicable to consumer assistance entities because the State requirements are incorporated into the entities' Federal regulatory requirements, at this time we do not intend to enforce State requirements using §155.206. We believe that States are in the best position to enforce their own requirements.

Comment: We requested comment on whether CMS should have concurrent enforcement authority under the provisions of §155.206 with the HHS Office of the Inspector General (OIG), and if so, what process OIG would follow in enforcing these CMPs. The vast majority of commenters who responded to this request recommended against concurrent enforcement authority and believed that CMS is better situated than OIG to enforce CMPs for noncompliant consumer assistance entities. These commenters reasoned that because of CMS's expertise and familiarity with the outreach and enrollment process, as well as CMS's working

relationships with consumer assistance entities, CMS would be the most effective enforcement authority and is in a better position to effectively collaborate with consumer assistance entities and pursue corrective action, when appropriate, to resolve issues that may arise. Only one commenter expressed a preference for including concurrent enforcement authority in §155.206 so that the OIG could exercise enforcement authority under appropriate circumstances.

Response: We agree with the commenters who recommended against concurrent enforcement authority that, at least initially, CMS should have sole responsibility for CMP enforcement against noncompliant consumer assistance entities under this section. CMPs assessed under this section would be penalties for programmatic violations, and we agree that CMS is in the best position to investigate and enforce its own program standards. Additionally, consumer assistance entities who provide false or fraudulent information in an Exchange application on a consumer's behalf, or who improperly use or disclose a consumer's personally identifiable information, might be in violation of another CMP provision finalized in this rule, 45 CFR 155.285, which provides concurrent enforcement authority for CMS and OIG. Therefore, certain consumer assistance entity violations might fall under OIG jurisdiction, when appropriate. Additionally, as we indicated in the preamble to the proposed rule, we intend to continue to work collaboratively with consumer assistance entities to address noncompliance issues before they reach the level where a CMP might be assessed. Consequently, we do not anticipate that CMS will assess a large volume of CMPs against consumer assistance entities for noncompliance with Federal requirements. However, we note that we are not foreclosing the possibility that we would pursue the addition of OIG concurrent enforcement authority for these provisions at some point in the future.

Comment: We also requested comments on whether we should implement an expedited process through which HHS might assess and impose CMPs if extenuating circumstances exist or if necessary to protect the public. One commenter did not believe an expedited process was necessary because the regulation as proposed contained sufficient mechanisms to prevent or address abuse by consumer assistance entities. Another commenter suggested that an expedited process should only be implemented at the request of the entity being investigated to ensure that no entity was denied adequate time to gather evidence and respond to the investigation.

Response: We agree with the commenters' concerns. To ensure that consumer assistance entities are afforded adequate due process, we have not provided for an expedited investigative process in finalizing these provisions. Where exceptional circumstances exist, or if necessary to protect the public, HHS has the option to take swift action to address consumer assistance entity noncompliance by using remedies available pursuant to its agreements with these entities, such as the terms and conditions of Federal Navigator grants, agreements with Enrollment Assistance Program entities that provide non-Navigator in-person assistance, or agreements between HHS and certified application counselor designated organizations. If the circumstances warrant, we also will consider referring cases to appropriate law enforcement officials. Additionally, as we noted in the preamble to the proposed rule, we intend to continue to work collaboratively with consumer assistance individuals and entities to prevent noncompliance issues and address any problems that arise before they reach the level where CMPs might be assessed.

Comment: Many commenters supported HHS's intention to prioritize the use of alternative remedies over assessment of CMPs. A large number of commenters strongly supported giving consumer assistance entities the opportunity to enter into a corrective action

plan to correct the violation instead of paying a CMP. Some recommended that HHS require these entities to participate in a corrective action plan before assessing a CMP.

Response: We agree that alternative remedies should be used where appropriate, and we have crafted this provision to include flexibility for HHS to help prevent and resolve noncompliance issues in lieu of collecting a CMP. However, we do not believe that requiring corrective action plans from consumer assistance entities will be a suitable response to every instance of noncompliance. For example, if a consumer assistance entity's conduct is so egregious that in order to protect the public we have terminated our relationship with the entity pursuant to our agreement or contract with the entity, a corrective action plan may not be appropriate. Therefore, we are finalizing §155.206(a) as proposed.

Comment: We requested comment on whether all of the consumer assistance individuals and entities listed in proposed §155.206(b) should be subject to CMPs, and on whether other entities and individuals should be added to that list. Many commenters supported the inclusion of Navigator individuals and organizations, non-Navigator assistance personnel and entities, and certified application counselor designated organizations and individual certified application counselors operating in an FFE, as proposed. Several commenters recommended that volunteers serving as Navigators, non-Navigator assistance personnel, or certified application counselors should be exempt from CMPs under this section. One commenter argued that the Volunteer Protection Act protects volunteer certified application counselors from liability under this section. Another commenter suggested that Exchange employees should also be subject to CMPs.

Response: We believe that the consumer protection interests that are served by the CMP provisions under §155.206 are equally important whether they apply to volunteer or paid staff

providing application assistance. The application of the Volunteer Protection Act of 1997 to CMPs assessed against volunteers of Navigator, non-Navigator assistance, or certified application counselor organizations would be examined by courts or other reviewing entities on a case-by-case basis. We further clarify that no Navigators, non-Navigator assistance personnel, or certified application counselors in the FFEs would be volunteers for the Federal government because the consumer assistance entities with which they are affiliated provide services to the public, not to the Federal government.

While we will monitor the activities of FFE employees carefully and reserve the right to add them to this rule in the future, we do not believe it is necessary to extend these penalties to FFE employees at this time, because in our view, the range of employment-based remedies available to the FFE provides adequate enforcement authority in the event of employee misconduct. In addition, FFE employees might be subject to CMPs under §155.285 if they provide false or fraudulent information in an Exchange application or misuse consumers' personally identifiable information. We are finalizing §155.206(b) as proposed.

Comment: Many commenters addressed our proposed grounds for assessing CMPs at §155.206(c). Some commenters worried that the proposed grounds for assessing penalties were stated too broadly, and did not provide adequate notice to consumer assistance entities and personnel regarding the specific requirements and standards that would apply when a determination is made as to whether a CMP should be assessed for noncompliance. These commenters recommended that we specify the statutory and regulatory requirements with which consumer assistance entities and personnel must comply to avoid potential CMPs, and various commenters suggested that these might include the regulatory requirements specific to consumer assistance entities at 45 CFR 155.205, 155.210, 155.215, and 155.225; statutory and regulatory

nondiscrimination requirements at 42 U.S.C. 18116, 45 CFR 155.105(f), and 155.120(c); and the Affordable Care Act requirements on health insurance consumer information at 42 U.S.C. 300gg-93, and affordable choices of health benefit plans at 42 U.S.C. 18031.

Response: We agree that more specificity regarding the FFE requirements and standards that, if violated, might trigger CMPs under this section would help provide adequate notice to consumer assistance entities and help prevent inadvertent violations of those standards. Therefore, we have modified §155.206(c) to make more clear that the requirements and standards applicable to consumer assistance entities under this section refer to the Federal regulatory requirements applicable to consumer assistance entities that have been promulgated by the Secretary pursuant to section 1321(a)(1) of the Affordable Care Act, as well as the terms of any agreements, contracts, and grant terms and conditions between the consumer assistance entity and HHS, to the extent that these documents interpret those Federal regulatory requirements or set forth procedures for compliance with them. We note that HHS has authority to assess CMPs under section 1321(c)(2) of the Affordable Care Act only to enforce requirements that the Secretary establishes under section 1321(a)(1) of the Affordable Care Act. Therefore, Federal requirements that have not been established pursuant to section 1321(a)(1) of the Affordable Care Act could not be enforced pursuant to this section.

We have not included in the final rule a more specific list of the requirements that could be enforced under this section because we anticipate that these may change over time. However, we anticipate that any list of such requirements would include, but not be limited to, the requirements specific to consumer assistance entities at 45 CFR 155.205(c)-(e), 155.210, 155.215, and 155.225; the Exchange nondiscrimination requirements at 45 CFR 155.105(f) and 155.120(c); and the Exchange privacy and security requirements implemented pursuant to 45

CFR 155.260. Consumer assistance entities would also be required to comply with other future requirements when any such requirements go into effect.

Comment: Some commenters were concerned that consumer assistance entities might be penalized for inadvertent, technical, or administrative errors, or misunderstandings, and wanted to ensure that consumer assistance personnel would not be responsible for errors due to system issues, complex and changing systems, policies, workarounds, as well as lack of information from issuers. Other commenters expressed concern about being found in noncompliance on the basis of subregulatory guidance or frequently answered questions (FAQs) that they may not have seen or known about. Some commenters suggested that HHS develop a publicly available, searchable database or warehouse of rules and processes. Additional commenters requested that we provide clarity regarding the level of violation that might trigger investigation, and asked that we limit the use of CMPs to cases of egregious behavior, such as when the violation was a result of willful neglect or results in significant harm to a consumer.

Response: We expect that the changes we have made to proposed §155.206(c) in this final rule will help provide clarity regarding the standards consumers assistance entities must meet in order to avoid any potential CMPs under this section. We also understand commenters' concerns about changes in best practices and FAQs. As we explained above, HHS's enforcement authority under this section extends only to requirements that are established under section 1321(a)(1) of the Affordable Care Act. From time to time, we have issued and will continue to issue best practices, FAQs, and other subregulatory guidance interpreting these requirements. We further note that we offer anyone being investigated under this section an opportunity to respond under §155.206(e) and (g), and consumer assistance entities may use this opportunity to discuss any barriers they may have encountered to fulfilling their duties as

required, including confusion regarding requirements as interpreted through subregulatory guidance. Finally, pursuant to section 2723(b)(2)(C)(iii) of the PHS Act, we have provided in §155.206(k) that no penalties will be assessed for any period of time during which a consumer assistance entity neither knew nor exercising reasonable diligence should have known of the violation, or any time afterwards if the violation was corrected within 30 days and due to reasonable cause and not wilful neglect.

Comment: Some commenters asked us to further define “reasonably determined,” the standard in §155.206(c) for HHS’s finding that a consumer assistance entity has failed to comply with applicable Federal regulatory requirements.

Response: In §155.206(c), we proposed that a reasonable determination would be “based on the outcome of the investigative process outlined in paragraphs (d) through (i) of this section.” This standard is meant to capture the fact that a CMP would not immediately be imposed, but instead imposed only after HHS provides a process involving notice, consideration of any additional information or documentation submitted by the consumer assistance entity pursuant to §155.206(e), consideration of the factors outlined in §155.206(h), and the consumer assistance entity’s right to a hearing pursuant to §155.206(m). If HHS identifies circumstances that meet the standard set in §155.206(c), it will send a notice informing the consumer assistance entity of the assessment of a CMP under §155.206(l). The consumer assistance entity then has the right to request a hearing in front of an Administrative Law Judge in accordance with §155.206(m) before the CMP is levied.

Comment: Several commenters advocated against the duplication of penalties in instances where certain types of violations may already subject them to other types of penalties.

A few commenters noted that the Health Insurance Portability and Accountability Act already governs certain critical aspects of compliance related to protected health information.

Response: We understand commenters' concern about the potential for a violation to be punished twice under different enforcement schemes, and we have amended §155.206(h) to include a factor allowing HHS to take into consideration whether other remedies or penalties have been assessed and/or imposed for the same conduct or occurrence. It would be the responsibility of the consumer assistance entity to bring such information to HHS's attention.

Comment: Several commenters emphasized the need for consumer assistance training about CMP implementation, and more robust training regarding any rules whose violation might trigger a CMP investigation, including circumstances in which consumers' personally identifiable information (PII) can be collected, and appropriate uses and storage of PII. A few commenters were concerned that the restrictions on retaining consumer PII might prevent consumer assistance entities from keeping sufficient information to refute allegations of misconduct.

Response: We believe that the protection of consumer information is one of the most critical duties of consumer assistance entities. Section 155.215(b)(2)(xi) requires all Navigators in FFEs, including State Partnership Exchanges, as well as all non-Navigator assistance personnel to which §155.215 applies, to receive training on the privacy and security standards applicable under §155.260 for handling and safeguarding consumers' personally identifiable information. Section 155.215(b)(1)(iii) requires that all Navigators in FFEs, including State Partnership Exchanges, and all non-Navigator assistance personnel to which §155.215 applies, complete and achieve a passing score on all approved certification examinations prior to carrying out any consumer assistance functions under §155.205(d) and (e) or §155.210. And

§155.225(d)(3) requires certified application counselors to comply with the Exchange's privacy and security standards adopted consistent with §155.260, and applicable authentication and data security standards. To implement these requirements, HHS has included detailed privacy and security requirements in its agreements, contracts, and grant terms and conditions with the consumer assistance entities that are carrying out functions in States with an FFE, including a State Partnership Exchange. We recognize that these strong consumer protections restrict the personal consumer information that consumer assistance entities are able to retain and therefore limit the information available to them in preparing a response to a notice of investigation in §155.206(e). If any consumer assistance entity feels limited in their ability to respond to a notice of investigation, we encourage them to explain any rules and policies that prevented them from retaining information they believe would have been exculpatory. HHS may take such explanations into account under the factors outlined in §155.206(h).

Comment: We received a number of comments on our proposed bases for initiating an investigation of a potential violation in §155.206(d). Commenters supported explicitly allowing any entity, individual, or individual's authorized representative to file a complaint with HHS alleging that a consumer assistance entity has violated the FFE rules applicable to them. Some commenters asked HHS to clarify the process for filing complaints, including whether complaints filed at other HHS offices for other enforcement purposes would, if applicable, be shared with the office responsible for initiating investigations under §155.206 and trigger investigations under this section. Other commenters asked that we require consumer assistance entities to post information about the complaint process to ensure that consumers understand their rights about how to file a complaint.

Response: We anticipate providing further guidance regarding how and where individuals and entities may file complaints against consumer assistance entities or individuals. To ensure that the basis for initiating an investigation is sufficiently broad, we have modified proposed §155.206(d)(1) to clarify that all information received or learned by HHS, whether through communications from sources outside HHS or not, could trigger an investigation into consumer assistance entity noncompliance. For example, if HHS discovers possible noncompliance by reviewing data or information already available to it through its own monitoring efforts, rather than by reviewing new information given to it by external, non-HHS sources, under final §155.206(d)(1) that information could serve as the basis for initiating an investigation. We have also modified proposed §155.206(d)(1)(iii) to align it with language in §155.206(d)(1) and §155.206(d)(2) indicating that HHS may consider information “that a consumer assistance entity may have engaged or may be engaging” in noncompliance as described in §155.206(c). We are finalizing the rest of §155.206(d) as proposed.

Comment: A few commenters asked for clarification regarding the standards HHS will use to determine whether an investigation is warranted. As proposed, §155.206(e) required HHS to provide consumer assistance entities notice of an investigation and 30 days to respond with evidence, each time HHS learns of a potential violation. Instead, commenters requested that HHS make a preliminary assessment of complaints to determine their credibility before initiating a formal investigation under §155.206(e), to avoid imposing unnecessary administrative burdens on consumer assistance entities, and to prevent individuals and organizations from submitting complaints with the purpose of disrupting Exchange operations.

Response: We agree with commenters that HHS should not issue notice to a consumer assistance entity, with the accompanying 30 days to respond to the allegation, until HHS has

determined that a formal investigation is warranted. We have amended §155.206(e) to specify that HHS will provide a written notice to the consumer assistance entity when HHS performs a formal investigation, rather than each time it learns of a potential violation.

Comment: One commenter agreed that the CMP process, as proposed, provides a reasonable time frame to close out investigations. Another commenter asked that the time frame for consumer assistance entities to respond to the notice of investigation be increased from 30 days to 60 days.

Response: We believe 30 days to respond to HHS's notice of investigation in §155.206(e) is a reasonable amount of time, particularly because the consumer assistance entity may request an extension of another 30 days under §155.206(f) if the entity cannot prepare a response within the initial 30-day period. Therefore, we are finalizing the 30-day response period in §155.206(e) as proposed.

Comment: Commenters generally supported the proposed factors in §155.206(h) for determining noncompliance and the amount of any CMPs assessed. Several commenters appreciated the case-by-case nature of this process, and agreed that the determination should take into account factors like the consumer assistance entity's previous or ongoing record of compliance, the gravity and frequency of the violation, and any financial harm incurred by the consumer. One commenter suggested that HHS should assess penalties only if the violation is intentional and causes harm, and another asked that CMPs be suspended if the entity was acting in good faith on behalf of the individual assisted. One commenter recommended that we move the factor regarding the degree of culpability of the consumer assistance entity, proposed at §155.206(h)(2)(i), from the list of factors that HHS *may* consider under §155.206(h)(2), to the list of factors that HHS *must* consider under §155.206(h)(1).

Response: We believe that the factors as proposed in §155.206(h) are responsive to commenters concerns. For example, HHS is required to take into account the harm caused by a violation under §155.206(h)(1)(ii), which provides that HHS must take into account the gravity of the violation, which may be determined in part by whether the violation caused, or could reasonably be expected to cause, adverse impacts, and the magnitude of those impacts. We based these factors on a longstanding interpretation of what “gravity of the violation” means and what it may include under the HIPAA enforcement scheme at 45 CFR 150.317. HHS may also take into account the degree of culpability of the consumer assistance entity under §155.206(h)(2)(i). We believe this factor will generally play an important role in HHS’s determination of whether CMPs should be assessed, but we are finalizing this factor as proposed because the mandatory factors in §155.206(h)(1) track the requirements of section 2723(b)(2)(C)(ii) of the PHS Act, while the permissive factors in §155.206(h)(2) are not statutory requirements. Additionally, we believe that the limitations on CMPs described in §155.206(k) provide sufficient protections for consumer assistance entities acting in good faith on behalf of consumers. Therefore, we are finalizing the other factors listed in §155.206(h) as proposed, with the addition, as discussed above, of a factor regarding whether other remedies or penalties have been assessed and/or imposed for the same conduct or occurrence.

Comment: One commenter requested clarity regarding whether HHS could assess a lesser amount per day than the maximum of \$100, and recommended against the assessment of a lesser amount. One commenter suggested that when the number of individuals directly affected by the violation cannot be determined, there should be a maximum placed on the estimate calculated by HHS, based on the size of the consumer population previously assisted by the entity. One commenter requested that HHS exclude from the time frame for which a penalty is assessed any

time during which the investigation is being conducted, provided the entity or individual stops the behavior at issue during that period.

Response: The maximum penalty provided in §155.206(i) is the per-day limit on the amount of any CMP that may be assessed. HHS may determine that a lesser amount is appropriate, based on an analysis of the relevant factors in §155.206(h). We believe that a reasonable estimate of individuals directly affected, as we explained in the preamble to the proposed rule, would be based on available information, such as the data from a Federal Navigator grantee's quarterly or weekly report concerning the number of consumers assisted. Therefore, we do not think it is necessary to place a maximum on such an estimate based on the size of the population assisted by the entity. In addition, we have not included a requirement that would toll the maximum penalty from accruing while HHS conducts its investigation because of the possibility that consumers may continue to be affected by previous misconduct during this period, even if the entity has stopped the behavior at issue. However, under §155.206(k)(1)(ii), HHS cannot assess penalties for any period of time after a consumer assistance entity knew, or exercising reasonable diligence would have known, of the failure, if the violation was due to reasonable cause and not due to willful neglect and the violation was corrected within 30 days of the first day that any of the consumer assistance entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that the violation existed. Additionally, HHS may consider a consumer assistance entity's cessation of misconduct when determining whether penalties should be assessed and in what amount, under §155.206(h)(2)(ii). Taken together, we believe these factors strike the right balance to ensure that any CMPs assessed by HHS are reasonable and appropriate.

Comment: We requested comment on whether we should provide a cap on the total penalty that could be assessed by HHS in addition to the maximum per day penalty. The majority of commenters who responded to this request recommended that we implement such an aggregate cap. These commenters were concerned that the lack of such a cap might chill participation, particularly for those organizations with fewer resources, and might unduly penalize consumer assistance entities for mistakes made due to lack of sophistication or confusion during the initial open enrollment period. A few commenters recommended against implementing an aggregate penalty cap because the cost-benefit of CMPs for certain violations might not serve as an adequate deterrent. One commenter recommended a tiered system of caps based on the time frame of the violation.

Response: We agree with commenters that if we were to set an aggregate cap for CMPs assessed against a consumer assistance entity, CMPs might not serve as a sufficient deterrent for certain types of misconduct or noncompliance. Therefore, we are finalizing §155.206(i) as proposed. However, we have modified the text of §155.206(h) to make clear that, as was discussed in the preamble to the proposed rule, the factors listed are to be used not just to determine whether CMPs are warranted under the circumstances surrounding the violation, but also to determine the amount of any CMPs assessed. We believe this change will help HHS ensure that the amount of any penalty assessed is in proportion to the consumer assistance entity's violation.

Comment: One commenter suggested that the CMPs collected by HHS related to consumer harm should be distributed to consumers as restitution.

Response: Section 2723(b)(2)(G) of the PHS Act states that penalties collected under paragraph (b) of that Act must be “expended for the purpose of enforcing the provisions with

respect to which the penalty was imposed.” HHS does not interpret restitution to consumers to fall within this statutory purpose, and therefore does not interpret the statute to permit restitution to consumers. Accordingly, we do not provide for consumer restitution as an alternative use of CMPs collected under this authority.

Comment: One commenter expressed support for our proposal in §155.206(j) that HHS retain authority to settle or compromise on any penalties provided for in this section.

Response: We agree that HHS should have the flexibility to settle or compromise on any penalties that could be collected. We are therefore finalizing §155.206(j) as proposed.

Comment: Many commenters supported our proposal in §155.206(k) to implement the limitations that HHS will not assess a CMP where the entity did not know, or exercising reasonable diligence would not have known, of the violation; or for any period of time after a consumer assistance entity knew, or exercising reasonable diligence would have known, of the failure, if the violation was due to reasonable cause and not due to willful neglect and the violation was corrected within 30 days of the first day that any of the consumer assistance entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that the violation existed. Some commenters expressed that these limitations would help encourage a broader group of organizations with varying degrees of experience to participate as consumer assistance entities, and ensure that CMPs are reserved for the most egregious offenses. Several commenters also supported our proposal to place the burden on demonstrating the existence of the factors that trigger these limitations on the consumer assistance entity.

Response: We agree with these comments, and are finalizing §155.206(k)(1) and (2) as proposed. We believe these limitations will help balance the interests of HHS, the Exchange,

and consumers to have consumer assistance entities exercise reasonable diligence in understanding and executing their obligations, while not unnecessarily penalizing consumer assistance entities who are acting in good faith.

Comment: We requested comment on whether a statute of limitations should apply to actions under this section. One commenter responded to this request, suggesting that a statute of limitations period would be appropriate and recommending a period of 5 years.

Response: We agree that a statute of limitations period is appropriate. We believe such a period will help give assurance to consumer assistance entities that any violations will not be actionable indefinitely, particularly since we understand that some commenters are concerned about the potential for these penalties to discourage program participation. Additionally, HHS's goals in issuing this CMP rule are to encourage program compliance, prevent misconduct, and remedy violations promptly. We do not think these goals will be served by prosecuting violations many years after they have occurred.

The regulations finalized elsewhere in this rulemaking at §155.285 regarding application fraud and misuse of PII have adopted a six-year statute of limitations following the date of the occurrence. We believe that consistency with §155.285 regarding the statute of limitations period is important because the same conduct by a consumer assistance entity in an FFE might trigger CMPs under either that provision or under §155.206. Additionally, we believe that six years provides ample time for HHS to discover, investigate, and assess any potential CMP against a consumer assistance entity. We have therefore added a new §155.206(k)(3) to provide for a six-year statute of limitations period.

Comment: We requested comment on whether all aspects of 45 CFR Part 150, Subpart D should apply to appeals of CMPs assessed under §155.206. No commenters responded to this

request, although one commenter supported the proposed appeals process. One commenter recommended that CMPs should continue to accrue pending an appeal in the event the imposition of CMPs is upheld on appeal and the Exchange participant failed to correct the instance of noncompliance following the imposition.

Response: We are finalizing §155.206(m)-(n) as proposed. We do not believe it is necessary to provide that CMPs should continue to accrue pending appeal. If HHS receives or learns of any information indicating that a consumer assistance entity may have engaged or may be engaging in noncompliant activity in violation of §155.206(c), including any violation for the period following an initial assessment, such as the period during which an appeal is pending, HHS could initiate a new investigation and assess new CMPs as appropriate.

Comment: Several commenters agreed with our proposal that where conduct by consumer assistance entities may warrant CMPs under either §155.285 or §155.206, HHS has discretion to determine whether to assess a CMP under §155.285 or under §155.206. Other commenters recommended that consumer assistance entities be exempt from penalties under §155.285. A few argued that consumer assistance entities do not actually provide information as part of the process of applying for coverage or an exemption, and therefore it was difficult to see how they could provide false or fraudulent information in violation of section 1411(b) of the Affordable Care Act.

Response: We disagree that consumer assistance entities should be exempt from the provisions of §155.285. Any Navigator, non-Navigator assistance personnel, or certified application counselor who misuses consumer information in violation of section 1411(g) of the Affordable Care Act, or who knowingly enters false or fraudulent information in a consumer's application with or without the knowledge of the consumer, might be in violation of either

§155.285 or §155.206. Therefore, we maintain that where conduct by a consumer assistance entity may warrant CMPs under either §155.285 or §155.206, HHS should have discretion to determine whether to assess a CMP under §155.285 or under §155.206. We have also finalized the portion of §155.206(c) that indicates that HHS will not assess a CMP under §155.206 if a CMP has been assessed for the same conduct under §155.285. If a consumer assistance entity is in a situation where CMPs could be imposed under both §155.285 and §155.206, when determining whether to assess CMPs under §155.285, HHS will take the possibility that it may be penalizing conduct that is being investigated or has already been penalized under §155.206 into account as a factor under §155.285(b)(1)(viii).

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.206 of the proposed rule, with the following modifications. We modified proposed §155.206(c) to more clearly explain that HHS could assess a CMP against a consumer assistance entity for failure to comply with the Federal regulatory requirements applicable to the consumer assistance entity that have been implemented pursuant to section 1321(a)(1) of the Affordable Care Act, including provisions of any agreements, contracts, and grant terms and conditions that interpret those Federal regulatory requirements or establish procedures for compliance with them. We added language to final §155.206(d)(1), to specify that information learned, not just received, by HHS indicating that a consumer assistance entity may have engaged or may be engaging in activity specified in paragraph (c) may warrant an investigation. We modified §155.206(d)(1)(iii) to align with language elsewhere in this section that HHS may consider information “that a consumer assistance entity may have engaged or may be engaging” in noncompliance under §155.206(c), rather than information concerning “potential involvement” in such activity. We revised

§155.206(e) to specify that HHS must provide a written notice to a consumer assistance entity of its investigation, rather than requiring HHS to provide a written notice to an entity each time HHS learns of a potential violation. We revised §155.206(h) to clarify that, consistent with the preamble discussion of the proposed rule, the factors listed are to be used not just to determine whether CMPs are warranted, but also to determine the amount of any CMPs assessed. In §155.206(h)(1)(i), we removed the erroneous reference to corrective action plans “under section (c) of this section.” We also included a new factor at §155.206(h)(2)(iii) that allows HHS to take into consideration whether other remedies or penalties have been assessed and/or imposed for the same conduct or occurrence, and adjusted the numbering of the final factor (“Other such factors as justice may require”) from §155.206(h)(2)(iii) to §155.206(h)(2)(iv). In §155.206(i), we changed “the Exchange” to “HHS” for consistency with the rest of the section. We added new §155.206(k)(3) to provide for a six-year statute of limitations period. We corrected some numbering errors throughout §155.206(l). We also made several minor wording changes throughout final §155.206, to replace “Federally-facilitated Exchanges” with “a Federally-facilitated Exchange” and to use the abbreviation “CMP” consistently.

b. Navigator, Non-Navigator Assistance Personnel, and Certified Application Counselor Program Standards (§§155.210, 155.215, and 155.225)

1. Provisions Related to Non-Federal Requirements for Navigators, Non-Navigator Assistance Personnel, and Certified Application Counselors (§§155.210, 155.215, and 155.225)

In the proposed rule, we proposed amending §155.210(c)(1)(iii) to add new paragraphs (A) through (F) to specify a non-exhaustive list of certain non-Federal requirements that would prevent the application of the provisions of title I of the Affordable Care Act within the meaning of section 1321(d) of the Affordable Care Act, with respect to the Navigator program. We also

proposed amending § 155.215(f) to make clear that we would consider the same types of non-Federal requirements listed in proposed §155.210(c)(1)(iii)(A) through (F) (except for 155.210(c)(1)(iii)(D)) to prevent the application of the provisions of title I of the Affordable Care Act within the meaning of section 1321(d) of the Affordable Care Act, when applied to non-Navigator assistance personnel subject to § 155.215. Similarly, with respect to the certified application counselor program, we proposed amending §155.225(d) to add a new paragraph (d)(8) to specify that certified application counselors must meet any licensing, certification or other standards prescribed by the State or Exchange, if applicable, so long as such standards do not prevent the application of the provisions of title I of the Affordable Care Act within the meaning of section 1321(d) of the Affordable Care Act. We further proposed in §155.225(d)(8) to specify a non-exhaustive list of non-Federal requirements, similar to those listed in proposed §155.210(c)(1)(iii)(A) through (F) (except for 155.210(c)(1)(iii)(D)), that would prevent the application of the provisions of title I of the Affordable Care Act within the meaning of section 1321(d) of the Affordable Care Act, when applied to certified application counselors. We explained that the proposed amendments were intended as a non-exhaustive list of certain non-Federal requirements that prevent the application of the provisions of title I of the Affordable Care Act in one or more of the following three ways: (1) on their face, they prevent Navigators, non-Navigator assistance personnel subject to §155.215, and certified application counselors or their designated organizations from performing their Federally required duties; (2) on their face, they make it impossible for an Exchange to implement the consumer assistance programs it is authorized or required to operate in a manner consistent with Federal requirements; and (3) they conflict with Federal standards or requirements in specific factual circumstances based on how a non-Federal requirement is applied or implemented. In addition, we recognized that a Federal

court may also find other non-Federal requirements that we did not expressly mention in the proposed rule to be preempted within the meaning of section 1321(d) of the Affordable Care Act. We further explained that the proposed provisions would not preclude a State from establishing or implementing State law protections for its consumers, so long as such laws do not prevent the application of Federal requirements for the applicable consumer assistance programs. As an example, we stated that a State may require assisters to undergo fingerprinting or background checks before they can operate in a State, so long as a State's implementation of these additional requirements does not prevent the Exchange from implementing these programs in the State consistent with Federal standards or make it impossible for the assisters to perform their Federally-required duties.

First, in proposed §§155.210(c)(1)(iii)(A) and 155.225(d)(8)(i), we proposed to specify that non-Federal requirements which require Navigators, non-Navigator assistance personnel subject to §155.215, and certified application counselors to refer consumers to other entities not required to provide them with fair, accurate, and impartial information or act in the consumer's best interests, would prevent the application of the provisions of title I of the Affordable Care Act within the meaning of section 1321(d) of the Affordable Care Act because such non-Federal requirements would conflict with an assister's duty to provide fair, accurate, and impartial information or to act in the consumer's best interests. Second, we proposed to specify under §§155.210(c)(1)(iii)(B) and 155.225(d)(8)(ii) that non-Federal requirements that prevent Navigators, non-Navigator assistance personnel subject to §155.215, and certified application counselors from providing services to all persons to whom they are required to provide assistance would also prevent the application of the provisions of title I of the Affordable Care Act because assisters are required to provide information and services in a fair and impartial

manner and to provide information to employees about the full range of QHP options for which they are eligible, which we have interpreted to mean that assisters must have the ability to help any individual who presents themselves for assistance. With respect to proposed §§155.210(c)(1)(iii)(A) and (B), we explained that where a State has elected to establish and operate only a SHOP Exchange pursuant to 45 CFR 155.100(a)(2), and has opted under 45 CFR 155.705(d) to permit Navigator duties at §155.210(e)(3) and (4) in the State SHOP-only Exchange to be fulfilled through referrals to agents and brokers, we would not consider the State's exercise of this option under §155.705(d) to prevent the application of the provisions of title I of the Affordable Care Act, since that option is authorized under Federal law. Third, under §§155.210(c)(1)(iii)(C) and 155.225(d)(8)(iii), we proposed to specify that non-Federal requirements that prevent Navigators, non-Navigator assistance personnel subject to §155.215, and certified application counselors from providing advice regarding substantive benefits or comparative benefits of different health plans, would also prevent the application of the provisions of title I of the Affordable Care Act because assisters are required to provide information about QHPs, and to facilitate either selection of or enrollment in a QHP, and CMS interprets these requirements to mean that assisters must be prepared to discuss the terms and features of any coverage for which a consumer is or might be eligible, consistent with each consumer's expressed interests and needs. As proposed, these three provisions would apply to Navigators, non-Navigator assistance personnel subject to §155.215, and certified application counselors (or certified application counselor designated organizations) that are operating in State Exchanges or in FFEs. Fourth, under §§155.210(c)(1)(iii)(D), we proposed that a non-Federal requirement that required a Navigator (but not a certified application counselor or non-Navigator assistance personnel) to hold an agent or broker license or to carry errors and

omissions coverage (typically held only by licensed professionals such as agents and brokers) would also prevent the application of the provisions of title I of the Affordable Care Act because imposing these requirements on all Navigators in a State would mean that all Navigators would fall under only one type of entity listed in §155.210(c)(2), specifically, agents and brokers, in violation of the requirement set forth under §155.210(c)(2)(i) that there be two types of Navigator entities in each Exchange, and that at least one type must be a community and consumer-focused nonprofit group. We explained that we believed that the four provisions listed above should apply in both FFEs and State Exchanges because they address requirements that, in HHS's view, would facially conflict with Federal requirements or standards.

The proposed rule also specified two additional provisions regarding certain non-Federal requirements that would prevent the application of the provisions of title I of the Affordable Care Act with respect to FFEs only. We explained that these two provisions would not apply in State Exchanges since we had observed an enhanced ability for a State Exchange to work with other offices within the State to establish Exchange standards and coordinate the implementation of State law applicable to assisters in a manner that does not conflict with Federal standards or prevent the State Exchange from implementing consumer assistance programs consistent with Federal requirements. Under proposed §§155.210(c)(1)(iii)(E) and 155.225(d)(8)(iv), we proposed to specify that non-Federal requirements that impose standards that would prohibit individuals or entities from acting as Navigators, non-Navigator assistance personnel, or certified application counselors or certified application counselor designated organizations, when they would be eligible to participate in these respective capacities under FFE standards, would prevent the application of the provisions of title I of the Affordable Care Act within the meaning of section 1321(d) of the Affordable Care Act. We illustrated this provision in two examples.

First, we explained that a non-Federal requirement that prohibits consumer assistance entities and individuals from receiving any consideration, directly or indirectly, from a health insurance issuer offering health insurance coverage in or outside of an Exchange, even if not in connection with the enrollment of individuals into a QHP, would not only exceed applicable Federal conflict-of-interest standards but would also render ineligible certain entities, such as hospitals and community health care clinics, that would otherwise be eligible to serve as Navigators, non-Navigator assistance personnel subject to §155.215, or certified application counselors and organizations. Second, we explained that a non-Federal law that prohibits an individual or entity from serving in an assister program on the basis that the individual or entity does not maintain its principal place of business in that State (which could include an organization that is organized in the State, but maintains its principal place of business outside of the State), would prevent the FFE from implementing consumer assistance programs that it is required or authorized to implement.²²

Finally, under proposed §§155.210(c)(1)(iii)(F) and 155.225(d)(8)(v), we proposed to specify that in an FFE, non-Federal requirements that, as applied or as implemented in the State, prevent the application of Federal standards applicable to Exchanges, Navigators, non-Navigator assistance personnel subject to §155.215, or certified application counselors and certified application counselor designated organizations, would prevent the application of the provisions of title I of the Affordable Care Act within the meaning of section 1321(d). For example, with respect to the Navigator program, if a State with an FFE implemented a requirement that prevented the only Navigator entity operating in the State from continuing to perform its

²² The preamble discussion to the proposed rule addressed only non-Federal requirements that would interpret “principal place of business” to mean that an organization could have only one principal place of business nationwide, similar to the legal concept that may be used in determining corporate citizenship for purposes of establishing diversity jurisdiction in Federal court, as required under 28 U.S.C. 1332(c).

Federally-required duties, then such a provision, as applied, would prevent the Exchange from operating a Navigator program as required by section 1311(i)(1) of the Affordable Care Act and §155.210(a). As a second example, we explained that if a State imposed certain requirements as mandatory conditions for continuing to perform any applicable Federally-required duties, such as additional training or background or fingerprinting checks, which, on their face, we consider as generally permissible, but also set a deadline for compliance that made it impossible for any individual or entity approved by the FFE to comply on a timely basis, despite good faith efforts to comply, then as long as those assisters were prevented from fulfilling any of their Federally-required duties until they could come into compliance with the State requirements, the FFE would be prevented from operating the consumer assistance programs that it is required or authorized to implement consistent with Federal standards.

Comment: A large number of commenters commended HHS for listing specific examples of non-Federal standards that would, in HHS's view, prevent the application of the provisions of title I of the Affordable Care Act, within the meaning of its section 1321(d). The commenters stated that the level of specificity in the proposed provisions and accompanying preamble provided important clarity regarding the types of non-Federal requirements that would prevent Navigators, non-Navigator assistance personnel and certified application counselors from performing their Federally-required duties. In expressing their support, these commenters stated that enrollment into Exchange coverage and insurance affordability programs during the initial open enrollment period was aided in significant part by assistance offered through in-person assistance programs, and that these proposed regulations should be finalized to help facilitate the continued ability of assisters to provide in-person assistance during the 2014 coverage year as well as during the next Exchange open enrollment period in fall 2014 and beyond.

A few commenters objected to the proposed provisions and asserted that they were overly broad, and/or exceed the authority of HHS, in violation of the Tenth Amendment of the U.S. Constitution and the McCarran-Ferguson Act that provides, “[t]he business of insurance, and every person engaged therein, shall be subject to the laws of the several States which relate to the regulation or taxation of such business.” (15 U.S.C. 1012(a) (1945)) Citing 15 U.S.C. 1012(b), these commenters asserted that the McCarran-Ferguson Act exempts the business of insurance from most Federal regulation, providing that Federal statutes cannot be construed to invalidate, impair or supersede State insurance law unless they specifically relate to the business of insurance.

Response: We agree that Navigators, non-Navigator assistance personnel, and certified application counselors have played and will continue to play an important role in providing application assistance to consumers, with respect to enrollment in both QHPs and insurance affordability programs. It is therefore important, in the view of HHS, to provide guidance regarding which types of non-Federal laws would, within the meaning of section 1321(d) of the Affordable Care Act, prevent the application of the Federal requirements to which assisters and Exchanges are subject. The finalized provisions are a non-exhaustive list of non-Federal requirements that, in the view of HHS, prevent the application of the provisions of title I of the Affordable Care Act. We are therefore finalizing, with a few modifications, proposed §§155.210(c)(1)(iii)(A)-(D) and (F) and 155.225(d)(8)(i)-(iii) and (v).

We are not finalizing proposed §§155.210(c)(1)(iii)(E) and 155.225(d)(8)(iv). The concerns raised by commenters about the breadth of these provisions, and the questions raised in comments raised about the interpretations we provided in the preamble to the proposed rule of the substantive Federal requirements whose application would be prevented by certain non-

Federal requirements, have instead provided us with an opportunity to further define those substantive Federal requirements, consistent with our preamble discussion in the proposed rule, through the addition of language in §§155.210(d)(4) and (e)(7) and §§155.225(b)(3) and (g)(2) in the final rule.

With respect to the proposed requirement that Navigators, non-Navigator assistance personnel subject to §155.215 and certified application counselors maintain a physical presence in the Exchange service area, we are finalizing this requirement under §§155.210(e)(7) and 155.215(h) with respect to Navigators and non-Navigator assistance personnel subject to §155.215, but we are not finalizing this requirement with respect to certified application counselors under proposed §155.225(b)(1)(iii). We are also modifying the proposed regulation text in §§155.210(e)(7), 155.215(h) and are finalizing a new provision at §155.225(b)(3) to clarify that in an FFE, Navigators, non-Navigator assistance personnel subject to 155.215 and certified application counselors, respectively, are not required to maintain their principal place of business in the Exchange service area, defined as the entire area served by the Exchange. A requirement that these assister entities maintain their principal place of business within the Exchange service area for an FFE would limit the pool of entities which would be eligible to serve in this capacity, and could prevent the FFE from fully implementing the consumer assistance programs that it is required (or authorized) to implement, within the meaning of section 1321(d) of the Affordable Care Act.

With respect to the requirement under existing §§155.210(d)(4) and 155.215(a)(2)(i) (which applies §155.210(d)(4) to non-Navigator assistance personnel subject to §155.215 by cross-reference), and finalized in this rule at §155.225(g)(2), that Navigators, non-Navigator assistance personnel subject to §155.215 and certified application counselors, respectively, are

prohibited from receiving any consideration directly or indirectly from a health insurance issuer (or stop-loss insurance issuer) in connection with enrollment of any individuals in a QHP or non-QHP, we are modifying the text in §155.210(d)(4) and adding text in §155.225(g)(2) to clarify that in the FFE, this requirement does not mean that a health care provider shall be ineligible to operate in an assister program solely because it receives consideration from a health insurance issuer for health care services provided. We make these clarifications to make it easier for the public to understand the purpose and scope of the applicable Federal standards in the FFE and to identify circumstances in which additional non-Federal requirements would be in conflict with Federal requirements. This places in regulation text previous interpretations of these provisions, in which we have stated that “the prohibition on receiving direct or indirect consideration from a health insurance or stop loss insurance issuer [applies to] consideration received for enrolling individuals or employees in health insurance plans or stop loss insurance inside or outside the Exchanges; it does not apply to consideration received by a provider to support specific activities, such as the provision of medical services, that are not connected to the enrollment of individuals or employees in QHPs.” (78 FR 42832) In addition, this prohibition does not apply in situations where an individual or entity that is otherwise eligible to serve as a Navigator, non-Navigator assistance personnel subject to §155.215, certified application counselor or certified application counselor designated organization, in accordance with applicable Exchange standards, receives consideration from a health insurance or stop loss insurance issuer that is not in connection with the enrollment of any individual(s) in a QHP or non-QHP

We do not agree that HHS is exceeding its authority in finalizing the proposed provisions. These provisions set forth HHS’s interpretation of the preemption standard established by Congress in section 1321(d) of the Affordable Care Act, which provides that State

laws that do not prevent the application of the provisions of title I of the Affordable Care Act are not preempted. This preemption standard applies to all of the Federal requirements applicable to Navigators, non-Navigator assistance personnel and certified application counselors, as well as to all of the Federal requirements that Exchanges implementing these programs must follow, as all these standards are authorized and established under title I of the Affordable Care Act. In section 1321(d) of the Affordable Care Act, therefore, in HHS's view, Congress made clear that while States continue to have authority to enact laws that affect programs established under the provisions of title I of the Affordable Care Act, that authority is not unlimited. Rather, States do not have the authority to enact laws that prevent the application of the provisions of title I of the Affordable Care Act, including the provisions that provide authority and establish Federal requirements for the Navigator programs, non-Navigator programs, and certified application counselor programs.

Moreover, in promulgating the provisions in this final rule, HHS is simply interpreting how the preemption standard that Congress established in section 1321(d) of the Affordable Care Act applies to a non-exhaustive list of certain non-Federal requirements for these assister programs. HHS has a unique understanding of the statutes it administers and is responsible for interpreting, and Congress has expressly delegated to HHS, under section 1321(a)(1) of the Affordable Care Act, authority for issuing Federal regulations setting standards for meeting the requirements under the Affordable Care Act with respect to the establishment and operation of Exchanges, including the establishment and operation of the Navigator, non-Navigator, and certified application counselor programs. HHS expects that this final rule will provide valuable guidance to both States and assisters, as well as other stakeholders, by helping to resolve questions about the types of non-Federal laws that, in HHS's view, would prevent the application

of the provisions of title I of the Affordable Care Act, within the meaning of section 1321(d) of the Affordable Care Act. We recognize that a Federal court might find that other non-Federal requirements not listed in this rule would prevent the application of Federal requirements within the meaning of section 1321(d).

Comment: Some commenters, while supporting the provisions generally, also expressed concerns that the proposed regulations do not address non-Federal laws that create obstacles to the implementation of the goals of Federal law. Commenters urged us to specifically address requirements that impose unreasonable burdens for assisters in the performance of their Federally-required duties and expressed concern that by not doing so, HHS could be seen as interpreting section 1321(d) of the Affordable Care Act to preempt State law only when it is impossible for an assister or an Exchange to comply with both Federal and non-Federal requirements. Some of these commenters requested that HHS clarify that it does not mean to suggest that a non-Federal requirement that imposes an unreasonable burden on assisters or serves as an obstacle to the implementation of Federal law could not prevent the application of the provisions of title I of the Affordable Care Act, within the meaning of section 1321(d) of the Affordable Care Act.

Response: These provisions contain a non-exhaustive list of circumstances under which HHS would consider a non-Federal requirement applicable to Navigators, non-Navigator assistance personnel, or certified application counselors to prevent the application of provisions of title I of the Affordable Care Act, within the meaning of section 1321(d) of the Affordable Care Act. There may be other types of non-Federal requirements, not specified in these provisions, that would also prevent the application of Federal requirements related to the assister programs. We do not intend to suggest that non-Federal requirements which place unreasonable

burdens on assisters and assister entities or that create obstacles to the implementation of Federal law could not also prevent the application of title I of the Affordable Care Act within the meaning of section 1321(d) of the Affordable Care Act.

Comment: Some commenters supported the proposed regulations' acknowledgement of the State's role in imposing State-level registration and other reasonable consumer protections for its residents. However, a few commenters asserted that the proposed provisions would prevent States from establishing additional consumer protections and would therefore conflict with section 1321(d) of the Affordable Care Act.

Response: We clearly expressed in the preamble to the proposed rule, and reiterate here, that we do not intend the provisions regarding non-Federal requirements for assisters to suggest that a State cannot establish or implement additional State law protections for its consumers, such as requiring registration, passing fingerprinting and background checks, or completing State training, provided that its implementation of these additional requirements does not prevent the Exchange from implementing Navigator, non-Navigator and certified application counselor programs in the State consistent with Federal standards or prevent assisters in these programs from meeting Federal requirements. We acknowledge, however, that there is an apparent tension between the general permissibility of additional, non-conflicting State requirements and the language in proposed §§155.210(c)(1)(iii)(E) and 155.225(d)(8)(iv), in which we proposed that non-Federal requirements that would render ineligible any assister entities or individuals that would otherwise be eligible to participate in an FFE would prevent the application of Federal requirements for assisters. Because these provisions could have been construed, contrary to our intent, as limiting the States' authority or ability to implement reasonable consumer protection measures in addition to those established by the FFE, we have decided not to finalize them.

Instead, as we explain above, we are adding language to other provisions of the regulations governing the Navigator, non-Navigator, and certified application counselor programs to codify our interpretations of those provisions, consistent with our preamble discussion in the proposed rule and in other preambles (see 78 FR 42832), so that our existing policies related to these provisions are clarified.

First, we are adding language to current §155.210(d)(4), which applies to non-Navigator assistance personnel subject to §155.215 by cross-reference, as well as to new §155.225(g)(2) (which is being finalized in this rulemaking) to codify the principle we previously espoused in the preamble to the proposed rule: that a hospital or other health care provider shall not be ineligible to participate in the Navigator, non-Navigator assistance personnel, or certified application counselor program solely because it receives payment for health services from health insurance issuers. Our approach to finalizing this provision reflects the fact that HHS continues to have concerns regarding certain types of non-Federal requirements that were described in the preamble to the proposed rule. Specifically, we continue to have concerns about non-Federal requirements that would prohibit a hospital or other health care provider from participating in an assister program solely because it receives payment for health services from a health insurance issuer, because such non-Federal requirements could prevent the Exchange from operating an assister program that includes individuals and entities that are otherwise extremely well qualified.

We also continue to have concerns about non-Federal requirements that require Navigators, non-Navigator assistance personnel subject to §155.215, and certified application counselors or certified application counselor designated organizations to maintain their principal place of business in the State, even though we are not finalizing the specific provisions that were

directed at these types of non-Federal requirements in proposed §§155.210(c)(1)(iii)(E) and 155.225(d)(8)(iv). We have therefore decided to add text to the Federal standards being finalized in this rulemaking at §§155.210(e)(7) and 155.215(h) to clarify that although Navigators and non-Navigator personnel subject to §155.215 must maintain a physical presence in the Exchange service area, they shall not be rendered ineligible to participate in the applicable assister program merely because their principal place of business is outside of the Exchange service area. While we are not finalizing the proposed requirement in §155.225(b)(1)(iii)) which would have required an organization to maintain a physical presence in the Exchange service area in order to be designated as a certified application counselor organization by an Exchange, we are finalizing in §155.225(b)(3) the clarification that an organization shall not be rendered ineligible to participate in the applicable assister program merely because its principal place of business is outside of the Exchange service area. We hope that by codifying these principles through amendments to the regulations governing these assister programs, we will resolve any confusion caused by our proposals at §§155.210(c)(1)(iii)(E) and 155.225(d)(8)(iv), while at the same time addressing the concerns about non-Federal requirements that motivated these proposals and were presented in the preamble discussion related to those proposals.

Comment: Several commenters recommended that the list of provisions specifying non-Federal requirements that would prevent the application of the provisions of title I of the Affordable Care Act remain non-exhaustive and that HHS should continue to engage in monitoring of non-Federal requirements and their effects on consumer assistance functions that are required or permitted in an Exchange. A few commenters urged HHS to monitor the implementation of non-Federal requirements and their effects on assister programs, with one

commenter suggesting that HHS be more proactive by delineating a process for how it will review non-Federal standards in the event that these provisions become finalized as proposed.

Response: We agree that, at this time, HHS should not attempt to provide an exhaustive list of provisions specifying the types of non-Federal requirements that would prevent the application of Federal requirements. We agree that continued monitoring of the passage and implementation of non-Federal requirements as they apply to Navigators, non-Navigator assistance personnel subject to §155.215, and certified application counselors is critical to ensuring the implementation and ultimate success of consumer assistance functions of an Exchange to provide meaningful assistance to all consumers who seek such assistance. HHS has monitored, and will continue to monitor, new and existing non-Federal requirements as they are issued and implemented, and will continue to assess whether such laws prevent the application of the provisions of title I of the Affordable Care Act.

Comment: We received comments on whether all the proposed provisions regarding non-Federal requirements should apply in State Exchanges or whether only some of the provisions would apply to State Exchanges, as proposed. A few commenters expressed support for applying certain of the proposed provisions in all types of Exchanges, while applying other types of provisions only in FFEs (including State Partnership Exchanges). Others recommended that the provisions should apply consistently “across-the-board” to all Exchanges because doing so would create a bright line across all Exchanges and make it easier for all stakeholders to administer the various consumer assistance programs in an efficient, cohesive fashion and would minimize confusion if a State transitions from an FFE to a State Exchange.

Response: In light of the fact that we are not finalizing proposed §§155.210(c)(1)(iii)(E) and 155.225(d)(8)(iv) in this final rule (and our related decision to instead clarify certain Federal

standards as they apply to assisters in the FFE, as discussed above), there are five preemption provisions being finalized in this rule under renumbered §§155.210(c)(1)(iii)(A)-(E) and four preemption provisions being finalized in both §155.215(f)(1)-(4) and §155.225(d)(8)(i)-(iv). We agree with commenters that these specific provisions, as finalized, should be directed at non-Federal requirements in all Exchanges, including State Exchanges. We continue to anticipate, based on our observations thus far, that a State Exchange would have an enhanced ability to coordinate with other State offices to ensure that State law applicable to assisters does not prevent the application of Federal requirements applicable to Navigators, non-Navigators and certified application counselors. However, we acknowledge that it is possible that a non-Federal requirement, as applied or implemented in a State, could prevent a State Exchange from operating the consumer assistance programs it is required (or authorized) to implement, or otherwise prevent the Exchange from implementing applicable consumer assistance programs consistent with Federal requirements, or could prevent consumer assistance entities or individuals in the State from performing their Federally-required duties. Rather than rule out the possibility that an “as-applied” conflict could occur with respect to a State Exchange, as captured in the provisions that were proposed at §§155.210(c)(1)(iii)(F) and 155.225(d)(8)(v) to be applicable only in an FFE, we are extending the applicability of these provisions, now renumbered as §§155.210(c)(1)(iii)(E) and 155.225(d)(8)(iv), and reformatted in §155.215(f)(4), so that they apply equally to all types of Exchanges. Therefore, in finalizing these provisions, we have removed the reference to a “Federally-facilitated Exchange.”

We are also amending §155.210(e)(2) in the final rule, to specify, consistent with our discussion in the preamble to the proposed rule (see, for example, 79 FR 15828-15829), that in addition to the existing requirements under this provision and 155.210(e)(3) that Navigators must

provide information and services in a fair, accurate, and impartial manner and must facilitate selection of a QHP, the duties of a Navigator include providing information that assists consumers with submitting the eligibility application; clarifying the distinctions among health coverage options, including QHPs; and helping consumers make informed decisions during the health coverage selection process. Under existing provisions at 45 CFR 155.215(a)(2)(i), these duties will also apply to non-Navigators subject to §155.215. In addition, in this rulemaking, we are finalizing a new §155.225(c)(1), to make certified application counselors subject to a similar set of duties.

We have also made a minor change to the parallel provisions for Navigators, non-Navigator personnel subject to §155.215, and certified application counselors that are being finalized under §155.210(c)(1)(iii)(E), §155.215(f)(4) and §155.225(d)(8)(iv). Specifically, we changed the reference to standards that would, as applied or as implemented in a State, prevent the application of Federal requirements applicable to the Exchange's implementation of the respective Navigator, non-Navigator assistance personnel or certified application counselor program "consistent with Federal requirements," by deleting "consistent with Federal requirements" to eliminate redundancy.

Comment: Several commenters expressed support for the clear and specific acknowledgement in proposed §155.215(f) that non-Navigator assistance personnel subject to §155.215 must meet non-Federal requirements, as applicable, except when such non-Federal requirements prevent the application of the provisions of title I of the Affordable Care Act. As originally proposed, §155.215(f) did not specify the types of non-Federal requirements which would prevent the application of title I of the Affordable Care Act, but instead incorporated them by reference to applicable provisions under proposed §155.210(c)(1)(iii). A few commenters

requested that HHS, in the interest of added clarity and ease of comprehension, revise proposed §155.215(f) to spell out in the text of this provision the non-exhaustive list of non-Federal requirements that would prevent the application of the provisions of title I of the Affordable Care Act as applied to non-Navigator assistance personnel, rather than cross-referencing the applicable provisions under §155.210(c)(1)(iii), as we had originally proposed.

Response: We agree with the comment that, consistent with section 1321(d) of the Affordable Care Act, non-Navigator assistance personnel subject to §155.215 must meet any non-Federal requirements that may apply to them, so long as such requirements do not prevent the application of the provisions of title I of the Affordable Care Act. In the interest of added clarity and comprehension, we have modified this provision to add subparagraphs (1) through (4) to §155.215(f), in which we list the previously cross-referenced provisions proposed in the Navigator rule at §155.210(c)(1)(iii).

Comment: Several commenters supported the clear and specific acknowledgement in proposed § 155.225(d)(8) that certified application counselors and their designated organizations must meet non-Federal requirements, as applicable, except when such non-Federal requirements prevent the application of the provisions of title I of the Affordable Care Act. A few commenters asserted that the certified application counselor program operating in an FFE should not be subject to non-Federal requirements because, in the commenters' view, this program was created under HHS's regulatory authority—not by statute.

Response: We are finalizing the provisions of §155.225(d)(8) with modifications consistent with those made to the parallel Navigator and non-Navigator provisions. These finalized provisions establish that certified application counselors must meet licensing,

certification, or other standards prescribed by a State or Exchange, so long as they do not prevent the application of the provisions of title I of the Affordable Care Act.

It is unclear to HHS why some commenters believe that a certified application counselor program operating in an FFE should not be subject to non-Federal requirements simply because it was established through an HHS regulation implementing the Affordable Care Act, rather than being expressly provided for by the statute. As we have previously explained, the Secretary established the certified application counselor program under the authority provided in section 1321(a)(1) of the Affordable Care Act. Section 1321(a)(1) directs and authorizes the Secretary to issue regulations setting standards for meeting the requirements under title I of the Affordable Care Act, with respect to, among other things, the establishment and operation of Exchanges. Therefore, the certified application counselor program is authorized by the statute, even if the program was established through rulemaking. Whether a certified application counselor organization should be subject to non-Federal requirements will turn on application of the preemption standard set forth in section 1321(d) of the Affordable Care Act, namely whether the non-Federal requirement prevents the application of the provisions of title I of the Affordable Care Act, regardless of whether it is operating in an FFE.

