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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 144, 147, 153, 155, and 156

[CMS-9957-P]

RIN 0938-AR82

Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, Premium Stabilization Programs, and Market Standards

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule sets forth financial integrity and oversight standards with respect to Affordable Insurance Exchanges; Qualified Health Plan (QHP) issuers in Federally-facilitated Exchanges (FfEs); and States with regard to the operation of risk adjustment and reinsurance programs. It also proposes additional standards with respect to agents and brokers. These standards, which include financial integrity provisions and protections against fraud and abuse, are consistent with Title I of the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010, referred to collectively as the Affordable Care Act.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [OFR--insert date 30 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-9957-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to **<http://www.regulations.gov>**. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-9957-P,

P.O. Box 8010,

Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-9957-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members. Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Leigha Basini at (301) 492-4307, or Noah Isserman at (301) 492-4401 for general information.

Ariel Novick at (301) 492-4309, for matters related to cost-sharing reductions and advance payments of the premium tax credit.

Adam Shaw at (410) 786-1091, for matters related to the risk adjustment, reinsurance and risk corridors programs.

Shelley Bain at (301) 492-4453, or Anne Pesto at (410) 786-3492, for matters related to Part 155, Subpart M.

Cindy Yen at (301) 492-5142, for matters related to Part 155, Subparts C and E, and Part 156.

Scott Dafflitto at (301) 492-4198, for matters relating to SHOP.

Jacob Ackerman at (301) 492-4179, for matters related to Parts 144 and Part 147 and the single risk pool.

Rebecca Zimmermann at (301) 492-4396, for matters related to quality standards, Part 156, Subpart L.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard,

Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

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Acronyms and Short Forms

Because of the many organizations and terms to which we refer by acronym in this proposed rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

Affordable Care Act The Affordable Care Act of 2010 (which is the collective term for the Patient Protection and Affordable Care Act (Pub. L. 111-148) and the Health Care and Education Reconciliation Act (Pub. L. 111-152))

ALJ Administrative Law Judge

APTC Advance payments of the premium tax credit

ARF Allowable rating factor

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

DOI State Department of Insurance

DOL U.S. Department of Labor

FEHB	Federal Employees Health Benefits
FFE	Federally-facilitated Exchange
FFE API	Federally-facilitated Exchange application programming interface
FF-SHOP	Federally-facilitated Small Business Health Options Program
GAAP	Generally-accepted accounting principles
GAAS	Generally accepted auditing standards
GAGAS	Generally accepted governmental auditing standards
GAO	United States Government Accountability Office
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191)
IRS	Internal Revenue Service
MLR	Medical Loss Ratio
NAIC	National Association of Insurance Commissioners
NCQA	National Committee for Quality Assurance
OIG	Office of the Inspector General of the U.S. Department of Health and Human Services
OMB	Office of Management and Budget
PHS Act	Public Health Service Act
PII	Personally Identifiable Information
PRA	Paperwork Reduction Act
QHP	Qualified Health Plan
SHOP	Small Business Health Options Program

The Code Internal Revenue Code of 1986

TIN Taxpayer Identification Number

Executive Summary:

Starting on January 1, 2014, qualified individuals and qualified employers will be able to be covered by private health insurance through competitive marketplaces called Affordable Insurance Exchanges, or “Exchanges” (also called Health Insurance Marketplaces). This proposed rule sets forth oversight and financial integrity standards with respect to Exchanges, QHP issuers in Federally-facilitated Exchanges (FFE), and States with regard to the operation of risk adjustment and reinsurance programs. It also proposes additional standards for special enrollment periods, survey vendors that may conduct enrollee satisfaction surveys on behalf of QHP issuers in Exchanges, issuer participation in an FFE, and States’ operation of a SHOP. Finally, it proposes additional standards for agents and brokers, geographic rating areas, and guaranteed availability and renewability. Nothing in these proposed regulations would limit the authority of the Office of the Inspector General of the U.S. Department of Health and Human Services (OIG) as prescribed by the Inspector General Act of 1978 or any other law.

Although many of the proposed provisions in this proposed rule would become effective by 2014, we do not believe that affected parties will have difficulty complying with the provisions by their effective dates, because most of the proposed standards are based on existing standards currently in effect in the private market, were previously proposed through the Blueprint process, discussed in agency-issued sub-regulatory guidance, or were discussed in the

preambles to the Exchange Establishment Rule,¹ Premium Stabilization Rule,² and the HHS Notice of Benefit and Payment Parameters for 2014.³ In addition to general comments on the substance of the proposed provisions, we seek input on ways to implement these proposed policies to minimize burden.

Table of Contents

I. Background

- A. Legislative Overview
- B. Stakeholder Consultation and Input
- C. Structure of the Proposed Rule

II. Provisions of the Proposed Rule

- A. Part 144 – Requirements Related to Health Insurance Coverage
- B. Part 147 – Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets
- C. Part 153 – Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment under the Affordable Care Act
 - 1. Subpart A - General Provisions
 - 2. Subpart C - State Standards Related to the Reinsurance Program
 - 3. Subpart D - State Standards Related to the Risk Adjustment Program

¹ Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers, 77 FR 18310 (March 27, 2012).

² Patient Protection and Affordable Care Act; Standards Related to Reinsurance, Risk Corridors and Risk Adjustment, 77 FR 17220 (March 23, 2012).

³ Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2014 and Amendments to the HHS Notice of Benefit and Payment Parameters for 2014, 78 FR 15410 and 15541 (Mar. 11, 2013).

4. Risk Adjustment Methodology
5. Subpart E - Health Insurance Issuer and Group Health Plan Standards Related to the Reinsurance Program
6. Subpart F – Health Insurance Issuer Standards Related to the Risk Corridors Program
7. Subpart G – Health Insurance Issuer Standards Related to the Risk Adjustment Program
8. Subpart H - Distributed Data Collection for HHS-Operated Programs
- D. Part 155 – Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act
 1. Subpart A – General Provisions
 2. Subpart B – General Standards Related to the Establishment of an Exchange
 3. Subpart C – General Functions of an Exchange
 4. Subpart D – Exchange Functions in the Individual Market: Eligibility Determinations for Exchange Participation and Insurance Affordability Programs
 5. Subpart E – Exchange Functions in the Individual Market: Enrollment in Qualified Health Plans
 6. Subpart H – Exchange Functions: Small Business Health Options Program (SHOP)
 7. Subpart M – Oversight and Program Integrity Standards for State Exchanges
- E. Part 156 – Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges
 1. Subpart A – General Provisions
 2. Subpart C – Qualified Health Plan Minimum Certification Standards
 3. Subpart D – Federally-facilitated Exchange Qualified Health Plan Issuer Standards

4. Subpart E - Health Insurance Issuer Responsibilities with Respect to Advance Payments of the Premium Tax Credit and Cost-sharing Reductions
5. Subpart H – Oversight and Financial Integrity Standards for Issuers of Qualified Health Plans in Federally-facilitated Exchanges
6. Subpart I – Enforcement Remedies in Federally-facilitated Exchanges
7. Subpart J – Administrative Review of QHP Issuer Sanctions in Federally-facilitated Exchanges
8. Subpart K – Cases Forwarded to Qualified Health Plans and Qualified Health Plan Issuers in Federally-facilitated Exchanges by HHS
9. Subpart L – Quality Standards
10. Subpart M – Qualified Health Plan Issuer Responsibilities

III. Collection of Information Requirements

IV. Response to Comments

V. Regulatory Impact Analysis

I. 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 proposed rule, we refer to the two statutes collectively as the “Affordable Care Act.” Subtitles A and C of Title I of the Affordable Care Act reorganized, amended, and added to the provisions of part A of Title XXVII of the Public Health Service Act (PHS Act) relating to health insurance issuers in the group and individual markets and to group

health plans that are non-Federal governmental plans. As relevant here, these PHS Act provisions include section 2701 (fair health insurance premiums), section 2702 (guaranteed availability of coverage), and section 2703 (guaranteed renewability of coverage).

Starting on October 1, 2013 for coverage starting as soon as January 1, 2014, qualified individuals and qualified employers will be able to purchase QHPs – private health insurance that has been certified as meeting certain standards – through competitive marketplaces called Exchanges or Health Insurance Marketplaces. The Departments of Health and Human Services, Labor, and the Treasury have been working in close coordination to release guidance related to QHPs and Exchanges in several phases. The word “Exchanges” refers to both State Exchanges, also called State-based Exchanges, and Federally-facilitated Exchanges (FFE). In this proposed rule, we use the terms “State Exchange” or “FFE” when we are referring to a particular type of Exchange. When we refer to “FFEs,” we are also referring to State Partnership Exchanges, which are a form of FFEs.

In this proposed rule, we encourage State flexibility within the boundaries of the law. Sections 1311(b) and 1321(b) of the Affordable Care Act provide that each State has the opportunity to establish an Exchange. Section 1311(b)(1) gives each State the opportunity to establish an Exchange that both facilitates the purchase of QHPs and provides for the establishment of a Small Business Health Options Program (SHOP) that will help qualified employers enroll their employees in QHPs. Section 1311(b)(2) contemplates the separate operation of the individual market Exchange and the SHOP under different governance and administrative structures, because it permits the individual market Exchange and SHOP to be merged only if States have adequate resources to assist both populations (individual and small employers) as a merged entity.

Section 1311(c)(4) of the Affordable Care Act directs the Secretary to establish an enrollee satisfaction survey system that would evaluate the level of enrollee satisfaction of members in each QHP offered through an Exchange with more than 500 enrollees in the previous year.

Section 1321(a) of the Affordable Care Act provides general 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(c)(1) requires the Secretary of Health and Human Services (referred to throughout this rule as the Secretary) to establish and operate an FFE within States that either: do not elect to establish an Exchange; or, as determined by the Secretary, will not have any required Exchange operational by January 1, 2014.

Section 1321(c)(2) of the Affordable Care Act authorizes the Secretary to enforce the Exchange standards using civil money penalties (CMPs) on the same basis as detailed in section 2723(b) of the PHS Act.⁴ 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 Title XXVII, Part A of the PHS Act when a State fails to substantially enforce these provisions.

Section 1311(d)(5)(A) of the Affordable Care Act provides that States, when establishing Exchanges, must ensure that such Exchanges are self-sustaining beginning in 2015, including allowing Exchanges to charge assessments or user fees to participating issuers to generate funding to support their operations. Section 1311(d)(5)(B) contains a prohibition on the wasteful

⁴ 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.

use of funds. When operating an FFE under section 1321(c)(1) of the Affordable Care Act, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) to collect and spend such user fees. In addition, 31 U.S.C. 9701 permits a Federal agency to establish a charge for a service provided by the agency. Office of Management and Budget (OMB) Circular A-25 Revised establishes Federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public.

Section 1311(e)(1)(B) of the Affordable Care Act specifies that an Exchange may certify a health plan as a QHP if the Exchange determines that making available such a health plan through the Exchange is in the interests of qualified individuals and qualified employers in the State or States in which the Exchange operates.

Section 1312(c) of the Affordable Care Act directs a health insurance issuer to consider all enrollees in all health plans (other than grandfathered health plans) offered by such issuer to be members of a single risk pool for each of its individual and small group markets. Section 1312(c) of the Affordable Care Act gives States the option to merge the individual and small group markets within the State into a single risk pool.

Section 1312(e) of the Affordable Care Act directs the Secretary to establish procedures under which a State may permit agents and brokers to enroll qualified individuals and qualified employers in QHPs through an Exchange, and to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions.

Section 1313 of the Affordable Care Act, combined with section 1321 of the Affordable Care Act, provides the Secretary with the authority to oversee the financial integrity, compliance with HHS standards, and efficient and non-discriminatory administration of State Exchange

activities. Section 1313(a)(6)(A) of the Affordable Care Act specifies that payments made by, through, or in connection with an Exchange are subject to the False Claims Act (31 U.S.C. 3729, et seq.) if those payments include any Federal funds.

Section 1341 of the Affordable Care Act establishes a transitional reinsurance program which begins in 2014 and is designed to provide issuers with greater payment stability as insurance market reforms are implemented and Exchanges facilitate increased enrollment. Section 1342 of the Affordable Care Act establishes a temporary risk corridors program which permits the Federal government and QHPs to share in gains or losses resulting from inaccurate rate setting from 2014 through 2016. Section 1343 of the Affordable Care Act establishes a permanent risk adjustment program which is intended to provide increased payments to health insurance issuers that attract higher-risk populations, such as those with chronic conditions, and eliminate incentives for issuers to avoid higher-risk enrollees.

Section 1401 of the Affordable Care Act amended the Internal Revenue Code (26 U.S.C.) to add section 36B, allowing a refundable premium tax credit to help individuals and families afford health insurance coverage. Under sections 1401, 1411, and 1412 of the Affordable Care Act and 45 CFR part 155, subpart D, an Exchange will make a determination of advance payments of the premium tax credit for individuals who enroll in QHP coverage through an Exchange and seek financial assistance. Section 1402 of the Affordable Care Act provides for the reduction of cost sharing for certain individuals enrolled in a QHP through an Exchange, and section 1412 of the Affordable Care Act provides for the advance payment of these reductions to issuers.

Section 1411(g) of the Affordable Care Act specifies that information provided by an applicant or received from a Federal agency may be used only for the purpose of, and to the

extent necessary in ensuring the efficient operation of the Exchange, including for the purpose of verifying the eligibility of an individual to enroll through an Exchange, to claim a premium tax credit or cost-sharing reduction, or for verifying the amount of the tax credit or reduction.

Section 1411(h) of the Affordable Care Act sets forth civil penalties that any person will be subject to if a person provides inaccurate information as part of the application or improperly uses or discloses information.

Unless otherwise specified, the provisions in this proposed rule related to the establishment of minimum functions of an Exchange are based on the general authority of Secretary under section 1321(a)(1) of the Affordable Care Act. Nothing in these proposed regulations would limit the authority of the OIG as prescribed by the Inspector General Act of 1978 or any other law.

B. Stakeholder Consultation and Input

HHS has consulted with stakeholders on a number of policies related to the operation of Exchanges, including the SHOP, and premium stabilization programs. HHS has held a number listening sessions with consumers, providers, employers, health plans, 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 grant process, and meetings with tribal leaders and representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties. We considered all of the public input as we developed the policies in this proposed rule.

C. Structure of the Proposed Rule

The regulations outlined in this proposed rule would be codified in 45 CFR parts 144, 147, 153, 155, and 156. Part 153 outlines select oversight provisions related to the premium

stabilization programs, such as maintenance of records, and sanctions for failing to establish a dedicated distributed data environment. Part 155 outlines the standards relative to the establishment, operation, and minimum functionality of Exchanges, including oversight provisions related to State Exchanges, such as those pertaining to financial integrity and maintenance of records. It also includes standards for States' establishment of a SHOP and agents and brokers. Part 156 outlines the standards for health insurance issuers with respect to participation in an Exchange, including minimum certification standards for QHPs and select oversight provisions related to QHP issuers in FFEs, such as those pertaining to maintenance of records, compliance reviews, and sanctions. It also includes provisions related to quality, the handling of consumer cases by issuers, and issuer standards related to the SHOP.

We note that this rule includes standards for the SHOP to coordinate with the functions of the individual market Exchange for determining eligibility for insurance affordability programs in §155.705(c). This provision was previously proposed in recent rulemaking and published in the **Federal Register** (78 FR 4723) on January 22, 2013. We received several comments on this provision. Some commenters supported the proposal in §155.705(c), while other commenters raised concerns that the proposed rules were overly burdensome and unrealistic in scope and practicability.

After review of comments, and in light of the proposal included in this rule permitting a State to operate only a SHOP including the changes to part 155 of this rule, we are repropounding §155.705(c) in this rulemaking.

II. Provisions of the Proposed Regulations

A. Part 144 – Requirements Related to Health Insurance Coverage

In §144.102(c), we propose a technical correction to clarify whether coverage sold through associations is group or individual coverage under the PHS Act. The Market Reform Rule⁵ provided, among other things, that if health insurance coverage “is offered to an association’s employer-member that is maintaining a group health plan that has fewer than two participants who are current employees on the first day of the plan year,” the coverage is considered individual health insurance coverage for purposes of Title XXVII of the PHS Act. This statement reflects the definition of “individual market” under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), but does not reflect the amendments made by the Affordable Care Act redefining “small employer” to include an employer with an average of at least one employee.⁶ Accordingly, we propose to delete the reference to group health plans with fewer than two participants who are current employees on the first day of the plan year from the rule. We propose conforming amendments to the definitions of “group market” and “individual market” in §144.103.

In §144.103, we propose to amend the definition of “policy year” with respect to non-grandfathered coverage in the individual market or in a market in which the State has merged the individual and small group risk pools, pursuant to section 1312(c)(3) of the Affordable Care Act and implementing regulations at 45 CFR 156.80(c). Under this proposal, “policy year” means a calendar year for which health insurance coverage provides coverage for health benefits. This is consistent with the proposed technical clarification to §147.104 discussed below.

⁵ Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review” 78 FR 13406 (February 27, 2013).

⁶ Section 2791(e)(1)(B) and (e)(4) of the PHS Act.

We also propose to amend the definitions of “small employer” and “large employer” in §144.103, consistent with PHS Act section 2791(e), as amended by the Affordable Care Act. Section 2791(e)(2) generally defines a large employer as an employer with an average of at least 101 employees. Section 2791(e)(4) generally defines a small employer as an employer with an average at least one but not more than 100 employees. Pursuant to section 1304(b)(3) of the Affordable Care Act, each State has the option to limit small employers to having no more than 50 employees until 2016.

Although the Affordable Care Act amended the definitions of “small employer” and “large employer” for purposes of the PHS Act, ERISA and the Code continue to define a small employer as one that has 50 or fewer employees.⁷ Additionally, although the Affordable Care Act removed an exception for very small plans contained in PHS Act section 2721(a) (providing that title XXVII of PHS Act generally does not apply to plans (and health insurance coverage offered in connection with such plans) with less than two participants who are current employees), parallel provisions in ERISA (section 732(a)) and the Code (section 9831(a)(2)) generally continue to provide that the requirements of part 7 of ERISA, and chapter 100 of the Code, do not apply to such plans. The Departments of HHS, Labor, and the Treasury recognize that these statutory changes may create a conflict between the provisions of title XXVII of the PHS Act and part 7 of ERISA and chapter 100 of the Code with respect to insured group health plans. We solicit comments on what interpretations of the statute, if any, are necessary to ensure smooth implementation across the PHS Act, ERISA, and the Code, including comments to help

⁷ See Affordable Care Act Implementation FAQs – Set 5, Q8 (December 22, 2010). Available at: http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html.

ensure that shared provisions are administered to have the same effect at all times, as required under HIPAA section 104 and the Departments' Memorandum of Understanding.⁸

B. Part 147 – Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

1. Fair Health Insurance Premiums (§147.102)

Section 2701 of the PHS Act, as added by the Affordable Care Act, and implementing regulations at 45 CFR 147.102, direct a health insurance issuer offering non-grandfathered health insurance coverage in the individual and small group markets, beginning with plan or policy years starting in 2014, to limit any variation in premium rates with respect to a particular plan or coverage to family size, age, tobacco use, and geographic rating area. Under §147.102(c), generally, issuers in the individual and small group markets must calculate premiums on a per-member basis by adding the rate of each covered family member or employees and their dependents to determine the total family or group premium, respectively.

HHS has received several inquiries since the issuance of the Market Reform Rule asking whether geographic rating in the small group market is based on employee or employer address. HHS has also received several inquiries asking which rating areas should be used for individual market coverage if family members live in multiple locations.

PHS Act section 2701(a)(4) and §147.102(c) require any rating variation for age and tobacco use to be applied on a per-member basis, but do not impose the same requirement on rating for geography. Accordingly, consistent with guidance released on April 26, 2013

⁸ See 64 FR 70164 (December 15, 1999).

describing our intended clarification,⁹ we propose to clarify in §147.102(a)(1)(ii) that the rating area is determined in the small group market using the principal business address of the group policyholder, and in the individual market, using the address of the primary policyholder, regardless of the location of other individuals covered under the plan or coverage. This would apply both inside and outside of the Exchange and SHOP. We seek comment on this proposal.

Additionally, to clarify the connection between the premium rating requirements of PHS Act section 2701 and the single risk pool requirement of section 1312(c) of the Affordable Care Act, we propose in §147.102(a) to add a cross-reference to the single risk pool standard codified in 45 CFR 156.80. Because of this connection, HHS considers both provisions to be subject to the general enforcement authority under PHS Act section 2723.

2. Guaranteed Availability and Renewability of Coverage (§§147.104, 147.106)

Section 2702 of the PHS Act, as amended by the Affordable Care Act, generally directs a health insurance issuer that offers health insurance coverage in the individual or “group market” in a State to accept every individual or employer in the State that applies for such coverage. Section 2703 of the PHS Act, as amended by the Affordable Care Act, generally requires an issuer in the individual or “group” market to renew or continue in force coverage at the option of the plan sponsor or individual, as applicable. Both of these statutes and their implementing regulations, codified at 45 CFR 147.104 and 147.106, do not distinguish between the different segments of the group market, meaning the large group and small group markets. We explained in the preamble of the Market Reform Rule (78 FR 13419), in the context of the market

⁹ Questions and Answers Related to the Health Insurance Market Reforms, (April 26, 2013). Available at: http://www.cms.gov/CCHIO/Resources/Fact-Sheets-and-FAQs/qa_hmr.html.

withdrawal exception to guaranteed renewability, that because the statutory language refers only to the “group market,” the regulations implement the statute without segmenting the group market.

After further review and consideration of the statutory provisions, we are proposing to clarify that the guaranteed availability and renewability requirements apply within the applicable market segment (the individual, small group, or large group market). This clarification is consistent with the information we provided in a document titled, “Frequently Asked Questions on Health Insurance Marketplaces,” dated May 14, 2013.¹⁰ We recognize that issuers in the large group and small group markets may be subject to distinct requirements under the PHS Act (for example, requirement to cover the essential health benefits package under section 2707(a)) and that failing to segment the markets for purposes of guaranteed availability and guaranteed renewability would have consequences not contemplated by the PHS Act. Accordingly, we propose amendments recognizing the distinction of the large group and small group markets for purposes of the guaranteed availability and guaranteed renewability requirements. The proposed clarifications would make clear, for example, that a health insurance issuer must offer to a large employer all products that are approved for sale in the large group market, but not those products approved for sale only in the small group market, and vice versa. We propose similar amendments recognizing the distinction of the large group and small group segments of the group market for purposes of the guaranteed renewability provisions.

¹⁰ Available at: <http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/marketplace-faq-5-14-2013.pdf>.

Also, in §147.104(b)(2), we propose a clarification that, as of January 1, 2015, all non-grandfathered coverage in the individual market or in a market in which the State has merged the individual and small group risk pools, pursuant to section 1312(c)(3) of the Affordable Care Act and implementing regulations at 45 CFR 156.80(c), must be offered on a calendar year basis. This simply clarifies the intent of the Market Reform Rule. It is essential that all non-grandfathered coverage in the individual and merged markets be on a calendar year basis as of January 1, 2015 to line up with coverage in the Exchanges and also to be consistent with the requirements of the single risk pool in §156.80. For purposes of new enrollment effective on any date other than January 1, the first policy year following such enrollment may comprise a prorated policy year, ending on December 31.

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

In this part, we propose certain provisions related to program integrity for State-operated risk adjustment and reinsurance programs. Specifically, we propose an accounting requirement for State-operated reinsurance and risk adjustment programs, and requirements relating to summary reports and independent external audits for these programs. We also propose a provision restricting the use of reinsurance funds for administrative expenses, which we discussed in the preamble to the HHS Notice of Benefit and Payment Parameters for 2014¹¹ (2014 Payment Notice). In addition, we propose record retention standards for States operating risk adjustment, and for contributing entities and reinsurance-eligible plans when HHS operates

¹¹ Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2014, 78 FR 15410 (March 11, 2013).

reinsurance on behalf of a State. We seek comment on these proposals. We set forth a general description of these provisions in a document titled, “Frequently Asked Questions on Health Insurance Marketplaces,” dated May 14, 2013.¹²

We intend to engage in further consultations with stakeholders, and to propose additional standards related to the oversight of the premium stabilization programs in future regulations and guidance, including standards governing data validation for risk adjustment when HHS operates that program on behalf of a State.

1. Subpart A – General Provisions

a. Definitions (§153.20)

In this section, we propose an amendment to the definition of a “contributing entity.” The current definition states that “Contributing entity means a health insurance issuer or self-insured group health plan. A self-insured group health plan is responsible for the reinsurance contributions, though it may elect to use a third party administrator or administrative services only contractor for transfer of the reinsurance contributions.” This definition does not address the situation in which the benefit provided to a participant under a group health plan is partially insured, and partially self-insured (for example, the medical benefits are provided under a self-insured arrangement but the prescription drug benefits are provided under an insured arrangement, or vice versa). However, the reinsurance contribution counting rules at 45 CFR 153.405(f), which we promulgated in the 2014 Payment Notice, do address this situation, and place liability for reinsurance contributions on the plan. We propose to amend the definition of

¹² Available at: <http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/marketplace-faq-5-14-2013.pdf>.

“contributing entity” to clarify that for purposes of that definition, a self-insured group health plan includes a group health plan that is partially self-insured and partially insured, but only where the insured coverage does not constitute major medical coverage (whether or not the self-insured coverage is major medical coverage).¹³ This amendment would clarify that if a group health plan is structured in such a manner, the group health plan would be liable for reinsurance contributions under the counting rules applicable to self-insured group health plans at 45 CFR 153.405(f), but if the insured coverage is major medical coverage, the issuer is liable for the contributions. For a discussion of group health plans under which certain coverage options under the plan are insured and other coverage options are self-insured, see the last paragraph of the preamble discussion of proposed §153.400 below.

2. Subpart C - State Standards Related to the Reinsurance Program

Section 1341 of the Affordable Care Act provides for the establishment of a transitional reinsurance program in each State to help stabilize premiums for coverage in the individual market from 2014 through 2016. The reinsurance program is designed to alleviate the need to build into premiums the unknown costs of enrolling individuals with significant unmet medical needs. In subparts C and E of 45 CFR part 153, finalized on March 23, 2012 in the Premium Stabilization Rule (77 FR 17220), we established standards for the administration of the reinsurance program. Below, we propose certain provisions related to the oversight of State-operated reinsurance programs.

a. Maintenance of Records (§153.240(c))

¹³ We described some of the characteristics of major medical coverage in the 2014 Payment Notice, at 78 FR 15456. We propose further clarification of this concept below.

We propose to amend 45 CFR 153.240(c), a maintenance of records requirement applicable when a State establishes the reinsurance program, to be consistent with proposed §153.310(c)(4), a maintenance of records requirement for State-operated risk adjustment programs, which is discussed below. We propose to amend §153.240(c) such that if a State establishes a reinsurance program, the State would be directed to maintain documents and records relating to the reinsurance program, whether paper, electronic, or in other media, for each benefit year for at least 10 years, and make them available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity. The documents and records must be sufficient to enable an evaluation of the State-operated reinsurance program's compliance with Federal standards. States would also be directed to ensure that their contractors, subcontractors, and agents similarly maintain and make relevant documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees. We note that a State may satisfy this standard by archiving these documents and records and ensuring that they are accessible if needed in the event of an investigation, audit, or other review. We seek comment on this proposal.

b. General Oversight Requirements for State-Operated Reinsurance Programs (§153.260)

HHS expects that States will operate the reinsurance program under section 1341 of the Affordable Care Act in an effective and efficient manner, and in accordance with the provisions of subpart C of 45 CFR part 153. We are therefore proposing, pursuant to our authority under sections 1321(a)(1) and 1341 of the Affordable Care Act, certain general oversight requirements for State-operated reinsurance programs. In §153.260(a), we propose that a State establishing the reinsurance program would be directed to ensure that its applicable reinsurance entity keeps, for each benefit year, an accounting of the following: (1) all reinsurance funds received from HHS

for reinsurance payments and for administrative expenses; (2) all claims for reinsurance payments received from issuers of reinsurance-eligible plans; (3) all reinsurance payments made to issuers of reinsurance-eligible plans; and (4) all administrative expenses incurred for the State's reinsurance program. This accounting must be kept in accordance with generally accepted accounting principles (GAAP), consistently applied. This accounting would enable HHS to ensure that the appropriate amount of reinsurance funds collected by the Federal government is spent for reinsurance payments and administrative expenses. We seek comment on this proposal.

In §153.260(b), we propose that a State that establishes the reinsurance program would be directed to submit to HHS and make public a summary report on its reinsurance program operations for each benefit year, in the manner and timeframe specified by HHS. This report must include a summary of the accounting for the benefit year as set forth in proposed §153.260(a). We note that, in the interest of transparency, HHS intends to publish periodic reports on its operation of the reinsurance program on States' behalf. We anticipate that these reports will not correspond entirely in format and substance to those required of States that operate the reinsurance program due to the fact that HHS is already subject to a number of auditing and program integrity requirements, including requirements relating to periodic reviews of improper payments of Federal funds under the Improper Payments Elimination and Recovery Act of 2010.