Comment: Some commenters asserted that since 45 CFR 155.225(a) established that “the Exchange must have a certified application counselor program that complies with the requirements of this section,” it follows that it is the responsibility of “the Exchange” to regulate certified application counselors, and therefore any State that has opted for HHS to operate an FFE has relinquished authority to regulate the certified application counselor program in the State. In support of this view, the commenters noted a Federal court decision at St. Louis Effort for AIDS, et al. v. Huff, No. 13-4246-CV-C-ODS, 2014 WL 273201, at *9 (W.D. Mo. Jan. 23,

2014) (order granting preliminary injunction). This decision is currently on appeal before the United States Court of Appeals for the Eighth Circuit, St. Louis Effort for AIDS v. Huff, No. 14-1520 (8th Cir. Appeal docketed Mar. 6, 2014). Accordingly, commenters recommended that proposed §155.225(d)(8) be modified to state: “meets any licensing, certification, or other standards prescribed by the State or Exchange, as applicable” (emphasis added).

Response: The issue presented in these comments is the subject of pending litigation before the United States Court of Appeals for the Eighth Circuit in St. Louis Effort for AIDS v. Huff, No. 14-1520 (8th Cir. Appeal docketed Mar. 6, 2014). In light of that ongoing litigation, we are refraining from making the recommended change to §155.225(d)(8) of the final rule at this time. We will consider making changes in the future.

Comment: We received several comments in support of proposed §§155.210(c)(1)(iii)(A) and 155.225(d)(8)(i), with a few of these commenters noting that these provisions could bring an ancillary benefit of enhancing conflict-of-interest rules and mitigating the risk that assisters might receive “kickbacks” from entities not required to act impartially. Several of these commenters requested that we modify the provision to mirror the characterization included in the preamble by adding “insurance agents and brokers” explicitly into the rule text, in addition to retaining “other entities not required to provide fair, accurate, and impartial information.” On the other hand, a few commenters objected to the characterization in the preamble discussion of the proposed rule that, in their view, implied that licensed health insurance agents and brokers are permitted to engage in unfair acts or make false and misleading statements. The commenters explained that in most States, licensing and unfair trade practices laws require agents and brokers to refrain from engaging in deceptive behavior or making misrepresentations regarding benefits and terms of coverage.

A few commenters, while supporting the proposed provision's specification that mandated referrals to third parties not required to provide information in a fair, impartial, accurate manner are in conflict with applicable Federal standards, also requested that we explain that this provision applies only to non-Federal requirements that mandate such referrals, and asked that we confirm that assisters would be permitted to refer consumers to agents and brokers voluntarily in specific circumstances, such as when the consumer's needs exceed the assister's expertise, or when the assister or entity lacks the capacity and resources to assist all individuals who seek assistance. In addition, a few commenters recommended that HHS clarify that this provision should not be construed to mean that assisters are barred from making referrals to entities not required to provide fair, accurate, and impartial information. These commenters suggested, for example, that assisters should be permitted to make such referrals when a consumer requests a specific recommendation regarding which plan to choose, because making a specific plan recommendation might violate an assister's duties under the applicable Federal standards, and doing so might also violate certain State laws that prohibit anyone other than a licensed health insurance agent or broker from recommending a plan. In addition, a few commenters asserted that it is appropriate for Navigators to fulfill requirements to assist small employers with enrollment through referral to agents and brokers in instances where Navigators do not have expertise in small business insurance, because agents and brokers continue to be an important source of information and enrollment assistance for both individuals and for small employers.

Response: We are finalizing this provision as proposed, with one modification with respect to proposed §155.225(d)(8)(i). We do not believe that the regulation, or our discussion in the preamble to the proposed rule, suggests that agents and brokers engage in unfair or deceptive

practices. We nonetheless believe that that the proposed language describing “entities not required to act in the best interests of applicants assisted” was confusing on this point, and have replaced it, consistent with the changes we are finalizing in this rule to 155.225(c)(1), with a reference to “entities not required to provide fair, accurate, and impartial information.” We decline to mention agents and brokers explicitly in the regulation text, because, as some commenters point out, agents and brokers may be required to act impartially and may be subject to standards that would require them to provide fair, accurate, and impartial information in a way that is similar to Exchange-approved consumer assistance entities and individuals.

We agree with the commenters who supported our view in the proposed rule that a non-Federal requirement mandating that Navigators, non-Navigator assistance personnel subject to §155.215, and certified application counselors refer consumers to third parties not obligated to provide fair, accurate, and impartial information would conflict with the Federal duties required of Navigators, non-Navigator assistance personnel subject to §155.215, and certified application counselors and their designated organizations under various authorities: for Navigators, sections 1311(i)(3)(B) and 1311(i)(5) of the Affordable Care Act, as well as 45 CFR 155.210(e)(2) and 155.215(a)(1)(iii); for Non-Navigator assistance personnel, 45 CFR 155.215 (a)(2)(i) and (iv); and for certified application counselors, 45 CFR 155.225(c)(1) as amended in this final rule. In light of the regulation text changes, discussed in greater detail below, that we make under §155.225(c)(1) to align that provision more consistently with the standards that apply across Exchange consumer assistance programs, and to explicitly specify that certified application counselors must provide information “in a fair, accurate, and impartial manner,” we are clarifying the language of final §155.225(d)(8)(i). Specifically, we are finalizing §155.225(d)(8)(i) to specify that a referral to a third party that is not required to “act in the best

interest” of applicants assisted, as required under § 155.225(d)(4), or to a third party that is not required to provide information in a fair, accurate, and impartial manner, as required under the clarifications to §155.225(c)(1) that we make in this final rule, would prevent certified application counselors from meeting Federal standards that apply to them. To reiterate and, in recognition of the fact that a third party may be required to act in the best interest of the applicants they assist or provide information in a fair, accurate, and impartial manner to the same extent that a certified application counselor is required to, we would not construe a non-Federal requirement that required such a referral to that particular type of third party to prevent the application of the provisions of title I of the Affordable Care Act.

In addition, these comments present us with the opportunity to explain that we interpret certain Federal standards applicable to Navigators, non-Navigator assistance personnel subject to §155.215, and certified application counselors and their designated organizations to prohibit these assisters from making specific plan recommendations. With respect to Navigators and the non-Navigator assistance personnel who are subject to §155.215, the recommendation of a specific plan would be inconsistent with CMS’s interpretation of 45 CFR 155.210(e)(2) and (3) (applicable to Navigators in all Exchanges) and 45 CFR 155.215(a)(1)(iii) (applicable to Navigators in an FFE) and (a)(2)(i) and (iv) (applicable to non-Navigator assistance personnel subject to §155.215, which require these assisters to provide information in a fair, accurate, and impartial manner, including by acknowledging other programs; to provide information to individuals and employees about the full range of QHP options and insurance affordability programs for which they are eligible; and to facilitate selection of a QHP. With respect to certified application counselors, the recommendation of a specific plan would violate their duties to act in the best interests of the consumer (45 CFR 155.225(d)(4)), to provide information to

individuals and employees about the full range of QHP options and insurance affordability programs for which they are eligible, and help to facilitate their enrollment in QHPs and insurance affordability programs (45 CFR 155.225(c)(1) and (3)). Specifically, in our view, permitting assisters to recommend a specific plan would undermine one overall purpose of consumer assistance programs, which is to provide interpretive guidance that enables consumers to become fully informed and health literate, to assess the full range of their coverage options and the strengths and weaknesses of different options or plans based on the information provided to them, and ultimately to be able to make their own informed choices about which coverage option best meets their needs and budget. Further, Federal standards require an assister to act to “facilitate” plan selection or enrollment (as applicable), which we interpret to mean that the act of plan selection and enrollment itself rests with the consumer (see our previously expressed interpretations of these requirements in preamble at 78 FR 42844-45). Consistent with these principles, we are amending §155.210(e)(2) in the final rule, to specify that in addition to the existing requirement under this provision that Navigators provide information and services in a fair, accurate, and impartial manner, the duties of a Navigator include providing information that assists consumers with submitting the eligibility application; clarifying the distinctions among health coverage options, including QHPs; and helping consumers make informed decisions during the health coverage selection process. We are also adding these standards through amendments to §155.225(c)(1) in the final rule, to clarify the existing duty of certified application counselors to provide information to individuals and employees about the full range of QHP options and affordability programs for which they are eligible which includes providing fair, impartial, and accurate information that assists consumers with submitting the eligibility

application; clarifying the distinctions among health coverage options, including QHPs; and helping consumers make informed decisions during the health coverage selection process.

While consumers need to make the ultimate decision regarding the type of coverage that best meets their health care needs and budget, assisters may facilitate enrollment in a QHP by providing comprehensive information about the substantive benefits and features of a plan, clarifying the similarities and distinctions among plans, and assisting consumers with making informed decisions in the plan selection process, consistent with the consumer's expressed interests and needs. Therefore, as part of facilitating a consumer's enrollment in a QHP, or selection of a QHP, Navigators, non-Navigator assistance personnel subject to §155.215, and certified application counselors may provide information to the consumer that includes, but is not limited to, information regarding plan features such as deductibles, coinsurance and copayments, coverage limitations or exclusions, identifying plans for which an eligible consumer may receive CSRs or other Federal financial assistance (for example, Ryan White HIV/AIDS Program premium and cost-sharing assistance) and information about whether a particular provider or hospital is included within a plan's network. Offering this type of information is particularly important for consumers, who, without such assistance, might otherwise not complete the enrollment process or might not have all of the information they need to make a plan selection.

To the extent an assister is asked by a consumer to recommend a plan, we interpret the above-cited authorities as requiring the assister to refrain from providing a recommendation or otherwise steering a consumer to a particular plan. In addition, if a consumer asks an assister to recommend a specific plan, an assister should remind the consumer that they are prohibited from making plan recommendations because Federal standards require them to remain fair and impartial. The assister may, consistent with the consumer's expressed needs and desires,

determine that it is appropriate to inform the consumer of the general availability of licensed, Exchange-trained health insurance agents and brokers as a resource that could provide specific plan recommendations, if licensed health insurance agents or brokers are permitted to do so under State law. The assister may direct the consumer to listings of agents and brokers; however, the assister should not make a referral to any specific agent or broker or specific set of agents or brokers.

With one limited exception,²³ assisters may not fulfill their Federally-required duties through referrals to agents and brokers. As we have stated previously, Navigators subject to §155.215 (that is, Navigators in the FFEs and State Partnership Exchanges) and non-Navigator assistance personnel subject to §155.215 must be prepared to serve both SHOP and the individual market Exchange, including small businesses with SHOP (see §155.215(b)(1)(v) and 78 FR 42835-36). Certified application counselors in the FFEs are expected to assist employees with SHOP options and are permitted, but not required, to assist small employers with SHOP.²⁴ In the event that a particular consumer's individual needs go beyond the assister's expertise, or the assister or entity lacks the resources to assist all individuals who present themselves for assistance, an assister may, consistent with the consumer's expressed needs and desires, determine that it is in the consumer's best interests to inform the consumer of the general availability of other consumer assistance entities who may possess the requisite expertise and capacity to assist them, including the Exchange Call Center, non-Navigator assistance personnel or certified application counselors. With respect to the FFEs, we note that HHS maintains on its Web site and at its Call Center a public registry of Exchange-approved consumer assistance

²³ §155.705(d) permits a State operating a State SHOP-only Exchange to allow Navigators to fulfill certain Navigator duties under §155.210(e)(3) and (4) through referrals to agents and brokers.

²⁴ See question 40 at <http://marketplace.cms.gov/help-us/common-qandas-about-cac-designation.pdf>

resources in each FFE, including Navigators, non-Navigators, and certified application counselor organizations. HHS also maintains on its website links to agent and broker trade association Web sites, which would allow a consumer to look up agents and brokers in a particular local area. We encourage State Exchanges to make consumer assistance resources publicly available in a similar manner and understand that many, if not most, State Exchanges have done so.

Comment: Many commenters indicated support for proposed §§155.210(c)(1)(iii)(B) and 155.225(d)(8)(ii) and agreed that non-Federal requirements that prevent Navigators, non-Navigator assistance personnel subject to 155.215, and certified application counselors from providing services to any individual who presents him or herself for assistance would prevent the application of the provisions of title I of the Affordable Care Act and should be interpreted as in conflict with the requirement for Navigator and non-Navigator assistance personnel subject to §155.215 to provide information and services fairly and impartially. However, a few commenters asserted that one type of non-Federal requirement discussed in the preamble to the proposed rule, which would require assisters to suggest or encourage any consumer who is insured, or previously bought insurance through the aid of an agent or broker, to consult with that agent or broker before enrolling in a plan, serves a legitimate purpose because it is designed to prevent consumers from making uninformed or impulsive decisions. These commenters asserted that these non-Federal requirements do not prevent assisters from performing their Federal obligations because they require merely “advising” an insured consumer that they should consider talking to an insurance professional before changing health plans and do not necessarily result in the assister being unable to perform application and enrollment assistance for these types of consumers, to the extent that these consumers reject the assister’s advice to consult with an agent or broker. Some commenters argued that certain non-Federal requirements of this nature

strike the right balance and should not be viewed as preventing assisters from performing their Federally-mandated duties. Specifically, these commenters reasoned that although certain non-Federal requirements of this nature require an assister to advise an individual to consult first with a health insurance professional with whom they may have consulted previously, they permit an assister to continue to provide services to that insured individual if that individual expresses a preference not to consult with that health insurance professional.

Response: We are not persuaded by comments suggesting that assisters can uphold their duties to provide information in a fair and impartial manner and act in the consumer's best interests if they are required to advise a consumer to consult with an insurance professional when they learn that the consumer is insured or previously purchased health insurance with the aid of an agent or broker. While such non-Federal requirements might be intended to prevent consumers from making impulsive or uninformed decisions, the same is true of the Federal standards for Navigators, non-Navigator assistance personnel, and certified application counselors. These Federal standards are designed to ensure that these Exchange-approved assisters help a consumer make a fully informed decision. Specifically, assisters must provide information in a fair, accurate, and impartial manner, provide information on the full range of QHP options for which they are eligible, clarify distinctions among QHPs, and act in the consumer's best interests. Assisters must also provide fair, impartial, and accurate information that assists consumers with submitting the eligibility application; clarify the distinctions among health coverage options, including QHPs; and help consumers make informed decisions during the health coverage selection process, as specified in the modifications made to §155.210(e)(2) (which is made applicable to certain non-Navigators through reference in §155.215(a)(2)(i)) and §155.225(c)(1) of this final rule.

Further, we note that under existing regulations at §155.210(d)(4) and 155.215(a)(2)(i) and regulations finalized in this final rule at §155.225(g)(2), Navigators, non-Navigator assistance personnel subject to §155.215, and certified application counselors are subject to a conflict of interest standard which prohibits them from receiving consideration, directly or indirectly, in connection with enrollment in a QHP or non-QHP; and the requirement that one of these assisters refer or direct a consumer to another individual, such as an agent or broker, who receives such consideration in connection with QHP enrollment, would be inconsistent with this conflict of interest requirement under Federal law.

Comment: One commenter asserted that proposed §§155.210(c)(1)(iii)(B) and 155.225(d)(8)(ii)'s specification that prohibitions against an assister's ability to provide services to any individual who presents him or herself for assistance would prevent the application of the provisions of title I of the Affordable Care Act, were too broadly worded because they referred to "services" generically, and suggested that the provision be revised to read "services required of [assisters] by the Affordable Care Act to all persons to whom they are required to provide assistance." The commenter further asserted that the consumer assistance programs created under the Affordable Care Act are intended to assist the uninsured, and therefore consumers such as employers and employees with employer-sponsored insurance offered through the small group market as well as those shopping in the individual market who already have insurance are not the types of consumers to whom assisters are intended or required to provide assistance.

Response: We are not modifying the regulation text in the manner suggested by the commenter. We do not agree with the commenter's view that the consumer assistance programs were created to serve the uninsured exclusively. As we explained in the preamble to the proposed rule, we interpret the requirement that Navigators and non-Navigator assistance personnel

subject to §155.215 provide information and services fairly and impartially to require that that these assisters provide services to all consumers seeking assistance and have explained in preambles to prior rulemakings that all Navigators and non-Navigator assistance personnel should have the ability to help any individual who presents him or herself for assistance (see 78 FR 20589 and 78 FR 42830). Further, §155.215(b)(1)(v) requires that Navigators in FFEs and State Partnership Exchanges, and non-Navigator assistance personnel subject to §155.215 be prepared to serve both the individual market Exchange and SHOP. In addition, section 1311(i)(3)(D) of the Affordable Care Act and §155.210(e)(4) provide that Navigators are required to assist “any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under such plan or coverage” (emphasis added).²⁵ Similarly, if a non-Federal requirement barred certified application counselors from assisting an employee with Exchange coverage, then such a requirement would prevent them from performing all of their Federal duties in amended § 155.225(c)(1) and in existing §155.225(c)(2) to provide information to employees about the full range of QHP options for which they are eligible – including providing fair, impartial, and accurate information that assists consumers with submitting the eligibility application; clarifying the distinctions among health coverage options, including QHPs; and helping consumers make informed decisions during the health coverage selection process and assist employees to apply for coverage in a QHP through the Exchange and for insurance affordability programs. Accordingly, assisters would violate these various Federal standards if they withheld application or enrollment services from a consumer on the basis of any particular status, including status as an insured individual.

²⁵ §155.705(d) permits a State operating a State SHOP-only Exchange to allow Navigators to fulfill certain Navigator duties under §155.210(e)(3) and (4) through referrals to agents and brokers.

Comment: We solicited specific comments related to the exception noted in proposed §§155.210(c)(1)(iii)(A) and (B) with respect to non-Federal requirements for Navigators in States with a State SHOP-only Exchange and a FFE for the individual market. A commenter supported our approach in the proposed rule to provide an exception in proposed §§155.210(c)(1)(iii)(A) and (B) to account for existing Federal regulations that allow SHOP-only State Exchanges to permit Navigators to fulfill certain requirements through referral to agents and brokers.

Response: We are finalizing §§155.210(c)(1)(iii)(A) and (B) and §155.225(d)(8)(i) and (ii), as proposed, without modification. As we explained in the preamble to the proposed rulemaking promulgating §155.705(d), we believe that building and operating just a SHOP allows a State to move towards operating both a SHOP and an individual market Exchange. (78 FR 37044) Additionally, where the State elects to establish and operate only a SHOP Exchange, there will be two separate Navigator programs operating in the State: a Federal Navigator program for the individual market, and a State Navigator program for the SHOP. In conjunction with the various other areas of flexibility provided to States electing to operate a State SHOP-only Exchange, we continue to believe that it is prudent to give a State SHOP-only Exchange the flexibility to choose to focus its Navigator program on outreach and education to small employers by permitting SHOP Navigators to satisfy their duties under §§155.210(e)(3) and (4) through referrals to agents and brokers. Giving States this extra level of flexibility could further incentivize States to operate a SHOP Exchange as an intermediate step towards establishing and operating both a SHOP and an individual market Exchange in the future, because it could reduce operational costs in running a SHOP, and could help leverage existing coordination regarding small group market enrollment activities with the agent and broker community in the State, as

may be applicable. While we recognize that allowing Navigators to fulfill two of their duties via referrals to agents and brokers might appear somewhat inconsistent with our general view that referrals to third parties who are not required to act impartially would prevent Navigators from meeting Federal standards, we believe that the benefit of providing administrative flexibility to a State SHOP-only Exchange's operation in this regard, and thus providing perhaps greater incentive to States to operate a SHOP-only Exchange, compensates for the potential fact that a SHOP Navigator, if he or she makes referrals to agents and brokers, might be referring consumers to individuals who might not have the same duty to provide fair and impartial information. We therefore note, as we did in the preamble to the proposed rule, that we would not consider State laws or regulations that permit a State SHOP-only Exchange to take the option authorized under Federal regulations at §155.705(d) to prevent the application of the provisions of title I of the Affordable Care Act.

Comment: We received a number of comments in support of proposed §§155.210(c)(1)(iii)(C) and 155.225(d)(8)(iii) and the view expressed in those proposals that non-Federal requirements that prohibit assisters from providing advice regarding substantive benefits or comparative benefits of different health plans would prevent assisters from fulfilling their duty to facilitate selection of or (as applicable) enrollment in a QHP. In support of these proposals, commenters reasoned that while consumers should make the ultimate decision about what type of coverage meets their health care needs and budget, providing comprehensive information about the substantive benefits and features of a plan, clarifying the distinctions among plans, and assisting consumers with making informed decisions in the plan selection process, consistent with the consumer's expressed interests and needs, are critical components of facilitating enrollment in a QHP, particularly for consumers, who, without such assistance, might

not complete the enrollment process. However, many commenters indicated that the inclusion of the word “advice” in the proposed provision improperly implies that assisters are permitted to make recommendations regarding plan selection or are permitted to “negotiate” insurance, which are duties preserved for licensed health insurance agents and brokers in most States. To address this concern, these commenters recommended that we replace the word “advice” with “information.” On the other hand, many other commenters urged retention of the word “advice” because the use of this term in non-Federal laws and regulations is ambiguous enough to pose a conflict with an assister’s duties under Federal requirements, given the nature of the information that assisters must provide in order to facilitate selection (or enrollment) in a QHP.

Response: In light of these comments, we are finalizing this provision with a few modifications. We reiterate that as an aspect of assisters’ Federally-required duties under §§155.210(e)(2) and (3) (Navigators in all Exchanges), 155.215(a)(1)(iii) (Navigators in FFEs), 155.215(a)(2)(iv) (Non-Navigators in FFEs), and 155.225(c)(1) and (3) (certified application counselors in all Exchanges) to facilitate (as applicable) selection of a QHP or enrollment of eligible individuals in QHPs and insurance affordability programs and to provide information about coverage options, they are required to engage in substantive discussions about the terms and features of any coverage for which a consumer is or might be eligible, consistent with the consumer’s expressed interests and needs. (See 79 FR 15829). This includes, but is not limited to, providing information regarding features such as deductibles, coinsurance and copayments, coverage limitations or exclusions, plans for which an eligible consumer may receive CSRs, and/or whether a particular provider or hospital is included within a plan’s network. (79 FR 15829). We understand the difficulty faced by assisters to understand where the line should be drawn between a prohibition on “advice” and the “information” they are required to give to

perform their duties, given the nature of the information that assisters must provide to fulfill their duties to provide fair and impartial information concerning enrollment in QHPs and insurance affordability programs and facilitate enrollment. In light of the need for further clarity, we have modified the applicable existing Federal standards, as we explained above, to clarify explicitly in the regulation text that providing fair, impartial, and accurate information that assists consumers with submitting the eligibility application, clarifying the distinctions among health coverage options, including QHPs, and helping consumers make informed decisions during the health plan coverage process, are components of an assister's Federally required duties. We are making these additions to the applicable Federal regulations for Navigators at §155.210(e)(2), which applies to non-Navigator assistance personnel subject to §155.215 by a cross-reference at §155.215(a)(2)(i), and to the applicable certified application counselor regulations at §155.225(c)(1).

In addition, we agree that while consumers need to make the ultimate decision about what type of coverage meets their health care needs and budget, providing comprehensive information about the substantive benefits and features of a plan, clarifying the similarities and distinctions among plans, and assisting consumers with making informed decisions in the plan selection process, consistent with the consumer's expressed interests and needs, are a critical part of assisters' required duties, particularly for consumers, who, without such assistance, might otherwise not complete the enrollment process or might not have all of the information they need to make a plan selection. Therefore, a non-Federal requirement that prohibits assisters from providing "advice" regarding substantive benefits or comparative features of different health plans would prevent the application of the provisions of title I of the Affordable Care Act, insofar as such a requirement, as interpreted or applied under State law, would prohibit assisters

from doing any of the following: (1) providing fair, impartial, and accurate information that assists consumers with submitting the eligibility application; (2) clarifying the distinctions among health coverage options, including QHPs; or (3) helping consumers make informed decisions during the health coverage selection process. We have always interpreted the Affordable Care Act and our regulations implementing its provisions to prohibit Navigators, non-Navigator personnel subject to §155.215, and certified application counselors from recommending a particular plan or steering a consumer toward a particular plan or plans as because of their specified duties to distribute fair and impartial information to consumers and act in the consumer's best interests, while at the same time requiring them to provide consumers with all relevant and applicable information about the coverage options available to them. For example, we have stated that a Navigator cannot make the decision for an applicant as to which QHP to select, but they may play an important role in facilitating a consumer's enrollment in a QHP by providing fair, impartial, and accurate information that assists consumers with submitting the eligibility application, clarifying the distinctions among QHPs, and helping qualified individuals make informed decisions during the health plan selection process (78 FR 20583; see also 79 FR 15829).

Comment: We received a number of comments in support of our proposal at §155.210(c)(1)(iii)(D) that non-Federal requirements that would require Navigators to hold an agent or broker license or carry errors or omissions insurance would prevent the application of the requirement at 155.210(c)(2) that there to be at least two types of Navigator entities, including at least one community and consumer-focused nonprofit organization. However, many commenters stated that this provision should be modified to apply more broadly to include other types of assisters, such as non-Navigator assistance personnel subject to §155.215, certified

application counselors and certified application counselor designated organizations. Further, a number of commenters recommended broadening the scope of the proposed provision to include other types of financial responsibility requirements, such as surety bond requirements or security deposits. These commenters noted that in some cases Navigators and other assisters have reported difficulty in obtaining surety bonds because issuers have been unwilling to underwrite a business service for which it is difficult to assess risk. Further, commenters described how some Navigators experienced so much difficulty in obtaining a surety bond from a vendor that they could only meet a non-Federal surety bond requirement by purchasing errors and omissions coverage. They reasoned that the potential imposition of civil money penalties for violations of privacy and security standards under §155.260 or program standards (as proposed in §§155.206 and 155.285), as well as the availability of a special enrollment period for assister misconduct in accordance with §155.420(d)(10), would be sufficient remedies in the event that an assister causes consumer harm, such that a surety bond would not be necessary to protect consumers. On the other hand, a few commenters indicated that the proposed rule's scope was appropriate and indicated that non-Federal requirements that require some form of financial responsibility, such as a surety bond, serve as an added consumer protection to make a consumer whole in the event of fraud or some other wrongdoing on the part of the assister. These commenters further reasoned that requiring assisters to hold a surety bond or other proof of financial responsibility does not necessarily inhibit a community and consumer-focused nonprofit organization from participating in any consumer assistance program because surety bonds are generally available to all types of businesses.

Response: We are finalizing this provision as proposed, with one modification. We appreciate commenters' concerns about the lack of parity that results from not extending this

provision to non-Navigator assistance personnel subject to §155.215 and certified application counselors. At this time, however, we decline to extend this provision to these other types of consumer assistance programs because we are not able to discern a facial conflict between non-Federal requirements that would require non-Navigator assistance personnel or certified application counselors to hold an agent or broker license or carry errors and omissions insurance coverage and the Federal standards applicable to these programs. However, we recognize that within the meaning of the statutory preemption standard set forth at section 1321(d) of the Affordable Care Act and proposed §§155.210(c)(1)(iii)(F) and 155.225(d)(8)(v), there might be specific factual circumstances in which these types of non-Federal requirements would prevent these individuals or entities from fulfilling their Federally required duties or would prevent an Exchange from operating the non-Navigator or certified application counselor programs that it is required (or authorized) to implement consistent with Federal requirements. In such cases, non-Federal requirements that require non-Navigator assistance personnel subject to §155.215 or certified application counselors or their designated organizations to hold an agent or broker license or carry errors and omissions insurance or other forms of financial responsibility might prevent the application of the provisions of title I of the Affordable Care Act.

In addition, at this time, we believe it is appropriate to limit the scope of this provision so that it is directed only at non-Federal laws requiring Navigators to hold an agent or broker license and are not finalizing the reference to laws that require Navigators to carry errors or omissions insurance, as proposed. As we explained in the preamble to the proposed rule, requiring that each Navigator be a licensed agent or broker would mean, in effect, that all Navigators would be agents and brokers, and would therefore prevent the application of §155.210(c)(2), which established the requirement that in all Exchanges, at least two types of

entities, including one community and consumer-focused nonprofit group, must serve as Navigators. HHS has previously advised (see 77 FR 18331-32) that such requirements would prevent the application of §155.210(c)(2). Since we understand, based on the comments, that in at least some jurisdictions, errors and omissions insurance coverage is not exclusively available to agents and brokers and other types of professionals might carry it, we cannot discern a facial conflict between a non-Federal requirement requiring errors and omissions insurance and Federal requirements applicable to Navigators or the Exchange. However, as we made clear in prior rulemaking and now make explicit here in finalizing the regulation text, any non-Federal requirement that would, in effect, require all Navigators to be licensed agents or brokers would prevent the application of the Federal standards that apply to an Exchange's operation of the Navigator program (specifically, would prevent the application of 45 CFR 155.210(c)(2)) and therefore would prevent the application of the provisions of title I of the Affordable Care Act. By removing the reference to errors and omissions coverage, we do not intend to foreclose the possibility that there might be specific factual circumstances under which a non-Federal financial responsibility requirement that does not facially conflict with a Federal requirement might, as applied or implemented, prevent the application of Federal requirements for Navigators within the meaning of section 1321(d) of the Affordable Care Act.

Comment: Many commenters indicated support for proposed §§155.210(c)(1)(iii)(E) and 155.225(d)(8)(iv) and the accompanying preamble discussion illustrating HHS's views regarding situations in which non-Federal requirements prevent otherwise eligible and qualified Exchange-approved assisters from operating in a State with an FFE. In particular, these commenters stated that non-Federal requirements that prohibit consumer assistance entities from receiving any consideration, directly or indirectly, from a health insurance issuer, even if not in connection

with QHP enrollment, are unnecessary and have precluded some extremely qualified organizations from serving as an Exchange-approved assister organization. A few commenters recommended that HHS explain the interplay of this proposed provision and existing §155.210(d)(4) (applicable to Navigators and, through 155.215(a)(2)(i), to non-Navigator assistance personnel subject to §155.215) and the parallel provision under proposed §155.225(g)(2) (for certified application counselors and their designated organizations) prohibiting these assisters from receiving any consideration directly or indirectly from any health insurance issuer or issuer of stop loss insurance in connection with the enrollment of any individuals (or employees, for Navigators) in a QHP or a non-QHP. The commenters explained that it appeared that these Federal standards were “somewhat in conflict” with the proposed rule’s preamble discussion which stated that in HHS’s view, a non-Federal requirement that imposes prohibitions on receiving any financial compensation from a QHP issuer even if not in connection with enrollment, would go beyond these Federal conflict-of-interest rules.

Response: As discussed above, we are not finalizing proposed §§155.210(c)(1)(iii)(E) and 155.225(d)(8)(iv). We are convinced by the concerns raised by commenters that it may not be possible to specify through rulemaking where the line should be drawn between non-Federal eligibility standards that prevent the application of Federal requirements and those that do not. These types of non-Federal requirements will likely need to be analyzed on a case by case basis. For example, a non-Federal requirement that, in its application, effectively limits the pool of assisters in the Exchange, to such an extent that the Exchange cannot operate its consumer assistance functions effectively, might prevent the application of the provisions of title I of the Affordable Care Act within the meaning of section 1321(d) of the Affordable Care Act.

As already addressed in detail above, we are not finalizing §§155.210(c)(1)(iii)(E) and 155.225(d)(8)(iv), but have determined that the better approach is to clarify in regulation text two standards that we discussed in the preamble connected to these proposed provisions. First, we specify that in an FFE, an entity that seeks to become a Navigator entity, non-Navigator assistance personnel entity subject to §155.215, or certified application counselor organization shall not be ineligible to operate as an assister entity solely because its principal place of business is outside of the Exchange service area. Second, we specify that in an FFE, no health care provider shall be ineligible to operate as a Navigator, non-Navigator assistance personnel subject to §155.215, or a certified application counselor solely because it receives consideration from a health insurance issuer for health care services provided. We are finalizing these standards, consistent with discussions set forth in preamble discussions in the proposed rule and in prior rulemaking (78 FR 42832), through the provisions at §§155.210(e)(7), 155.215(h) and 155.225(b)(3), with respect to the principal place of business standard, and in §155.210(d)(4) (made applicable to non-Navigator assistance personnel through §155.215(a)(2)(i)) and §155.225(g)(2), with respect to the consideration standard.

Comment: We received an overwhelming number of comments that supported including proposed §§155.210(c)(1)(iii)(F) and 155.225(d)(8)(v) in the final rule because the provisions appropriately recognized that other non-Federal requirements not specified expressly in other proposed provisions might also prevent the application of title I of the Affordable Care Act, if, as implemented or applied in a State, they would prevent assisters from performing their Federally required duties or prevent the Exchange from implementing the consumer assistance programs consistent with Federal standards. A few commenters recommended that this provision apply to State Exchanges in addition to FFEs. Several commenters identified a myriad of other types of

non-Federal requirements that, in the commenters' view, should be expressly included in the finalized regulations under these provisions, such as: establishing requirements for current Navigator grantees after Navigator grants have been awarded, setting unreasonable or duplicative training requirements, setting unreasonable time limitations on meeting State standards, imposing unreasonable costs on Navigators or other assisters, imposing credit rating reporting requirements, requiring a GED or high school diploma, or implementing State requirements in a manner that is unduly burdensome for Navigators or that disadvantages certain Navigator entities.

Response: We are finalizing proposed §§155.210(c)(1)(iii)(F) and 155.225(d)(8)(v), which is now renumbered in this final rule under §§155.210(c)(1)(iii)(E) and 155.225(d)(8)(iv), as proposed, with a few modifications. We agree with the commenters who found that the proposed provisions appropriately recognize that non-Federal requirements, including but not limited to registration requirements, fingerprinting or background checks, and additional training, may not be in conflict with Federal standards on their face, but nevertheless could, as implemented or applied in a State, ultimately prevent assisters from meeting the Federal standards that apply to them or interfere with the Exchange's ability to operate the consumer assistance programs it is required (or authorized) to implement consistent with Federal requirements. In such circumstances, the non-Federal requirements would, in HHS's view, prevent the application of the provisions of title I of the Affordable Care Act within the meaning of section 1321(d). Consistent with our approach in the proposed rule, we do not think it is necessary or appropriate to enumerate in the final regulation text every type of non-Federal requirement that would fall under this provision. We view this provision largely as interpreting one way that the statutory preemption standard under section 1321(d) of the Affordable Care Act

could apply to non-Federal requirements pertaining to assister programs in an Exchange. We decline to specify every conceivable type of non-Federal requirement which would, as applied or on its face, prevent the application of Federal requirements for assisters or assister programs in an Exchange. In many cases, the identification of such non-Federal requirements will depend on highly fact-specific circumstances that would be impractical, if not impossible, to enumerate in an exhaustive list. As explained in greater detail above, we agree with the recommendation that this provision should apply to State Exchanges in addition to FFEs because the preemption standard under section 1321(d) of the Affordable Care Act is generally applicable to all types of Exchanges. Therefore, in finalizing this provision, we have removed the reference that would have limited its applicability to FFEs. In addition, we have revised the provision to incorporate language included in preamble discussion to the proposed rule to state that a non-Federal requirement would also prevent the application of the provisions of title I of the Affordable Care Act if, as applied or implemented in the State, it prevents the Exchange's implementation of the applicable assister program consistent with Federal requirements under section 1311(i) of the Affordable Care Act, and 45 CFR 155.205, 155.210, 155.215, and 155.225. For example, if a State registration requirement is implemented in a way that makes it impossible for any individuals or entities to operate as an Exchange-approved assister, that requirement would prevent the Exchange from operating the consumer assistance program that it is required (or authorized) to implement. As such, we believe it is important to clarify this possibility explicitly in the regulation text.

Comment: A few commenters recommended that HHS specify that non-Federal requirements that prohibit certain health centers from performing voter registration activity would also prevent the application of title I of the Affordable Care Act, since the National Voter

Registration Act of 1993 (“NVRA”) requires States to designate all offices in the State that provide “public assistance” (which may include health centers who are Exchange-approved consumer assistance entities) as “voter registration agencies” to perform voter registration activities (42 U.S.C. 1973gg-5(a)(2)(A)).

Response: Because title I of the Affordable Care Act does not address voter registration activities, HHS expresses no view in this rulemaking regarding whether State laws regulating voter registration activities would be preempted by the NVRA.

2. Navigator, Non-Navigator Assistance Personnel, and Certified Application Counselor Program Standards (§§155.210, 155.215, and 155.225)

In the proposed rule, we also proposed a number of provisions to bring the standards for Navigators, non-Navigator assistance personnel subject to §155.215, and certified application counselors into alignment. Specifically, with respect to Navigators and non-Navigator assistance personnel subject to §155.215, we proposed that they must obtain consumer authorization before accessing an applicant’s personally identifiable information (PII), and that a record of authorization be provided, just as is already the case for certified application counselors under §155.225(f). In addition, we proposed that Navigators and non-Navigator assistance personnel subject to §155.215 must not charge any applicant or enrollee, or request or receive any form of remuneration from or on behalf of an applicant or enrollee, for application or other assistance related to the applicable assister’s duties, just as is already the case for certified application counselors under §155.225(g). With respect to the certified application counselor program, we proposed that certified application counselors must be recertified on at least an annual basis and complete Exchange-required training, just as is already the case for Navigators in FFEs and State Partnership Exchanges and Non-Navigator assistance personnel subject to §155.215, under

§155.215(b). Further, we proposed that certified application counselors and their organizations would be prohibited from receiving consideration, directly or indirectly, from health insurance issuers or stop loss issuers in connection with the enrollment of any individuals in a QHP or a non-QHP, just as is already the case for all Navigators and for non-Navigator assistance personnel subject to §155.215, under §§155.210(d)(4) and 155.215(a)(2)(i).

We also proposed a number of new standards for Navigators, non-Navigator assistance personnel subject to §155.215, and certified application counselors. First, we proposed to require that these entities and individuals maintain a physical presence in their Exchange service area. We also proposed the following prohibitions on their conduct: providing compensation to individual Navigators, non-Navigator assistance personnel subject to §155.215, or certified application counselors on a per-application, per-individual assisted, or per-enrollment basis; providing gifts, including gift cards or cash, unless they are of a nominal value, or providing promotional items that market or promote the products or services of a third party, to any applicant or potential enrollee in connection with or as an inducement for application assistance or enrollment; soliciting any consumer for application or enrollment assistance by going door-to-door or through other unsolicited means of direct contact, including calling a consumer to provide application or enrollment assistance without the consumer initiating the contact; and initiating any telephone call to a consumer using an automatic telephone dialing system, or an artificial or prerecorded voice.

Comment: Commenters generally supported the alignment of provisions applicable to Navigators, non-Navigator assistance personnel subject to §155.215, and certified application counselors. However, some commenters raised concerns that applying the newly proposed provisions at §155.225(g)(3)-(6), without modification, to certified application counselors would

be overly burdensome and would discourage individuals and organizations from serving as certified application counselors or certified application counselor entities.

Response: We understand the concerns raised by commenters about potential burdens that the new provisions might place on certified application counselors. However, we are finalizing the certified application counselor provisions consistent with the finalization of parallel provisions for Navigators and the non-Navigator assistance personnel that are subject to §155.215. The purpose of aligning these provisions is to ensure that consumers are all afforded the same protections, no matter which type of assister they seek services from. As a result, we are not modifying the provisions specifically applicable to certified application counselors, except to bring them generally into alignment with the way we have finalized the parallel provisions for Navigators and the non-Navigator assistance personnel subject to §155.215. There are two instances where the provisions are not parallel because it is not appropriate due to fundamental differences between the certified application counselor program and the Navigator and non-Navigator assistance personnel programs. We are not finalizing any restriction for certified application counselors regarding the use of Exchange funds to purchase gifts and promotional items because certified application counselors are generally not expected to receive Exchange funds. These distinctions are further discussed below.

Comment: Commenters agreed with and supported the proposal at §155.210(d)(5) prohibiting Navigators and non-Navigator assistance personnel subject to §155.215 (applicable through a cross-reference to §155.210(d) in §155.215(a)(2)(i)) from charging for application assistance services. Some commenters requested clarification that this does not otherwise prohibit an assister from charging for other services the assister might provide, such as clinical or legal services.

Response: Given support from commenters for the provision prohibiting Navigators and non-Navigator assistance personnel from charging consumers for application or other assistance services, we are finalizing this provision without change. We note that the language in the provision specifically limits this prohibition to charging for application assistance or other assistance provided as part of Navigator duties. We interpret the cross-reference in §155.215(a)(2)(i) to this provision in §155.210(d) to similarly limit the prohibition to charging for application assistance or other assistance provided as part of the duties of non-Navigator assistance personnel who are subject to §155.215. We also note that this provision would not prohibit Navigators or non-Navigator assistance personnel subject to §155.215 from charging consumers for services, such as clinical health care services or legal aid services, that are not provided as part of their duties as Navigators or non-Navigator assistance personnel.

Comment: We requested comment on the proposal to prohibit compensation paid to Navigators (proposed at §155.210(d)(6)), non-Navigators subject to §155.215 (applicable through a cross-reference to §155.210(d) in §155.215(a)(2)(i)), or certified application counselors (at §155.225(g)(3)) on a per-application, per-individual-assisted, or per-enrollment basis. We also asked whether there might be other alternatives for building rewards for performance without creating adverse incentives. Several commenters agreed that compensation paid to individual assistance personnel on a per-application, per individual-assisted, or per-enrollment basis could provide adverse incentives and invite behavior that is not in the best interest of consumers. These commenters recommended, for the same reasons, that we extend the prohibition so that Exchange-funded assister entities, and not just individual assisters, should not be compensated on a per-application, per individual-assisted, or per-enrollment basis. Other commenters raised concerns about this prohibition, noting that some State Exchanges are already

using compensation models that would be prohibited by the proposed rule, and recommending that these States should be allowed to continue using their current compensation models. These commenters requested that, at a minimum, States currently using these compensation models be given an adequate transition period, with one recommendation being that this standard not become effective before the start of open enrollment for 2016 coverage in the individual market Exchanges. In general, commenters opposed to this prohibition recommended that HHS further evaluate these compensation models, and assess their effects in States using them, prior to regulating their use.

Response: We appreciate the concerns raised by commenters regarding this provision. We are finalizing these provisions, but have edited them to apply only to Navigators, non-Navigator assistance personnel, and certified application counselors in FFEs. We moved proposed §155.210(d)(6) to §155.215(i) and specified that it is applicable only to Navigators in FFEs, including State Partnership Exchanges, and to non-Navigator assistance personnel in FFEs and State Partnership Exchanges, by indicating that it applies only to Navigators and non-Navigator assistance personnel operating in an Exchange operated by HHS during the exercise of its authority under §155.105(f). This provision is not applicable to Navigators and non-Navigator assistance personnel in State Exchanges, even if those non-Navigator assistance personnel are funded with Exchange Establishment Grants. We have made a similar edit to §155.225(g)(3), by indicating that this provision applies only beginning November 15, 2014, and only to certified application counselors operating in an FFE, including a State Partnership Exchange.

We are making these modifications in an effort to balance the interests of the FFEs and State Exchanges. We understand that there are some State Exchanges currently using these types

of compensation models for Navigators, non-Navigator assistance personnel, and/or certified application counselors. These States have noted successful enrollment efforts with these compensation models, and it is not our intent to disrupt compensation practices that are currently used or authorized by State Exchanges. However, for assisters operating in the FFEs, including State Partnership Exchanges, we have an interest and a concern in ensuring that they are not incentivized to hurry through an assistance session with a consumer, and possibly to avoid assisting those consumers who may have complex situations that require them to have extra time for completing an application. Additionally, these compensation structures create an incentive for Navigators, non-Navigator assistance personnel, and certified application counselors to focus primarily on facilitating enrollment in or selection of a QHP, as applicable, which is only one of the several duties required of Navigators and certified application counselors, and is not a required duty under Federal regulations for non-Navigator assistance personnel (although non-Navigator assistance personnel subject to §155.215 may provide this assistance).²⁶ We will continue to evaluate and monitor the use of these compensation models in State Exchanges, while we give further consideration to whether the proposed prohibitions should apply to all Navigators, non-Navigator assistance personnel, and certified application counselors in all Exchanges.

For all assisters to whom the final provisions will apply, the provisions prohibiting compensation on a per-application, per-individual-assisted, or per-enrollment basis will become applicable November 15, 2014 to coincide with the beginning of the 2015 open enrollment period for the individual market Exchanges.

²⁶ Non-Navigator assistance personnel subject to §155.215 are only required to carry out one of the Navigator duties set forth at §155.210(e), the duty at §155.210(e)(2) to provide fair, accurate, and impartial information and services that acknowledge other health programs; however non-Navigator assistance personnel subject to §155.215 are not prohibited from carrying out the other duties outlined for Navigators at §155.210(e).

Comment: Commenters generally supported the principle behind prohibiting Navigators (at proposed §155.210(d)(7)), non-Navigator assistance personnel subject to §155.215 (through the cross reference to §155.210(d) in §155.215(a)(2)(i)), and certified application counselors (at §155.225(g)(4)) from providing gifts, unless they are of nominal value, or providing promotional items that market or promote the products or services of a third party to applicants or potential enrollees as an inducement for application assistance or enrollment. However, most commenters who responded to this proposal raised concerns that the proposed language was too broad and would prohibit creative outreach and education strategies both relating to the FFE and to other community services. For example, some commenters raised a concern about whether this provision would prohibit an organization from reimbursing travel costs for consumers traveling long distances to receive application assistance, or from providing supplies or materials for legitimate care purposes (for example, diabetic testing supplies or medication samples) which in many cases would exceed \$15. One commenter, on the other hand, raised a concern that this provision expressly allows the provision of gifts up to \$15 in value, since we defined nominal value in the proposed rule 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. In addition, commenters worried that the third-party promotional item prohibition would prevent assisters from providing promotional materials about the Exchange or other community resources, noting that promotional materials about other community resources can help connect consumers with additional supportive services. Commenters indicated that the use of gifts and promotional items have helped them successfully encourage individuals to seek application assistance, and therefore that a prohibition on using these tools in connection with application assistance would be too proscriptive. Many commenters recommended expressly excluding outreach and

education activities from the prohibition on third-party promotional items. Commenters also requested clarification about parameters regarding the provision of gifts and third-party promotional items.

Response: In light of the numerous comments received regarding this issue, we are modifying this provision to make clear that gifts and third-party promotional items are prohibited only when they are used to induce enrollment. In other words, gifts and third-party promotional items are prohibited when they are conditioned on an applicant's enrollment in coverage with the help of the assister or the assister's organization. This means that while nominal gifts and third-party promotional items may be provided as a way of encouraging consumers to seek or receive application assistance, they cannot be conditioned on a consumer's actually enrolling in coverage. We agree with commenters that prohibiting gifts and third-party promotional items in connection with application assistance would potentially prohibit assisters from providing items promoting other available community services, such as an item which promotes the services of a school, hospital, or clinic in the community, simply because it was provided at the same time a consumer is present for Exchange application assistance. We do not want to prohibit assisters from providing items that are inherently beneficial to consumers only because a consumer is present for Exchange application assistance and not for other services.²⁷ Therefore, promotional items may be provided so long as they are not provided to induce enrollment. We have finalized §155.210(d)(6) (renumbered from §155.210(d)(7) of the proposed rule) and §155.225(g)(4) to reflect this policy, and have omitted the language prohibiting the provision of gifts or third-party promotional items "in connection with" enrollment, and finalized the prohibition on providing

²⁷ As previously noted, though, Navigators are not permitted to solicit customers for their other, non-Navigator-related services in connection with their Navigator duties (79 FR 15831). Therefore, while Navigators may provide items that are inherently beneficial to a consumer at the same time the consumer is receiving application assistance, these items may not be used as a means of soliciting the consumers for their other, non-Navigator-related services.

them “as an inducement for enrollment.” We have also omitted the provisions’ reference to application assistance, and only finalized the language relating to inducing enrollment.

Further, the nominal value limit does not apply to third-party promotional items, so these items may exceed \$15 in value. We note that we would consider items such as diabetic testing supplies to be third-party promotional items to the extent that they have the effect of promoting the brand for the supplies that are provided. We also note that there may be other Federal laws regarding providing promotional-items to consumers, and these regulations do not supersede those laws. Therefore, assisters should ensure their compliance with all applicable laws.

We are also modifying this provision to make clear that reimbursement for legitimate expenses, such as (but not limited to) expenses for travel or postage that a consumer incurs in seeking Exchange application assistance may exceed the nominal value threshold of \$15. We anticipate that the circumstances where such reimbursement exceeds this amount will be rare. However, we acknowledge that commenters have indicated there may be times when consumers might incur expenses that exceed \$15 when seeking Exchange application assistance, and we would not want to prohibit a reimbursement for legitimate expenses that exceed this amount.

Because we are modifying the provisions to be less proscriptive, we are also adding a new provision at §155.210(d)(7) (applicable to non-Navigator assistance personnel to whom §155.215 applies through a cross-reference to §155.210(d) in §155.215(a)(2)(i)) to clarify that in no event is it permissible for a Navigator or for non-Navigator assistance personnel subject to §155.215 to use Exchange funds to purchase gifts or third-party promotional items for provision to applicants or potential enrollees. Pursuant to Affordable Care Act section 1311(d)(5)(B), all Exchanges, both FFEs (including State Partnership Exchanges) and State Exchanges, are prohibited from using any funds intended for the administrative and operational expenses of the

Exchange for promotional giveaways. HHS would consider any funds used by an Exchange to pay for Navigator grants, to contract with or otherwise pay non-Navigator assistance personnel subject to §155.215 carrying out the consumer assistance functions under 45 CFR 155.205(d) and (e), and any Federal Exchange Establishment grant funds used to pay for non-Navigator activities,²⁸ to be funds intended for the administrative and operational expenses of the Exchange. Therefore, Navigators and non-Navigator assistance personnel subject to §155.215 are prohibited from using funding received from an Exchange to purchase items for promotional giveaways. In this final rule, therefore, we are also prohibiting Navigators and non-Navigator assistance personnel subject to §155.215 from using Exchange funds to purchase gifts, including gift cards and cash, and promotional items.

We are not including a provision regarding the use of Exchange funds by certified application counselors because certified application counselors generally are not expected or required to receive Exchange funds.

Comment: Commenters generally supported our proposals at §§155.210(d)(8) and 155.225(g)(5) prohibiting Navigators, certified application counselors, and non-Navigator assistance personnel subject to §155.215 (through the cross-reference in §155.215(a)(2)(i) to §155.210(d)), from soliciting any consumer for application or enrollment assistance by going door-to-door or through other unsolicited means of direct contact. However, most commenters who addressed these provisions were concerned that the proposals might also prohibit solicitation with respect to outreach and education activities. Commenters noted that the proposed language would inhibit outreach activities that have proven effective with respect to

²⁸ While section 1311(i)(6) of the Affordable Care Act prohibits Exchanges from using Exchange Establishment grant funds on Navigator grants, these funds can be used to fund the activities of non-Navigator assistance personnel (see 78 FR 20583-84).

Medicaid and CHIP outreach. Additional commenters noted that some organizations have had great success during the 2014 open enrollment with door-to-door outreach and that at times some consumers were ready to enroll and wanted immediate application assistance. These commenters are concerned that the proposed language would prohibit these methods going forward. Some commenters requested that we clarify the definitions of “application or enrollment assistance” and “unsolicited means” to help establish clear parameters of what is and is not prohibited.

Response: We agree that that door-to-door consumer education and outreach can be a useful and effective method for improving public awareness about the Affordable Care Act, insurance affordability programs, and the Exchanges. We have edited the final provisions at §155.210(d)(8) and §155.225(g)(5) to clarify that the prohibitions on door-to-door solicitation for “application or enrollment assistance” prohibit assisters from engaging in door-to-door solicitation for the purpose of offering in-home application or enrollment assistance; they do not prohibit assisters from going door-to-door to conduct general consumer education or outreach, including to let the community know that the organization is available to provide application and enrollment assistance services to the public. In final §155.210(d)(8) and §155.225(g)(5), therefore, we specified that outreach and education activities may be conducted by going door-to-door or through other unsolicited means of direct contact, including calling a consumer.

We clarify that nothing in these provisions would prohibit a Navigator, non-Navigator assistance personnel, or certified application counselor from providing in-home application assistance, if such assistance is requested by a consumer. We note that in cases where a consumer is ill or has a disability that would make meeting an assister outside of the consumer’s home difficult or impossible, in-home application and enrollment assistance might be

appropriate. In these or other cases in which the consumer prefers in-home assistance or such assistance is appropriate for the consumer, the request for in-home assistance must come from the consumer and the consumer must give their consent. In such cases, we also recommend that two assistance personnel should go to the home, not one, because this is a best practice that promotes the safety of both the consumer and the assister.

We further explain that by “unsolicited means,” we refer to any means of contacting consumers directly to help them apply for or enroll in coverage through the Exchange, where the consumer did not initiate, request, or give prior consent to the contact, although we reiterate that this provision does not apply to public education and outreach activities. Additionally, we have added language to allow for assisters to contact consumers for application assistance in cases where the individual assister or assister entity has a relationship with the consumer, but we note that other State or Federal laws may apply with regards to these preexisting relationships, and those laws must also be complied with.

Comment: Commenters acknowledged the concerns that HHS addressed through the proposal that would prohibit Navigators (at §155.210(d)(9)), non-Navigator assistance personnel (through the cross reference to §155.210(d) in §155.215(a)(2)(i)), and certified application counselors (at §155.225(g)(6)), from making robocalls, or calls that use an automatic telephone dialing system or an artificial or prerecorded voice, when initiating contact with consumers. However, commenters were concerned that the language of this proposal might be overly broad and might prohibit effective uses of such tools in ways that have strong benefits for consumers. For example, some organizations have used such tools to provide notice to consumers about upcoming enrollment events, sometimes partnering with other community organizations to target certain populations. Other organizations pointed out that in the future, such tools might be useful

to remind consumers when it is time to re-enroll in coverage. Some commenters noted that many States already have laws that would apply to assisters to protect consumers from unwanted solicitation, and therefore further prohibitions are unnecessary. Many commenters provided recommendations for revising the proposed language and requested that certain clarifications be made if the proposed provision is finalized. For example, commenters recommended revising the language to allow the use of these tools for consumers who have previously provided contact information via an outreach or education event, or for consumers who may have a pre-existing relationship with the organization itself (for example, as a patient or a client). Health centers, in particular, requested a clarification that this provision would not prohibit their use of these tools in their capacity as a health center since, for example, automated dialing is frequently used to remind health center patients about upcoming appointments. Some commenters also noted that certain “in-reach” activities that use these types of tools are required of organizations in order for them to be eligible for HRSA grants provided in the Health Center Outreach and Enrollment Assistance program, and therefore this proposed provision could create a conflict for these organizations.

Response: We understand that many entities operating as Navigators, non-Navigator assistance entities subject to §155.215, and certified application counselors also function as other types of organizations with an existing client base, such as community health clinics, hospitals, or primary care associations. These prohibitions on assister conduct are not meant to disrupt any outreach or in-reach strategies that these organizations use to connect with their client base outside of their work as Exchange Navigators, non-Navigator assistance personnel, or certified application counselors. Therefore, we clarify that the provision prohibiting Navigators (at §155.210(d)(9)), non-Navigator assistance personnel (through the cross-reference to §155.210(d)

in §155.215(a)(2)(i)), and certified application counselors (at §155.225(g)(6)) from making calls using an automatic dialing system would not prohibit a health center from automatically dialing patients to remind them of upcoming health care appointments. We also appreciate commenters' interest in using automatic calls to communicate with consumers with whom they already have a relationship. Therefore, we are finalizing §155.210(d)(9) and §155.225(g)(6) with an exception added for cases where the individual assister or assister entity has a pre-existing relationship with the consumer. Although the edited regulation text at §155.210(d)(9) refers to Navigators, we interpret the cross-reference in §155.215(a)(2)(i) to §155.210(d) mean that that provision also applies to non-Navigator assistance personnel to whom §155.215 applies. We are also noting that other State or Federal laws may apply with regards to these pre-existing relationships, and those laws must also be complied with, and have included this caveat in the final §155.210(d)(9) and §155.225(g)(6). We will monitor and evaluate this practice.

Comment: Some commenters requested that the disclosure of an assister's functions and responsibilities required under existing §155.225(f)(1) and new §§155.210(e)(6)(i) and 155.215(g)(1) also include disclosure of the nondiscrimination requirements applicable to the assister.

Response: We agree that the nondiscrimination requirements applicable to the assister, such as those described in §155.120(c) and §155.105(f), would be appropriate information to include as part of the disclosure. While §155.210(e)(6), §155.215(g), and §155.225(f) require assisters to inform consumers about the assister's functions and responsibilities, we have not outlined specific content for this disclosure in these provisions.

Comment: Commenters supported the proposed requirements that all Navigators (at §155.210(e)(6)) and the non-Navigator assistance personnel subject to §155.215 (at §155.215(g)) obtain authorization from consumers before accessing their personally identifiable information, together with our proposal in these provisions, as well as in the proposed amendment to existing §155.225(f), that the Exchange must establish a reasonable retention period for maintaining these records. In FFEs, we proposed that this period would be three years, unless a different retention period has already been provided under other applicable Federal law. Some commenters recommended that we identify a specific period of time for which the authorization will be valid, such as two years, so that the authorization will automatically expire at the end of that time frame, as well as a separate period of time after the expiration for which the assister must maintain the record of the authorization. Some commenters requested a retention period of only one year because plan years operate on a 12-month cycle.