In §153.260(c), we propose that a State that establishes the reinsurance program engage an independent qualified auditing entity to perform a financial and programmatic audit of the program for each benefit year in accordance with generally accepted auditing standards (GAAS). This auditing entity would be licensed, be in good standing in one or more States, and be free

from bias or the appearance of bias. This entity may be a government entity. Pursuant to proposed §153.260(c)(2), the State would be directed to ensure that this audit addresses the prohibitions set forth in proposed §153.265 (concerning improper use of reinsurance funds for administrative expenses). We seek comment on this proposal, and intend to provide more information on auditing standards in future guidance.

In paragraph (c)(1), we propose that the State provide to HHS the results of the independent external audit for each benefit year, and in paragraph (c)(3), we propose that the State identify to HHS any material weakness or significant deficiency identified in the audit (as these terms are defined in GAAS issued by the American Institute of Certified Public Accountants, and Government Auditing Standards issued by the Government Accountability Office (GAO)¹⁴). We further propose that the State address in writing to HHS how it intends to correct any such material weakness or significant deficiency. To ensure transparency and accountability of a State-operated reinsurance program's finances and activities, we propose in paragraph (c)(4) that the State make public a summary of the results of the external audit, including any material weakness or significant deficiency in a manner and timeframe specified by HHS. We believe that these measures are necessary to ensure the proper use of reinsurance contributions under the national contribution rate, which HHS will collect from all contributing entities pursuant to 45 CFR 153.220. We seek comment on this proposal.

c. Restrictions on Use of Reinsurance Funds for Administrative Expenses (§153.265)

¹⁴ See, Government Auditing Standards (2011 Revision), available at: <http://www.gao.gov/yellowbook>. For public companies, the Public Company Accounting Oversight Board (PCAOB) sets audit standards. See, <http://pcaobus.org/Standards/Auditing/Pages/default.aspx>. For non-public companies, the AICPA sets audit standards. See, <http://www.aicpa.org/Research/Standards/AuditAttest/Pages/SAS.aspx>.

To achieve the intended purposes of the reinsurance program, reinsurance contributions collected must be spent on reinsurance payments, payments to the U.S. Treasury, and on reasonable expenses to administer the reinsurance program. As stated in the 2014 Payment Notice, the total reinsurance contributions to be collected for Federal administrative expenses for operating reinsurance for the 2014 benefit year is \$20.3 million, resulting in a national per capita contribution rate of \$0.11 annually for HHS administrative expenses. The funds for administrative expenses will be collected by HHS from all contributing entities, and will be apportioned as follows: \$0.055 of the total administrative expenses collected per capita will be allocated to administrative expenses incurred in the collection of contributions from contributing entities; and \$0.055 of the total administrative expenses collected per capita will be allocated to expenses incurred for activities supporting the administration of payments to issuers of reinsurance-eligible plans.

The total amounts allocated towards administrative expenses for reinsurance payments will be allocated in proportion to the State-by-State total requests for reinsurance payments made under the national reinsurance payment parameters. Thus, if a State that operates reinsurance receives total requests for reinsurance payments under the national reinsurance payment parameters that represent 5 percent of the total requests received for all States, then the State would receive a disbursement of 5 percent of the reinsurance contributions allocated to expenses incurred to support administration of payments to reinsurance-eligible plans to support its administration of reinsurance payments in that State. Pursuant to proposed §153.260(a), a State operating reinsurance would be directed to keep an accurate accounting of the reinsurance funds received from HHS for administrative expenses and all the administrative expenses incurred for the State-operated reinsurance program. If a State incurs fewer expenses in operating reinsurance

for a benefit year than are allocated to it under the national reinsurance contribution rate, the State would be directed to carry over those funds for use in operating reinsurance in subsequent benefit years.

Section 1311(d)(5)(B) of the Affordable Care Act prohibits an Exchange from utilizing any funds intended for the administrative and operational expenses of the Exchange for staff retreats, promotional giveaways, excessive executive compensation, or promotion of Federal or State legislative and regulatory modifications. In §153.265, we propose to extend these prohibitions to State-operated reinsurance programs so that a State establishing the reinsurance program would be directed to ensure that its applicable reinsurance entity does not use any funds for the support of operations of the reinsurance program, including any reinsurance contributions collected under the national contribution rate for administrative expenses, for any of the prohibited purposes stated in section 1311(d)(5)(B) of the Affordable Care Act. We seek comment on this proposal.

3. Subpart D - State Standards Related to the Risk Adjustment Program

The risk adjustment program is a permanent program created by section 1343 of the Affordable Care Act that transfers funds from lower-risk, non-grandfathered plans to higher-risk, non-grandfathered plans in the individual and small group markets, inside and outside of the Exchanges. In subparts D and G of 45 CFR part 153, finalized March 23, 2012 (77 FR 17220), we established standards for the administration of the risk adjustment program. A State approved (or conditionally approved) by the Secretary to operate an Exchange may establish a risk adjustment program. Alternatively, a State may have HHS operate a risk adjustment program on its behalf. Pursuant to our authority under sections 1321(a)(1) and 1343 of the Affordable Care

Act, we propose below certain provisions related to the oversight of State-operated risk adjustment programs.

a. Maintenance of Records (§153.310(c)(4))

In §153.310(c)(4), we propose that a State operating a risk adjustment program would be directed to maintain documents and records relating to the risk adjustment program, whether paper, electronic, or in other media, for each benefit year for at least 10 years, and make them available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity. The documents and records must be sufficient to enable the evaluation of a State-operated risk adjustment program's compliance with Federal standards. States would also be directed to ensure that their contractors, subcontractors, and agents maintain and make those documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees. We note that a State may satisfy this standard by archiving these documents and records and ensuring that they are accessible if needed in the event of an investigation, audit, or other review. This provision is consistent with the requirements set forth in proposed §153.240(c), which contains record retention standards for State-operated reinsurance programs. We seek comment on this proposal.

b. Interim Report and State Summary Report (§153.310(d))

In §153.310(d)(3), we propose that, in addition to the requirements set forth in 45 CFR 153.310(d)(1) and (d)(2), to obtain recertification from HHS to operate risk adjustment for a third benefit year, a State would be directed to, in the first benefit year for which it operates risk adjustment, provide to HHS an interim report, in a manner specified by HHS, that includes a detailed summary of its risk adjustment activities in the first 10 months of the benefit year. We propose that this report would be due no later than December 31st of the first benefit year for

which a State operates risk adjustment. The interim report is intended to provide HHS with the information needed to assess the State's compliance with the applicable Federal standards related to risk adjustment. We note that because the process for receiving certification to operate risk adjustment begins more than one year before the beginning of the applicable benefit year, the first benefit year for which an interim report based on the first year's operations could be used for certification purposes is the third benefit year. We intend to provide more information on the risk adjustment interim report in future guidance, and we seek comment on the content and format of this report.

We propose to amend 45 CFR 153.310(f) and re-designate it as §153.310(d)(4). In §153.310(d)(4), we propose that in order to obtain recertification from HHS to operate risk adjustment for each benefit year after the third benefit year for which it is certified, each State operating a risk adjustment program would be directed to submit to HHS and make public a detailed summary of risk adjustment program operations for the most recent benefit year for which risk adjustment operations have been completed, in the manner and timeframe specified by HHS. We propose in §153.310(d)(4)(i) that this summary report include the results of a programmatic and financial audit for the benefit year of the State-operated risk adjustment program conducted by an independent qualified auditing entity in accordance with GAAS. As discussed above, this entity, which may be a government entity, must be licensed and in good standing in one or more States, and must be free from bias or the appearance of bias. In §153.310(d)(4)(ii), we propose that the summary report would identify to HHS any material weakness or significant deficiency (as these terms are defined in GAAS issued by the American Institute of Certified Public Accountants, and Government Auditing Standards issued by the

GAO¹⁵) identified in the external audit and address in writing to HHS how the State intends to correct any such material weakness or significant deficiency.

We seek comment on these proposals, including on the content and format of the summary reports.

c. General Oversight Requirements for State-operated Risk Adjustment Programs (§153.365)

To enable HHS to recertify States to operate risk adjustment pursuant to 45 CFR 153.310(d), HHS proposes in §153.365 that a State operating a risk adjustment program keep an accounting of all receipts and expenditures related to risk adjustment payments and charges and the administration of risk adjustment-related functions and activities for each benefit year. This accounting would be kept in accordance with GAAP, consistently applied. This requirement parallels proposed §153.260(a), which applies to the reinsurance program when operated by a State.

4. Risk Adjustment Methodology

a. Modification to the Transfer Formula in the HHS Risk Adjustment Methodology (78 FR at 15430-15434)

In the Payment Notice (78 FR 15430-34), we noted our intent to modify the risk adjustment payment transfer formula in order to accommodate community rated States that utilize family tiering rating factors. In non-community rated States, family policy premiums must be developed by summing the applicable rates of each individual covered under the policy, as

¹⁵ See, Government Auditing Standards (2011 Revision), available at: <http://www.gao.gov/yellowbook>. For public companies, the Public Company Accounting Oversight Board (PCAOB) sets audit standards. See, <http://pcaobus.org/Standards/Auditing/Pages/default.aspx>. For non-public companies, the AICPA sets audit standards. See, <http://www.aicpa.org/Research/Standards/AuditAttest/Pages/SAS.aspx>.

required under 45 CFR 147.102(c)(1). In the case of families with more than three children in non-community rated States, only the applicable rates of the three oldest covered children under age 21 are counted towards the family policy premium rate (for example, for a family with four children under age 21, only the applicable individual rates of the three oldest children would count towards the family policy premium). These family rating requirements do not apply to community rated States that utilize family tiering rating factors. In community rated States, family tiering rating factors do not have to yield premiums that are equal to the sum of each policy member's applicable rate, nor do they have to be set in a way that only counts the rates of the oldest three children under age 21 within a family policy. For example, a community rated State could establish a family tiering rating factor of 1.0 for an adult policy, 1.8 for a policy covering one adult and one or more children, 2.0 for a policy covering two adults, and 2.8 for a policy covering two adults and one or more children.

In order to account for the differences in family rating practices between family tiering States and non-family tiering States, we are proposing two changes to the risk adjustment payment transfer formula that HHS will use when operating risk adjustment on behalf of a State. These changes would only apply to States that are using family tiering rating structures. In the 2014 Payment Notice, we stated that billable members exclude children who do not count towards family rates (that is, children who do not count toward family policy premiums are excluded) (78 FR 15432, 15434). We propose to clarify that in the case of family tiering States, billable members would be based on the number of children that implicitly count towards the premium under a State's family rating factors. For example, assume a State has the following four family tiers: one adult; one adult plus one or more children; two adults; and two adults plus one or more children. Under this tiering structure, only one child would be counted as a billable

member in the payment transfer formula, because additional children covered under a family policy would not affect the policy's premium.

Additionally, we are proposing a modification to the allowable rating factor (ARF) formula that would be used for family tiering States. In the Payment Notice (78 FR 15433), the ARF is calculated as the member month weighted average of the age factor applied to each billable enrollee. In non-family tiering States, the ARF is intended to measure the extent to which plans are increasing or decreasing their premiums based on allowable age rating factors. In the case of family tiering States, premium revenue will not vary by age-specific rating factors. Rather, policy level premiums will vary only based on the family tiering factors. In order to capture the impact of the family tiering factors on plans' premium revenue we are proposing that the ARF formula for family tiering States be based on the family tiering factors instead of age rating factors.

Specifically, for family tiering States, the ARF would be calculated at the level of the subscriber, as follows:

$$ARF_f = \frac{\sum_s (ARF_s \cdot M_s)}{\sum_s (M_s)}$$

where ARF_s is the rating factor for the subscriber (s) (based on family size/composition) and M_s is the number of billed person-months that are counted in determining the subscriber (s) premium.

We note that aside from the changes to the billable member months definition and the ARF formula discussed above, payment transfers in family tiering States will be calculated using

the formulas provided in the Payment Notice (78 FR at 15431-34). Additionally, the changes to the billable member month definition and the ARF formula would not apply to community rated States that do not implement family tiering rating factors.

5. Subpart E - Health Insurance Issuer and Group Health Plan Standards Related to the Reinsurance Program

a. Reinsurance Contribution Funds (§153.400)

In some health coverage arrangements, an insured group health plan may provide benefits through more than one policy to the same covered lives, where each policy standing alone does not constitute major medical coverage, but the total benefits do.¹⁶ Under such an arrangement, a group health plan could, for example, have two policies with different issuers, one providing benefits for hospitalization and the other providing benefits for outpatient treatments and prescription drugs, with the same individuals simultaneously enrolled in both policies. In such a situation, the question has been raised as to whether the issuers would be required to make reinsurance contributions for the insured policies since neither policy would constitute major medical coverage, and whether the group health plan would be required to make reinsurance contributions because it would not be a self-insured plan.

Therefore, to clarify the application of the rules (solely for the purpose of reinsurance contributions), we propose to amend paragraph (a)(1)(i) of 45 CFR 153.400(a) and add a new paragraph (a)(3) that would address liability for reinsurance contributions in cases where an insured group health plan provides health insurance coverage through more than one policy to

¹⁶ We note that, after 2014, such arrangements generally would only be permissible in the large employer group context, as issuers of small employer group market insurance coverage are required to provide all essential health benefits under any policy they offer that does not qualify as “excepted benefits.”

the same covered lives, where, as described above, none of the policies provides major medical coverage individually, but their combined benefits meet the definition of major medical coverage. This paragraph (a)(3) would be an exception to the rule under paragraph (a)(1)(i), which provides that an issuer of health insurance coverage is not required to make reinsurance contributions for coverage to the extent the coverage is not major medical coverage.

Under the proposed paragraph (a)(3), notwithstanding paragraph (a)(1)(i), a health insurance issuer providing coverage under a group health plan would make reinsurance contributions for lives under its health insurance coverage even if the insurance coverage does not constitute major medical coverage, if (i) the group health plan provides health insurance coverage for the same covered lives through more than one insurance policy that in combination constitute major medical coverage but individually do not; (ii) the lives are not covered by self-insured coverage of the group health plan (except for self-insured coverage limited to excepted benefits); and (iii) the health insurance coverage under the policy offered by the health insurance issuer represents a percentage of the total health insurance coverage offered in combination by the group health plan greater than the percentage offered under any of the other policies. Clause (i) describes the arrangement described in the paragraphs above. Clause (ii) makes clear that this exception would apply where group health coverage was divided only among insurance policies, and no portion of the coverage is self-insured.¹⁷ Finally, clause (iii) describes how to determine which issuer is liable for reinsurance contributions in the situation described above – where multiple insurance policies cover the same lives in an insured group health plan and each

¹⁷ As discussed in relation to the amendment to 45 CFR 153.20 above, where a group health plan has mixed self-insured and insured coverage, liability for reinsurance contributions, if any, falls upon the self-insured plan, as already established under our rules.

insurance policy is not major medical coverage, but in combination they are. We propose in that clause that an issuer of health insurance coverage providing a percentage of the benefits provided by the group health plan that is greater than the percentage provided by any of the other insurance policies would be liable for the reinsurance contributions. We further propose that for purposes of paragraph (a)(3), the percentage of coverage offered under various policies would be determined based on the average premium per covered life for those policies. In the event that the percentage of coverage for two or more insurance policies is equal, the issuer of the policy that provides the greatest portion of in-network hospitalization benefits will be responsible for reinsurance contributions. For example, if an insured group health plan covered the same lives under two different health insurance policies, one with a monthly average premium per covered life of \$250 and the other with a monthly average premium per covered life of \$200, the issuer of the insurance policy with the monthly average premium per covered life of \$250 would be liable for the reinsurance contributions.

Because an issuer of group health insurance coverage that does not, by itself, constitute major medical coverage, may not be aware of the existence of, or premium for, other health insurance coverage obtained by a plan sponsor covering the same lives under a group health plan, we are considering directing such an issuer to seek a representation from the plan sponsor regarding the relative percentage of coverage offered by the issuer. We seek comment on whether and in what circumstances an issuer should be entitled to rely upon such representations and what other means we should consider for ensuring that the relevant issuer knows of its obligation to make the reinsurance contributions, including with respect to any role that the employer should have in ensuring that issuers have information necessary to determine which issuer is responsible for reinsurance contributions.

We seek comment on these proposals, as well as alternative approaches that should be considered for determining responsibility for reinsurance contributions in such circumstances. For example, the liability rules could impose responsibility for the reinsurance contributions on the issuer of the coverage that provides the hospitalization coverage or the rules could allocate liability among the issuers in proportion to the benefits offered under the respective policies.

We are also considering proposing a definition for “major medical coverage” that would provide additional clarity around the responsibility to make payments. While HHS believes that responsibility for issuers and group health plans is clear, we seek comment on what further clarification is needed and what the definition should be.

Finally, we have received inquiries as to how reinsurance contribution obligations would be addressed in the case of a group health plan under which some benefit options for employees are insured by an issuer, and some options offer benefits without the involvement of an issuer in insuring the benefits (because either the group health plan or some non-issuer entity assumes the risk for that coverage option). We are proposing that in such a case, if a coverage option is insured by an issuer, the issuer would be responsible for the reinsurance contribution associated with that coverage option. If an employee coverage option under such a group health plan is not insured (because either the group health plan or other non-issuer assumes the risk), then the group health plan would be responsible for the reinsurance contribution associated with that coverage option. We seek comment on this proposed approach.

b. Maintenance of Records (§153.405(h) and §153.410(c))

Pursuant to our obligation to safeguard Federal funds, we propose to amend §153.405 by adding paragraph (h), in which we propose that a contributing entity would be directed to maintain documents and records, whether paper, electronic, or in other media, sufficient to substantiate the

enrollment count submitted pursuant to that section for at least 10 years, and make that evidence available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity, for verification of reinsurance contribution amounts. We also propose to amend §153.410 by adding paragraph (c), in which we propose that an issuer of a reinsurance-eligible plan in a State where HHS operates reinsurance would be directed to maintain documents and records, whether paper, electronic, or in other media, sufficient to substantiate the requests for reinsurance payments made pursuant to that section for at least 10 years, and make that evidence available upon request from HHS, the OIG, the Comptroller General, or their designees, (or, in a State where the State is operating reinsurance, the State or its designee), to any such entity, for verification of reinsurance payment requests. We note that these standards may be satisfied if the contributing entity or issuer of a reinsurance-eligible plan archives the documents and records and ensures that they are accessible if needed in the event of an investigation, audit, or other review. These proposed provisions are consistent with the requirements for record retention under the False Claims Act and those set forth in proposed §153.620(b), which apply to issuers of risk adjustment covered plans. We seek comment on these proposals.

6. Subpart F – Health Insurance Issuer Standards Related to the Risk Corridors Program

Section 1342(a) of the Affordable Care Act provides that “a qualified health plan offered in the individual or small group market” is to participate in the risk corridors program. In the Exchange Establishment Rule, we stated that a stand-alone dental plan is “a type of qualified health plan.” However, we did not intend for all requirements applicable to a QHP to apply to stand-alone dental plans. For example, under 45 CFR 155.1065(a)(3), certain QHP standards are not applicable to a stand-alone dental plan if they cannot be met, given the limited benefit package offered by the plan. We believe that it would not be appropriate to subject stand-alone

dental plans to the risk corridors program because such plans are considered excepted benefits plan under section 2791(c) of the PHS Act, meaning that these plans are not subject to the Federal prohibition on underwriting premiums or the requirement to base pricing using the single risk pool or fair health insurance premiums limitations. Thus, although States have the option to prohibit underwriting for excepted benefits plans, and issuers of stand-alone dental plans in an FFE may voluntarily choose to underwrite these plans, we believe that, in general, an issuer of a stand-alone dental plan will not be subject to the same rate-setting uncertainty in 2014 as the issuer of a major medical plan, and will not need the premium risk-sharing protections of risk corridors.¹⁸

We note that stand-alone dental plans are similarly excluded from participation in the two other premium stabilization programs – reinsurance and risk adjustment. We also note that, consistent with the exclusion of excepted benefits plans from the medical loss ratio (MLR) requirements, stand-alone dental claims would not be pooled along with an issuer’s other claims for the purposes of determining “allowable costs” in the risk corridors calculation, as defined at 45 CFR 153.500. We seek comment on this approach.

7. Subpart G – Health Insurance Issuer Standards Related to the Risk Adjustment Program

We propose to amend §153.620(b) to add a standard that would direct an issuer that offers risk adjustment covered plans to maintain documents and records, whether paper,

¹⁸ In the preamble to the Exchange Establishment Rule, we note that each Exchange can require, as a condition of certification, comprehensive medical QHPs to offer and price the pediatric dental EHB (if covered) separately, if doing so would be in the best interest of consumers. For the 2014 coverage year, CMS will not require comprehensive medical QHP issuers that provide pediatric dental coverage to offer and price the pediatric dental EHB separately from the rest of the plan in connection with certification by an FFE. We have provided this guidance in Chapter 4 of the 2014 Letter to Issuers on Federal and Partnership Marketplaces (April 5, 2013).

electronic, or in other media, sufficient to enable the evaluation of the issuer's compliance with applicable risk adjustment standards, and to make that evidence available upon request from HHS, OIG, the Comptroller General, or their designees (or in a State where the State is operating risk adjustment, the State or its designee), to any such entity. This standard, which is consistent with other records maintenance standards in this proposed rule, would direct an issuer of a risk adjustment covered plan to retain additional records – not only those pertaining to data validation – to substantiate its compliance with risk adjustment standards, whether risk adjustment is operated by HHS or a State. We note that we anticipate that the bulk of the record maintenance obligations will relate to data validation, but that certain records, for instance those relating to premium rating or small group status, will not. We seek comment on this proposal.

8. Subpart H - Distributed Data Collection for HHS-Operated Programs

a. Failure to Comply with HHS-operated Risk Adjustment and Reinsurance Data

Requirements (§153.740)

In §153.740(a), we propose that HHS may pursue an enforcement action for CMPs against an issuer in a State where HHS operates the reinsurance or risk adjustment program, if an issuer fails to: (a) establish a secure, dedicated distributed data environment pursuant to 45 CFR 153.700(a); (b) provide HHS with access to enrollee-level plan enrollment information, enrollee claims data, or enrollee encounter data through its dedicated distributed data environment pursuant to 45 CFR 153.710(a); (c) otherwise comply with the requirements of 45 CFR 153.700 through 153.730; (d) adhere to the reinsurance data submission requirements set forth in 45 CFR 153.420; or (e) adhere to the risk adjustment data submission and data storage requirements set forth in 45 CFR 153.610 through 153.630.

Risk Adjustment: For risk adjustment covered plans, HHS will need access to the risk adjustment enrollee-level plan enrollment information, enrollee claims data, or enrollee encounter data from the issuer by April 30th of the year following the applicable benefit year in order to calculate payment transfers based on claims experience and premiums as set forth in 45 CFR 153.730. Pursuant to section 1321(c)(2) of the Affordable Care Act, in HHS's role in operating risk adjustment on behalf of a State, to enforce the risk adjustment standards, we propose to apply the standards in proposed §156.805 in connection with the imposition of CMPs under this section. If a risk adjustment covered plan does not comply with the requirements set forth in 45 CFR 153.610 through 153.630 and 45 CFR 153.700 through 153.730, we intend to apply the proposed sanction so that the level of the enforcement action would be proportional to the level of the violation. While we would reserve the right to impose penalties up to the maximum amounts proposed in §156.805(c), as a general principle, we intend to work collaboratively with issuers to address problems in establishing dedicated distributed data environments in 2014. In our application of the proposed sanction, we would take into account the totality of the issuer's circumstances, including such factors as an issuer's previous record (if any), the frequency and level of the violation, and any aggravating or mitigating circumstances. Our intent is to encourage QHP issuers to address non-compliance and not to severely affect their financial condition, especially where the issuer demonstrates good faith in monitoring compliance with applicable standards, identifies any suspected occurrences of non-compliance, and attempts to remedy any non-compliance. We note that HHS would reserve the right to impose, or not impose, CMPs as appropriate. For instance, if an issuer of a risk adjustment covered plan does not establish a dedicated distributed data environment or provide access to the necessary risk adjustment data to permit HHS to timely calculate the applicable risk adjustment

transfer amounts, we are proposing that HHS will assess the default risk adjustment charge described below. However, HHS may elect to pursue CMPs in conjunction with the imposition of the default risk adjustment charge if an issuer failed to comply with applicable data security or privacy standards, putting the interests of third-parties at risk.

Reinsurance: Similar to our proposal for risk adjustment covered plans, we propose that an issuer of a reinsurance-eligible plan may be subject to CMPs for failure to comply with 45 CFR 153.420, or 45 CFR 153.700 through 153.730. In our application of the proposed sanction, we would take into account the totality of the issuer's circumstances, including such factors as an issuer's previous record (if any), the frequency and level of the violation, and any aggravating or mitigating circumstances. In certain cases, we may not pursue CMPs. For example, if an issuer of a reinsurance-eligible plan fails to set up a dedicated distributed data environment or meet certain data requirements stated above, and as a consequence, HHS would not have the necessary data to calculate or distribute reinsurance payments for the reinsurance-eligible plan, the reinsurance-eligible plan would not receive reinsurance payments that it otherwise might have received. However, HHS would reserve the right to pursue CMPs irrespective of whether or not an issuer becomes ineligible for reinsurance payments as a result of failing to comply with 45 CFR 153.420, or 45 CFR 153.700 through 153.730.

b. Default Risk Adjustment Charge

As described in the Premium Stabilization Rule and the 2014 Payment Notice, HHS will employ a distributed data collection approach for risk adjustment. Under this approach, issuers in States where HHS operates risk adjustment will be required to establish dedicated, secure data

environments, and provide HHS with access to “masked”¹⁹ enrollee-level plan enrollment information, enrollee claims data, and enrollee encounter data pursuant to 45 CFR 153.710 and 45 CFR 153.720. We would not store any enrollee PII or individual claim-level information in connection with this data collection, except for the purposes of data validation and audit. We believe that this approach minimizes issuer burden while protecting enrollees’ privacy. Issuers must provide access to required risk adjustment data by April 30th of the year following a benefit year in order for HHS to calculate risk adjustment payment transfer amounts pursuant to 45 CFR 153.730.

In cases where an issuer does not set up a dedicated distributed data environment or submits inadequate risk adjustment data, HHS would not have the required risk adjustment data from the issuer to calculate risk scores or payment transfers. This data is necessary to properly calculate risk adjustment payments and charges for the entire applicable market for the State. If HHS cannot perform this calculation for a particular issuer, risk adjustment payment transfers would be affected for all other issuers in the State market because payments transfers are determined within a market within a State such that they will net to zero. Therefore, we believe that we must establish an administrative capability to calculate payments and charges for all plans, to avoid penalizing those plans that submit timely, complete risk adjustment data.

Pursuant to section 1343(b) of the Affordable Care Act, we have the authority to develop and apply criteria and methods for carrying out risk adjustment activities, such as applying a default charge to issuers in the individual or small group market that fail to provide complete

¹⁹ As described at 45 CFR 153.720(b), masked data means data associated with a unique identifier, where the unique identifier does not include the enrollee’s PII.

data. Under the HHS-operated risk adjustment methodology, we require a balanced payment transfer approach in which issuers with a higher risk enrollee population will receive a payment, while issuers with a lower risk enrollee population will be assessed a charge in order to stabilize premiums; these transfers will be calculated simultaneously and will net to zero in each market in each State. Under the balanced payment transfer approach, we believe we must calculate risk adjustment transfers for issuers that fail to provide data in a timely fashion into the risk adjustment payment transfer formula so that compliant issuers are not penalized. If issuers that would otherwise be subject to risk adjustment charges do not comply with these standards, payments to compliant issuers would be smaller and charges owed by compliant issuers would be larger.

Therefore, in §153.740(b), we propose that if an issuer of a risk adjustment covered plan fails to establish a dedicated distributed data environment or fails to provide HHS with access to risk adjustment data in such environment by April 30th of the year following the applicable benefit year in accordance with §153.610(a), §153.700, §153.710, or §153.730, such that HHS cannot apply its Federally certified risk adjustment methodology to calculate the plan's risk adjustment payment transfer amount in a timely fashion, HHS would assess a default risk adjustment charge. We note that delaying our calculation of risk adjustment payment transfers in a market in a State until all risk adjustment covered plans submit complete risk adjustment data would weaken the integrity of the April 30th data submission deadline and would jeopardize related deadlines for the risk corridors and MLR programs. We seek comment on our proposed default charge approach. We intend to provide future guidance on any applicable review processes available to those issuers for whom we propose to assess a default charge.

We are considering two different methods for calculating the default risk adjustment charge. One option would be to use the highest per-member-per-month charge among risk adjustment covered plans in a risk pool in the market in the plan's geographic rating area. A second option would be to use a per-member-per-month default charge that is two standard deviations above the mean charge in the market in the plan's geographic rating area. With respect to this second option, we believe that a two standard deviation calculation will adequately encourage compliance with the applicable data requirements while remaining tied to the market realities of the applicable geographic rating area.

In order to calculate a plan's risk adjustment payment transfer amount, we must consider the enrollment data of the plan. As such, if a risk adjustment covered plan fails to provide HHS with enrollment data, we propose that the default charge would be based on the average enrollment in the State market. If enrollment data is provided, we propose that the default charge would be based on average annual enrollment for the plan in a risk pool in the State market. We seek comment on these methods, other appropriate methods for calculating a default risk adjustment charge, and other sources of data HHS could use to determine enrollment data for non-compliant issuers, such as MLR or NAIC filings, or information supplied by a State Department of Insurance (DOI). We also seek comment on whether to allocate a non-compliant issuer's default charge to issuers in the market as part of payments and charges in the concurrent benefit year, during a subsequent benefit year, or sometime between annual payments and charges processes.

D. Part 155 - Exchange Establishment Standards And Other Related Standards Under The Affordable Care Act

1. Subpart A – General Provisions

a. Definitions (§ 155.20)

Section 1311(b) of the Affordable Care Act provides States with the opportunity to establish and operate an Exchange that both facilitates the purchase of QHPs and provides for the establishment of a SHOP. Previously, we have interpreted this provision to mean that a State must elect to carry out both these functions in order to establish an “Exchange” in accordance with the Affordable Care Act.²⁰ However, since we advanced that interpretation of the statute, some States in which HHS would otherwise operate both the individual market Exchange and the SHOP have expressed a desire to establish and operate only a SHOP, and not to establish and operate an individual market Exchange. In light of HHS’s limited resources, and these States’ willingness to take on operation of the SHOP-specific functions required by the Affordable Care Act, we now interpret sections 1311(b) and 1321 of the Affordable Care Act to permit a State to elect to establish just a SHOP.²¹ This interpretation is supported by the language in section 1311(b)(2) of the Affordable Care Act, which contemplates the separate operation of the individual market Exchange and the SHOP under different governance and administrative structures, because it permits the individual market Exchange and SHOP to be merged only if the State has adequate resources to assist both populations (individuals and small employers) as a merged entity. It is also supported by section 1321(c) of the Affordable Care Act, which provides that if a State will not have “any required Exchange operational” the Secretary shall “establish and operate such Exchange” (emphasis added). Thus, under the interpretation we now

²⁰ See Exchange Establishment Rule, 77 FR at 18395, *see also id.* at 18314, 18316, and 18326.

²¹ We previously signaled our intent to propose this approach through rulemaking. See <http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/shop-marketplace-5-10-2013.pdf>

propose, if the State will establish only a SHOP, and will not operate the individual market Exchange, the Secretary must establish and operate the individual market Exchange.

We propose to amend 45 CFR 155.20 to reflect this new flexibility for States by modifying the definition for “Exchange.”

Exchange

We propose that “Exchange” would mean a governmental agency or non-profit entity that meets the applicable standards of Part 155 and makes QHPs available to qualified individuals and/or qualified employers. Unless otherwise identified, under the proposed definition this term would include an Exchange serving the individual market for qualified individuals and a SHOP serving the small group market for qualified employers, regardless of whether the Exchange is established and operated by a State (including a regional Exchange or subsidiary Exchange) or by HHS.

We also clarify that we intend the phrase “meets the applicable standards of this part” in the proposed amendment to the definition to refer to any applicable standard of Part 155, including but not limited to the proposed amendments to §§ 155.100, 155.105, and 155.200 discussed below, and the special rules applicable to regional Exchanges pursuant to § 155.140 (together with the proposed amendments to that section). Pursuant to the proposed amendment to the definition, there could be several types of Exchanges operating in a State, all of which would meet the regulatory definition, so long as the applicable standards of Part 155 were met. We further clarify that there must be an individual market Exchange and a SHOP in each State. We invite general comments on this proposal, including on whether we should amend provisions of Part 155 in addition to those we propose amending here to provide States with the flexibility to establish and operate only a SHOP.

We are also adding a new definition for “issuer customer service representative.”

Issuer customer service representative

For the same reasons that we propose adding §155.415 below, we propose to define an “issuer customer service representative” to mean an employee, contractor, or agent of a QHP issuer that provides assistance to applicants and enrollees, but is not licensed as an agent, broker, or producer under State law.

We are also making a clarification regarding the definition of “qualified health plan.”

Qualified health plan

With regard to the definition of “qualified health plan” in the preamble to the Exchange Establishment Rule, we stated that health plans that are “substantially the same” as a QHP are treated as the same QHP for purposes of 45 CFR 156.255(b), which requires a QHP issuer to charge the same premium rate for each QHP of the issuer without regard to whether the plan is offered through an Exchange or whether the plan is offered directly from the issuer or through an agent. In the Premium Stabilization Rule, we offered similar guidance with respect to which plans offered outside the Exchange would be considered the same QHP for purposes of the risk corridors program (77 FR 17237), and stated that HHS might clarify this standard in future rulemaking or guidance.

We are now proposing to specify that, for a plan offered outside the Exchange to be considered the same plan as one that is certified as a QHP and offered through the Exchange, among other things, the benefits package, provider network, service areas, and cost-sharing structure of the two offerings must be identical. Under this proposal, a plan that is certified as a QHP and that meets the requirements for sale in the applicable market outside of the Exchange is a QHP for the entire applicable market within a State. We note that nothing in this proposal

would relieve an issuer of a plan that has been certified as a QHP by the Exchange from the requirement to charge the same premium for the QHP sold to consumers outside of the Exchange (pursuant to sections 1301(a)(C)(iii) of the Affordable Care Act and 45 CFR 156.255(b) and 45 CFR 147.104).

We also propose to clarify that a plan sold to consumers outside of the Exchange would only be subject to the risk corridors program if it is the same as a QHP actually offered by that issuer on the Exchange. We believe that sections 1301(a)(1)(A) and 1311(e) of the Affordable Care Act, and the definition of a QHP at 45 CFR 155.20, contemplate certification of a QHP for offer on the Exchange, so that (with the exception of stand-alone dental plans) a plan sold to consumers exclusively outside of the Exchange could not obtain QHP certification. We note that the EHB final rule²² outlined an arrangement where health insurance issuers could offer a health plan to an individual without the pediatric dental EHB if the issuer is reasonably assured that the individual has obtained the EHB through an Exchange-certified stand-alone dental plan (78 FR 12853).

We believe that the proposed policy set forth in this section is consistent with the intent of the statute and existing regulations with respect to the offering and certification of QHPs, and helps to maintain the integrity of the risk corridors program, which we believe is intended primarily to stabilize premiums of plans offered through the Exchanges.

We request comment on all aspects of this approach, particularly on issues that may be raised by this approach for State requirements for product or policy form filings, including

²² Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation (78 FR 12834) (February 25, 2013)

filings for coverage riders (whether mandatory or optional), State-required benefits, and State-required service areas (including tiered networks within service areas). We seek comment on whether the criteria laid out above – benefits, provider network, service areas, and cost-sharing structure – are the proper criteria for determining whether offerings are the same plan, and whether additional criteria such as allowances for de minimis variations that do not change plan actuarial value should be included, or whether no criteria are necessary because it is clear from State oversight processes when a plan is the same plan or a different plan. We also seek comment on how this proposed approach would affect what is considered a new plan offering, and the potential impact of this proposal on plan renewals. Finally, we seek comment on the operational feasibility of the proposed requirements, particularly with regard to issuers in the small group market.

2. Subpart B – General Standards Related to the Establishment of an Exchange

a. Establishment of a State Exchange, Approval of a State Exchange, (§§ 155.100, 155.105, and 155.140)

Consistent with our proposed amendments to the definition of “Exchange” in § 155.20, we propose to amend § 155.100 to permit a State to operate only a State-based SHOP while the individual market Exchange is operated as an FFE. This proposed amendment would permit a State to elect to establish and operate only the SHOP and to focus on effective implementation of that program. A State that is electing to establish only a SHOP must establish an Exchange entity – consistent with section 1311(d)(1) of the Affordable Care Act and §§155.100(b) and 155.110 – to perform only the SHOP functions.

We considered whether to propose allowing a State to establish and operate only the individual market Exchange while HHS operates the SHOP, but decided not to do so for the

reasons described below. Accordingly, under the proposed amendments, a State could not elect to establish and operate just the individual market Exchange. We believe that building and operating the SHOP is an excellent way for a State to move towards operating both a SHOP and an individual market Exchange. Further, while a State operating a SHOP has a variety of options available to ensure a robust choice of QHPs and issuers, for example, through its direct regulation of the individual and small group insurance markets, these options may not be available to HHS because they would require HHS to go beyond its traditional market role under the PHS Act. The only tool HHS can rely upon for incentivizing issuer participation in the SHOP is the QHP certification process, and this tool is a limited one if the individual market Exchange is operated by the State.²³ Additionally, if the State has already built the structure and systems needed to run an individual market Exchange, it would be inefficient and burdensome for HHS to step in and build those functions solely so that it can operate the SHOP, when the State would be in a better position to operate both Exchanges. Therefore, we have not proposed that a State be allowed to operate an individual market Exchange while the Department is responsible for the operation of an FF-SHOP in the State. As discussed above, we seek comment generally on this proposal, and particularly on this aspect of it.

We propose in §155.100(a)(3) that a State that has timely applied for certification of an Exchange for 2014, and that has received conditional approval for its application, would be able to modify its Blueprint pursuant to 45 CFR §155.105(e) to exclude the operation of the individual market Exchange functions for 2014.²⁴ Because such States have been preparing to

²³ See, HHS Notice of Benefit and Payment Parameters for 2014 Proposed Rule, 77 FR 73185.

²⁴ In guidance, we have previously signaled our intent to propose this approach through rulemaking. See Small Business Health Options Program (SHOP)-Only Marketplace FAQs (May 10, 2013).

establish and operate both the individual market and SHOP Exchanges, they would be in a position to establish and operate just the SHOP in 2014. In contrast, States that have not received conditional approval to operate both Exchanges, but which want to operate only a SHOP for 2014, would have to develop a fully functioning SHOP by the time open enrollment begins on October 1, 2013; this is a compressed time frame to accomplish establishment and full operation. Therefore, under this proposed rule, States that have not received conditional approval for 2014 may not exercise the option to operate only a SHOP for the 2014 plan year. For the 2015 plan year and beyond, we would consider new Blueprints from States proposing to operate only the SHOP, pursuant to 45 CFR §155.106. We seek comment on this proposed approach.

We further propose to amend §155.105 so that the Exchange approval criteria set forth therein would be consistent with the Exchange operational models now proposed in §§155.20, 155.100, and 155.200, and to permit HHS to operate only a FFE that will make QHPs available to qualified individuals when a State has elected to operate only an Exchange providing for the establishment of a SHOP pursuant to proposed §155.100(a)(2). In paragraphs (b)(1) and (b)(2) we clarify that a State establishing and operating only a SHOP would have to perform the minimum functions described in subpart H and all applicable references to other subparts contained therein, and need not comply with other provisions that by their express terms apply only to an individual market Exchange.

We propose to amend paragraph (f) to clarify that where a State has elected to establish and operate only a SHOP, the FFE must meet the requirements set forth in §§155.120(c),

155.130, and subparts C, D, E, and K of this part; however, it need not implement the standards for the establishment of a SHOP described in subpart H. We seek comment on this proposal.

We are also proposing an amendment to §155.105(f) to clarify that the regulatory provisions that will apply in an FFE include the nondiscrimination requirements of §155.120(c). Section 155.120(c), as written, applies to all Exchanges, and its previous omission from the list of provisions referenced in §155.105(f) was inadvertent.

We propose to amend §155.140 to clarify how a subsidiary or regional Exchange may operate in light of the proposed amendments to permit a State to establish and operate an Exchange only providing for the establishment of a SHOP. Under this proposal, a State establishing and operating only a SHOP could still establish subsidiary SHOP Exchanges. Multiple States that wish to establish and operate only SHOPS could still form a regional Exchange only providing for the establishment of a SHOP across the region covered by the participating states.

Previously, we had created the standards for regional and subsidiary Exchanges such that the geographic area served by such Exchanges must be the same for the individual market Exchange and the SHOP.²⁵ We propose in paragraph (c)(2)(ii) to generally preserve this standard, except in the case of an Exchange established pursuant to proposed §155.100(a)(2).

In paragraph (c)(2)(ii)(A), we propose that in the case of a regional Exchange established pursuant to proposed §155.100(a)(2) to provide only for the establishment and operation of a SHOP, the regional SHOP would be required to encompass a geographic area that matches the

²⁵ See Exchange Establishment Rule, 77 FR 18322.

combined geographic areas of the individual market Exchanges established by HHS to serve the States establishing the regional SHOP.

In paragraph (c)(ii)(B), we propose that in the case of a subsidiary Exchange established pursuant to §155.100(a)(2) to provide only for the establishment and operation of a SHOP, the combined geographic area of all subsidiary SHOPS established by the State would be required to encompass the geographic area of the individual market Exchange established by HHS to serve the State.

In addition, under 45 CFR 153.310(a), a State that elects to operate an Exchange is eligible to establish a risk adjustment program using a methodology that has obtained federal certification. We are considering whether a State that elects to operate a SHOP but not an individual market Exchange under the proposed approach described above should be eligible to establish a risk adjustment program, and in particular whether such a State should be eligible to establish a risk adjustment program only for the small group market or should be required to establish the program for both markets. We seek comment on this issue.

3. Subpart C – General Functions of the Exchange

a. Functions of an Exchange (§155.200)

Consistent with the proposed amendments described above to §§155.20, 155.100, 155.105, and 155.140, which permit a State to operate only an Exchange providing for the establishment of a SHOP, in §155.200 we propose that a State operating only an Exchange which provides for the establishment of a SHOP need perform only the minimum functions described in subpart H and all applicable provisions of other subparts referenced therein. Under such circumstances, the Exchange operated by HHS need not perform the minimum functions related to the establishment of a SHOP.

b. Ability of States to Permit Agents and Brokers to Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs (§155.220)

Section 1312(e) of the Affordable Care Act authorizes the Secretary to establish procedures that permit agents and brokers to enroll qualified individuals and qualified employers in QHPs through an Exchange, and to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions, to the extent allowed by States.

In 45 CFR 155.220(c), 155.220(d), and 155.220(e), we established general Exchange standards that agents and brokers must meet to assist individuals in enrolling in QHPs and applying for advance payments of the premium tax credit and cost-sharing reductions, including registration, training, compliance with the privacy and security standards adopted by the Exchange, compliance with applicable State law, and execution of an agreement with the Exchange. Section 155.220(c)(3) established additional standards for agents and brokers that use Internet Web sites to assist qualified individuals in enrolling in a QHP.

In CMS's guidance titled "Role of Agents, Brokers, and Web-brokers in Health Insurance Marketplaces,"²⁶ we further clarified that in States where an FFE is operating, agents or brokers assisting individuals in selecting or enrolling in individual market QHPs through an FFE may use one of two pathways. First, an agent or broker may use a QHP issuer's Internet Web site to assist or enroll individuals, if the agent or broker has a relationship with an issuer, and the issuer has direct enrollment capabilities. Alternatively, an agent or broker may use an FFE Internet Web site to assist individuals.

²⁶ Role of Agents, Brokers, and Web-brokers in Health Insurance Marketplaces, (May 1, 2013). Available at: <http://www.cms.gov/CCHIO/Resources/Regulations-and-Guidance/Downloads/agent-broker-5-1-2013.pdf>

Regardless of what pathway they use, all agents and brokers must register with CMS before they may assist qualified individuals in enrolling in individual market coverage through an FFE. Once an agent or broker has completed the registration process, which includes undergoing basic CMS identity proofing, completing an FFE training course, and signing an agreement with CMS, he or she will receive an active FFE user identification number, which will be the agent's or broker's unique identifier in an FFE. This would allow CMS to monitor and oversee the activities of agents and brokers in an FFE, which is discussed in more detail later in this section, and would also facilitate payment for agent and broker services from issuers.

Web-broker Policies and Procedures

Section 155.220(c)(3) establishes standards that apply if an agent or broker uses its publicly-facing Internet Web site to assist individuals in selecting or enrolling in a QHP through the Exchange. Agents or brokers who do so are referred to as "Web-brokers" for the purposes of this proposed rule. We propose amending §155.220(c)(3)(i), which currently requires that a Web-broker meet all standards for disclosure and display of QHP information contained in §§155.205(b)(1) and 155.205(c). In particular, §155.205(b)(1) requires the display of standardized comparative information on each available QHP, including its: (a) premium and cost-sharing information; (b) summary of benefits and coverage; (c) metal level (bronze, silver, gold, or platinum); (d) enrollee satisfaction survey results; (e) quality ratings; (f) medical loss ratio, (g) transparency of coverage measures, and (h) provider directory.

After taking into consideration concerns from issuers, we propose to limit the Web-broker's obligation to disclose and display the QHP information to all the information provided to the Web-broker by the Exchange or directly by the issuer. We recognize that an Exchange may not be able to provide all Web-brokers with certain data elements necessary to meet the

§155.205(b)(1) requirements, such as premium and rate information, depending upon confidentiality requirements, the extent to which Web-brokers are appointed by individual QHP issuers, and State laws regarding agent and broker appointments. We also recognize that some of the required data, such as quality rating and enrollee satisfaction survey results, may not be available in the first year of Exchange operations, in which case Web-brokers would also not need to display this information. We seek comment on whether this provision should be limited to FFEs.

We note that we do not intend this amendment to alter Web-brokers' obligations to meet all existing standards for disclosure and display of QHP information contained in §155.205(c), regardless of the availability of QHP issuer information from issuers or the Exchange. Additionally, the Web-broker should display all information provided by the Exchange or an issuer in a manner that is as consistent with the requirements in §155.205(b)(1) as possible. We solicit comments on how to monitor this provision to ensure that Web-brokers display QHP information received by an Exchange or QHP issuers in a manner consistent with the QHP information displayed on an Exchange Web site.

Even if a Web-broker is unable to display certain QHP information identified in §155.205(b)(1) because it is not provided by the Exchange or a QHP issuer, it must still display a list of all available QHPs for the consumers to view, as required by §155.220(c)(3)(ii). We also propose that, to address situations where the Web-broker is unable to display certain QHP information identified in §155.205(b)(1), the Web-broker must display a link to the Exchange Web site so the consumer may obtain the additional information.

Instead of modifying only §155.220(c)(3)(i), we considered removing §155.220(c)(3)(ii), which requires Web-brokers to provide consumers with the ability to view all QHPs offered

through the Exchange. We decided not to propose this approach so that the consumer would be aware of all available QHP options, even if some of the specific plan details may not be available on the Web-broker's Internet Web site. We invite comment on this proposal.

We also propose to amend §155.220(c)(3) by adding a new paragraph (c)(3)(vii), which would require Web-brokers' Internet Web sites in an FFE to prominently display language notifying consumers that: (a) the Web-broker's Internet Web site is not an FFE Web site; (b) the Web-broker's Web site might not display all QHP data available on the Exchange Web site; (c) the Web-broker has entered into an agreement with HHS pursuant to § 155.220(d); and (d) the Web-broker agrees to comply with standards specified in § 155.220(c) and (d). We believe that this additional standard is in the best interest of the consumers in an FFE, as it will help consumers distinguish between an FFE Web site and the Internet Web sites of Web-brokers, and it will inform consumers that agents and brokers must comply with FFE standards and requirements before they can assist and enroll consumers. We welcome comments on this proposal. HHS expects to make available an application programming interface that would permit Web-brokers to use their public-facing Internet Web sites to assist consumers in enrolling through individual market QHPs offered through an FFE ("FFE API"). An FFE API would allow a person seeking to enroll in a QHP to initiate his or her shopping experience on a Web-broker's Internet Web site, connect securely to an FFE Web site to complete the eligibility application and determination process, and return securely to the Web-broker's Internet Web site compare and select QHPs.

We understand that some Web-brokers may enter into arrangements with other agents and brokers under which those agents and brokers would be able to enroll qualified individuals in an FFE through the Web-broker's Internet Web site. We are concerned about these

arrangements that would allow other agents and brokers to use the Web-broker's connection to HHS, because they would not require the agent or broker to be a party to the Web-broker's agreement with HHS, or to become an employee or subcontractor of the Web-broker. We are considering prohibiting such arrangements outright, in part because such entities are not a party to the Web-broker's agreement with HHS. However, we also want to make sure that agents and brokers have many possible avenues to participate in the FFE. If we do not prohibit such arrangements, we believe that a Web-broker should not be able to enter into these arrangements unless the Web-broker ensures that the agent or broker using its connection to HHS agrees to comply with the same FFE standards and requirements applicable to Web-brokers under §155.220(c) and (d). We therefore propose to add a new § 155.220(c)(4) that would require any Web-broker who makes an Internet Web site available to other agents and brokers for this purpose to require as a condition of agreement or contract that the agent or broker accessing and using the Internet Web site complies with §155.220(c) and (d). We also propose that the Web-broker would be required to provide to HHS a list of agents and brokers who are under such arrangements, and that the Web-broker be required to ensure that the agent or broker accessing or using the Internet Web site would be required to comply with the policies that the Web-broker would be required to develop under §155.220(d)(4), as proposed below. Because we would require the agent or broker accessing or using the Web-broker's connection to comply with §155.220(d), that agent or broker would also have to enter into a Web-broker agreement with HHS. If the agent or broker accessing or using the Internet Web site fails to comply with either provision, both parties to the arrangement would be found to be noncompliant with the regulatory requirements, and HHS would have cause to terminate its agreements with both

parties. We seek comments on this circumstance and proposal, on whether these arrangements should be prohibited outright, and on whether there are other options to consider.

Agent and Broker Policies and Procedures on Privacy and Security in an FFE

Section 155.220(d)(3) currently directs all agents or brokers assisting qualified individuals with enrollment in QHPs to comply with the Exchange privacy and security requirements. We propose to establish a new standard in §155.220(d)(4) requiring agents and brokers assisting or enrolling consumers in the individual market of an FFE to establish policies and procedures implementing the privacy and security standards pursuant to §155.220(d)(3); to train their employees, representatives, contractors, and agents with regard to those policies and procedures on a periodic basis; and to ensure that their employees, representatives, contractors, and agents comply with those policies and procedures. Because agents and brokers will have access to PII provided by consumers we want to ensure that the agents and brokers have appropriate procedures, training and monitoring safeguards in place to protect PII. We invite comments on the appropriate frequency of retraining requirements.

Standards for Agent and Broker Agreement Termination in an FFE

We propose adding a new §155.220(f), which would require agents and brokers who wish to terminate their agreement with an FFE to send to HHS a 30-day advance written notice of the intent to terminate. This notice would also include the intended date of termination. If the notice does not specify a date of termination, or the date is not acceptable to HHS, HHS may set a date that will be no less than 30 days from the date of the agent or broker's notice of termination. We believe that this additional standard would be in the best interest of FFE consumers, as the 30-day pre-termination period would allow agents and brokers to complete any application or enrollment activity initiated prior to the notice. As of the date of termination, an

agent or broker would not be able to conduct business in an FFE, although the agent's or broker's related duty to protect and maintain the privacy and security of PII it has created, collected, accessed, or acquired during its period of relationship with an FFE would survive the termination. We are considering whether to require such agents and brokers to also directly notify their clients of the termination plan during the pre-termination period. We welcome comment on this proposal.

We also propose to establish new standards for agents and brokers in the FFEs, so that agents and brokers that register with an FFE have a clear understanding of the rights and standards governing their participation in an FFE. In new section §155.220(g), we propose the standards under which HHS may terminate an agent's or broker's agreement with an FFE for cause.

In §155.220(g)(1), we propose that HHS may pursue termination with notice of an agent's or broker's agreement with an FFE executed pursuant to §155.220(d) if, in HHS's determination, a specific finding of noncompliance or pattern of noncompliance is sufficiently severe. Under this proposal, termination of the agreement with notice would mean that after a 30-day opportunity to cure, HHS would take necessary steps to prohibit an agent or broker from assisting or enrolling individuals in an individual market QHP offered through an FFE, or a Web-broker's ability to securely exchange information with HHS.

In §155.220(g)(2), we propose that an agent or broker would be considered noncompliant if HHS finds that the agent or broker violated: (a) any standard specified under §155.220; (b) any term or condition of its agreement with the FFE, including but not limited to the FFE privacy and security standards; (c) any applicable State law; or (d) any other applicable Federal law.

We propose that if HHS finds noncompliance or patterns of noncompliance to be sufficiently severe, such a finding would form the basis for a termination for cause. We believe that HHS must maintain the ability to terminate an agent's or broker's agreement for cause to protect the interest of consumers in cases of severe violations and patterns of violations, particularly violations with respect to privacy and security protections. Specific findings of noncompliance that HHS might determine to be sufficiently severe to warrant termination for cause would include, but not be limited to, violations of the Exchange privacy and security standards. Patterns of noncompliance that HHS might determine to be sufficiently severe to warrant termination for cause would include, for example, repeated violations of any of the standards set forth in §155.220 for which the agent or broker was previously found to be noncompliant. We seek comment on this proposal and on other circumstances that should result in an HHS termination for cause.

Prior to pursuing the termination of an agent's or broker's agreement for cause, we are considering implementing informal procedures, which may be published in future sub-regulatory guidance. The informal procedures would allow agents and brokers, at HHS discretion, to resolve certain noncompliance issues within a time period determined reasonable by HHS. Through this informal process, HHS would notify an agent or broker of the reason for the potential termination, the potential consequences of continued noncompliance, and any applicable administrative procedures. However, HHS would retain the right to bypass these informal procedures.

Upon identification of a sufficiently severe violation under the proposed §155.220(g)(2), HHS would formally notify the agent or broker of the specific finding of noncompliance or pattern of noncompliance, as proposed in §155.220(g)(3). The agent or broker would then have

a period of 30 days from the date of the notice to correct the noncompliance to HHS's satisfaction, through good-faith efforts. If after 30 days, the noncompliance is not appropriately addressed, HHS may terminate the agreement for cause. In §155.220(g)(4), we propose that termination for cause would result in the loss of the ability to assist individuals enroll in QHPs and transact data with HHS, including transactions through the FFE API. We believe this approach would provide an opportunity for agents and brokers to remedy any noncompliance issue in advance of a potential termination for cause.

We request comment on the informal resolution approach we are considering implementing through future sub-regulatory guidance, specifically on whether we should consider any alternative proposals. We also solicit comment on the appropriate time length for a cure period, and on whether we should include a provision permitting HHS to terminate an agent's or broker's agreement immediately and permanently for cause if findings of noncompliance are sufficiently egregious. We are also considering an option that would allow HHS to immediately but temporarily suspend an agent or broker by prohibiting the agent or broker from assisting individuals to enroll in a QHP offered through the FFE and/or ability to securely exchange information with HHS, including through the FFE API, without advance notice. We are considering this option because there may be instances where a specific violation could pose immediate harm to consumers or to HHS's ability to properly administer the FFE. Under this scenario, as soon as possible following the temporary suspension, HHS would notify the agent or broker of HHS's action and the noncompliance issue. If the agent or broker satisfactorily addresses the issue, HHS would notify the agent or broker that the temporary suspension had been lifted. We request comments on this approach, and the circumstances under which it would be needed.

We further propose a new section §155.220(h) to establish a one-level process through which an agent or broker may request reconsideration of HHS's decision to terminate the agreement for cause. In §155.220(h)(2), we propose that an agent or broker must submit a request for reconsideration to an appropriate HHS designee ("reconsideration entity") within 30 calendar days of the date of the notice in order to obtain a reconsideration. In §155.220(h)(3), we propose that the reconsideration entity would provide the agent or broker with a written reconsideration decision within 30 calendar days of the date it receives the request for reconsideration. This decision would constitute HHS's final determination.

We believe this approach would afford agents and brokers an opportunity to furnish any facts and information that might not have been considered as part of HHS's decision to terminate the agreement for cause, and to provide due process. We intend to provide future guidance on the manner and form in which agents and brokers should present requests for reconsideration, HHS's designation of an appropriate reconsideration entity, and additional procedures related to agent and broker revocation and reconsideration. We invite comments on this reconsideration proposal.

We expect that States will continue to license and monitor agents and brokers, and will continue to oversee and regulate all agents and brokers, both inside and outside of the Exchange. We expect that all State laws related to agents and brokers, including State laws related to appointments, contractual relationships with issuers, and licensing and marketing requirements, will continue to apply. Therefore, to avoid duplication of oversight activities related to agents and brokers enrolling or assisting consumers through an FFE, HHS will focus its oversight activities primarily on ensuring that agents and brokers in an FFE meet the standards outlined in

§155.220. In particular, HHS plans to focus its oversight efforts on protecting the privacy and security of PII, to the extent this is not already covered under existing State or Federal law.