Response: We are modifying these provisions to specify that in FFEs, the minimum retention period for the authorization form is no less than six years, unless a longer retention period has already been provided in applicable Federal law in the FFEs, including State Partnership Exchanges. The six-year minimum retention period is consistent with the statute of limitations that has been included in the CMP provisions being finalized in this rule under 45 CFR 155.206 and 155.285, because we recognize that it may be relevant to some CMP investigations whether authorization for the disclosure of a consumer's personally identifiable information was given to an assister. We also note that there are record retention requirements already applicable to Navigators in the FFEs and State Partnership Exchanges under Federal grant laws, such as 45 CFR 92.42 and 45 CFR 74.53. Since we are specifying a minimum retention period of six years in this final rule, if a shorter retention period is provided under other

applicable Federal requirements, the six-year minimum provided in §155.210(e)(6)(ii), §155.215(g)(2), and §155.225(f)(2) will apply. We have modified these provisions to reflect this policy by indicating that in FFEs, the retention period is no less than six years, unless a different and longer retention period has already been provided under other applicable Federal law. Because we are aligning the requirement to obtain the authorization and maintain a record of the authorization so that there are consistent requirements for Navigators, non-Navigator assistance personnel subject to §155.215, and certified application counselors, we think it is appropriate to apply a consistent retention period standard to all three assister types as well and are therefore modifying the provisions for consistency across all three assister types.

We are not adding language to include an automatic expiration date for the authorization because it could become burdensome for a consumer consistently seeking services from the same assister to have to routinely fill out a new authorization form, and for the assister to have to maintain each new form for a minimum of six years. We do note, however, that consumers are allowed to revoke their authorization at any time, and may place a time restriction on the authorization, if they desire.

Comment: Many commenters requested that we create a standard authorization form for assisters to use, rather than leaving it to assisters to create their own form, which commenters believed would cause assisters to incur considerable costs. Commenters also recommended that low literacy levels should be taken into consideration when creating the form, and that the form be translated into at least the top 15 languages to meet the needs of limited English proficient consumers served in an FFE.

Response: We support the commenters' suggestion to have a model form to use for obtaining this authorization, and share the commenters' concerns about the costs to assisters of

creating an authorization form if there were no model form available. We note that, for Navigators in FFEs, including State Partnership Exchanges, a model form is included in the grant award materials, and for certified application counselors in FFEs and State Partnership Exchanges, a model form is among the documents provided to certified application counselor designated organizations upon designation by the Exchange; in both cases, these forms are provided in both English and Spanish versions. HHS intends to develop a model form for use by non-Navigator assistance personnel in FFEs and State Partnership Exchanges in the future. We will take into consideration the comments regarding literacy levels and language translations as we develop a model authorization form for use by non-Navigator assistance personnel subject to §155.215, and as we review the current Navigator and certified application counselor model forms for the FFEs and State Partnership Exchanges.

Comment: Some commenters requested that the disclosure to consumers include information about the permissible and impermissible ways an assister may use a consumer's personally identifiable information, as well as how consumers may opt out of follow-up from the assister.

Response: These regulations do not require specific content in the consumer authorization form. However, we note that the model authorization form currently provided in the FFE and State Partnership Exchange Navigator grant award materials and to certified application counselor designated organizations in the FFEs, including State Partnership Exchanges, includes information about how a consumer's personally identifiable information may be used, as well as an option for consumers to authorize follow-up contact from the Navigator or certified application counselor, as applicable. As we develop a model form for

non-Navigator assistance personnel in the FFEs and State Partnership Exchanges, we will also consider including these same content elements.

Comment: Commenters submitted several requests and recommendations regarding the form of the authorization. Many commenters requested that the authorization be allowed to be collected and maintained in electronic form to help reduce the costs and burden associated with paper forms. Some commenters also requested that a voice-recorded authorization be allowed when assisters are helping consumers over the phone. Additionally, several commenters requested that Exchanges be permitted to retain the record of authorization on behalf of the assister, noting that some State Exchanges are already doing this.

Response: We note that these regulations do not specify acceptable formats for obtaining the authorization or for maintaining its record. Additionally, to allow for the flexibility in State Exchanges requested by commenters, we have modified the proposed language specifying that the authorization be provided “in a form and manner as determined by the Secretary” to indicate that the authorization must instead be provided in a form and manner as determined by the Exchange. As a result of this change, each Exchange will have discretion to determine the appropriate form and manner for these authorizations. In response to commenters’ concerns about whether these regulations would prohibit a State Exchange from retaining these authorizations on behalf of their assisters, we have also revised the language in this provision of the final rule to indicate that the form and manner of the assistance entity’s or personnel’s maintenance of the authorization is to be determined by the Exchange. This modification will allow State Exchanges that have chosen to retain these authorizations on behalf of their assisters to continue to do so, provided it is consistent with the “form and manner as determined by the Exchange.”

We acknowledge that the language regarding the form and manner of obtaining or maintaining the authorization was not included with respect to certified application counselors at proposed §155.225(f)(2). To align the provision with those provisions applicable to Navigators and non-Navigator assistance personnel subject to §155.215, we are adding this language to §155.225(f)(2).

Finally, we are deleting the cross references in proposed §155.210(e)(6)(ii) to 45 CFR 92.42 and 45 CFR 74.53 due to the potential for these cross references to become obsolete or inaccurate in the future. We believe the remaining phrase “other applicable Federal law” will capture the intent of the cross references to ensure that Navigators comply with retention periods for maintaining these records in accordance with all Federal laws that may apply. This cross reference was only included in the proposed provision applicable to Navigators; therefore no change is necessary to the provisions at §155.215(g)(2) or §155.225(f)(2).

Comment: Several commenters raised concerns about the requirement for Navigators, non-Navigator assistance entities subject to §155.215, and certified application counselor designated organizations to maintain a physical presence in their Exchange service area under proposed §155.210(e)(7) and §155.225(b)(1)(iii). Commenters claimed that this proposed provision eliminates vital flexibility for consumer assistance personnel, noting that these assistance personnel often provide effective service over the phone or internet. Commenters pointed out that in large, rural, or frontier States, consumers often rely on remote assistance. Commenters also mentioned that some State Exchanges are working on software that would allow assistance personnel to help clients remotely, by facilitating screen sharing and split screen views for assistance personnel and clients, and these commenters expressed the concern that the proposed language would inhibit such technological innovations. Commenters requested that, at

a minimum, clarification be provided that this provision will not affect the ability of assisters to provide remote assistance to consumers. However, there were a few commenters who supported this requirement, and recommended that the provision be broadened to require Navigator organizations, non-Navigator assistance entities subject to §155.215, and certified application counselor organizations to maintain a principal place of business within their Exchange service area.

Response: The proposed requirement that Navigators, non-Navigator assistance personnel subject to §155.215, and certified application counselors maintain a physical presence in their service area so that face-to-face assistance can be provided was designed to ensure that these consumer assistance personnel understand and are able to meet the specific needs of the communities they serve, to foster trust between these consumer assistance personnel and community members, and to encourage participation in the Navigator, non-Navigator assistance, and certified application counselor programs by individuals whose backgrounds and experiences reflect those of the communities they serve.

In light of the comments we received indicating that this requirement may be too restrictive for certified application counselor organizations already providing remote assistance, we are not finalizing proposed §155.225(b)(1)(iii) which would have required certified application counselor organizations to maintain a physical presence in the Exchange service area. We understand that unique circumstances may exist that would make remote assistance more effective or practical than face-to-face assistance, particularly when a certified application counselor is providing services to individuals or populations that might otherwise be difficult to reach. We continue to believe that face-to-face, in-person assistance is important, and we encourage certified application counselors to provide this type of assistance as much as possible.

We will continue to evaluate the effectiveness of remote assistance offered by certified application counselors and certified application counselor organizations, to determine whether a physical presence requirement may be necessary in the future.

We are finalizing these requirements at §155.210(e)(7) and §155.215(h) that Navigators and non-Navigator assistance personnel subject to §155.215 must maintain a physical presence in the Exchange service area, so that face-to-face assistance can be provided to applicants and enrollees. We believe this provision will improve the ability of Navigators and non-Navigator assistance personnel subject to § 155.215 to provide culturally competent application and enrollment assistance. As we explained in the preamble to the proposed rule, this requirement may also facilitate State consumer protection efforts.

We agree with commenters that remote application and enrollment assistance can be extremely important and effective, especially as a way to provide this assistance to consumers in rural or remote areas. Therefore, we want to make clear that nothing in this provision prohibits Navigators or non-Navigator assistance personnel subject to §155.215 from providing assistance via the telephone, Internet, or through other remote means, as long as the organization with which they are affiliated also maintains a physical presence in the Exchange service area, consistent with §155.210(e)(7) and §155.215(h). We also clarify that Exchange service area refers to the entire area served by the Exchange, and not to smaller regions within the area served by the Exchange.

We disagree with comments suggesting that these assister organizations should be required to maintain a principal place of business within their Exchange service area. Many trusted national organizations have State or local branches that operate as Navigators, non-Navigator assistance personnel subject to §155.215, or certified application counselors, and who,

partly because of their physical presence in the State, are able to provide high-quality assistance tailored to the needs of their communities. Therefore, we are finalizing §155.210(e)(7) as proposed with a modification to specify that in an FFE, no individual or entity shall be ineligible to operate as a Navigator solely because its principal place of business is outside of the Exchange service area. With respect to the certified application counselor program, we are adding a new §155.225(b)(3) to specify that in an FFE, no individual or entity shall be ineligible to operate in this program solely because its principal place of business is outside of the Exchange service area.

We indicated in the preamble to the proposed rule that we were proposing to make the same provision specifying that Navigators maintain a physical presence in their Exchange service area under §155.210(e)(7) also applicable to non-Navigator assistance personnel subject to §155.215, and we proposed adding a new paragraph under §155.215 for that purpose. However, the rule text of the proposed rule omitted the new paragraph under §155.215. In the final rule, therefore, we are correcting this oversight, and adding this standard to §155.215 as a new paragraph §155.215(h) to specify that all non-Navigator assistance personnel subject to §155.215 who operate in FFEs must maintain a physical presence in the Exchange service area, so that face-to-face assistance can be provided to applicants and enrollees. Similarly, we are modifying this provision to add a specification that no individual or entity shall be ineligible to operate as non-Navigator assistance personnel subject to §155.215 solely because its principal place of business is outside of the Exchange service area.

Summary of Regulatory Changes

We revised §155.210(c)(1)(iii) to remove reference to “errors and omissions insurance” and replaced it with “any requirement that, in effect, would require all Navigators in the Exchange to be licensed agents and brokers.”

We are not finalizing proposed §§155.210(c)(1)(iii)(E) and 155.225(d)(8)(iv).

We renumbered proposed §§155.210(c)(1)(iii)(F) and 155.225(d)(8)(v) as new §§155.210(c)(1)(iii)(E) and 155.225(d)(8)(iv). We modified newly renumbered §§155.210(c)(1)(iii)(E) and 155.225(d)(8)(iv) to extend these provisions to all Exchanges by removing the reference to “in a Federally-facilitated Exchange” and by specifying that non-Federal standards that would, as applied or implemented in a State, prevent the application of Federal requirements applicable to Navigators (or non-Navigator assistance personnel subject to §155.215), or certified application counselors or designated organizations or, as added in this final rule, “the Exchange’s implementation of the [respective assister] program” would prevent the application of the provisions of title I of the Affordable Care Act. We revise §155.215(f) to add subparagraphs (1) through (4) explicitly under that provision, rather than incorporating by reference parallel provisions in the applicable Navigator standards under §155.210(c)(1)(iii), as was proposed.

We revised §§155.210(d)(4) and 155.225(g)(2) to add that in an FFE no health care provider individual or entity shall be ineligible to operate as Navigators (or non-Navigator assistance personnel subject to §155.215), or certified application counselors or certified application counselor designated organizations solely on the basis of receiving consideration from a health insurance issuer for health care services provided.

We also revised §155.210(e)(7) to provide that in an FFE, no individual or entity shall be ineligible to operate as a Navigator solely because its principal place of business is outside of

the Exchange service area. We added §155.215(h) to create a parallel provision to §155.210(e)(7) for non-Navigator assistance personnel subject to §155.215, as was discussed in the preamble to the proposed rule. We did not finalize §155.225(b)(1)(iii), but we added a new §155.225(b)(3) to specify that in an FFE, no individual or entity shall be ineligible to operate as a certified application counselor or designated organization solely because its principal place of business is outside of the Exchange service area.

We moved §155.210(d)(6) to §155.215(i) and limited this provision, as well as §155.225(g)(3), to Navigators, non-Navigator assistance personnel, and certified application counselors operating in FFEs, including State Partnership Exchanges, and revised these provisions to specify that they do not take effect until November 15, 2014.

We renumbered proposed §155.210(d)(7) to §155.210(d)(6), and revised newly renumbered §155.210(d)(6) along with §155.225(g)(4) to clarify that gifts, gift cards, or cash, and promotional items that market or promote the products or services of a third party provided by assisters to consumers are prohibited for the purpose of inducing enrollment, and that gifts, gift cards, or cash may exceed nominal value for the purpose of providing reimbursement for legitimate expenses incurred by a consumer in effort to receive Exchange application assistance, such as (but not limited to) travel or postage expenses. We also add new §155.210(d)(7) to 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 revised §§155.210(d)(8) and 155.225(g)(5) to clarify that the prohibitions on door-to-door solicitation for application or enrollment assistance do not prohibit Navigators, non-Navigator assistance personnel, or certified application counselors from going door-to-door to

conduct general consumer education or outreach, or from soliciting consumers with whom the assister has a preexisting relationship so long as other applicable State and Federal laws are complied with.

We revised §§155.210(d)(9) and 155.225(g)(6) to clarify that the prohibitions on using an automatic telephone dialing system or an artificial or prerecorded voice to initiate a telephone call to a consumer, do not prohibit Navigators, non-Navigator assistance personnel, or certified application counselors from using those means to communicate with consumers with whom they already have a relationship, so long as other applicable State and Federal laws are complied with.

We revised §§155.210(e)(2) and 155.225(c)(1) to add that the duties of Navigators, non-Navigator assistance personnel subject to §155.215, and certified application counselors includes a duty to provide information in a fair, accurate, and impartial manner to individuals and employees about the full range of QHP options and insurance affordability programs for which they are eligible, which includes providing fair, impartial, and accurate information that assists consumers with submitting the eligibility application, clarifying the distinctions among QHPs, and helping consumers make informed decisions during the health coverage selection process.

We made technical edits to preserve the grammatical pattern that appears in the existing list at §155.210(d)(1)-(4) and extended it through §155.210(d)(9) by placing semicolons after each subparagraph and moving the “or” following proposed §155.210(d)(5) to follow §155.210(d)(8).

We revised §§155.210(e)(6)(ii) and 155.215(g)(2) to change the word “Secretary” to “Exchange” to allow for State Exchanges to determine their own appropriate form and manner for obtaining the consumer authorization that is required for a Navigator or non-Navigator assistance personnel to obtain access to the consumer’s personally identifiable information. We

also specified that the Navigator and non-Navigator assistance personnel subject to §155.215 must maintain a record of the authorization provided “in a form and manner as determined by the Exchange,” and that the period is no less than six years (not three years, as proposed), unless a different and longer retention period has already been provided. In §155.210(e)(6)(iii), we removed reference to 45 CFR 92.42 and 45 CFR 74.53 and retain only “other applicable Federal law.” We also revised § 155.225(f)(2) to add parallel language to require certified application counselors to obtain and maintain record of the authorization in a form and manner as determined by the Exchange, and to specify that the retention period is no less than six years, unless a different and longer retention period has already been provided under other applicable Federal law.

We revised proposed §155.225(d)(8)(i) to replace the phrase “act in the best interest of applicants” with the phrase “provide fair, accurate, and impartial information.”

c. Payment of Premiums (§155.240)

In order to address situations in which enrollees have mid-month changes in enrollment, we proposed in §155.240(e) standards for providing partial month premiums. First, we proposed to provide flexibility for Exchanges to establish a standardized methodology for partial month premiums or to rely on issuers to prorate premiums in accordance with State law and issuer policies. Second, we proposed in §155.240(e)(1) that, for the FFE, the premium for coverage lasting less than one month must equal the product of the premium for one month of coverage divided by the number of days in the month and the number of days for which coverage is being provided in the month.

Comment: We received several comments expressing general support for the proposed provisions in §155.240(e). Commenters also specifically supported the proposed methodology

for partial month premiums in the Federally-facilitate Exchange. Commenters viewed the methodology proposed in §155.240(e)(1) as an equitable and beneficial solution to a common issue that consumers face with respect to their health insurance premiums. The methodology proposed for the FFE was also noted as being simple and easy for consumers to understand. Additionally, several of these commenters requested that HHS require all Exchanges to use the partial month premium methodology originally proposed for the FFE to promote consistency across Exchanges.

Response: We appreciate the support received for the proposed provisions in §155.240(e). We maintain that Exchanges are in the best position to determine the methodology used for partial month premiums within their jurisdiction. However, in the case of the FFE, the methodology we proposed is appropriate given the Exchange's unique circumstances. Specifically, CMS jointly administers the FFEs currently operating in multiple States, each of which may have different rules for proration and, therefore, the administrative burden to enforce varying rules across these States would be overwhelming without the implementation of a single, standard approach. For example, in order to provide the appropriate amount of advance premium tax credit to the issuer, the issuer must inform the Exchange of the premium amount charged to each individual. Without a standardized approach in the FFE, this information would come to us in a variety of forms in accordance with various State laws and issuer practices for partial month premiums, which would be burdensome to manage. Consequently, we note that the standards for partial month premiums in the FFE apply even if State requirements in those FFE States differ from this final rule. There is also a customer service advantage to using a single methodology because it makes it easier for customer service representatives to explain one clear, comprehensive policy for all consumers throughout the FFE. Because of the high degree of

variability across the States in the FFE, we maintain that the proposed methodology for calculating prorated premiums is the most efficient and equitable approach. We are finalizing the regulation as proposed.

Comment: A few members of the issuer community provided comment on the implementation of the proposed provision for the FFE. We received comments requesting that HHS limit premium proration to the FF-SHOP and not extend the policy to the individual market FFE. Commenters argued that current standard industry practices are simpler and more cost effective for issuers because they do not require reconciliation of daily proration. A commenter also noted that, because the Exchange will not perform premium aggregation in the individual market, there is no need to adopt a standard method for proration of premiums. Commenters noted that implementing the proposed policy would require reconfiguration of issuer information technology systems, including billing mechanisms, which takes significant time and investment; therefore, commenters requested that implementation not occur before the 2015 benefit year. These commenters also requested that the requirement not be implemented retroactively and, instead, for months prior to the effective date of this policy, issuers have the flexibility to use their own proration methodology or follow State law.

Response: While premium aggregation is a compelling reason to adopt premium proration, there are numerous other reasons to adopt it as noted in the comment response above and in the proposed rule's preamble. We previously have been asked by States and issuers for guidance in this area and implementing a standard policy for the FFE will establish a clear standard with which issuers can comply and for consumers to understand. Issuers have also told us that proration of partial month premiums is a methodology that can be implemented. We believe that having a policy in place is vastly preferable to operating without any guidance and

we remain committed to working closely with issuers on implementation. In order to ensure that issuers have sufficient time to implement this proposal, the FFE will implement it effective January 1, 2015. Issuers may also choose to implement the policy immediately. We also note that, in response to the comment, we will not seek retroactive implementation of the partial month premium policy for the FFE but note that State Exchanges have flexibility to determine how to implement their policy in this area.

Comment: One commenter expressed concern that the preamble to this section specified the events for which an Exchange may require proration of premiums, such as voluntary withdrawal. The commenter believed that these policies are more suitably addressed at the State level, where they can reflect a State's unique market dynamics.

Response: The examples used in the preamble to the proposed rule were illustrative of the policy but not intended to replace our previous guidance for partial month enrollments found at 45 CFR 155.420 and 155.430.

Comment: Finally, one commenter requested clarification as to whether a prorated premium could count as a first month's premium (for example, in the case of a newborn) and how that would also impact the 3-month grace period provided in §156.270(d) and (e).

Response: A partial month premium does count as a first month's premium. Additionally, payment of a prorated premium in full can be considered payment in full for the purpose of the 3-month grace period in §156.270(d) and (e).

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.240 without modification.

d. Privacy and Security of Personally Identifiable Information (§155.260)

We proposed amending §155.260(g) to add a reference to §155.285, which is being added as part of this final rule. Section 155.285 specifies the grounds for imposing CMPs, the notice required to be given to a person when a civil money penalty is assessed, and factors to be used to determine the amount of CMPs assessed, as well as some aspects of the process for imposing CMPs. We proposed this addition to §155.260(g) to clearly link these two regulatory provisions and to ensure that readers fully understand how CMPs will be assessed for any improper use or disclosure of information.

Comment: We received some comments in support of the proposed amendments to §155.260(g). However, a few commenters also requested additional amendments to the provision. For example, one commenter requested that we amend §155.260(g) to clarify that outreach and follow-up efforts made by community assisters is not impeded by the reference to §155.285. Specifically, the commenter encouraged HHS to specify that, with receipt of express consumer consent, PII can be used to conduct outreach to follow up with individuals who still need to complete applications or for outreach to help individuals maintain and renew existing health coverage. Another commenter suggested that the provision note that the use and retention of PII is permissible with the consumer's consent, in order to ensure consistency with the Navigator provisions at §155.210(e)(6) and §155.225(f) which permit such use. The commenter also requested amendments to §155.260(a) and (b) to specify that retention of PII is permissible with the consent of the consumer.

Response: We acknowledge the importance of consumer assistance entities being able to contact consumers in order to follow-up regarding applications for coverage or annual renewals. However, §155.260 as proposed, does not impede these types of outreach. Rather, §155.260 prohibits improper use and disclosure of information, as described in the preamble to the

proposed rule at §155.285. Similarly, a Navigator's use of information as described in §155.210(e)(6) and §155.225(f) is not prohibited under §155.260(g) and we do not see the need to include further clarification of that in the rule. Finally, the requested amendments to §155.260(a) and (b) are outside the scope of this proposed rule. Therefore, we intend to finalize §155.260(g) as proposed.

Comment: Some commenters expressed concern about the proposed amendment. Commenters thought the reference to §155.285 was duplicative and that the application of §155.260 may, in some cases, be broader than the specific prohibitions on disclosure intended by section 1411(g) of the Affordable Care Act and should not be linked to §155.260.

Response: We disagree with the contention that the reference to §155.285 in §155.260 is duplicative. The cross-reference links the improper use and disclosure of PII to the imposition of CMPs as prescribed in section 1411(g) and (h) of the Affordable Care Act. Therefore, we finalize the provision as proposed.

Comment: We received many comments to both §155.260 and §155.285 requesting clarification about the role of PII with respect to CMPs.

Response: Because of the relationship between §155.260 and §155.285, we address comments on §155.206 in the preamble related to §155.285(a) of this final rule.

Summary of Regulatory Changes

We are finalizing the addition to §155.260 as proposed, with a minor change where we have inserted the numerical penalty amount instead of a reference to section 1411(h) of the Affordable Care Act where the maximum penalty is specified.

e. Bases and Process for Imposing Civil Money Penalties for Provision of False or Fraudulent Information to an Exchange or Improper Use or Disclosure of Information (§155.285)

In §155.285(a), in accordance with the grounds on which penalties may be imposed as specified in section 1411(h) of the Affordable Care Act, we proposed the circumstances under which HHS may impose CMPs on a person if HHS determines that the person has provided false or fraudulent information as prohibited by section 1411(h)(1) or improperly used or disclosed information in violation of section 1411(g). In §155.285(a)(1)(i), we proposed that if any person fails to provide correct information under section 1411(b) of the Affordable Care Act and such failure is attributable to negligence or disregard of any regulations of the Secretary, the person may be subject to a CMP. Under proposed §155.285(a)(1)(i), if a person fails to make a reasonable attempt to provide accurate, complete and comprehensive information and as a result provides incorrect information, the person may be subject to a CMP.

Second, in §155.285(a)(1)(ii), we proposed that if a person knowingly and willfully provides false or fraudulent information under section 1411(b) of the Affordable Care Act, the person may be subject to a CMP. We noted that if consumer assistance personnel such as an agent, broker, Navigator, certified application counselor, or non-Navigator assistance personnel, were to in some manner directly provide false or incorrect information required under section 1411(b), they may also be subject to a CMP. Third, in §155.285(a)(1)(iii), we proposed that if a person knowingly and willfully uses or discloses information in violation of Affordable Care Act section 1411(g), the person may be subject to a CMP. In §155.285(a)(1)(iii)(A) through (C), we proposed types of activities that would be in violation of section 1411(g) of the Affordable Care Act and in §155.285(a)(2), we proposed a definition of the term “person.”

In §155.285(b), we proposed the factors that HHS may take into consideration when determining the amount of CMPs to impose. In §155.285(b)(3), we implemented the reasonable cause exception of section 1411(h)(1)(A)(ii) of the Affordable Care Act pursuant to which no

penalty will be imposed under §155.285(a)(1)(i) if HHS determines that there was a reasonable cause for the failure to provide correct information required on an Exchange application and that the person acted in good faith.

In §155.285(c), we proposed maximum penalties for each different type of violation. In §155.285(d), we proposed standards for a notice of intent to issue a CMP that HHS must send to the person against whom the CMP may be imposed. In §155.285(d)(1)(i)-(viii), we proposed eight elements that must be included in the notice. We proposed that the person may request a hearing before an ALJ on the proposed penalty by filing a request pursuant to the procedure that will be outlined in the notice of intent to impose a penalty that the person receives.

In §155.285(e), we proposed the consequences for a person who fails to request a hearing in a timely manner. We proposed that HHS may assess the proposed CMP 60 calendar days after the date of issuance printed on the notice of intent to issue a CMP. In §155.285(e)(1), we proposed that HHS will notify the person in writing of any penalty that has been imposed, the means by which the person can satisfy the penalty, and the date on which the penalty is due. We proposed in §155.285(e)(2) that a person has no right to appeal a penalty with respect to which the person has not timely requested a hearing.

In §155.285(f), we proposed to use the existing appeals framework in regulation at 45 CFR Part 150, Subpart D. In §155.285(g), we proposed that CMS and OIG will share enforcement authority to impose the CMPs in §155.285.

In §155.285(h), we proposed a settlement authority provision to ensure CMS is able to settle any issue or case described in §155.285(a) if necessary. Finally, in §155.285(i), we proposed a six year statute of limitations, beginning from the date on which the violation occurred, within which HHS may impose a CMP against a person.

Comment: We received some comments regarding §155.285(a)'s reference to basing the imposition of a CMP on “credible evidence” if HHS “reasonably determines” that someone has violated the rule. The commenters recommended that, because a CMP could be potentially significant, the standard should be based on a preponderance of the evidence. The commenters also noted that this standard is consistent with the Administrative Procedures Act.

Response: We maintain that the standard proposed in §155.285(a) is appropriate in light of the fact that a CMP is not immediately imposed but, instead, imposed only after a process involving notice and the right to a hearing is provided. If HHS identifies circumstances that meet the standard set in §155.285(a), the resultant action is a notice informing the person of the potential imposition of a CMP. The person then has the right to request a hearing in front of an ALJ in accordance with h§155.285(d)(2) before the CMP is levied. For these reasons, we finalize the standard as proposed.

Comment: We received one comment regarding the definition of negligence, provided in §155.285(a)(i)(A). The commenter sought clarification as to what is considered a “reasonable” attempt to provide accurate, complete, and comprehensive information.

Response: The proposed definition of “negligence” is modeled on section 6662 of the Internal Revenue Code and was incorporated based on the similarities between providing information on tax filing forms and completing an application for Exchange coverage. This definition should provide CMS and the public with ample history on which they may rely to assess negligence in this context. We also believe this definition is appropriate because it holds actions that are made through honest mistake and error (which are protected by the reasonable cause provision in §155.285(b)(3)) not culpable for a violation. We finalize the definition as proposed.

Comment: We received many comments regarding the imposition of CMPs under §155.206 and §155.285. Some commenters recommended that HHS retain discretion to impose CMPs under both sections, citing some violations under §155.285 will also violate consumer assistance standards and, in those instances, HHS should levy penalties under both provisions. These commenters noted that allowing penalties under both provisions will give Navigators and assisters in the Federally-facilitate Exchange an extra incentive to maintain the privacy of those they assist. Another group of commenters recommended that where violations of §155.206 and §155.285 overlap, HHS should use its discretion to impose a CMP under only one section. Similarly, many commenters in this cohort urged HHS to exempt consumer assistance entities from §155.285, explaining that assistance personnel do not actually provide information as part of the process of applying for coverage or an exemption, and therefore it was difficult to see how they could provide false or fraudulent information in violation of §155.285. These commenters considered imposing violations for consumer assistance entities under both sections would be duplicative.

Response: We disagree that consumer assistance personnel should be exempt from the provisions of 45 CFR 155.285. Any Navigator, non-Navigator assistance personnel, or certified application counselor who encourages a consumer to submit false or fraudulent information and then enters that information into the application for the consumer, or enters false or fraudulent information without the knowledge of the consumer, might be in violation of either §155.285 or §155.206. Therefore, we maintain that where conduct by a consumer assistance entity may warrant CMPs under either §155.285 or §155.206, HHS should have discretion to determine whether to impose a CMP under §155.285 or under §155.206. If a consumer assistance entity is

in a situation where CMPs could be imposed under both §155.206 and §155.285, CMS will take that into account as a factor under §155.285(b)(1)(viii).

Comment: Commenters expressed a general concern that the provisions of §155.285 might have a chilling effect on consumer assistance entities, particularly those that rely on voluntary participation. These commenters urged us to limit CMPs to egregious violations of selected requirements where there are no other enforcement mechanisms in place. Commenters felt that fewer people might be willing to become assisters if they feared being held responsible for CMPs, particularly for information provided and attested to by applicants.

Response: We understand the concerns raised by commenters about the potential for these penalties to discourage participation as a consumer assistance entity. However, we are finalizing the provisions, and their application to consumer assistance entities, as proposed. The purpose of these provisions is to ensure consumer information is safeguarded, no matter where it is in the eligibility or enrollment process or whether the consumer seeks the assistance of a consumer assistance entity. HHS's goal in issuing the CMP rule is to encourage program compliance, prevent misconduct, and remedy violations promptly. We do not think these goals will be served by lessening the proposed standards for imposing CMPs.

Comment: We received comments expressing support for the grounds proposed for imposing CMPs. These commenters viewed the authority to impose CMPs as an effective way to safeguard the use of consumer information. However, many commenters also sought clarification about what constitutes improper use and disclosure of PII under the NPRM and in relation to section 1411(g) of the Affordable Care Act. Several of these commenters requested that §155.285 be amended to note that, with receipt of consent, PII can be used to conduct outreach to follow up with individuals who still need to complete applications or for outreach to

help individuals maintain and renew existing health coverage. Other commenters feared any relaxation of PII standards would compromise consumer information and cause harm.

Response: Protection of consumer information is one of the most critical duties of consumer assistance entities and Exchanges. Section 155.260 provides privacy and security standards handling and safeguarding consumers' PII. Section 155.260 also provides that the Secretary can determine additional uses and disclosures of PII and develop a framework through which Exchanges can seek the Secretary's approval of other requested uses and disclosures of eligibility and enrollment PII that would ensure the efficient operation of the Exchange, comply with other applicable law and policy, and require the consent of the individual subject of the PII prior to the requested use or disclosure. Uses and disclosures of information that are not permitted by §155.260 or otherwise permitted by statute or regulation, therefore, are prohibited. Those prohibited uses and disclosures are the focus of the penalties imposed in §155.285 to the extent they are knowing and willful. But, we note that some uses and disclosures, as specified in rule, are permissible with the specific consent of the consumer.

Comment: We received several comments on the definition of "person" in §155.285(a)(2). Some commenters found the broad definition of "person" warranted for imposing CMPs for violations of section 1411(g) of the Affordable Care Act. However, a portion of commenters requested that HHS exclude assisters from the definition of "person." We also received one comment noting that the inclusion of QHP issuers potentially creates confusion regarding the source of required application information provided to establish eligibility to purchase a QHP.

Response: Exchanges involve the coordination of a wide variety of individuals and entities for their success. Therefore, our definition of "person" is broad to encompass each of

these and the possibility that they could engage in the actions enumerated in §155.285(a)(1). We want to ensure that these individuals and entities are on notice of the penalties they could incur for the misuse of information. The inclusion of assisters and similar consumer assistance entities within §155.285 is discussed in detail above in the comment response to questions regarding the application of §155.206 and §155.285 to assisters. Finally, the inclusion of QHP issuers in the definition is purposeful for the reasons noted above and we do not share the concern of the commenter that this creates confusion. Many of the entities included in the definition are required to provide information for use by the Exchange, including QHP issuers; however, it is only the provision of false or fraudulent information or improper use or disclosure of information that is penalized. We finalize the definition as proposed.

Comment: We received many comments in support of the proposed provisions of §155.285(b), which lists the factors used to determine the amount of CMPs imposed. A few commenters suggested additional factors to be considered including, whether the violation resulted in other legal consequences for an individual, attempts at taking corrective action, and the extent to which assistance personnel were deceived by the consumer into providing false or incorrect information.

Response: We appreciate the support we received for the proposed factors used to determine the amount of CMPs imposed. We have considered the factors commenters suggested and find that only minor revisions to the proposed set of factors are necessary. For example, we have added one additional factor at subparagraph (b)(1)(viii) to include a factor allowing HHS to take into consideration whether other remedies or penalties have been imposed for the same conduct or occurrence. We have also clarified the scope of the factors in subparagraphs (b)(2)(i) and (ii) to account for violations that could have resulted in financial harm or could have caused

harm to an individual's reputation, respectively. We note that harm to an individual's reputation could include, for example, actions impacting a consumer's credit rating or incurring costs on behalf of another person without their knowledge or consent. Additionally, §155.285 does not require a corrective action plan, so we do not include corrective steps taken in the factors provided. We believe the extent to which assistance personnel were deceived by the consumer is adequately encompassed in subparagraph (b)(2). Therefore, we finalize the provisions with the modifications to §155.285(b)(1)(viii) and (b)(2)(i) and (ii) as noted above.

Comment: We received considerable support for the reasonable cause provision proposed in §155.285(b)(3). In addition, several commenters sought clarification or safe harbors regarding circumstances where false information is provided due to a mistake or misunderstanding. We received a couple comments requesting a safe harbor specifically for QHP issuers who rely on information provided to them from both the Exchange and consumers, since QHP issuers may have no way to verify information independently. Another commenter sought a safe harbor for conduct relating to calendar years 2014 and 2015 because of the uncertain environment issuers worked in during initial open enrollment. Commenters believed that levying a CMP in such cases would be too severe.

Response: Section 155.285(b)(3) states that no penalty will be imposed if HHS determines that there was a reasonable cause for the failure to provide correct information and that the person acted in good faith. The situations commenters cited would likely fall within this exception. We note that violations must be knowing and willful and information provided merely by mistake and in good faith is not subject to a CMP.

Comment: We received a handful of comments regarding the imposition of penalties, as described in §155.285(c). A few commenters expressed general support for the proposed

provisions. One commenter shared concern that there is no maximum penalty defined, which could cause financial devastation to some consumer assistance entities. A couple commenters requested more clarity on what constitutes a submission of information and questioned whether an application which is started on the phone but completed online results in two submissions or one. Another commenter was concerned about permitting HHS to estimate the number of consumers affected by the violation to calculate the maximum penalty. The commenter supported, instead, using the number of consumers directly affected by the violation or placing a maximum on the estimate calculated by HHS based on the size of the consumer population served by the consumer assistance entity to prevent unreasonable penalties for the assister community. Finally, one commenter requested clarification that §155.285(c) does not limit penalties under State law or a State's ability to take action to protect consumers.

Response: Although §155.285(c) provides a maximum cap per violation, there is no global cap on CMPs. CMPs are intended to discourage the misuse of information; therefore, we believe that providing a global cap on CMPs would defeat there intended purpose. In response to the questions received, we note that one application, no matter the number of modes used to complete it, is considered one submission for purposes of imposing a CMP. This concern is further mitigated by the availability of an appeal prior to the imposition of a penalty during which this issue may be explored. We finalize the provisions as proposed. Finally, in response to the request for clarity about the role of State law in relation to §155.285, we note that the standards in §155.285 do not limit a State's ability to impose penalties or protect consumers under State law.

Comment: In response to §155.285(d), we received a comment requesting that notices be written clearly and be culturally and linguistically.

Response: All Exchange-related notices, including those related to CMPs, must comply with the requirements for notices established in §155.230.

Comment: Some commenters requested that §155.285(e) be amended to provide additional time to request a hearing. The commenters noted, that under the proposed regulation, there are no additional options for an individual who misses the 60-day timeframe to request a hearing. One commenter suggested permitting additional time to request a hearing under a good cause exception. Another commenter suggested permitting an additional 60-day period to request a hearing following the due date of a CMP payment. The commenter noted that a payment date may provide more effective notice to the individual and also that many entities may have segregated chains of duty and the appropriate person may not be notified in time to request a hearing.

Response: We disagree with commenters that 60 days from the date of the notice in §155.285(d) is insufficient for an individual to request a hearing. We believe 60 days to be neither too short to provide adequate notice nor too long to delay the process of imposing a CMP. We finalize the provision as proposed.

Comment: As proposed in §155.206, several commenters recommended that CMS first require any consumer assistance entity that is alleged to have provided false information or improperly used or disclosed information to enter into a corrective action plan before a CMP could be issued.

Response: We believe that §155.285 provides HHS or OIG sufficient flexibility to offer an entity or individual an opportunity to take corrective action or propose a plan of corrective action to avoid penalties prior to HHS or OIG issuing a notice of intent to impose a civil money

penalty. Particularly, HHS might offer an opportunity for corrective action in relation to minor infractions that expose entities or individuals to a penalty under §155.285.

Comment: Some commenters requested clarification regarding payment methodologies and timeframes for CMPs. For example, one commenter questioned whether the entirety of the penalty would be due upon payment of taxes or upon notification of being found guilty of a violation.

Response: We do not provide this level of detail in the regulation at this time. We will address this issue in the future.

Comment: One commenter expressed disagreement with the proposed six-year statute of limitations in §155.285(i). The commenter noted that between IRS review, issuer validation of payments, and other methods of cross-referencing and auditing, each incident of a violation should be able to be discovered within two years. The commenter also noted that a longer statute of limitations may lead to collection procedures, such as wage garnishments, to collect unpaid debt, which can extend the efforts needed to collect the money for a CMP.

Response: We believe the six-year statute of limitations period is appropriate. This period is not indefinite and, therefore, will hopefully not discourage efforts by consumer assistance entities. However, HHS's goal in issuing the CMP rule is to encourage program compliance, prevent misconduct, and remedy violations promptly and, therefore, we do not want to provide a period that is too short to encourage strict compliance with the rule and provide protection for PII. We believe six years provides sufficient time for HHS to discover and investigate any potential CMPs and acknowledges the reality that in many situations, misuse of a consumer's personally identifiable information may not be discovered by a consumer and reported to HHS for some time after the unlawful use.

Comment: Several commenters advocated against duplication of penalties in instances where certain types of violations may already subject them to other types of penalties. A few commenters noted that the Health Insurance Portability and Accountability Act already governs certain critical aspects of compliance related to the protection of consumer personal information.

Response: We understand commenters' concern about the potential duplication of penalties, and have amended §155.285(b)(1) to include a factor allowing HHS to take into consideration whether other remedies or penalties have been imposed for the same conduct or occurrence. It would be the responsibility of the entity to bring such information to HHS's attention. However, we also note that HHS will consider referring cases to appropriate law enforcement officials based on the facts and circumstances of the violation.

Comment: One commenter requested clarification regarding whether an individual would be held accountable for repayment of an overpayment of the advance premium tax credit or CSRs paid on a consumer's behalf, in addition to a CMP.

Response: The provisions of §155.285 concern only the imposition of CMPs and not payment or repayment of advance payments of the premium tax credit or CSRs as a result of the misuse of information. This provision has no effect on the Department of Treasury's authority to recoup overpayments of the advance payment of the premium tax credit or CSRs paid on a consumer's behalf.

Comment: We received one comment that, although, we reference PII, it is not defined in regulation.

Response: There are various definitions of PII, and we believe the adoption of any one of them at this stage may unduly limit HHS's ability to adequately redress violations of the rule. Given the advanced state of technology and developments in the way information may be

manipulated, combined, and ultimately used to re-identify persons based on de-identified data, we believe that PII is an evolving concept that may not be fully captured in a single definition. We, therefore, will not provide a specific definition of PII in the text of §155.285 at this time. We do note that OMB Memoranda M-07-16 (May 22, 2007) generally defines PII as information which can be used to distinguish or trace an individual's identity, such as their name, social security number, biometric records, alone, or when combined with other personal or identifying information that is linked or linkable to a specific individual, such as date and place of birth, mother's maiden name.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.285 of the proposed rule regarding CMPs, with the following modifications: In an effort to prevent confusion, in §155.285(c) we have removed the references to section 1411(h)(1) and (2) of the Affordable Care Act and have instead inserted the numerical maximum penalty amounts. In §155.285(a)(1)(ii), we have added “or fraudulent” after “knows to be false” to make the text consistent with section 1411(h)(1) of the Affordable Care Act. In §155.285(b)(1) and (2), we have added language to clarify that the factors in these provisions are “including, but not limited to” the factors listed in their subparagraphs. In §155.285(b)(1)(viii), we have added a factor allowing HHS to take into consideration whether other remedies or penalties have been imposed for the same conduct or occurrence. We have clarified the scope of the factors in subparagraphs (b)(2)(i) and (ii) to account for violations that could have resulted in actual or potential financial harm or could have resulted in actual or potential harm to an individual's reputation, respectively. We have made a minor change to the wording in §155.285(d)(2) by substituting the word “appeal” for “request.” We have also made a technical correction to substitute “the notice of intent to issue a civil money

penalty” in §155.285(d)(2) with a cross reference to §155.285(f). In §155.285(f), we have rephrased the paragraph to read “HHS has proposed to impose” rather than “HHS has imposed.” Finally, we are substituting the reference to “CMS” with “HHS” in (g)(1) and, in consultation with OIG, we are finalizing concurrent jurisdiction with respect to §155.285(a)(1)(ii) and not §155.285(a)(1)(iii) at this time.

3. Subpart D—Exchange Functions in the Individual Market: Eligibility Determinations for Exchange Participation and Insurance Affordability Programs

a. Verification Process Related to Eligibility for Insurance Affordability Programs (§155.320)

In §155.320(d)(4), we established an option under which a State Exchange could rely on HHS to conduct verifications of enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan for purposes of eligibility for advance payments of the premium tax credit. This option was made available for eligibility determinations that are effective on or after January 1, 2015. However, we have determined that the benefit gained by having HHS provide this function is outweighed by the information technology development and administrative and consumer complexity that would be introduced for a State through this approach. As such, we proposed to strike paragraph (d)(4).

Comment: We received comments from several State Exchanges urging HHS to retain the option of the employer-sponsored coverage verification process. Many of the comments focused on the need for State Exchanges to develop functionality and administrative capacity to verify employer-sponsored coverage in the absence of this Federally-managed service and the administrative and financial burden this would place on State Exchanges. One commenter suggested retaining the service at the Federal level would take advantage of economies of scale rather than burdening each State Exchange, individually. Several States noted that their system

builds and operating budgets could not accommodate this change in time for the 2015 benefit year and recommended that, if HHS does finalize the proposal, HHS postpone eliminating the service for an additional year.

Response: We appreciate the comments received from State Exchanges on this proposed rule change. We understand the administrative costs and development burden associated with providing verifications for Exchange determinations. However, even with the Federally-managed service, State Exchanges and HHS would need to develop a way to send, receive, and process the information and provide dual customer service functionality to communicate with consumers. In addition, the State Exchange would need to modify systems to integrate the HHS verification response into what should be a near-real-time eligibility process. Therefore, we do not believe that there are significant efficiencies to be gained by providing this service to State Exchanges. However, we do understand the time and budget constraints some State Exchanges face in order to adjust their processes to accommodate this change and agree that additional time is needed for States to come into compliance with this requirement. Therefore, we are finalizing the provision as proposed, removing the original regulatory language at §155.320(d)(4), but extending the flexibility previously provided at 78 FR 42257 to permit State Exchanges to implement the sample-based reviews for employer-sponsored coverage for eligibility determinations for insurance affordability programs starting January 1, 2016.

Comment: Additionally, some commenters shared concern that employer coverage data currently available to States is insufficient to perform this verification and that a comprehensive national resource is needed to sufficiently perform the verification. Without such a source, the commenters noted that States would have to employ and administer an alternative data source, causing a lack of uniform documentation and verification across Exchanges. The commenters

suggested that HHS allow self-attestation to be sufficient verification until HHS can make available approved data sources for verification.

Response: Verification standards for employer-sponsored coverage are provided in 45 CFR 155.320(d)(2) and include: (1) Federal employment data from the Office of Personnel Management, which is currently provided to State Exchanges by HHS, (2) SHOP data that is available to the State Exchange, and (3) any electronic data sources that are available to the Exchange and which have been approved by HHS. We remain committed to working with State Exchanges to develop effective solutions for verifying enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan, and will work to make any additional electronic data sources that become available to HHS equally available to State Exchanges.

Summary of Regulatory Changes

We are finalizing the changes to §155.320(d)(4) as proposed but note that we are extending the flexibility previously provided at 78 FR 42257 to permit State Exchanges to implement the sample-based reviews for employer-sponsored coverage for eligibility determinations for insurance affordability programs starting January 1, 2016.

b. Eligibility Redetermination During a Benefit Year (§155.330)

In the proposed rule, we proposed a technical correction in paragraph (d)(2)(ii) of §155.330 to remove the reference to paragraph (e)(3) of this section. In the final rule, titled, “Medicaid and Children’s Health Insurance Programs: Essential Health Benefits in Alternative Benefit Plans Eligibility Notices, Fair Hearing and Appeal Processes and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment, 78 FR 32319, we previously removed paragraph

(e)(3) from this section. As such, we clarified in the proposed rule that paragraph (d)(2)(ii) should only refer to the standards specified in paragraph (e)(2) of this section.

Summary of Regulatory Changes

We did not receive any comments on this proposal and are finalizing the provision as proposed.

4. Subpart E—Exchange Functions in the Individual Market: Enrollment in Qualified Health Plans

a. Enrollment of Qualified Individuals in a QHP (§155.400)

In §155.400, we proposed to add paragraph (e) to establish that Exchanges may, and the FFE would, require payment of the first month's premium to effectuate enrollments.

We also proposed to add paragraph (f), which would authorize Exchanges to provide requirements to QHP issuers regarding the instructions for processing electronic enrollment-related transactions.

Additionally, in §156.265 we proposed to establish a requirement for issuers in the FFEs to collect premiums no later than the day before the coverage effective date. Our intention was to give the Exchange the flexibility to establish policy and process rules regarding premium payment.

Comment: One commenter suggested that the Exchange should not provide instructions to issuers regarding payment of the first month's premium for enrollments. The commenter recommended that the Exchange should allow issuers to establish their own business rules on first month's premium for enrollments. However, another commenter supported establishing a date by which an enrollee must make a first premium payment to effectuate coverage creating greater transparency for payment deadlines and reducing cancellations of coverage due to failure

to pay in a timely manner. We also received a comment that urged us to amend the regulation to allow payment of the first premium up to the day before the coverage effective date, rather than allowing plans to set payment dates that are earlier than this day. The commenter also suggested that issuers should be required to provide timely invoicing for consumers,

Response: We recognize that decisions regarding payment of the first month's premium have traditionally been a business decisions made by issuers. Accordingly, we are not finalizing §156.265(d)(2) which would revise premium payment dates for first month's premiums in the FFE, and are deleting current §156.265(d)(2). We will therefore redesignate §156.265(d)(1) as §156.265(d). However, because we appreciate the comment about giving consumers adequate time to pay their first month's premium, we maintain the proposed §155.400(e) in the final rule to allow Exchanges to establish a consistent process throughout each Exchange regarding first month's premium. In particular, each Exchange can determine how to handle first month's premium payment dates for special enrollment periods that may occur close to or after the effective date. We believe giving each Exchange the flexibility to establish uniform guidance for all issuers for first month's premium for enrollments will benefit the Exchange, issuers, and consumers by ensuring a consistent operational procedure. It is our expectation that QHP issuers will send consumers their bills within one to two business days after receiving enrollment transactions to accomplish the goal of timely effectuating coverage.

Comment: We received several comments that acknowledged establishing a payment due date the day before coverage is effective in most situations, but there are several scenarios that commonly occur today that make this approach challenging and in some cases, impossible to implement. For example, the birth of a child can cause retroactive coverage in which the premium cannot be paid by the effective date, or an individual may lose minimal essential

coverage and be given an effective date with only one day prior to coverage effectiveness in which to pay. There are also instances where the consumer does not receive the bill until after the due date. One commenter voiced concern that some States give 10 day grace periods and recommended that we should allow the FFE the same flexibility offered to SBEs when it comes to how the first premium payment effectuates coverage.

Response: For similar reasons given above, we are not finalizing §156.265(d)(2) which would establish premium payment dates for first month's premiums and expect the FFE to address this in subregulatory guidance.

Summary of Regulatory Changes

We are finalizing §155.400(e) and (f) of the proposed rule without modification. Additionally, we are finalizing the provisions proposed in §156.265(d)(1) of the proposed rule as the entire paragraph (d), and we are not finalizing any §156.265(d)(2), allowing each Exchange to establish its own premium payment dates.

b. Initial and Annual Open Enrollment Periods (§155.410)

In 45 CFR 155.410(d), we specified that starting in 2014, the Exchange must provide a written annual open enrollment notification to each enrollee no earlier than September 1, and no later than September 30. In 45 CFR 155.335(d), we specified that notice of annual redetermination for coverage effective January 1, 2015 be provided as a single, consolidated notice with the notice specified in 45 CFR 155.410(d). In the 2015 Payment Notice, we amended 45 CFR 155.410(e) to specify that for the benefit year beginning on January 1, 2015, the annual open enrollment period begins on November 15, 2014. Accordingly, we believe that it is appropriate to modify the timing of the notice of annual open enrollment and annual redetermination. We proposed two options for this notice: (1) shifting the period during which

the notice would be sent by a month, so that the notice would be sent no earlier than October 1, and no later than October 31, and (2) shifting the period during which the notice would be sent by a month and lengthening this period so that the notice would be sent no earlier than October 1, and no later than November 15, provided that electronic notices are available for any consumer who contacts the Exchange on November 15. We sought comment on which of these options we should implement, or if we should implement another option.

Comment: We received many comments from States, issuers, and consumer advocates about the timeline for issuing the notice of annual open enrollment and annual redetermination. The majority of comments from States and the issuer community support the extended timeframe of October 1 to November 15. States noted the additional flexibility to decide when to send the notice as a benefit to the extended timeframe. Issuers also saw a benefit to extending the timeframe because it would allow for additional attempts to contact enrollees if the first contact was unsuccessful. Several consumer advocacy groups found the shorter timeframe of October 1 to October 31 preferable because it would permit consumers two weeks advance notice before open enrollment and additional time for consumers to contact enrollment assisters and assemble any documents needed for redetermination.

A limited number of commenters supported timeframes outside the two proposed options. One supported keeping the original timeframe for sending the notice no earlier than September 1 and no later than September 30; another sought flexibility to send notices no earlier than August 1. We also received a comment expressing concern over shifting the timeframe either way due to misalignment between open enrollment notices, issuer 90-day renewal notices, and Exchange redetermination notices.

Response: In order to best meet the needs of Exchanges, which are responsible for sending the notices, and consumers, who need enough information about open enrollment in a timely manner, we are finalizing §155.410(d) to state that, starting in 2014, the Exchange must provide a written notice of annual open enrollment and redetermination to each enrollee no earlier than the first day of the month before the open enrollment period begins and no later than the first day of the open enrollment period. This reflects the second of our proposed options.

Comment: We received one comment recommending that the notice be provided to existing enrollees as well as: (1) potential enrollees who submitted applications after the close of the last open enrollment period and were subsequently determined eligible for a QHP but unable to enroll, (2) individuals who had applied for a special enrollment period but were denied during the past year, (3) individuals who had requested enrollment information from the Exchange during the period between open enrollment periods, and (4) individuals who were terminated from a QHP during the period between open enrollments periods.

Response: This comment is outside the scope of the provisions included in the proposed rule; however, we note that §155.335(c) provides that the Exchange must provide every qualified individual with an annual redetermination notice that, for coverage effective January 1, 2015, must be provided as a single, coordinated notice including notice of the annual open enrollment period. Therefore, outreach will extend to individuals beyond current enrollees. We also note that Exchanges have the flexibility to conduct outreach beyond the individuals cited in the rule.

Comment: One commenter requested the addition of language clarifying that States may set an open enrollment period for the Exchange that is broader than the Federal open enrollment period.

Response: This comment is beyond the scope of this rulemaking and we direct the commenter to the open enrollment period rule at 45 CFR 155.410.

Summary of Regulatory Changes

We are amending §155.410(d) to state that, starting in 2014, the Exchange must provide written notice of annual open enrollment to each enrollee no earlier than the first day of the month before the open enrollment period begins and no later than the first day of the open enrollment period.

c. Special Enrollment Periods (§155.420)

In 45 CFR 155.420, we set forth provisions for special enrollment periods. In the proposed rule, we proposed amending §155.420(b)(2)(ii), (d)(1), (d)(6)(iii) and (e), which pertain to the special enrollment period for loss of coverage; §155.420(b)(2)(i) and (iii), which pertain to effective dates for certain special enrollment periods; and §155.420(c), which pertains to the length of the special enrollment periods.

In paragraph (b)(2)(i), we proposed to provide flexibility for coverage effective dates in the case of birth, adoption, placement for adoption, or placement in foster care. We require the Exchange to ensure that coverage is effective for a qualified individual or enrollee on the date of birth, adoption, placement for adoption, or placement in foster care, unless Exchanges permit the qualified individual or enrollee to elect a later coverage effective date. If the Exchange permits the qualified individual or enrollee to elect a later coverage effective date, the Exchange must ensure coverage is effective on the date elected by the qualified individual or enrollee.

In §147.104(b)(2), we specified that a health insurance issuer in the individual market must provide, with respect to individuals enrolled in non-calendar year individual health insurance policies, a limited open enrollment period. Accordingly, in order to align Exchange

regulations with those of the broader insurance market, in paragraph (d)(1), we proposed that the Exchange permit qualified individuals and their dependents to enroll in or change from one QHP to another if they are enrolled in a non-calendar year individual health insurance policy in 2014 described in §147.104(b)(2), even if issuers of such non-calendar year policies offer to renew the policy. Thus, consumers whose individual health insurance policies would renew outside the Exchange open enrollment period would have an opportunity to enroll in an Exchange, just as they would if their policies were offered for renewal during the Exchange open enrollment period. Without this addition, consumers with individual health insurance policies renewing outside the Exchange open enrollment period would be required to renew such policies, and wait to terminate the policies during the Exchange open enrollment period, should they wish to enroll through the Exchange, thus disadvantaging these consumers as compared to consumers enrolled in calendar year individual market policies.

In 26 CFR 1.5000A-2(b)(1)(ii)(C), the Secretary of the Treasury specified that coverage of pregnancy-related services under section 1902(a)(10)(A)(i)(IV) and (a)(10)(A)(ii)(IX) of the Social Security Act (42 U.S.C. 1396a(a)(10)(A)(i)(IV), (a)(10)(A)(ii)(IX)) was not minimum essential coverage. In order to ensure that women losing eligibility for coverage of pregnancy-related services as described above are not left without an option to enroll in a QHP after the conclusion of Medicaid eligibility, in paragraph (d)(1), we proposed that the Exchange permit qualified individuals and their dependents to enroll in a new QHP if they lose eligibility for such pregnancy-related services. We solicited comments regarding whether there are other situations in which an individual loses coverage that is not defined as minimum essential coverage and should be provided with a special enrollment period.

We proposed to add to paragraph (c) to specify that the Exchange must permit qualified individuals and their dependents to access the special enrollment periods described in paragraph (d)(1) for up to 60 days prior to the end of the qualified individual's or his or her dependent's existing coverage. This is consistent with existing regulations in paragraph (d)(6)(iii) that are specific to an individual who is enrolled in an eligible employer-sponsored plan who is determined newly eligible for advance payments of the premium tax credit based in part on a finding that such individual is ineligible for qualifying coverage in an eligible employer-sponsored plan. To improve the clarity and structure of this rule, we proposed to move the language in paragraph (d)(6)(iii) regarding the 60 days prior access to the special enrollment period to paragraph (c). The proposed change, to paragraph (d)(1) that would expand the ability to report a change and select a plan in advance to all individuals who are described in paragraph (d)(1) is designed to allow an individual who is losing eligibility for coverage outside the Exchange to transition to coverage offered through an Exchange without a gap in coverage, but with protections to ensure that advance payments of the premium tax credit are not provided in advance of the loss of eligibility for minimum essential coverage outside the Exchange. Accordingly, we note that individuals are not eligible for advance payments of the premium tax credit until they are no longer enrolled in minimum essential coverage outside the Exchange. While consumers will be able to report the loss of coverage and select a QHP offered on the Exchange in advance of the loss, their coverage effective date will be no earlier than the first day of the month following the loss of coverage (for example, if the loss of minimum essential coverage is on May 31, 2014 and the consumer reports the loss on March 5, 2014, coverage will not be effective until June 1, 2014). Lastly, we proposed to make conforming changes to

paragraphs (b)(2)(ii) and (e) to align with the changes in terminology proposed in paragraph (d)(1).

In paragraphs (d)(4), (d)(5), (d)(9) and (d)(10), we provide special enrollment periods for errors of the Exchange or HHS, contract violations by the QHP, exceptional circumstances and misconduct by a non-Exchange entity. Existing paragraph (b)(2)(iii) specifies that for a plan selection made during one of the special enrollment periods under paragraphs (d)(4), (d)(5), and (d)(9), coverage must be effective on an appropriate date based on the circumstances of the special enrollment period, in accordance with guidelines issued by HHS, and provides two options for that effective date. We proposed to add special enrollment periods triggered under paragraph (d)(10) to those special enrollment periods for which these special coverage effective dates are available. In order to ensure that the Exchange has sufficient flexibility with which to address the types of scenarios that may trigger these special enrollment periods, we proposed to amend paragraph (b)(2)(iii) to remove the restriction to these two options. The resulting proposed regulatory text would allow the Exchange to set an effective date based on what is appropriate to the circumstances, in accordance with any guidelines issued by HHS. Similarly, in order to ensure that the Exchange sets the length of these same special enrollment periods to be appropriate to the circumstances of the specific enrollment period, we proposed to modify paragraph (c) to specify that the Exchange may define the length of these special enrollment periods as appropriate based on the circumstances of the special enrollment period, in accordance with any guidelines issued by HHS. We believe that this flexibility is important to ensure that the special enrollment periods can be implemented as intended.

Section 155.420(e) clarifies what qualifies as loss of coverage for purposes of the special enrollment period described in paragraph (d)(1). We proposed to modify this paragraph to

clarify that voluntary termination does not qualify as loss of coverage for purposes of a special enrollment period, since the intent of this special enrollment period is to ensure that an individual who is losing coverage can transition to the Exchange without interruption, and not to allow an individual to switch from another form of coverage to the Exchange during the year when the other form of coverage remains available and he or she does not qualify for another special enrollment period described in this section. We solicited comments regarding this clarification.

Comment: We received comments both in support of, and opposed to, the proposed language providing flexibility for Exchanges to allow either retroactive coverage back to the date of the birth, adoption, placement for adoption, or placement in foster care, or a coverage effective date later than the date of the birth, adoption, placement for adoption, or placement in foster care.. Some commenters supported providing prospective enrollment at the option of the Exchange, and the consumer. Other commenters opposed allowing retroactive coverage and preferred that Exchanges follow regular effective dates. One commenter suggested we clarify that coverage may be effective no later than the first of the month following the occurrence of the triggering event. Additionally, commenters sought clarification on the length of time before the coverage may become effective following the triggering event

Response: Section 1311(c)(6)(C) of the Affordable Care Act which references section 9801 of the Internal Revenue Code of 1986 requires retroactivity for birth, adoption, or placement for adoption, and we received commenter support for allowing retroactive or prospective enrollment at the option of the Exchange. We therefore are finalizing paragraph (b)(2)(i) with the clarification that coverage may be effective no later than the first of the month following the occurrence of the triggering event at the option of the consumer. Without this clarification there is a potential for adverse selection whereby a consumer could choose an

effective date on which they knew services would be utilized. Accordingly, we are finalizing this provision with the clarification. State Exchanges have flexibility when and if they will provide the option.

Comment: One commenter recommended allowing for mid-month coverage effective dates in the case of loss of minimum essential coverage, as described in paragraph (d)(1) of this section.

Response: We do not intend to allow for mid-month coverage effective dates in the case of loss of minimum essential coverage at this time. The language in (c)(2)(i) provides consumers with adequate flexibility to avoid a gap in coverage. We appreciate the comment and may consider mid-month coverage effective dates in future rulemaking.

Comment: Commenters encouraged clarification on effective dates provided in §155.420(b)(2)(iii). Specifically, commenters recommended allowing for retroactive effective dates back to when the triggering event occurred and recommended retroactivity be at the option of the consumer.

Response: The language proposed in this section does not prohibit Exchanges from providing retroactive coverage for special enrollment periods as described in paragraphs (d)(4), (d)(5), (d)(9), or (d)(10) of this section. Rather, the proposed language provides flexibility for Exchanges to determine the appropriate effective date based on the circumstances of the special enrollment period. Exchanges may provide retroactive coverage at the choice of the consumer provided it is deemed appropriate by the Exchange. Accordingly, we are finalizing this paragraph as proposed.

Comment: Commenters asked that HHS consistently define and apply effective dates and lengths of special enrollment periods to increase consistent application across enrollees. One

commenter requested HHS develop a minimum length of 60 days for all special enrollment periods.

Response: As provided in paragraph (b)(2)(iii) of this section, Exchanges must ensure that coverage is effective on an appropriate date based on the circumstances of the special enrollment period. Due to the unique circumstances of each special enrollment period, it could be harmful to the consumer to implement a general effective date policy. If a consumer does not agree with a special enrollment decision they may request an appeal of the effective date as provided in §155.505(b)(1)(i). Therefore, we are finalizing this paragraph as proposed.

Comment: One commenter recommended that special enrollment periods conclude at the end of the enrollment period, or when an individual selects a QHP, whichever is sooner.

Response: The current regulation at §155.410(a)(1) provides that “The Exchange must provide an initial open enrollment period and annual open enrollment periods consistent with this section, during which qualified individuals may enroll in a QHP and enrollees may change QHPs.” This regulation does not provide for limiting consumers’ opportunity to enroll during the specified enrollment periods. Because the language recommended by the commentator would directly conflict with §155.410(a)(1), we decline to accept this recommendation.

Comment: One commenter requested the length of the special enrollment period provided in §155.420(d)(6)(iii) be extended to allow the employee time to receive the notice of their COBRA rights. The commenter also requested clarification that a consumer could elect COBRA coverage prior to their coverage effective date.

Response: We believe that providing the individual with the flexibility provided in (c)(2)(ii) of this section to select an Exchange QHP based on their anticipated loss of qualifying employer sponsored coverage up to 60 days in advance of the loss combined with the 60 day

special enrollment period provided in (c)(1) of this section will minimize any potential gap in coverage resulting from a loss of employment notwithstanding the required timeline associated with the employer notifying the group plan administrator and the group plan administration notifying the employee of their COBRA rights. On May 2, 2014 we published a bulletin that provided a special enrollment period for persons eligible for COBRA and COBRA beneficiaries. Additionally, on May 2, 2014 the Department of Labor released revised model notices for group health plans to provide to covered employees and their families which provides updated information on COBRA benefits and the Exchange. Finally, we note that an individual could elect to enroll in COBRA coverage and enroll in Exchange coverage when he or she loses employer-sponsored coverage, and disenroll from COBRA when Exchange coverage becomes effective. The consumer is not eligible for advance payments of the premium tax credit or CSRs while enrolled in COBRA. Accordingly, we are finalizing as proposed.

Comment: One commenter requested that HHS extend the proposal to allow individuals prior access to a special enrollment period for individuals who are gaining access to a new QHP as a result of a move.

Response: While we did not solicit comments on this provision. In future rulemaking we may allow consumers eligible for special enrollment periods other than those provided in (c)(2)(i) of this section to report in advance.

Comment: Commenters supported the proposed flexibility provided for consumers to select a plan in advance of the triggering events described in paragraphs (d)(1) and (d)(6)(iii) of this section, which pertain to the loss of coverage or qualifying coverage in an eligible employer-sponsored plan, respectively to prevent a gap in coverage.

Response: Given commenter support, we are finalizing this provision with clarification. We note that a consumer who loses coverage as described in paragraphs (d)(1) or (d)(6)(iii) may report a loss of coverage 60 days before or 60 days after the loss. If plan selection occurs on or before the date of the loss, the effective date will be the first day of the month following plan selection. If plan selection is made after the date of the loss, Exchanges may choose to either follow regular effective dates under paragraph (b)(1) of this section or allow for an effective date of the first of the month following plan selection, as the previous rule allowed for both scenarios. The FFE allows for coverage to be effective the first day of the month following plan selection when plan selection is made after the loss. For purposes of (d)(1) and (d)(6)(iii), the date of the “loss of coverage” means the last day a consumer would have coverage. Exchanges will have the flexibility provided under (b)(3)(i) of this section to allow for earlier effective dates if all issuers in the service area agree.

Comment: Multiple commenters supported the proposed additions to establish a special enrollment period for consumers who are enrolled in non-calendar year individual health insurance policies. Commenters requested HHS align the length of the special enrollment period in accordance with 45 CFR 147.104(b)(2). Additionally, commenters requested this special enrollment period be provided to consumers whose transitional policy, or group health plan, is renewing.

Response: Section 147.104(b)(2) allows consumer to report the non-renewal in the plan 30 days prior to the date the policy year ends while 147.104(b)(4) provides 60 days for the special enrollment period. The proposed rule allows consumers to report their intent not to renew a non-calendar year policy (including a transitional policy) 60 days in advance of the date the policy year ends and select a plan although the coverage effective date will not be until the first

day of the month following the termination date. Additionally, the proposed rule provides 60 days from that date to select a QHP through the Exchange. We are finalizing this provision in the proposed rule without modification. Since the intention of this provision is to align with the market rules, we are citing directly to §147.104(b)(2). In addition, on May 2, 2014 we released guidance allowing consumers in this scenario to report a loss of coverage to the Exchange under the authority provided in paragraph (d)(9) of this section.

Comment: Commenters were supportive of the newly established special enrollment period for women losing pregnancy-related Medicaid coverage.

Response: We are finalizing the language as proposed.

Comment: Commenters requested special enrollment periods be established for a variety of triggering events including; pregnancy, tobacco cessation after six months which may impact the consumer's premium, same sex couples who enter into a legally recognized relationship other than marriage, individuals who make an individual responsibility payment for not having coverage in 2014, and persons who are victims of domestic violence. Additionally, commenters requested HHS regulate on certain special enrollment periods which exist in sub-regulatory guidance including; benefit display errors and loss of exemptions.

Response: We did not solicit comment on this provision and the comments received are out of scope with this regulation. However, Exchanges retain the flexibility provided in paragraph (d)(4) and (d)(9) of this section to define errors of the Exchange and provide special enrollment periods for exceptional circumstances to provide such special enrollment periods as determined appropriate by the Exchange. For instance, the Federally-facilitated Exchange recently provided guidance that survivors of domestic abuse are eligible for a limited duration special enrollment period as a result of guidance released by the Internal Revenue Service.

Comment: Multiple commenters responded to our solicitation regarding situations other than loss of eligibility of pregnancy-related services in which an individual loses coverage that is not defined as minimum essential coverage and should be provided a special enrollment period. Suggestions included; AmeriCorps, Indian Health Service, student health coverage that is not designated minimum essential coverage, foreign health coverage that is not designated minimum essential coverage, excepted benefits offered by an employer, medically needy Medicaid coverage, and family planning Medicaid services.

Response: To ensure individuals who lose certain types of limited Medicaid coverage which generally meets their primary and specialty health care needs, but which is not recognized as minimum essential coverage, have the option to enroll in a QHP at the conclusion of Medicaid eligibility, we are expanding the special enrollment period to include loss of medically needy as well as pregnancy-related coverage which is not recognized as minimum essential coverage. With respect to the loss of medically needy coverage, we are limiting beneficiaries to one special enrollment period per calendar year based on loss of medically needy coverage. This enables individuals with only medically needy coverage to enroll in a QHP outside of the open enrollment period, but avoids permitting individuals to switch QHPs multiple times a year each time they reach the end of their medically needy budget period within the same calendar year. We are not extending a special enrollment period to individuals who lose Medicaid coverage of family planning services, as such coverage is limited to a narrow set of benefits which does not meet the covered individuals' primary or specialty health care needs, other than family planning services. HHS may provide a special enrollment period for other similar situations in future rulemaking or guidance. In addition, on May 2, 2014 we published a bulletin that provided a special enrollment period for individuals who are beginning service in the AmeriCorps State and

National, VISTA, or NCCC programs and for individuals who are concluding their service in the AmeriCorps State and National, VISTA, or NCCC programs and are losing access to short-term limited duration coverage or self-funded coverage.

Comment: We received comments requesting we clarify the criteria for qualifying events described in paragraphs (d)(4), (d)(5), (d)(9), and (d)(10). Commenters also requested clarification on the process for notifying consumers who are impacted by an exchange error.

Response: We believe the ability for Exchanges to respond appropriately to the circumstances surrounding an individual's special enrollment period is necessary. CMS has previously issued guidance describing guidelines on the criteria for special enrollment periods which fall under the authority of paragraphs (d)(4), (d)(9), and (d)(10) in the FFE.

Comment: Commenters recommended amending paragraph (d)(6)(i) to include individuals who are not current Exchange enrollees. Such revision would allow the following groups of consumers to utilize the special enrollment period; people who live in States that did not adopt Medicaid expansion, people who divorce during the year, victims of domestic violence that occurs after May 31, 2014, people who experience the death of a spouse, and people who lose a job but did not enroll in employer-sponsored coverage because of high costs.

Response: We note that many individuals in these circumstances may have other triggering events that would qualify them for an existing special enrollment period. However, we remain concerned that expanding paragraph (d)(6)(iii) could result in adverse selection and destabilization of the individual insurance market. We have provided sub-regulatory guidance on special enrollment periods under paragraph (d)(4) and (d)(9) of this section including for COBRA beneficiaries, survivors of domestic abuse, and people who divorce during the year and

may continue to do so in the future. Accordingly, we are finalizing as proposed without additional modification.

Comment: We received comments both for and against the proposed addition to paragraph (e) of this section stating that voluntary termination does not qualify an individual for a loss of coverage special enrollment period.

Response: The proposed language clarifies existing regulations that termination includes voluntary termination by an enrollee. The intention of paragraph (e) of this section is to stabilize the market by preventing individuals from voluntarily terminating their coverage and then utilizing the loss of minimum essential coverage special enrollment period provided in paragraph (d)(1) of this section. Accordingly, we are finalizing as proposed.

Summary of Regulatory Changes

We are finalizing the provisions proposed in section § 155.420 of the proposed rule with the following modifications. In paragraph (b)(2)(i), we provide that coverage must be effective on the date of the birth, adoption or placement for adoption, placement for foster care, or the Exchange may allow the consumer to select a coverage effective date of the first of the month following the date of birth, adoption, placement for foster care, or placement for adoption. In paragraph (b)(2)(ii), we clarify that coverage is effective the first day of the month following plan selection. In paragraph (b)(2)(iii) we provide flexibility for Exchanges to ensure coverage is effective based on the specific circumstances of the special enrollment period. We also have added a new paragraph (b)(2)(iv) that clarifies a consumer's ability to select a plan 60 days before and after a loss of coverage described in subparagraph (d)(1) and (d)(6)(iii). Finally, in paragraph (d)(1), we define the date of the loss of coverage for each triggering event described

under paragraph and establish a special enrollment period for individuals losing medically needy coverage.

d. Termination of Coverage (§155.430)

We proposed to add paragraph (e) to §155.430 to establish the difference between a termination and a cancellation and establish the significance of a reinstatement action in the context of QHP coverage offered through an Exchange. Specifically, we proposed to specify that a cancellation is a specific type of termination action taken that ends a qualified individual's coverage on or before the effective date, thus rendering coverage as never effective. In contrast, a termination is an action taken after the effective date of coverage that ends an enrollee's coverage effective on a date after the coverage effective date. In a cancellation, the effect of the QHP's action would be that a qualified individual does not receive coverage from the QHP, whereas in a termination the QHP covers the enrollee for some period of time and would be liable for covered services that the enrollee received during the time period between the coverage effective date and the termination date, under the terms of the coverage. A reinstatement action is a correction of an erroneous termination or cancellation action resulting in restoration of an enrollment with no break in coverage.

In addition to establishing the difference between cancellations and terminations, we also proposed that an Exchange may establish operational standards for QHP issuers for implementing terminations, cancellations, and reinstatements. Enrollment systems for both SBEs and the FFE continue to evolve, and we believe that the Exchange's ability to issue operational instructions will enable both the Exchange and the issuer community to respond more effectively to changing systems and changing processes. We believe the effectiveness of

this approach has been demonstrated in other programs administered by CMS, specifically the Medicare Advantage and Medicare Part D programs.

Further, we proposed to clarify in paragraph (d)(6) that the termination effective date for a QHP would be the day before the effective date of coverage in a different QHP even in cases of retroactive enrollments. This could occur when a consumer is granted a special enrollment period to change QHPs with a retroactive coverage effective date under 155.420(b)(2)(iii). For coverage that is terminated retroactively, CMS would adjust any applicable payments to the original QHP issuer based on the retroactive termination date, in order to recoup any advance payments of the premium tax credit and cost-sharing reductions made to the former issuer for the enrollee. The Exchange would be required to ensure that the former issuer refunds or credits any premium paid to the issuer by the enrollee and reverse claim payments for services rendered during the retroactive coverage period. We sought comment on whether to add a specific requirement to this effect on issuers in Part 156.

Conversely, in the case of a retroactive coverage date, CMS would provide the gaining issuer any applicable advance payments of the premium tax credit and CSRs based on the retroactive coverage effective date. CSR reconciliation would occur for all CSRs provided beginning with the retroactive coverage date. The gaining issuer would collect the enrollee's portion of the premium for all months of coverage and would be required to adjudicate the enrollee's claims incurred during the retroactive period, and provide any applicable CSRs.

Comment: We received several comments supporting the provision ensuring that consumers receive the benefit of the advance payments of the premium tax credits and CSRs to which they are entitled and refunded any premiums from the issuer from which the consumer terminated coverage. However, some commenters opposed the requirement for issuers to refund

out-of-pocket payments since those payments are made by consumers directly to providers. Another commenter asked for clarification of the impact of a retroactive termination and effective date on deductibles and accumulators.

Response: The Exchange must ensure that appropriate actions are taken following a retroactive termination. Under the policy finalized in this rule, when a retroactive termination and enrollment results in the enrollee changing issuers, the Exchange must ensure that the former issuer refunds or credits any premium paid to the issuer by or for the enrollee for coverage after the retroactive date, reverses any claims for services provided after the retroactive termination date, and recoups payments made to providers for services provided to the enrollee after the retroactive termination date. The former issuer must also ensure that providers refund to the enrollee any cost sharing paid by or for the enrollee (other than CSRs to be reimbursed by the Federal government). CMS will also recoup any advance payments of the premium tax credit and CSRs provided to the issuer for the enrollee back to the retroactive termination date

The gaining issuer in turn, should collect the enrollee's portion of the premium and is responsible for any covered services incurred, in each case for the period following the retroactive effective date of coverage. CMS will also provide the gaining issuer any applicable advance payments of the premium tax credit and CSRs for the enrollee back to the retroactive effective date of coverage. (We intend to provide additional guidance regarding how issuers should handle a claim that spans a period of time in which the enrollee has coverage from two separate issuers in such circumstances.) Providers are responsible for billing the gaining issuer for any covered services incurred back the retroactive enrollment date, and the issuer must ensure that the provider collects only the cost sharing for the covered service to reflect the enrollee's cost-sharing obligation for the service under the gaining issuer. We acknowledge that

such an adjustment may result in the enrollee owing the provider additional funds, depending on the cost sharing and benefit structure of the new plan. We note that consistent with 45 CFR 156.410(c)(1) and our CMS Bulletin to Exchanges on the Availability of Retroactive Advance Payments of the PTC and CSRs in 2014 Due to Exceptional Circumstances, dated February 27, 2014, any refund or credit for any excess cost sharing or premium paid for or on behalf of the individual must be provided (or begin to be provided in the case of a credit) with 45 calendar days of the date of discovery of the excess cost sharing or premium paid.

If an applicant switches QHP issuers, we do not require out-of-pocket amounts paid under the prior plan to carry over to the new QHP issuer, but defer to issuers and State laws with regard to how out-of-pocket payments under the former issuer's plan should be accounted for in the deductibles and limitations on cost sharing under the new issuer's plan. Comment: We received a comment recommending that if a consumer enrolls in a different QHP with the same issuer, the issuer should not be required to reverse claim payments, and should not be required to refund out-of-pocket payments, but could instead apply any cost-sharing paid to the new QHP's annual limitation on cost sharing. The same commenter also sought clarification on how out-of-pocket payments for prescription drugs, most of which are adjudicated at the point of sale, will be handled in the case of a change in QHP issuers with a retroactive effective date.

Response: We are finalizing the proposed provision as proposed, noting that the processes set forth in the final rule are designed to ensure that consumers are provided the CSRs and advance payments of the premium tax credit for which they determined eligible, and are refunded any excess premiums paid or out-of-pocket payments made by or for the enrollee for covered benefits and services incurred. Applying enrollee cost sharing or other out-of-pocket spending already paid to the new QHP's accumulators, such as deductibles, or limitations on cost

sharing or out-of-pocket spending, will not always be equivalent to providing a refund. For example, for an enrollee that does not exceed the deductible for a benefit year, simply accumulating excess cost sharing already paid may mean the enrollee will have paid more in cost sharing than required under the new plan. However, we recognize that, when the enrollee switch plans within the same issuer (or between variations of the same plan), reversing the claims and providing refunds may not be the most efficient way of adjusting the enrollee's portion of the premium and any differences in cost sharing. Therefore, in such circumstances, the Exchange and the issuer will be considered to be in compliance with the policy set forth in this rule as long as the enrollee's premium payments and cost sharing are adjusted to reflect the enrollee's obligations under the new plan or variation and providers are made whole. Thus, the issuer may elect to make the enrollee whole for cost sharing directly through a refund or credit without requiring the provider to provide any refund directly to the enrollee, and may net provider payments to reflect the provider's obligations and payments due. Furthermore, consistent with 45 CFR 156.425(b), in the case of a change in assignment to a different plan variation (or standard plan without CSRs) of the same QHP in the course of a benefit year under this section, the QHP issuer must ensure that any cost sharing paid by the applicable individual under the previous plan variations (or standard plan without CSRs) for that benefit year is taken into account in the new plan variation.

Under the policy and processes set forth in this final rule, prescription claims should be treated in the same manner as other claims.

Comment: Many commenters supported the new definitions for terminations and cancellations to codify the existing practices included in the enrollment standards as well as the inclusion of a definition for reinstatement. One commenter did not recommend guidance to

issuers to follow operational instructions issued by the Exchange given the limited nature of retroactive effective dates that result in a termination. However, another commenter recommended that that HHS require, not solely permit, Exchanges to establish operational procedures for issuers in these circumstances and place a requirement on issuers to follow the established procedures. In doing so, all issuers participating in the Exchange would be required to comply with similar procedures on terminations, cancellations, and reinstatements to ensure a consistent process. Additionally, the commenter stated that simplifying the procedures among QHP issuers would be in the consumers' interest and avoid consumer confusion, especially in situations where members of the household may be in different QHPs.

Response: We agree that if an Exchange establishes operational instructions for implementing terminations, cancellations, and reinstatements, then issuers should be required to follow such procedures. However, we still believe it is up to the Exchange to determine whether or not to establish procedures. Therefore, we are finalizing §155.430(e) as proposed, while adding a corresponding paragraph (j) to §156.270, to specify that QHP issuers must follow the transaction rules established by the Exchange in accordance with §155.430(e).

Comment: We received a comment requesting that CMS reconsider the implementation of the 90-day grace period and require that health plans pay any claims during the entire grace period.

Response: We note that the comment is outside the scope of this rulemaking. Requirements for issues regarding grace periods are addressed at 45 CFR §156.270.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.430 of the proposed rule without modification. However, we are adding §156.270(j) to specify that QHP issuers must follow the

transaction rules established by the Exchange in accordance with §155.430(e) based on comments we solicited and ensuring a consistency of operational procedures among issuers in the Exchange.

5. Subpart F—Appeals of Eligibility Determinations for Exchange Participation and Insurance Affordability Programs

a. General Eligibility Appeals Requirements (§155.505)

In §155.505, we proposed a technical correction to paragraph (b)(4) by removing “; and” at the end of the paragraph and adding a period in its place.

Summary of Regulatory Changes

We receive no comments on this proposal and are finalizing the provision as proposed.

b. Dismissals (§155.530)

In §155.530, we proposed to amend paragraph (a)(1) to provide an additional method for appellants to withdraw appeal requests. The existing provision requires an appellant who wishes to withdraw his or her appeal request to do so in writing (hard copy or electronic). We proposed to include the alternative for an appellant to withdraw his or her appeal by telephone, if the appeals entity is capable of accepting telephonic withdrawals. In paragraphs (a)(1)(i)(A) and (B), we proposed the requirements for providing a telephonic withdrawal process. Specifically, we proposed that the appeals entity must record in full the appellant’s statement and telephonic signature made under penalty of perjury, and provide a written (in hard copy or electronically) confirmation to the appellant documenting the telephonic interaction. We sought comment on this proposed amendment, including the proposed requirements for accepting telephonic withdrawals and the potential misalignment with Medicaid fair hearing rules caused by this proposed amendment.

Comment: Nearly all the comments we received in response to the proposal to provide the option for telephonic withdrawals were supportive. This included many positive comments from State Exchanges. Commenters noted the additional method to withdraw appeals would ease the burden on appeals entities by protecting resources while providing an efficient means for consumers to end their appeal at their discretion. We also received support from consumer advocate groups for the proposed provision requiring written documentation of the telephonic interaction as well as the proposed requirement that the appellant's telephonic statement be recorded in full and include a telephonic signature made under penalty of perjury. However, we also received a comment requesting that we not finalize the provisions requiring the appellant's telephonic statement be recorded in full and a written confirmation because they are burdensome and duplicative. The commenter suggested that simply providing written documentation of a telephonic withdrawal with an option for the appellant to request to vacate the withdrawal within a specific period of time is sufficient.

Response: We agree with commenters that incorporating this option for telephonic withdrawals will assist appeals entities in maintaining an efficient process by providing a convenient method for appellants to end an appeal at their option, thereby, protecting resources for other appeals-related activities. We understand the concern that the requirements for providing a telephonic withdrawal process are significant and call for both a full recording of the appellant's telephonic withdrawal and a confirmation of the telephonic withdrawal sent in writing. However, the appellant's right to a hearing is the central concern of the appeals process and any mechanism for relinquishing the right to the hearing must include sufficient safeguards. The requirement for both a recording and a written confirmation of the telephonic withdrawal are meant to ensure that the appellant's right to a hearing is safeguarded. Further, we note that the

preamble to the proposed rule acknowledged that the requirement to provide confirmation of a telephonic withdrawal can be met through issuance of the dismissal notice, which is required to contain instructions on how to request to vacate the dismissal in accordance with §155.530(b)(3). Therefore, we finalize the provision for telephonic withdrawal as proposed.

Comment: A few commenters cited the potential vulnerabilities of appellants under a telephonic withdrawal process. For instance, appellants may be vulnerable to coaching by appeals entity staff to withdraw their appeal over the telephone. Similarly, an appellant may feel pressured to withdraw an appeal prematurely after an informal resolution if the appeals entity initiates such a discussion with the appellant by telephone. However, the commenter also acknowledged that if an appellant initiates the call to withdraw the appeal, no such concern exists. One commenter recommended that HHS create scripted information about the significance of withdrawing an appeal that includes an attestation of understanding by the consumer to be used by Exchange appeals entities to help protect appellants.

Response: While there is potential for undue influence on an appellant to close an appeal in some cases, we also realize that appeals entities aim to run an efficient process. As noted above, we believe the process we have proposed fairly balances these concerns and provides sufficient protections for appellants, including the requirement that telephonic withdrawals be recorded in full, made under penalty of perjury, and confirmed in writing. In addition, withdrawals result in dismissal notices under §155.530(b), which provide for the opportunity to request to vacate a dismissal for good cause. With these protections in place, we are confident that appellant's interests will be safeguarded.

Comment: We received one comment on the alignment of our proposed policy with Medicaid fair hearing rules. The commenter opposed the potential misalignment caused by the

proposed provision and noted that only permitting a written withdrawal, as in the current rule and in Medicaid fair hearing rules, is a strong consumer protection measure.

Response: Although the option to implement telephonic withdrawals will put the Exchange rules out of alignment with the Medicaid fair hearing rules, it is our intent to provide a modernized appeals process that can take advantage of technology and still safeguard appellant rights, as noted above. CMS is considering its policy regarding written and telephonic withdrawals in Medicaid and may issue future guidance on this issue. However, we note that as a result of this current incongruence in rules, appeals entities must ensure that appellants are afforded the appropriate rights. Individuals appealing denials of Medicaid eligibility may not withdraw their appeal via telephone, even if the appeals entity meets the requirements for providing such a process under the Exchange rule. Current appellants of Medicaid eligibility determinations may only withdraw an appeal in writing in accordance with 42 CFR 431.223(a).

Comment: Some commenters suggested that the written confirmation of the telephonic withdrawal should include a mechanism for challenging the validity of the telephonic signature.

Response: As noted in the preamble to the proposed rule, the requirement to provide confirmation of a telephonic withdrawal can be met through issuance of the dismissal notice, which is required to contain instructions on how to request to vacate the dismissal in accordance with §155.530(b)(3). However, even if the appeals entity decides to provide confirmation of the telephonic withdrawal in a notice separate from the dismissal notice, a dismissal notice, including instructions on requesting to vacate a dismissal, is required in the case of a withdrawal nonetheless. Therefore, all appellants who provide a telephonic withdrawal will receive instructions on requesting to vacate the dismissal, which would have the effect of reopening the appeal.

Comment: We received one comment suggesting that telephonic withdrawals only be accepted through the Exchange toll-free number and that assisters, Navigators, and certified application counselors not be authorized to accept telephonic withdrawals.

Response: If an appeals entity wishes to provide telephonic withdrawals in accordance with the final requirements, the appeals entity must maintain a phone line, capable of recording calls from appellants for the purposes of withdrawing an appeal. Whether that phone line is the same as the Exchange's customer service number or not is at the discretion of the appeals entity. We also note that, although appellants may seek assistance from assisters, Navigators, and certified application counselors, these consumer support entities are not authorized to operate any portion of the Exchange appeals process, including accepting telephonic withdrawals.

Summary of Regulatory Changes

We are finalizing the provision as proposed and note, as in the proposed rule, that this change also impacts employer appeal withdrawals by cross-reference at §155.555(f)(1).

c. Employer Appeals Process (§155.555)

We proposed to amend §155.555 by redesignating paragraphs (d)(1) through (d)(4) to more clearly delineate between the requirements associated with valid appeal requests versus invalid appeal requests. We note that under this proposed redesignation, paragraph (d)(4) would become new paragraph (d)(2), stating that upon receipt of an invalid appeal request, the appeals entity must promptly and without undue delay send written notice to the employer that the appeal request is not valid because it fails to meet the requirements of this section. New paragraph (d)(2) would also provide introductory language for the requirements provided in paragraphs (d)(2)(i) through (iv). The result of these proposed revisions would be to separate the

requirements for valid appeal requests in redesignated paragraph (d)(1) and the requirements for invalid appeal requests in new paragraph (d)(2).

Summary of Regulatory Changes

We received no comments on the proposed redesignations and are finalizing the redesignations as proposed.

6. Subpart G—Exchange Functions in the Individual Market: Eligibility Determinations for Exemptions

a. Required Contribution Percentage

Under section 5000A of the Code, an individual must maintain minimum essential coverage for each month, qualify for an exemption, or make a shared responsibility payment. Sections 5000A(d) and (e) provide for nine categories of exemptions, and authorize the Secretary to determine individuals' eligibility for some of the exemptions, including the hardship exemption. Sections 1.5000A-3(a) through (h) of 26 CFR enumerate the circumstances in which an individual may be exempt from the shared responsibility payment. These grounds for exemption include: (1) under 26 CFR 1.5000A-3(e), the individual lacks affordable coverage because the individual's annualized required contribution for minimum essential coverage for the month exceeds the required contribution percentage of the individual's household income; (2) under 26 CFR 1.5000A-3(h), the individual has in effect a hardship exemption certification issued by an Exchange because, based on the individual's projected household income, the individual is not eligible for affordable minimum essential coverage; and (3) as described in 45 CFR 155.605(g)(5), the individual and one or more employed members of his or her family have been determined eligible for affordable self-only employer-sponsored coverage through their respective employers, but the aggregate cost of employer-sponsored coverage for all the

employed members of the family exceeds 8 percent of household income for that calendar year. Determining eligibility for these exemptions requires comparison between the individual's share of the costs for obtaining minimum essential coverage and a certain percentage of the individual's household income, actual or projected, for the taxable year (the required contribution percentage). Under section 5000A(e)(1)(A) of the Code, the required contribution percentage is 8 percent. Section 5000A(e)(1)(D) of the Code and 26 CFR 1.5000A-3(e)(2)(ii) further provide that, for plan years beginning in any calendar year after 2014, the percentage will be the percentage determined by the Secretary to reflect the excess of the rate of premium growth between the preceding calendar year and 2013 over the rate of income growth for that period.

As discussed below, in this final rule, we establish a methodology for determining the excess of the rate of premium growth over the rate of income growth for a period, and establish the required contribution percentage for the 2015 calendar year. For calendar years after 2015, the required contribution percentage will be published in the annual HHS notice of benefit and payment parameters. We also define the required contribution percentage under §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. Finally, we modify §155.605(g)(5), which currently sets the required contribution percentage at 8 percent, so that the required contribution percentage for purpose of section 5000A in future years reflects the required contribution percentage for the applicable calendar year.

Methodology for Determining the Excess of the Rate of Premium Growth Over the Rate of Income Growth

In the proposed rule, we outlined and requested comments on methodologies for determining the excess of the rate of premium growth over the rate of income growth. We

discussed an approach under which the rate of premium growth over the rate of income growth for a particular calendar year would be calculated as the quotient of (x) one plus the rate of premium growth between the preceding calendar year and 2013, divided by (y) one plus the rate of income growth between the preceding calendar year and 2013. We sought comment on whether we should constrain this ratio to be greater than or equal to one, as well as the impact of these constraints on the excess of the rate of premium growth over the rate of income growth. We sought comment on this and other approaches for determining the excess of the rate of premium growth over the rate of income growth, and in particular, whether the excess of the rate of premium growth over income growth should be calculated based on the difference between the growth rates, the ratio of the growth rates, or through other methods, and whether the result should be subject to other adjustments.

In response to comments, we are finalizing the methodology outlined in the proposed rule, such that the rate of premium growth over the rate of income growth for a particular calendar year will be the quotient of (x) one plus the rate of premium growth between the preceding calendar year and 2013, carried out to ten significant digits, divided by (y) one plus the rate of income growth between the preceding calendar year and 2013, carried out to ten significant digits. The quotient will be carried out to ten significant digits, and multiplied by the required contribution percentage for 2014 (8 percent). The result will then be rounded to the nearest hundredth of a percent, to yield the required contribution percentage for the calendar year. We do not constrain this percentage to be greater than or equal to one, or subject it to other adjustments or constraints.

Comment: Several commenters supported our proposal that we perform this calculation using a ratio rather than a difference. One commenter suggested the formula be the quotient of

(x) one plus the rate of premium growth between the preceding calendar year and 2013, over (y) one plus the difference between the rate of premium growth between the preceding calendar year and 2013, and the rate of income growth between the preceding calendar year and 2013, stating that this would minimize volatility of the formula. Some commenters supported permitting the ratio to be less than one, while another commenter suggested that the ratio should be constrained to be greater than or equal to one, to avoid the required contribution increasing when both premium growth and income growth are negative. One commenter suggested a ceiling on the index factor of 1.1 to ensure that premium contributions do not increase by more than 1 percent of consumers' incomes.

Response: We believe that the methodology described above most accurately measures the relationship between changes in premiums and income. While we recognize some of the policy concerns raised by commenters, we believe that any constraints on the ratio could result in the required contribution percentage not fully reflecting the growth rates of premiums and income, which we believe is the general intent of the statute.

Comment: Some commenters recommended delaying any adjustments to the required contribution percentage. One commenter stated that adjustments to the required contribution percentage and to the applicable percentages used to calculate the premium tax credits under section 36B of the Code should be delayed until at least 2016, to permit fuller assessments of the consequences of these adjustments. Another commenter suggested delaying any increase in premium contributions for the foreseeable future, noting significant technical and administrative costs, such as revising online calculators and coding Exchange functions.

Response: While we recognize the commenters' concerns, we believe the required contribution percentage should track premium and income changes from year to year, and

delaying this adjustment would conflict with the general intent of the statute. We also anticipate that the operational changes associated with these adjustments will be manageable.

Premium Growth: In the proposed rule, we sought comment on whether we should use the premium adjustment percentage as a measure of premium growth for the purpose of calculating the adjustment to the required contribution percentage, and whether that adjustment should be constrained through the use of ceilings or floors. We also sought comment on whether other data sources or methods should be used to measure premium growth.

Taking into consideration the comments received, we are finalizing our proposal to measure the rate of premium growth for a calendar year by using the premium adjustment percentage for the year, without any adjustments or constraints. We provided in the 2015 Payment Notice²⁹ that the premium adjustment percentage, described at 45 CFR 156.130(e), will be published each year in the HHS notice of benefit and payment parameters, and will be used to adjust certain cost-sharing parameters established by the Affordable Care Act. As established in the 2015 Payment Notice, the premium adjustment percentage for 2015 is 4.213431463 percent.

Comment: Several commenters supported setting the rate of premium growth equal to the premium adjustment percentage. One commenter stated we should not consider constraining the annual rate of premium growth to equal or exceed zero, while another commenter argued that premium growth should be constrained to be a positive number. Another commenter suggested that HHS use actual, rather than projected, growth in private insurance premiums, and suggested that HHS delay implementation of any adjustment until the 2016 plan year, when a number of significant market changes would have concluded and when actual premium growth between

²⁹ Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2015, 79 FR 13744 (March 11, 2014).

2014 and 2015 will be known. One commenter was concerned that the trend in employer plan premiums may understate premium growth in the individual market.

Response: The premium adjustment percentage is calculated 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. As discussed in the 2015 Payment Notice, these projected premiums reflect premiums from nearly the entire private health insurance market. However, because these projected premiums will exclude premiums from the individual market, which are likely to be subject to a number of short-term effects related to implementation of market reforms, we believe these projections provide an appropriate measure of average per capita premiums for health insurance coverage for the initial years. However, as noted in the proposed rule, after the initial year(s) of implementation of market reforms, we may propose to change the methodology for calculating the premium adjustment percentage.

Income Growth: In the proposed rule, we discussed measuring the rate of income growth for a calendar year as the percentage by which the per capita GDP for the preceding calendar year exceeds the per capita GDP for 2013, carried out to ten significant digits. We stated that we were considering using the projections of per capita GDP used for the NHEA.³⁰ We sought comment on alternative sources of income data that we should consider, and whether adjustments should be made to our data source, or to the methodology outlined in the proposed rule. We also sought comment on whether we should seek to measure income growth per person under the age of 65 or per worker.

³⁰ See Table 1 in <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2012.pdf>.

In response to comments, in this final rule, we are establishing as the measure of income growth for a calendar year the percentage by which the per capita GDP for the preceding calendar year exceeds the per capita GDP for 2013, carried out to ten significant digits, using the projections of per capita GDP used for the NHEA. Under this methodology, the rate of income growth for 2015 is 3.608458790 percent. This measure is based on data sources that are consistent with the data sources used for determining premium projections, resulting in a consistent estimate of the ratio of premiums to income. In future years we may consider alternative income measures.

Comment: Commenters supported using per capita GDP for the purpose of calculating income growth, stating that this is a widely used measure of income. One commenter noted that it would not be technically sound to measure growth in GDP per person under age 65 or per worker, because GDP estimates are not available for those subsets of the population. Another commenter suggested that we consider whether per capita GDP sufficiently accounts for inflation and housing costs, and whether it overstates the income growth rate for lower income populations. Another commenter urged HHS not to use wage growth.

Response: Following consideration of comments received, we believe that growth in per capita GDP provides the most comprehensive and accurate measure of income growth available at this time. This measure is also consistent with the data that the CMS Office of the Actuary uses to project premiums for the NHEA. We may consider revising this measure in the future to account for future circumstances or data availability, including if alternative income measures or subsets of GDP become available.

Comment: One commenter stated that in order to avoid an increase in the required contribution percentage during a recession, the annual change in per capita GDP should be

constrained to equal or exceed zero, and that benchmark revisions should not be allowed to affect the calculation of the rate of income growth. Another commenter suggested that the formula should account for negative income changes, such that in a year where income decreases, there should be a decrease in the affordability threshold. Another commenter opposed negative income growth, because it would increase the required contribution percentage during times of economic decline.

Response: We acknowledge that in a recession a negative change in per capita GDP could result in an increase in the ratio of premiums to income. However, we note that such occurrences have been rare in recent decades, and constraining income growth to be positive would risk the required contribution percentage not fully reflecting the growth rates of premiums and income, which we believe is the general intent of the statute.

Required Contribution Percentage for 2015

The required contribution percentage for 2014 is 8.00 percent. Based on the methodology finalized in this final rule, the rate of premium growth over the rate of income growth for 2015 is $1.04213431463/1.0360845879$ or 1.005839028. This results in a required contribution percentage for 2015 of 8.00×1.005839028 , or 8.05 percent, when rounded to the nearest one-hundredth of one percent.

Summary of Regulatory Changes

We define the required contribution percentage under §155.600(a) to mean the product of eight 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. We are also amending §155.605(g)(5), so that the required contribution percentage for this exemption in future years reflects the required contribution percentage for the applicable calendar year.

b. Options for Conducting Eligibility Determinations for Exemptions (§155.625)

In §155.625, we established an option under which a State Exchange could adopt an eligibility determination for an exemption from the shared responsibility payment that was made by HHS, provided that certain conditions were met. We proposed to revise §155.625 to remove the option for a State Exchange to adopt an eligibility determination for an exemption from the shared responsibility payment made by HHS for applications submitted on or after November 15, 2014. Under this proposal, HHS would continue to provide support in this area for applications up until that date.

Comment: We received several comments, many from State Exchanges, urging HHS not to eliminate the option described in §155.625(b). Commenters opposed this change because of the burden, in terms of cost, time and resources it would put on State Exchanges to accommodate the provision of exemption determinations. Several commenters from State Exchanges noted that resources have already been allocated and timelines already established for the systems development and shared the concern that States will not have the resources or administrative capacity to carry out this function by November 15, 2014. Under the proposed timeline, one commenter anticipated that State Exchanges would, at best, only be able to implement a paper-based and manual exemption eligibility determination process. One commenter shared the belief that the current process could be modified to HHS' concerns by asking the consumer to include the information that only State Exchanges have, such as the lowest cost bronze plan. A majority of commenters agreed that, if HHS proceeds with the proposed change, State Exchanges need additional time to develop their own exemption processes; therefore, commenters suggested that implementation begin November 15, 2015. Finally, one commenter agreed that having a single entity conduct exemption determinations makes the most sense but, to achieve this, HHS must

provide clear implementation standards to guide State Exchanges and consumers for uniform application of the law.

Response: We appreciate the comments received on this proposed change, particularly those from State Exchanges. We acknowledge the impact of such a change on State Exchanges in terms of administrative costs and development timelines. As noted below, we are providing Exchanges additional time to make this change.

Additionally, and as previously stated in the proposed rule, we support this change because the current procedure introduces significant information technology development and administrative burden into a process that could otherwise be executed at a single entity. For example, it requires coordinated information sharing systems between State Exchanges and HHS to send, receive, and process the information needed to make an exemption determination, particularly for those exemptions that require information only held by the State Exchange, such as the cost of the lowest-cost bronze plan net of advance payments of the premium tax credit. Furthermore, the current process requires dual customer service responsibilities at both HHS and the State Exchange, which creates challenges for consumers and Exchange customer service representatives. Therefore, we do not believe that there are significant efficiencies to be gained by HHS providing this service to State Exchanges.

HHS is committed to providing technical assistance to State Exchanges to develop the capacity to handle the minimum functions of granting certificates of exemption. HHS has developed and released a set of model paper applications that can be adopted by State Exchanges and will consider providing additional guidance, such as example standard operating procedures, to assist State Exchanges as they develop their own exemption processes. We do understand the time and budget constraints State Exchanges face in order to adjust their processes to

accommodate this change and agree that additional time is needed for State Exchanges to come into compliance with this requirement. Accordingly, we are finalizing the provision with an amendment to eliminate the option for HHS to provide exemption determinations for State Exchanges for applications submitted after the start of open enrollment for the 2016 plan year.

Summary of Regulatory Changes

We are amending §155.625(a) and (b) to state that the Exchange may adopt an exemption eligibility determination made by HHS for applications submitted before the start of open enrollment for the 2016 plan year.

7. Subpart H—Exchange Functions: Small Business Health Options Program

a. Functions of a SHOP (§155.705)

Sections 155.705(b)(2) and (3) currently provide that, for plan years beginning on or after January 1, 2015, all SHOPS must make available to qualified employers the option of selecting an actuarial value level of coverage as described in section 1302(d)(1) of the Affordable Care Act and make all QHPs at that level available to qualified employees (“employee choice”). Additionally, pursuant to section 1312(a)(2) of the Affordable Care Act, qualified employers may provide support for coverage of employees under a QHP by selecting any level of coverage under section 1302(d) to be made available to employees, and each employee of an employer that elects a level of coverage may choose to enroll in a QHP that offers coverage at that level. Based on communications with issuers and State Insurance Commissioners early in 2014, HHS became concerned that, in some circumstances, implementing employee choice in 2015 might significantly disrupt some small group markets, and it might therefore have a negative effect on the ability of small business owners to access coverage.

To address these concerns, we proposed to amend §155.705(b)(2) and (3) to provide for a one year transition policy under which a SHOP would be permitted to not implement employee choice in 2015 under specific circumstances: (1) if employee choice would result in significant adverse selection in the State's small group market that could not be fully remediated by the single risk pool or premium stabilization programs; or (2) if there is an insufficient number of issuers offering QHPs or qualified SADPs to allow for meaningful plan choice among QHPs or qualified SADPs for all actuarial value levels in the State's SHOP. We proposed that meaningful choice would mean sufficient competition in the market to allow for participation in the SHOP from multiple issuers throughout the State.

We proposed that a State regulatory agency, such as the State Department of Insurance, could submit a recommendation to the State's SHOP (or in the case of an FF-SHOP, to the Secretary) showing why either of the two proposed circumstances applied in 2015. We sought comment on whether the State regulatory agency recommendation should include a mitigation plan describing the process the State regulatory agency would take to ensure that full implementation of employee choice in 2016 would not result in the occurrence of either proposed circumstance. We proposed that the State would be required to provide in the recommendation to the SHOP concrete evidence that one of the two proposed circumstances applied. The SHOP would then evaluate the State's recommendation and determine whether the State's small group market would be significantly adversely affected as a result of the implementation of employee choice.

In the preamble to the proposed rule, we also recognized the importance of the timing of a State regulatory agency's recommendation and the SHOP's decision regarding employee choice under this proposal. Whether or not employee choice is available in a SHOP may be

relevant information for issuers to consider as they make QHP submissions, but State regulatory agencies also need time to evaluate market dynamics before they can make a recommendation about whether the SHOP should not implement employee choice in 2015. We considered establishing a deadline for the State regulatory agency's recommendation to the SHOP. We considered a timeline under which State regulatory agencies would make recommendations prior to the close of the initial QHP certification application window, with sufficient time for issuers to decide whether or not to participate in SHOP for the following plan year. We also considered a second timeline as follows: (1) all issuers interested in participating in SHOP would apply during the initial application window; (2) State regulatory agencies then would have a specific window of time within which to make a recommendation regarding whether to not implement employee choice in 2015 based on the applications received; (3) the SHOP would then have a specific window of time to decide whether to implement employee choice in 2015 based on that recommendation; (4) issuers could, based upon the SHOP's decision, decide whether to maintain, modify, or withdraw their QHP applications. In the FF-SHOPs, under this second scenario, issuers would be able to submit applications after the initial deadline to apply for QHP certification had passed.

We are finalizing this provision with the following modifications. First, based on a careful re-evaluation of the two conditions under which the State regulatory agency could make the proposed recommendation, we have recognized that some issuers have concerns about the potential for adverse selection in the small group market under employee choice and these concerns might cause them to price their products and plans higher than they might otherwise price them if the SHOP did not offer employee choice. Therefore, in the final rule, we specify that a State Insurance Commissioner could recommend to the SHOP that employee choice not be

implemented in that State in 2015 if the Commissioner can adequately explain that this would be in the best interest of small employers and their employees and dependents, given the likelihood that implementing employee choice would cause issuers to price their products and plans higher than they would otherwise price them. Second, we are finalizing the first timeline in the proposed rule, and are requiring that a State Insurance Commissioner make its recommendation to the SHOP, and that the SHOP make its decision about implementing employee choice, sufficiently in advance of the end of the QHP certification application window such that issuers can make informed decisions about whether to participate in the SHOP. In the FF-SHOPs, State Insurance Commissioner must submit to HHS their recommendation on or before June 2, 2014. This will provide HHS (as operator of the FF-SHOPs) sufficient time to review any recommendations. HHS anticipates that its decision regarding the implementation of employee choice in States with an FF-SHOP would be made by June 10, 2014, which would provide sufficient time for issuers to decide whether to participate in the SHOP for the following year.

Comment: We received several comments in support of providing an opportunity for a State to recommend that a SHOP not implement employee choice in 2015, so that States and issuers could develop a Statewide plan for a full and successful implementation of employee choice in 2016. We also received several comments opposing the proposal, stating that employee choice is both statutorily required and is a core element necessary to establish SHOP's value and attract participation by small employers. One commenter urged HHS to not implement employee choice in 2015 only when there is clear harm that outweighs any of the value presented by employee choice and there is no other way to mitigate such harm. Several commenters expressed concern that an additional year without employee choice will not reduce the ultimate impact of any adverse selection concerns, but will just postpone its effects until 2016. Commenters

expressed concern that the deferral of employee choice could go on for years, and could possibly be permanent.

Response: We believe that the option to permit a State to recommend that employee choice not be implemented, if the State fulfills the regulatory requirements, might be important to preserve market stability in certain States in 2015. We recognize that some State Insurance Commissioners and issuers have concerns about the potential for adverse selection in the small group market in light of the fact that employee choice will be a new feature in many markets and issuers at this point in time may feel that they do not have sufficient data available concerning expected enrollee risk in an employee choice environment. This may lead issuers to price coverage more conservatively than they otherwise would price it, even taking into account premium stabilization programs and other considerations. Further, we understand that some State Insurance Commissioners believe that this potential for adverse selection will result in less robust issuer participation in a SHOP that offers employee choice.

Therefore, consistent with the proposal that this policy reflect issuer and State concerns about adverse selection we are finalizing §155.705(b)(3)(vi) to allow a SHOP to elect to provide employers only with the option set forth at paragraph (b)(3)(ii)(B), or in the case of a FF-SHOP, only with the option set forth at paragraph (b)(3)(iv)(B) only if the State's Insurance Commissioner can adequately explain that it is his or her expert judgment, based on a documented assessment of the full landscape of the small group market in his or her State, that not implementing employee choice in 2015 would be in the best interest of small employers and their employees and dependents, given the likelihood that implementing employee choice would cause issuers to price products and plans higher in 2015 due to the issuers' beliefs about adverse selection. This transitional policy only applies for plan years beginning in 2015. We expect that by

2016, States and issuers will be able to learn from the experiences of issuers in a wider range of SHOPs that have implemented employee choice so that any adverse selection concerns will no longer be material. For example, we believe that by 2016, issuers will have much more information on which to make pricing and plan design decisions for an employee choice environment. HHS anticipates that the conditions for a State to recommend a transition in employee choice will apply in a subset of markets, and HHS remains committed to implementing employee choice in all SHOPs by 2016. In any event, in light of the statutory language providing that employee choice should be implemented in all SHOPs, this policy will not be extended beyond 2015. HHS will approve an FF-SHOP State's recommendations with the understanding that the transitional policy applies for one year.

While the rule would also permit State-based SHOPs to decide against implementing employee choice in 2015, HHS believes it is unlikely that State-based SHOPs will opt not to implement employee choice in 2015 because most of them currently offer employee choice.

We are not finalizing the proposal that States include a statement describing how the plan to increase meaningful choice or reduce adverse selection concerns for 2016 and beyond in their recommendation because HHS anticipates that the conditions that would support the State recommendation required under this final rule will not apply in most markets.

Comment: One commenter does not support allowing States to not implement employee choice because the participation provision in 45 CFR § 156.200(g) requires issuers with more than a 20 percent share of the State's small group market share participate in the FF-SHOP as a condition of participating in the FFE individual market. Therefore, most issuers participating in the FFE are unlikely to decline participating in an FF-SHOP. The commenter expressed the view that employee choice would make it easier for plans that do not meet the 20 percent threshold to

participate in an FF-SHOP, thus expanding the competitive choices available to small business employees.

Response: 45 CFR 156.200(g) was finalized to help provide employers a choice of QHPs in FF-SHOPs. While employee choice may encourage rather than limit choice of issuers and plans, we believe that States are in the best position to make an assessment of the choice of issuers and plans that are available at this time.

Comment: We received several comments on the proposed circumstance under which a State Insurance Commissioner could recommend that the SHOP not implement employee choice based on significant adverse selection that could not be remediated by the single risk pool or the premium stabilization programs. One commenter recommended that adverse selection could be addressed by limiting choice within one issuer. Another commenter stated that risk adjustment would eliminate the risk of adverse selection, but that this would not happen until several months after the State must submit its recommendation regarding employee choice. Another expressed concern about employers continuing to offer grandfathered health plans.

Response: We generally agree with the commenters who questioned including the adverse selection circumstance as drafted in the proposed rule and agree that the single risk pool, risk adjustment program, and other considerations are likely to address adverse selection concerns in the small group market, including small group markets in which the SHOP offers employee choice. Nonetheless, we recognize that some State Insurance Commissioners and issuers have concerns about the potential for adverse selection in the small group market due to employee choice, given that this will be a new feature in many markets and issuers at this point in time may feel that they do not have sufficient data available concerning expected enrollee risk in an employee choice environment. This may lead to issuers to price products and plans more

conservatively than they otherwise would price, even taking into account premium stabilization programs and other considerations. We also understand that some State Insurance Commissioners believe that issuer concerns about adverse selection will result in less robust issuer participation in a SHOP that offers employee choice. Accordingly, in this final rule, we have modified the proposed recommendation that the State Insurance Commissioner would submit regarding adverse selection to better capture the circumstances under which issuers' concerns about adverse selection might negatively affect the small group market.

Comment: Several commenters provided recommendations about how to define meaningful choice. Such definitions ranged from ensuring employees have a choice among health plans within those metal levels to ensuring there was at least one plan in every metal level.

Response: In response to concerns from commenters, HHS is not finalizing the provision of the proposed rule that would permit the State Insurance Commissioner to recommend that the SHOP not implement employee choice based on a lack of meaningful choice among QHPs or SADPs. Instead, HHS is modifying the proposal to permit State Insurance Commissioners to submit a written recommendation to the SHOP adequately explaining that it is the State Insurance Commissioner's expert judgment, based on a documented assessment of the full landscape of the small group market in his or her State, that not implementing employee choice would be in the best interests of small employers and their employees and dependents, given the likelihood that implementing employee choice would cause issuers to price products and plans higher in 2015 due to the issuers' beliefs about adverse selection. A State Commissioner's recommendation must be based on concrete evidence, including but not limited to discussions with those issuers expected to participate in the SHOP in 2015.

Comment: Several commenters are concerned about whether HHS will be ready to fully implement employee choice in the FF-SHOPs and recommended that concerns about operational readiness be added to the list of circumstances under which a State may recommend not implementing employee choice in 2015. They also stated that FF-SHOP functionality and design would also need to be completed well in advance of the launch and must be scalable to all FF-SHOP States.

Response: HHS, with the assistance of appropriate vendors, has finalized business requirements necessary for the launch of the FF-SHOP online portal for 2015. We do not expect that operational and technological processes will pose a limitation to implementing employee choice and premium aggregation services in the FF-SHOPs.

Comment: Some commenters support allowing a SHOP to have the discretion of determining whether employee choice would have to exist for both medical QHPs and SADPs. One commenter stated that SADPs do not have the protections of the single risk pool, risk corridors, and risk adjustment, which differentiates SADPs from QHPs.

Response: Because of operational limitations in the build of the FF-SHOP online portal, employee choice will either be implemented or not implemented for both SADPs and QHPs in the FF-SHOPs, depending on whether State Insurance Commissioners submit recommendations consistent with this final rule. However, State-based SHOPs could choose to provide employee choice for medical QHPs and SADPs, or vice versa for the 2015 plan year, if their IT systems can accommodate employee choice variation by plan type, and if a recommendation from a State Insurance Commissioner consistent with this final rule would support that approach.

Comment: Some commenters recommended that HHS require that the State's recommendation include concrete, specific details of employee choice's estimated impact on the

small group market. One commenter specifically recommended that the requirement for concrete evidence be included in regulatory text. Other commenters recommended that HHS adopt a more simplified waiver process giving States, including State-based SHOPs, greater discretion and flexibility in choosing SHOP options that meet local needs. These commenters stated that HHS should not include requirements, criteria, or standards that prescribe or limit State flexibility or State decision-making processes regarding implementation of employee choice. Additionally, some commenters urged HHS to require that a State's recommendation include a mitigation plan describing how any adverse effects of not implementing employee choice in 2015 would be addressed so that these conditions do not persist into 2016. One commenter recommended that the requirement for a mitigation plan should indicate how the State intends to increase stand-alone dental plan participation in the employee choice market. Some commenters believe that all States should be required to have a public review and comment period on the State's recommendation to not implement employee choice in 2015 and that all evidence should be subject to public review and comment.