Prior to releasing additional guidance on agent and broker activities in the FFE, we intend to collaborate with State DOIs to further develop standard operating procedures for an FFE that will be critical to HHS oversight of agents and brokers working with an FFE. We encourage comment on the information required to carry out these activities, and on any existing definitions, timeframes, or procedures described in our proposed amendments to §155.220.

c. Electronic Information Exchange with Covered Entities (§155.270)

Section 155.270 of 45 CFR directs Exchanges that perform electronic transactions with a covered entity to use standards, implementation specifications, operating rules, and code sets adopted by the Secretary in 45 CFR parts 160 and 162. When 45 CFR 155.270 was finalized in its current form, HHS believed that the HIPAA standard transactions, as defined in 45 CFR Parts 160 and 162, were the most appropriate standards for transmitting information electronically between Exchanges and issuers. Since then, the Accredited Standards Committee X12, also known as “ASC X12,”²⁷ which governs the electronic transactions addressed in 45 CFR 160 and 162, has determined that the current transaction used to communicate payment-related information, the HIPAA ASC X12 005010X218 (820), cannot provide the program-level payment information necessary for the risk adjustment, reinsurance, and risk corridors programs, and therefore does not meet the business requirements of the Affordable Care Act programs. As a result, the ASC X12 standards body developed and finalized the ASC X12 005010X306 (820), referred to as the “HIX 820.” The HIX 820 has the same security and technical requirements as

²⁷ ASC X12 is chartered by the American National Standards Institute. See, <http://www.x12.org/>.

HIPAA standards, but it is a new implementation of the transaction, so it has not yet been adopted by the Secretary in 45 CFR parts 160 and 162. We believe that the HIX 820 is the most appropriate method for transmitting payment-related information between the Exchange and a covered entity. For this reason, and to provide for flexibility should similar situations arise in the future, we propose to amend §155.270 to specify that to the extent that an Exchange performs electronic transactions with a covered entity, an Exchange must use standards, implementation specifications, operating rules, and code sets that are adopted by the Secretary in 45 CFR parts 160 and 162 or that are otherwise approved by HHS. We further propose to approve the HIX 820 transaction for transmitting payment-related information between the Exchange and a covered entity. We seek comment on this proposal.

d. Oversight and Monitoring of Privacy and Security Requirements (§155.280)

In §155.280, consistent with section 1411(g) and (h) of the Affordable Care Act, we propose that HHS will monitor any individual or entity who would be subject to the privacy and security requirements as established and implemented by an Exchange under §155.260.

We propose in §155.280(a) that HHS will oversee and monitor the FFEs and non-Exchange entities associated with FFEs for compliance with the privacy and security standards established and implemented by the FFEs pursuant to §155.260 for compliance with those standards. HHS will monitor State Exchanges for compliance with the privacy and security standards established and implemented by the State Exchanges pursuant to §155.260. In addition, we propose that State Exchanges will oversee and monitor non-Exchange entities associated with the State Exchange for compliance with the standards implemented by the State Exchange pursuant to §155.260.

In §155.280(b), we propose the oversight activities that HHS may conduct in order to ensure adherence to the privacy and security requirements in §155.260. These may include, but are not limited to, audits, investigations, inspections and any reasonable activities necessary for appropriate oversight of compliance with the Exchange privacy and security standards as permitted under sections 1313(a)(2) and (a)(3) of the Affordable Care Act.

In §155.280(c)(1)(i) and (ii), we propose definitions for the terms “incident” and “breach” as they apply to privacy and security. We considered but declined to use the definitions for these terms provided under the HIPAA regulations because the protected health information (PHI) that triggers the HIPAA requirements is considered a subset of PII,²⁸ and we believe that the HIPAA definitions would not provide broad enough protections to satisfy the requirements under the Privacy Act of 1974 (5 U.S.C. 552a), the e-Government Act of 2002 (Pub. Law 107-347), other laws to which HHS is subject, or the expectations of the other Federal agencies that will be providing PII to facilitate Exchange eligibility determinations. We considered the definitions and explanations for “incident” in the following publications: OMB Memorandum M-06-19, OMB Memorandum M-07-16, and the National Institute of Standards and Technology Special Publication 800-61, and propose that “incident” would mean, the act of violating an explicit or implied security policy, which includes attempts (either failed or successful) to gain unauthorized access to a system or its data, unwanted disruption or denial of service, the unauthorized use of a system for the processing or storage of data; and changes to system hardware, firmware, or software characteristics without the owner's knowledge, instruction, or

²⁸ Compare the definitions of individually identifiable health information and protected health information at 45 CFR §160.103 and the definition of PII in Office of Management and Budget (OMB) Memorandum M-07-16 (see 77 FR 18340 for an explanation of how the OMB definition of PII applies to Exchanges).

consent. We propose that the definition for “breach” be the same as the definition in OMB Memorandum M-07-16, Safeguarding and Responding to the Breach of Personally Identifiable Information, which defines “breach” as the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, unauthorized access, or any similar term referring to situations where persons other than authorized users and for an other than authorized purpose have access or potential access to personally identifiable information, whether physical or electronic. We welcome comment on the use of these definitions for incident and breach as they relate to PII.

In §155.280(c)(2) we propose that in the event of an incident or breach, the entity where the incident or breach occurs would be responsible for reporting and managing it according to the entity’s documented incident handling or breach notification procedures. We believe that incident handling and breach notification procedures should be among the written policies and procedures required for Exchanges under §155.260(d). Non-Exchange entities associated with the Exchanges would be required to have policies and procedures in place for reporting breaches and incidents as a condition of the contracts or agreements that are required under §155.260(b). Under §155.260(a)(3)(viii), Exchanges would also be required to establish accountability standards that would include the development and implementation of policies and procedures including incident handling and breach notification procedures.

In §155.280(c)(3) we propose that FFEs, non-Exchange entities associated with FFEs, and State Exchanges must report all privacy and security incidents and breaches to HHS within one hour of discovering the incident or breach. We also propose that a non-Exchange entity associated with a State Exchange must report all privacy and security incidents and breaches to the State Exchange with which they are associated. We welcome comment on these proposals.

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

a. Eligibility Process (§155.310)

In our consultations with states and in the operational development of Exchanges, we have identified with States the need to establish a standardized process for handling applications that are submitted without information that is necessary for determining eligibility. It is our understanding that States have an existing process for handling incomplete applications for other programs, such as Medicaid, and may want to establish a consistent process for handling incomplete applications submitted to the Exchange. Accordingly, the language of this proposed regulation is designed to provide flexibility to States so they may align this process with Medicaid and CHIP. Further, we intend to work with States to implement these procedures and in 2014 to accommodate States with processes established for handling incomplete applications that does not match the process described in these regulations.

We are adding §155.310(k), to provide that if an application filer does not provide sufficient information on an application for the Exchange to conduct an eligibility determination for enrollment in a QHP through the Exchange, or for insurance affordability programs (if the application includes a request for an eligibility determination for insurance affordability programs), the Exchange will provide notice through the eligibility determination notice described in 45 CFR 155.310(g). The notice would indicate that information necessary to complete an eligibility determination is missing, specifying the missing information, and include instructions on how to provide the missing information. We propose that the Exchange will provide the applicant with a period of no less than 15 days and no more than 90 days from the date this notice is sent to the applicant to provide the necessary information. Further, we propose

that during this period, the Exchange will not proceed with the applicant's eligibility determination or provide advance payments of the premium tax credit or cost-sharing reductions, unless an application filer has provided sufficient information to determine his or her eligibility for enrollment in a QHP through the Exchange, in which case the Exchange must make such a determination for enrollment in a QHP. We propose that the Exchange may make an eligibility determination for enrollment in a QHP through the Exchange if an applicant has provided sufficient information to make an eligibility determination for enrollment in a QHP through the Exchange. For example, if there is sufficient information to determine eligibility for enrollment in a QHP, but an applicant who requested an eligibility determination for insurance affordability programs has not provided information regarding employer-sponsored coverage, which is needed to determine eligibility for advance payments of the premium tax credit and cost-sharing reductions, the Exchange will determine the applicant's eligibility for enrollment in a QHP through the Exchange but may not provide advance payments of the premium tax credit or cost-sharing reductions.

We believe this process is consistent with current Medicaid and CHIP policies regarding the process for handling incomplete applications. We propose a flexible timeframe of no less than 15 days and no more than 90 days. While we believe it does not benefit an applicant to have a long timeframe because no advance payments of the premium tax credits and cost-sharing reductions will be provided during the period, we understand that State Medicaid and CHIP agencies use periods similar to this length, and we also believe that it is important to allow flexibility for the Exchange to align with the time period for inconsistencies, which is a period of 90 days as specified in 45 CFR 155.315(f)(2)(ii). We note that the online and telephonic applications are structured to minimize situations in which an applicant can fail to provide

necessary information. Accordingly, we anticipate that this paragraph will be implicated most frequently with respect to paper applications. We seek comment on this proposal, including whether Exchange flexibility is appropriate; whether 15 days and 90 days are the right lower and upper limits; and whether additional language is needed to ensure coordination between the Exchange, Medicaid, and CHIP.

b. Verification of eligibility for minimum essential coverage other than through an eligible employer-sponsored plan (§155.320)

As finalized in the Exchange Establishment Rule, §155.320(b) specifies standards related to the verification of eligibility for minimum essential coverage other than through an eligible employer-sponsored plan. We propose to redesignate paragraph (b)(1) as (b)(1)(i) and (b)(2) as (b)(1)(ii) to consolidate the standards for Exchange responsibilities in connection with verification of eligibility for minimum essential coverage other than through an eligible employer-sponsored plan. In paragraph (b)(1)(i), we also propose to add the phrase “for verification purposes” to the end of existing text. This would clarify that HHS would provide a response to the Exchange to verify the information transmitted from the Exchange to HHS about an applicant’s eligibility for or enrollment in minimum essential coverage other than through an eligible employer sponsored plan, Medicaid, CHIP, or the Basic Health Program. The Exchange would submit specific identifying information to HHS and HHS would verify applicant information with information from the Federal and State agencies or programs that provide eligibility and enrollment information regarding minimum essential coverage. Such agencies or programs may include but are not limited to Veterans Health Administration, TRICARE, and Medicare. HHS will work with the appropriate Federal and State agencies to complete the appropriate computer matching agreements, data use agreements, and information exchange

agreements which will comply with all appropriate Federal privacy and security laws and regulations. The information obtained from Federal and State agencies will be used and redisclosed by HHS as part of the eligibility determination and information verification process set forth in subpart D of part 155.

In connection with the proposal to redesignate paragraph (b)(2) to paragraph (b)(1)(ii), we are not proposing any change to the text of the provision as previously finalized. Consistent with the authorizations for the disclosure of certain information under 42 CFR 435.945(c) and 457.300(c), this regulation provides for an Exchange to verify whether an applicant has already been determined eligible for coverage through Medicaid, CHIP, or the Basic Health Program, using information obtained from the agencies administering such programs.

Finally, we propose to add paragraph (b)(2) to provide that consistent with 45 CFR 164.512(k)(6)(i) and 45 CFR 155.270, a health plan that is a government program providing public benefits, is expressly authorized to disclose PHI, as that term is defined at 45 CFR 160.103, that relates to eligibility for or enrollment in the health plan to HHS for verification of applicant eligibility for minimum essential coverage as part of the eligibility determination process for advance payments of the premium tax credit or cost-sharing reductions. We intend for this provision to enable any health plan that is a government program within the scope of 45 CFR 164.512(k)(6)(i) to disclose the protected health information necessary for HHS to be able to verify of minimum essential coverage as required to conduct eligibility determinations for insurance affordability programs. We seek comment on this proposal.

c. Administration of Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions (§155.340)

We propose to amend §155.340 by adding paragraph (h), which sets forth additional requirements applicable when a State Exchange is facilitating the collection and payment of premiums to QHP issuers. We propose that if the Exchange discovers that it did not reduce an enrollee's premium by the amount of the advance payment of the premium tax credit in accordance with 45 CFR 155.340(g), the Exchange would be required to refund to the enrollee any excess premium paid by or for the enrollee. The Exchange would also notify the enrollee of the improper application of the advance payment of the premium tax credit no later than 30 calendar days after the Exchange discovers it. We note that an Exchange may provide the refund to the enrollee by reducing the enrollee's portion of the premium in the following month, as long as the reduction is provided no later than 30 calendar days after the Exchange discovers the improper application of the advance payment of the premium tax credit. If the Exchange elects to provide the refund by reducing the enrollee's portion of the premium for following month and the refund exceeds the enrollee's portion of the premium for the following month, then the Exchange would need to refund to the enrollee the excess, no later than 30 calendar days after the Exchange discovers the improper application of the advance payment of the premium tax credit. These provisions are similar to the policy we propose in §156.460, when a QHP issuer is collecting premiums directly from enrollees and fails to apply the advance payment of the premium tax credit to the enrollee's portion of the premiums. The parallel requirements are designed to ensure that all enrollees, regardless of whether a QHP issuer or the Exchange is collecting premiums, are afforded the same level of protection.

We are considering requiring the Exchange to provide to HHS for each quarter, in a manner and timeframe specified by HHS, a report detailing the occurrence of any improper application of the advance payment of the premium tax credit. We believe that it is important

that an Exchange timely address improper applications of the advance payments of the premium tax credit in order to mitigate potential harm to enrollees. However, we recognize that, given operational constraints, it may be difficult at this point for Exchanges to develop systems that can produce these types of quarterly reports for the 2014 benefit year. Therefore, we are considering requiring Exchanges to provide such reports to HHS beginning in the 2015 benefit year. We seek comment on whether HHS should establish a minimum error rate or threshold before an Exchange is required to inform HHS of such improper applications of the advance payment of the premium tax credit in a quarterly report, as well as what an appropriate error rate or threshold should be. For example, we are considering requiring issuers to report the number of enrollees for whom the Exchange improperly applied the advance payment of the premium tax credit compared to the total number of enrollees in the Exchange receiving Federal premium subsidies. We also seek comment on whether such reports should be provided to HHS less frequently than quarterly.

5. Subpart E – Exchange Functions in the Individual Market: Enrollment in Qualified Health Plans

a. Allowing issuer customer service representatives to assist with eligibility applications (§155.415)

Section 1413 of the Affordable Care Act directs the Secretary to establish, subject to minimum requirements, a streamlined enrollment process for enrollment in QHPs and all insurance affordability programs. Many issuers currently have customer service representatives who assist applicants in the application and plan selection process and assist enrollees in making changes to their coverage. Some of these representatives might not be licensed by the State as agents, brokers, or producers. Accordingly, we propose to add section §155.415 that would, at

the Exchange's option and to the extent permitted by State law, permit issuer customer service representatives who do not meet the definition of agent or broker in §155.20 to assist qualified individuals in the individual market with: (a) applying for an eligibility determination or redetermination for coverage through the Exchange; (b) applying for insurance affordability programs; and (c) facilitating the selection of a QHP offered by the issuer represented by the customer service representative, provided that such issuer customer service representatives meet the proposed requirements set forth in §156.1230(a)(2).

b. Special Enrollment Periods (§155.420)

In accordance with section 1311(c)(6)(C) of the Affordable Care Act, the Secretary must establish special enrollment periods for all Exchanges, including special enrollment periods specified in section 9801 of the Internal Revenue Code of 1986 and under circumstances similar to such periods under Part D of title XVIII of the Social Security Act. Under this authority, we propose to amend §155.420(d) to clarify that a special enrollment period will be available when a Exchange determines that a consumer has been incorrectly or inappropriately enrolled in coverage due to misconduct on the part of the non-Exchange entity. We propose to add a new paragraph §155.420(d)(10) to create this new special enrollment period for qualified individuals. We propose to limit this special enrollment opportunity to the individual market Exchange and not extend it to the SHOP.

We propose that the Exchange would extend a special enrollment period to a qualified individual when, in the determination of the Exchange, misconduct on the part of a non-Exchange entity has caused the qualified individual to be enrolled incorrectly or inappropriately in coverage such that they are not enrolled in QHP coverage as desired, are not enrolled in their

selected QHP, or have been determined eligible for but are not receiving advance payments of the premium tax credit or cost-sharing reductions.

Non-Exchange entities will be performing enrollment activities, including providing assistance with enrollment activities, and in some cases will be enrolling consumers directly in QHPs. Consumers would be harmed if they fail to enroll in a health plan or are enrolled in a QHP they did not select as a result of misconduct on the part of a non-Exchange entity. Consumers would also be harmed if they are eligible for, but not receiving advance payments of the premium tax credit or cost-sharing reductions as a result of misconduct on the part of a non-Exchange entity. The proposed provision would ensure that all qualified individuals and enrollees have similar protections against these harms.

For purposes of this proposed provision, we would interpret a non-Exchange entity providing enrollment assistance or conducting enrollment activities to include, but not be limited to, those individuals and entities that are authorized by the Exchange to assist with enrollment in QHPs (such as a Navigator, as described in §155.210; non-Navigator consumer assistance personnel, as authorized by §155.205(d) and (e); a certified application counselor, as described in proposed §155.225; an agent or broker assisting consumers in an Exchange under §155.220; issuer customer service representatives assisting consumers in an Exchange under proposed §155.415; or a QHP conducting direct enrollment under proposed §156.1230).

We further propose in §155.420(d)(10) that misconduct on the part of a non-Exchange entity providing enrollment assistance or conducting enrollment activities could include, but would not be limited to, the failure of a non-Exchange entity to comply with applicable requirements set forth in Exchange regulations or other applicable Federal or State laws.

For purposes of the proposed provision, the Exchange could base the determination triggering the special enrollment period on findings of HHS or a State; the Exchange's evaluation of consumer complaints, including the complaint of the affected individual; audits; information provided by the consumer, issuer, or non-Exchange entity; or other mechanisms. All requests for special enrollment periods, including those that may be initiated by the Exchange through its own audits or other mechanisms, should be evaluated by the Exchange as part of the eligibility determination process established pursuant to 45 CFR 155.310. We expect to develop further guidance and standard operating procedures for making the determinations that would trigger this special enrollment period. If a qualified individual is harmed due to an error or inaction on the part of a non-Exchange entity, the qualified individual may also seek to demonstrate the existence of exceptional circumstances to the Exchange under existing regulations at §155.420(d)(9). If the Exchange determines that the error or inaction on the part of the non-Exchange entity caused the qualified individual to be harmed (including, but not limited to failure to be enrolled in a health plan, enrolled in the incorrect health plan or failure to receive advance payments of the premium tax credit or cost-sharing reduction), the Exchange may provide for a special enrollment opportunity to correct the error.

We solicit comments on these proposals.

6. Subpart H – Exchange Functions: Small Business Health Options Program (SHOP)

a. Standards for the establishment of a SHOP (§155.700)

We propose to amend §155.700 by adding a definition for “SHOP application filer.”

We propose that “SHOP application filer” would mean an applicant, an authorized representative, an agent or broker of the employer, or an employer filing for its employees where not prohibited by other law. By broadening who can file an employee application beyond just an

employee, we propose to permit the entities that have traditionally assisted employees in filing applications to provide such assistance.

b. Functions of a SHOP (§155.705)

In §155.705, we propose adding paragraph (b)(6)(i) so that a SHOP would require QHP issuers to make changes to rates at a uniform time that is no more frequently than quarterly. This proposed paragraph would conform to the proposed issuer standard at §156.80 regarding the frequency of indexed rate updates. In paragraph (b)(6)(ii), we propose providing issuers participating in the FF-SHOP with the maximum amount of flexibility permitted under §156.80 as proposed in this rule and new (b)(6)(i), standardizing the effective dates for rate updates in the FF-SHOP, and providing that FF-SHOP issuers would have to submit rates to HHS 60 days in advance of the effective date. Consistent with technical guidance provided to issuers through the Health Insurance Oversight System on April 8, 2013, issuers would be able to submit updated quarterly rates for the FF-SHOP no sooner than for the third quarter of 2014, due to current system limitations.²⁹

We are also re-proposing a new paragraph (c). We previously proposed this paragraph in a recent rulemaking³⁰ to coordinate SHOP functions with the functions of the individual market Exchange for determining eligibility for insurance affordability programs. We propose that in Exchanges where the State or Federal government operates both the individual market and SHOP Exchanges, the SHOP would provide data related to the eligibility and enrollment for a qualified employee (that is, an employee who is enrolled in a QHP through the SHOP or is

²⁹ See Rate Changes for Small Group Market Plans and System Processing of Rates (April 8, 2013).

³⁰ See 78 FR 4723.

eligible to enroll in coverage through a SHOP because of an offer of coverage from a qualified employer) to the individual market Exchange that corresponds to the service area in which the SHOP is operating. We intend this proposal to ensure that the Exchange can use SHOP data for purposes of verifying enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan. We now re-propose this standard with an exemption for a State operating only a SHOP. Developing such data sharing would be a challenge in such a State.

In paragraph (d), we propose to provide additional flexibility to States with respect to the operation of the SHOP Navigator program when the State has elected to establish and operate only the SHOP. In most cases, there need not be separate Navigator programs for the SHOP and individual market Exchange. However, when the SHOP is operated by the State, and the individual market Exchange is operated by the Federal government, there would be two Navigator programs: a Federal Navigator program for the individual market Exchange, and a State Navigator program for the SHOP. We propose to clarify that when a State establishes and operates a SHOP independently of a Federally-facilitated individual market Exchange, as proposed in this rulemaking, the SHOP would have the flexibility to focus its Navigator program on outreach and education to small employers. If the State takes this option, SHOP Navigators would be able to fulfill their statutory and regulatory obligations under section 1311(i) of the Affordable Care Act and 45 CFR §155.210 to facilitate enrollment in QHPs, and to refer consumers with complaints, questions, and grievances to applicable offices of health insurance consumer assistance or ombudsmen, by referring small businesses to agents and brokers for these types of assistance, so long as State law permits agents and brokers to carry out these functions. The option of carrying out these two Navigator functions via referrals to agents and brokers

would not be available in any other circumstances. Additionally, this provision would not prevent a State operating a separate SHOP from requiring SHOP Navigators to perform the full range of Navigator services with equal focus and without making referrals to agents and brokers, if it so desires.

c. Application Standards for SHOP (§155.730)

In §155.730, we propose amending the application filing standard to relieve SHOPS of having to accept paper applications and accept applications by telephone. Such relief may reduce the cost of operating a SHOP while permitting SHOPS to provide applications in the manner that will best serve their enrollees. Nothing in this proposed standard would prohibit SHOPS from accepting paper applications or applications by telephone. Additionally, in this section we clarify that an employer or an employee application may be filed by a “SHOP application filer,” that is, an applicant, an authorized representative of the applicant, an agent or broker, and, if not prohibited by other law, an employer filing on behalf of employees. By broadening who can file an employee application beyond just an employee, we propose to permit the entities that have traditionally assisted employees in filing applications to provide such assistance.

d. Termination of Coverage (§155.735)

In §155.735, we propose that each SHOP would be required to develop uniform standards for the termination of coverage in a QHP. Standardizing the timing, form, and manner of a group’s termination in the SHOP would ensure that an employer offering coverage through multiple health insurance issuers (that is, in a SHOP offering employee choice) will be subject to uniform, predictable termination policies. Some SHOPS have considered developing termination standards using their authority to establish a uniform enrollment timeline and process pursuant to

§155.720(b). We propose this section to clarify the authority for SHOPs to establish termination standards and to set such standards for the FF-SHOP. Because SHOPs will not be required to offer employee choice and premium aggregation until plan years beginning on or after January 1, 2015, we created a transition policy such that these standards would be required starting in 2015. However, we are proposing these standards now, for two reasons. First, State Exchanges may desire to implement employee choice and premium aggregation in 2014 and, if so, would be required to apply these standards. Second, we are proposing these standards in response to comments received from issuers on the Exchange Final Rule and 2014 Payment Notice requesting detailed guidance well in advance of implementation to so that they are better able to build conforming systems.

Proposed paragraph (b) addresses employer requests for termination of employer group coverage. In paragraph (b)(1), we propose that each SHOP would be required to set policies regarding advance notice of such terminations and when coverage will end following the SHOP's receipt of notice that an employer wishes to terminate coverage.

In paragraph (b)(2), we propose that employer-requested terminations of employer group coverage through an FF-SHOP would be effective only on the last day of a month. We also propose that notice of termination would have to be received from the employer on or before the 15th of a given month for it to be effective on the last day of that month. If notification of termination is provided after the 15th of the month, we propose the group's coverage be terminated on the last day of the following month.

Proposed paragraph (c) addresses terminations of employer group coverage for non-payment of premiums. In paragraph (c)(1), we propose that each SHOP would be required to establish standards for termination due to non-payment, including defining grace periods, due

dates for premium payments made to a SHOP pursuant to §155.705(b)(4), employer and employee notices, and reinstatement policies. Standardized grace periods, due dates for payment and reinstatement policies, and notices would ensure that an employer offering coverage through multiple health insurance issuers is subject to clear and consistent rules.

In paragraph (c)(2), we propose the policies for terminations for non-payment of premiums in the FF-SHOP. As proposed, payment for a group's coverage for a given month would be due to the FF-SHOP by the first day of the coverage month. Additionally, we propose that the employer would have a 31-day grace period from the first day of the coverage month for making this payment. Having reviewed the State-provided small group market payment grace periods rules that currently exist, we believe a grace period of this length would never be shorter than the protections currently offered by any State and therefore does not prevent the application of existing State law.

In paragraph (c)(2)(iii), we propose that an employer would have 30 days from the date of its termination from coverage under the FF-SHOP to request the reinstatement of its group in the previous coverage. Additionally, we propose that the employer would pay in full all outstanding premiums and the premium for the next month's coverage before reinstatement could occur.

Proposed paragraph (d) addresses terminations of employee or dependent coverage. In paragraph (d)(1), we propose that each SHOP would be required to establish consistent policies across QHP issuers regarding the process and effective dates for termination of employee and dependent coverage in the SHOP. Furthermore, this provision would clarify the specific circumstances under which the SHOP would be permitted to terminate an employee's coverage.

In paragraph (d)(2), we propose that in the FF-SHOP, terminations for the reasons enumerated in paragraph (d)(1) would be effective on the last day of the month in which the FF-SHOP receives notice of the event. We further propose that the FF-SHOP must have received notice prior to the proposed date of the termination. Notwithstanding the standards promulgated in 45 CFR §147.120, under this proposed standard a person who loses coverage as a dependent when she turns 26 years old would have to be covered on the parent's plan through the end of the month.

In paragraph (e), we direct that all SHOPS comply with the general administrative requirements of §155.430(c). This compliance would ensure that the SHOP keeps sufficient records of terminations and that reasonable accommodations would be made for enrollees with disabilities.

In paragraph (f), we propose that the standards set in this section would apply to all SHOPS for coverage beginning on or after January 1, 2015. Additionally, because these provisions propose to harmonize issuer termination policies where employee choice exists, we propose that SHOPS offering employee choice and premium aggregation prior to January 1, 2015 would need to comply with these standards by the time they are operational. We do not expect this provision to place additional burden on such States, as we expect them to have already developed such policies consistent with this proposal pursuant to §155.720(b).

7. Subpart M – Oversight and Financial Integrity Standards for State Exchanges

Sections 1311, 1313, and 1321 of the Affordable Care Act provide the Secretary with oversight of financial integrity and program integrity in the State Exchanges. More specifically, the statutory authority for HHS oversight of the programmatic integrity of an Exchange is found in section 1313(a)(1) of the Affordable Care Act, which requires an Exchange to keep an

accurate accounting of all activities as stated above, and section 1313(a)(2) of the Affordable Care Act which gives the Secretary the authority to investigate the affairs of an Exchange and examine the properties and records of an Exchange in relation to activities undertaken by an Exchange. In addition, section 1313(a)(5) of the Affordable Care Act directs the Secretary to provide for the efficient and non-discriminatory administration of Exchange activities and to implement any measure or procedure that the Secretary determines is appropriate to reduce fraud and abuse. The key principles underlying the Secretary's State Exchange oversight program design include: effectiveness, efficiency, integrity, coordination, transparency and accountability in State Exchange operations. The State Exchange oversight program builds on existing State oversight efforts, where possible, by coordinating with State authorities to address compliance issues and concerns. State Exchange compliance with the Affordable Care Act and the regulatory requirements being proposed in this proposed rule (if finalized) would include submitting financial and operational reports and maintaining records in a standardized fashion.

These proposed standards will enable HHS to carry out its responsibility of ensuring that Federal funds are used appropriately in the administration of State Exchange activities. Therefore, we are proposing that the State Exchange must submit to HHS financial reports and must oversee its activities to ensure that it is complying with Federal requirements, such as those governing eligibility determinations for advance payments of the premium tax credit and cost-sharing reductions.

These sections, §155.1200 and §155.1210, would ensure that the State Exchange has financial and operational safeguards in place to avoid making inaccurate eligibility determinations, including those related to advance payment of the premium tax credit, cost-sharing reductions, and enrollments. These sections are not intended to be a part of any

prospective measurement program that may be required under the Improper Payments Elimination and Recovery Act at 31 U.S.C. 3321.

We are not proposing that these standards should be applicable to the FFE, because CMS, which will operate the FFE, is already subject to similar standards in its role as a government agency. For example, OMB Circular A-123 dated December 21, 2004, provides instruction on internal controls (financial and operational) for Federal agencies.

a. General Financial Integrity and Oversight Requirements (§155.1200)

Section 1313(a)(1) of the Affordable Care Act requires an Exchange to keep an accurate accounting of all activities, receipts, and expenditures, and annually submit to the Secretary a report concerning such accounting. In §155.1200(a), we propose that the State Exchange maintain an accounting of all its receipts and expenditures, in accordance with GAAP. In addition, we propose that the State Exchange develop and implement a process for monitoring all Exchange-related activities for effectiveness, efficiency, integrity, transparency and accountability. We believe that these activities would help to ensure State Exchange compliance with Federal requirements as set forth in Part 155 and ensure the appropriate administration of Federal funds, including advance payment of the premium tax credit and cost-sharing reductions. In §155.1200(b), we propose that the State Exchange submit several types of reports to HHS. The State Exchange would submit at least annually a report to allow for transparency of State Exchanges activities. The report must include a financial statement presented in accordance with GAAP. This report is due to HHS by April 1st of each year. Additionally, the State Exchange must submit reports in a form and manner to be specified by HHS regarding eligibility and enrollment. These reports will focus on eligibility determination errors, non-discrimination safeguards, accessibility of information, and fraud and abuse incidences. The State Exchange

must also submit performance monitoring data that includes financial sustainability, operational efficiency, and, consumer satisfaction. We solicit comments on our approach, including comments on the content, format, and timing of such reports.

Section 1313(a)(3) of the Affordable Care Act requires that an Exchange be subject to an annual audit by the Secretary. In §155.1200(c), we propose that the State Exchange engage an independent qualified auditing entity, whether governmental or private, which meets accepted professional and business standards and follows generally accepted governmental auditing standards (GAGAS), to perform an independent external financial and programmatic audit of the State Exchange. This entity should be selected to avoid any real or potential perception of conflict of interest, including being free from personal, external and organizational impairments to independence or the appearance of such impairments of independence. External audits are a standard practice used to maintain accountability and internal controls. An external audit will help ensure the consistency and accuracy of State Exchange financial reporting and program activities. We propose that this requirement may be satisfied through an audit by an independent State-government entity. The State Exchange will submit to HHS, concurrent with the annual report, the results of the audit along with proposals on how it will remedy any material weakness or significant deficiency (the terms “material weakness” and “significant deficiency” are defined in OMB Circular A-133, Audits of States, Local Governments and Non-Profit Organizations).

In §155.1200(d), we propose that independent audits address specific processes and activities of State Exchanges including financial and programmatic activities and those related to the verification and determination of applicants’ eligibility for enrollment in the State Exchanges and the subsequent enrollments. We propose that the external audit address whether the Exchange is complying with §155.1200(a)(1) by keeping an accurate accounting of Exchange

receipts and expenditures in accordance with generally accepted accounting principles (GAAP). We note that accurate eligibility determinations by the State Exchanges are important to the implementation of the Affordable Care Act. Failure to apply Federal standards appropriately could result in improper Federal payments in the form of advance payments of the premium tax credit and cost sharing reductions. Therefore, we also propose that the external audits and annual reports required under paragraphs (b) and (c) of this section address State Exchange processes and procedures to comply with the standards for Exchanges under 45 CFR Part 155 related to advance payments of the premium tax credit and cost-sharing reductions. These standards include the requirements under subpart D regarding eligibility determinations, including the requirements regarding the confidentiality, disclosure, maintenance, and use of information as set forth in 45 CFR 155.302(d)(3); subpart E regarding individual market enrollment in QHPs; and subpart K regarding QHP certification. We propose that such audits and annual reports assess whether a State Exchange has processes and procedures in place to prevent improper eligibility determinations and enrollment transactions. Assessing whether State Exchanges are complying with Federal requirements in these areas will assist in ensuring that eligible individuals are appropriately enrolled and receiving appropriate advance payments of the premium tax credit and cost-sharing reductions. Determining whether there are appropriate internal controls and standard operating procedures in place to identify and correct weaknesses in these particular areas will mitigate the creation of improper payments, thereby safeguarding Federal funds.

We seek comment on the proposed annual audits, and other activities that State Exchanges should specifically be required to audit annually or on an interim basis.

b. Maintenance of Records (§155.1210)

Under section 1313(a)(2) of the Affordable Care Act, the Secretary, in coordination with the Inspector General of HHS, may investigate, examine properties and records, and require periodic reports from the State Exchange. Under section 1313(a)(3) of the Affordable Care Act, the State Exchange is subject to annual audits by the Secretary. We anticipate conducting a limited number of targeted audits each year, informed by information from the external audit, annual report, prospective measurement programs of improper payments, consumer complaints, or other data sources. To prepare for such audits, the State Exchange would be required to maintain records pursuant to this section. Preparation for such audits would also require the State Exchange to ensure its contractors, subcontractors, and agents maintain these records.

In §155.1210, we propose the requirements for records maintenance for the State Exchange. We propose that the State Exchange and its contractors, subcontractors, and agents maintain records for 10 years, including documents and records (whether paper, electronic or other media) and other evidence of accounting procedures and practices of the State Exchange. These records must be sufficient and appropriate to respond to any periodic auditing, inspection or investigation of the State Exchange's financial records or to enable HHS or its designee to appropriately evaluate the State Exchange's compliance with Federal requirements. In addition, we propose that the State Exchange must make all records of this section available to HHS, the OIG, the Comptroller General, or their designees, upon request. We have proposed this 10-year retention period to be consistent with the statute of limitations for the False Claims Act at 31 U.S.C. 3731. We request comment on auditing procedures and the length of document retention requirements.

E. Part 156 – Health Insurance Issuer Standards Under The Affordable Care Act, Including Standards Related To Exchanges

1. Subpart A – General Provisions

a. Definitions (§156.20)

We propose to amend 45 CFR 156.20 by adding the definitions for “Delegated entity,” “Downstream entity,” “Enrollee satisfaction survey vendor,” and “Registered user of the enrollee satisfaction survey data warehouse,” in alphabetical order to read as follows:

Delegated entity

We propose to define a delegated entity as any party, including an agent or a broker that enters into an agreement with a QHP issuer to provide administrative services or health care services to qualified individuals, qualified employers, or qualified employees and their dependents.

Downstream entity

We propose to define a downstream entity as any party, including an agent or a broker, that enters into an agreement with a delegated entity or with another downstream entity for purposes of providing administrative or health care services related to the agreement between the delegated entity and the QHP issuer. The term “downstream entity” is intended to reach the entity that directly provides administrative services or health care services to qualified individuals, qualified employers, or qualified employees and their dependents.

Enrollee satisfaction survey vendors

We propose to define an “enrollee satisfaction survey vendor” as an organization that has relevant survey administration experience (for example, Consumer Assessment of Healthcare Providers and Systems (CAHPS[®]) surveys), organizational survey capacity, and quality control procedures for survey administration.

Exchange

An “Exchange” has the meaning given to the term in §155.20 of this subchapter.

Registered user of the enrollee satisfaction survey data warehouse

We propose to define a “registered user of the enrollee satisfaction survey data warehouse” as enrollee satisfaction survey vendors, QHP issuers, and Exchanges authorized to access CMS’s secure data warehouse to submit survey data and to preview survey results prior to public reporting.

b. Single Risk Pool (§156.80)

We are proposing to add a new paragraph (d)(3) in §156.80 to clarify when issuers may modify rates under the single risk pool provision. These proposed market-wide rate modification limitations would align with the limitations on rate setting schedules in the Exchange and SHOP, which is necessary to reduce the risk of adverse selection between plans offered outside the Exchange and QHPs offered through the Exchange. Furthermore, the frequency of rate modifications affects the rate review process because each time an issuer adjusts its index rate, the new rates of all of its plans must be subjected to rate review.

Accordingly, in paragraph (d)(3)(i), we propose that issuers in individual markets or markets in which the individual and small group risk pools were merged by the State would be permitted to make changes to their market-wide adjusted index rate and plan-specific pricing on an annual basis, as discussed in the preamble to the Market Reform Rule (78 FR 13422). In a State in which the individual and small group risk pools were merged by the State, an issuer would be able to adjust its index rate and plan-specific pricing no more frequently than annually, since the stricter standard of the individual market must be applied to the entire merged market for consistency throughout the single risk pool.

In paragraph (d)(3)(ii), we propose that issuers in the small group market generally would be permitted to make such changes on a quarterly basis, beginning with rates effective for the third quarter of 2014. This proposal is consistent with technical guidance provided to issuers through the Health Insurance Oversight System on April 8, 2013.³¹ These quarterly rates would apply to both new and renewing business for the entire plan year, depending on the plan year of the employer. For example, if an employer's plan year begins February 1 and the issuer had adjusted its index rate on January 1, the issuer's January 1 rate would apply to the employer's plan only on February 1. Additionally, although the issuer would be able to adjust its index rate on a quarterly basis in the small group market, any new rates set by the issuer after February 1 would apply only upon the plan's renewal the following year. As discussed in section II.D.6.b of this preamble and the April 8, 2013 technical guidance to issuers, due to current system limitations, the submission of rates updated on a quarterly basis (or any basis other than an annual basis) cannot currently be processed for QHPs in the FF-SHOPs. Accordingly, in order to align with the timing of the adjustments permitted in the SHOP based on these operational considerations, issuers would be required under the amendment to this section to set rates for non-grandfathered plans in the small group market on an annual basis market-wide until the FF-SHOPs' capability to process quarterly rate updates is established. We anticipate that the FF-SHOPs will be capable of processing quarterly updated rates effective for the third quarter of 2014.

2. Subpart C – Qualified Health Plan Minimum Certification Standards

a. Additional Standards Specific to SHOP (§156.285)

³¹ Rate Changes for Small Group Market Plans and System Processing of Rates (April 8, 2013).

We propose to amend §156.285 to ensure that all QHP issuers offering coverage in a SHOP comply with the termination of coverage requirements proposed at §155.735 as a condition of certification for plan years beginning on or after January 1, 2015, when §155.735 will apply to all SHOPS. Some SHOPS may decide to implement employee choice and premium aggregation before January 1, 2015, and §155.735 would apply in such SHOPS as an operational requirement.

3. Subpart D - Federally-Facilitated Exchange Qualified Health Plan Issuer Standards

a. Changes of Ownership of Issuers of Qualified Health Plans in the Federally-Facilitated Exchange (§156.330)

Proposed §156.330 describes the notice required to be submitted by QHP issuers offering QHPs through FFEs, including the FF-SHOPs, when such issuers undergo a change of ownership, as recognized by the State in which the issuer offers the QHP, during the term of its QHP agreement. We propose that the issuer be required to notify HHS, in a manner to be specified by HHS, and provide the legal name, the Taxpayer Identification Number (TIN) of the new owner, and the effective date of the change at least 30 days prior to the date of change. We also propose that the new owner must agree to adhere to all applicable statutes and regulations. These provisions would provide HHS with adequate notice so that it could monitor or audit the new owner to ensure that the new owner meets all QHP certification standards and clarify that the new owner would agree to adhere to all applicable statutes and regulations. We considered proposing a standard similar to that in the Medicare Parts C and D programs, in which HHS, the current issuer, and the prospective new issuer would enter into a novation agreement prior to the change of ownership. We further considered requiring the prospective new issuer to submit financial and solvency information to HHS in advance of the change of ownership. However,

based on research of existing State law, we believe that such standards could largely duplicate existing State requirements. We welcome comments about the 30-day notice requirement, about the information being requested when a change of ownership occurs, and about whether to specifically require a novation.

b. Standards for Downstream and Delegated Entities (§156.340)

Section 1321(a)(1)(B) of the Affordable Care Act establishes that the Secretary must issue regulations setting forth standards for the offering of QHPs through the Exchanges. Based on this general authority, we propose in §156.340 standards for delegated and downstream entities, similar to existing standards for such entities that contract with Medicare Advantage organizations, described at 42 CFR 422.504(i)(3)-(4). In §156.340(a), we propose the general requirement that, notwithstanding any relationship(s) that a QHP issuer may have with delegated or downstream entities, the QHP issuer maintains responsibility for its compliance and the compliance of any of its delegated or downstream entities, with all applicable standards, including those we propose at §156.340(a)(1) through (4). In paragraphs (a)(1) through (a)(4), we propose that the QHP issuer be required to comply with Federal standards, specifically the obligations as set forth under: subpart C of part 156, which governs QHP minimum certification standards; subpart K of part 155, which governs Exchange functions pertaining to QHP certification; subpart H of part 155, which governs the Exchange functions of the SHOP; standards in §155.220 with respect to assisting with enrollment in QHPs; and standards in §156.705 and §156.715 for maintenance of records and compliance reviews for QHP issuers operating in an FFE and an FF-SHOP.

Because a QHP issuer generally cannot enforce an agreement to which it is not a party, we believe that the most legally effective way to ensure that a QHP issuer retains the necessary

control and oversight over its delegated or downstream entities would be to require that all agreements governing the relationships among a QHP issuer and its delegated and downstream entities (that is, those between the QHP issuer and its delegated entity; those between the delegated entity and any downstream entity; and those between downstream entities) contain provisions specifically describing each of the delegated and downstream entity's obligations to fulfill the QHP issuer's responsibilities proposed in paragraph (a) of this section. Such a requirement would be similar to the existing requirement for agreements governing the relationship among entities that contract with Medicare Advantage organizations, described at 42 CFR 422.504(i)(3)-(4). Therefore, in §156.340(b)(1)-(2), we propose that all agreements among the QHP issuer's delegated and downstream entities be required to specify delegated activities and reporting responsibilities, and either provide for revocation of the delegated activities and reporting standards, or specify other remedies in instances where HHS or the QHP issuer determines that such parties have not performed satisfactorily.

Furthermore, we propose in §156.340(b)(3) that all agreements among the QHP issuer's delegated and downstream entities be required to specify that the delegated or downstream entity must comply with all applicable laws and regulations relating to the standards specified under paragraph (a) of this section. In §156.340(b)(4) of this proposed rule, we propose that the QHP issuer's agreement with any delegated or downstream entity must specify that the delegated and downstream entity must permit access by the Secretary and the OIG or their designees in connection with their right to evaluate through audit, inspection, or other means, to the delegated or downstream entity's books, contracts, computers, or other electronic systems, including medical records and documentation, relating to the QHP issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the final date of the

agreement period. Such a requirement would be similar to the existing requirement for agreements governing the relationship among entities that contract with Medicare Advantage organizations, described at 42 CFR 422.504(i)(2)-(4).

Finally, we propose in §156.340(b)(5) that all existing agreements contain specifications described in paragraph (b) of this section by no later than January 1, 2015. We believe the effective date recognizes the time that QHP issuers may need to amend existing agreements with delegated and downstream entities to comply with the requirements under paragraph (b). For agreements that are newly entered into as of October 1, 2013, we propose an effective date for the specifications described in paragraph (b) of this section to be no later than the effective date of the agreement.

4. Subpart E – Health Insurance Issuer Responsibilities with Respect to Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions

In this subpart, pursuant to section 1321(a)(1)(B) of the Affordable Care Act, we propose standards for oversight of QHP issuers with respect to cost-sharing reductions and advance payments of the premium tax credit. We believe that it is important to establish robust oversight relating to cost-sharing reductions and advance payments of the premium tax credit in order to ensure that Federal funds are used efficiently and in full compliance with the provisions of the Affordable Care Act, and that consumers receive the financial assistance afforded them under the statute. The standards proposed in this subpart are consistent with the information we provided in the “Frequently Asked Questions on Health Insurance Marketplaces” dated May 14, 2013.³²

³² Available at: <http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/marketplace-faq-5-14-2013.pdf>.

In particular, we propose requirements and timeframes for refunds to eligible enrollees and providers when a QHP issuer incorrectly applies the cost-sharing reductions or advance payments of the premium tax credit, or incorrectly assigns an individual to a plan variation (or standard plan without cost-sharing reductions), resulting in the enrollee or the provider paying a portion of the cost sharing or premium amount that should otherwise have been reduced. The proposed provisions are intended to ensure that enrollees and providers are promptly refunded any excess cost sharing they should not have paid.

a. Definitions (§156.400)

Section 156.400 of this subpart defines a “most generous,” and a “more generous,” plan variation. We propose to supplement those definitions by clarifying that the definitions of a “least generous,” and a “less generous,” plan variation have the opposite meanings of the existing definitions of a “most generous,” or a “more generous” plan variation. Specifically, we propose that, as between two plan variations (or a plan variation and a standard plan without cost-sharing reductions), the plan variation or standard plan without cost-sharing reductions designed for the category of individuals first listed in 45 CFR 155.305(g)(3) would be deemed the less generous one. The term less generous is used in this proposed rule to address circumstances in which a QHP issuer would reassign an enrollee from a more generous plan variation to a less generous plan variation (or standard plan without cost-sharing reductions), as discussed in greater detail below. We also propose a technical modification to change “QHP or plan variation” to “standard plan or plan variation” to clarify that a plan variation is not distinct from a QHP.

b. Improper Plan Assignment and Application of Cost-Sharing Reductions (§156.410(c)-(d))

To address misapplication of cost-sharing reductions due to an enrollee, in §156.410, we propose to add new paragraphs (c) and (d) to specify the actions a QHP issuer would take if it does not provide the appropriate cost-sharing reductions to an individual, or if it does not assign an individual to the appropriate plan variation (or standard plan without cost-sharing reductions) in accordance with §156.410(a)-(b) or §156.425(a)-(b) of this subpart. The QHP issuer is responsible under these provisions for ensuring that individuals are assigned to the appropriate plan variation (or standard plan without cost-sharing reductions) and ensuring that the cost-sharing reduction is applied when the cost sharing is collected. We believe that enrollees and providers should be held harmless if the QHP issuer misapplies the cost-sharing reduction, such that the QHP issuer should not recoup excess funds paid for the individual or to the provider. However, because we believe an enrollee should be afforded at a minimum the financial assistance specified in the statute and regulations, we believe that the QHP issuer should be responsible for refunding any excess cost sharing paid by the enrollee or provider, as applicable.

Accordingly, in paragraph (c)(1), we propose that if a QHP issuer fails to ensure that an individual assigned to a QHP plan variation receives the cost-sharing reductions required under the applicable plan variation, taking into account the requirement regarding cost sharing previously paid under other plan variations of the same QHP under §156.425(b), the QHP would notify the enrollee of the improper application of the cost-sharing reductions and refund any excess cost sharing paid by or for the enrollee during such period no later than 30 calendar days after discovery of the improper application of the cost-sharing reductions. This refund would be paid to the person or entity that paid the excess cost sharing, whether the enrollee or the provider.

In paragraph (c)(2), we propose that if a QHP issuer provides an enrollee assigned to a plan variation more cost-sharing reductions than required under the applicable plan variation,

taking into account §156.425(b) concerning continuity of deductibles and out-of-pocket amounts, if applicable, then the QHP issuer will not be eligible for reimbursement of any excess cost-sharing reductions provided to the enrollee, and may not seek reimbursement from the enrollee or the provider for any of the excess cost-sharing reductions. As noted above, because the QHP issuer is responsible for ensuring the cost-sharing reduction is provided appropriately, we do not believe that the QHP issuer should be able to recoup overpayments of cost-sharing reductions that resulted from the QHP issuer's own errors.

In paragraph (d), we propose that if a QHP issuer does not comply with §156.410(b) by improperly assigning an enrollee to a plan variation (or standard plan without cost-sharing reductions), or the QHP issuer does not change the enrollee's assignment due to a change in eligibility in accordance with §156.425(a), in each case, based on the eligibility and enrollment information or notification provided by the Exchange, then the QHP issuer would, no later than 30 calendar days after discovery of the improper assignment, reassign the enrollee to the applicable plan variation (or standard plan without cost-sharing reductions) and notify the enrollee of the improper assignment.

If a QHP issuer reassigns an enrollee from a more generous to a less generous plan variation of a QHP (or a standard plan without cost-sharing reductions), for example from a silver plan variation with an 87 percent AV to a silver plan variation with an 73 percent AV, to correct an improper assignment on the part of the issuer pursuant to proposed paragraph (d)(1), the QHP issuer will not be eligible for, and may not seek from the enrollee or provider, reimbursement for any of the excess cost-sharing reductions provided to or for the enrollee following the effective date of eligibility required by the Exchange. Because the QHP issuer is responsible for assigning and reassigning the enrollee to a plan variation of a QHP (or standard

plan without cost-sharing reductions) and because of the reliance interests of the enrollee, we believe that the QHP issuer should not be able to recover excess cost-sharing reductions if it erroneously assigns an individual to a more generous plan variation. This aligns the policy proposed in this section with respect to the misapplication of the cost-sharing reductions.

Conversely, proposed paragraph (d)(2) provides that, if a QHP issuer reassigns an enrollee from a less generous plan variation (or a standard plan without cost-sharing reductions) to a more generous plan variation of a QHP (for example from a silver plan variation with an 87 percent AV to a silver plan variation with an 94 percent AV) to correct an improper assignment on the part of the issuer, the QHP issuer would recalculate the individual's liability for cost sharing paid between the effective date of eligibility required by the Exchange and the date on which the issuer effectuated the change. The QHP issuer would refund any excess cost sharing paid by or for the enrollee during such period, no later than 30 calendar days after discovery of the incorrect assignment. This refund would be paid to the person or entity that paid the excess cost sharing, whether the enrollee or the provider. For example, if a QHP issuer improperly assigned an individual to a silver plan variation with an 87 percent AV for the plan year starting January 1, 2014, but on March 1, 2014, discovers that the individual should have been assigned to a silver plan variation with a 94 percent AV, then the QHP issuer would be required to reassign the individual to the silver plan variation with a 94 percent AV by March 31, 2014. The issuer would also refund any excess cost sharing paid by or for the enrollee between January 1, 2014 and the date the reassignment is effectuated, that is, March 31, 2014.

We seek comment on the proposed approach, including the 30 calendar day timeframe for QHP issuers to reassign an individual to the correct plan variation and refund any excess cost sharing paid by or for the enrollee. We also seek comment on whether the timeframe should

depend on the point in the month the issuer discovers the improper assignment, considering the amount of time issuers may require to effectuate the reassignment, as well as the impact on enrollees due to a delay in reassignment. We note that the date of the reassignment will not affect the initial effective date of eligibility, and that the enrollee would still be refunded any excess cost sharing paid by or for the enrollee between the effective date of eligibility and the date of the reassignment.

We are also considering requiring that, for each quarter, a QHP issuer provide to HHS and the Exchange, in a manner and timeframe specified by HHS, a report detailing the occurrence of any improper applications of cost-sharing reductions in violation of the standards finalized and proposed in §156.410(a) and (c) and §156.425(b), as well as instances when it did not refund any excess cost sharing paid by or for an enrollee in accordance with proposed §156.410(c)(1) and §156.410(d)(2), or was reimbursed for excess cost sharing provided in violation of proposed §156.410(d)(1). This quarterly report would alert HHS and the Exchange to patterns of such errors or omissions, and could identify areas where issuer performance can be improved. However, we recognize that, given operational constraints, it may be difficult at this point for QHP issuers to develop systems that can produce these types of quarterly reports for the 2014 benefit year. Therefore, we are considering requiring issuers to produce these reports beginning in the 2015 benefit year. We seek comment on the proposed approach, including whether such reports should be provided less frequently. We also seek comment on whether HHS should establish a minimum error rate or threshold before a QHP issuer is required to inform HHS of such improper applications of cost-sharing reductions in the quarterly report, as well as what an appropriate error rate or threshold should be.

c. Failure to Reduce an Enrollee's Premium to Account for Advance Payments of the Premium Tax Credit (§156.460(c))

We also propose to add new paragraph (c) to §156.460, related to the failure to reduce an enrollee's share of premium to account for advance payments of the premium tax credit. In paragraph (c), we propose that if a QHP issuer discovers that it did not reduce the portion of the premium charged to or for the enrollee for the applicable month(s) by the amount of the advance payment of the premium tax credit as required in §156.460(a)(1), the QHP issuer would be required to refund to the enrollee any excess premium paid by or for the enrollee and notify the enrollee of the improper assignment no later than 30 calendar days after the QHP issuer discovers the improper assignment. We note that a QHP issuer may provide the refund to the enrollee by reducing the enrollee's portion of the premium in the following month, as long as the reduction is provided no later than 30 calendar days after the QHP issuer discovers the improper assignment. If the QHP issuer elects to provide the refund by reducing the enrollee's portion of the premium for the following month, and the refund exceeds the enrollee's portion of the premium for the following month, then the QHP issuer would need to refund to the enrollee the excess no later than 30 calendar days after the QHP issuer discovers the improper assignment.

Additionally, we are also considering that for each quarter beginning in 2015, a QHP issuer would be required to provide a report to HHS and the Exchange, in a manner and timeframe specified by HHS, detailing the occurrence of instances of improper applications of the requirements of §156.460. This would be similar to the quarterly reporting requirements with respect to the misapplication of cost-sharing reduction discussed in the previous section of this subpart, and we note that we would anticipate utilizing a single process for issuers to submit such quarterly reports. We seek comment on the proposed approach, including the timeframe for

issuers to refund any excess premiums to enrollees, the timeframes for providing the quarterly report to HHS and the Exchange, whether HHS should also establish a minimum rate or threshold before a QHP issuer is required to notify HHS of any such instances, and what an appropriate rate or threshold would be.

d. Oversight of the Administration of Cost-sharing Reductions and Advance Payments of the Premium Tax Credit Programs (§156.480)

In §156.480, we propose general provisions related to the oversight of QHP issuers in relation to cost-sharing reductions and advance payments of the premium tax credit. Cost-sharing reduction reimbursements and advance payments of the premium tax credit are Federal funds, which will pass from HHS directly to QHP issuers. Therefore, we believe that it is necessary for HHS to oversee QHP issuer compliance in these areas, regardless of whether the QHP is offered through a State Exchange or an FFE. We seek comment on this approach, including with respect to how HHS may coordinate with State Exchanges and State authorities to address non-compliance with Federal requirements regarding cost-sharing reductions or advance payments of the premium tax credit. We note that in States where there is a State Exchange, the State has enforcement authority over QHP issuers that are not in compliance with the standards set forth in subpart E of this Part. If the State does not enforce such standards against the QHP issuers in the individual market participating on the State Exchange, HHS will enforce QHP issuer compliance with these requirements, including the imposition of CMPs as provided for under Section 1321(c) of the Affordable Care Act. In instances where HHS enforces QHP issuer compliance with respect to cost-sharing reductions and advanced payments of the premium tax credit, we envision CMPs would be imposed using the same standards and processes as proposed for QHP issuers in an FFE in subpart I of this Part.

To effectively oversee the provision of cost-sharing reductions and advance payments of the premium tax credit by issuers of QHPs on State Exchanges, we propose to apply certain standards proposed in part 156, subpart H for QHP issuers participating in FFEs to QHP issuers participating in the individual market on a State Exchanges. In paragraph (a), we propose to extend the standards set forth in proposed §156.705 concerning maintenance of records to a QHP issuer in the individual market on a State Exchange in relation to cost-sharing reductions and advance payments of the premium tax credit. We also propose that QHP issuers ensure that any delegated entities and downstream entities adhere to these requirements, in parallel with the standards for QHP issuers on an FFE proposed in §156.340. We believe applying these provisions to QHP issuers participating in State Exchanges is necessary to allow HHS, pursuant to its oversight authority, to access records and investigate compliance with the requirements of this subpart. We note that a QHP issuer and its delegated entities and downstream entities may satisfy this standard by maintaining the relevant records for a period of 10 years and ensuring that they are accessible if needed in the event of an investigation or audit.

We also propose that QHP issuers participating in State Exchanges and FFEs be subject to reporting and oversight requirements that are intended to assist in monitoring a QHP issuer's compliance with Federal standards with regard to cost-sharing reductions and advance payments of the premium tax credit, in order to safeguard Federal funds distributed through these programs, and to correct improper payments to the QHPs.

In paragraph (b), we propose that an issuer that offers a QHP in the individual market through a State Exchange or an FFE report to HHS annually, in a timeframe and manner required by HHS, summary statistics with respect to administration of cost-sharing reductions and advance payments of the premium tax credit. This proposed provision would permit HHS to

obtain summary information regarding cost-sharing reductions and advance payments of the premium tax credit across a broad range of issuers to identify systemic issues and errors, without requiring annual audits. We contemplate that this information will include (1) the total amount of cost-sharing paid under each plan variation, including the amount paid by the individual and amount reduced by the cost-sharing reductions program, (2) an annual error rate reflecting the misapplication of the cost-sharing reductions and advance payments of the premium tax credit by plan variation, and (3) the total number of enrollees who received a refund as well as the total and average refunds made to enrollees and providers by plan variation resulting from underpayments. Additionally, in paragraph (c), as is required under other Federal programs such as Medicare Advantage, we propose that HHS or its designee may audit an issuer that offers a QHP in the individual market through a State Exchange or an FFE to assess compliance with the requirements of this subpart. An audit may be triggered by sources such as the annual reports proposed in §156.480(b) of this Part, consumer complaints, and information received from State regulatory agencies. We note that we intend to coordinate any audits of QHP issuers in an FFE with the compliance reviews proposed in §156.715 of subpart H. We seek comment on these proposed reporting requirements, including the operational readiness of issuers to report these data, our proposed approach to audits, and how such oversight activities may be coordinated with State Exchange oversight activities to avoid duplication of effort.

5. Subpart H – Oversight & Financial Integrity Requirements for Issuers of Qualified Health Plans in Federally-Facilitated Exchanges

a. Maintenance of Records for the Federally-facilitated Exchanges (§156.705)

Section 1313(a)(2) of the Affordable Care Act authorizes HHS to examine records and solicit reports regarding activities undertaken by the Exchanges. So that HHS can prepare for

and successfully complete compliance reviews and audits to account for expenditures and protect against fraud and abuse, we propose that QHP issuers must retain certain records. The record retention standards we propose in this section are similar to those already established for the Medicare Advantage Program, and described at 42 CFR 422.504(d).