Response: We are finalizing language in this rule requiring that the State's recommendation must be sent by the State's Insurance Commissioner to HHS (as operator of the FF-SHOP) or to the State-based SHOP and must be based on documented assessment of the full landscape of the State's small group market. HHS is not being prescriptive about the specific types of evidence that must be included in this documented assessment, as this evidence may vary based on the State's small group market. However, the documented assessment of the full landscape of the State's small group market in a State must support the Insurance Commissioner's expert judgment that not implementing employee choice would be in the best interests of small employers and their employees and dependents, given the likelihood that

implementing employee choice would cause issuers to price products and plans higher in 2015 due to the issuers' beliefs about adverse selection. A State Insurance Commissioner's recommendation would need to be based on concrete evidence, including but not limited to discussions with those issuers expected to participate in the SHOP in 2015. Nonetheless, in order that SHOPS will make an informed, fair decision about whether to approve a State's recommendation, HHS has included in this final rule text the overarching standards on which the State Insurance Commissioner must base its recommendation. We think that the finalized standard accommodates the unique variation of States' small group markets and provides flexibility to States in making their recommendation to a SHOP. The timeline and schedule that is being finalized in this rule does not make it feasible for FF-SHOPS to solicit public input on a State's recommendation not to implement employee choice. However, State-based SHOPS and State Insurance Commissioners who make recommendations about not implementing employee choice in 2015 may choose to have a public comment period on their proposed recommendation. If a State elects to hold a public comment period, it must submit a summary of all comments received with its recommendation to not implement employee choice in 2015 to the relevant SHOP.

Comment: We received several comments about how to address the timing issue presented in the preamble of the proposed rule. Some commenters prefer the timing option whereby the State agency would have to make recommendations prior to the close of the initial QHP certification application window, and stated that this provides time for QHPs to make informed participation decisions. One commenter recommended that the decision and announcement of a State's recommendation regarding employee choice be made no later than one month prior to the deadline for filing rates for the 2015 benefit year to assure actuarially

sound rates. One commenter preferred the second proposed timeline from the preamble of the proposed rule whereby issuers would have the option to maintain, modify, or withdraw their products from the SHOP market after the SHOP's employee choice decision has been made. Another commenter asked how issuers would file rates without knowing whether employee choice is required and was concerned that the timing of the letters from the States and the State decision were not in alignment with the QHP certification timelines.

Response: HHS is finalizing in this rule that a State Insurance Commissioner should submit a recommendation to the SHOP, and that the SHOP should make a decision based on that recommendation, sufficiently in advance of the close of the QHP certification application window such that issuers can make informed decisions about whether to participate in the SHOP. In a FF-SHOP, State Insurance Commissioners must submit to HHS the recommendation on or before June 2, 2014, and HHS will make a decision based on any recommendations submitted by that deadline before the close of the QHP certification application window. Only States interested in not implementing employee choice would need to make a recommendation. State Insurance Commissioners making such recommendations should submit them via email to shop@cms.hhs.gov. HHS expects that no later than June 10, 2014, the FF-SHOP will post the list of States approved for their transition of employee choice for one year, creating a public record. HHS will make publicly available the State's recommendation to the FF-SHOP and the results of its review in a written decision explaining whether HHS agreed with the State's recommendation. This timeline ensures that HHS' decisions will be made prior to the close of the initial QHP certification application window for the FF-SHOPs, with sufficient time for issuers to decide whether or not to participate in the FF-SHOP in 2015.

This timeline reduces uncertainty for issuers because issuers will know if employee choice is being offered in a SHOP prior to the end of the QHP application period. Issuers will be able to make a decision about SHOP participation based on final information about whether employee choice will be implemented and will be less likely to seek to modify their rates or withdraw their applications.

State-based SHOPs will be required to follow the same timeline as FF-SHOPs, but exact dates for State Insurance Commissioner recommendations and SHOP decisions may differ from the FF-SHOP.

Summary of Regulatory Changes

We are finalizing the provision as proposed, with the modification that a SHOP's decision not to implement employee choice in 2015 should be based on a written recommendation submitted by the State Insurance Commissioner adequately explaining that it is the Insurance Commissioner's expert judgment, based on a documented assessment of the full landscape of the small group market in his or her State, that not implementing employee choice would be in the best interests of small employers and their employees and dependents, given the likelihood that implementing employee choice would cause issuers to price products and plans higher in 2015 due to the issuers' beliefs about adverse selection. A State Insurance Commissioner's recommendation must be based on concrete evidence, including but not limited to discussions with those issuers expected to participate in the SHOP in 2015. We clarify that this policy only applies in 2015 by adding the word "only." We also changed in § 155.705(b)(3)(vi) the word options to be singular as one option is available for FF-SHOPs and another for State-based SHOPs. Finally, we have established in the final rule the first of two proposed timelines under which States to make their recommendations to SHOP.

b. Enrollment Periods under SHOP (§155.725)

We proposed amendments to §155.725(c) and (e) to amend the dates for the annual open enrollment periods for qualified employers and qualified employees in all SHOPs, both State-based and Federally-facilitated. In proposed §§155.725(c)(1), we proposed to align the start of annual employer election periods in all SHOPs for plan years beginning in 2015 with the start of open enrollment in the corresponding individual market Exchange for the 2015 benefit year. Under the proposal, the annual employer and employee election periods would begin no sooner than November 15, 2014 with employers making selections first, followed by employees. We are finalizing this proposal with one modification. Based on comments we received through the public comment period, we are modifying §155.725(c)(1) to limit this provision to FF-SHOPs. State-based SHOPs may start their annual employer election periods earlier than November 15, 2014. We further clarify that nothing in this rule eliminates the rolling monthly enrollments in the SHOPs outlined at 45 CFR 155.725(b) and the requirement also outlined at 45 CFR 155.725(b) that a plan year in the SHOP be 12 months.

We note that pursuant to §147.104(b)(1)(i), group coverage purchased in the SHOP between November 15 and December 15 of each year is not subject to employer contribution or group participation rules. As explained in Chapter 5 of the 2015 Letter to Issuers published on March 14, 2014, FF-SHOPs do not enforce minimum participation requirements between November 15 and December 15 of each year, but they are enforced upon initial enrollment and at renewal outside of this window. Aligning the start of the annual employer election period in the FF-SHOPs with the start of the individual market Exchange such that the employer election period would begin no sooner than November 15, 2014, will provide qualified employers and employees with a period of time to enroll for 2015 coverage when the FF-SHOP minimum

participation provisions are not enforced. State-based SHOPs wishing to begin annual employer election periods prior to November 15 may extend the window of time when employers are not subject to employer contribution or group participation rules. For example, a State-based SHOP may extend the window of time during which minimum contribution and participation rules are not applicable from October 15 through December 15, so long as November 15 through December 15 is included in the time period.

In §§155.725(c)(2) and 155.725(e), we proposed to remove the required minimum lengths of both the annual employer election period and the employee open enrollment period to provide additional flexibility to all SHOPs and qualified employers. The existing minimum standards may make it difficult for groups participating in the SHOP to renew coverage in a timely manner, as under those minimums, it might take 75 days or longer to complete a group renewal. This proposal will permit employers to expedite their enrollment timeline. Also, this proposal increases a qualified employer's access to the most up-to-date rate information by permitting alignment with the quarterly rate update cycle. We are finalizing these provisions as proposed.

Comment: We received several comments on our proposal to align the start of the employer election periods for plan years beginning in 2015 with the start of open enrollment in the corresponding individual market Exchange for the 2015 plan year, as amended in the 2015 Payment Notice, so that the annual employer and employee election periods would begin no sooner than November 15, 2014. Some commenters supported having a uniform timeline for enrollment in the individual Exchange and SHOPs, to reduce confusion, improve efficiencies, and possibly bring about cost savings. Another commenter believed that there are too many election periods for different populations and therefore recommends that the annual open

enrollment period be more spread out. One commenter recommended that employers be able to make decisions whether to participate in the SHOP prior to November 15 so that employees can shop in both Exchanges beginning November 15. We also received several comments recommending that State-based SHOPs should have the flexibility to maintain their own employer election periods to remain in alignment with the broader small group market in the State. Several commenters noted that aligning the timing of the SHOP employer election period for 2015 with the individual market annual open enrollment period may pose challenges for certain State-based SHOPs, and encouraged HHS to maintain the flexibility afforded to State-based SHOPs discussed in the preamble to the Exchange Establishment final rule at 77 FR 18402–18403. For example, commenters observed that some State-based SHOPs see benefits from dedicating staff to separate enrollment periods for individuals and employees of qualified employers, rather than administering these enrollment periods concurrently.

Response: To ensure States have the flexibility to operate their State-based SHOPs in a manner that works in their small group markets, we are finalizing this provision as proposed, but limiting it to FF-SHOPs. State-based SHOPs will be able to begin their employer and employee election periods in a manner that works with their small group markets.

Comment: Some comments were received in support of the proposal to remove the 30-day minimum timeframe for the employer and employee annual election period. However, several comments were also received stating that removing this minimum timeframe would cause system and human resource strain by forcing SHOP enrollment into a more compressed timeframe. Some commenters also stated that this approach does not compare favorably with traditional small group insurance coverage. One commenter stated that employers need a

minimum of 30 days to evaluate their options, costs, and budget forecasts for the upcoming year and employees would then need a similar timeframe to make a decision by the 15th of the month.

Response: We believe that removing the 30-day minimum timeframe requirement provides the most flexibility to SHOPs, employers and employees, and allows consumers to obtain SHOP coverage in a quicker timeframe. This flexibility allows employers and employees to complete their shopping in a more condensed time, if desired. We note that nothing in this final rule removes the ability of a State-based SHOP or an employer to establish enrollment periods lasting at least 30 days.

Summary of Regulatory Changes

We are finalizing the amendments proposed in §155.725 of the proposed rule with the modification that the provision aligning the annual employer election period with the start of the start of open enrollment in the corresponding individual market Exchange for the 2015 benefit year applies only in FF-SHOPs. State-based SHOPs may start their annual employer election periods earlier than November 15, 2014.

c. SHOP Employer and Employee Eligibility Appeals Requirements (§155.740)

We proposed to amend §155.740(g) by redesignating paragraphs (g)(1) through (g)(3) to more clearly delineate the requirements associated with valid appeals separately from those associated with invalid appeals.

We proposed to amend §155.740(i)(1)(i) by cross-referencing the withdrawal standards proposed in the individual market at §155.530(a)(1). Under current rules, an appellant who wishes to withdraw his or her appeal request must do so in writing (hard copy or electronic). The amended provision would allow an appellant to withdraw his or her appeal request in writing or by telephone, if the appeals entity is capable of accepting telephonic withdrawals.

Comment: We received a handful of comments regarding the proposed change to the SHOP appeals withdrawal procedure and all were supportive of the change. As with the individual market provision, commenters cited the benefits to having a telephonic withdrawal option, including increased efficiency for appellants to conclude the appeals process. Commenters also noted with support the importance of recording the telephonic interaction and providing written confirmation of the withdrawal along with instructions on how to request to vacate a withdrawal in order to protect the appellant's right to a hearing.

Response: We agree with commenters that incorporating this option for telephonic withdrawals for SHOP employer and employee appeals will assist appeals entities in maintaining an efficient process by providing a convenient method for appellants to end an appeal at their option. We also consider the requirements to record the appellant's telephonic withdrawal and the telephonic signature under penalty of perjury in full along with sending written confirmation of the withdrawal to be critical safeguards for appellants and appreciate the support commenters expressed for these aspects of the process. We, therefore, finalize the provision for telephonic withdrawal as proposed.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §155.740 without modification.

8. Subpart O—Quality Reporting Standards for Exchanges

In §155.1400, we proposed that the Exchange must prominently display on its website, in accordance with 45 CFR 155.205(b)(1)(v), quality rating information assigned for each QHP under the QRS, as calculated by HHS and in a form and manner specified by HHS, starting in 2016. We stated our intentions to have a beta testing period in 2015 to provide early feedback to Exchanges and QHP issuers and begin public reporting of quality rating information during the

2016 open enrollment period for the 2017 coverage year. The standards for QHP issuers regarding the collection and submission of validated quality measures data for the QRS are described in Part 156, Subpart L of this final rule.

Comment: Many commenters agreed with the proposed provision and supported our approach for HHS to provide calculated quality rating information for display on an Exchange website on an annual basis for the open enrollment period. One commenter requested clarification as to whether HHS will select and calculate the QRS rating for both the FFE and State Exchanges, or whether the State Exchanges will be able to select and calculate their own QRS ratings independent of HHS. Commenters suggested that State Exchanges be allowed to calculate quality ratings using the same approach as the FFE but with data for plans operating within the State's Exchange and that beta test data be used to compare QHP quality rating results from HHS with State Exchange results to determine relative comparability in national versus State approaches.

Response: We clarify that HHS will be obtaining data from all QHP issuers from all Exchanges consistent with §156.1120(a) and using a standardized methodology to calculate QHP quality ratings for display on the FFE website and to provide for display to State Exchanges on their websites. We believe that an approach where each Exchange displays quality ratings calculated by HHS based on a standard scoring methodology allows for reliable, uniform, and comparable QHP ratings across Exchanges. The HHS-calculated scores and rating information provided to a State Exchange by HHS will be for the QHPs offered on the Exchange in that State. We anticipate sharing the validated QRS summary measure level data with State Exchanges; however State Exchanges will be required to display the HHS-calculated quality ratings for QHPs offered on the Exchange in their respective States. At the same time, we

believe it is important that States have opportunity to build on this uniform strategy by displaying additional quality measures that reflect local priorities and we anticipate issuing future guidance that will include standards for States who wish to exercise this flexibility.

Comment: Many commenters urged HHS to require that State Exchanges display the data directly on their websites instead of linking to a Federal website.

Response: We understand commenters' concerns regarding providing consumers direct access to QHP quality data on the Exchange website where they are choosing a plan and these comments will help inform consumer testing and final guidance regarding display of quality rating information. We agree that health plan quality-related information should be provided to consumers in an easily understandable format and manner to support the comparison of plan options. We intend to provide details regarding display requirements in future technical guidance and will work with State Exchanges that do not have the technical capacity to display data directly on their websites during the initial implementation phase-in period.

Comment: Several commenters supported flexibility for States to display additional quality data and recommended that such data be collected and displayed consistently with the Federal measures. Other commenters expressed concern regarding States posting additional data because of the potential for conflicting measures to confuse consumers. They also expressed concern about consumer comprehension of displayed QRS data and allowing for approaches to meet diverse needs including regional, cultural, language, and demographic differences. One commenter suggested criteria for establishing governing principles for States choosing to display additional quality information, such as requiring States to only use NQF-endorsed measures or required measures for QHP accreditation. Another commenter suggested that States such as

California that have implemented their own QHP quality ratings be used to inform quality reporting on the FFE.

Response: We maintain in the final rule that the Exchange must prominently display the Federal QRS rating information, as calculated by HHS, and results from the ESS for each QHP on its website. We believe that the Federal quality standards regarding QRS establishes a foundation for a uniform, national strategy for monitoring quality activities in the Exchanges with a core set of measures and standard approaches to health plan quality reporting. We also believe it is important that States have the opportunity to build on this uniform strategy with the display of additional measures that reflect local priorities. We anticipate issuing future guidance that will include standards for States who wish to exercise this flexibility. However, we clarify that HHS would not include any State-level data in calculations for the Federal QRS. HHS is currently conducting research and consumer testing regarding display of consumer-friendly information and terminology of health plan quality data and as we noted in the proposed rule, we intend to issue technical guidance including standardized display requirements in the near future. We will work with States to prevent display of both Federal and State-level quality measure data in a manner that confuses consumers.

Comment: Many commenters supported a five-star display for QRS ratings that would ensure consistency across commercial and Medicare markets and increase enrollee familiarity with the rating systems. One commenter recommended that CMS report QHP summary ratings at half-star levels (for example, 3.5, 4.0, 4.5) to enable consumers to better distinguish between plans, similar to the Medicare Advantage and Part D ratings.

Response: As stated in the proposed rule, we intend to display star ratings that would be similar in style and format to that of Medicare Advantage and Prescription Drug Plan ratings.

These comments regarding display requirements will inform the future technical guidance that we intend to issue in the near future. For more detailed information on the proposed QRS scoring specifications approach, including the proposed process of scoring QHPs and converting scores into ratings on a five-star scale, we refer commenters to the March 28, 2014, draft QRS Scoring Specifications document available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/QRS-Scoring-Specification.pdf>.

Comment: We also received a number of comments on quality measures for dental plans, sampling design and methodology for the ESS, quality rating and survey measure sets, QRS framework, process for selection of ESS vendors and quality reporting for QHPs offered outside the Exchange.

Response: We have not addressed such comments, and others that are not directly related to the proposed rule, because they are outside the scope of this rulemaking.

Summary of Regulatory Changes

For the reasons described above, we are finalizing the provision as proposed.

b. Enrollee Satisfaction Survey System (§155.1405)

In §155.1405, we proposed that the Exchange would prominently display results from the ESS on its website, in accordance with §155.205(b)(1)(iv), as calculated by HHS, and in a form and manner specified by HHS, starting in 2016. We also proposed that the display of the QRS information (which incorporates member experience data from the ESS) by an Exchange would meet the requirement of displaying the ESS information and satisfy the standard outlined in 45 CFR 155.205(b)(1)(iv). The standards for QHP issuers regarding the collection and submission of validated data for the ESS are described in Part 156, Subpart L of this final rule.

Comment: The majority of commenters supported the proposed display requirement for Exchanges in §155.1405. Several commenters did not support the approach to provide State Exchanges the flexibility to make ESS beta test results publicly available in 2015 because these results are intended for process improvement and not official. Some commenters supported allowing all Exchanges to make the beta test information available in 2015 to identify best practices and provide access to information to support consumer choice. One commenter suggested requiring several criteria to be met prior to publicly presenting ESS 2015 beta test results.

Response: We agree that the purpose of the 2015 ESS beta test results is primarily for process improvement. However, we also believe that if reliable QHP-level assessment scores are available in the ESS beta test results, this information could provide important early feedback to Exchanges and consumers. We intend to provide State Exchanges and QHP issuers with the ESS beta test results with appropriate disclaimers including that beta test results are not finalized and are part of the survey development process. HHS would not require nor restrict a State Exchange from posting this information on its website but would encourage inclusion of appropriate disclaimers to inform the consumer about the limitations of the data (for example, the information reflects beta test results that are not finalized and are part of the survey development process). HHS does not plan on posting the 2015 ESS beta test results on the FFE website.

Comment: Many commenters urged HHS to have a uniform policy for ESS scoring calculations and for display and require that complete ESS results, by metal-tier level, be made publicly available on all Exchange websites for consumers, accessible to researchers and advocates. One commenter expressed concern with displaying all ESS results including those

scores not used in the QRS because of concerns that the survey may not capture information regarding a QHP's quality that are applicable to areas that a health plan can directly influence.

Response: We intend to provide the HHS standardized, calculated full ESS results to State Exchanges and to display the results at the product-level on the FFE website and will provide further details regarding display of the data, to consumers, in future technical guidance. As noted in the proposed rule, we believe that by displaying the QRS information (which incorporates member experience data from the ESS), an Exchange would meet the requirement, during the initial years of implementation, of displaying the ESS information and satisfy the standards outlined in 45 CFR 155.205(b)(1)(iv) and 45 CFR 155.1405. Therefore, State Exchanges will have the flexibility, in the initial years, to decide whether to display the full ESS results, as calculated by HHS. In the initial years, we believe that display of ESS results should align with the QRS and be presented at the product-level. We anticipate using the metal level data, as reported to HHS, to inform ESS implementation in future years and will re-examine the possibility of displaying the ESS results at a more granular level following an analysis of the 2015 beta test results. We believe that the ESS will provide valuable information regarding QHPs offered on Exchanges to consumers since it is largely based on the industry standard CAHPS® 5.0 Health Plan Survey that assesses commercial and Medicaid health plans. In addition, we are considering different ways to make QHP quality data, including ESS results, publicly available and accessible to consumers in a meaningful way.

Comment: A few commenters urged HHS to require State Exchanges to have a plan preview period for review of the ESS results. Some commenters requested that HHS provide access to full ESS results to issuers during a plan preview period, similar to QRS measure data.

One commenter urged HHS to offer a three month plan preview period for QRS and ESS results at a different time than review of quality ratings for Medicare Advantage plans.

Response: We appreciate the comments in support of HHS imposing a requirement on State Exchanges to have a plan preview period for review of the QRS and ESS results and may consider adopting this approach in future rulemaking. We note that some State Exchanges already have instituted a plan preview process for issuers to have the opportunity to review and correct data provided for display on Exchange websites. HHS also intends to host a plan preview period of QRS and ESS data for all QHP issuers participating in all Exchanges. We intend to balance alignment of data collection, submission, and plan preview timeframes for the QRS and ESS with existing processes, with the goal of minimal burden to issuers and State Exchanges.

Summary of Regulatory Changes

We are finalizing this provision as proposed.

H. Part 156—Health Insurance Issuer Standards under the Affordable Care Act, Including Standards Related to Exchanges

1. Subpart B – Essential Health Benefits Package

a. Prescription Drug Benefits (§156.122)

Section 156.122(c) requires issuers that provide EHB to have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the plan. In the proposed rule, we sought comment on amending the sought comment on amending the formulary exceptions standards under §156.122(c) to require that these processes can be expedited when necessary based on exigent circumstances, such as when an enrollee is suffering from a serious health condition or an enrollee is in a current course of treatment using a non-

formulary drug. We considered, for example, whether issuers should be required to render decisions regarding formulary exceptions requests within 24 hours following the issuers' receipt of the exceptions requests, as suggested in the "2014 Letter to Issuers on Federally-facilitated and State Partnership Exchanges"(2014 Letter to Issuers).³¹ As clarification, the prescription drug standard in §156.122(a)(1) was not intended to discourage issuers from offering clinically appropriate drugs to enrollees, including combination drugs. We sought comment on what specific standards would be appropriate for defining this expedited exceptions process, and on all other aspects of this proposal.

Comment: Some commenters supported the proposal to add additional parameters in regulation for the exceptions process and had recommendations regarding the parameters, including the timing of the reviews and the need for expedited reviews due to exigent circumstances. Many commenters supported a general 72-hour review timeframe and a 24-hour review timeframe due to exigency when the life or immediate health of the insured is at stake. Several of these commenters recommended other standards in use today, such as the standards in the Medicare Part D program or Department of Labor standards for coverage determinations, and supported greater uniformity. Of those commenters who supported greater uniformity, the majority of commenters favored a process similar to that in Medicare Part D. Conversely, some commenters did not support any additional regulatory standards regarding the exceptions process. These commenters cited the timing of the rulemaking, potential for conflicting State law, desire for flexibility in prescription drug management practices, and desire for a better understanding of drug access issues.

³¹ See Appendix C of the 2014 Letter to Issuers on Federally-facilitated and State Partnership Exchanges (April 5, 2013). Available at: http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2014_letter_to_issuers_04052013.pdf.

Response: We have heard from several stakeholders about enrollee difficulty in accessing, understanding, and using issuers' exception processes under §156.122(c), since there is currently no requirement for uniformity across plans. Based on comments regarding the need for a uniform standard, we are finalizing standards for a health plan's exceptions process that includes a process for exigent circumstances. Specifically, we are modifying §156.122(c) to include a policy that allows an enrollee (or enrollee's designee) or the enrollee's prescribing physician (or other prescriber) to request an expedited exceptions process based on exigent circumstances that are defined as when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug. We are also finalizing a requirement that issuers must provide a decision on an exception request based on exigent circumstances and notify the enrollee (and the prescribing physician or other prescriber as appropriate) of the determination no later than 24 hours after receiving the request. We believe that this policy will better ensure enrollee access to critical medications in a timely manner. These provisions are effective for the 2015 plan year.

Comment: Commenters asked for clarification on operational considerations for implementing any specific exceptions process requirements, including a definition of "exigent," when any timeframes begin, how long the enrollee has access to the medication if granted an exception, and if the enrollee is required to have access to the drug throughout the review processes.

Response: The timeframe for expedited (24-hour) review begins when the issuer or its designee receives an exception request based on exigent circumstances. An enrollee or the enrollee's prescribing physician (or other prescriber) should strive to submit a complete request;

however, issuers should not fail to commence review if they have not yet received information that is largely procedural but not necessary to begin review. Further, issuers should not request irrelevant or overly burdensome information.

We believe an exigency exists when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug. Either the enrollee (or enrollee's designee) or prescribing physician (or other prescribing provider as appropriate) may submit the request for an expedited review based on exigent circumstances. Issuers must be equipped to intake these requests in writing, electronically, and telephonically.

As part of the request for an expedited review based on exigent circumstances, the prescribing physician or other prescriber should support the request by including an oral or written statement that (1) an exigency exists and the basis for the exigency (that is, the harm that could reasonably come to the enrollee if the requested drug were not provided within the timeframes specified by the issuer's standard drug exceptions process), and (2) a justification supporting the need for the non-formulary drug to treat the enrollee's condition, including a statement that all covered formulary drugs on any tier will be or have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects.

Following a favorable decision on the expedited request, the enrollee must be provided access to the prescribed drug without unreasonable delay. Therefore, issuers need to be prepared to communicate rapidly with pharmacies and pharmacy benefit managers, as applicable. At a minimum, we expect issuers to update certificates of coverage to reflect the availability of this process and to be able to provide instruction to enrollees or their designees and providers or their designees regarding how to use the process. While these review standards are specific to the

expedited review process, we encourage issuers to have a similar type of review process in place for their non-expedited review under §156.122(c).

While some commenters recommended that issuers be required to provide coverage of the drug in question pending the outcome of the expedited request, we are also cognizant that some commenters opposed the proposal altogether and that we are finalizing an expedited timeframe for coverage determination under this process due to exigency as no more than 24 hours. Therefore, while we encourage issuers to provide the drug pending the outcome of the exceptions request, we are not requiring it at this time.

We are also concerned about enrollees having to continue to make requests under §156.122(c) throughout the plan year to access the same clinically appropriate drug not on the plan's formulary, whether for each refill or otherwise, and for exceptions granted pursuant to the exigent circumstance exceptions process, issuers must make the drug available to the enrollee for the duration of the exigency. We will monitor this issue to consider whether we should propose additional standards through rulemaking.

Comment: Some commenters requested clarification as to whether drugs accessed through the exceptions process under §156.122(c) should count towards the plan's annual limit on cost sharing as established under §156.130(a), and other commenters noted concerns about cost-sharing and tiering for drugs accessed through the exceptions process. Other commenters commented on a variety of other issues related to the EHB prescription drug policy that were not mentioned in the proposed rule.

Response: Because these issues are not specifically related to the exigent circumstance exceptions process standards for §156.122(c) and the preamble to the proposed rule, we consider

them to be outside the scope of the rulemaking but will take them under consideration for future rulemaking.

Comment: Commenters noted that there is no requirement to cover combination drugs considered first line therapy, but other commenters supported efforts to better ensure access to combination drugs, as well as requested requirements related to new drugs. Some commenters requested clarification that combination drugs do not have any special regulatory status in plans that must comply with EHB standards.

Response: The requirements at §156.122(a)(1) were intended to be the minimum standard for an issuer providing EHB. The intention of the exceptions process at §156.122(c) is for enrollees to request and gain access to clinically appropriate drugs that are not on the plan's formulary, which could include combination drugs considered first line therapies and new drugs, particularly when these drugs are supported by sound science and widely accepted guidelines. While there is no mandate that a health plan cover these drugs under §156.122(a)(1), in absence of coverage under §156.122(a)(1), combination drugs or new drugs may be determined to be clinically appropriate for an enrollee under §156.122(c). We do not intend for this policy to create any special regulatory status for combination drugs.

Comment: Some commenters recommended that HHS use its enforcement authority for non-compliance with the exceptions process. Some commenters also recommended that HHS collect tracking data on the use of the exceptions process and provide assistance to enrollees who were denied coverage through the exceptions process.

Response: Because States generally are the primary enforcers of the EHB prescription drug policy, we are not collecting nationwide data on the use of the exceptions process. Enrollees

who are having difficulty accessing a health plan's exceptions process should first contact the issuer and then contact the State's Department of Insurance if necessary.

Summary of Regulatory Changes

Based on comments received, we are finalizing revisions to §156.122(c) to require that a health plan's procedures include an expedited exceptions process based on exigent circumstances that is defined as when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug and that the health plan must make its coverage determination on such requests within no more than 24 hours after receiving them and continue to provide the drug for the duration of the exigency.

b. Cost-Sharing Requirements (§156.130)

Under §156.130(a), cost sharing for 2014 for self-only coverage may not exceed the annual dollar limit described in section 223(c)(2)(A)(ii)(I) of the Code. The proposed rule also provided that under §156.130(b), for a plan year beginning in calendar year 2014, the annual deductible for a health plan in the small group market for self-only coverage could not exceed \$2,000. However, §156.130(b) is being removed from the regulation text to comply with Public Law 113-93, which eliminated the limits on deductibles for plans in the small group market.

For 2015 and later years, the annual limitation on cost sharing is to be increased by an amount equal to the product of the annual dollar amount described in section 223(c)(2)(A)(ii)(I) of the Code and the premium adjustment percentage established pursuant to paragraph (e) of that section. (The limitation for other than self-only coverage is twice the limitation for self-only coverage.) Under §156.130(d), any increase in these annual limits that does not result in a multiple of \$50 is to be rounded to the next lowest multiple of 50 dollars.

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. The 2015 Payment Notice established our methodology for calculating the premium adjustment percentage.

In calculating limitations on cost sharing and small group deductible in the proposed 2015 Payment Notice, we rounded these limitations up to the next lowest multiple of \$50. However, we subsequently learned that the IRS convention for interpreting similar language for a number of longstanding tax parameters – such as indexing methodologies for the alternative minimum tax and the standard deduction – is to round down to the nearest applicable multiple. For example, the Department of the Treasury, in a rule on how employers should calculate average annual full-time-equivalent wages for purposes of the small employer health insurance tax credit, provides that if the result is not a multiple of \$1,000, employers should round the result to the next lowest multiple of \$1,000.³²

As a result, we proposed to align our rounding rules with those used by the Department of the Treasury and the Internal Revenue Service, by amending §156.130(d) to specify that when indexing the annual limitation on cost sharing and the annual limitation on small group deductibles for years after 2014, we will round to the multiple of 50 dollars that is lower than the number calculated by the formula.

Under the proposed amendment, using the 2015 premium adjustment percentage of 4.213431463 percent we established in the 2015 Payment Notice and the 2014 maximum annual

³² See 26 CFR 1.45R-2(f)(1).

limitation on cost sharing of \$6,350 for self-only coverage, which was published by the IRS on May 2, 2013,³³ the 2015 maximum annual limitation on cost sharing would be \$6,600 for self-only coverage and \$13,200 for other than self-only coverage.

Similarly, under the proposed amendment to §156.130(d), we applied the premium adjustment percentage for 2015 to calculate the annual limit on deductibles for the small group market for 2015. However, after the proposed rule was published, on April 1, 2014, the President signed into law Protecting Access to Medicare Act for 2014, which includes a provision that eliminates the annual limitation on deductibles for plans in the small group market. Therefore, there is no annual limitation on deductibles for small group plans, and the premium adjustment percentage is no longer applicable.

Comment: A number of commenters supported our proposal to round the annual limitation on cost sharing down to a lower multiple of \$50, to be consistent with the practice at the Department of the Treasury. A few commenters requested that HHS use this final rule to amend the regulation to reflect new law, which eliminates the annual limit on deductibles for small group plans.

Response: We agree with the comments and are removing references to an annual limit on deductibles for plans in the small group market from our regulations. We also note that issuers do not need to make any changes to their 2014 plan cost-sharing structures as a result of this change.

Summary of Regulatory Changes

We are finalizing our proposal regarding rounding as proposed, and we are removing from our regulations references to the annual limit on deductibles for plans in the small group

³³ See <http://www.irs.gov/pub/irs-drop/rp-13-25.pdf>.

market under §156.130(b) from §156.130(c) and (d), and are removing §156.130(b). The 2015 maximum annual limitation on cost sharing is \$6,600 for self-only coverage and \$13,200 for other than self-only coverage.

2. Subpart C – General Functions of an Exchange

a. QHP Issuer Participation Standards (§156.200)

In §156.200(b)(5), we proposed technical amendments to clarify that implementing and reporting for the QRS and implementing a quality improvement strategy are conditions of participation in an Exchange. Specifically, we proposed to include a reference to sections 1311(c)(3) and (c)(1)(E) of the Affordable Care Act to correctly align with other quality standards listed as part of QHP certification standards, including the ESS.

We also proposed to amend §156.200 to add paragraph (h) to require that, in order to receive QHP certification, the offering issuer attest that, subsequent to receiving such certification, it will comply with all operational requirements contained in Part 156, Subparts D, E, H, K, L, and M. We proposed to add paragraph (h) to ensure that issuers seeking QHP certification understand and have fully committed to compliance with all operational requirements.

Summary of Regulatory Changes

We received comments in support of the proposed amendments and therefore are finalizing §156.200(b)(5) and (h) as proposed.

b. Enrollment Process for Qualified Individuals (§156.265)

We refer readers to the preamble in connection with §155.400 of this final rule for a discussion of comments on §156.265.

3. Subpart G—Minimum Essential Coverage

a. Other Coverage That Qualifies as Minimum Essential Coverage (§156.602)

The Affordable Care Act added section 5000A of the Code, which requires all non-exempt individuals to maintain minimum essential coverage or pay 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; (4) coverage under a grandfathered health plan. In addition, section 5000A(f)(1)(E) of the Code directs the Secretary, in coordination with the Secretary of the Treasury, to designate other health benefits coverage as minimum essential coverage.

The Treasury Department and the IRS published final regulations under Code section 5000A on August 30, 2013 (78 FR 53646).³⁴ On July 1, 2013, HHS published final regulations implementing certain functions of an Exchange for determining eligibility for and granting certain exemptions from the individual shared responsibility payment (78 FR 39494).³⁵ The HHS final regulations, codified in 45 CFR 156.602 and 156.604, also designate certain types of coverage as minimum essential coverage, and outline substantive and procedural requirements for other types of coverage to apply for recognition as minimum essential coverage.

We proposed to amend §156.602 by adding paragraph (e) to designate certain types of foreign group health coverage for expatriates as minimum essential coverage. These proposed

³⁴ Shared Responsibility Payment for Not Maintaining Minimum Essential Coverage, 78 FR 53646 (August 30, 2013).

³⁵ Patient Protection and Affordable Care Act; Exchange Functions: Eligibility for Exemptions; Miscellaneous Minimum Essential Coverage Provisions, 78 FR 39494 (July 1, 2013).

provisions would codify previous CMS guidance published on October 31, 2013,³⁶ with some additional detail.

We are not finalizing this section of the proposed rule at this time. We will consider finalizing the proposal in the future, and will address comments received on the proposal at that time. In the interim, stakeholders and others can rely on the published October 31, 2013 guidance.

Summary of Regulatory Changes

We are not finalizing the provision proposed in §156.602(e) of the proposed rule at this time.

b. Requirements for Recognition as Minimum Essential Coverage for Types of Coverage Not Otherwise Designated Minimum Essential Coverage in the Statute or This Subpart (§156.604)

We proposed a technical correction in §156.604 to clarify that health insurance issuers and plan administrators, in addition to sponsors of coverage and government agencies, may apply to HHS on behalf of a plan or coverage for recognition as minimum essential coverage.

Summary of Regulatory Changes

We received no comments on this proposal and are finalizing the provision as proposed.

4. Subpart I—Enforcement Remedies in Federally-Facilitated Exchanges

a. Available Remedies; Scope (§156.800)

In §156.800(d), we proposed that HHS may consult and share information about QHP issuers with other Federal and State regulatory and enforcement entities to the extent that the

³⁶ See CCIIO Sub-Regulatory Guidance: Process for Obtaining Recognition as Minimum Essential Coverage (October 31, 2013). Available at: <http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/mec-guidance-10-31-2013.pdf>.³⁷ Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, and Eligibility Appeals, 78 FR 54070 (August 30, 2013) (to be codified at 45 CFR parts 147, 153, 155, and 156).

consultation and information is necessary for HHS to determine whether an enforcement remedy under subpart I is appropriate.

Comment: We received multiple comments in support of our proposed regulation, including comments that requested we consider expanding this authority to include sharing information about QHP issuers to other State and Federal regulatory and enforcement entities that may need this information for their oversight purposes.

Response: Because we intend to share information about QHP issuers used for oversight and enforcement activities with other State and Federal regulatory and enforcement entities, and such entities have legitimate oversight and enforcement purposes for using such information, we agree that it is not necessary or appropriate for us to limit the ways in which such entities could use the information we would be sharing in a manner that would prohibit legitimate oversight and enforcement activities. We are finalizing the regulation accordingly.

Summary of Regulatory Changes

We are finalizing §156.800(d) as proposed, with the modification of removing “to the extent that the consultation and information is necessary for HHS to determine whether an enforcement remedy under subpart I is appropriate” and replacing it with “to the extent that the consultation and information is necessary for purposes of State or Federal oversight activities.”

b. Bases and Process for Imposing Civil Money Penalties in Federally-Facilitated Exchanges (§156.805)

We did not receive comments on the proposed addition of §156.805(d)(3) and are finalizing the provision as proposed.

c. Notice of Non-Compliance (§156.806)

We proposed adding §156.806 to explain that HHS will provide a written notice to the issuer, to include a description of the potential violation, a 30-day period for the QHP issuer to respond and to provide additional information to refute an alleged violation.

Comment: Some commenters requested that we permit extensions to the 30-day period for QHP issuers to respond and to provide additional information to refute an alleged violation. One of these commenters also requested that we allow QHP issuers to have 60 days, rather than the proposed 30 days, to respond and provide additional information.

Response: We believe that 30 days provides QHP issuers with sufficient opportunity to respond and provide additional information to refute an alleged violation. Additionally, a QHP issuer that fails to act within the 30-day period will have an opportunity to request a hearing under Subpart J of 45 CFR Part 156. The QHP issuer will have the opportunity present its arguments and supporting documents at the time of the hearing.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §156.806 of the proposed rule without modification.

d. Bases and Process for Decertification of a QHP Offered by an Issuer Through a Federally-Facilitated Exchange (§156.810)

In §156.810, we proposed several modifications to better align our bases for decertification, including bases for expedited decertifications, with regulatory provisions which have been finalized and to clarify certain regulatory text. We proposed rewording paragraph (a)(6) to clarify that the certification criteria means the standards under subpart C of this part. We also proposed in §156.810(d) that the FFE will be able to pursue an expedited decertification for violation of paragraph (a)(6). Additionally, we proposed clarifying in paragraph (a)(9) that

violation of State or Federal law relating to internal claims and appeals and external review processes are bases for decertification under this paragraph. We proposed aligning the standards set forth under subparts K and M with the bases for decertification. We proposed adding a paragraph (12) to reflect that HHS may decertify a QHP if the QHP issuer substantially fails to meet the requirements related to the cases forwarded to QHP issuers under Subpart K, and adding a paragraph (13) to reflect that HHS may decertify a QHP if the QHP issuer substantially fails to meet the requirements in Subpart M.

Comment: We received general comments supporting our modifications to §156.810, including the inclusion of §156.810(a)(6) as a basis for expedited decertification and clarification that HHS may pursue decertifications for violations of applicable standards under Subpart C of 45 CFR Part 156. In addition, we received comments requesting that HHS not include violations of the provisions set forth under Subparts K and M as bases for decertification because the commenters indicated that not all of the provisions proposed under these Subparts have been finalized. One of the commenters requested that we extend the good faith policy adopted for 2014 until all provisions under these Subparts have been finalized.

Response: We recognize that there may be instances in which new regulations proposed under Subparts K or M have not yet been finalized. In such instances, HHS would not enforce these regulations until they have been finalized absent a separate authority to enforce these regulations. In the meantime, there are provisions set forth under Subparts K and M that have been finalized and are enforceable, and accordingly, we believe that our proposed modification

to include those provisions in §156.810 is appropriate.³⁷ In the 2015 Letter to Issuers, we stated that we did not intend to extend the 2014 good faith compliance safe harbor.

Comment: One commenter requested that we expressly limit expedited decertifications to violations that put QHP enrollees' ability to access necessary medical items or services at risk or substantially compromise the operation of the Exchange.

Response: We believe there may a few rare situations in which expedited decertifications may be necessary, but which may not be resulting from violations that put QHP enrollees' ability to access necessary medical items or services at risk or substantially compromise the operation of the Exchange. For example, if a QHP issuer loses its ability offer a QHP based on an applicable State law or State action, HHS would need a mechanism to remove the QHP from the Exchange expeditiously. Recognizing that such possibility should be rare, but possible, we decline to limit expedited decertifications as requested, and finalize this section as proposed.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §156.810 of the proposed rule, correcting only the numbering of the added provisions in paragraph (a).

5. Subpart L—Quality Standards

a. Establishment of Standards for HHS-Approved Enrollee Satisfaction Survey Vendors for Use by QHP Issuers in Exchanges (§156.1105)

We proposed to amend §156.1105 to include monitoring and appeals processes for HHS-approved ESS vendors that would apply for plan years beginning 2015. In paragraph (d), we proposed that HHS will monitor HHS-approved ESS vendors to ensure ongoing compliance

³⁷ Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, and Eligibility Appeals, 78 FR 54070 (August 30, 2013) (to be codified at 45 CFR parts 147, 153, 155, and 156).

with the application and approval standards in paragraphs (a) and (b). Further, we proposed that if HHS determines that an approved vendor is non-compliant with the standards outlined in paragraph (b), they may be removed from the approved list described in paragraph (c) and/or the submitted survey results may be ineligible to be included for ESS results. Lastly, we proposed in paragraph (e) an appeals process for an ESS vendor that submits an application to HHS for approval, as described in paragraph (a), and is not approved. Specifically, we proposed that an ESS vendor may appeal HHS's decision by notifying HHS in writing within 15 days of the notification of not being approved by HHS and submitting additional documentation demonstrating how the vendor meets the standards in paragraph (b). HHS would review the submitted documentation and make a final approval determination within 30 days from receipt of the additional documentation. An ESS vendor that becomes approved via the appeals process would be included in the approved list, described in paragraph (c).

Comment: Many commenters supported the provisions in §156.1105 relating to the monitoring and appeals processes for ESS vendors. Several commenters requested clarification how, if HHS determines survey results ineligible to be included in ESS results because of a non-compliant vendor, the affected QHP's global quality rating would be calculated and displayed. Commenters urged HHS to minimize such circumstances when results would not be published and to have adequate disclaimers explaining the reason for ESS results that are unavailable. A few commenters urged HHS to add a hold harmless provision to mitigate the harm on compliant QHPs who should not be penalized due to vendor behavior and to have alternative processes in such circumstances such as permit use of prior year's scores.

Response: We clarify that, if HHS determines an ESS vendor to be non-compliant with the required standards and its survey results are deemed ineligible to be included in ESS results,

HHS would designate those ESS measures that are included in the QRS as not being available for the current reporting year. Similar to the business relationships that issuers have with survey vendors to administer other CAHPS®-like surveys for other products (for example, Medicare Advantage), we expect issuers to work closely with their contracted vendors to mitigate harm on compliant QHPs. In such circumstances, we will work with affected QHP issuers and ESS vendors and consider approaches so that having unavailable ESS data is minimized (that is, opportunity to re-administer the survey using a compliant vendor). These standards and processes have been informed by our experience with the Medicare CAHPS® survey vendor program, under which it has been a rare occurrence for a vendor to be found non-complaint and its survey results deemed ineligible. We maintain and finalize the standards in 156.1105 as proposed.

Summary of Regulatory Changes

We are finalizing the provisions proposed in §156.1105 of the proposed rule without modification.

b. Quality Rating System (§156.1120)

In §156.1120, we proposed standards for QHP issuers offering coverage on Exchanges to collect and report the necessary information to implement the QRS pursuant to section 1311(c)(3) of the Affordable Care Act. In paragraph (a), we proposed data submission requirements for a QHP issuer for the information necessary to calculate the quality ratings for coverage offered on Exchanges under the QRS, and in §156.1120(b), we proposed to direct a QHP issuer to annually submit data necessary to calculate the QHP's quality ratings to HHS and the Exchange, on a timeline and in a standardized form and manner specified by HHS. In paragraph (a)(1), we proposed that a QHP issuer must submit data to calculate quality ratings for

each QHP that has been offered in an Exchange for at least one year. In paragraph (a)(2), we proposed to direct a QHP issuer to submit data that has been validated in a form and manner specified by HHS.

In paragraph (a)(3), we proposed that a QHP issuer must include information in its data submission only for those QHP enrollees at the reporting level specified by HHS that is necessary to calculate the quality ratings.

We noted that multi-State plans, as defined in §155.1000(a), are subject to reporting QRS data for calculation of quality ratings by HHS, as described in paragraph (a). The U.S. Office of Personnel Management (OPM) will provide guidance on quality reporting to issuers with whom it holds multi-State plan contracts.

Lastly, in paragraph (c), we proposed that an issuer may reference its QHP's quality rating information in its marketing materials, in a manner specified by HHS. Similarly, in the subsequent section 156.1125 regarding the ESS, we proposed a similar marketing standard in §156.1125(c) that a QHP issuer may reference the ESS results for its QHPs in its marketing materials, in a manner specified by HHS.

Comment: Many commenters expressed concern that the proposed data validation process provides an unfair advantage to NCQA, would lead to NCQA having a monopoly and eliminate competition among accrediting entities. Commenters also noted that the proposed approach could disadvantage those issuers seeking accreditation from the other two recognized accrediting entities. Some commenters stated that some issuers may incur additional fees for services already purchased by URAC which may increase consumer premiums and affect their ability to continue participating in Exchanges.

Response: We acknowledge that in the initial years of QRS implementation, some QHP issuers may incur additional costs and burden for data validation since the QRS measure stewards may not be aligned with their chosen accrediting entity. However, we believe that the majority of QHP issuers offering coverage through the Exchanges in the initial years already have established relationships with HEDIS (Healthcare Effectiveness Data and Information Set) compliance auditors such that there should be minimal overall costs and burdens to the health care system. We refer commenters to the relevant estimated burden and costs in the Marketplace Quality Standards PRA package that is associated with the NPRM and available at <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>. We believe that aligning QRS measure validation requirements with the existing processes of the measure stewards provides consistency to ensure that valid and appropriate data are used to calculate quality rating information for public reporting. HHS anticipates refining the QRS over time as we gain experience about measures that are the most appropriate to the Exchange and approaches to quality measurement and health plan reporting evolve. As the QRS matures, we intend to consider changes to measures as well as ways to minimize the burden of QRS data collection, validation and submission. In addition, we are exploring ways to further streamline and align the accreditation standards with the quality reporting requirements to reduce duplicative and overlapping requirements.

Comment: Several commenters requested clarification of the data validation process and suggested alignment and coordination with the measure stewards so that there would not be multiple, independent audit requirements. They did not support having independent third party validation and monitoring by HHS because of concerns of duplicative requirements and cost.

One commenter expressed concern regarding combining the HEDIS and CAHPS® validation processes causing issues with coordination with vendors and unnecessary burden.

Response: We clarify that we intend to direct QHP issuers to follow the data validation process of the QRS measure stewards. We do not intend to combine data validation processes for HEDIS and CAHPS® or ESS measure data; however, we clarify that, consistent with § 156.1125(b)(2), the survey sample data that the QHP issuer will need to provide to their contracted ESS vendor would need to be validated in a form and manner specified by HHS. We anticipate directing QHP issuers to use an independent third party to perform this validation. We intend to allow issuers to use the same third party validator used for QRS measures for validating the ESS survey sample, similar to the HEDIS CAHPS® process. We anticipate releasing technical guidance in 2014 to provide further details regarding data validation, finalized measures and measure specifications. We agree with commenters and believe that it is important to align and coordinate with existing data validation and submission requirements.

Comment: Several commenters requested that if HHS uses proprietary measures related to one accrediting entity, that HHS require that those data sets and quality measures be made freely available to all QHP issuers and to recognized accrediting entities to avoid imposing additional regulatory costs on those issuers seeking accreditation through the other entities. Some commenters requested consideration of allowing reporting of either HEDIS or quality measure data from the other two accrediting entities.

Response: We understand commenters' concerns regarding the need to make information on the QRS measure data sets available to all QHP issuers. We intend to provide details including QRS quality measure specifications (which will include details on the underlying measures that comprise the QRS) in technical guidance to be posted on an HHS website. Any

organization may use the QRS measure specifications to report its performance without charge, and health plans may share their results. However, to designate the results as HEDIS data, the results must have been audited by an NCQA-Certified HEDIS Auditor. A successful audit ensures reliability and comparability of results for measures that are designated as HEDIS. We believe that requiring submission of a standard set of QRS quality measures, validated in a consistent manner as specified by the measure stewards, for all QHP issuers is critical to the goals of the QRS including the ability to provide reliable, comparable, and uniform quality data to consumers regardless of the Exchange. In addition, we considered non-HEDIS health plan quality measures during the measure selection process. However, based on the measure selection and measure set evaluation criteria, that were developed using the National Quality Forum (NQF) Measure Evaluation Criteria and the Measures Application Partnership (MAP) Measure-Selection Criteria (which factored in importance, performance gap, reliability and validity, feasibility and alignment) the majority of proposed measures to be included in the QRS for the initial years are HEDIS measures. As noted in the proposed rule, after considering public comments and review of the measures outlined in the November 19, 2013 Federal Register Notice with Comment³⁸ on the QRS framework (QRS Notice), we intend to finalize the quality measures and anticipate publishing the finalized 2015 QRS measure set in the near future on a HHS website. We anticipate greater availability over time of more robust, data-driven clinical quality measures specified for health plans and which provide meaningful information regarding changes in a patient's health outcome and intend to continue to seek feedback regarding evolution of the QRS. In addition, we are exploring ways to further streamline and align the

³⁸ Patient Protection and Affordable Care Act; Exchanges and Qualified Health Plans, Quality Rating System (QRS) Framework, Measures and Methodology; Notice with Comment, 78 FR 69418 (Nov. 19, 2013).

accreditation standards with the quality reporting requirements to reduce duplication and minimize the burden of QRS data collection, validation and submission.

Comment: One commenter requested that the QHP rating information be accessible in an easy electronic format and that the rating methodology be released to issuers at the same time as the scores are released to allow issuers to estimate their own ratings.

Response: We agree and clarify that the QRS and ESS information will be easy to access in an electronic format. We intend to minimize burden by providing QRS and ESS information to issuers in an electronic format such as through Electronic File Transfers so that the vast majority of stakeholders would be able to easily download and view the data. Further we clarify that the 2015 beta test QRS scoring specifications and technical guidance which will include the ESS scoring methodology, would be released in 2014, in advance of the release of scores, to provide issuers ample time to estimate ratings if they so choose.

Comment: Many commenters suggested revisions to the QRS measure set. Some commenters urged CMS to incorporate all CAHPS® measures from the ESS into the QRS and not just a subset.

Response: As we noted earlier in the rule, we appreciate comments related to the QRS measure set, as well as the ESS measures, and they will inform future modifications and evolution of Exchange quality reporting; however, these comments are outside the scope of this rulemaking.

Comment: Several commenters supported the proposed approach for product-level reporting for the QRS in the initial years because more granular reporting would not be feasible due to potential sample size issues. One commenter urged CMS to clarify what it means by product-level reporting and to align the level of reporting with the process used by accreditors.

Many commenters recommended collection and reporting for the QRS at the metal tier level because consumer experience will be different for plans at different metal levels and this information is critical for enrollees' ability to make informed decisions about a particular plan.

Response: Although we acknowledge that consumer experience and characteristics may be different for QHPs at different metal levels, we believe that it is necessary, in the initial years of implementation, to provide a balanced approach regarding the level of data collection and public display for the QRS and ESS. We believe that there are fewer potential sample size issues with ESS reporting versus QRS reporting based on the populations eligible to participate in the ESS (that is, most measures include the entire enrollee population) and the limitations of eligible populations for the majority of QRS clinical quality measures (that is, most measures do not include the entire patient population, rather a subset of the population for which a clinical action is being measured). We also believe it is important to align the initial reporting of QRS information with the product-level requirements for QHP accreditation requirements. While we are maintaining the requirement that ESS data be submitted at the metal tier level, we anticipate aligning the public display of the ESS results with the QRS at the product-level for consistency across the quality measures and associated accreditation standards. We will re-examine the possibility of displaying the ESS results at a more granular level following an analysis of the 2015 beta test results. HHS is currently researching implementation of a process to collect data in a way that would allow us to assess the feasibility of level of coverage (for example, platinum, gold, silver, bronze, and catastrophic) reporting for the QRS as Exchange s mature and QHP enrollment grows. We maintain in the final rule that a QHP issuer must submit data at the level that will be specified by HHS but reiterate that the level of data submission may not align with the level of public reporting during the initial implementation of the QRS and ESS to provide

greater flexibility regarding calculating scores based on different factors including adequate sample sizes and reliable measurement data.

Comment: Many commenters urged HHS to review and monitor the content of marketing materials as part of ongoing compliance reviews. Some commenters did not support the proposed marketing provision without accompanying HHS guidelines and a review process for marketing materials.

Response: We are finalizing the marketing provisions for the QRS and ESS, in §156.1120 and §156.1125 respectively, as proposed. We believe that it is important to set initial guidelines regarding referencing the QRS ratings and ESS results in issuer marketing materials for its respective QHPs and will be issuing future technical guidance that provides details regarding use and display of QRS and ESS results in issuer marketing materials. We note that we will consider effective and streamlined approaches of reviewing marketing materials as QHP issuer monitoring and oversight activities evolve in future years. As we stated in the Exchange final rule, States have significant experience with, and existing infrastructure to support monitoring and oversight of health plan marketing activities. We encourage a streamlined approach of incorporating review of a QHP issuer's marketing materials referencing quality ratings and ESS results as part of an Exchange's monitoring and oversight activities.

Comment: Some commenters supported the proposal to allow data collection based on combined populations if the plan offerings are the same inside and outside the Exchange to enhance sample size and reliability of data. Several commenters did not support the proposed approach because of potential differences that may be reflected in quality, confusion for consumers and skewed QRS results. One commenter noted that some issuers may only offer QHPs on the Exchanges and therefore may not have the ability to combine data with products

offered outside the Exchange. Commenters urged HHS to reconsider the proposed approach and consider alternatives such as comparison within a peer group.

Response: We agree with commenters regarding potential differences in enrollee characteristics of QHPs offered inside and outside the Exchange that may impact QRS and ESS results. We believe that it is important for the reliability and validity of the QRS to have adequate sample sizes and have the appropriate enrollee data to reflect meaningful information and differences regarding QHP quality to consumers selecting plans in the Exchange. During the 2015 beta testing period, we will not use data from QHPs outside the Exchange. We will assess the impact that this approach has on quality ratings in the beta test and will consider the feasibility of alternative approaches to ensure appropriate sample size and reliability of data. We anticipate issuing future guidance on whether plan offerings outside the Exchange that would be considered the same as one that is certified as a QHP and offered through the Exchange, as defined in § 153.500, can be included in the QRS and ESS.

Comment: Several commenters supported alignment of accreditation standards with QRS, ESS and QIS reporting. One commenter supported continued use of HEDIS and CAHPS® measures to ensure alignment with accrediting entities.

Response: We agree with commenters and note that to minimize burden and costs, it is important that alignment of QHP accreditation standards and quality reporting in the Exchanges be achieved as much as possible. We are considering updating standards for recognized accrediting entities and QHP accreditation in the near future and will solicit comment at that time regarding the potential of deeming QHP issuers and recognized accrediting entities in compliance with the accreditation requirements related to clinical quality measures and patient experience ratings by meeting the ESS and QRS requirements. We expect to continue use of

robust, evidence-based measures including HEDIS, CAHPS® and other measures that reflect the National Quality Strategy priorities.

Comment: Many commenters supported the proposed timeframes of QRS and ESS implementation including 2015 beta testing and public reporting during the 2016 open enrollment period for the 2017 coverage year. A few commenters urged HHS to finalize the QRS measures and measure specifications to provide to issuers by May 2014 at the latest so that issuers would have sufficient time to collect and submit data in time for beta testing. A few commenters expressed concern that consumers would have to wait until the 2016 open enrollment period to access quality rating information. And some commenters requested further delay for implementation because of the disproportionate financial and staff burden on new and smaller plans.

Response: We believe that the 2015 beta testing and 2016 public reporting timeframes are appropriate and consistent with QHP issuer accreditation requirements for the FFE and most State Exchanges to report clinical quality and CAHPS® data in 2016. In addition, we believe the proposed timeframes offer a balanced approach to providing consumers with meaningful, tested QHP quality information and providing issuers ample time to prepare for collection and submission of validated data. The majority of plans already have established processes and experience for similar, existing quality reporting and we acknowledge that new and smaller plans may have increased burden; however, we believe that the phase in implementation of QRS and ESS beginning in 2015 with beta testing is the appropriate approach. We anticipate publishing the finalized QRS measure set soon after the publication of this final rule.

Summary of Regulatory Changes

We are finalizing the proposed provision with the following modification: In paragraph §156.1120(a)(3), we replace “at the reporting level specified by HHS” with “at the level specified by HHS” to better distinguish between the level at which collection of QRS data as well as the level of public display of QRS data that would be required.

c. Enrollee Satisfaction Survey (§156.1125)

At §156.1125(a), we proposed to direct QHP issuers to contract with an HHS-approved ESS vendor, as identified by §156.1105, to administer the ESS of the QHP’s enrollees. We also proposed to direct a QHP issuer to authorize its contracted ESS vendor to report survey results to HHS and the Exchange on the issuer’s behalf. In paragraph (b), we proposed several data requirements to clarify the standards for collection and submission of ESS data. At §156.1125(b)(1), we proposed to direct a QHP issuer to collect data of eligible enrollees for each QHP with more than 500 enrollees in the previous year that has been offered in an Exchange for at least one year following a survey sampling methodology provided by HHS. In paragraph (b)(2), we proposed to direct a QHP issuer to submit data, necessary to conduct the ESS, that has been validated in a form and manner specified by HHS. In paragraph (b)(3), we proposed to direct a QHP issuer to include only those QHP enrollees at the reporting level specified by HHS, for data submitted for the ESS.