We propose in §156.705(a) that issuers offering QHPs in an FFE maintain all documents and records (whether paper, electronic, or other media) and other evidence of accounting procedures and practices, which are critical for HHS to conduct activities necessary to safeguard the financial and programmatic integrity of the FFEs. We propose that such activities include: (1) periodic auditing of the QHP issuer's financial records related to the QHP issuer's participation in an FFE, and to evaluate the ability of the QHP issuer to bear the risk of potential financial losses; and (2) compliance reviews and other monitoring of a QHP issuer's compliance with all Exchange standards applicable to issuers offering QHPs in the FFE listed in part 156. We considered requiring maintenance of other types of records, but we propose limiting our scope to Exchange-specific records as applicable to the FFEs. We seek comment on the type and scope of records we propose must be maintained by QHP issuers participating in the FFEs.

In §156.705(b), we propose to clarify that the records described in proposed paragraph (a) of this section include the sources listed in proposed §155.1210(b)(2), (b)(3), and (b)(5). Our intent is to align record maintenance standards of the FFEs and State Exchanges to the extent possible.

In §156.705(c), we propose that issuers offering QHPs in an FFE must maintain the records described in this section, as well as records required by §155.710 (to determine SHOP eligibility), for 10 years. This proposed standard parallels standards in part 155 as well as existing part 153 standards (45 CFR 153.240(c), 153.520(e) and 153.620(b) and proposed

§§153.310(c)(4), 153.405(h), and 153.410(c)). It is also consistent with the statute of limitations for the False Claims Act (31 U.S.C. 3731(b)). Our proposed 10-year record retention requirement supports the Federal government's right under the False Claims Act to investigate and pursue claims based on violations involving Federal funds that have occurred within the last 10 years.

Proposed §156.705(d) explains that the records referenced in paragraph (a) must be made available to HHS, the OIG, the Comptroller General, or their designees, upon request.

These proposed standards pertain only to Exchange-specific areas of concern (for example, matters pertaining to advance payments of premium tax credits or cost-sharing reductions) within the FFEs, as HHS would expect the State DOI to oversee the maintenance of records pertaining to other aspects of QHP issuer operations as required under State law. We welcome comments on these proposed standards.

b. Compliance Reviews of QHP Issuers in Federally-facilitated Exchanges (§156.715)

Section 1313(a)(5) of the Affordable Care Act requires the Secretary to establish any measure or procedure that the Secretary has authority to implement in Title I of the Affordable Care Act or any other act to protect against fraud and abuse. Additionally, in accordance with section 1321 of the Affordable Care Act, the Secretary has the authority to issue regulations on the establishment and operation of an Exchange, the offering of QHPs through the Exchange, the establishment of reinsurance and risk adjustment programs, and other requirements as the Secretary determines appropriate.

Based on this authority, we propose in §156.715(a) that issuers offering QHPs in an FFE be subject to compliance reviews by HHS to ensure ongoing compliance with Exchange standards applicable to issuers offering QHPs in the FFE. We envision our oversight of QHP

issuers in FFEs to be primarily focused on Exchange standards applicable only to issuers offering QHPs in the FFE because oversight of market-wide standards will generally be performed by States as part of their regulatory oversight. We intend to rely on data related to these standards to inform our selection of the QHP issuers for compliance reviews. We anticipate that the majority of QHP issuers selected for compliance review will be identified using a risk-based approach and include an analysis of the data collected by an FFE during certification and the plan year. Given the primary role States play in regulating health insurance, these compliance reviews will be less rigorous than in Medicare Advantage. In paragraph (b), we describe the proposed scope of documents that HHS may inspect as part of the compliance review. We propose that HHS may review the records of the QHP issuer pertaining to its activities within an FFE, which include but are not limited to the QHP issuer's books and contracts, policy manuals and other QHP plan benefit information provided to the QHP issuer's enrollees, and the QHP issuer's policies and procedures related to the QHP issuer's activities in an FFE. We further propose that the scope of information subject to the compliance review include any other information reasonably necessary, as determined by HHS, for HHS to: (a) evaluate the QHP's issuer's compliance with Exchange standards applicable to issuers offering QHPs in the FFE and their performance in the FFE; (b) verify that the QHP issuer has performed the duties attested to as part of the QHP certification process; and (c) assess the likelihood of fraud and abuse. An example of an area that may be reviewed, evaluated, or inspected is compliance with proper application and documentation of advance payments of the premium tax credit and cost-sharing reductions. We invite comment regarding other areas that should be included or considered for inclusion in the compliance reviews.

We note that under section 1311(e)(1)(B) of the Affordable Care Act, which is codified in 45 CFR 155.1000(c), the Exchange may make the health plan available on the Exchange if doing so is in the interest of the qualified individuals and qualified employers. Accordingly, under §156.715(c), we propose that HHS's findings from compliance reviews may be used in conjunction with other findings related to the QHP issuer's compliance with certification standards to confirm that permitting the issuer's QHPs to be available in an FFE is in the interest of qualified individuals and qualified employers as provided under §155.1000(c)(2).

In §156.715(d), similar to requirements for Medicare Part C audits, we propose that QHP issuers in an FFE make available to HHS the issuer's premises, physical facilities, and equipment for compliance reviews. We believe that on-site reviews are standard within the health insurance industry across a broad range of products and that QHP issuers would therefore be used to such a standard, even if they have not participated in the Medicare Part C program. We expect to focus our compliance review efforts around FFE-related standards and activities, which we believe will reduce the burden on QHP issuers that have been selected for compliance reviews. We considered the two ways of conducting compliance reviews: an onsite review for which reviewers would be physically present on the QHP issuer's premises, and a desk review, during which the reviews would be conducted off-site. Recognizing the need to be flexible depending on the specific circumstances giving rise to the need for a compliance review, we propose that HHS will have the discretion to conduct either an onsite or desk review. We further propose in this paragraph that §156.715, as proposed, is not intended to supplant the application of any other Federal laws and regulations related to information privacy and security.

In §156.715(e), we propose a time period for which HHS may conduct compliance reviews. We propose that HHS may conduct compliance reviews of a QHP issuer's operations

during any plan benefit year for up to 10 years from the last day of that plan benefit year, except when a QHP is no longer available through an FFE, HHS would be able to conduct a compliance review of the last plan benefit year of that QHP only up to 10 years from the last day that the QHP's certification was effective. For example, if a QHP's current benefit plan year ended on December 31, 2014, then HHS may conduct a compliance review of that benefit plan year until December 31, 2024. If QHP was decertified on May 1, 2014, then HHS may conduct a compliance review of the QHP's last benefit plan year until May 1, 2024. In the event that the 10 year review period ends during an ongoing compliance review, the ongoing compliance review would be permitted to continue beyond the 10 year review period. We invite comments on this proposal.

6. Subpart I - Enforcement Remedies in Federally-Facilitated Exchanges

In subpart I, we propose the enforcement remedies that may be used in an FFE with respect to QHP issuers participating in an FFE.

a. Available Remedies; Scope (§156.800)

Section 1321(c)(2) of the Affordable Care Act authorizes the Secretary to enforce Exchange standards applicable to issuers offering QHPs in the FFE using CMPs as detailed in section 2723(b) of the PHS Act "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 Title XXVII, Part A of the PHS Act when a State fails to substantially enforce these provisions.

Section 1311(d)(4) of the Affordable Care Act requires an Exchange to implement procedures for the certification, recertification, and decertification of health plans as QHPs. Accordingly, we propose that HHS may determine that a QHP offered through an FFE will be

decertified and no longer offered through an FFE under specified circumstances, including where the QHP no longer meets the conditions of the general certification criteria under 45 CFR 155.1000(c). We intend to focus our enforcement efforts on Exchange standards applicable to issuers offering QHPs in the FFE given that enforcement of market-wide standards will generally be performed by States as part of their traditional regulatory roles. In the interest of avoiding duplication of efforts, we intend to generally rely on determinations by States that have the authority to enforce Federal standards related to participation in a Federally-facilitated Exchange and are in fact, substantially enforcing these standards. In §156.800, paragraphs (a) and (b), we propose CMPs and QHP decertification, respectively, as the two formal enforcement actions that HHS may take against issuers of QHPs offered in an FFE. These are the two tools that the Affordable Care Act authorizes the Secretary to use for addressing areas of non-compliance of QHP issuers in FFEs. As with our proposed approach to monitoring QHP issuers participating in an FFE, we intend to coordinate our enforcement actions with State efforts in order to streamline the oversight of QHP issuers by HHS and States and to avoid inappropriately duplicative enforcement actions. We solicit comment on the use of these proposed compliance tools. We also invite comments on how HHS can collaborate with States on enforcement actions.

b. Bases and Process for Imposing Civil Money Penalties in Federally-facilitated Exchanges (§156.805)

In §156.805(a), we propose the bases on which HHS can impose CMPs on QHP issuers in FFEs. We propose imposing CMPs where there misconduct in the FFE or substantial non-compliance with Exchange standards applicable to issuers offering QHPs in the FFE. Examples include falsifying information furnished to an individual or entity upon which HHS relies to make evaluations of the QHP issuer's ongoing compliance with Exchange standards applicable

to issuers offering QHPs in the FFE, or which have the effect of hindering the operations of an FFE. We intend to apply these penalties in a manner such that the level of the enforcement action would vary based on our assessment of the scope or level of the violation, taking into account the issuer's previous record of compliance, the frequency of the violation, and any aggravating or mitigating factors. Because QHPs are one of several commercial market insurance products operating in State markets, HHS will seek not to unnecessarily duplicate or interfere with the traditional regulatory roles played by State DOIs. HHS generally intends to focus its QHP oversight to Exchange standards applicable to issuers offering QHPs (for example, correctly administering advance payments of the premium tax credits and cost-sharing reductions and offering benefits consistent with those set forth in the QHP applications approved by HHS) because oversight of market-wide standards will generally be performed by States in their traditional regulatory roles. . We will also seek to work collaboratively with State Departments of Insurance on topics of mutual concern, in the interest of efficiently deploying oversight resources and avoiding unnecessarily duplicative regulatory roles. We seek comment on this proposal.

In §156.805(b), we propose factors that HHS may take into consideration in determining the amount of CMPs to assess. HHS recognizes that 2014 will be a transitional year for issuers offering QHPs. As a general principle, while HHS proposes to establish authority to impose penalties consistent with this proposed rule, we note that we intend to work collaboratively with issuers to address problems that may arise, particularly in 2014. We propose that an issuer's previous and ongoing record of compliance; the level of the violation, including the frequency of the violation and the impact of the violation on affected individuals; as well as any aggravating or mitigating circumstances be taken into consideration. Section 2723(b)(2)(C) of the PHS Act

limits the CMP amount to \$100 for each day for each individual adversely affected. Therefore in §156.805(c), we propose that the maximum amount of penalty imposed for each violation to be \$100 per day for each QHP issuer, for each individual adversely affected by the non-compliance. For violations where the number of individuals adversely affected by the non-compliance cannot be determined, we propose giving HHS the authority to estimate the number of individuals likely to be adversely affected by the non-compliance. We solicit comment on these proposals in addition to comments on whether an appropriately fixed maximum penalty amount per occurrence, per submission, or per some other relevant marker, or alternatively on a formula for estimating the number of individuals adversely affected by the violation would be more appropriate.

We expect this amount to be necessary and adequate for encouraging issuers to correct identified occurrences of non-compliance as quickly as possible. Our intent is to encourage QHP issuers to address issues of non-compliance rather than to impose a punitive monetary assessment, especially in situations where the issuer demonstrates good faith in monitoring compliance with applicable standards, identifying any occurrences of non-compliance, and resolving of issues of non-compliance. We believe that taking into consideration the various factors proposed in paragraph (b) provides HHS flexibility to consider the totality of the circumstances in determining a reasonable amount of CMP to assess. In paragraph (d), we propose standards for notifying QHP issuers of the intent to assess a civil money penalty, which notice must include an explanation of the QHP issuer's right to a hearing under subpart J of this part, which appeals process we propose to model after the process that applies to appeals of HIPAA violations. Section 156.805(e) contains our proposed provisions on the consequences of failing to timely request a hearing, which we have modeled after 45 CFR 150.347.

We seek comment on the content and scope of these provisions.

c. Bases and Process for Decertification of a QHP Offered by an Issuer through the Federally-facilitated Exchanges (§156.810)

Section 1311(d)(4) of the Affordable Care Act directs that each Exchange must implement procedures for the certification, recertification, and decertification of health plans as QHPs, consistent with guidelines developed by the Secretary. We have considered the possibility of decertification at (1) the issuer level, (2) the QHP level, and (3) both at the issuer level and at the QHP level. We considered all three options because some of the bases for decertification include failure to comply with applicable standards at the issuer level, while others uniquely involve compliance at the QHP level. However, since certification is granted at the plan (QHP) level, we propose that decertification should also occur at the QHP level.

In §156.810(a), we propose the bases for decertification. We considered events that are likely to undermine the integrity or operations of an FFE, harm the health of enrollees by limiting access to healthcare, and or substantially interfere with HHS' ability to ensure that QHPs offered in an FFE are in the interests of qualified individuals and qualified employers. Recognizing that QHP issuers are voluntarily electing to participate in an FFE, and that participation is not required by any statutory mandate, we expect the majority of QHP issuers to cooperate with HHS in resolving any issues of non-compliance. As such and absent any extraordinary circumstances, we expect few decertifications, especially in the first plan year. With these considerations in mind, we propose in paragraph (a)(1), that a QHP may be decertified if the issuer substantially fails to comply with Federal laws and regulations applicable to QHP issuers participating in an FFE. In paragraphs (a)(2), (3), and (4), we propose that a QHP may be decertified if the issuer substantially fails to comply with other specific Federal standards

applicable to its participation in an FFE, as related to the risk adjustment program, transparency in coverage, QHP marketing and benefit design, privacy and security standards, and advance payment of the premium tax credit and cost-sharing reductions. In paragraph (a)(5), we propose that a QHP may be decertified if the issuer operates in a manner that hinders the efficient and effective administration of an FFE. In paragraph (a)(6), we propose that failure of a QHP to meet the requirements of the applicable certification criteria would be a basis for decertification. In paragraph (a)(7), we propose that a QHP may be decertified when there is credible evidence that the issuer has committed or participated in fraudulent or abusive activities affecting the Exchange, including submission of false or fraudulent data. In paragraphs (a)(8) and (9), we propose as bases for decertification, when the QHP issuer substantially fails to meet Federal standards related to enrollees' ability to access necessary medical items and services which failure could have the effect of seriously harming enrollees. In paragraph (a)(10), we propose as a basis for decertification, when the State recommends to HHS that the QHP should no longer be available in an FFE. We note that in the first year, we expect decertification under these bases to be used only in extreme cases, and only after the issuer has a sufficient opportunity to come into compliance, unless the deficiency is egregious and the harm to enrollees or to the integrity or operations of the FFE is immediate and severe.

In §156.810(b)(1), we propose that HHS may consider a previous or ongoing regulatory or enforcement actions taken by a State against a QHP issuer as a factor in determining whether to decertify a QHP offered by that issuer. We believe this is important to ensure that mitigating factors identified by the State are thoroughly considered in the decision to decertify a QHP. We believe that, by collaborating with the State in which a QHP is being considered for decertification, we can make a more informed decision about whether decertification is an

appropriate course of action by HHS. In paragraph (b)(2), we propose that HHS may decertify a QHP offered by an issuer in an FFE based on a determination or action of a State as they relate to the issuer offering QHPs in an FFE, including, but not limited to, when a State places an issuer or its parent organization into receivership or when the State has recommended to HHS that a QHP should no longer be made available in an FFE. We invite comments on whether these bases are appropriate.

In §156.810(c) and (d), we propose two processes for decertification actions, in consideration of the different bases which may result in decertification. Where the basis for decertification does not put the QHP enrollees' ability to access necessary medical items and services at risk or substantially compromise the integrity of FFEs, we propose a standard decertification process under §156.810(c). Under the standard process, we propose that written notice of the decertification would be sent to the QHP issuer, enrollees in the QHP being decertified, and the State DOI in the State in which the QHP is being decertified. The written notice would specify the effective date of the decertification, which would not be earlier than 30 days after the date of issuance of the notice. Additionally, we propose that the written notice would state the reason for the decertification, including the legal basis; inform the issuer of the effect of decertification and the procedure for appeal; and inform the QHP enrollees of the effect of decertification and the availability of a special enrollment period under §155.420.

Where the basis for a decertification is one in which the QHP enrollees' ability to access necessary medical items or services is at risk or the integrity of an FFE is substantially compromised, we propose that the QHP issuer would be subject to an expedited decertification process under §156.810(d). This would include cases in which there is credible evidence of fraud, the issuer substantially fails to provide enrollees of its QHPs access to necessary medical

items or services, or other specified circumstances. We propose that the expedited decertification process would be similar to the standard process, except that the effective date of the decertification could be immediate. We recognize that, under the expedited decertification process, a QHP issuer may lose enrollees during the appeal process. However, given that the bases for expedited decertification are limited to when the enrollees' ability to access needed health items or services is at risk or the integrity of an FFE is substantially compromised, and that enrollees should be offered an opportunity to transition to another QHP in these circumstances, we believe that this expedited decertification process is appropriate. Furthermore, the QHP issuer's interests are adequately protected by the opportunity for a hearing after decertification, and the potential for QHP reinstatement depending on the outcome of the appeal process

Both the standard and expedited decertification processes would afford the issuer of the decertified QHP the right to appeal the decertification through an administrative hearing process under §156.810(e), only the timing of that appeal would differ. We propose that, under the standard decertification process, the appeal would be available prior to the decertification; under the expedited decertification process, the appeal generally would be available post-decertification. Under §156.810(e), we propose that an issuer may appeal the decertification of a QHP offered by that issuer by filing a request for hearing under part 156, subpart J. If the issuer makes a request for hearing and the decertification is proceeding under the standard process, we propose that the decertification would not take effect until after the final administrative decision in the appeal, notwithstanding the effective date specified in the notice of decertification. If the decertification is proceeding under the expedited process, we propose that the decertification would still take effect on the effective date specified in the notice of decertification; however, we

propose that the certification of the QHP could be reinstated immediately upon issuance of a final administrative decision that the QHP should not be decertified.

We welcome comment on all of the proposed decertification procedures, specifically, we invite comment on the two processes for decertification (standard and expedited) and the bases for each process.

7. Subpart J - Administrative Review of QHP Issuer Sanctions in a Federally-facilitated Exchange

a. Administrative Review in a Federally-facilitated Exchange (§§156.901-156.963)

Section 1321(c)(2) of the Affordable Care Act authorizes the Secretary to use CMPs as a means to enforce the Exchange standards, including in an FFE. Section 1311(d)(4)(A) of the Affordable Care Act authorizes Exchanges, including an FFE, to take action to decertify QHPs offered through the Exchange. Enforcement actions taken by a Federal agency are generally subject to the Administrative Procedure Act, 5 U.S.C. 554 and 556. Consequently, we believe that QHP issuers in an FFE that are subject to an enforcement action authorized by the Affordable Care Act and proposed subpart I of 45 CFR part 156 are entitled to the protections provided by the Administrative Procedure Act, including a hearing.

(1) Civil Money Penalty

45 CFR 150.401 through 150.463 sets forth an administrative hearing process for individuals and entities against whom a CMP has been imposed in the individual and group health markets. This process is intended to provide the individual or entity an opportunity to submit evidence to be considered by the administrative law judge (ALJ). 45 CFR 150.401 through 150.463 establish the evidentiary and procedural rules governing the administrative hearing. Under these provisions, the ALJ decides whether there is a basis for assessing a CMP

against the individual or entity and whether the amount assessed is reasonable. In order to appeal the CMP, an individual or entity must request a hearing within 30 days after the date of the issuance of a notice of assessment. If no hearing is requested, the assessment constitutes a final and un-appealable order.

We believe that the process set forth in 45 CFR 150.401 through 150.463 is similar to the processes most States have in place for issuers to appeal State enforcement actions. These regulations also established the administrative review process for enforcement actions against individuals and entities for HIPAA violations, which have been expanded to apply to appeals of market-wide reform enforcement actions. Because the process established in 45 CFR Part 150 is similar to existing State appeals processes, and we expect that issuers should be familiar with HIPAA enforcement processes given the long history of that statute, we believe there is significant benefit in modeling the administrative hearing process for appeals of sanctions against QHP issuers in an FFE after the process established in Part 150. Furthermore, we believe that the process as described in the relevant sections of Part 150 sufficiently protects the procedural rights of QHP issuers. Therefore, we propose in 45 CFR 156.901 through 156.963 an administrative appeals process modeled after that set forth in 45 CFR 150.401 through 150.463. We seek comment on whether this process, as proposed, should include additional protections and whether certain provisions could be eliminated to expedite the administrative review process and reduce administrative burden. We also invite comments on whether other models, such as the appeals process for CMPs under section 1128A of the Social Security Act, would be more appropriate models to use. We propose numbering these sections in a manner similar to the numbering in Part 150 for simplicity.

(2) Decertification of QHPs

Section 1311(d) of the Affordable Care Act requires an FFE to implement procedures for decertification of QHPs offered through an FFE. 45 CFR 155.1080 codifies this requirement and, in paragraph (d) requires an FFE to establish a process for appealing the decertification of a QHP. We considered two approaches to the decertification appeals process. The first approach would be to expand the proposed process for CMP appeals to include appeals of decertifications of QHPs offered in an FFE. Under this approach, the issuer of a QHP that is being decertified would have the opportunity to request a hearing before an ALJ. The appeals process would be governed by explicit procedural and evidentiary rules that would afford issuers due process protections. As explained above, this approach is modeled after the HIPAA administrative hearing process for CMPs assessed against issuers in the group and individual markets, and is and similar to appeals processes that currently exist at the State level. We note that the HIPAA administrative process has been expanded to apply to appeals of enforcement actions of market-wide reform standards. We believe this approach would be familiar to QHP issuers and would therefore cause minimal confusion and uncertainty. The second approach that we considered is the hearing process used for terminations of contracts with Medicare Part C organizations under 42 CFR 422.510(a), which appeals process is described at 42 CFR part 422, subpart N. Under this approach, the hearing would take place before a hearing officer rather than an ALJ. Although the Medicare Part C approach might take less time to result in a final administrative decision on decertification, we considered the possibility that QHP issuers that are unfamiliar with the Medicare program could be confused by this hearing process. Therefore, after careful consideration of the benefits and risks of the two approaches, we propose modeling the hearing process for QHP decertification after the HIPAA process. Similar to our proposal for the CMP appeals hearing process, for decertification hearings, we propose generally to adopt the

regulatory process set forth 45 CFR part 150, subpart D. Although we propose to preserve the large majority of the regulatory text from part 150, there are two principal exceptions. In §156.903(a), we propose modifying the part 150 approach to expand the scope of the ALJ's authority to issue a decision concerning the decertification of a QHP in an FFE. In §156.917(a), we propose modifying the part 150 approach by including a paragraph (a)(3) to provide that the ALJ has the authority to hear and decide whether a basis exists for an FFE's determination to decertify a QHP. In other places, where necessary, we make conforming amendments to refer to appeals of decertifications as well as of CMP assessments; otherwise, our intent is to not alter the regulatory process set forth in 45 CFR part 150, subpart D. We seek comment on whether this appeals process should include additional protections or whether certain aspects of the part 150 approach could be eliminated to expedite the administrative review process and reduce administrative burden. We also invite comments on whether other models, such as the appeals process for CMPs under section 1128A of the Social Security Act, would be more appropriate models to use.

8. Subpart K– Cases Forwarded to Qualified Health Plans and Qualified Health Plan Issuers in Federally-facilitated Exchanges by HHS

a. Standards (§156.1010)

We propose in §156.1010 to set requirements for resolving cases forwarded to the QHP issuer operating in an FFE by HHS. A case is communication brought by a complainant that expresses dissatisfaction with a specific person or entity subject to State or Federal laws regulating insurance, concerning the person or entity's activities related to the offering of insurance, other than a communication with respect to an adverse benefit determination as defined in 45 CFR 147.136(a)(2)(i). Cases could include concerns about the operations of a

QHP issuer operating in an FFE such as: waiting times when contacting an issuer's call center, the demeanor of customer service personnel, or the failure to receive materials related to coverage under the QHP, such as the Summary of Benefits and Coverage. While we expect that most cases will be brought by or on behalf of QHP applicants and enrollees, some cases may be brought by providers or other interested parties. HHS recognizes that States currently play an important role in handling various types of cases related to health plans and issuers, and HHS envisions the States will continue to play an important role in assisting applicants, enrollees, providers and others. We anticipate that many cases will be presented in the first instance to the State DOI and will be addressed by the State in accordance with its own laws, regulations, and processes. For a case forwarded to a QHP issuer operating in an FFE by a State, the QHP issuer is expected to comply with applicable standards established by State laws and regulations. Additionally, some cases not related to FFE-specific topics will be brought to HHS rather than to the State. HHS intends to work with each State to ensure that such cases are addressed by the State in accordance with its own laws, regulations, and processes. We intend that cases received by a QHP issuer operating in an FFE directly from a complainant or the complainant's authorized representative will be handled by the issuer through its internal customer service process. For cases related to FFE-specific topics brought to HHS, we propose that such cases will be addressed and resolved by HHS and the issuer, as appropriate, pursuant to the proposed standards in §156.1010.

In §156.1010(a), we propose the definition of a case. In §156.1010(b), we propose that QHP issuers operating in an FFE must investigate and resolve, as appropriate, cases brought by a complainant or the complainant's authorized representative and forwarded to the issuer by HHS. QHP issuers operating in an FFE are reminded that issues and inquiries related to an

adverse benefit determination as defined in 45 CFR 147.136(a)(2)(i) are not covered by this proposed section, and are subject to the regulations governing internal claims appeals and external review in 45 CFR 147.136.

Section 156.1010(c) proposes that cases may be forwarded to a QHP issuer operating in an FFE through a casework tracking system developed by HHS, or through other means as determined by HHS. Cases may be input into a tracking system developed by HHS by a variety of individuals, including HHS staff, Navigators and other assistors, and Consumer Assistance Programs.

Section 156.1010(d) proposes that cases forwarded by HHS to a QHP issuer operating in an FFE must be resolved within 15 calendar days of receipt of the case. We propose that such cases involving the need for urgent medical care must be resolved no more than 72 hours after receipt of the case. QHP issuers operating in an FFE must make every effort to quickly resolve cases when an enrollee has an urgent need to access needed medical items and services, pursuant to proposed paragraph (e) of this section. We further propose that, for cases forwarded by HHS to a QHP issuer operating in an FFE, where applicable State laws and regulations establish timeframes for case resolutions that are stricter than the standards under this paragraph, QHP issuers are required to comply with the stricter State laws and regulations.

In 156.1010(e) we propose that an urgent case is one in which there is an immediate need for health services because a non-urgent standard could seriously jeopardize the enrollee's or potential enrollee's life, or health or ability to attain, maintain, or regain maximum function.

In §156.1010(f), for cases forwarded by HHS we propose that QHP issuers operating in an FFE are required to provide notice to complainants regarding the disposition of a case as soon as possible upon resolution of the case, but in no event later than seven (7) business days after

the case is resolved. Notification may be by verbal or written means as determined most expeditious by the QHP issuer.

In §156.1010(g), we propose that the QHP issuer operating in an FFE must document in a casework tracking system developed by HHS, or by other means determined by HHS, that the case has been resolved, no later than seven (7) business days after resolution of the case. The resolution record must include a clear and concise narrative explaining how the case was resolved including information about how and when the complainant was notified of the resolution.

In §156.1010(h) we propose that cases received by a QHP issuer operating in an FFE from the State in which the issuer offers QHPs must be investigated and resolved according to applicable State laws and regulations. In addition, QHP issuers operating in an FFE must cooperate fully with a State, HHS, or any other appropriate regulatory authority that is handling a case.

HHS will use casework data within the HHS developed casework tracking system, including data entered by HHS and other users such as QHP issuers operating in FFEs, Consumer Assistance Programs, and Navigators, to identify trends, areas of concern, and compliance issues.

9. Subpart L – Quality Standards

a. Establishment of Standards for HHS-approved Enrollee Satisfaction Survey Vendors for Use by QHP Issuers in Exchanges (§156.1105)

Section 1311(c)(4) of the Affordable Care Act directs the Secretary to develop an enrollee satisfaction survey that evaluates the level of enrollee satisfaction with each QHP that is offered through an Exchange, for QHPs that had more than 500 enrollees in the previous year.

The results of the evaluation are to be publicly reported on the Exchange's Internet portal, in a manner that allows for easy comparison of enrollee satisfaction levels among comparable plans. HHS intends to begin public reporting of these survey results in 2016. 45 CFR 155.200(d) directs Exchanges to oversee the implementation of enrollee satisfaction surveys and the assessment and ratings of health care quality and outcomes, in accordance with sections 1311(c)(1), 1311(c)(3) and 1311(c)(4) of the Affordable Care Act. Further, as part of minimum certification standards, 45 CFR 156.200(b)(5) directs QHP issuers to disclose and report information on health care quality and outcomes and implement appropriate enrollee satisfaction surveys.