In paragraph (d), we proposed to direct a QHP issuer to submit data necessary to conduct the survey to its contracted ESS vendor on a timeline and in a form and manner specified by HHS. We stated our intention to align the timeframes of the proposed reporting requirements for the ESS and the QRS.

We also noted that Multi-State Plans, as defined in 45 CFR 155.1000(a), are subject to providing the data described in paragraph (b). The OPM will provide guidance on ESS reporting to issuers with whom it holds Multi-State Plan contracts.

Comment: The majority of commenters supported the proposed approach of aligning the ESS with existing CAHPS® surveys and processes. Some commenters requested that we leverage the annual, existing CAHPS® survey to meet the ESS requirement. One commenter requested clarification of how the CAHPS® 5.0 Adult Medicaid Survey would be modified for the Exchanges.

Response: We have leveraged existing CAHPS® surveys and processes in the development of the ESS (or QHP Enrollee Survey). In addition, we are considering approaches and will seek comment in future rulemaking for further alignment of QHP issuer accreditation and quality reporting in the Exchanges, including but not limited to ESS reporting. We clarify that the QHP Enrollee Survey includes all of the CAHPS® Health Plan 5.0 (Adult Medicaid) items with additional items based on a comprehensive review of the literature and related surveys, focus groups, stakeholder discussions, and input from a technical expert panel, as we described in the PRA supporting statements available under CMS Form Number 10488 at <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

Comment: One commenter urged HHS to use the term “experience”, rather than “satisfaction” when describing the survey because “experience” is considered a more objective and relevant source of data. A few commenters sought clarification regarding enrollee eligibility for the ESS and the QHP sample size requirements. Two commenters recommended larger

sample sizes to ensure adequate response rates and to align with commercial CAHPS® or other satisfaction surveys.

Response: We have used the term ESS in this rule to mirror the statutory language of section 1311(c)(4) of the Affordable Care Act. However, the name of the ESS survey that will be administered to enrollees is “QHP Enrollee Experience Survey”. We incorporate the size requirement in 156.1125(b) to align with the statutory language in section 1311(c)(4) that requires the development of an ESS to evaluate enrollee satisfaction with QHPs offered through an Exchange, “for each such qualified health plan that had more than 500 enrollees in the previous year.” We agree that adequate sample sizes and response rates are needed for statistically valid measurement rates. For more information on our approach to adequate sample size and response rates for the survey, we refer commenters to the PRA supporting statements available under CMS Form Number 10488 at <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

Comment: A few commenters supported collecting and reporting ESS measure data at the metal tier level to provide meaningful, disaggregated information to consumers. However, several commenters acknowledged that sample sizes could be too small to ensure valid and reliable measurement, especially in the early years of the Exchanges and therefore urged HHS to follow the same approach as QRS data collection, at the product-level.

Response: We believe that, similar to the approach for QRS data collection and reporting, it is important to have a balanced approach that will allow for us to provide useful information to consumers while ensuring that the data is statistically significant and reliable. We agree with commenters and acknowledge that sample sizes may be too small to report at the metal-tier level and therefore maintain in the final rule the intention to publicly display ESS measure data at the

product-level in alignment with the QRS. However, we note that we believe that there are fewer potential sample size issues with ESS reporting versus QRS reporting based on the populations eligible to participate in the ESS. Most measures for the ESS include the entire enrollee population, while the majority of QRS measures are limited because they would not extend to the entire patient population. Similar to the QRS, we clarify that we intend to require QHPs to submit data at a level specified by HHS that will allow for us to determine the feasibility of using more granular levels for data reporting and public display in the future. At this point in time, we anticipate requiring the submission of ESS data at the more granular metal tier level and will be issuing technical guidance in the near future that provides further details regarding the ESS data reporting process.

Marketplace Survey

Sections 1313 and 1321(a) of the Affordable Care Act provide the Secretary with general authority to establish standards and regulations related to Exchanges, QHPs, and other components of title I of the Affordable Care Act. In §155.1200(b)(3), we direct State Exchanges to submit performance monitoring data on an annual basis, which would include information on consumer satisfaction. Pursuant to this legal authority, HHS proposed a consumer experience survey, or the Marketplace survey, to assess consumer experience with the Exchanges³⁹ including obtaining information regarding aspects such as the application and eligibility determination process for Medicaid/Children's Health Insurance Program (CHIP) coverage and the Insurance Affordability Programs.

Comment: Many commenters supported establishing the Marketplace survey and directing State Exchanges to submit survey sampling data to HHS. Commenters also urged HHS

³⁹ Agency Information Collection Activities: Health Insurance Marketplace Consumer Experience Surveys: Enrollee Satisfaction Survey and Marketplace Survey Data Collection; Notice, 78 FR 65658 (Nov. 1, 2013).

to provide full access to the public of survey results, similar to the ESS. A few commenters recommended inclusion of Medicaid eligibles and data based on various demographics such as gender, language preference, and disability status.

Response: We maintain that the purpose of the Marketplace survey is to inform the quality improvement of Exchanges; we, therefore, intend to provide Exchanges with the results of the Marketplace survey and will consider ways to make this information available to the public. We appreciate the comments regarding suggestions for sampling data criteria which will inform future years of Marketplace survey implementation and may consider directing State Exchanges to submit survey sampling data to HHS. For more information on the Marketplace Survey, we refer commenters to the PRA supporting statements available under the CMS Form Number 10488 at <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

Summary of Regulatory Changes

We are finalizing the proposals for ESS and Marketplace Surveys with the following modification: In paragraph §156.1125(b)(3), we replace “at the reporting level specified by HHS” with “at the level specified by HHS” to better distinguish between the level at which collection and submission of ESS data by QHP issuers that would be required, as opposed to the level of public display or reporting of ESS data by Exchanges that would be required.

I. Part 158 – Issuer Use of Premium Revenue: Reporting and Rebate Requirements

1. Subpart A – Disclosure and Reporting

a. ICD–10 Conversion Expenses (§158.150)

In September 2012, the Secretary changed the date on which issuers are required to adopt ICD-10 as the standard medical code set from October 1, 2013 to October 1, 2014.

Subsequently, the Protecting Access to Medicare Act of 2014 (Pub. L. 113-93), enacted on April 1, 2014, mandated that this date be further delayed to October 1, 2015. Because the ICD-10 implementation date has been postponed past 2013, issuers may incur conversion costs beyond 2013 that would otherwise have been incurred only in 2012 and 2013. Therefore, in the proposed rule, we proposed to permit issuers to continue including their ICD-10 conversion costs as activities that improve health care quality (QIA), up to 0.3 percent of an issuer's earned premium in the relevant State and market, through the MLR reporting year in which ICD-10 implementation is required by the Secretary.

Comment: We received several comments supporting inclusion of ICD-10 conversion costs in QIA past 2013, as well as several comments opposing inclusion of these costs past 2014. Some commenters supporting the extension also requested that the 0.3 percent cap be raised to 0.4 percent.

Response: Because data continue to show that ICD-10 expenses have not, on average, exceeded 0.3 percent of premium, we are not raising the cap to 0.4 percent. In addition, because we recognize that the recent Congressional delay of the ICD-10 implementation date to 2015 may cause issuers to continue to incur implementation costs, such as concurrently maintaining ICD-9 and ICD-10 systems and performing additional testing, we are continuing to allow inclusion of ICD-10 conversion costs in QIA through the MLR reporting year in which ICD-10 implementation is required by the Secretary.

Summary of Regulatory Changes

We are finalizing the changes to §158.150 as proposed.

2. Subpart B—Calculating and Providing the Rebate

a. MLR and Rebate Calculations in States with Merged Individual and Small Group Markets (§§158.211, 158.220, 158.231)

In the proposed rule, we proposed to amend §158.220(a) and §158.231(a) to specify that the individual and small group market data must always be aggregated if a State requires these two markets to be merged, and to amend §158.211 to clarify that if a State establishes a higher MLR standard for the merged market, this higher standard must be used to calculate any rebates for the merged market.

Comment: We received one comment supporting the requirement to use the higher State MLR standards in calculating rebates. We received no comments specific to the proposed data aggregation standard in States that require the individual and small group markets to be merged.

Response: We appreciate the comment regarding the higher State MLR standards.

Summary of Regulatory Changes

We are finalizing the amendments proposed in §§158.211, 158.220, and 158.231 of the proposed rule without modification.

b. Accounting for Special Circumstances (§158.221)

On November 14, 2013, the Federal government announced a policy under which, if certain conditions were met, it would decline to enforce certain specified 2014 market reforms against certain non-grandfathered health insurance coverage in the individual or small group market renewed between January 1, 2014 and October 1, 2014, and requested that States adopt a similar non-enforcement policy.⁴⁰ CMS noted in the Proposed 2015 Payment Notice (78 FR 72322) that this transitional policy would not have been anticipated by issuers in setting rates for

⁴⁰ Letter to Insurance Commissioners, Center for Consumer Information and Insurance Oversight, November 14, 2013. Available at: <http://www.cms.gov/CCIIO/Resources/Letters/Downloads/commissioner-letter-11-14-2013.pdf>.

2014 and stated that we were exploring modifications to different programs (including but not limited to the MLR program) to help mitigate the impact of this policy.

As we explained in the proposed rule, issuers that provided transitional coverage may have incurred additional administrative costs, such as expenses related to developing and sending required consumers notices, and creating and submitting new policy and rate filings. As further stated in the proposed rule, we also recognize that issuers of QHPs in the individual and small group markets may have incurred costs due to technical issues during the launch of the State Exchanges and FFEs.

Therefore, in the proposed rule, we proposed to account for the special circumstances of plans affected by the transitional policy and plans affected by the technical issues during the launch of the State Exchanges and FFEs by amending §158.221 to allow for an adjustment to the MLR calculation for such issuers. Specifically, we proposed to allow issuers offering transitional coverage in the individual and small group markets to multiply the incurred claims and expenses for quality improving activities incurred in 2014 in the MLR numerator by 1.0001. We also proposed to allow issuers offering coverage through the State and Federal Exchanges in the individual and small group markets to multiply the incurred claims and expenses for quality improving activities incurred in 2014 in the MLR numerator by 1.0004. These adjustments would only extend to issuers in the individual and / or small group markets that offered transitional coverage or participated in the State Exchanges and FFEs, and only for the 2014 reporting year. A transitional policy cost adjustment to the formula for calculating an issuer's MLR would not apply in States that did not implement the transitional policy, or in States that did, to issuers that did not elect to implement it. Similarly, the proposed adjustment to the

formula for calculating an issuer's MLR related to the initial Exchange technical issues would not be available to issuers that did not elect to participate in the Exchanges.

Comment: Some commenters expressed support for adjustments to the MLR formula for plans affected by the transitional policy and plans affected by the technical issues during the launch of the State and Federal Exchanges. These commenters also expressed concern that the adjustments are inadequate, but none provided specific data to support this assertion or suggested specific alternative adjustments. Commenters requested that both adjustments also be provided for 2013; one of these commenters requested that the adjustment related to Exchange technical issues continue in 2015; while two of these commenters requested that the adjustment related to transitional policy continue while transitional coverage remains in force. One commenter additionally recommended that instead of multiplying the MLR numerator by an adjustment factor, CMS permit issuers to deduct actual administrative costs related to Exchange implementation from the MLR denominator. Another commenter recommended this alternative approach (that is, to permit a deduction of actual administrative expenses) for costs related to the transitional policy, and recommended that CMS waive the Exchange user fee for issuers affected by Exchange implementation problems instead of the proposed adjustment. Both these commenters argued that such alternative approaches would benefit issuers who meet or exceed the MLR standard.

In contrast, other commenters expressed concern that adjustments to the MLR formula may undermine the MLR program's effectiveness in keeping premiums down, and urged CMS not to extend the proposed adjustments beyond 2014. One commenter further requested that issuers be required to demonstrate that they in fact incurred additional administrative costs.

Response: The proposed adjustments were based on the best data available to us, and the types of expenses we considered were the types of expenses described by the commenters. Absent more specific and substantiated recommendations with accompanying supporting data, we do not have a basis for increasing the adjustments. Further, the costs issuers incurred in connection with the transitional policy are often one-time and will decline over time, and the same is true of the Exchanges-related costs as the functioning of the Exchanges improves in 2015. Lastly, we recognize that the proposed adjustments to the MLR numerator only provide relief to issuers that did not meet the MLR standard, since such adjustments would merely cause issuers meeting the MLR standard to exceed the standard by a larger percentage than they already did. However, we find that the alternative adjustments to the MLR denominator suggested by some commenters have similar limitations. In addition, such alternative adjustments would be more administratively burdensome to implement than the proposed uniform adjustments, and would be more susceptible to abuse. We believe that the proposed adjustments appropriately account for the special circumstances related to implementation of the transitional policy and initial technical problems of the Exchanges, while still requiring issuers to comply with the statutory MLR requirement.

Summary of Regulatory Changes

We are finalizing the amendments proposed in §158.221 of the proposed rule without modification.

c. Distribution of De Minimis Rebates (§158.243)

The MLR December 7, 2011 final rule defines the threshold amounts below which rebates are considered to be de minimis and sets forth the provisions for distribution of such rebates. In the proposed rule, we proposed to amend the provisions for de minimis rebates in

§158.243 to clarify how issuers must distribute rebates where: (1) all of an issuer's rebates are de minimis, or (2) distribution of de minimis rebates to enrollee(s) whose rebates are not de minimis would result in an enrollee receiving a rebate that exceeds the enrollee's annual premium. In these two situations, we proposed requiring the issuer to distribute de minimis rebates to enrollees in the policies that generated the de minimis rebates, and not to aggregate such rebates and distribute them to other enrollees whose rebates are not de minimis.

Comment: We received several comments opposing the proposed amendments to the de minimis provisions. The commenters argue that requiring distribution of any de minimis rebates directly to enrollees is contrary to the rationale behind the MLR de minimis provision. The commenters assert that the administrative burden of directly distributing de minimis rebates would exceed the benefit to consumers. One of these commenters recommended including the total amount of de minimis rebates, when all of an issuer's rebates are de minimis, in premium rate calculations for the following year. This commenter also recommended that in cases where distribution of de minimis rebates to enrollee(s) whose rebate are not de minimis would result in an enrollee receiving a rebate that exceeds the enrollee's annual premium, the issuer be allowed to place the excess of the aggregated de minimis rebate over premium in a reserve fund, and use it first toward the cost of operating this fund, and second in premium rate calculations for the following year. Another commenter recommended that issuers be allowed to distribute the de minimis rebates to the State for use in health education.

Response: We acknowledge the commenters' concern that the administrative costs of directly distributing de minimis rebates may impose administrative costs in excess of the rebate amounts. At this time, few, if any, enrollees are known to be affected by the two situations described in the proposed rule. Therefore, in order to consider alternative approaches to the

treatment of de minimis rebates in these two situations, we are not finalizing the proposed clarifications and will address this issue in future rulemaking.

Summary of Regulatory Changes

We are not finalizing the amendments proposed in §158.243 of the proposed rule at this time.

IV. Provisions of Final Regulations

For the most part, this final rule incorporates the provisions of the proposed rule. Those provisions of this final rule that differ from the proposed rule are as follows:

Changes to §144.103

- Adds definitions of “product” and “plan” and clarifies that standards for uniform modification related to benefits and cost sharing apply at the plan-level.

Changes to §146.152

- Applies the definition of uniform modification of coverage and renewal notice requirements to issuers offering coverage in the small group market.
- Indicates that a State may only broaden the uniform modification standard criteria addressing cost-sharing structure and service area.
- Adds language to clarify and amend the term “pursuant to applicable Federal or State requirements.”
- Deletes the reference to “counties” in the service area criterion.

Changes to §146.180

- Adds that an opt-out election for multiple self-funded, non-Federal governmental plans subject to a single collective bargaining agreement must specify each group health plan subject to the agreement.

- Adds that a sponsor submitting opt-out elections for multiple self-funded, non-Federal governmental plans that are not subject to a collective bargaining agreement, must submit a separate opt-out election document for each such plan.
- Replaces the special rule for timely filings of opt-out elections by U.S. mail with a special rule for timely filings of opt-out elections in electronic format, and provides that if the latest filing date falls on a Saturday, Sunday, or a State or Federal holiday, CMS accepts filings submitted the next business day.

Changes to §147.106

- Applies the definition of uniform modification of coverage and renewal notice requirements only to issuers offering coverage in the individual and small group markets.
- Adds language to clarify and amend the term “pursuant to applicable Federal or State requirements.”
- Indicates that a State may only broaden the uniform modification standard criteria addressing cost-sharing structure and service area.
- Deletes the reference to “counties” in the service area criterion.
- Adds that Medicare eligibility or entitlement is not a basis for nonrenewal or termination of an individual's health insurance coverage in the individual market.

Changes to §148.122

- Applies the definition of uniform modification of coverage and renewal notice requirements to issuers offering coverage in the individual market.
- Adds language to clarify and amend the term “pursuant to applicable Federal or State requirements.”

- Indicates that a State may only broaden the uniform modification standard criteria addressing cost-sharing structure and service area.
- Deletes the reference to “counties” in the service area criterion.

Changes to §148.220

- Aligns introductory text with the statutory language.
- Clarifies that, to be an excepted benefit, fixed indemnity insurance in the individual market can be provided only to individuals who attest in their application (1) that they have other health coverage that is minimum essential coverage; or (2). that they are treated as having minimum essential coverage due to their status as a bona fide resident of any possession of the United States pursuant to Code section 5000A(f)(4)(B).
- Clarifies that fixed indemnity insurance pays in a fixed dollar amount per period of hospitalization or illness, per service, or both.
- Requires notice to be displayed in the application for the fixed indemnity insurance (as opposed to the plan materials).
- Adds a new paragraph specifying an applicability date for the minimum essential coverage and notice requirements to policies issued on or after January 1, 2015. For policies issued before that date, this paragraph also specifies an applicability date for the notice requirement to plan years beginning on or after January 1, 2015, and for the attestation requirement, to plan years beginning on or after October 1, 2016.

Changes to the Allocation of Reinsurance Contributions

- Modifies our allocation of reinsurance collections if those collections fall short of our estimates for a particular benefit year: we will allocate the reinsurance collections for

that benefit year first to the reinsurance payment pool, and second to administrative expenses and the U.S. Treasury.

Changes to §155.120

- Makes technical revisions to §155.120(c) to clarify that organizations must comply with other, non-Exchange, applicable non-discrimination statutes.
- Revises §155.120(c)(2) to clarify that organizations that limit their provision of certified application counselor services to a defined population under this exception must still comply with the non-discrimination provisions in paragraph (c)(1)(ii) with respect to the provision of these services to that defined population.

Changes to §155.206

- Clarifies that the requirements applicable to consumer assistance entities under this section refer to the applicable Federal regulatory requirements that have been implemented pursuant to section 1321(a)(1) of the Affordable Care Act, including provisions of any agreements, contracts, and grant terms and conditions between HHS and the consumer assistance entity that interpret those statutory and regulatory requirements or establish procedures for compliance with them.
- Clarifies that HHS must provide a written notice to a consumer assistance entity of its investigation, rather than requiring HHS to provide a written notice to an entity each time HHS learns of a potential violation.
- Adds a factor allowing HHS to take into consideration whether other remedies or penalties have been imposed for the same conduct or occurrence.
- Provides a six-year statute of limitations period.

Changes to §155.210

- Removes the provision specifying non-Federal standards that prohibit any individual or entity from acting as Navigators that would be eligible to participate under standards applicable to the FFE.
- Renumbers and extends to all Exchanges the provision regarding non-Federal standards that would, as applied or implemented in a State, prevent the application of Federal requirements applicable to Navigators. Adds specification for requirements that prevent the Exchange's implementation of the Navigator program consistent with Federal requirements.
- Revises the provision specifying requirements to carry errors and omissions coverage and replaces it with "any requirement that, in effect, would render all Navigators in the Exchange to be licensed agents and brokers."
- Adds that in an FFE, no health care provider individual or entity shall be ineligible to operate as a Navigator solely because it receives consideration from a health insurance issuer for health care services provided.
- Adds that in an FFE, no individual or entity shall be ineligible to operate as a Navigator solely on the basis that it does not maintain its principal place of business in the Exchange service area.
- Moves the provision prohibiting compensation on a per-application, per-individual-assisted, or per-enrollment basis to §155.215 to apply only in the FFE.
- Adds that gifts, gift cards, or cash may exceed nominal value for the purpose of providing reimbursement for legitimate expenses incurred by a consumer in effort to receive Exchange application assistance, such as, but not limited to, travel or postage expenses.

- Adds that Exchange funds cannot be used to purchase gifts or gift cards, or promotional items that market or promote the products or services of a third party.
- Adds that consumers may be solicited by going door-to-door or other unsolicited means of direct contact, including calling a consumer if there is a pre-existing relationship and other applicable laws are complied with.
- Adds that outreach and education activities may include going door-to-door or other unsolicited means of direct contact, including calling a consumer.
- Adds that automatic telephone dialing system or an artificial or prerecorded voice may be used to initiate contact consumers if there is a pre-existing relationship and other applicable laws are complied with.
- Changes the requirement to obtain authorization to access a consumer's personally identifiable information in a form and manner determined by the Secretary to a form and manner determined by the Exchange, adds that the authorization must be retained in a form and manner determined by the Exchange, and clarifies the retention period is no less than six years. Removes explicit reference to Federal regulations at 45 CFR 92.42 and 45 CFR 74.53.
- Clarifies that the duty to provide information in a fair, accurate and impartial manner includes providing fair, impartial, and accurate information that assists consumers with submitting the eligibility application, clarifying the distinctions among QHPs, and helping consumers make informed decisions during the health coverage selection process.

Changes to §155.215

- Expressly enumerates, rather than incorporates applicable provisions under §155.210 by reference, the provisions regarding non-Federal standards that would prevent the application of the provisions of title I of the Affordable Care Act as applied to the non-Navigator assistance personnel program subject to §155.215.
- Removes the provision specifying non-Federal standards that prohibit any individual or entity from acting as non-Navigator assistance personnel subject to §155.215 that would be eligible to participate under standards applicable to the FFE.
- Extends to all Exchanges the provision regarding non-Federal standards that would, as applied or implemented in a State, prevent the application of Federal requirements applicable to non-Navigator assistance personnel subject to §155.215. Adds specification for requirements that prevent the Exchange's implementation of the non-Navigator assistance program consistent with Federal requirements.
- Adds that in an FFE, no health care provider individual or entity shall be ineligible to operate as non-Navigator assistance personnel solely because it receives consideration from a health insurance issuer for health care services provided.
- Adds that in an FFE, no individual or entity shall be ineligible to operate as non-Navigator assistance personnel solely on the basis that it does not maintain its principal place of business in the Exchange service area.
- Adds a provision prohibiting compensation on a per-application, per-individual-assisted, or per-enrollment basis to §155.215 to apply only in the Federally-facilitated Exchange.
- Adds an effective date of November 15, 2014 for the prohibition on compensation on a per-application, per-individual-assisted, or per-enrollment basis.

- Changes the requirement to obtain and maintain authorization to access a consumer's personally identifiable information in a form and manner determined by the Secretary to a form and manner determined by the Exchange, and clarifies the retention period is no less than six years.

Changes to §155.225

- Adds duty to provide information to individuals and employees about the full range of QHP options and insurance affordability programs for which they are eligible, which includes providing fair, impartial, and accurate information that assists consumers with submitting the eligibility application, clarifying the distinctions among QHPs, and helping consumers make informed decisions during the health coverage selection process.
- Revises provision specifying referrals to third parties not required to act in the best interest of applicants assisted to those not required to provide fair, accurate, and impartial information.
- Removes the provision specifying non-Federal standards that prohibit any individual or entity from acting as certified application counselors that would be eligible to participate under standards applicable to the FFE.
- Renumbers and extends to all Exchanges the provision regarding non-Federal standards that would, as applied or implemented in a State, prevent the application of Federal requirements applicable to certified application counselors. Adds specification for requirements that prevent the Exchange's implementation of the certified application counselor program consistent with Federal requirements.

- Adds that in an FFE, no health care provider individual or entity shall be ineligible to operate as certified application counselors solely because it receives consideration from a health insurance issuer for health care services provided.
- Removes proposed requirement to maintain a physical presence in the Exchange service area. Adds that in an FFE, no individual or entity shall be ineligible to operate as a certified application counselor solely on the basis that it does not maintain its principal place of business in the Exchange service area.
- Adds that gifts, gift cards, or cash may exceed nominal value for the purpose of providing reimbursement for legitimate expenses incurred by a consumer in effort to receive Exchange application assistance, such as, but not limited to, travel or postage expenses.
- Adds that consumers may be solicited by going door-to-door or other unsolicited means of direct contact, including calling a consumer if there is a pre-existing relationship and other applicable laws are complied with.
- Adds that outreach and education activities may include going door-to-door or other unsolicited means of direct contact, including calling a consumer.
- Adds that automatic telephone dialing system or an artificial or prerecorded voice may be used to initiate contact consumers if there is a pre-existing relationship and other applicable laws are complied with.
- Adds an effective date of November 15, 2014 for the prohibition on compensation on a per-application, per-individual-assisted, or per-enrollment basis, and limits the application of this provision to certified application counselors in FFEs.
- Adds a requirement to obtain and maintain authorization to access a consumer's personally identifiable information in a form and manner determined by the Secretary to

a form and manner determined by the Exchange, and changes the retention period for the authorization to access a consumer's personally identifiable information to no less than six years.

Changes to §155.260

- Inserts the numerical penalty amount instead of a reference to section 1411(h) of the Affordable Care Act where the maximum penalty is specified.

Changes to §156.265

- Revises the provisions proposed in 156.265(d)(1) of the proposed rule as the entire paragraph (d), and removes all 156.265(d)(2), allowing each Exchange to establish its own premium payment dates.

Changes to §156.270

- Directs that QHP issuers must follow the transaction rules established by the Exchange in accordance with §155.430(e).

Changes to §155.285

- Removes the references to sections 1411(h)(1) and (2) of the Affordable Care Act and instead inserts the numerical maximum penalty amounts.
- Adds a factor allowing HHS to take into consideration whether other remedies or penalties have been imposed for the same conduct or occurrence at §155.285(b)(1)(viii).

Changes to §155.410

- Clarifies that starting in 2014, the Exchange must provide written notice of annual open enrollment to each enrollee no earlier than the first day of the month before the open enrollment period begins and no later than the first day of the open enrollment period.

Changes to §155.420

- Clarifies that later coverage effective dates for birth, adoption, placement for adoption, or placement for foster care will be effective the first of the month.
- Clarifies that earlier effective dates are allowed if all issuers in an Exchange agree to effectuate coverage only on the first day of the specified month.
- Adds that consumers may report a move in advance of the date of the move.
- Establishes a special enrollment period for individuals losing medically needy coverage.

Changes to § 155.625

- Clarifies, in paragraphs (a) and (b), that the Exchange may adopt an exemption eligibility determination made by HHS for applications submitted before the start of open enrollment for 2016.

Changes to §155.705

- Revises the conditions under which a SHOP may permit a one-year transition to employee choice.
- Adds a time frame for submission of the State Insurance Commissioner's recommendation that employee choice not be implemented and for the SHOP's decision based on that recommendation.
- Clarifies that the transitional policy only applies in 2015.
- Revised in 155.705(b)(3)(vi) that options should be singular as one option is available for FF-SHOPs and another for State-based SHOPs

Changes to §155.725

- Limits the annual employer and employee election period, which begins no sooner than November 15, 2014, so that it applies only in FF-SHOPs.

Changes to §156.122

- Requires a health plan's exception process to include the ability to expedite the reviews for exigent circumstances.

Changes to §156.130

- Removes the annual limitation on deductibles for small group plans.

Changes to §156.1120 and §156.1125

- Clarifies, for the QRS and the ESS, the distinction between the required level of data submission and collection by QHP issuers, specified by HHS, and the level of public reporting or display by Exchanges.

Changes to §158.243

- Does not finalize requirements for distribution of de minimis rebates.

V. Waiver of Delay in Effective Date

Section 553(d) of the APA (5 U.S.C. 553(d)) requires that a final rule be effective not less than 30 days from the date of its publication in the **Federal Register** and the Congressional Review Act (5 U.S.C. 801(a)(3)), which requires a 60-day delayed effective date for major rules. This 30-day delay in effective date can be waived, however, if otherwise provided by an agency for good cause found and published with the rule. For the reasons set forth below, we find good cause to waive the 30-day delay in effective date in connection with the amendments made in this rule at §155.705 related to employee choice, because the delay is impracticable and contrary to the public interest.

A 30-day delay in the effectiveness of the amendments made to § 155.705 in this rule would mean that, in States with an FF-SHOP, State Insurance Commissioners could not comply with the deadline to recommend that employee choice not be implemented, and for a SHOP to

make a decision based on that recommendation, as set forth in the rule. Pursuant to §155.705(b)(3)(vii), HHS requires that both the State Insurance Commissioner's recommendation and the SHOP's decision be completed prior to the end of the window within which QHPs can submit applications for QHP certification, and that in States with an FF-SHOP, the State Insurance Commissioner's recommendations must be submitted on or before June 2, 2014. The QHP certification application window for the FFE is expected to open on May 27, 2014, and is expected to close on June 27, 2014. This would mean that issuers would not know whether employee choice would be available in a State within an FF-SHOP prior to the close of the QHP application window. Accordingly, issuers would be unable to make fully informed decisions about SHOP participation and appropriate product pricing when compiling and submitting their QHP certification applications, including the rate information included in their applications. This uncertainty regarding implementation of employee choice potentially could result in fewer QHPs being offered in the State's FF-SHOP or products being unnecessarily priced higher than necessary, which would negatively affect the small employers that would participate in the FF-SHOP, as well as their employees. In order to avoid these potential harms to small employers and employees, we believe the 30-day delay in the effective date of this provision would be impracticable and contrary to the public interest.

Additionally, it was impracticable for HHS to have proposed this approach sooner. The full scope of the issuer and State concerns about implementing employee choice that motivated the amendments to §155.705 were not made known to HHS until early 2014. HHS previously had anticipated that its 2013 decision not to require employee choice in SHOPs in 2014 would provide issuers of QHPs and SADPs with ample time to prepare to fully implement employee choice for plan years beginning in 2015. However, early in 2014, HHS learned that some issuers

and State Departments of Insurance continued to be concerned about the potential effect of employee choice on State small group markets. Because employee choice is, for the most part, a relatively new concept in the small group market and because many issuers and States do not have a lot of experience in an employee choice environment, we understand that some issuers believe they do not have sufficient information to make pricing and plan design decisions for 2015 that would not adversely affect small group market consumers.

For the reasons outlined above, CMS finds good cause under the APA, 5 U.S.C. 553(d)(3) to waive the delay in effective date and proceed directly with the issuance of a final rule with an immediate effective date.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 30-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 final rule contains information collection requirements (ICRs) that are subject to review by OMB. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues, which contain ICRs. All comments received on these ICRs will be addressed at the time the 30-day notice is published to solicit public comments.

A. ICRs Regarding Recertification for Certified Application Counselors (§155.225)

Under §155.225(d)(7), certified application counselors are required to be recertified on at least an annual basis after successfully completing recertification training as required by the Exchange. Each Exchange is required to establish its own recertification process and standards consistent with these requirements. We expect that establishing a process for recertification will include creating a recertification request form (or similar document) in Exchanges that directly certify certified application counselors. We estimate that up to 18 State Exchanges will develop their own recertification request form.⁴¹ We estimate that the development of a recertification request form, as may be applicable for Exchanges that directly certify certified application counselors, will take a health policy analyst (at \$49.35 labor cost per hour) up to 1 hour to create, a senior manager (at \$79.08 cost per hour) up to .5 hours (30 minutes) for review, and an attorney up to .5 hours (at \$90.15 labor cost per hour) for legal review. We estimate that the one-time burden will be two hours with a cost burden of \$134 for each Exchange, and the total burden for 18 State Exchanges will be 36 hours with a cost burden of \$2,412.

There are recordkeeping requirements associated with developing and maintaining a request form. We estimate that the time burden associated with maintaining a copy of the request form will be .016 hours (1 minute); we assume that a mid-level health policy analyst will maintain electronic copies of the form at minimal cost, which we estimate as \$0.79 as a one-time

⁴¹ We estimate 18 State Exchanges (which includes Utah's SHOP) will develop their own processes for recertification. HHS will establish a single process in all FFEs.

requirement for the Exchange. The total burden for 18 Exchanges is estimated to be 1.08 hours and the total cost burden will be \$14.22.

There will also be third-party disclosure requirements for 18 State Exchanges associated with reviewing each certified application counselor's recertification request, which will require the Exchange to notify the individual of the result of its review and issue a new certificate for each individual who successfully completes recertification. This notice requirement will apply to the Exchange on an annual basis. We estimate that it will take a mid-level health policy analyst in the Exchange up to .08 hours (5 minutes) to notify an individual. The estimated cost burden is \$4.11 for each individual notice, including the certificate. For purposes of this analysis, we estimate that there will be approximately 30,000 certified application counselors nationwide, or approximately 10,600 application counselors in 18 State Exchanges. The total cost burden will be approximately \$2,422 for each State Exchange. The total burden for 18 State Exchanges will be approximately 883 hours and the total cost burden will be \$43,593. There will be recordkeeping requirements associated with issuing each individual notice. We estimate that the time burden associated with maintaining a copy of the notice and certificate will be .016 hours (1 minute); we assume that a mid-level health policy analyst, with a labor cost of \$49.35 an hour, will maintain electronic copies of the form at minimal cost, which we estimate as \$0.79 per notice for each individual certified application counselor. The total recordkeeping burden for 10,600 certified application counselors in 18 State Exchanges is estimated to be 170 hours and the total cost burden will be \$8,374, or \$265 per Exchange.

For Exchanges that designate organizations to directly certify certified application counselors under §155.225(b)(1), there will be requirements associated with implementing a recertification process under the applicable Exchange's standards. We expect that this process

will include creating and issuing a recertification request form (or similar document) for an organization's certified application counselors to submit to indicate their intention to be recertified and provide an updated conflicts of interest disclosure or other attestations as may be required. We estimate that up to 5,000 designated organizations will develop their own recertification request form. We estimate that the development of a recertification request form will take a health policy analyst (at \$49.35 labor cost per hour) up to 1 hour to create, a senior manager (at \$79.08 labor cost per hour) up to .5 hours (30 minutes) for review, and an attorney (at \$90.15 labor cost per hour) up to .5 hours (30 minutes) for legal review. We estimate that the one-time cost burden will be \$134 for each organization. The total one-time burden for 5,000 organizations nationwide will be 10,000 hours and the total cost burden will be \$670,000.

There will be recordkeeping requirements associated with developing and maintaining a request form. We estimate that the time burden associated with maintaining a copy of the request form will be .016 hours (1 minute); we assume that a mid-level health policy analyst with a labor cost of \$49.35 an hour will maintain electronic copies of the form at minimal cost, which we estimate as \$0.79 as a one-time requirement for each organization. The total one-time burden for 5,000 organizations nationwide is estimated to be 80 hours and the total cost burden will be \$3,950.

There will also be third-party disclosure requirements for designated organizations associated with reviewing each certified application counselor's recertification request, which will require the organization to notify the individual of the result of its review and issue a new certificate as appropriate. This notice requirement will apply to the organization on an annual basis. For purposes of estimating the burden on designated organizations, we assume that of the estimated 30,000 certified application counselors nationwide, approximately 19,400 will be

directly certified by designated organizations, or four certified applications counselors on average per designated organization. We estimate that it will take a mid-level health policy analyst up to .08 hours (5 minutes) to notify an individual and issue a new certificate. The estimated cost burden is \$4.11 for each individual notice. For an estimated 19,400 certified application counselors nationwide, or approximately four certified application counselors on average in each organization, the total cost burden will be approximately \$16.44 for each organization. The total burden for 5,000 designated organizations nationwide will be approximately 1,617 hours and the total cost burden will be approximately \$79,734.

There will be recordkeeping requirements associated with issuing a certificate. We estimate that the time burden associated with maintaining a copy of each certificate issued at recertification will be .016 hours (1 minute). We assume that a mid-level health policy analyst with a labor cost of \$49.35 an hour will maintain electronic copies of the form at minimal cost, which we estimate as \$0.79 per certificate for each organization. The total recordkeeping cost per organization will be \$3.16. The total burden for 5,000 organizations nationwide will be 323 hours and the total cost burden will be approximately \$ 15,326.

There will be third-party disclosure requirements for individual certified application counselors associated with completing the requirements for recertification, whether done directly through the Exchange or through an Exchange-designated certified application counselor organization. Such recertification requirements will include completing Exchange required training and might also include satisfying other requirements consistent with the Exchange-established processes, such as providing conflicts of interest disclosures, other attestations and submitting a recertification request form (or similar document) and other attestations. These requirements will apply to certified application counselors on an annual basis. Although nothing

prohibits individual certified application counselors or organizations from being funded through sources such as applicable private, State, or Federal programs, we expect that certified application counselors will not be guaranteed any specific funding. We estimate the professional wage of certified application counselors for this type of work as equivalent to that of an eligibility interviewer for assistance from government programs and agency resources. We estimate that it will take a certified application counselor with a labor cost of \$26.65 an hour up to 0.17 hours (10 minutes) to complete and submit the recertification request to the organization or Exchange, as applicable. The estimated cost burden will be \$4.53 for each individual seeking recertification. We estimate that there will be approximately 30,000 recertification requests provided, for a total burden of 5,000 hours and a total cost burden of \$135,915 for all certified application counselors nationwide.

There will be third-party disclosure requirements associated with taking recertification training. We expect that an individual certified application counselor will provide proof to the organization or Exchange that he or she has successfully completed the recertification training, in accordance with the Exchange's process. We estimate that it will take a certified application counselor with a labor cost of \$26.65 an hour up to .03 hours (2 minutes) to provide the training certificate to the organization or Exchange, as may be required. The total estimated cost burden is \$0.80 for each individual seeking recertification. We estimate that there will be approximately 30,000 training certificates provided, and the total burden will be 1,000 hours, with a total cost burden of \$24,000 for all certified application counselors nationwide.

In addition, there will be recordkeeping requirements associated with the training certification. We expect each person who receives training will obtain and maintain a record of training certification. We estimate that the time burden associated with maintaining proof of

training certification is .016 hours (1 minute), since we assume this proof will be maintained through electronic copies, at minimal cost. The total cost estimated for each individual to maintain proof of training certification will be \$0.43. The total burden will be 500 hours and the total cost burden will be \$12,900 for all certified application counselors nationwide.

B. ICRs Regarding Consumer Authorization (§§ 155.210 and 155.215)

For purposes of the ICRs associated with these provisions, we use the same labor cost estimates that were used in the final Navigator and non-Navigator assistance personnel standards rule (Patient Protection and Affordable Care Act; Exchange Functions: Standards for Navigators and Non-Navigator Assistance Personnel, July 17, 2013, 78 FR 42842). Navigator personnel and non-Navigator assistance personnel to which §155.215 applies are estimated to have a labor cost of \$20 per hour. Project leads for Navigator and non-Navigator assistance entities to which §155.215 applies are estimated to have a labor cost of \$29 per hour. Senior executives for Navigator and non-Navigator assistance entities to which §155.215 applies are estimated to have a labor cost of \$48 per hour. These are estimates commonly used for estimating paperwork burden and do not represent a recommendation or a requirement of how much Navigator and non-Navigator personnel to which §155.215 applies are to be paid. There is nothing in the regulations that require any of these workers to be paid any specific amount.

In the ICR currently approved under OMB control number 0938-1220, we noted that there were 105 Navigator grantee organizations at that time in FFEs, including SPEs, and we estimated that there were 3,000 individuals working as Navigators. We estimated the number of non-Navigator assistance project leads to be 300 and 1,800 for personnel and we use those estimates here as well.

In accordance with §155.210(e)(6) and §155.215(g), Navigators, as well as those non-Navigator personnel to whom §155.215 applies, will be required to maintain procedures to inform consumers of the functions and responsibilities of Navigators and non-Navigator assistance personnel (as applicable), and to obtain authorization for the disclosure of consumer information to the Navigator or non-Navigator assistance personnel (as applicable). This will be a one-time requirement for the organization. We estimate that it will take a Navigator or non-Navigator assistance personnel project lead up to 2 hours to create the form for providing authorization to applicants, and a Navigator or non-Navigator senior executive up to 1 hour to review the procedure, for a total time burden of up to 3 hours. We estimate the cost burden associated with creating this procedure will be \$106 per organization. The total cost for all 105 Navigator grantee organizations is estimated to be \$11,130. The total cost for all 300 non-Navigator assistance personnel organizations is estimated to be \$31,800.

There are also recordkeeping requirements associated with developing and maintaining a model agreement and authorization form. Each organization is expected to maintain a copy of the executed forms. We estimate that the time burden associated with maintaining a copy of executed agreement and authorization forms for each consumer will be 0.016 hours (1 minute); we assume these will be maintained through electronic copies with minimal cost.

In addition, there will be burdens on individual Navigators, as well as those non-Navigator assistance personnel to whom §155.215 applies. Under §155.210(e)(6) and §155.215(g), respectively, Navigators and non-Navigator assistance personnel will be required to inform consumers of the functions and responsibilities of Navigators and non-Navigator assistance personnel and obtain authorization for the disclosure of consumer information to a Navigator or non-Navigator assistance personnel prior to obtaining the consumer's personally

identifiable information. In the final rule on certified application counselors (78 FR 42824, 42854-42855), we estimated that it will take a certified application counselor 0.25 hours (15 minutes) to provide consumers with information about the functions and responsibilities of a certified application counselor, obtain their authorizations, and provide any applicable conflict of interest disclosures. Because here we are only estimating the time required to provide consumers with information about the functions and responsibilities of a Navigator or non-Navigator assistance personnel and obtain their authorization, we estimate that it will take a Navigator or non-Navigator assistance personnel 0.1667 hours (10 minutes) to perform this task. The total cost estimate for the consumer authorization process for Navigators and non-Navigator assistance personnel therefore will be \$3.33. The total time burden on all 3,000 Navigators is estimated to be approximately 500 hours, and the total cost burden on all 3,000 Navigators is estimated to be \$9,990. The total time burden on all 1,800 non-Navigator assistance personnel is estimated to be 300 hours, and the total cost burden on all 1,800 non-Navigator assistance personnel is estimated to be \$5,994.

C. ICRs Regarding Enrollee Satisfaction & Marketplace Surveys (§§155.1200, 156.1105 and 156.1125)

In §156.1105 of this rule, we establish a monitoring and appeals process for HHS-approved ESS vendors. Specifically, in §156.1105(d), we establish a process in which HHS will monitor approved vendors for ongoing compliance. HHS may require additional information from approved vendors to be periodically submitted in order to ensure continued compliance. We estimate that HHS will receive applications from approximately 40 ESS vendors. We estimate that it will take no longer than one hour for each vendor (at a cost of \$24.10 per hour) to comply

with any additional monitoring by HHS. Therefore, we estimate a total annual burden of 40 hours for all vendors for a total cost burden estimate of \$964.00.

In §156.1105(e) of this rule, we establish a process by which an ESS vendor that is not approved by HHS can appeal HHS's determination. It is estimated that filing an appeal with HHS will take no longer than one hour. We estimate that five survey vendors that apply may not be approved and all of those vendors will appeal HHS's determination and submit additional documentation to HHS. Therefore, we estimate five responses, for a total of five burden hours, for a total cost of \$120.50.

The burden estimate associated with quality standards for QHP issuers related to the ESS outlined in §156.1125 will include the time and effort required for QHP issuers to collect, submit and validate ESS data on an annual basis. The burden and cost related to the survey respondents and ESS vendors associated with the ESS has been approved under OMB Control Number 0938-1221. In addition, we estimate that each QHP will need an average of 54 hours or \$1,349.60 for the ESS to be administered by mail, phone and/or by web for its QHPs. Assuming a total of 575 QHP issuers, we estimate that the annual burden will be 31,050 hours or \$776,020.

The burden with the Marketplace survey under §155.1200(b)(3) will include the time, cost and effort related to survey respondents and has been approved under OMB Control Number 0938-1221. In addition, we will revise the information collection currently approved under OMB Control Number 0938-1119 to account for any additional burden for an Exchange if sampling data is needed from State Exchanges for CMS to administer the Marketplace survey.

D. ICR Regarding Quality Rating System (§156.1120)

The burden and cost estimates associated with quality standards for QHP issuers related to the QRS outlined in §156.1120 include estimates for QRS measure data collection, validation,

and submission to CMS. We estimate that a total of 575 QHP issuers will collect and report QRS measure data, by product type, using administrative data sources and medical records. Using the BLS labor category estimates for a general operations manager, computer programmer, business operations specialist, registered nurse, and medical records and health information analyst, the estimated annual cost and hourly burden for a QHP issuer will be 1650 hours or \$117,424, for an issuer who has performance measures data collection experience. We estimate that approximately eighty percent of all issuers, or 460 issuers, have such experience. We anticipate additional software purchases to generate measure data and rates and increased third-party data validation fees for issuers that do not have the experience in data collection and reporting for the QRS as required in §156.1120. Therefore, we estimate that the additional cost burden for each of the remaining 115 issuers will be approximately \$102,500 in the initial year as they develop their data collection systems and processes, for a total of approximately \$11,787,500. We estimate 948,750 hours or \$67,518,800 as the total annual burden for the anticipated 575 QHP issuers to collect and report QRS data.

E. ICRs Regarding Quality Standards for Exchanges (§§155.1400 and 155.1405)

In §155.1400 and §155.1405, we direct that each Exchange must display, on its website, quality rating and ESS result information for QHPs offered on the Exchange. We estimate 18 State Exchanges and the FFE will collect the relevant QRS and ESS information for display. The burden estimate associated with these standards will include collection of the necessary data by each Exchange to display on its website. This burden and cost for Exchanges are currently approved under OMB Control Number 0938-1156 in the total estimates related to §155.205(b) which requires the Exchange to maintain an up-to-date Internet Website that provides

information including ESS and quality ratings, on available QHPs offered on the Exchange. The provisions of this final rule will not affect the burden.

F. ICR Regarding Medical Loss Ratio Requirements (§§158.150, 158.211, 158.220, 158.221, and 158.231)

This rule amends the MLR provisions regarding the treatment of ICD-10 conversion costs. This rule further provides MLR calculation adjustments for issuers affected by the transitional policy announced in the CMS letter dated November 14, 2013 and for issuers participating in the Exchanges. This rule also clarifies how issuers are to calculate their MLRs in States that require the small group market and individual market to be merged. Both MLRs and rebates are reported on the MLR annual reporting form.

The burden for the existing information collection requirement is approved under OMB Control Number 0938–1164. This includes the annual reporting form and instructions that are currently used by issuers to submit MLR information to HHS. The MLR annual reporting form collects information on all distributed and owed rebate amounts. Prior to the July 31, 2015 deadline for the submission of the annual MLR report for the 2014 MLR reporting year, and in accordance with the PRA, HHS plans to solicit public comment and seek OMB approval for an updated MLR annual form that will reflect the changes in MLR calculations. We do not anticipate that the amendments finalized in this rule will increase the burden on issuers because the changes utilize data that is a subset of information that issuers already submit to HHS.

G. ICRs Regarding Civil Money Penalties (§§155.206 and 155.285)

Section 155.206 describes the bases and processes HHS proposes to use to impose CMPs on noncompliant consumer assistance personnel and organizations. Section 155.285 describes the bases and processes HHS proposes to use to impose CMPs on persons who provide false or

fraudulent information required under section 1411(b) of the Affordable Care Act or who knowingly and willfully use or disclose information in violation of section 1411(g) of the Affordable Care Act. The ICRs in these provisions are exempt from PRA requirements in accordance with 5 CFR 1320.4(a)(2) because this information will be collected during the conduct of an administrative action or investigation involving an agency against specific individuals or entities.

H. ICRs Regarding Fixed Indemnity Insurance, Notice of Discontinuation, Notice of Renewal, Certifications of Creditable Coverage and HIPAA Opt-Out Election Notice, (§§146.152, 146.180, 147.106, 148.122, 148.124, and 148.220)

In §148.220 of this rule, we require that issuers of individual market fixed indemnity insurance provide a notice stating that the coverage is not a substitute for major medical coverage and that lack of minimum essential coverage may result in an additional payment with one's taxes. For policies issued after January 1, 2015 the notice must be included in the application for coverage and for policies issued before that date, the notice must be delivered shortly before the first renewal date occurring on or after January 1, 2015. HHS has provided the exact text of the notice and it will not need to be customized. Sections 146.152, 147.106 and 148.122 of this rule provide that issuers that discontinue a product in the group or individual market, and issuers that provide the option to renew coverage in the small group or individual market, must provide written notices to enrollees in a form and manner specified by the Secretary. HHS will provide the exact text of the notices in future guidance and they will not need to be customized. The burden associated with these notices are not subject to the Paperwork Reduction Act of 1995 in accordance with 5 CFR 1320.3(c)(2).

Certifications of creditable coverage under §148.124 will no longer be required to be provided starting December 31, 2014. The burden is currently approved under OMB Control Number 0938-0702. In the individual market, the anticipated reduction in annual burden hours will be 835,517, with an anticipated reduction in cost of \$25,625,306. The burden for HIPAA Opt-out Election notices under §146.180 is currently approved under OMB Control Number 0938-0702 as well. Electronic submission of opt-out election notice will also reduce costs for plans by eliminating the need for mailing paper forms.

I. Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing a summary of this proposed information collection for public comment. Interested persons are invited to send comments regarding this collection's proposed 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.

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have also submitted to the Office of Management and Budget (OMB) the proposed information collection for their emergency review. While the collection is necessary to ensure compliance with an initiative of the Administration, we are requesting emergency review under 5 CFR

1320(a)(2)(i) because public harm is reasonably likely to result if the regular clearance procedures are followed. The approval of this data collection process is essential to ensuring that States seeking to transition to employee choice in 2015 can submit recommendations to the SHOP by the deadline established in this final rule, which, in the FF-SHOPs, is on or before June 2, 2014. Without an emergency clearance process, many States seeking to not implement employee choice in 2015 will not be able to submit their recommendation and have it reviewed in a timely manner by the SHOP. Given the short time until the QHP certification window opens and closes, it is critical that the information concerning this process be posted by the day of publication of this final rule so issuers are aware if their particular States will not be implementing employee choice in 2015 before they decide to participate and submit their final rates for certification during the initial QHP certification window. If CMS is required to delay recommendation collection and review, this will severely impede its ability to implement this transitional policy in the FF-SHOPs.

ICR Regarding 2015 Transition to Employee Choice (§155.705)

For the FF-SHOP States that would like to submit a recommendation that the FF-SHOP not implement employee choice in 2015, pursuant to §155.705(b)(2), there will be a formal application process. This process will include the submission of a recommendation by the State's Insurance Commissioner. The written recommendation must adequately explain that it is the State Insurance Commissioner's expert judgment, based on a documented assessment of the full landscape of the small group market in his or her State, that not implementing employee choice would be in the best interests of small employers and their employees and dependents, given the likelihood that implementing employee choice would cause issuers to price products and plans higher in 2015 due to the issuers' beliefs about adverse selection. A State Insurance

Commissioner's recommendation would need to be based on concrete evidence, including but not limited to discussions with those issuers expected to participate in the SHOP in 2015.

We estimate that the development of an application by the Insurance Commissioner will take up to 40 hours to create (at \$50.00 labor cost per hour). We estimate that up to 16 States will submit the application and the one-time cost burden will be \$2,000 for each State. The total burden for all States is estimated to be 640 hours or \$32,000.

We are requesting OMB review and approval of this emergency collection by **May 27, 2014**, with a 180-day approval period. Written comments and recommendations for this emergency request only will be considered from the public if received by the date and address noted below.

Copies of the supporting statement and any related forms can be found at:

<http://www.cms.hhs.gov/PaperworkReductionActof1995> or can be obtained by e-mailing your request, including your address, phone number, OMB number, and CMS document identifier, to: Paperwork@cms.hhs.gov, or by calling the Reports Clearance Office at: 410-786-1326.

When commenting on this proposed information collection, please reference the CMS document identifier and the OMB control number. To be assured consideration, comments and recommendations must be received in one of the following ways by **May 23, 2014**:

1. Electronically. You may submit 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) 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 (CMS-10523)

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

and,

OMB Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

New Executive Office Building, Room 10235

Washington, D.C. 20503

Fax Number: 202-395-6974

VII. Regulatory Impact Analysis

A. Summary

This final rule addresses various requirements applicable to health insurance issuers, Exchanges, Navigators, non-Navigator assistance personnel, and other entities under the Affordable Care Act. Specifically, the rule establishes standards related to product discontinuation and renewal, quality reporting, non-discrimination standards, minimum certification standards and responsibilities of QHP issuers, the SHOP, and enforcement remedies in FFEs. It also provides a number of amendments relating to the premium stabilization programs, calculation of annual limit on cost sharing, the MLR program, certified application counselor programs, affordability exemptions, standards regarding how enrollees may request access to non-formulary drugs under exigent circumstances, and guaranteed availability and renewability of coverage requirements. Additionally, it establishes the grounds for imposing CMPs on persons who provide false or fraudulent information to the Exchange and on persons

improperly using or disclosing information; and modifies standards related to opt-out provisions for self-funded non-Federal governmental plans and individual market provisions under HIPAA.

CMS has crafted this rule to implement the protections intended by Congress in an economically efficient manner. We have examined the effects of this rule as required by Executive Order 12866 (58 FR 51735, September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)). In accordance with OMB Circular A-4, CMS has quantified the benefits, costs and transfers where possible, and has also provided a qualitative discussion of some of the benefits, costs and transfers that may stem from this final rule.

B. Executive Orders 13563 and 12866

Executive Order 12866 (58 FR 51735) directs 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 (76 FR 3821, January 21, 2011) is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866.

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a final rule--(1) having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a

serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year), and a "significant" regulatory action is subject to review by the OMB. HHS has concluded that this rule is likely to have economic impacts of \$100 million or more in any one year, and therefore meets the definition of "significant rule" under Executive Order 12866. Therefore, HHS has provided an assessment of the potential costs, benefits, and transfers associated with this final regulation.

1. Need for Regulatory Action

Starting in 2014, qualified individuals and qualified employers are able to obtain coverage provided through Exchanges. The provisions, amendments and clarifications in this final rule address stakeholder concerns and inquiries and help ensure smooth functioning of health insurance markets and Exchanges and ensure that individuals have access to high quality and affordable health insurance coverage. In addition, this rule amends the methodologies for calculating the MLR to address ICD-10 conversion costs, MLR and rebate calculations in States that require the individual and small group markets to be merged, and to accommodate the special circumstances of issuers affected by the transitional policy announced in the CMS letter dated November 14, 2013, and issuers participating in the State and Federal Exchanges.

2. Summary of Impacts

In accordance with OMB Circular A-4, Table VII.1 below depicts an accounting statement summarizing CMS’s assessment of the benefits, costs, and transfers associated with this regulatory action. The period covered by the RIA is 2014 – 2018.

HHS anticipates that the provisions of this final rule will help ensure that all consumers have access to quality and affordable health care coverage and are able to make informed choices, ensure smooth operation of Exchanges, ensure that premium stabilization programs work as intended, provide flexibility to SHOPs and employers, and protect consumers from fraudulent and criminal activities and help to mitigate issuers’ unexpected administrative costs and uncertainties around operations and the risk pool, and to stabilize the market as it continues to transition to full compliance with Affordable Care Act requirements. Affected entities such as QHP issuers, Navigators and non-Navigator assistance personnel, designated certified application counselor organizations, certified application counselors, survey vendors, and States may incur costs to comply with the provisions in this final rule, including administrative costs related to notices, surveys, training, and recertification requirements. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

Table VII.1: Accounting Table

Benefits:
Qualitative: * Ensure access to affordable and quality health insurance coverage for all individuals * Minimize unnecessary terminations of coverage and ensure predictability and continuity for consumers * Allow consumers to make informed choices * Lower out-of-pocket costs for individuals who purchase fixed indemnity insurance * Possible reduction in cost sharing due to adjustment in methodology for calculating annual limitations on cost-sharing * Help ensure sufficiency of funds in the reinsurance payment pool * Ensure consumer protection and privacy and security of PII * Discourage fraudulent or criminal activity by consumer assistance personnel and entities * Provide additional flexibility to FF-SHOPs and employers and allow employers to select plans with updated rate information

* Improve consistency of MLR calculations among issuers in States with merged individual and small group markets and improve accuracy of rebate payments				
Costs:	Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized (\$millions/year)	\$48.78 million ¹	2013	7	2014-2018
	\$49.52 million ¹	2013	3	2014-2018
Net annual costs to enrollees related to ESS and Marketplace survey; recertification of certified application counselors by States; costs to States to submit recommendations to not implement employee choice in 2015; administrative costs incurred by survey vendors to appeal application denials; administrative costs to QHP issuers related to data submissions for QRS and ESS administration; costs related to notice and disclosure requirements for certified application counselor recertification; consumer authorization for Navigators and non-Navigator personnel; and a reduction in costs for issuers in the individual market due to discontinuation of certification of creditable coverage.				
Qualitative: * Costs to certified application counselors to obtain required training for recertification * Reduction in costs to consumers due to ability to make requests to dismiss appeals by telephone * Costs to issuers to comply with the standards for expedited review of a formulary exception request based on exigent circumstances				
Transfers:	Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized (\$millions/year)	\$2.93 million	2013	7	2014-2018
	\$2.99 million	2013	3	2014-2018
Net annual transfer of rebate dollars to enrollees from shareholders or nonprofit stakeholders, resulting from adjustment in MLR methodology for issuers in States with merged individual and small group markets				
Qualitative: * Possible reduction in rebates paid by issuers to enrollees due to adjustment in MLR methodology for issuers affected by the November 2013 transitional policy and unexpected costs during the implementation of the Exchanges, and to account for ICD-10 conversion costs * Possible transfer of transitional reinsurance program funds collected by the Federal government to non-grandfathered reinsurance-eligible plans in the individual market * Possible increase in total risk corridors payment amounts made by the Federal government and decrease in total risk corridors receipts				

1. Note: Approximately \$13 million in costs are estimated in the RIA below and the remaining costs related to ICRs are estimated in section VI above.

3. Anticipated Benefits, Costs and Transfers

The impacts of the existing regulations that are being amended and clarified in this final rule have already been addressed in RIAs included in previous rulemaking. This RIA only

includes the impacts of new provisions and any changes to previous estimates as a result of amendments to existing provisions.

Benefits

Provisions of this final rule will help ensure that all individuals have access to affordable and quality health insurance coverage and the necessary information to make informed choices. Making quality rating and ESS information available to consumers will allow them to make informed choices and provide issuers with an incentive to improve quality of care and consumer experience. The results from the Marketplace survey will drive quality improvement in Exchanges by collecting information on the consumer experience with the Exchange. In addition, the quality rating and ESS information will also provide regulators and stakeholders with information to use for monitoring and oversight purposes. The amendments to special enrollment periods will ensure that individuals who experience loss of coverage or exceptional circumstances have continued access to healthcare. The provisions regarding the formulary exceptions process will ensure that enrollees will have continued access to necessary prescription drugs.

The provisions of this final rule also establish minimum Federal standards that determine whether coverage modifications constitute continuance of an existing product in a market within a State for products offered both through and outside of an Exchange in the individual and small group markets. This will minimize unnecessary terminations of coverage and ensure predictability and continuity for consumers, while providing issuers the flexibility to make the necessary adjustments to coverage. The notices of product discontinuance and renewal will ensure that consumers have necessary information regarding their choices and the changes in coverage.

The amendments for fixed indemnity insurance will allow such plans to be sold as secondary to other health insurance coverage that meets the definition of minimum essential coverage. Such plans may also be sold to individuals who are deemed to have minimum essential coverage based on their status as bona fide residents of U.S. territories. This will allow individuals that buy such coverage to lower their out-of-pocket costs.

The adjustments to the transitional reinsurance program will help ensure that the reinsurance payment pool is sufficient to provide the premium stabilization benefits intended by the statute. This policy may lower premiums by reducing the uncertainty associated with reinsurance payments to individual market plans eligible for reinsurance payments. The adjustments to the risk corridors formula for the 2015 benefit year will help to mitigate issuers' unexpected administrative costs and uncertainties around operations and the risk pool, and to stabilize the market as it continues to transition to full compliance with Affordable Care Act requirements.

The provisions in this final rule will ensure that non-Federal requirements do not prevent Navigators, non-Navigator assistance personnel, certified application counselors and organizations from providing information and assisting individuals to make informed choices and obtain health insurance coverage. The provisions in this rule also specify some of the standards for Navigator and certified application counselor conduct that will ensure consumer protection and ensure that Navigators provide information and services concerning enrollment in QHPs in a fair and impartial manner and that certified application counselors act in consumers' best interests. The rule will also provide HHS with the authority to impose CMPs on Navigators, non-Navigator assistance personnel, certified application counselors, and certified application counselor organizations in the FFE who violate certain Exchange standards applicable to them.

This will ensure that consumers interacting with the Exchange receive high-quality assistance and robust consumer protections. The provisions to impose CMPs for provision of false or fraudulent information, and improper use or disclosure of information will also ensure privacy and security of consumers' PII.

Aligning the start of annual employer election periods in the FF-SHOPs with the start of open enrollment in the corresponding individual market Exchange will benefit issuers. A uniform QHP filing and review timeline for both markets for 2015 will reduce confusion and provide efficiencies to scale in review, providing potential resource savings to QHP issuers. Removing the required minimum lengths of both the employer election period and the employee open enrollment period will provide additional flexibility to State-based SHOPs and employers and allow employers to select plans with the most up-to-date rate information.

The amendment to provide a one-year transition policy under which a SHOP will be permitted to not implement employee choice in 2015 will alleviate State and issuer concerns that employee choice would cause issuers to price their products and plans higher in 2015 due to issuers' beliefs about adverse selection. Allowing for this transitional policy in 2015 will provide minimal disruption to small group markets.

The amendment to our methodology for calculating the annual limitation on cost sharing may reduce cost sharing paid by some enrollees in the individual market.

The amendments to the MLR methodology in States that require the small group market and individual market to be merged will improve the consistency of MLR calculations among issuers in those States and improve the accuracy of rebate payments.

The methodology for determining the required contribution percentage will provide that determinations of affordability exemptions will take into account the rate of premium growth

over the rate of income growth. We do not anticipate that this approach will significantly alter the number of individuals who are expected to enroll in health insurance plans or make shared responsibility payments.

Costs

Affected entities will incur costs to comply with the provisions of this final rule. Costs related to ICRs subject to PRA are discussed in detail in section VI and include administrative costs incurred by survey vendors to appeal application denials; costs to QHP issuers related to data submissions for QRS, ESS administration; costs related to notice and disclosure requirements for certified application counselor recertification, consumer authorization for Navigators and non-Navigator assistance personnel; costs to States to submit a recommendation for a 2015 transition to employee choice; and a reduction in costs for issuers in the individual market due to discontinuation of certification of creditable coverage. In this section, we discuss other costs related to the provisions of this rule.

Each Exchange must establish its own recertification process for certified application counselors and designated certified application counselor organizations. We expect that establishing a process for recertification will include updating recertification training materials in all Exchanges. We estimate that up to 18 State Exchanges will develop their own training materials. We expect that an Exchange will develop training materials for recertification on an annual basis. We assume that it will take a mid-level health insurance analyst (with an hourly labor cost of \$49.35) 8 hours to update the training, 4 hours for a computer programmer (at \$52.50 per hour) to update the online training module and 1 hour by a senior manager (at \$79.08 per hour) to review. The total cost for each State Exchange is estimated to be approximately \$680, and the total cost for 18 State Exchanges will be approximately \$12,240.

The requirement for appeals entities to dismiss an appeal if the request is received via telephonic signature (if the appeals entity is capable of accepting telephonic withdrawals) will make the process more efficient and may reduce costs to the appellant.

The ESS will impact enrollees responding to the survey, survey vendors and QHP issuers offering coverage in the Exchanges. In 2014, a psychometric test of the survey will be carried out, while in 2015 a beta test will be performed. The cost to issuers is addressed in section VI. We anticipate that in 2014, 4,200 enrollees will participate in the psychometric test and in 2015 onwards, 6,000,040 enrollees will complete the survey. The total cost in 2014 of administering the survey to enrollees is estimated to be approximately \$45,549 and the total cost to enrollees and survey vendors is estimated to be approximately \$6,507,964 in 2015 and future years. In 2014, only one survey vendor will conduct the psychometric test and in the following years, about 40 vendors are expected to conduct the survey.⁴² In addition, each QHP issuer will have to contract with an ESS vendor. We estimate approximately \$16,000 as the annual cost for a QHP issuer to contract with an ESS vendor, for a total annual cost of \$9.2 million for 575 QHP issuers.

The Marketplace survey will be administered by a survey vendor under contract with HHS. A psychometric test will be conducted in 2014 with a beta test in 2015. Consumers will incur burden to respond to the survey. We estimate that each response will take 0.4 hours for a total of 3,150 responses requiring 1,260 hours in 2014 and a total of 61,200 responses requiring

⁴² Detailed burden estimates can be found in the Supporting Statement for the Health Insurance Marketplace Consumer Experience Surveys: Enrollee Satisfaction Survey and Marketplace Survey Data Collection, found at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

24,480 hours in 2015 onwards. Total costs will be approximately \$30,366 in 2014 and \$589,968 in following years.⁴³

Issuers that provide EHB should already have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the plan. This final rule includes standards for a health plan's exception process that includes an expedited process for exigent circumstances. This final rule requires issuers to provide a decision on an exception request based on exigent circumstances and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber as appropriate) of the determination no later than 24 hours after receiving the request. Depending on their current formulary exceptions processes, some issuers may incur costs to modify them to comply with these requirements.

Transfers

Previously, the MLR regulation permitted inclusion of ICD-10 conversion costs in quality improving activity expenses only through the 2013 MLR reporting year. However, the date by which issuers are required to adopt ICD-10 as the standard medical code has been postponed past 2013. Therefore, this final rule permits issuers to include their ICD-10 conversion costs through the MLR reporting year in which the Secretary requires conversion to be completed. Based on the 2012 MLR data, we estimate that the ICD-10 provision reduced total rebates for 2012 by less than 2 percent.

This final rule also accounts for the special circumstances of issuers affected by the CMS November 2013 transitional policy by allowing those issuers to multiply the incurred claims and expenses for quality improving activities incurred in 2014 in the MLR numerator by 1.0001.

⁴³ Detailed burden estimates can be found in the Supporting Statement for the Health Insurance Marketplace Consumer Experience Surveys: Enrollee Satisfaction Survey and Marketplace Survey Data Collection, found at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

This adjustment is limited to issuers that provided transitional coverage in the individual or small group markets in States that adopted the transitional policy. In addition, this final rule accounts for the special circumstances of the issuers that provided coverage through the State and Federal Exchanges by allowing those issuers to multiply the incurred claims and expenses for quality improving activities incurred in 2014 in the numerator by 1.0004. This adjustment is limited to issuers offering coverage in the individual or small group markets through the Exchanges. Based on the 2012 MLR data, we estimate that the adjustment for issuers affected by the transitional policy and for issuers affected by the Exchanges rollout may reduce the total rebates by 0.5 percent for 2014.

In addition, this final rule amends the MLR methodology to clarify how issuers must calculate MLRs in States that require the small group market and individual market to be merged for MLR calculation purposes. This will improve the consistency of MLR calculations among issuers in those States and improve the accuracy of rebate payments. Currently, only Massachusetts and Vermont require the small group market and individual market to be merged (Vermont requirements take effect in 2014). If an issuer met the respective MLR standards in the separate markets, then this provision will not have any impact on rebates. However, if an issuer met the MLR standards only in one market and merging the two markets results in the issuer meeting (or being unable to meet) the MLR standards in the merged market, the issuer may have to pay lower (or higher) rebates and there will be a transfer from enrollees to issuers (or from issuers to enrollees). Based on the 2012 MLR data, we anticipate that this change may result in issuers paying an additional \$3.8 million in rebates.

This rule revises the allocation of reinsurance contributions collected for the 2014 and 2015 benefit years so that if reinsurance collections fall short of our estimates, reinsurance

collections are allocated first to the reinsurance pool, and second to administrative expenses and the U.S. Treasury on a pro rata basis. We expect that this policy will not have a significant effect on transfers, because we estimate that we will collect the full amount of reinsurance contributions to fully fund the reinsurance payment pool. This policy may lower premiums by reducing the uncertainty associated with reinsurance payments to individual market plans eligible for reinsurance payments. The Affordable Care Act creates a temporary risk corridors program for the years 2014, 2015, and 2016 that applies to QHPs, as defined in §153.500. The risk corridors program creates a mechanism for sharing gains and losses between the Federal government and QHP issuers. The Affordable Care Act establishes the risk corridors program as a Federal program; consequently, HHS will operate the risk corridors program under Federal rules. The risk corridors program will help protect against inaccurate rate setting in the early years of the Exchanges by limiting the extent of issuer losses and gains. For the 2015 benefit year, we are adjusting the risk corridors formula to help mitigate QHP issuers' unexpected administrative costs. Although our initial modeling suggests that this adjustment can increase the total risk corridors payment amount made by the Federal government and decrease risk corridors receipts, we believe that this temporary program will be budget neutral on the net over three years.

C. Regulatory Alternatives

Under the Executive Order, CMS is required to consider alternatives to issuing rules and alternative regulatory approaches. CMS considered the regulatory alternatives below:

1. Collecting ESS Data at the Product Level Instead of Each Product Per Metal Tier

Under this alternative, HHS would have required QHPs to collect ESS data from a single sample for each product (versus each product in each metal tier). This option would have

reduced the cost for issuers who offer the same product in multiple tiers. However, collecting data at the product level would have prevented consumers from understanding differences in enrollee satisfaction at the individual product per tier level, which may vary with differences in cost sharing. This would have reduced the benefits that consumers derive from ESS data.

2. Using Medicaid CAHPS® As Is Instead of Adding Additional and New Questions to the ESS

Under this alternative, HHS would have required QHPs to collect enrollee satisfaction information using the Medicaid CAHPS® instrument without further enhancement. The ESS will include more questions than the Medicaid CAHPS®—including detailed questions about the patient’s costs—that are particularly appropriate to Exchange enrollees. Eliminating these questions would have reduced the cost to issuers, but also would have reduced benefits that consumers derive from the ESS data.

3. Collecting QRS Data for Each Product Per Metal Tier Instead of at the Product Level

Under this alternative, HHS would have required QHPs to collect the QRS data at the same level (individual product per metal tier) as they collect ESS information. Assuming that QHPs offer each product in two metal tiers this option would have doubled the cost to QHPs of collecting QRS data. However, it might not have appreciably increased consumer information about QHPs in the early years of the Exchanges if the quality of care in the same product does not differ significantly within tiers (that is, the variation should only be by the configuration of cost sharing within a limited range of actuarial value). Further, a QHP’s enrollment size at the product metal level may be too small in the early years of Exchange implementation to ensure reliable results.

4. Using the Medicare Advantage (MA) CAHPS® Instrument and Star System

Under this alternative, HHS would have required QHPs to collect enrollee satisfaction information from Exchange enrollees using the MA CAHPS® instrument. The ESS presently includes 29 more questions than MA CAHPS®. Use of the MA CAHPS® would have reduced the cost to consumers and also the QHP cost of data entry. However, the MA CAHPS® instrument and Star ratings are designed for a different population and are not necessarily suitable to measure experience among Exchange enrollees. It also would have had limited applicability for use by consumers for QHP comparison and selection purposes.

CMS believes that the options adopted for this final rule will be more efficient ways to extend the protections of the Affordable Care Act to enrollees without imposing significant burden on issuers and States.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies that issue a rule to analyze options for regulatory relief of small businesses if a rule has a significant 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 nonprofit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000 (States and individuals are not included in the definition of “small entity”). HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 percent to 5 percent.

As discussed in the Web Portal interim final rule with comment period published on May 5, 2010 (75 FR 24481), HHS examined the health insurance industry in depth in the RIA we prepared for the proposed rule on establishment of the Medicare Advantage program (69 FR 46866, August 3, 2004). In that analysis it was determined that there were few, if any, insurance

firms underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) that fell below the size thresholds for “small entity” established by the SBA. Based on data from MLR annual report submissions for the 2012 MLR reporting year,⁴⁴ out of 510 companies offering comprehensive health insurance policies nationwide, there are 58 small entities, each with less than \$35.5 million in earned premiums, that offer individual or group health insurance coverage and will therefore be subject to the provisions of this final rule.⁴⁵ Forty three percent of these small entities belong to holding groups, and many if not all of these small entities are likely to have other lines of business (for example, insurance business other than health insurance, and business other than insurance) that will result in their revenues exceeding \$35.5 million. Based on this analysis, HHS expects that the provisions of this final rule will not affect a substantial number of small issuers.

The amendments to the annual employer and employee election periods in the SHOPs, including removing the required minimum lengths of both the employer election period and the employee open enrollment period will benefit State-based SHOPs and employers. HHS does not anticipate that this will impose any costs on small employers.

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, may be small entities and will incur costs to comply with the provisions of this final 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

⁴⁴ These data can be accessed at <http://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

⁴⁵ The size threshold for “small” business established by the SBA is currently \$35.5 million in annual receipts for health insurance issuers. See “Table of Small Business Size Standards Matched To North American Industry Classification System Codes,” effective July 23, 2013, U.S. Small Business Administration, available at <http://www.sba.gov>.

Federally required training or completing continuing education or recertification in FFEs.

Further, the cost burden related to continuing education and recertification, and recordkeeping will generally be considered an allowed cost that will be covered by the Navigator grants for the FFEs, and these grant funds may be drawn down as the grantee incurs such costs. The costs associated with these proposals may also be covered by other compensation provided by an Exchange, such as payments through contracts to non-Navigator assistance personnel. Though it is very likely that all costs associated with these proposals will be largely covered by affected entities' and individuals' funding sources, HHS cannot guarantee that all such costs will be covered because of the possibility of budget limitations applicable to the FFE in any given period, and because there may be variations in how State Exchanges provide funding for these programs. To the extent that all such costs will not be covered by these funding sources, other outside sources may also be available to cover unfunded costs that remain. Costs incurred by designated certified application counselor organizations related to continuing education and recertification and recordkeeping are expected to be low. In some circumstances funds from sources outside of the Exchange, including Federal funds such as Health Resources and Services Administration (HRSA) grants to health centers, or private or State funds may be available to cover certified application counselor costs.

E. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 requires that agencies assess anticipated costs and benefits before issuing any final rule that includes a Federal mandate that could result in expenditure in any one year by State, local or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold level is approximately \$141 million.

UMRA does not address the total cost of a final rule. Rather, it focuses on certain categories of cost, mainly those “Federal mandate” costs resulting from--(1) imposing enforceable duties on State, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs.

This final rule includes mandates on State governments and the private sector. Issuers, non-Navigator assistance personnel, certified application counselors and Exchanges are expected to incur costs of approximately \$13 million in 2014 and approximately \$85 million in 2015 onwards to comply with the provisions of this final rule. However, beginning in 2015, issuers in the individual market will experience a reduction in costs of approximately \$26 million due to the discontinuation of the certification of creditable coverage. Consistent with policy embodied in UMRA, this final rule has been designed to be the least burdensome alternative for State, local and tribal governments, and the private sector while achieving the objectives of the Affordable Care Act.

F. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

Since States are the primary regulators of health insurance coverage, State laws will continue to apply to health insurance coverage and the business of insurance. A State’s authority to pass and implement additional State requirements that affect programs established under the provisions of title I of the Affordable Care Act is not unlimited, however, but extends only to the implementation of requirements that would not prevent the application of the

provisions of title I of the Affordable Care Act, including but not limited to those provisions which provide authority for functions of an Exchange, such as the application assistance provided by Navigator programs, non-Navigator programs and certified application counselor programs.

The final rule provides that non-Navigator assistance personnel subject to §155.215, and certified application counselors must meet any licensing, certification or other standards prescribed by the State so long as such standards do not prevent the application of the provisions of title I of the Affordable Care Act, within the meaning of section 1321(d) of the Affordable Care Act. The final rule also includes a non-exhaustive list of non-Federal requirements applicable to Navigators, non-Navigator assistance personnel subject to §155.215, and certified application counselors that, in HHS's view, prevent the application of the provisions of title I of the Affordable Care Act, within the meaning of section 1321(d) of the Affordable Care Act. They include non-Federal requirements that require referrals to entities or individuals not required to provide impartial information or act in a consumer's best interest; non-Federal requirements that prevent Navigators, non-Navigator assistance personnel subject to §155.215, or certified application counselors from providing services to all individuals seeking assistance; non-Federal requirements that prevent these assisters from providing information regarding substantive benefits or comparative benefits of different health plans; non-Federal requirements that facially, or as applied, make it impossible to fulfill required duties; non-Federal standards that would, as applied or as implemented in a State, prevent an Exchange's implementation of the programs for Navigators, non-Navigator personnel subject to §155.215 and certified application counselors consistent with Federal requirements; and non-Federal requirements that Navigators hold an agent or broker license or requirements that, in effect, would require all

Navigators in the Exchange to be licensed agents and brokers. These provisions provide HHS's interpretation of how the preemption standard that Congress established in section 1321(d) of the Affordable Care Act applies to this non-exhaustive list of non-Federal requirements for these assister programs.

The final rule establishes Federal standards to determine whether coverage modifications constitute the continuance of an existing product in a market within a State for coverage offered both through and outside of an Exchange in the individual and small group markets. Some States may have different definitions of what changes to a health insurance product constitute modifications and what changes constitute terminations and re-filings of new products. The definitions finalized in this rule will preempt any conflicting State definitions. The guaranteed renewability sections of the PHS Act provide in pertinent part that a uniform modification of coverage must be "consistent with State law." We interpret this statutory language as governing the extent or type of modifications that may legally be made under State law. As discussed in the preamble to the final rule published on February 27, 2013 under section 2703 of the PHS Act (78 FR 13419), State laws that prevent issuers from uniformly modifying coverage to comply with Federal law requirements would, in effect, prevent the application of such requirements and therefore be preempted. States, however, have the flexibility to broaden the scope of two of the criteria for what is considered a uniform modification, but not narrow its scope.

Some States already have requirements for and publicly report health plan quality and outcomes data, and we want to encourage State flexibility and innovation, consistent with the Affordable Care Act. In addition to prominently displaying quality rating information for each QHP, as calculated by HHS in accordance with the QRS, a State Exchange may display additional QHP quality-related information, as appropriate.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policymaking discretion of the States, HHS has engaged in efforts to consult with and work cooperatively with affected States. HHS has consulted with stakeholders on policies related to the operation of Exchanges, including the SHOP and the premium stabilization programs. HHS has held a number of listening sessions with State representatives to gather public input. HHS consulted with State representatives through regular meetings with the NAIC and regular contact with States through the Exchange Establishment grant and Exchange Blueprint approval processes.

Throughout the process of developing this final rule, HHS has attempted to balance the States' interests in regulating health insurance issuers and other entities, such as Navigators, non-Navigator assistance personnel, and certified application counselors with creating a Federal baseline for protecting the consumers' interests. By doing so, it is HHS' view that it has complied with the requirements of Executive Order 13132. Under the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to this rule, HHS certifies that the CMS Center for Consumer Information and Insurance Oversight has complied with the requirements of Executive Order 13132 for the attached final rule in a meaningful and timely manner.

G. Congressional Review Act

This final 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 General for review.

List of Subjects45 CFR part 144

Health care, Health insurance, Reporting and record keeping requirements.

45 CFR Part 146

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

45 CFR Part 148

Administrative practice and procedure, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements

45 CFR Part 153

Administrative practice and procedure, Adverse selection, Health care, Health insurance, Health records, Organization and functions (Government agencies), Premium stabilization, Reporting and recordkeeping requirements, Reinsurance, Risk adjustment, Risk corridors, Risk mitigation, State and local governments.

45 CFR Part 154

Administrative practice and procedure, Claims, Health care, Health insurance, Health plans, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Health care access, Health insurance, Reporting and recordkeeping requirements, State and local governments, Cost-sharing reductions, Advance

payments of premium tax credit, Administration and calculation of advance payments of the premium tax credit, Plan variations, Actuarial value.

45 CFR Part 156

Administrative appeals, Administrative practice and procedure, Administration and calculation of advance payments of premium tax credit, Advertising, Advisory Committees, Brokers, Conflict of interest, Consumer protection, Cost-sharing reductions, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, American Indian/Alaska Natives, Individuals with disabilities, Loan programs-health, Organization and functions (Government agencies), Medicaid, Payment and collections reports, Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, and Youth.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Health plans, Penalties, Reporting and recordkeeping requirements, Premium revenues, Medical loss ratio, Rebating.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR parts 144, 146, 147, 148, 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 adding new definitions of “plan” and “product” in alphabetical order to read as follows:

§144.103 Definitions.

* * * * *

Plan means, with respect to an issuer and a product, the pairing of the health insurance coverage benefits under the product with a metal tier level (as described in sections 1302(d) and (e) of the Affordable Care Act) and service area. The product comprises all plans offered within the product, and the combination of all plans offered within a product constitutes the total service area of the product.

* * * * *

Product means a discrete package of health insurance coverage benefits that a health insurance issuer offers using a particular product network type within a service area.

* * * * *

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 146.152 is amended by—

a. Revising paragraphs (b)(4), (c)(1) and (f); and

b. Adding new paragraph (h).

The revision and addition read as follows:

§146.152 Guaranteed renewability of coverage for employers in the group market.

* * * *

(b) * * *

* * * *

(4) Termination of product. The issuer is ceasing to offer coverage in the market in accordance with paragraph (c) or (d) of this section and applicable State law.

* * * *

(c) * * *

(1) The issuer provides notice in writing, in a form and manner specified by the Secretary, to each plan sponsor provided that particular product in that market (and to all participants and beneficiaries covered under such coverage) of the discontinuation at least 90 days before the date the coverage will be discontinued;

* * * *

(f) Exception for uniform modification of coverage. (1) Only at the time of coverage renewal may issuers modify the health insurance coverage for a product offered to a group health plan in the following—

(i) Large group market; and

(ii) Small group market if, for coverage available in this market (other than only through one or more bona fide associations), the modification is consistent with State law and is effective uniformly among group health plans with that product.

(2) For purposes of paragraph (f)(1)(ii) of this section, modifications made uniformly and solely pursuant to applicable Federal or State requirements are considered a uniform modification of coverage if:

(i) The modification is made within a reasonable time period after the imposition or modification of the Federal or State requirement; and

(ii) The modification is directly related to the imposition or modification of the Federal or State requirement.

(3) For purposes of paragraph (f)(1)(ii) of this section, other types of modifications made uniformly are considered a uniform modification of coverage if the health insurance coverage for the product in the small group market meets all of the following criteria:

(i) The product is offered by the same health insurance issuer (within the meaning of section 2791(b)(2) of the PHS Act);

(ii) The product is offered as the same product network type (for example, health maintenance organization, preferred provider organization, exclusive provider organization, point of service, or indemnity);

(iii) The product continues to cover at least a majority of the same service area;

(iv) Within the product, each plan has the same cost-sharing structure as before the modification, except for any variation in cost sharing solely related to changes in cost and utilization of medical care, or to maintain the same metal tier level described in sections 1302(d) and (e) of the Affordable Care Act; and

(v) The product provides the same covered benefits, except for any changes in benefits that cumulatively impact the rate for any plan within the product within an allowable variation of +/- 2 percentage points (not including changes pursuant to applicable Federal or State requirements).

(4) A State may only broaden the standards in paragraphs (f)(3)(iii) and (iv) of this section.

* * * * *

(h) Notice of renewal of coverage. If an issuer in the small group market is renewing grandfathered coverage as described in paragraph (a) of this section, or uniformly modifying grandfathered coverage as described in paragraph (f) of this section, the issuer must provide to each plan sponsor written notice of the renewal at least 60 calendar days before the date the coverage will be renewed in a form and manner specified by the Secretary.

5. Section 146.180 is revised to read as follows:

§146.180 Treatment of non-Federal governmental plans.

(a) Opt-out election for self-funded non-Federal governmental plans—(1) Requirements subject to exemption. The PHS Act requirements described in this paragraph are the following:

(i) Limitations on preexisting condition exclusion periods in accordance with section 2701 of the PHS Act as codified before enactment of the Affordable Care Act.

(ii) Special enrollment periods for individuals and dependents described under section 2704(f) of the PHS Act.

(iii) Prohibitions against discriminating against individual participants and beneficiaries based on health status under section 2705 of the PHS Act, except that the sponsor of a self-funded non-Federal governmental plan cannot elect to exempt its plan from requirements

under section 2705(a)(6) and 2705(c) through (f) that prohibit discrimination with respect to genetic information.

(iv) Standards relating to benefits for mothers and newborns under section 2725 of the PHS Act.

(v) Parity in mental health and substance use disorder benefits under section 2726 of the PHS Act.

(vi) Required coverage for reconstructive surgery following mastectomies under section 2727 of the PHS Act.

(vii) Coverage of dependent students on a medically necessary leave of absence under section 2728 of the PHS Act.

(2) General rule. For plan years beginning on or after September 23, 2010, a sponsor of a non-Federal governmental plan may elect to exempt its plan, to the extent the plan is not provided through health insurance coverage (that is, it is self-funded), from one or more of the requirements described in paragraphs (a)(1)(iv) through (vii) of this section.

(3) Special rule for certain collectively bargained plans. In the case of a plan that is maintained pursuant to a collective bargaining agreement that was ratified before March 23, 2010, and whose sponsor made an election to exempt its plan from any of the requirements described in paragraphs (a)(1)(i) through (iii) of this section, the provisions of paragraph (a)(2) of this section apply for plan years beginning after the expiration of the term of the agreement.

(4) Examples—(i) Example 1. A non-Federal governmental employer has elected to exempt its self-funded group health plan from all of the requirements described in paragraph (a)(1) of this section. The plan year commences September 1 of each year. The plan is not subject to the provisions of paragraph (a)(2) of this section until the plan year that commences on

September 1, 2011. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraphs (a)(1)(iv) through (vii) of this section.

(ii) Example 2. A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from all of the requirements described in paragraph (a)(1) of this section. The collective bargaining agreement applies to five plan years, October 1, 2009 through September 30, 2014. For the plan year that begins on October 1, 2014, the plan sponsor is no longer permitted to elect to exempt its plan from the requirements described in paragraph (a)(1) of this section. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraphs (a)(1)(iv) through (vii) of this section.

(5) Limitations. (i) An election under this section cannot circumvent a requirement of the PHS Act to the extent the requirement applied to the plan before the effective date of the election.

(A) Example 1. A plan is subject to requirements of section 2727 of the PHS Act, under which a plan that covers medical and surgical benefits with respect to a mastectomy must cover reconstructive surgery and certain other services following a mastectomy. An enrollee who has had a mastectomy receives reconstructive surgery on August 24. Claims with respect to the surgery are submitted to and processed by the plan in September. The group health plan commences a new plan year each September 1. Effective September 1, the plan sponsor elects to exempt its plan from section 2727 of the PHS Act. The plan cannot, on the basis of its exemption election, decline to pay for the claims incurred on August 24.

(B) [Reserved]

(ii) If a group health plan is co-sponsored by two or more employers, then only plan enrollees of the non-Federal governmental employer(s) with a valid election under this section are affected by the election.

(6) Stop-loss or excess risk coverage. For purposes of this section—

(i) Subject to paragraph (a)(6)(ii) of this section, the purchase of stop-loss or excess risk coverage by a self-funded non-Federal governmental plan does not prevent an election under this section.

(ii) Regardless of whether coverage offered by an issuer is designated as “stop-loss” coverage or “excess risk” coverage, if it is regulated as group health insurance under an applicable State law, then for purposes of this section, a non-Federal governmental plan that purchases the coverage is considered to be fully insured. In that event, a plan may not be exempted under this section from the requirements described in paragraph (a)(1) of this section.

(7) Construction. Nothing in this part should be construed as imposing collective bargaining obligations on any party to the collective bargaining process.

(b) Form and manner of election—(1) Election requirements. The election must meet the following requirements:

(i) Be made in an electronic format in a form and manner as described by the Secretary in guidance.

(ii) Be made in conformance with all of the plan sponsor's rules, including any public hearing requirements.

(iii) Specify the beginning and ending dates of the period to which the election is to apply. This period can be either of the following periods:

(A) A single specified plan year, as defined in §144.103 of this subchapter.

(B) The “term of the agreement,” as specified in paragraph (b)(2) of this section, in the case of a plan governed by collective bargaining.

(iv) Specify the name of the plan and the name and address of the plan administrator, and include the name and telephone number of a person CMS may contact regarding the election.

(v) State that the plan does not include health insurance coverage, or identify which portion of the plan is not funded through health insurance coverage.

(vi) Specify each requirement described in paragraph (a)(1) of this section from which the plan sponsor elects to exempt the plan.

(vii) Certify that the person signing the election document, including (if applicable) a third party plan administrator, is legally authorized to do so by the plan sponsor.

(viii) Include, as an attachment, a copy of the notice described in paragraph (f) of this section.

(ix) In the case of a plan sponsor submitting one opt-out election for all group health plans subject to the same collective bargaining agreement, include a list of plans subject to the agreement.

(x) In the case of a plan sponsor submitting opt-out elections for more than one group health plan that is not subject to a collective bargaining agreement, submit a separate election document for each such plan.

(2) “Term of the agreement” defined. Except as provided in paragraphs (b)(2)(i) and (ii) of this section, for purposes of this section “term of the agreement” means all group health plan years governed by a single collective bargaining agreement.

(i) In the case of a group health plan for which the last plan year governed by a prior collective bargaining agreement expires during the bargaining process for a new agreement, the

term of the prior agreement includes all plan years governed by the agreement plus the period of time that precedes the latest of the following dates, as applicable, with respect to the new agreement:

(A) The date of an agreement between the governmental employer and union officials.

(B) The date of ratification of an agreement between the governmental employer and the union.

(C) The date impasse resolution, arbitration or other closure of the collective bargaining process is finalized when agreement is not reached.

(ii) In the case of a group health plan governed by a collective bargaining agreement for which closure is not reached before the last plan year under the immediately preceding agreement expires, the term of the new agreement includes all plan years governed by the agreement excluding the period that precedes the latest applicable date specified in paragraph (b)(2)(i) of this section.

(3) Construction—(i) Dispute resolution. Nothing in paragraph (b)(1)(ii) of this section should be construed to mean that CMS arbitrates disputes between plan sponsors, participants, beneficiaries, or their representatives regarding whether an election complies with all of a plan sponsor's rules.

(ii) Future elections not preempted. If a plan must comply with one or more requirements described in paragraph (a)(1) of this section for a given plan year or period of plan coverage, nothing in this section should be construed as preventing a plan sponsor from submitting an election in accordance with this section for a subsequent plan year or period of plan coverage.

(c) Filing a timely election—(1) Plan not governed by collective bargaining. Subject to paragraph (c)(4) of this section, if a plan is not governed by a collective bargaining agreement, a plan sponsor or entity acting on behalf of a plan sponsor must file an election with CMS before the first day of the plan year.

(2) Plan governed by a collective bargaining agreement. Subject to paragraph (d)(4) of this section, if a plan is governed by a collective bargaining agreement that was ratified before March 23, 2010, a plan sponsor or entity acting on behalf of a plan sponsor must file an election with CMS before the first day of the first plan year governed by a collective bargaining agreement, or by the 45th day after the latest applicable date specified in paragraph (b)(2)(i) of this section, if the 45th day falls on or after the first day of the plan year.

(3) Special rule for timely filing. If the latest filing date specified under paragraphs (c)(1) or (c)(2) of this section falls on a Saturday, Sunday, or a State or Federal holiday, CMS accepts filings submitted on the next business day.

(4) Filing extension based on good cause. CMS may extend the deadlines specified in paragraphs (c)(1) and (2) of this section for good cause if the plan substantially complies with the requirements of paragraph (e) of this section.

(5) Failure to file a timely election. Absent an extension under paragraph (c)(4) of this section, a plan sponsor's failure to file a timely election under paragraph (c)(1) or (2) of this section makes the plan subject to all requirements of this part for the entire plan year to which the election would have applied, or, in the case of a plan governed by a collective bargaining agreement, for any plan years under the agreement for which the election is not timely filed.

(d) Additional information required—(1) Written notification. If an election is timely filed, but CMS determines that the election document (or the notice to plan enrollees) does not

meet all of the requirements of this section, CMS may notify the plan sponsor, or other entity that filed the election, that it must submit any additional information that CMS has determined is necessary to meet those requirements. The additional information must be filed with CMS by the later of the following dates:

(i) The last day of the plan year.

(ii) The 45th day after the date of CMS's written notification requesting additional information.

(2) Timely response. For submissions via hard copy via U.S. Mail, CMS uses the postmark on the envelope in which the additional information is submitted to determine that the information is timely filed as specified under paragraph (d)(1) of this section. If the latest filing date falls on a Saturday, Sunday, or a State or Federal holiday, CMS accepts a postmark on the next business day.

(3) Failure to respond timely. CMS may invalidate an election if the plan sponsor, or other entity that filed the election, fails to timely submit the additional information as specified under paragraph (d)(1) of this section.

(e) Notice to enrollees—(1) Mandatory notification. (i) A plan that makes the election described in this section must notify each affected enrollee of the election, and explain the consequences of the election. For purposes of paragraph (e) of this section, if the dependent(s) of a participant reside(s) with the participant, a plan need only provide notice to the participant.

(ii) The notice must be in writing and, except as provided in paragraph (e)(2) of this section with regard to initial notices, must be provided to each enrollee at the time of enrollment under the plan, and on an annual basis no later than the last day of each plan year (as defined in §144.103 of this subchapter) for which there is an election.

(iii) A plan may meet the notification requirements of paragraph (e) of this section by prominently printing the notice in a summary plan description, or equivalent description, that it provides to each enrollee at the time of enrollment, and annually. Also, when a plan provides a notice to an enrollee at the time of enrollment, that notice may serve as the initial annual notice for that enrollee.

(2) Initial notices. (i) If a plan is not governed by a collective bargaining agreement, with regard to the initial plan year to which an election under this section applies, the plan must provide the initial annual notice of the election to all enrollees before the first day of that plan year, and notice at the time of enrollment to all individuals who enroll during that plan year.

(ii) In the case of a collectively bargained plan, with regard to the initial plan year to which an election under this section applies, the plan must provide the initial annual notice of the election to all enrollees before the first day of the plan year, or within 30 days after the latest applicable date specified in paragraph (b)(2)(i) of this section if the 30th day falls on or after the first day of the plan year. Also, the plan must provide a notice at the time of enrollment to individuals who—

(A) Enroll on or after the first day of the plan year, when closure of the collective bargaining process is reached before the plan year begins; or

(B) Enroll on or after the latest applicable date specified in paragraph (b)(2)(i) of this section if that date falls on or after the first day of the plan year.

(3) Notice content. The notice must include at least the following information:

(i) The specific requirements described in paragraph (a)(1) of this section from which the plan sponsor is electing to exempt the plan, and a statement that, in general, Federal law imposes these requirements upon group health plans.

(ii) A statement that Federal law gives the plan sponsor of a self-funded non-Federal governmental plan the right to exempt the plan in whole, or in part, from the listed requirements, and that the plan sponsor has elected to do so.

(iii) A statement identifying which parts of the plan are subject to the election.

(iv) A statement identifying which of the listed requirements, if any, apply under the terms of the plan, or as required by State law, without regard to an exemption under this section.

(f) Subsequent elections—(1) Election renewal. A plan sponsor may renew an election under this section through subsequent elections. The timeliness standards described in paragraph (c) of this section apply to election renewals under paragraph (f) of this section.

(2) Form and manner of renewal. Except for the requirement to forward to CMS a copy of the notice to enrollees under paragraph (b)(1)(viii) of this section, the plan sponsor must comply with the election requirements of paragraph (b)(1) of this section. In lieu of providing a copy of the notice under paragraph (b)(1)(viii) of this section, the plan sponsor may include a statement that the notice has been, or will be, provided to enrollees as specified under paragraph (e) of this section.

(3) Election renewal includes provisions from which plan not previously exempted. If an election renewal includes a requirement described in paragraph (a)(1) of this section from which the plan sponsor did not elect to exempt the plan for the preceding plan year, the advance notification requirements of paragraph (e)(2) of this section apply with respect to the additional requirement(s) of paragraph (a) of this section from which the plan sponsor is electing to exempt the plan.

(4) Special rules regarding renewal of an election under a collective bargaining agreement—(i) If protracted negotiations with respect to a new agreement result in an extension

of the term of the prior agreement (as provided under paragraph (b)(2)(i) of this section) under which an election under this section was in effect, the plan must comply with the enrollee notification requirements of paragraph (e)(1) of this section, and, following closure of the collective bargaining process, must file an election renewal with CMS as provided under paragraph (c)(2) of this section.

(ii) If a single plan applies to more than one bargaining unit, and the plan is governed by collective bargaining agreements of varying lengths, paragraph (c)(2) of this section, with respect to an election renewal, applies to the plan as governed by the agreement that results in the earliest filing date.

(g) Requirements not subject to exemption—(1) Genetic information. Without regard to an election under this section that exempts a non-Federal governmental plan from any or all of the provisions of §§146.111 and 146.121, the exemption election must not be construed to exempt the plan from any provisions of this part that pertain to genetic information.

(2) Enforcement. CMS enforces these requirements as provided under paragraph (j) of this section.

(h) Effect of failure to comply with certification and notification requirements—

(1) Substantial failure—(i) General rule. Except as provided in paragraph (h)(1)(iii) of this section, a substantial failure to comply with paragraph (e) or (g)(1) of this section results in the invalidation of an election under this section with respect to all plan enrollees for the entire plan year. That is, the plan is subject to all requirements of this part for the entire plan year to which the election otherwise would have applied.

(ii) Determination of substantial failure. CMS determines whether a plan has substantially failed to comply with a requirement of paragraph (e) or (g)(1) of this section based

on all relevant facts and circumstances, including previous record of compliance, gravity of the violation and whether a plan corrects the failure, as warranted, within 30 days of learning of the violation. However, in general, a plan's failure to provide a notice of the fact and consequences of an election under this section to an individual at the time of enrollment, or on an annual basis before a given plan year expires, constitutes a substantial failure.

(iii) Exceptions—(A) Multiple employers. If the plan is sponsored by multiple employers, and only certain employers substantially fail to comply with the requirements of paragraph (e) or (g)(1) of this section, then the election is invalidated with respect to those employers only, and not with respect to other employers that complied with those requirements, unless the plan chooses to cancel its election entirely.

(B) Limited failure to provide notice. If a substantial failure to notify enrollees of the fact and consequences of an election is limited to certain individuals, the election under this section is valid only if, for the plan year with respect to which the failure has occurred, the plan agrees not to apply the election with respect to the individuals who were not notified and so informs those individuals in writing.

(2) Examples—(i) Example 1. A self-funded, non-Federal group health plan is co-sponsored by 10 school districts. Nine of the school districts have fully complied with the requirements of paragraph (e) of this section, including providing notice to new employees at the time of their enrollment in the plan, regarding the group health plan's exemption under this section from requirements of this part. One school district, which hired 10 new teachers during the summer for the upcoming school year, neglected to notify three of the new hires about the group health plan's exemption election at the time they enrolled in the plan. The school district has substantially failed to comply with a requirement of paragraph (e) of this section with respect

to these individuals. The school district learned of the oversight six weeks into the school year, and promptly (within 30 days of learning of the oversight) provided notice to the three teachers regarding the plan's exemption under this section and that the exemption does not apply to them, or their dependents, during the plan year of their enrollment because of the plan's failure to timely notify them of its exemption. The plan complies with the requirements of this part for these individuals for the plan year of their enrollment. CMS would not require the plan to come into compliance with the requirements of this part for other enrollees.

(ii) Example 2. Two non-Federal governmental employers cosponsor a self-funded group health plan. One employer substantially fails to comply with the requirements of paragraph (e) of this section. While the plan may limit the invalidation of the election to enrollees of the plan sponsor that is responsible for the substantial failure, the plan sponsors determine that administering the plan in that manner would be too burdensome. Accordingly, in this example, the plan sponsors choose to cancel the election entirely. Both plan sponsors come into compliance with the requirements of this part with respect to all enrollees for the plan year for which the substantial failure has occurred.

(i) Election invalidated. If CMS finds cause to invalidate an election under this section, the following rules apply:

(1) CMS notifies the plan sponsor (and the plan administrator if other than the plan sponsor and the administrator's address is known to CMS) in writing that CMS has made a preliminary determination that an election is invalid, and States the basis for that determination.

(2) CMS's notice informs the plan sponsor that it has 45 days after the date of CMS's notice to explain in writing why it believes its election is valid. The plan sponsor should provide applicable statutory and regulatory citations to support its position.

(3) CMS verifies that the plan sponsor's response is timely filed as provided under paragraph (c)(3) of this section. CMS will not consider a response that is not timely filed.

(4) If CMS's preliminary determination that an election is invalid remains unchanged after CMS considers the plan sponsor's timely response (or in the event that the plan sponsor fails to respond timely), CMS provides written notice to the plan sponsor (and the plan administrator if other than the plan sponsor and the administrator's address is known to CMS) of CMS's final determination that the election is invalid. Also, CMS informs the plan sponsor that, within 45 days of the date of the notice of final determination, the plan, subject to paragraph (i)(1)(iii) of this section, must comply with all requirements of this part for the specified period for which CMS has determined the election to be invalid.

(j) Enforcement. To the extent that an election under this section has not been filed or a non-Federal governmental plan otherwise is subject to one or more requirements of this part, CMS enforces those requirements under part 150 of this subchapter. This may include imposing a civil money penalty against the plan or plan sponsor, as determined under subpart C of part 150.

(k) Construction. Nothing in this section should be construed to prevent a State from taking the following actions:

(1) Establishing, and enforcing compliance with, the requirements of State law (as defined in §146.143(d)(1)), including requirements that parallel provisions of title XXVII of the PHS Act, that apply to non-Federal governmental plans or sponsors.

(2) Prohibiting a sponsor of a non-Federal governmental plan within the State from making an election under this section.

**PART 147 – HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP
AND INDIVIDUAL HEALTH INSURANCE MARKETS**

6. 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.

7. Section 147.104 is amended by revising paragraph (b)(1)(i) and adding paragraph (h) to read as follows:

§147.104 Guaranteed availability of coverage.

* * * * *

(b) * * *

(1) * * *

(i) Group market. (A) Subject to paragraph (b)(1)(i)(B) of this section, a health insurance issuer in the group market must allow an employer to purchase health insurance coverage for a group health plan at any point during the year.

(B) In the case of a group health plan in the small group market that cannot comply with employer contribution or group participation rules for the offering of health insurance coverage, as allowed under applicable State law and in the case of a QHP offered in the SHOP, as permitted by §156.1250(c) of this subchapter, a health insurance issuer may restrict the availability of coverage to an annual enrollment period that begins November 15 and extends through December 15 of each calendar year.

(C) With respect to coverage in the small group market, and in the large group market if such coverage is offered through a Small Business Health Options Program (SHOP) in a State,

coverage must become effective consistent with the dates described in §155.725(a)(2) of this subchapter, except as provided in paragraph (b)(1)(iii) of this section.

* * * * *

(h) Construction. Nothing in this section should be construed to require an issuer to offer coverage otherwise prohibited under applicable Federal law.

8. Section 147.106 is amended by—

- a. Revising paragraphs (b)(4), (c)(1), and (e);
- b. Redesignating paragraphs (f), (g), and (h) as paragraphs (h), (i) and (j), respectively;

and

- c. Adding new paragraphs (f) and (g).

The revisions and additions read as follows:

§147.106 Guaranteed renewability of coverage.

* * * * *

(b) * * *

(4) Termination of product. The issuer is ceasing to offer coverage in the market in accordance with paragraph (c) or (d) of this section and applicable State law.

* * * * *

(c) * * *

(1) The issuer provides notice in writing, in a form and manner specified by the Secretary, to each plan sponsor or individual, as applicable, provided that particular product in that market (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.

* * * * *

(e) Exception for uniform modification of coverage. (1) Only at the time of coverage renewal may issuers modify the health insurance coverage for a product offered to a group health plan or an individual, as applicable, in the following:

(i) Large group market.

(ii) Small group market if, for coverage available in this market (other than only through one or more bona fide associations), the modification is consistent with State law and is effective uniformly among group health plans with that product.

(iii) Individual market if the modification is consistent with State law and is effective uniformly for all individuals with that product.

(2) For purposes of paragraphs (e)(1)(ii) and (iii) of this section, modifications made uniformly and solely pursuant to applicable Federal or State requirements are considered a uniform modification of coverage if:

(i) The modification is made within a reasonable time period after the imposition or modification of the Federal or State requirement; and

(ii) The modification is directly related to the imposition or modification of the Federal or State requirement.

(3) Other types of modifications made uniformly are considered a uniform modification of coverage if the health insurance coverage for the product in the individual or small group market meets all of the following criteria:

(i) The product is offered by the same health insurance issuer (within the meaning of section 2791(b)(2) of the PHS Act);

(ii) The product is offered as the same product network type (for example, health maintenance organization, preferred provider organization, exclusive provider organization, point of service, or indemnity);

(iii) The product continues to cover at least a majority of the same service area;

(iv) Within the product, each plan has the same cost-sharing structure as before the modification, except for any variation in cost sharing solely related to changes in cost and utilization of medical care, or to maintain the same metal tier level described in sections 1302(d) and (e) of the Affordable Care Act; and

(v) The product provides the same covered benefits, except for any changes in benefits that cumulatively impact the plan-adjusted index rate (as described in §156.80(d)(2) of this subchapter) for any plan within the product within an allowable variation of +/- 2 percentage points (not including changes pursuant to applicable Federal or State requirements).

(4) A State may only broaden the standards in paragraphs (e)(3)(iii) and (iv) of this section.

(f) Notice of renewal of coverage. (1) If an issuer in the individual market is renewing non-grandfathered coverage as described in paragraph (a) of this section, or uniformly modifying non-grandfathered coverage as described in paragraph (e) of this section, the issuer must provide to each individual written notice of the renewal before the date of the first day of the next annual open enrollment period in a form and manner specified by the Secretary.

(2) If an issuer in the small group market is renewing coverage as described in paragraph (a) of this section, or uniformly modifying coverage as described in paragraph (e) of this section, the issuer must provide to each plan sponsor or individual, as applicable, written notice of the

renewal at least 60 calendar days before the date of the coverage will be renewed in a form and manner specified by the Secretary.

(g) Construction. (1) Nothing in this section should be construed to require an issuer to renew or continue in force coverage for which continued eligibility would otherwise be prohibited under applicable Federal law.

(2) Medicare eligibility or entitlement is not a basis for nonrenewal or termination of an individual's health insurance coverage in the individual market.

* * * * *

PART 148 – REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

9. The authority citation for part 148 is revised 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.

10. Section 148.101 is revised to read as follows:

§148.101 Basis and purpose.

This part implements sections 2741 through 2763 and 2791 and 2792 of the PHS Act. Its purpose is to guarantee the renewability of all coverage in the individual market. It also provides certain protections for mothers and newborns with respect to coverage for hospital stays in connection with childbirth and protects all individuals and family members who have, or seek, individual health insurance coverage from discrimination based on genetic information.

11. Section 148.102 is revised to read as follows:

§148.102 Scope, applicability, and effective dates.

(a) Scope and applicability. (1) Individual health insurance coverage includes all health insurance coverage (as defined in §144.103 of this subchapter) that is neither health insurance coverage sold in connection with an employment-related group health plan, nor short-term, limited-duration coverage as defined in §144.103 of this subchapter.

(2) The requirements that pertain to guaranteed renewability for all individuals, to protections for mothers and newborns with respect to hospital stays in connection with childbirth, and to protections against discrimination based on genetic information apply to all issuers of individual health insurance coverage in the State.

(b) Applicability date. Except as provided in §148.124 (certificate of creditable coverage), §148.170 (standards relating to benefits for mothers and newborns), and §148.180 (prohibition of health discrimination based on genetic information), the requirements of this part apply to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after June 30, 1997.

§148.103 [Removed]

12. Section 148.103 is removed.

13. Section 148.120 is revised to read as follows:

§148.120 Guaranteed availability of individual health insurance coverage to certain individuals with prior group coverage.

The rules for guaranteeing the availability of individual health insurance coverage to certain eligible individuals with prior group coverage have been superseded by the requirements of §147.104 of this subchapter, which set forth Federal requirements for guaranteed availability of coverage in the group and individual markets.

14. Section 148.122 is amended by—

- a. Revising paragraphs (a), (c)(3), (d)(1), and (g); and
- b. Adding new paragraph (i).

The revision and addition read as follows:

§148.122 Guaranteed renewability of individual health insurance coverage.

(a) Applicability. This section applies to non-grandfathered and grandfathered health plans (within the meaning of §147.140 of this subchapter) that are individual health insurance coverage. See also §147.106 of this subchapter for requirements relating to guaranteed renewability of coverage with respect to non-grandfathered health plans.

* * * *

(c) * * *

(3) Termination of product. The issuer is ceasing to offer coverage in the market in accordance with paragraph (d) or (e) of this section and applicable State law.

* * * *

(d) * * *

(1) Provides notice in writing, in a form and manner specified by the Secretary, to each individual provided coverage of that type of health insurance at least 90 calendar days before the date the coverage will be discontinued.

* * * *

(g) Exception for uniform modification of coverage. (1) An issuer may, only at the time of coverage renewal, modify the health insurance coverage for a product offered in the individual market if the modification is consistent with State law and is effective uniformly for all individuals with that product.

(2) For purposes of paragraph (g) of this section, modifications made uniformly and solely pursuant to applicable Federal or State requirements are considered a uniform modification of coverage if:

(i) The modification is made within a reasonable time period after the imposition or modification of the Federal or State requirement; and

(ii) The modification is directly related to the imposition or modification of the Federal or State requirement.

(3) For purposes of paragraph (g) of this section, other types of modifications made uniformly are considered a uniform modification of coverage if the health insurance coverage for the product meets all of the following criteria:

(i) The product is offered by the same health insurance issuer (within the meaning of section 2791(b)(2) of the PHS Act);

(ii) The product is offered as the same product network type (for example, health maintenance organization, preferred provider organization, exclusive provider organization, point of service, or indemnity);

(iii) The product continues to cover at least a majority of the same service area;

(iv) Within the product, each plan has the same cost-sharing structure as before the modification, except for any variation in cost sharing solely related to changes in cost and utilization of medical care, or to maintain the same metal tier level described in sections 1302(d) and (e) of the Affordable Care Act; and

(v) The product provides the same covered benefits, except for any changes in benefits that cumulatively impact rate for any plan within the product within an allowable variation of +/- 2 percentage points (not including changes pursuant to applicable Federal or State requirements).

(4) A State may only broaden the standards in paragraphs (g)(3)(iii) and (iv) of this section.

* * * * *

(i) Notice of renewal of coverage. If an issuer is renewing grandfathered coverage as described in paragraph (b) of this section, or uniformly modifying grandfathered coverage as described in paragraph (g) of this section, the issuer must provide to each individual written notice of the renewal at least 60 calendar days before the date the coverage will be renewed in a form and manner specified by the Secretary.

15. Section 148.124 is revised to read as follows:

§148.124 Certification and disclosure of coverage.

(a) General rule. The rules for providing certificates of creditable coverage and demonstrating creditable coverage have been superseded by the prohibition on preexisting condition exclusions. See §147.108 of this subchapter for rules prohibiting the imposition of a preexisting condition exclusion.

(b) Applicability. The provisions of this section apply beginning December 31, 2014.

16. Section 148.126 is revised to read as follows:

§148.126 Determination of an eligible individual.

The rules for guaranteeing the availability of individual health insurance coverage to certain eligible individuals with prior group coverage have been superseded by the requirements of §147.104 of this subchapter, which set forth Federal requirements for guaranteed availability of coverage in the group and individual markets.

17. Section 148.128 is revised to read as follows:

§148.128 State flexibility in individual market reforms—alternative mechanisms.

The rules for a State to implement an acceptable alternative mechanism for purposes of guaranteeing the availability of individual health insurance coverage to certain eligible individuals with prior group coverage have been superseded by the requirements of §147.104 of this subchapter, which set forth Federal requirements for guaranteed availability of coverage in the group and individual markets.

18. Section 148.220 is amended by—

- a. Revising the introductory text and paragraph (b)(3);
- b. Redesignating paragraphs (b)(4) through (6) as paragraphs (b)(5) through (7), respectively; and
- c. Adding new paragraph (b)(4).

The revisions and additions read as follows:

§148.220 Excepted benefits.

The requirements of this part and part 147 of this subchapter do not apply to any individual coverage in relation to its provision of the benefits described in paragraphs (a) and (b) of this section (or any combination of the benefits).

* * * * *

(b) * * *

(3) Coverage only for a specified disease or illness (for example, cancer policies) if the policies meet the requirements of §146.145(b)(4)(ii)(B) and (C) of this subchapter regarding noncoordination of benefits.

(4) Hospital indemnity or other fixed indemnity insurance only if—

(i) The benefits are provided only to individuals who attest, in their fixed indemnity insurance application, that they have other health coverage that is minimum essential coverage

within the meaning of section 5000A(f) of the Internal Revenue Code, or that they are treated as having minimum essential coverage due to their status as a bona fide resident of any possession of the United States pursuant to Code section 5000A(f)(4)(B).

(ii) There is no coordination between the provision of benefits and an exclusion of benefits under any other health coverage.

(iii) The benefits are paid in a fixed dollar amount per period of hospitalization or illness and/or per service (for example, \$100/day or \$50/visit) regardless of the amount of expenses incurred and without regard to the amount of benefits provided with respect to the event or service under any other health coverage.

(iv) A notice is displayed prominently in the application materials in at least 14 point type that has the following language: “THIS IS A SUPPLEMENT TO HEALTH INSURANCE AND IS NOT A SUBSTITUTE FOR MAJOR MEDICAL COVERAGE. LACK OF MAJOR MEDICAL COVERAGE (OR OTHER MINIMUM ESSENTIAL COVERAGE) MAY RESULT IN AN ADDITIONAL PAYMENT WITH YOUR TAXES.”