In order to carry out these functions, we propose processes under which HHS would approve and oversee enrollee satisfaction survey vendors that will administer enrollee satisfaction surveys on behalf of QHP issuers. In future rulemaking, we intend to direct QHP issuers to contract with HHS-approved enrollee satisfaction survey vendors to fulfill the requirements established in 45 CFR 156.200(b)(5). The enrollee satisfaction survey vendors would need to be approved by mid-2014 to allow time for QHP issuers to contract with these vendors by late 2014, well before any relevant quality reporting standards must be implemented. We have previously stated that quality reporting standards (including the enrollee satisfaction survey) would be implemented in 2016, and available for consumers to use during 2017 open enrollment.³³ This implementation timeline is reflective of the earliest possible time that issuers would be able to report performance data on their QHP populations. HHS intends to also utilize

³³ General Guidance on Federally-facilitated Exchanges, May 16, 2012. Available at <http://cciio.cms.gov/resources/files/ffe-guidance-05-16-2012.pdf>.

the enrollee satisfaction survey information to engage in oversight activities of QHP issuers and in QHP recertification decisions.

We also intend to establish, in future rulemaking, that the enrollee satisfaction survey be modeled on the CAHPS[®] Health Plan survey which typically assesses patients' satisfaction with their health care, personal doctors, and health plans. To administer the CAHPS[®] survey to Medicare Parts C and D enrollees, Medicare Parts C and D utilize a similar process to the one we are proposing in § 156.1105 to approve enrollee satisfaction survey vendors. We anticipate that enrollee satisfaction survey vendors would also be responsible for submitting survey results directly to HHS and other entities specified by HHS, such as Exchanges. We also plan to promulgate additional quality reporting standards for QHP issuers and Exchanges. We seek comment on this proposed approach to approving and monitoring enrollee satisfaction survey vendors.

In § 156.1105(a), we propose an application and approval process for enrollee satisfaction survey vendors. We propose that only HHS-approved enrollee satisfaction survey vendors could administer the survey on behalf of QHP issuers. We believe that this proposed process will help to ensure that survey results are valid, reliable, and unbiased. This process would also allow QHP issuers to easily find approved vendors since we plan to publish a list of approved vendors. We propose that enrollee satisfaction survey vendors will be approved for one-year terms, which could mean that, to maintain their HHS approval, each vendor would submit annual applications to HHS demonstrating that the vendor meets all of the application and approval requirements. Survey vendor application forms will be developed and released at a later date. Survey vendors that are not approved by HHS are invited to re-apply. HHS will work with those vendors so that they could meet the standards specified in § 156.1105(b) for re-application.

We are also considering developing a process for revoking HHS approval of vendors and a related appeals process in future rulemaking. We seek comment on these processes.

In paragraph (b), we propose the standards that an enrollee satisfaction survey vendor must meet to be approved by HHS.

We have not proposed specific minimum business criteria in paragraph (b)(11) for enrollee satisfaction survey vendors. However, we intend to align these criteria with existing criteria set for Medicare Advantage CAHPS[®] Survey vendors, including but not limited to relevant survey experience and organizational survey capacity. Specifically, we are considering the following criteria: (a) having at least two years of experience conducting similar types of survey administration; (b) possessing appropriate staff credentials and expertise to conduct survey administration; and (c) minimum facility requirements, such as ability to store secure data. We seek comment on these minimum business criteria and any additional criteria that we should consider.

Finally, we propose in paragraph (c) that once HHS has approved enrollee satisfaction survey vendors, HHS would publish a list of approved entities on an HHS Web site.

10. Subpart M – Qualified Health Plan Issuer Responsibilities

a. Confirmation of HHS Payment and Collections Reports (§156.1210)

We anticipate sending each applicable issuer a monthly payment and collections reports that will show, with respect to certain provisions under Title I of the Affordable Care Act, payments HHS owes to the issuer, as well as those the issuer owes HHS. For the 2014 calendar year, we anticipate this report will include advance payments of the premium tax credit and advance payments of cost-sharing reductions that HHS is paying to the issuer for each policy listed on the payment report, any amounts owed by the issuer for FFE user fees, as well as any

adjustments from previous payments under those programs. Any applicable issuer will need to review this payment and collections report against the payments it expects for each policy based on the eligibility and enrollment information transmitted by the Exchange, and, any amounts it expects HHS to collect for FFE user fees. In order to ensure accurate payments and make adjustments, in §156.1210, we propose that, within 15 calendar days of the date of a payment and collections report, the issuer would either confirm to HHS that the payment and collections report accurately lists payments owed by HHS and the issuer for the timeframe specified in the payment and collections report, or describe to HHS any inaccuracy it identifies in these amounts (including incorrect payment amounts, or extra or missing policies in the report). These notifications would be provided in a format specified by HHS. HHS will work with issuers to resolve any discrepancies between the amounts listed in the payment and collections report and the amounts the issuer believes it should receive for the time period specified on the report.

This proposed provision will help align enrollment and eligibility data transmitted by the Exchange, payments provided by and collected by HHS, and the issuer's own records of payments due. In addition to the provisions proposed in §156.410 and §156.460 of this Part, this proposed provision will also help ensure that the correct amounts of advance payments of the premium tax credit and advance cost-sharing reductions are paid to issuers on behalf of eligible individuals. We note the need to protect enrollees from unanticipated tax liability that could result if the advance payments of the premium tax credit they receive are greater than the amounts of premium tax credit available to them. We seek comment on this provision, and in particular on the length of time issuers should have to respond to the payment and collections report.

b. Direct Enrollment With the QHP Issuer in a Manner Considered to be Through the Exchange (§156.1230)

Section 1413 of the Affordable Care Act directs the Secretary to establish, subject to minimum requirements, a streamlined enrollment process for enrollment in QHPs and all insurance affordability programs. We anticipate that many individuals will approach issuers directly for purposes of QHP enrollment. Many issuers currently use their Web sites to enroll individuals into health coverage. Accordingly, consistent with HHS's guidance titled "Affordable Exchanges Guidance: Letter to Issuers on Federally-facilitated and State Partnership Exchanges"³⁴, we propose to add paragraph §156.1230(a)(1)(i) that would allow, at the Exchange's option, a QHP issuer to enroll an applicant who initiates enrollment directly with the QHP issuer in a manner that is considered enrollment through the Exchange if the QHP issuer follows the enrollment process for qualified individuals set forth in §156.265.

We are also proposing paragraphs (a)(1)(ii) – (a)(1)(v) whereby QHP issuers that seek to directly enroll a qualified individual in a manner considered to be through the Exchange would be required to meet certain minimum consumer protections. The proposed protections would ensure that consumers know how to access available coverage options and are able to make informed plan selections. We propose in a new paragraph §156.1230(a)(1)(ii) that QHP issuers that seek to directly enroll qualified individuals in a manner considered to be through the Exchange must provide applicants the ability to view the QHPs offered by the issuer with data elements set forth at 45 CFR 155.205(b)(1). Under this proposal, QHP issuers would need to

³⁴ Affordable Exchanges Guidance: 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

ensure their Web sites provide standardized comparative information on each available QHP offered by the QHP issuer, including premium and cost-sharing information; the summary of benefits and coverage established under section 2715 of the PHS Act; identification of whether the QHP is a bronze, silver, gold or platinum metal level or a catastrophic plan; the results of the enrollee satisfaction survey, as described in section 1311(c)(4) of the Affordable Care Act; quality ratings assigned in accordance with section 1311 (c)(3) of the Affordable Care Act; MLR information as reported to HHS in accordance with 45 CFR Part 158; transparency of coverage measures reported to the Exchange during certification; and the provider directory in accordance with §156.230. We note that for 2014, the information referenced in 45 CFR 155.205(b)(1)(iv), (v), and (vii) will not be required because the information will not be available.

We also propose in §156.1230(a)(1)(iii) that QHP issuers that seek to directly enroll qualified individuals in a manner considered to be through the Exchange using the issuer's Web site must clearly distinguish between QHPs for which the consumer is eligible and non-QHPs that the issuer may offer. We propose that this distinction must also clearly articulate that APTC and CSRs apply only to QHPs offered through the Exchange.

In addition, in §156.1230(a)(1)(iv) we propose that QHP issuers that seek to directly enroll qualified individuals in a manner considered to be through the Exchange be required to notify applicants of the availability of other QHP products offered through the Exchange to consumers, regardless of whether they apply through a Web site, in-person or by phone. The QHP issuer would also be required to display the Web link to or describe how to access the Exchange Web site. We seek comment if HHS should require a universal disclaimer to be displayed by the issuer that informs applicants that other coverage options exist in the Marketplace and that not all coverage options are displayed.

In §156.1230(a)(1)(v) we propose that a QHP issuer be required to ensure that, when an applicant initiates enrollment directly with the QHP issuer and the QHP issuer seeks to directly enroll the applicant in a manner considered to be through the Exchange, the applicant is allowed to select an APTC amount, if applicable, in accordance with §155.310(d)(2), provided that the applicant makes the attestations required by §155.310(d)(2)(ii).

In §156.1230(a)(2) we propose that, if permitted by the Exchange pursuant to §155.415 of this part, a QHP issuer seeking to directly enroll applicants in a manner considered to be through the Exchange enter into an agreement with the Exchange prior to allowing any of its customer service representatives to assist qualified individuals in the individual market with: (a) applying for an eligibility determination or redetermination for coverage through the Exchange; (b) applying for insurance affordability programs; or (c) facilitating the selection of a QHP offered by the issuer represented by the customer service representative whereby the QHP issuer would agree to require each of its customer service representatives to at a minimum: (i) receive training on QHP options and insurance affordability programs, eligibility, and benefits rules and regulations; (ii) comply with the Exchange's privacy and security standards adopted consistent with §155.260; and (iii) comply with applicable State law related to the sale, solicitation, and negotiation of health insurance products, including applicable State law related to agent, broker, and producer licensure; confidentiality; and conflicts of interest. We solicit comments on these proposals.

We also propose to add paragraph (a)(3) to ensure that the premium that a QHP issuer charges to a qualified individual or enrollee is the same as was accepted by the Exchange in its certification of the QHP issuer after accounting for any APTC. We propose that if the QHP issuer identifies an error in the amount it has charged the qualified individual, the QHP issuer

must retroactively correct the error no later than 30 calendar days after its discovery. We also propose that for issuers of QHPs in the FFE, HHS may review the premiums charged to qualified individuals through the compliance reviews proposed in §156.715(a).

Finally, in paragraph (b), we state that the individual market FFE will permit the conduct set forth in this section, to the extent permitted by applicable State law.

c. Enrollment Process for Qualified Individuals (§156.1240)

We realize that a segment of the population that will seek health insurance coverage through an Exchange will not have bank accounts or credit cards, and we have received numerous questions and comments on this topic. These people should be able to access coverage through an Exchange on the same basis as those with a bank account or credit card and should not be unable to access coverage merely due to the inability to pay their share of the premium. Therefore, we propose to require QHP issuers at a minimum accept a variety of payment formats, including, but not limited to, paper checks, cashier's checks, money orders, and replenishable pre-paid debit cards, so that individuals without a bank account will have readily available options for making monthly premium payments. Issuers may also offer electronic funds transfer from a bank account and automatic deduction from a credit or debit card as payment options. We seek comment on this proposal and whether other payment methods should be included.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office and Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB,

section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The following sections of this document contain estimates of burden imposed by the associated information collection requirements (ICRs); however, not all of these estimates are subject to the ICRs under the PRA for the reasons noted. Salaries for the positions cited were mainly taken from the Bureau of Labor Statistics (BLS) Web site (http://www.bls.gov/oco/ooh_index.htm).

The salaries for the health policy analyst and the senior manager were taken from the Office of Personnel Management Web site. Fringe Benefits estimates were taken from the BLS March 2013 Employer Costs for Employee Compensation Report.³⁵

A. ICRs Regarding Program Integrity Provisions Related to State Operation of the Reinsurance Program (§153.260)

In §153.260 of this proposed rule, we direct a State-operated reinsurance program to: (1) keep an accurate accounting of reinsurance contributions, payments, and administrative expenses; (2)

³⁵ BLS March 2013 Employer Costs for Employee Compensation Report (March 12, 2013). Available at <http://www.bls.gov/news.release/ecec.toc.htm>

submit to HHS and make public a summary report on program operations; and (3) engage an independent qualified auditing entity to perform a financial and programmatic audit for each benefit year. Fewer than 10 States have informed HHS that they will operate reinsurance for the 2014 benefit year. While these reinsurance records requirements are subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(c)(4) and 44 USC. 3502(3)(A)(i), since fewer than 10 entities would be affected. Therefore, we are not seeking approval from OMB for these information collection requirements.

B. ICRs Regarding Program Integrity Provisions Related to State Operation of the Risk Adjustment Program (§153.310(c)(4) and §153.310(d)(3)-(4), and §153.365)

In §153.310(c)(4), §153.310(d)(3)-(4), and §153.365 of this proposed rule, we require a State operating risk adjustment to: (1) retain records for a 10-year period; (2) submit an interim report in its first year of operation; (3) submit to HHS and make public a summary report on program operations for each benefit year; and (4) keep an accurate accounting for each benefit year of all receipts and expenditures related to risk adjustment payments, charges, and administrative expenses. Fewer than 10 States have informed HHS that they will operate risk adjustment for the 2014 benefit year. Since the burden associated with collections from fewer than 10 entities is exempt from the PRA under 5 CFR 1320.3(c)(4) and 44 USC. 3502(3)(A)(i), we are not seeking approval from OMB for the risk adjustment information collection requirements. However, if more than nine States elect to operate risk adjustment in the future, we will seek approval from OMB for these information collections.

C. ICRs Regarding Maintenance of Records for Contributing Entities and Reinsurance-eligible Plans (§153.405(h) and §153.410(c))

In §153.405(h) and §153.410(c), we propose record retention standards for contributing entities and reinsurance-eligible plans. In proposed §153.405(h), we require contributing entities to maintain documents and records, whether paper, electronic, or in other media, sufficient to substantiate the enrollment count submitted pursuant to this section for a period of at least 10 years, and must make that evidence available upon request to HHS, the OIG, the Comptroller General, or their designees, to any such entity, for purposes of verification of reinsurance contribution amounts. This requirement may be satisfied if the contributing entity archives the documents and records and ensures that they are accessible if needed in the event of an investigation or audit.

We estimate that 26,200 contributing entities will be subject to this requirement, based on the Department of Labor's (DOL) estimated count of self-insured plans and the number of fully insured issuers that we estimate will make reinsurance contributions.³⁶ We believe that most of these contributing entities will already have the systems in place for record maintenance, and that the additional burden associated with this requirement is the time, effort, and additional labor cost required to maintain the records. On average, we estimate that it will take each contributing entity approximately 5 hours annually to maintain records. We estimate that it will take an insurance operations analyst 5 hours (at \$38.49 an hour) to meet these requirements. On average, the cost for each contributing entity would be approximately \$192.45 annually. Therefore, for 26,200 contributing entities, we estimate an aggregate burden of \$5,042,190 and 131,000 hours as a result of this requirement.

³⁶ We use an estimate of self-insured entities published by the DOL in the March 2013 "Report to Congress: Annual Report of Self-insured Group Health Plans," which reflects only those self-insured health plans (including 19,800 self-insured plans and 4,000 plans that mixed self-insurance and insurance) that are required to file a Form 5500 with the DOL.

In proposed §153.410(c), we require issuers of reinsurance-eligible plans to maintain documents and records, whether paper, electronic, or in other media, sufficient to substantiate the requests for reinsurance payments made pursuant to this section for a period of at least 10 years, and must make that evidence available upon request to HHS, the OIG, the Comptroller General, or their designees, (or, in the case of a State operating reinsurance, the State or its designees), to any such entity, for purposes of verification of reinsurance payment requests. We estimate that 1,900 issuers of reinsurance-eligible plans will be subject to this requirement, based on HHS's most recent estimate of the number of fully insured issuers that will submit requests for reinsurance payments. On average, we estimate that it will take each issuer of a reinsurance-eligible plan approximately 10 hours annually to maintain records. We estimate that it will take an insurance operations analyst 10 hours (at \$38.49 an hour) to meet these requirements. On average, the cost estimate for each issuer is approximately \$384.90 annually. Therefore, for 1,900 issuers, we estimate an aggregate burden of \$731,310 and 19,000 hours as a result of this requirement.

The burden estimates for these two recordkeeping requirements are broad estimates that include not only the maintenance of data, but all records and documents that may be necessary to substantiate the enrollment count and requests for reinsurance payments made pursuant to 45 CFR 153.405 and 153.410, respectively. Because the scope of these requirements is substantially less than the scope of the recordkeeping requirement applicable to a State operating reinsurance, these estimates are lower than those that were set forth for State-operated reinsurance programs record maintenance requirement (45 CFR 153.240(c)) in the Premium Stabilization Rule published March 23, 2012 (77 FR 17220), and the associated information collection request approved under OMB Control Number 0938-1155. We note that we will account for the

additional burden associated with submitting this information to HHS in a future information collection request that will go through the requisite notice and comment period and subsequent OMB review and approval process.

D. ICRs Related to Ability of States to Permit Agents and Brokers to Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in Qualified Health Plans in the Federally-facilitated Exchange (§155.220)

Section 155.220 authorizes HHS to terminate an agent's or broker's agreement with an FFE if HHS determines that the agent or broker is out of compliance with the standards outlined in 45 CFR 155.220. Section 155.220(g) sets forth the process whereby an agent or broker can request reconsideration of HHS's termination. Specifically, the agent or broker must submit the request for reconsideration within 30 calendar days of receipt of the date of the notice of termination.

The burden estimates for the reporting requirements in §155.220 reflect our assumption that there will be 254,095 agents and brokers registered in an FFE. The NAIC indicates that there are between 600,000 and 700,000 total licensed brokers selling health insurance at any point in time in the United States. We selected the midpoint, 650,000, as our estimate of the number of licensed brokers. We estimate that 37 percent of these brokers are in States with State Exchanges. This means an estimated 63 percent, or 409,500, are in FFE States. We estimate that 85 percent, or 348,000, will be registered in an FFE. States have traditionally overseen agents and brokers in the health insurance market and we expect that States will continue in that regulatory role and be the primary regulator of agents and brokers in their respective States. Given that our oversight of agents and brokers will be narrowly tailored to FFE-specific standards, we expect terminations to be infrequent, especially in the first plan year. For purposes

of this burden estimate, we assume that two agents or brokers will have their access suspended or revoked and that both agents or brokers will appeal these actions. We solicit comments on these assumptions.

As stated in §155.220(g)(2), an agent or broker may submit a request for reconsideration of any termination decision by HHS within 30 calendar days of notification of the decision. We assume the need to terminate an agent's or broker's agreement with an FFE will occur only rarely. For purposes of this initial burden estimate we estimate that revocation notices will be sent to 2 agents or brokers each year. The hour burden associated with this action is the time and effort needed by the agent or broker to create the written request and submit it electronically to HHS. The associated costs are labor costs for gathering the necessary background information and then preparing and submitting the request.

We assume that all agents and brokers who receive a notice of termination will submit a request for reconsideration. We expect the request to address the issues presented in the original notice of termination from HHS. The hours involved in preparing and submitting this request may vary. For the purpose of this burden estimate we estimate that it will take 18 hours for an agent or broker to prepare and submit this request: 10 hours (at \$28.81 an hour) for the brokerage clerk to gather and assemble necessary background materials and 8 hours (at \$41.15 an hour) for the agent or broker to prepare the written request and submit it electronically. This is a total of 18 hours annually at a cost of \$617.30 per agent or broker. Therefore, we estimate an aggregate burden of 36 hours at a cost of \$1,234.60 for the two agents or brokers. We solicit comments on these estimates.

E. ICRs Related to the Eligibility Process (§155.310)

Section §155.310(k) provides that if an Exchange does not have enough information to conduct an eligibility determination for advance payments of the premium tax credit or cost-sharing reductions, the Exchange must provide notice to the applicant regarding the incomplete application. We anticipate that this notice requirement is not a separate notice to an individual but text within the eligibility determination notice described in §155.310(g) and discussed in a separate information collection request that is associated with the notice of proposed rulemaking that published on January 22, 2013 (78 FR 4594). We therefore do not include a separate burden estimate to develop this notice but the time and cost associated with this notice is included within the estimate in §155.310(g).

Section 155.310(k)(2) provides that the Exchange must provide the applicant with a period of no less than 15 days and no more than 90 days from the date on which the notice is sent to the applicant to provide the information needed to complete the application to the Exchange.

Given the fact that the Exchange eligibility process is entirely new and involves the use of new electronic data sources in combination with a new application, it is not possible to provide estimates for the number of applicants for whom we expect to have an incomplete application. However, we anticipate that this number will decrease as applicants become more familiar with the eligibility process, as more data become available electronically, and as customer service resources evolve based on experience.

Therefore, we estimate the time and effort for one individual to comply with this provision. We expect that this will take an individual one hour to gather the relevant documentation and enter the missing information online or contact the call center to provide the necessary information. Our estimate that it will take an individual one hour to gather the relevant documentation depends on whether or not the individual already has the necessary

documentation on hand, or whether the documents are presently unavailable and the individual needs to spend additional time to gather the documentation. As such, it could take significantly less time if an individual already had the documents on hand, or potentially more time if certain documents were unavailable at the time an individual needed to complete the application.

F. ICRs Related to Oversight and Financial Integrity Standards for State Exchanges (§155.1200 to §155.1210)

In subpart M of part 155, we describe the information collection and third-party disclosure standards related to the oversight and financial integrity of State Exchanges.

Section 155.1200(a)(1)-(3) requires the State Exchange to follow GAAP and to monitor and report to HHS all Exchange-related activities. This includes keeping an accurate accounting of all Exchange receipts and expenditures. The burden associated with this reporting requirement is the time and effort needed to develop and submit Exchange-related activities to HHS. The State Exchanges will electronically maintain the information as a result of normal business practices; therefore, the burden does not include the time and effort needed to maintain the Exchange-related activity information. State Exchanges most likely will already have accounting systems in place to store accounting information. The burden associated with this requirement includes a computer programmer taking 8 hours (at \$48.61 an hour) to modify the system to maintain and monitor the information required under §155.1200(a)(1) through (3), an analyst taking 8 hours (at \$58.05 an hour) to pull the necessary data under §155.1200(a)(1) through (3) in the State Exchange accounting system, and a senior manager taking 2 hours (at \$77.00 an hour) to oversee the development and transmission of the reported data. We estimate that it will take 18 total hours at a cost of \$1,007.28 for each State Exchange. We estimate the total burden to be 324 hours for a total cost of \$18,131.04 for all State Exchanges.

Section 155.1200(b)(1) requires the State Exchange to submit a financial statement, in accordance with GAAP to HHS. The information under §155.1200(b) must be submitted at least annually by April 1 to HHS and must also be publicly displayed. The burden associated with this reporting requirement is the time and effort needed to develop and submit the financial statement to HHS. The State Exchanges will electronically submit the information. Therefore, the burden is the time and effort needed to develop and publically display the financial statement. The State Exchanges will electronically maintain the information as a result of normal business practices, therefore the burden does not include the time and effort needed to develop and maintain the financial information. The burden associated with this requirement includes a computer programmer taking 40 hours (at \$48.61 an hour) to design the financial statement report, an analyst taking 8 hours (at \$58.05 an hour) pulling the necessary data and inputting it into the financial statement report, and a senior manager taking 2 hours (at \$77.00 an hour) overseeing the development and transmission of the reported data. We estimate a burden of 50 total hours for each State Exchange at a cost of \$2,562.80, for a total cost of \$45,410.40 for all Exchanges.

Section 155.1200(b)(2) requires the State Exchange to submit eligibility and enrollment reports to HHS. The State Exchanges will electronically maintain the information as a result of normal business practices, therefore the burden does not include the time and effort required to develop and maintain the source information. The burden associated with this reporting requirement includes the time and effort necessary for a computer programmer taking 40 hours (at \$48.61 an hour) to design the report template, an analyst taking 8 hours (at \$58.05 an hour) to compile the statistics for the report for submission to HHS, a privacy officer taking 8 hours (at \$64.98 an hour) and senior manager taking 2 hours (at \$77.00 an hour) overseeing the development and

submission of the reported data. The burden also includes the time and effort necessary to post the data on the State Exchange Web site. We estimate an initial year burden of 58 hours at a cost of \$3,082.64 to each State Exchange and a total burden of 1,044 hours at a cost of \$55,487.52 for all State Exchanges.

As discussed in §155.1200(b)(3), the State Exchange will report performance monitoring data to HHS. The performance monitoring data includes information on financial sustainability, operational efficiency, and consumer satisfaction which will be reported on an annual basis. The State Exchanges will electronically maintain the information as a result of normal business practices developed under Establishment Grants from HHS for this purpose. Therefore the burden does not include the time and effort needed to develop and maintain the performance data. The burden associated with meeting the reporting requirement includes the time and effort necessary for a computer programmer taking 40 hours (at \$48.61 an hour) to design the report, for an analyst taking 12 hours (at \$58.05 an hour) to pull data into the report and prepare for submission to HHS and for a senior manager taking 2 hours (at \$77.00 an hour) to oversee the development and transmission of the reported data. Section 155.1200(b) requires the State Exchange to submit to HHS and to display publicly financial, eligibility and enrollment reports and performance data at least annually. For those measures reported annually, we estimate that in the initial year a burden of 54 hours for the State Exchanges at a cost of \$2,795.00 each and a total burden of \$50,031.00.

Section 155.1200(c) (1) through (3) direct the State Exchange to engage an independent audit/review organization to perform an external financial and programmatic audit of the State Exchange. The State Exchange must provide the results of the audit and identify any material weakness or significant deficiency and any intended corrective action. The burden associated

with meeting this third party disclosure requirement includes the burden for an analyst level employee taking 3 hours (at \$48.61 an hour) to pull data into a report, the time and effort necessary for a health policy analyst taking 2 hours (at \$58.05 an hour) to prepare the report of the audit results, and the time for senior management taking 1 hours (at \$77.00 an hour) to review and submit to HHS. We estimate a burden of 6 hours for each State Exchange at a cost of \$338.93 and a total burden of \$6,100.74.

As stated in §155.1210(a), the State Exchange and its contractors and subcontractors must maintain for 10 years, books, records, documents, and other evidence of accounting procedures and practices. Section 155.1210(b) specifies the records contain information concerning management and operation of the State Exchange's financial and other record keeping systems. The records must include financial statements, including cash flow statements, and accounts receivable and matters pertaining to the costs of operation. Additionally, the records must contain any financial report filed with other Federal programs or State authorities. Finally, the records must contain data and records relating to the State Exchange's eligibility verifications and determinations, enrollment transactions, appeals, plan variation certifications, QHP contracting data, consumer outreach, and Navigator grant oversight information. State Exchanges most likely already have systems in place to store records. The burden associated with this record keeping requirement includes the time and effort necessary for a network administrator taking 16 hours (at \$46.86 an hour) to modify the State systems to maintain the information required under §155.1210(b), for a health policy analyst taking 8 hours (at \$58.05 an hour) to enter the data under §155.1210(b) into the State Exchange record retention system, and for senior management taking 2 hours (at \$73.41 an hour) to oversee record collection and retention. We estimate that it will take 26 hours for the State Exchange to comply with this

requirement for a total of 468 hours. We estimate one year burden for the State Exchanges at a cost of \$1360.98 each and a total burden of \$24,497.64.

G. ICRs Related to Change of Ownership (§156.330)

The QHP issuer must notify HHS of the change in a manner to be specified by HHS and provide the legal name and tax identification number of the new owner of the QHP and the effective date of the change of ownership. The information must be submitted at least 30 days prior to the effective date of the change of ownership. The burden associated with the QHP issuer notifying HHS of a change of ownership includes a health policy analyst taking 1 hour to draft a notice of change of ownership and 1 one hour for a senior manager to review the notice and transmit it electronically to HHS. We estimate that it will cost a QHP issuer \$128.43 to comply with this reporting requirement. At this time, we cannot estimate the number of QHP issuers that will be reporting changes of ownership. When it becomes clearer as to the potential number that may report a change of ownership, we will update our estimates to reflect the potential number.

H. ICRs Related to Oversight of Cost-sharing Reductions and Advance Payments of the Premium Tax Credit (§156.480)

In proposed §156.480(a), we propose to extend the standards set forth in proposed §156.705 concerning maintenance of records to a QHP issuer in the individual market on State Exchange with respect to cost-sharing reductions and advance payments of the premium tax credit. We believe that the burden of maintaining records related to cost-sharing reductions and advance payments of the premium tax credit for QHP issuers in an FFE is already accounted for in the burden for proposed §156.705, described elsewhere in the Collection of Information section of this proposed rule. On average, we estimate each QHP issuer in a State Exchange will

incur a cost of approximately \$2,232.54 to comply with this record maintenance requirement. This reflects 46 hours of work by an insurance operations analyst (at \$38.49 an hour) and 6 hours by a senior manager (at \$77 an hour), for a total of 52 burden hours. Based on our most recent estimates, we assume that there will be approximately 791 QHP issuers in the individual market on State Exchanges in 2014. Therefore, we estimate an aggregate burden of 41,132 hours and a total cost of approximately \$1,765,939.10 as a result of this requirement.