(v) The requirement of paragraph (b)(4)(iv) of this section applies to all hospital or other fixed indemnity insurance policy years beginning on or after January 1, 2015, and the requirement of paragraph (b)(4)(i) of this section applies to hospital or other fixed indemnity insurance policies issued on or after January 1, 2015, and to hospital or other fixed indemnity policies issued before that date, upon their first renewal occurring on or after October 1, 2016.

* * * * *

PART 153 – STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

19. The authority citation for part 153 continues to read as follows:

Authority: Secs. 1311, 1321, 1341–1343, Pub. L. 111–148, 24 Stat. 119.

20. Section 153.500 is amended by revising the definition of “Adjustment percentage” to read as follows:

§ 153.500 Definitions.

* * * * *

Adjustment percentage means, with respect to a QHP:

(1) For benefit year 2014, for a QHP offered by a health insurance issuer with allowable costs of at least 80 percent of after-tax premium in a transitional State, the percentage specified by HHS for such QHPs in the transitional State; and otherwise zero percent.

(2) For benefit year 2015, for a QHP offered by a health insurance issuer in any State, two percent.

* * * * *

PART 154 – HEALTH INSURANCE ISSUER RATE INCREASES: DISCLOSURE AND REVIEW REQUIREMENTS

21. 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).

22. Section 154.102 is amended by revising the definition of “Product” to read as follows:

§154.102 Definitions.

* * * * *

Product means a package of health insurance coverage benefits with a discrete set of rating and pricing methodologies that a health insurance issuer offers in a State. The term product includes any product that is discontinued and newly filed within a 12-month period when

the changes to the product meet the standards of §147.106(e)(2) or (3) of this subchapter (relating to uniform modification of coverage).

* * * * *

PART 155 – EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

23. 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).

24. Section 155.120 is amended by revising paragraph (c) to read as follows:

§155.120 Non-interference with Federal law and non-discrimination standards.

* * * * *

(c) Non-discrimination. (1) In carrying out the requirements of this part, the State and the Exchange must:

- (i) Comply with applicable non-discrimination statutes; and
- (ii) Not discriminate based on race, color, national origin, disability, age, sex, gender identity or sexual orientation.

(2) Notwithstanding the provisions of paragraph (c)(1)(ii) of this section, an organization that receives Federal funds to provide services to a defined population under the terms of Federal legal authorities that participates in the certified application counselor program under §155.225 may limit its provision of certified application counselor services to the same defined population, but must comply with paragraph (c)(1)(ii) of this section with respect to the

provision of certified application counselor services to that defined population. If the organization limits its provision of certified application counselor services pursuant to this exception, but is approached for certified application counselor services by an individual who is not included in the defined population that the organization serves, the organization must refer the individual to other Exchange-approved resources that can provide assistance. If the organization does not limit its provision of certified application counselor services pursuant to this exception, the organization must comply with paragraph (c)(1)(ii) of this section.

25. Section 155.206 is added to read as follows:

§155.206 Civil money penalties for violations of applicable Exchange standards by consumer assistance entities in Federally-facilitated Exchanges.

(a) Enforcement actions. If an individual or entity specified in paragraph (b) of this section engages in activity specified in paragraph (c) of this section, the Department of Health and Human Services (HHS) may impose the following sanctions:

- (1) Civil money penalties (CMPs), subject to the provisions of this section.
- (2) Corrective action plans. In the notice of assessment of CMPs specified in paragraph (l) of this section, HHS may provide an individual or entity specified in paragraph (b) of this section the opportunity to enter into a corrective action plan to correct the violation instead of paying the CMP, based on evaluation of the factors set forth in paragraph (h) of this section. In the event that the individual or entity does not follow such a corrective action plan, HHS could require payment of the CMP.

(b) Consumer assistance entities. CMPs may be assessed under this section against the following consumer assistance entities:

(1) Individual Navigators and Navigator entities in a Federally-facilitated Exchange, including grantees, sub-grantees, and all personnel carrying out Navigator duties on behalf of a grantee or sub-grantee;

(2) Non-Navigator assistance personnel authorized under §155.205(d) and (e) and non-Navigator assistance personnel entities in a Federally-facilitated Exchange, including but not limited to individuals and entities under contract with HHS to facilitate consumer enrollment in QHPs in a Federally-facilitated Exchange; and

(3) Organizations that a Federally-facilitated Exchange has designated as certified application counselor organizations and individual certified application counselors carrying out certified application counselor duties in a Federally-facilitated Exchange.

(c) Grounds for assessing CMPs. HHS may assess CMPs against a consumer assistance entity if, based on the outcome of the investigative process outlined in paragraphs (d) through (i) of this section, HHS has reasonably determined that the consumer assistance entity has failed to comply with the Federal regulatory requirements applicable to the consumer assistance entity that have been implemented pursuant to section 1321(a)(1) of the Affordable Care Act, including provisions of any agreements, contracts, and grant terms and conditions between HHS and the consumer assistance entity that interpret those Federal regulatory requirements or establish procedures for compliance with them, unless a CMP has been assessed for the same conduct under 45 CFR 155.285.

(d) Basis for initiating an investigation of a potential violation. (1) Information. Any information received or learned by HHS that indicates that a consumer assistance entity may have engaged or may be engaging in activity specified in paragraph (c) of this section may

warrant an investigation. Information that might trigger an investigation includes, but is not limited to, the following:

- (i) Complaints from the general public;
- (ii) Reports from State regulatory agencies, and other Federal and State agencies; or
- (iii) Any other information that indicates that a consumer assistance entity may have engaged or may be engaging in activity specified in paragraph (c) of this section.

(2) Who may file a complaint. Any entity or individual, or the legally authorized representative of an entity or individual, may file a complaint with HHS alleging that a consumer assistance entity has engaged or is engaging in an activity specified in paragraph (c) of this section.

(e) Notice of investigation. When HHS performs an investigation under this section, it must provide a written notice to the consumer assistance entity of its investigation. This notice must include the following:

- (1) Description of the activity that is being investigated.
- (2) Explanation that the consumer assistance entity has 30 days from the date of the notice to respond with additional information or documentation, including information or documentation to refute an alleged violation.

(3) State that a CMP might be assessed if the allegations are not, as determined by HHS, refuted within 30 days from the date of the notice.

(f) Request for extension. In circumstances in which a consumer assistance entity cannot prepare a response to HHS within the 30 days provided in the notice of investigation described in paragraph (e) of this section, the entity may make a written request for an extension from HHS detailing the reason for the extension request and showing good cause. If HHS grants the

extension, the consumer assistance entity must respond to the notice within the time frame specified in HHS's letter granting the extension of time. Failure to respond within 30 days, or, if applicable, within an extended time frame, may result in HHS's imposition of a CMP depending upon the outcome of HHS's investigation of the alleged violation.

(g) Responses to allegations of noncompliance. In determining whether to impose a CMP, HHS may review and consider documents or information received or collected in accordance with paragraph (d)(1) of this section, as well as additional documents or information provided by the consumer assistance entity in response to receiving a notice of investigation in accordance with paragraph (e)(2) of this section. HHS may also conduct an independent investigation into the alleged violation, which may include site visits and interviews, if applicable, and may consider the results of this investigation in its determination.

(h) Factors in determining noncompliance and amount of CMPs, if any. In determining whether there has been noncompliance by the consumer assistance entity, and whether CMPs are appropriate:

(1) HHS must take into account the following:

(i) The consumer assistance entity's previous or ongoing record of compliance, including but not limited to compliance or noncompliance with any corrective action plan.

(ii) The gravity of the violation, which may be determined in part by—

(A) The frequency of the violation, taking into consideration whether any violation is an isolated occurrence, represents a pattern, or is widespread; and

(B) Whether the violation caused, or could reasonably be expected to cause, financial or other adverse impacts on consumer(s), and the magnitude of those impacts;

(2) HHS may take into account the following:

(i) The degree of culpability of the consumer assistance entity, including but not limited to—

(A) Whether the violation was beyond the direct control of the consumer assistance entity; and

(B) The extent to which the consumer assistance entity received compensation—legal or otherwise—for the services associated with the violation;

(ii) Aggravating or mitigating circumstances;

(iii) Whether other remedies or penalties have been assessed and/or imposed for the same conduct or occurrence; or

(iv) Other such factors as justice may require.

(i) Maximum per-day penalty. The maximum amount of penalty imposed for each violation is \$100 for each day for each consumer assistance entity for each individual directly affected by the consumer assistance entity's noncompliance; and where the number of individuals cannot be determined, HHS may reasonably estimate the number of individuals directly affected by the violation.

(j) Settlement authority. Nothing in §155.206 limits the authority of HHS to settle any issue or case described in the notice furnished in accordance with paragraph (e) of this section or to compromise on any penalty provided for in this section.

(k) Limitations on penalties. (1) Circumstances under which a CMP is not imposed. HHS will not impose any CMP on:

(i) Any violation for the period of time during which none of the consumer assistance entities knew, or exercising reasonable diligence would have known, of the violation; or

(ii) The period of time after any of the consumer assistance entities knew, or exercising reasonable diligence would have known, of the failure, if the violation was due to reasonable cause and not due to willful neglect and the violation was corrected within 30 days of the first day that any of the consumer assistance entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that the violation existed.

(2) Burden of establishing knowledge. The burden is on the consumer assistance entity or entities to establish to HHS's satisfaction that the consumer assistance entity did not know, or exercising reasonable diligence would have known, that the violation existed, as well as the period of time during which that limitation applies; or that the violation was due to reasonable cause and not due to willful neglect and was corrected pursuant to the elements in paragraph (k)(1)(ii) of this section.

(3) Time limit for commencing action. No action under this section will be entertained unless commenced, in accordance with §155.206(l), within six years from the date on which the violation occurred.

(l) Notice of assessment of CMP. If HHS proposes to assess a CMP in accordance with this section, HHS will send a written notice of this decision to the consumer assistance entity against whom the sanction is being imposed, which notice must include the following:

- (1) A description of the basis for the determination;
- (2) The basis for the CMP;
- (3) The amount of the CMP, if applicable;
- (4) The date the CMP, if applicable, is due;
- (5) Whether HHS would permit the consumer assistance entity to enter into a corrective action plan in place of paying the CMP, and the terms of any such corrective action plan;

(6) An explanation of the consumer assistance entity's right to a hearing under paragraph (m) of this section; and

(7) Information about the process for filing a request for a hearing.

(m) Appeal of proposed sanction. Any consumer assistance entity against which HHS has assessed a sanction may appeal that penalty in accordance with the procedures set forth at 45 CFR part 150, subpart D.

(n) Failure to request a hearing. (1) If the consumer assistance entity does not request a hearing within 30 days of the issuance of the notice of assessment of CMP described in paragraph (l) of this section, HHS may require payment of the proposed CMP.

(2) HHS will notify the consumer assistance entity in writing of any CMP that has been assessed and of the means by which the consumer assistance entity may pay the CMP.

(3) The consumer assistance entity has no right to appeal a CMP with respect to which it has not requested a hearing in accordance with paragraph (m) of this section unless the consumer assistance entity can show good cause in accordance with §150.405(b) of this subchapter for failing to timely exercise its right to a hearing.

26. Section 155.210 is amended—

- a. By revising paragraph (c)(1)(iii);
- b. In paragraph (d)(3) by removing “or,” after the semicolon;
- c. By revising paragraph (d)(4);
- d. By adding paragraphs (d)(5) through (9) and (e)(6) and (7); and
- e. By revising paragraph (e)(2).

The revision and additions read as follows:

§155.210 Navigator program standards.

* * * *

(c) * *

(1) * *

(iii) Meet any licensing, certification or other standards prescribed by the State or Exchange, if applicable, so long as such standards do not prevent the application of the provisions of title I of the Affordable Care Act. Standards that would prevent the application of the provisions of title I of the Affordable Care Act include but are not limited to the following:

(A) Except as otherwise provided under §155.705(d), requirements that Navigators refer consumers to other entities not required to provide fair, accurate, and impartial information.

(B) Except as otherwise provided under §155.705(d), requirements that would prevent Navigators from providing services to all persons to whom they are required to provide assistance.

(C) Requirements that would prevent Navigators from providing advice regarding substantive benefits or comparative benefits of different health plans.

(D) Requiring that a Navigator hold an agent or broker license or imposing any requirement that, in effect, would require all Navigators in the Exchange to be licensed agents or brokers.

(E) Imposing standards that would, as applied or as implemented in a State, prevent the application of Federal requirements applicable to Navigator entities or individuals or applicable to the Exchange's implementation of the Navigator program.

* * * *

(d) * *

(4) Receive any consideration directly or indirectly from any health insurance issuer or issuer of stop loss insurance in connection with the enrollment of any individuals or employees in a QHP or a non-QHP. Notwithstanding the requirements of this paragraph (d)(4), in a Federally-facilitated Exchange, no health care provider shall be ineligible to operate as a Navigator solely because it receives consideration from a health insurance issuer for health care services provided;

(5) Charge any applicant or enrollee, or request or receive any form of remuneration from or on behalf of an individual applicant or enrollee, for application or other assistance related to Navigator duties;

(6) Provide gifts, including gift cards or cash, unless they are of nominal value, or provide promotional items that market or promote the products or services of a third party, to any applicant or potential enrollee as an inducement for enrollment. Gifts, gift cards, or cash may exceed nominal value for the purpose of providing reimbursement for legitimate expenses incurred by a consumer in effort to receive Exchange application assistance, such as, but not limited to, travel or postage expenses;

(7) Use 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;

(8) Solicit any consumer for application or enrollment assistance by going door-to-door or through other unsolicited means of direct contact, including calling a consumer to provide application or enrollment assistance without the consumer initiating the contact, unless the individual has a pre-existing relationship with the individual Navigator or Navigator entity and other applicable State and Federal laws are otherwise complied with. Outreach and education

activities may be conducted by going door-to-door or through other unsolicited means of direct contact, including calling a consumer or

(9) Initiate any telephone call to a consumer using an automatic telephone dialing system or an artificial or prerecorded voice, except in cases where the individual Navigator or Navigator entity has a relationship with the consumer and so long as other applicable State and Federal laws are otherwise complied with.

(e) * * *

(2) Provide information and services in a fair, accurate, and impartial manner, which includes providing information that assists consumers with submitting the eligibility application; clarifying the distinctions among health coverage options, including QHPs; and helping consumers make informed decisions during the health coverage selection process. Such information must acknowledge other health programs;

* * * * *

(6) Ensure that applicants—

(i) Are informed of the functions and responsibilities of Navigators;

(ii) Provide authorization in a form and manner as determined by the Exchange prior to a Navigator's obtaining access to an applicant's personally identifiable information, and that the Navigator maintains a record of the authorization provided in a form and manner as determined by the Exchange. The Exchange must establish a reasonable retention period for maintaining these records. In Federally-facilitated Exchanges, this period is no less than six years, unless a different and longer retention period has already been provided under other applicable Federal law; and

(iii) May revoke at any time the authorization provided the Navigator pursuant to paragraph (e)(6)(ii) of this section.

(7) Maintain a physical presence in the Exchange service area, so that face-to-face assistance can be provided to applicants and enrollees. In a Federally-facilitated Exchange, no individual or entity shall be ineligible to operate as a Navigator solely because its principal place of business is outside of the Exchange service area.

* * * * *

27. Section 155.215 is amended by adding paragraphs (f) through (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.

* * * * *

(f) State or Exchange standards. All non-Navigator entities or individuals carrying out consumer assistance functions under §155.205(d) and (e) in an Exchange operated by HHS during the exercise of its authority under §155.105(f) and all non-Navigator assistance personnel funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act must meet any licensing, certification, or other standards prescribed by the State or Exchange, if applicable, so long as such standards do not prevent the application of the provisions of title I of the Affordable Care Act. Standards that would prevent the application of the provisions of title I of the Affordable Care Act include but are not limited to the following:

(1) Requirements that non-Navigator entities or individuals refer consumers to other entities not required to provide fair, accurate, and impartial information.

(2) Requirements that would prevent non-Navigator entities or individuals from providing services to all persons to whom they are required to provide assistance.

(3) Requirements that would prevent non-Navigator entities or individuals from providing advice regarding substantive benefits or comparative benefits of different health plans.

(4) Imposing standards that would, as applied or as implemented in a State, prevent the application of Federal requirements applicable to non-Navigator entities or individuals or applicable to the Exchange's implementation of the non-Navigator assistance personnel program.

(g) Consumer authorization. All non-Navigator entities or individuals carrying out consumer assistance functions under §155.205(d) and (e) in an Exchange operated by HHS during the exercise of its authority under §155.105(f) and all non-Navigator assistance personnel funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act must establish procedures to ensure that applicants—

(1) Are informed of the functions and responsibilities of non-Navigator assistance personnel;

(2) Provide authorization in a form and manner as determined by the Exchange prior to a non-Navigator assistance personnel's obtaining access to an applicant's personally identifiable information, and that the non-Navigator assistance personnel maintains a record of the authorization provided in a form and manner as determined by the Exchange. The Exchange must establish a reasonable retention period for maintaining these records. In Federally-facilitated Exchanges, this period is no less than six years, unless a different and longer retention period has already been provided under other applicable Federal law; and

(3) May revoke at any time the authorization provided the non-Navigator assistance personnel pursuant to paragraph (g)(2) of this section.

(h) All non-Navigator entities carrying out consumer assistance functions under §155.205(d) and (e) in an Exchange operated by HHS during the exercise of its authority under §155.105(f) and all non-Navigator assistance personnel funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act must maintain a physical presence in the Exchange service area, so that face-to-face assistance can be provided to applicants and enrollees. In a Federally-facilitated Exchange, no individual or entity shall be ineligible to operate as a non-Navigator entity or as non-Navigator assistance personnel solely because its principal place of business is outside of the Exchange service area.

(i) Prohibition on compensation per enrollment. Beginning November 15, 2014, Navigators and Non-Navigator assistance personnel carrying out consumer assistance functions under §§155.205(d) and (e) and 155.210, if operating in an Exchange operated by HHS during the exercise of its authority under §155.105(f), are prohibited from providing compensation to individual Navigators or non-Navigator assistance personnel on a per-application, per-individual-assisted, or per-enrollment basis.

28. Section 155.225 is amended—

- a. By adding paragraph (b)(3);
- b. By revising paragraph (c)(1);
- c. In paragraph (d)(5) by removing “and” after the semicolon;
- d. In paragraph (d)(6) by removing the period at the end of the paragraph and adding a semicolon in its place;
- e. By adding paragraphs (d)(7) and (8); and

f. By revising paragraphs (f)(1) and (2) and (g).

The revisions and additions read as follows:

§155.225 Certified application counselors.

* * * * *

(b) * * *

(3) In a Federally-facilitated Exchange, no individual or entity shall be ineligible to operate as a certified application counselor or organization designated by the Exchange under paragraph (b) of this section solely because its principal place of business is outside of the Exchange service area.

(c) * * *

(1) Provide information to individuals and employees about the full range of QHP options and insurance affordability programs for which they are eligible, which includes providing fair, impartial, and accurate information that assists consumers with submitting the eligibility application; clarifying the distinctions among health coverage options, including QHPs; and helping consumers make informed decisions during the health coverage selection process;

* * * * *

(d) * * *

(7) Is recertified on at least an annual basis after successfully completing recertification training as required by the Exchange; and

(8) Meets any licensing, certification, or other standards prescribed by the State or Exchange, if applicable, so long as such standards do not prevent the application of the

provisions of title I of the Affordable Care Act. Standards that would prevent the application of the provisions of title I of the Affordable Care Act include but are not limited to the following:

(i) Requirements that certified application counselors refer consumers to other entities not required to provide fair, accurate, and impartial information.

(ii) Requirements that would prevent certified application counselors from providing services to all persons to whom they are required to provide assistance.

(iii) Requirements that would prevent certified application counselors from providing advice regarding substantive benefits or comparative benefits of different health plans.

(iv) Imposing standards that would, as applied or as implemented in a State, prevent the application of Federal requirements applicable to certified application counselors, to an organization designated by the Exchange under paragraph (b) of this section, or to the Exchange's implementation of the certified application program.

* * * *

(f) * * *

(1) Are informed of the functions and responsibilities of certified application counselors;

(2) Provide authorization in a form and manner as determined by the Exchange prior to a certified application counselor obtaining access to an applicant's personally identifiable information, and that the organization or certified application counselor maintains a record of the authorization in a form and manner as determined by the Exchange. The Exchange must establish a reasonable retention period for maintaining these records. In Federally-facilitated Exchanges, this period is no less than six years, unless a different and longer retention period has already been provided under other applicable Federal law; and

* * * *

(g) Fees, consideration, solicitation, and marketing. Organizations designated by the Exchange under paragraph (b) of this section and certified application counselors must not—

(1) Impose any charge on applicants or enrollees for application or other assistance related to the Exchange;

(2) Receive any consideration directly or indirectly from any health insurance issuer or issuer of stop-loss insurance in connection with the enrollment of any individuals in a QHP or a non-QHP. In a Federally-facilitated Exchange, no health care provider shall be ineligible to operate as a certified application counselor or organization designated by the Exchange under paragraph (b) of this section solely because it receives consideration from a health insurance issuer for health care services provided;

(3) Beginning November 15, 2014, if operating in a Federally-facilitated Exchange, provide compensation to individual certified application counselors on a per-application, per-individual- assisted, or per-enrollment basis;

(4) Provide gifts, including gift cards or cash, unless they are of nominal value, or provide promotional items that market or promote the products or services of a third party, to any applicant or potential enrollee as an inducement for enrollment. Gifts, gift cards, or cash may exceed nominal value for the purpose of providing reimbursement for legitimate expenses incurred by a consumer in effort to receive Exchange application assistance, such as, but not limited to, travel or postage expenses.

(5) Solicit any consumer for application or enrollment assistance by going door-to-door or through other unsolicited means of direct contact, including calling a consumer to provide application or enrollment assistance without the consumer initiating the contact, unless the individual has a pre-existing relationship with the individual certified application counselor or

designated organization and other applicable State and Federal laws are otherwise complied with. Outreach and education activities may be conducted by going door-to-door or through other unsolicited means of direct contact, including calling a consumer; or

(6) Initiate any telephone call to a consumer using an automatic telephone dialing system or an artificial or prerecorded voice, except in cases where the individual certified application counselor or designated organization has a relationship with the consumer and so long as other applicable State and Federal laws are otherwise complied with.

29. Section 155.240 is amended by adding paragraph (e) to read as follows:

§155.240 Payment of premium.

* * * * *

(e) Premium calculation. The Exchange may establish one or more standard processes for premium calculation.

(1) For a Federally-facilitated Exchange, the premium for coverage lasting less than one month must equal the product of—

(i) The premium for one month of coverage divided by the number of days in the month; and

(ii) The number of days for which coverage is being provided in the month described in paragraph (e)(1)(i) of this section.

(2) [Reserved]

30. Section 156.260 is amended by revising paragraph (g) to read as follows:

§155.260 Privacy and security of personally identifiable information.

* * * * *

(g) Improper use and disclosure of information. Any person who knowingly and willfully uses or discloses information in violation of section 1411(g) of the Affordable Care Act will be subject to a CMP of not more than \$25,000 per person or entity, per use or disclosure, consistent with the bases and process for imposing civil penalties specified at §155.285, in addition to other penalties that may be prescribed by law.

31. Section 155.285 is added to subpart C to read as follows:

§155.285 Bases and process for imposing civil penalties for provision of false or fraudulent information to an Exchange or improper use or disclosure of information.

(a) Grounds for imposing civil money penalties. (1) HHS may impose civil money penalties on any person, as defined in paragraph (a)(2) of this section, if, based on credible evidence, HHS reasonably determines that a person has engaged in one or more of the following actions:

(i) Failure to provide correct information under section 1411(b) of the Affordable Care Act where such failure is attributable to negligence or disregard of any rules or regulations of the Secretary with negligence and disregard defined as they are in section 6662 of the Internal Revenue Code of 1986:

(A) “Negligence” includes any failure to make a reasonable attempt to provide accurate, complete, and comprehensive information; and

(B) “Disregard” includes any careless, reckless, or intentional disregard for any rules or regulations of the Secretary.

(ii) Knowing and willful provision of false or fraudulent information required under section 1411(b) of the Affordable Care Act, where knowing and willful means the intentional provision of information that the person knows to be false or fraudulent; or

(iii) Knowing and willful use or disclosure of information in violation of section 1411(g) of the Affordable Care Act, where knowing and willful means the intentional use or disclosure of information in violation of section 1411(g). Such violations would include, but not be limited to, the following:

(A) Any use or disclosure performed which violates relevant privacy and security standards established by the Exchange pursuant to §155.260;

(B) Any other use or disclosure which has not been determined by the Secretary to be in compliance with section 1411(g)(2)(A) of the Affordable Care Act pursuant to §155.260(a); and

(C) Any other use or disclosure which is not necessary to carry out a function described in a contract with a non-Exchange entity executed pursuant to §155.260(b)(2).

(2) For purposes of this section, the term “person” is defined to include, but is not limited to, all individuals; corporations; Exchanges; Medicaid and CHIP agencies; other entities gaining access to personally identifiable information submitted to an Exchange to carry out additional functions which the Secretary has determined ensure the efficient operation of the Exchange pursuant to §155.260(a)(1); and non-Exchange entities as defined in §155.260(b) which includes agents, brokers, Web-brokers, QHP issuers, Navigators, non-Navigator assistance personnel, certified application counselors, in-person assistors, and other third party contractors.

(b) Factors in determining the amount of civil money penalties imposed. In determining the amount of civil money penalties, HHS may take into account factors which include, but are not limited to, the following:

(1) The nature and circumstances of the conduct including, but not limited to:

(i) The number of violations;

(ii) The severity of the violations;

(iii) The person's history with the Exchange including any prior violations that would indicate whether the violation is an isolated occurrence or represents a pattern of behavior;

(iv) The length of time of the violation;

(v) The number of individuals affected or potentially affected;

(vi) The extent to which the person received compensation or other consideration associated with the violation;

(vii) Any documentation provided in any complaint or other information, as well as any additional information provided by the individual to refute performing the violation; and

(viii) Whether other remedies or penalties have been imposed for the same conduct or occurrence.

(2) The nature of the harm resulting from, or reasonably expected to result from, the violation, including but not limited to:

(i) Whether the violation resulted in actual or potential financial harm;

(ii) Whether there was actual or potential harm to an individual's reputation;

(iii) Whether the violation hindered or could have hindered an individual's ability to obtain health insurance coverage;

(v) The actual or potential impact of the provision of false or fraudulent information or of the improper use or disclosure of the information; and

(vi) Whether any person received a more favorable eligibility determination for enrollment in a QHP or insurance affordability program, such as greater advance payment of the premium tax credits or cost-sharing reductions than he or she would be eligible for if the correct information had been provided.

(3) No penalty will be imposed under paragraph (a)(1)(i) of this section if HHS determines that there was a reasonable cause for the failure to provide correct information required under section 1411(b) of the Affordable Care Act and that the person acted in good faith.

(c) Maximum penalty. The amount of a civil money penalty will be determined by HHS in accordance with paragraph (b) of this section.

(1) The following provisions provide maximum penalties for a single “plan year,” where “plan year” has the same meaning as at §155.20:

(i) Any person who fails to provide correct information as specified in paragraph (a)(1)(i) of this section may be subject to a maximum civil money penalty of \$25,000 for each application, as defined at paragraph (c)(1)(iii) of this section, pursuant to which a person fails to provide correct information.

(ii) Any person who knowingly and willfully provides false information as specified in paragraph (a)(1)(ii) of this section may be subject to a maximum civil money penalty of \$250,000 for each application, as defined at paragraph (c)(1)(iii) of this section, on which a person knowingly and willfully provides false information.

(iii) For the purposes of this subsection, “application” is defined as a submission of information, whether through an online portal, over the telephone through a call center, or through a paper submission process, in which the information is provided in relation to an eligibility determination; an eligibility redetermination based on a change in an individual’s circumstances; or an annual eligibility redetermination for any of the following:

(A) Enrollment in a qualified health plan;

(B) Premium tax credits or cost sharing reductions; or

(C) An exemption from the individual shared responsibility payment.

(2) Any person who knowingly or willfully uses or discloses information as specified in paragraph (a)(1)(iii) of this section may be subject to the following civil money penalty:

(i) A civil money penalty for each use or disclosure described in paragraph (a)(1)(iii) of this section of not more than \$25,000 per use or disclosure.

(ii) For purposes of paragraph (c) of this section, a use or disclosure includes one separate use or disclosure of a single individual's personally identifiable information where the person against whom a civil money penalty may be imposed has made the use or disclosure.

(3) These penalties may be imposed in addition to any other penalties that may be prescribed by law.

(d) Notice of intent to issue civil money penalty. If HHS intends to impose a civil money penalty in accordance with this part, HHS will send a written notice of such intent to the person against whom it intends to impose a civil money penalty.

(1) This written notice will be either hand delivered, sent by certified mail, return receipt requested, or sent by overnight delivery service with signature upon delivery required. The written notice must include the following elements:

(i) A description of the findings of fact regarding the violations with respect to which the civil money penalty is proposed;

(ii) The basis and reasons why the findings of fact subject the person to a penalty;

(iii) Any circumstances described in paragraph (b) of this section that were considered in determining the amount of the proposed penalty;

(iv) The amount of the proposed penalty;

(v) An explanation of the person's right to a hearing under any applicable administrative hearing process;

(vi) A statement that failure to request a hearing within 60 calendar days after the date of issuance printed on the notice permits the assessment of the proposed penalty; and

(vii) Information explaining how to file a request for a hearing and the address to which the hearing request must be sent.

(2) The person may request a hearing before an ALJ on the proposed penalty by filing a request in accordance with the procedure to file an appeal specified in paragraph (f) of this section.

(e) Failure to request a hearing. If the person does not request a hearing within 60 calendar days of the date of issuance printed on the notice described in paragraph (d) of this section, HHS may impose the proposed civil money penalty.

(1) HHS will notify the person in writing of any penalty that has been imposed, the means by which the person may satisfy the penalty, and the date on which the penalty is due.

(2) A person has no right to appeal a penalty with respect to which the person has not timely requested a hearing in accordance with paragraph (d) of this section.

(f) Appeal of proposed penalty. Subject to paragraph (e)(2) of this section, any person against whom HHS proposed to impose a civil money penalty may appeal that penalty in accordance with the rules and procedures outlined at 45 CFR part 150, subpart D, excluding §§150.461, 150.463, and 150.465.

(g) Enforcement authority. (1) HHS. HHS may impose civil money penalties up to the maximum amounts specified in paragraph (d) of this section for any of the violations described in paragraph (a) of this section.

(2) OIG. In accordance with the rules and procedures of 42 CFR part 1003, and in place of imposition of penalties by CMS, the OIG may impose civil money penalties for violations described in paragraph (a)(1)(ii) of this section.

(h) Settlement authority. Nothing in this section limits the authority of HHS to settle any issue or case described in the notice furnished in accordance with § 155.285(d) or to compromise on any penalty provided for in this section.

(i) Limitations. No action under this section will be entertained unless commenced, in accordance with § 155.285(d), within 6 years from the date on which the violation occurred.

32. Section 155.320 is amended by revising the section heading to read as follows and by removing paragraph (d)(4).

§155.320 Verification process related to eligibility for insurance affordability programs.

* * * * *

33. Section 155.330 is amended by revising paragraph (d)(2)(ii) to read as follows:

§155.330 Eligibility redetermination during a benefit year.

* * * * *

(d) * * *

(2) * * *

(ii) Comply with the standards specified in paragraph (e)(2) of this section.

* * * * *

34. Section 155.400 is amended by adding paragraphs (e) and (f) 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 the first month's premium to effectuate an enrollment.

(f) Processing enrollment transactions. The Exchange may provide requirements to QHP issuers regarding the instructions for processing electronic enrollment-related transactions.

35. Section 155.410 is amended by revising paragraph (d) to read as follows:

§155.410 Initial and annual open enrollment periods.

* * * * *

(d) Notice of annual open enrollment period. Starting in 2014, the Exchange must provide a written annual open enrollment notification to each enrollee no earlier than the first day of the month before the open enrollment period begins and no later than the first day of the open enrollment period.

* * * * *

36. Section 155.420 is amended by revising paragraphs (b)(2)(i) through (iii), (c), (d)(1), (d)(6)(iii), and (e) heading and introductory text to read as follows:

§155.420 Special enrollment periods.

* * * * *

(b) * * *

(2) * * *

(i) In the case of birth, adoption, placement for adoption, or placement in foster care as described in paragraph (d)(2) of this section, the Exchange must ensure that coverage is effective for a qualified individual or enrollee on the date of birth, adoption, placement for adoption, or placement in foster care, or it may permit the qualified individual or enrollee to elect a coverage

effective date of the first day of the month following the date of birth, adoption, placement for adoption, or placement in foster care. If the Exchange permits the qualified individual or enrollee to elect a coverage effective date of the first day of the month following the date of birth, adoption, placement for adoption, or placement in foster care, the Exchange must ensure coverage is effective on such date elected by the qualified individual or enrollee.

(ii) In the case of marriage as described in paragraph (d)(2) of this section the Exchange must ensure that coverage is effective for a qualified individual or enrollee on the first day of the month following plan selection.

(iii) In the case of a qualified individual or enrollee eligible for a special enrollment period as described in paragraphs (d)(4), (d)(5), (d)(9), or (d)(10) of this section, the Exchange must ensure that coverage is effective on an appropriate date based on the circumstances of the special enrollment period.

(iv) In a case where a consumer loses coverage as described in paragraph (d)(1) or (d)(6)(iii) of this section, if the plan selection is made before or on the day of the loss of coverage, the Exchange must ensure that the coverage effective date is on the first day of the month following the loss of coverage. If the plan selection is made after the loss of coverage, the Exchange must ensure that coverage is effective in accordance with paragraph (b)(1) of this section or on the first day of the month following plan selection in accordance with paragraph (b)(2) of this section, at the option of the Exchange;

* * * * *

(c) Availability and length of special enrollment periods. (1) General rule. Unless specifically stated otherwise herein, a qualified individual or enrollee has 60 days from the date of a triggering event to select a QHP.

(2) Advance availability. (i) A qualified individual or his or her dependent who is described in paragraph (d)(1) of this section has 60 days before and after the loss of coverage to select a QHP.

(ii) A qualified individual or his or her dependent who is described in paragraph (d)(6)(iii) of this section has 60 days before and after the loss of eligibility for qualifying coverage in an eligible employer-sponsored plan to select a QHP.

(3) Special rule. In the case of a qualified individual or enrollee who is eligible for a special enrollment period as described in paragraphs (d)(4), (d)(5), (d)(9), or (d)(10) of this section, the Exchange may define the length of the special enrollment period as appropriate based on the circumstances of the special enrollment period, but in no event shall the length of the special enrollment period exceed sixty (60) days.

(d) * * *

(1) The qualified individual or his or her dependent either:

(i) Loses minimum essential coverage. The date of the loss of coverage is the last day the consumer would have coverage under his or her previous plan or coverage.

(ii) Is enrolled in any non-calendar year health insurance policy that will expire in 2014 as described in §147.104(b)(2) of this subchapter, even if the qualified individual or his or her dependent has the option to renew the expiring non-calendar year individual health insurance policy. The date of the loss of coverage is the date in 2014 of the expiration of the non-calendar year policy;

(iii) Loses pregnancy-related coverage described under section 1902(a)(10)(A)(i)(IV) and (a)(10)(A)(ii)(IX) of the Social Security Act (42 U.S.C. 1396a(a)(10)(A)(i)(IV), (a)(10)(A)(ii)(IX)). The date of the loss of coverage is the last day the consumer would have pregnancy-related coverage; or

(iv) Loses medically needy coverage as described under section 1902(a)(10)(C) of the Social Security Act only once per calendar year. The date of the loss of coverage is the last day the consumer would have medically needy coverage.

* * * * *

(6) * * *

(iii) A qualified individual or his or her dependent who is enrolled in an eligible employer-sponsored plan is determined newly eligible for advance payments of the premium tax credit based in part on a finding that such individual is ineligible for qualifying coverage in an eligible-employer sponsored plan in accordance with 26 CFR 1.36B-2(c)(3), including as a result of his or her employer discontinuing or changing available coverage within the next 60 days, provided that such individual is allowed to terminate existing coverage.

* * * * *

(e) Loss of coverage. Loss of coverage described in paragraph (d)(1) of this section includes those circumstances described in 26 CFR 54.9801-6(a)(3)(i) through (iii) and in paragraphs (d)(1)(ii) through (iv) of this section. Loss of coverage does not include voluntary termination of coverage or other loss due to—

* * * * *

37. Section 155.430 is amended by revising paragraph (d)(6) and adding paragraph (e) to read as follows:

§155.430 Termination of coverage.

* * * *

(d) * *

(6) In the case of a termination in accordance with paragraph (b)(2)(v) 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 any retroactive enrollments effectuated under §155.420(b)(2)(iii). In cases of retroactive terminations dates, the Exchange will ensure that appropriate actions are taken to make necessary adjustments to advance payments of the premium tax credit, cost-sharing reductions, premiums, and claims.

* * * *

(e) Termination, cancellation, and reinstatement. The Exchange may establish operational instructions as to the form, manner, and method for addressing each of the following:

(1) Termination. A termination is an action taken after a coverage effective date that ends an enrollee's coverage through the Exchange for a date after the original coverage effective date, resulting in a period during which the individual was covered by the issuer.

(2) Cancellation. A cancellation is specific type of termination action that ends a qualified individuals' enrollment on the date coverage became effective resulting in coverage never having been effective with the QHP.

(3) Reinstatement. A reinstatement is a correction of an erroneous termination or cancellation action and results in restoration of an enrollment with no break in coverage.

§155.505 [Amended]

38. Section 155.505 is amended in paragraph (b)(4) by removing “; and” at the end of the paragraph and adding a period in its place.

39. Section 155.530 is amended by revising paragraph (a)(1) to read as follows:

§155.530 Dismissals.

(a) * * *

(1) Withdraws the appeal request in writing or by telephone, if the appeals entity is capable of accepting telephonic withdrawals.

(i) Accepting telephonic withdrawals means the appeals entity—

(A) Records in full the appellant's statement and telephonic signature made under penalty of perjury; and

(B) Provides a written confirmation to the appellant documenting the telephonic interaction.

(ii) [Reserved]

* * * * *

40. Section 155.555 is amended by—

- a. Redesignating paragraphs (d) introductory text, (d)(1), (d)(2) introductory text, (d)(2)(i), (ii), (iii), (d)(3), and (d)(4) as paragraphs (d)(1) introductory text, (d)(1)(i), (d)(1)(ii) introductory text, (d)(1)(ii)(A), (B), (C), (d)(1)(iii), and (d)(2), respectively; and
- b. Revising new paragraph (d)(2) introductory text.

The revision reads as follows:

§155.555 Employer appeals process.

* * * * *

(d) * * *

(2) Upon receipt of an invalid appeal request, the appeals entity must promptly and without undue delay send written notice to the employer that the appeal request is not valid

because it fails to meet the requirements of this section. The written notice must inform the employer—

* * * * *

41. Section 155.600(a) is amended by adding a definition of “Required contribution percentage” in alphabetical order to read as follows:

§155.600 Definitions and general requirements.

(a) * * *

Required contribution percentage means the product of eight 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.

* * * * *

42. Section 155.605 is amended by revising paragraph (g)(5) to read as follows:

§155.605 Eligibility standards for exemptions.

* * * * *

(g) * * *

(5) Self-only coverage in an eligible employer-sponsored plan. The IRS may allow an applicant to claim an exemption for a calendar year if he or she, as well as one or more employed members of his or her family, as defined in 26 CFR 1.36B–1(d), has been determined eligible for affordable self-only employer-sponsored coverage pursuant to section 5000A(e)(1) of the Code through their respective employers for one or more months during the calendar year, but the aggregate cost of employer-sponsored coverage for all the employed members of the family exceeds the required contribution percentage of household income for that calendar year; or

* * * * *

43. Section 155.625 is revised to read as follows:

§155.625 Options for conducting eligibility determinations for exemptions.

(a) Options for conducting eligibility determinations. The Exchange may satisfy the requirements of this subpart—

- (1) Directly or through contracting arrangements in accordance with §155.110(a); or
- (2) For an application submitted before the start of open enrollment for 2016, through the approach described in paragraph (b) of this section.

(b) Use of HHS service. Notwithstanding the requirements of this subpart, for an application submitted before the start of open enrollment for 2016, the Exchange may adopt an exemption eligibility determination made by HHS, provided that—

- (1) The Exchange adheres to the eligibility determination made by HHS;
- (2) The Exchange furnishes to HHS any information available through the Exchange that is necessary for an applicant to utilize the process administered by HHS; and
- (3) The Exchange call center and Internet website specified in §155.205(a) and (b), respectively, provide information to consumers regarding the exemption eligibility process.

44. Section 155.705 is amended by—

- a. Revising paragraphs (b)(2) and (b)(3)(ii) introductory text and (b)(3)(iv) introductory text; and
- b. Adding paragraphs (b)(3)(vi) and (vii).

The revisions and addition read as follows:

§155.705 Functions of a SHOP.

* * * * *

(b) * * *

(2) Employer choice requirements. With regard to QHPs offered through the SHOP for plan years beginning on or after January 1, 2015, the SHOP must allow a qualified employer to select a level of coverage as described in section 1302(d)(1) of the Affordable Care Act, in which all QHPs within that level are made available to the qualified employees of the employer, unless the SHOP makes an election pursuant to paragraph (b)(3)(vi) of this section.

(3) * * *

(ii) Unless the SHOP makes an election pursuant to paragraph (b)(3)(vi) of this section, for plan years beginning on or after January 1, 2015, a SHOP:

* * * * *

(iv) Unless the Secretary makes an election pursuant to paragraph (b)(3)(vi) of this section, for plan years beginning on or after January 1, 2015, a Federally-facilitated SHOP will provide a qualified employer a choice of two methods to make QHPs available to qualified employees:

* * * * *

(vi) For plan years beginning in 2015 only, the SHOP may, elect to provide employers only with the option set forth at paragraph (b)(3)(ii)(B) of this section, or in the case of a Federally-facilitated SHOP, only with the option set forth at paragraph (b)(3)(iv)(B) of this section, only if the State Insurance Commissioner submits a written recommendation to the SHOP adequately explaining that it is the State Insurance Commissioner's expert judgment, based on a documented assessment of the full landscape of the small group market in his or her State, that not implementing employee choice would be in the best interests of small employers and their employees and dependents, given the likelihood that implementing employee choice would cause issuers to price products and plans higher in 2015 due to the issuers' beliefs about

adverse selection. A State Insurance Commissioner's recommendation must be based on concrete evidence, including but not limited to discussions with those issuers expected to participate in the SHOP in 2015.

(vii) For plan years beginning in 2015 only, a State Insurance Commissioner should submit the recommendation specified in paragraph (b)(3)(vi) of this section, and the SHOP should make a decision based on that recommendation sufficiently in advance of the end of the QHP certification application window such that issuers can make informed decisions about whether to participate in the SHOP. In a Federally-facilitated-SHOP, State Insurance Commissioners must submit to HHS the recommendation specified in paragraph (b)(3)(vi) of this section on or before June 2, 2014, and HHS will make a decision based on any recommendations submitted by that deadline before the close of the QHP certification application window.

* * * * *

45. Section 155.725 is amended by revising paragraphs (c) and (e) to read as follows:

§155.725 Enrollment periods under SHOP.

* * * * *

(c) Annual employer election period. (1) Notwithstanding any other paragraph in this section, for coverage beginning in 2015, in a Federally-facilitated SHOP a qualified employer's annual election period may begin no sooner than November 15, 2014.

(2) 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—

(i) The method by which the qualified employer makes QHPs available to qualified employees pursuant to §155.705(b)(2) and (3);

(ii) The employer contribution towards the premium cost of coverage;

(iii) The level of coverage offered to qualified employees as described in §155.705(b)(2) and (3); and

(iv) The QHP or QHPs offered to qualified employees in accordance with §155.705.

* * * *

(e) Annual employee open enrollment period. 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.

* * * *

46. Section 155.740 is amended by—

a. Redesignating paragraphs (g) introductory text, (g)(1) introductory text, (g)(1)(i), (g)(1)(ii), (g)(2), and (g)(3) as paragraphs (g)(1) introductory text, (g)(1)(i) introductory text, (g)(1)(i)(A), (g)(1)(i)(B), (g)(1)(ii), and (g)(2), respectively; and

b. Revising paragraph (i)(1)(i).

The revision read as follows:

§155.740 SHOP employer and employee eligibility appeals requirements.

* * * *

(i) * * *

(1) * * *

(i) Withdraws the request in accordance with the standards set forth in §155.530(a)(1); or

* * * *

47. Subpart O is added to read as follows:

Subpart O—Quality Reporting Standards for Exchanges

Sec.

155.1400 Quality rating system.

155.1405 Enrollee satisfaction survey system.

Subpart O—Quality Reporting Standards for Exchanges

§155.1400 Quality rating system.

The Exchange must prominently display the quality rating information assigned to each QHP on its website, in accordance with §155.205(b)(1)(v), as calculated by HHS and in a form and manner specified by HHS.

§155.1405 Enrollee satisfaction survey system.

The Exchange must prominently display results from the Enrollee Satisfaction Survey for each QHP on its website, in accordance with §155.205(b)(1)(iv), as calculated by HHS and in a form and manner specified by HHS.

**PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE
AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES**

48. The authority citation for part 156 is revised 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).

49. Section 156.122 is amended by revising paragraph (c) to read as follows:

§156.122 Prescription drug benefits.

* * * * *

(c) A health plan providing essential health benefits must have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the health plan.

(1) Such procedures must include a process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request an expedited review based on exigent circumstances.

(i) Exigent circumstances exist when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug.

(ii) A health plan must make its coverage determination on an expedited review request based on exigent circumstances and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 24 hours after it receives the request.

(iii) A health plan that grants an exception based on exigent circumstances must provide coverage of the non-formulary drug for the duration of the exigency.

(2) [Reserved]

50. Section 156.130 is amended by removing and reserving paragraph (b) and revising paragraphs (c) and (d) to read as follows:

§156.130 Cost-sharing requirements.

* * * * *

(c) Special rule for network plans. In the case of a plan using a network of providers, cost-sharing paid by, or on behalf of, an enrollee for benefits provided outside of such network

shall not count toward the annual limitation on cost-sharing (as defined in paragraph (a) of this section).

(d) Increase annual dollar limits in multiples of 50. For a plan year beginning in a calendar year after 2014, any increase in the annual dollar limits described in paragraph (a) of this section that does not result in a multiple of 50 dollars will be rounded down, to the next lowest multiple of 50 dollars.

* * * * *

51. Section 156.200 is amended by revising paragraph (b)(5) and adding paragraph (h) to read as follows:

§156.200 QHP issuer participation standards.

* * * * *

(b) * * *

(5) Implement and report on a quality improvement strategy or strategies described in section 1311(c)(1)(E) of the Affordable Care Act consistent with the standards of section 1311(g) of the Affordable Care Act, disclose and report information on health care quality and outcomes described in sections 1311(c)(1)(H), (c)(1)(I), and (c)(3) of the Affordable Care Act, and implement appropriate enrollee satisfaction surveys consistent with section 1311(c)(4) of the Affordable Care Act;

* * * * *

(h) Operational requirements. As a condition of certification of a QHP, an issuer must attest that it will comply with all QHP operational requirements described in subparts D, E, H, K, L, and M of this part.

52. Section 156.265 is amended by revising paragraph (d) to read as follows:

§156.265 Enrollment process for qualified individuals.

* * * *

(d) Premium payment. A QHP issuer must follow the premium payment process established by the Exchange in accordance with §155.240 of the subchapter.

* * * *

53. Section 156.270 is amended by adding a new paragraph (j) to read as follows:

§156.270 Termination of coverage for qualified individuals.

* * * *

(j) Operational instructions. QHP issuers must follow the transaction rules established by the Exchange in accordance with §155.430(e) of this subchapter.

54. Section 156.604 is amended by revising paragraphs (a)(2) heading and introductory text and (d) to read as follows:

§156.604 Requirements for recognition as minimum essential coverage for types of coverage not otherwise designated minimum essential coverage in the statute or this subpart.

(a) * * *

(2) Procedural requirements for recognition as minimum essential coverage. To be considered for recognition as minimum essential coverage, the sponsor of the coverage, government agency, health insurance issuer, or plan administrator must submit the following information to HHS:

* * * *

(d) Notice. Once recognized as minimum essential coverage, the sponsor of the coverage, government agency, health insurance issuer, or plan administrator must provide notice

to all enrollees of its minimum essential coverage status and must comply with the information reporting requirements of section 6055 of the Internal Revenue Code and implementing regulations.

55. Section 156.800 is amended by adding paragraph (d) to read as follows:

§156.800 Available remedies; Scope.

* * * * *

(d) Information sharing. HHS may consult and share information about QHP issuers with other Federal and State regulatory and enforcement entities to the extent that the consultation and information is necessary for purposes of State or Federal oversight and enforcement activities.

56. Section 156.805 is amended—

a. By adding paragraph (d)(3); and

b. By revising paragraph (e)(2).

The revisions and additions read as follows:

§156.805 Bases and process for imposing civil money penalties in Federally-facilitated Exchanges.

* * * * *

(d) * * *

(3) HHS will deliver notice under this paragraph by either hand delivery, certified mail, return receipt requested, or by overnight delivery service with signature upon delivery required.

(e) * * *

(2) HHS will notify the issuer in writing of any penalty that has been assessed under this subpart and of the means by which the QHP issuer or another responsible entity may satisfy the CMP assessment.

* * * *

57. Section 156.806 is added to read as follows:

§156.806 Notice of non-compliance.

If HHS learns of a potential violation described in §156.805 or if a State informs HHS of a potential violation, prior to imposing any CMPs, HHS must provide a written notice to the issuer, to include the following:

- (a) Describe the potential violation.
- (b) Provide 30 days from the date of the notice for the QHP issuer to respond and to provide additional information to refute an alleged violation.
- (c) State that a civil money penalty may be assessed if the allegations are not, as determined by HHS, refuted.

58. Section 156.810 is amended—

- a. By revising paragraph (a)(6);
- b. In paragraph (a)(9) by removing “or” after the semicolon;
- c. In paragraphs (a)(10) and (11) by removing the period and adding a semicolon in its place;
- d. By adding new paragraphs (a)(12) and (13); and
- e. By revising paragraph (d) introductory text.

The revisions and additions read as follows:

§156.810 Bases and process for decertification of a QHP offered by an issuer through a Federally-facilitated Exchange.

(a) * * *

(6) The QHP no longer meets the applicable standards set forth under subpart C of this part.

* * * * *

(12) The QHP issuer substantially fails to meet the requirements related to the cases forwarded to QHP issuers under subpart K of this part; or

(13) The QHP issuer substantially fails to meet the requirements related to the offering of a QHP under subpart M of this part.

* * * * *

(d) Expedited decertification process. For decertification actions on grounds described in paragraphs (a)(6), (7), (8), or (9) of this section, HHS will provide written notice to the QHP issuer, enrollees, and the State department of insurance in the State in which the QHP is being decertified. The written notice must include the following:

* * * * *

59. Section 156.1105 is amended by adding paragraphs (d) and (e) to read as follows:

§156.1105 Establishment of standards for HHS-approved enrollee satisfaction survey vendors for use by QHP issuers in Exchanges.

* * * * *

(d) Monitoring. HHS will periodically monitor HHS-approved enrollee satisfaction survey vendors to ensure ongoing compliance with the standards in paragraph (b) of this section. If HHS determines that an HHS-approved enrollee satisfaction survey vendor is non-compliant with the standards required in paragraph (b) of this section, the survey vendor may be removed from the approved list described in paragraph (c) of this section and/or the submitted survey results may be ineligible to be included for ESS results.

(e) Appeals. An enrollee satisfaction survey vendor that is not approved by HHS after submitting the application described in paragraph (a) of this section may appeal HHS's decision by notifying HHS in writing within 15 days from receipt of the notification of not being approved and submitting additional documentation demonstrating how the vendor meets the standards in paragraph (b) of this section. HHS will review the submitted documentation and make a final approval determination within 30 days from receipt of the additional documentation.

60. Section 156.1120 is added to subpart L to read as follows:

§156.1120 Quality rating system.

(a) Data submission requirement. (1) A QHP issuer must submit data to HHS and Exchanges to support the calculation of quality ratings for each QHP that has been offered in an Exchange for at least one year.

(2) In order to ensure the integrity of the data required to calculate the QRS, a QHP issuer must submit data that has been validated in a form and manner specified by HHS.

(3) A QHP issuer must include in its data submission information only for those QHP enrollees at the level specified by HHS.

(b) Timeline. A QHP issuer must annually submit data necessary to calculate the QHP's quality ratings to HHS and Exchanges, on a timeline and in a standardized form and manner specified by HHS.

(c) Marketing requirement. A QHP issuer may reference the quality ratings for its QHPs in its marketing materials, in a manner specified by HHS.

(d) Multi-State plans. Issuers of multi-State plans, as defined in §155.1000(a) of this subchapter, must provide the data described in paragraph (a) of this section to the U.S. Office of

Personnel management, in the time and manner specified by the U.S. Office of Personnel Management.

61. Section 156.1125 is added to subpart L to read as follows:

§156.1125 Enrollee satisfaction survey system.

(a) General requirement. A QHP issuer must contract with an HHS-approved enrollee satisfaction survey (ESS) vendor, as identified by §156.1105, in order to administer the Enrollee Satisfaction Survey of the QHP's enrollees. A QHP issuer must authorize its contracted ESS vendor to report survey results to HHS and the Exchange on the issuer's behalf.

(b) Data requirement. (1) A QHP issuer must collect data for each QHP, with more than 500 enrollees in the previous year that has been offered in an Exchange for at least one year and following a survey sampling methodology provided by HHS.

(2) In order to ensure the integrity of the data required to conduct the survey, a QHP issuer must submit data that has been validated in a form and manner specified by HHS, and submit this data to its contracted ESS vendor.

(3) A QHP issuer must include in its data submission information only for those QHP enrollees at the level specified by HHS.

(c) Marketing requirement. A QHP issuer may reference the survey results for its QHPs in its marketing materials, in a manner specified by HHS.

(d) Timeline. A QHP issuer must annually submit data necessary to conduct the survey to its contracted ESS vendor on a timeline and in a standardized form and manner specified by HHS.

(e) Multi-State plans. Issuers of multi-State plans, as defined in §155.1000(a) of this subchapter, must provide the data described in paragraph (b) of this section to the U.S. Office of

Personnel management, in the time and manner specified by the U.S. Office of Personnel Management.

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

62. The authority citation for part 158 is revised to read as follows:

Authority: Section 2718 of the Public Health Service Act (42 U.S.C. 300gg-18), as amended.

63. Section 158.150 is amended by revising paragraph (b)(2)(i)(A)(6) to read as follows:

§158.150 Activities that improve health care quality.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(A) * * *

(6) Commencing with the 2012 reporting year and extending through the first reporting year in which the Secretary requires ICD-10 as the standard medical data code set, implementing ICD-10 code sets that are designed to improve quality and are adopted pursuant to the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. 1320d-2, as amended, limited to 0.3 percent of an issuer's earned premium as defined in §158.130.

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64. Section 158.211 is amended by revising paragraph (a) to read as follows:

§158.211 Requirement in States with a higher medical loss ratio.

(a) State option to set higher minimum loss ratio. For coverage offered in a State whose law provides that issuers in the State must meet a higher MLR than that set forth in §158.210, the State's higher percentage must be substituted for the percentage stated in §158.210. If a State requires the small group market and individual market to be merged and also sets a higher MLR standard for the merged market, the State's higher percentage must be substituted for the percentage stated in §158.210 for both the small group and individual markets.

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65. Section 158.220 is amended by revising paragraph (a) to read as follows:

§158.220 Aggregation of data in calculating an issuer's medical loss ratio.

(a) Aggregation by State and by market. In general, an issuer's MLR must be calculated separately for the large group market, small group market and individual market within each State. However, if a State requires the small group market and individual market to be merged, then the data reported separately under subpart A of this part for the small group and individual market in that State must be merged for purposes of calculating an issuer's MLR and any rebates owing.

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66. Section 158.221 is amended by adding paragraphs (b)(6) and (7) to read as follows:

§158.221 Formula for calculating an issuer's medical loss ratio.

* * * * *

(b) * * *

(6) The numerator of the MLR in the individual and small group markets in States that adopted the transitional policy outlined in the CMS letter dated November 14, 2013 must be the amount specified in paragraph (b) of this section, except that issuers that provided transitional

coverage may multiply the total incurred claims and expenditures for activities that improve health care quality incurred in 2014 in the respective State and market by a factor of 1.0001.

(7) The numerator of the MLR in the individual and small group markets for issuers participating in the State and Federal Exchanges (sometimes referred to as “Marketplaces”) must be the amount specified in paragraph (b) of this section, except that the total incurred claims and expenditures for activities that improve health care quality incurred in 2014 in the respective State and market may be multiplied by a factor of 1.0004.

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67. Section 158.231 is amended by revising paragraph (a) to read as follows:

§158.231 Life-years used to determine credible experience.

(a) The life-years used to determine the credibility of an issuer's experience are the life-years for the MLR reporting year plus the life-years for the two prior MLR reporting years. If a State requires the small group market and individual market to be merged, then life-years used to determine credibility must be the life-years from the small group market and the individual market for the MLR reporting year plus the life-years from the small group market and the individual market for the two prior MLR reporting years.

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Dated: May 12, 2014.

Marilyn Tavenner,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: May 14, 2014.

Kathleen Sebelius,

Secretary,

Department of Health and Human Services.

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