In §156.480(b), we propose that, for each benefit year, an issuer that offers a QHP in the individual market through a State Exchange or an FFE report to HHS annually, in a timeframe and manner required by HHS, summary statistics with respect to cost-sharing reductions and advance payments of the premium tax credit. This proposed provision will permit HHS to obtain critical information regarding cost-sharing reductions and advance payments of the premium tax credit across a broad range of issuers to identify systemic problems and errors, without requiring intrusive annual investigations. We believe that QHP issuers will already have the information and data systems in place necessary to generate a summary report, and that there will only be a small additional burden as a result of this submission requirement. We estimate that it will take an insurance operations analyst 16 hours (at \$38.49 an hour) annually and one senior manager 2 hours (at \$77 an hour) to gather summary information and prepare a report for submission to HHS. Therefore, we estimate an additional burden of 21,600 hours and total costs of approximately \$923,808 for 1,200 QHP issuers (\$769.84, on average, for each QHP issuer) as a result of this requirement.

I. ICRs Related to Oversight and Financial Integrity Standards for Issuers of Qualified Health Plans in the Federally-facilitated Exchange (§156.705 to §156.715)

The burden estimates for the collections of information in Part 156, Subpart H, of the regulation reflect the assumption that an FFE will include 409 QHP issuers. The labor categories and salary estimates used to calculate the cost burden of these collections on issuers are derived from the Bureau of Labor Statistics' (BLS) May 2012 Occupational Employment Statistics data for selected occupations. These burden estimates generally reflect burden for the first year. We anticipate that the burden in subsequent years will be significantly lower because issuers will have met many of the requirements in the regulation, including developing automated processes that will reduce the total time, effort, and financial resources they need to expend in order to respond to the collections in this subpart. For this reason, these estimates should be considered an upper bound of burden for issuers.

Section 156.705 provides that issuers offering QHPs in an FFE must maintain all documents and records (whether paper, electronic or other media), and other evidence of accounting procedures and practices necessary for HHS to conduct activities necessary to safeguard the financial and programmatic integrity of the FFEs. Such activities include: (1) periodic auditing of the QHP issuer's financial records, including data related to the QHP issuer's ability to bear the risk of potential financial losses; and (2) compliance reviews and other monitoring of a QHP issuer's compliance with all Exchange standards applicable to issuers offering QHPs in the FFEs listed in part 156. These standards are limited to Exchange-specific records as applicable to the FFEs, and are not enforced by States as primary regulators. This standard mirrors the maintenance of records standard applicable to State Exchanges and set forth in §155.1210. The burden includes utilizing existing technology and systems to process and maintain this information. We estimate that it will take 100 hours at a cost of \$4,420.60 for a QHP issuer to maintain these records for a total of 30,000 hours and \$1,326,180.00.

Section 156.705(d) provides that QHP issuers must make all records described in paragraph (a) of this section available to HHS, the OIG, the Comptroller General, or their designees, upon request. In estimating the annual hour and cost burden on QHP issuers of making these records available to such authorities upon request, we assumed that such requests would normally be made in connection with a formal audit or compliance review or a similar process. Our burden estimates for this section address the hour and cost burden of making records available to HHS, the OIG, the Comptroller General, or their designees, for audit. Our estimates reflect our assumptions that about 47 QHP issuers would be subject to a formal audit in a given year and that the burden on issuers of making the records available would include the time, effort, and associated cost of compiling the information, reviewing it for completeness, submitting it to the auditor(s), and participating in telephone or in-person interviews. We anticipate using a risk-based approach to selection of the majority of QHP issuers for compliance review so that burdens to the issuer community would generally be linked to the QHP issuers' risk. We estimate it will take 90 hours at a cost of \$4,221.20 for an issuer to make their records available for an audit for a total of 9,000 hours and \$422,120.00 across all QHP issuers subject to this requirement, which we estimate at an upper end as 100 issuers.

Section 156.715 establishes the general standard that QHP issuers are subject to compliance reviews. Our burden estimates for §156.715 address the estimated annual hour and cost burden on QHP issuers of complying with the records disclosure requirements associated with compliance reviews conducted by an FFE.

Section 156.715 provides standards for compliance reviews in the FFEs, stating that QHP issuers offering QHPs in the FFEs may be subject to compliance reviews. This section also

describes the categories of records and information issuers must make available to an FFE in conducting such reviews.

Compliance reviews evaluate a QHP issuer's compliance with the Affordable Care Act and applicable regulations. Compliance reviews will target high-risk QHP issuers and not every issuer will be reviewed each year. The results of compliance reviews will also provide insight into trends across the compliance statuses of QHP issuers, enabling HHS to prioritize areas of oversight and technical assistance.

We assume that HHS will conduct desk reviews of 31 QHP issuers each year. For each QHP issuer desk review we estimate an average of 40 hours for administrative work to assemble the requested information, 19.5 hours to review the information for completeness, and 30 minutes to submit the information to HHS. There will also be an additional 10 hours to spend on phone interviews conducted by the reviewer and 2 hours to spend speaking through processes with the reviewer. We estimate it will take 72 hours at a cost of \$2,877.40 for an issuer to make information available to HHS for a desk review for a total of 2,232 hours and \$89,199.40 across all issuers that may be subject to this information collection requirement.

We assume that HHS will conduct onsite reviews of 16 QHP issuers each year. For each onsite review we estimate it will take an average of 40 hours for administrative work to assemble the requested information, 19.5 hours to review the information for completeness and 30 minutes to submit the information to HHS in preparation for an onsite review. An onsite review requires an additional 2 hours to schedule the onsite activities with the compliance reviewer, 4 hours for introductory meeting, 8 hours to tour reviewers onsite, 10 hours of interview time, 2 hours to walk through processes with the reviewer, and 4 hours for concluding meetings. This is a total of approximately 60 hours of preparation time and an additional 30 hours for onsite time for each

QHP. We estimate it will take 90 hours at a cost of \$3,566.84 for an issuer to make information available to HHS for an onsite review. We estimate that the burden for all respondents that may be subject to this information collection will be 1,440 hours at a cost of \$57,069.44.

In cases in which HHS could potentially require clarification around submitted information, HHS may need to contact QHP issuers within 30 days of information submission. This would be the case for approximately 20 issuers. We estimate it will take an issuer 2 hours at a cost of \$53.75 to respond to questions for a total of 40 hours and \$1,075.00.

J. ICRs Regarding Enforcement Remedies in Federally-facilitated Exchanges (§156.800 to §156.810)

Subpart I of Part 156 discusses the enforcement remedies in the FFEs. Section 156.800 authorizes HHS to impose sanctions on QHP issuers in an FFE that are not in compliance with Federal standards. These sanctions may be in the form of a CMP, as set forth in §156.805; or decertification of QHPs, as set forth in §156.810. The burden estimates for the collections of information in this Part reflect our assumption that there will be 409 QHP issuers and 12,000-18,000 QHPs in all FFEs.

Section 156.805(a) sets forth the general process and bases for imposing a CMP on issuers offering QHPs in an FFE. As explained in the preamble to Subpart I, HHS intends to work collaboratively with QHP issuers, where possible, especially during the first plan year, when problems arising concerning compliance with applicable standards. CMPs will be imposed only for serious issues of non-compliance. We expect to provide technical assistance to issuers, as appropriate, to assist them in maintaining compliance with the applicable standards. We also plan to coordinate with States in our oversight and enforcement activities to avoid inappropriately duplicative enforcement efforts. Consequently, we anticipate that CMPs will be

rare, especially in the first benefit year. For purposes of calculating the estimated burden, we assume that one issuer each year will be subject to a CMP and that the issuer will request an appeal of the enforcement action. We seek comment on these assumptions.

Section 156.810 sets forth the bases for the decertification of a QHP in an FFE and the general process for decertification. As with CMPs, HHS expects that decertification will be relatively infrequent, and reserved for only serious instances of non-compliance with applicable standards. Therefore, for purposes of this estimated burden, we assume that only one QHP in an FFE will be decertified each year. We assume that the issuer offering the decertified QHP will appeal the decertification action. We solicit comments on these assumptions.

Because we anticipate that fewer than 10 issuers would be subject to a decertification or CMP in a given year, we have not calculated a burden estimate. If the number of issuers approaches 10, we will submit a burden estimate at that time. We solicit comments on this section and these assumptions.

K. ICRs Regarding Administrative Review of QHP Issuer Sanctions in a Federally-facilitated Exchange (§156.901 to §156.963)

Subpart J of Part 156 sets forth the administrative process for issuers subject to a CMP or decertification of a QHP offered by the issuer to appeal the enforcement action. In this process, an ALJ decides whether there is a basis for HHS to assess a CMP against the issuer and whether the amount of an assessed penalty is reasonable, or whether there is a basis for decertifying a QHP offered by the issuer, as applicable. Section 156.905 (intended to parallel 45 CFR 150.405) provides that a party has a right to a hearing before an ALJ if it files a valid request for a hearing within 30 days after the date of issuance of HHS's notice of proposed assessment decertification. An issuer's request for a hearing must include the information listed in §156.907.

The burden associated with this request includes the time and effort needed by the issuer to create the written request and submit it electronically to the appropriate entity. The associated costs are labor costs for gathering the necessary background information and then preparing and submitting the written statement. The burden estimates for the collections of information in Part 156, Subpart J, of the regulation reflect the assumption that there will be a total of 409 QHP issuers in all FFEs.

We base our burden estimate on the assumptions that one issuer will be subject to CMPs and that one issuer will have a QHP that it offers in an FFE decertified. We assume that both issuers will choose to exercise their right to a hearing and will submit a valid request for hearing. The hours involved in preparing this request may vary; for the purpose of this burden estimate we estimate an average of 24 hours will be needed: 10 hours for the compliance officer to gather and assemble necessary background materials and prepare the written request, 12 hours for an attorney to review the background materials and written request and provide recommendations to the senior manager, and 2 hours for the senior manager to discuss the attorney's recommendations and submit the written request electronically. We estimate that it will take 24 hours at a cost of \$1,649.02 for an issuer to prepare and submit a request for a hearing for a total of 48 hours and \$3,298.04 for both issuers. This estimate includes any statement of good cause under §156.805(e)(3), if applicable. We solicit comments on these assumptions.

As stated in §156.905, an issuer has the right to a hearing before an ALJ if the issuer files a request for a hearing that complies with §156.907(a) within 30 days of the issuance of a notice of proposed assessment or decertification from HHS under §156.805 or §156.810. The request for a hearing must identify any factual or legal bases for the assessment or decertification with which the issuer disagrees. It must also describe with reasonable specificity the basis for the

disagreement, including any affirmative facts or legal arguments on which the respondent is relying. The request must also identify the relevant notice of assessment or decertification by date and attach a copy of the notice.

An issuer's request for a hearing must include the information listed in §156.907. The burden associated with this request includes the time and effort needed by the issuer to create the written request and submit it electronically to the appropriate entity. The only associated costs are labor costs for gathering the necessary background information and then preparing and submitting the written request.

Because we only estimate that one issuer per year would appeal a CMP and one issuer will have its QHP offered in an FFE decertified, we do not include this burden estimate in our overall calculation of burden for this proposed rule. We seek comment on this assumption.

L. ICRs Regarding Consumer Cases Related to Qualified Health Plans and Qualified Health Plan Issuers (§156.1010)

In subpart K of part 156, we describe the information collection requirements that pertain to the resolution of consumer cases related to QHPs and QHP issuers. Section 156.1010(e) states that QHP issuers must record a clear and concise narrative documenting the resolution of a consumer case in the HHS-developed casework tracking system. The burden associated with this requirement is the time and effort necessary for a QHP issuer to gather the necessary information related to the consumer complaint, draft the narrative, and enter the narrative into the electronic HHS-developed case tracking system. For the purpose of estimating burden, we estimate 1,200 issuers. We estimate that it will take approximately 60 hours annually at a cost of \$8,580.87 for the time and effort to develop and submit the narrative to HHS for a total of 72,000 hours and a cost of \$10,297,044.00 for all respondents.

M. ICRs Related to Quality Standards (§156.1105)

In subpart L of part 156, we describe the information collection and disclosure requirements that pertain to the approval of enrollee satisfaction survey vendors. The burden estimate associated with these disclosure requirements includes the time and effort required for survey vendors to develop, compile, and submit the application information and any documentation necessary to support oversight in the form and manner required by HHS. HHS is developing a model enrollee satisfaction survey vendor application that will include data elements necessary for HHS review and approval. In the near future, HHS will publish the model application and will solicit public comment. At that time, and per the requirements outlined in the PRA, we will estimate the burden on survey vendors for complying with this provision of the regulation. We solicit comment on the burden for the application and review process for these entities.

N. ICRs Related to Confirmation of Payment and Collection Reports (§156.1210)

In §156.1210, we propose that, within 15 calendar days of the date of a payment and collections report from HHS, the issuer must, in a format specified by HHS, either confirm to HHS that the payment and collections report accurately lists for the timeframe specified in the report applicable payments owed by the issuer to HHS and the payments owed to the issuer by HHS; or describe to HHS any inaccuracy it identifies in the payment and collections report. We believe that issuers will generally be able to perform this confirmation automatically, and that there will only be a small additional burden as a result of this requirement. We estimate that it will take an insurance operations analyst 1 hour (at \$38.49 an hour) monthly to make the comparison and note any discrepancies to HHS (approximately \$461.88 for each issuer annually). Based on our most recent estimates, we believe that 2,400 issuers will be affected by this requirement, resulting in aggregate burden of approximately \$1,108,512.

O. ICRs Related to Enrollment Process for Qualified Individuals (§156.1230)

Proposed §156.1230(a)(1)(ii) would require issuers who pursue the option to use their Web site to enroll qualified individuals into QHPs directly, to provide information on available QHPs. The QHP information required to be posted on the Web site would include premium and cost-sharing information, the summary of benefits and coverage, levels of coverage (“metal levels”) for each QHP, results of the enrollee satisfaction survey, quality ratings, medical loss ratio information, transparency of coverage measures, and a provider directory. Under proposed §156.1230(a)(1)(i), an issuer would also be required to direct an individual to complete an application with the Exchange and receive eligibility determinations from the Exchange to allow for an accurate plan selection process. Additionally, §156.1230(a)(1)(iv) would require the issuer Web site to inform applicants about the availability of other QHP products available through an Exchange and to display a Web link to the appropriate Exchange Web site. Finally, an issuer would submit enrollment information back to the Exchange.

The burden for this requirement would be for the issuer to develop its own template and code and integrate it with the Exchange. After this initial step, the burden on the issuer would be to maintain the Internet Web site by populating the Web site with information collected per information collection requirements in this rule and future rulemaking by HHS. We do not have an estimate on the number of issuers who will choose to utilize the direct to enrollment approach subject to these third-party disclosure requirements. We estimate that it will take 610 hours at a cost of \$32,104.25 for an issuer to meet these third-party disclosure requirements.

Proposed §156.1230(a)(2) would allow qualified individuals to apply for an eligibility determination or redetermination for coverage through the Exchange and insurance affordability programs, and select QHPs with the assistance of an issuer customer service representative if the

issuer customer service representative complies with the terms of an agreement between the issuer and the Exchange. The agreement would ensure that an issuer customer service representative receives training and provide additional standards governing the conduct of issuer customer service representatives.

The burden for this requirement would include the time and effort necessary to develop training materials for the customer service representative and the time and effort necessary to amend the agreement between the issuer and the Exchange if the Exchange implements this provision.

The Exchange would be required to develop training materials for issuer staff. We assume that the 18 State Exchanges will implement this standard. However, we expect Exchanges would use training materials that will either be developed by HHS for other types of assister training, including agent/broker training or use their own training materials that they have already developed for other assisters. Therefore, we anticipate that the time and costs associated with developing a training program for issuers will be minimal. We estimate it will take a training specialist 10 hours at \$26.64 an hour and a training and development manager 5 hours at \$64.43 an hour to develop training materials for the customer service representative, for a total time burden of 15 hours. The estimated cost burden for developing training materials for issuer customer service representatives for each Exchange is therefore \$588.55 with a total cost of \$10,593.90 across all respondents if 18 State Exchanges undertake these activities.

As specified in §156.1230(a)(2), each Exchange would amend its agreement with every issuer wanting its staff to assist consumers. We assume that the 18 State Exchanges will implement this standard. We estimate it will take a health policy analyst 20 hours at \$49.35 an hour and a senior manager 10 hours at \$79.08 an hour to amend an agreement with the issuer, for

a total time burden of 30 hours. The estimated burden for amending the agreements for each Exchange is therefore 30 hours at a cost of \$1,777.87 and a total cost of \$32,001.66.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the ADDRESSES section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, [CMS-9957-P]

Fax: (202) 395-6974; or

Email: OIRA_submission@omb.eop.gov

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the OMB.

A. Summary

As stated earlier in this preamble, this proposed rule sets financial integrity and oversight standards with respect to Exchanges; QHP issuers in an FFE; and States in regards to the operation of risk adjustment and reinsurance. It also proposes additional standards for special enrollment periods; survey vendors that may conduct enrollee satisfaction surveys on behalf of QHP issuers in Exchanges; issuer participation in an FFE; and States' operation of the SHOP. Finally, it proposes additional standards for SHOPS, agents and brokers and customer service representatives; privacy and security; geographic rating areas; and guaranteed availability and renewability.

HHS has crafted this proposed rule to implement the protections intended by Congress in an economically efficient manner. We have examined the effects of this proposed 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. No. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. No. 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, HHS has quantified the benefits and costs where possible, and has also provided a qualitative discussion of some of the benefits and costs that may stem from this proposed 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 proposed 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. OMB has designated this proposed rule as a “significant regulatory action.” Even though it is not certain whether it would have economic impacts of \$100 million or more in any one year, HHS has provided an assessment of the potential costs and benefits associated with this proposed regulation.

1. Need for Regulatory Action

Starting in 2014, qualified individuals and qualified employers will be able to use coverage provided by QHPs – private health insurance that has been certified as meeting certain standards – through Exchanges. A transitional reinsurance program and a permanent risk adjustment program would be in place to ensure premium stability for health insurance issuers as

enrollment increases and issuers enroll high-risk individuals. This proposed rule would establish general oversight requirements for State-operated reinsurance and risk adjustment programs; establish oversight of issuers inside and outside of the Exchange when HHS operates risk adjustment or reinsurance on behalf of a State; and establish oversight and monitoring of State Exchanges, FFEs, SHOPs (both State Exchanges and FFEs) and issuers of QHPs, specifically with respect to financial integrity, maintenance of records, and privacy and security of PII. This proposed rule would also restrict the use of funds for administrative expenses generated for State Exchanges and State-operated reinsurance programs; propose procedures for oversight of advance payments of the premium tax credit and cost-sharing reductions; propose procedures to ensure the accuracy of data collection, calculations, and submissions; allow a State to establish and operate only the SHOP and establish standards for SHOPs; establish requirements for customer service representatives and agents and brokers who assist consumers; establish requirements for enrollee satisfaction survey vendors; and propose additional standards for special enrollment periods.

2. Summary of Impacts

In accordance with OMB Circular A-4, Table V.1 below depicts an accounting statement summarizing HHS's assessment of the benefits and costs associated with this regulatory action. The period covered by the RIA is 2014 – 2017.

HHS anticipates that the provisions of this proposed rule will ensure smooth operation of Exchanges, integrity of the reinsurance and risk adjustment programs, safeguard the use of Federal funds, prevent fraud and abuse, increase access to healthcare coverage and provide consumer protections. Affected entities such as States, QHP issuers, agents, and brokers would incur costs to maintain records, submit reports to HHS and Exchanges, comply with privacy and

security standards for PII, provide records for compliance reviews, and to comply with enforcement actions. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

Table V.1: Accounting Table

Benefits:				
Qualitative:				
*Ensure integrity of reinsurance and risk adjustment programs, smooth functioning of State Exchanges and FFEs				
*Prevent fraud and abuse				
*Safeguard the use of Federal funds provided as cost-sharing reductions and advance payments of the premium tax credit and provide value for taxpayers' dollars				
*Enable a State to focus on effective implementation of the SHOP by allowing it to operate a State-based SHOP while the Exchange is operated as an FFE				
* Increased access to fair and unbiased customer assistance and information about coverage options for consumers, enabling consumers to make informed decisions				
*Ensure privacy and security protections				
*Ensure prompt refund of any excess premium paid or any excess cost sharing				
Costs:	Estimate	Year dollar	Discount rate percent	Period covered

Annualized Monetized (\$/year)	\$23.3 million ¹	2013	7	2014 - 2017
	\$23.2 million ²	2013	3	2014 - 2017
<p>Annual costs related to financial oversight, maintenance of records and reporting requirements for State Exchanges and State-operated reinsurance and risk-adjustment programs; record retention requirements for contributors and recipients for reinsurance programs; audit costs for State programs - Exchanges, risk adjustment and reinsurance; costs for QHP issuers related to reporting requirements, record maintenance, audits, Web site standards, training for customer service representatives, and documentation of resolution of consumer cases; costs to agents and brokers and QHPs related to enforcement actions.</p>				
<p>Qualitative:</p> <ul style="list-style-type: none"> *Costs to Exchanges and non-Exchange entities associated with FFEs and agents and brokers assisting consumers, to comply with privacy and security standards *Costs incurred by enrollee satisfaction survey vendors related to annual application and meeting HHS standards *Possible reduction in costs for SHOPs due to elimination of the requirement to accept paper applications and applications by telephone *Cost incurred by SHOPs to develop uniform standards for the termination of a group's coverage in a QHP and to keep sufficient records of terminations and reasonable accommodations 				

Note: 1. Approximately \$20.6 million of these costs are estimated in section III and \$2.7 million are estimated below in the RIA, including the audit costs in Table V.2. 2. Approximately \$20.5

million of these costs are estimated in section III and \$2.7 million are estimated below in the RIA, including the audit costs in Table V.2.

3. Anticipated Benefits and Costs

Starting in 2014, individuals and small businesses will be able to use health insurance coverage purchased through Exchanges. The Congressional Budget Office estimated that the number of people enrolled in coverage through Exchanges will increase from 7 million in 2014 to 26 million in 2017.³⁷ Exchanges will create competitive marketplaces where qualified individuals and qualified employers can shop for insurance coverage, and are expected to reduce the unit price of quality insurance for the average consumer by pooling risk and promoting competition.

The proposed rule would specify the standards and processes for the oversight and accountability of entities responsible for operations of the Exchanges and reinsurance and risk adjustment programs. Affected entities would include States, in their roles of establishing and operating Exchanges and SHOPS and administering reinsurance and risk adjustment programs; FFEs and FF-SHOPS; issuers of QHPs; health insurance issuers offering coverage both inside and outside of the Exchange when HHS operates risk adjustment or reinsurance on behalf of the State; contractors or other subsidiaries of these organizations; and insurance agents and brokers.

a. Benefits

This proposed rule would implement oversight, record maintenance and enforcement provisions that would ensure integrity of the reinsurance and risk adjustment programs, State

³⁷ “CBO’s February 2013 Estimate of the Effects of the Affordable Care Act on Health Insurance,” Congressional Budget Office, February 2013.

Exchanges and FFE functions; prevent fraud and abuse; and establish consumer protection measures.

The proposed rule includes provisions that would create a system of oversight, financial integrity and program integrity in the Exchanges and the risk adjustment, reinsurance and risk corridors programs. The proposed oversight requirements for HHS-operated and State-operated reinsurance and risk-adjustment programs would ensure that these programs are effective and efficient, and use program funds appropriately. The proposed standards would also ensure that Federal funds are used appropriately in the administration of State Exchange activities. By monitoring financial reports and overseeing State Exchange activities, HHS would safeguard the use of Federal funds provided as cost-sharing reductions and advance payments of the premium tax credit and provide value for taxpayers' dollars.

The proposed rule would also allow a State to operate a State-based SHOP while the Exchange is operated as an FFE. This would enable the State to focus on effective implementation of the SHOP and gain experience that would help prepare it to operate both a SHOP and State Exchange in the future. Each SHOP would also be required to develop uniform standards for the termination of coverage in a QHP, starting in 2015, unless the SHOP offers employee choice before then. Standardizing the timing, form, and manner of a group's termination in the SHOP would ensure that an employer offering coverage through multiple health insurance issuers (under the SHOP 'employee choice' model) will be subject to uniform, predictable termination policies.

The proposed rule would implement consumer protections that would ensure privacy and security of PII, increased access to customer assistance, information about coverage options and allow consumers to make informed coverage decisions. Permitting issuer customer service

representatives to assist individuals with applying for eligibility determinations or redeterminations for coverage through the Exchange would increase assistance available to consumers, while the training and compliance standards would ensure that such assistance is fair and unbiased. The proposed rule would establish requirements for customer service representatives and agents and brokers who assist consumers, requiring them to comply with registration and training requirements. The proposed rule would also establish standards under which HHS could terminate its relationship with agents and brokers in the FFE, to help ensure that agents and brokers continue to meet Exchange standards. In addition, the requirement for QHP issuers conducting direct enrollment to provide standardized comparative information on their Web-sites would ensure that consumers can readily differentiate and compare plan choices leading to informed decisions. Consumers without bank accounts or credits cards would also have a variety of payment options.

The provisions of this rule would also ensure that enrollees are promptly refunded any excess premium paid or any excess cost sharing they should not have paid. Individuals harmed by misconduct on the part of non-Exchange entities would also be eligible for a special enrollment period. A QHP would also be required to promptly reassign an enrollee improperly assigned to a plan variation (or standard plan without cost-sharing reductions), minimizing consumer harm.

The annual application requirement for enrollee satisfaction survey vendors would allow HHS to ensure that these entities participate in relevant training and post-training certification, follow protocols related to quality assurance and the use of HHS data, and adhere to privacy and security standards when handling data. This would help to ensure that ultimately the enrollee satisfaction survey data are reliable and valid and that the information is sufficiently protected.

The proposed enforcement actions such as CMPs and decertification of a QHP, termination of agent and broker agreement for participation in the individual market of an FFE, would improve program performance, reduce non-compliance by QHPs and agents and brokers, and decrease the likelihood of errors and adverse outcomes for consumers.

b. Costs

Affected entities would incur costs to comply with the provisions of this proposed rule. Costs related to information collection requirements subject to PRA are discussed in detail in section III and include administrative costs incurred by States, issuers and agents and brokers related to record maintenance and reporting requirements; oversight and financial integrity standards; enforcement actions; enrollment process for qualified individuals; and training requirements . In this section we discuss other costs related to the proposed provisions.

States operating reinsurance programs would be required to maintain records. The costs related to this provision are generally accounted for in the RIA of the Payment Notice and are not included in this RIA. States operating reinsurance would be required to keep an accurate accounting for each benefit year, of all reinsurance funds received from HHS for reinsurance payments and for administrative expenses, as well as all claims for reinsurance payments from issuers of reinsurance-eligible plans, all payments made to those issuers, and all administrative expenses incurred. State-operated reinsurance programs will already have a system in place to track reinsurance funds received from HHS, claims from and payments to issuers, and expenses incurred to operate the reinsurance program. The cost for States operating reinsurance to maintain any records associated with the reinsurance program was previously estimated in the RIA of the Payment Notice, and we believe that the administrative costs associated with this requirement are generally accounted for in that estimate.

State-operated reinsurance programs would submit to HHS annually and make public a summary report of their program operations, which would include a summary of the accounting kept pursuant to proposed §153.260(a). We assume that the data already collected and used to report to issuers and HHS would be the same used to prepare this annual report. Therefore, the cost associated with this requirement is the incremental time and cost to prepare an annual report to HHS and the public on program operations. We estimate it will take insurance management analysts 16 hours (at \$51 per hour) and a senior manager 2 hours (at \$77 per hour) to prepare the report. Therefore, we estimate it would cost each State that operates reinsurance approximately \$970 to submit this report to HHS. Because two States will operate reinsurance in the 2014 benefit year, we estimate that an aggregate cost of \$1,940 as a result of this requirement in the first year. We note that HHS will provide a portion of the reinsurance contributions it collects to a State operating reinsurance for the purposes of supporting State administration of reinsurance payments, which would likely cover the costs associated with this requirement.

A State operating a risk adjustment program would be directed to maintain documents and records relating to the risk adjustment program, whether paper, electronic or in other media, for each benefit year for at least 10 years, and make them available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity. The documents and records must be sufficient to enable the evaluation of a State-operated risk adjustment program's compliance with Federal standards. States would also be directed to ensure that their contractors, subcontractors, and agents maintain and make those documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees. States operating risk adjustment programs should already have the documents and records of accounting procedures needed for periodic audits. Therefore we estimate that the additional burden associated with this

requirement is the time, effort, and additional labor cost required to maintain and archive the records. We assume that it would take an insurance operations analyst 10 hours (at \$38.49 an hour) to maintain records. Therefore, the average cost for each state would be approximately \$385. Because one State will operate risk adjustment for the 2014 benefit year, we estimate an aggregate cost of \$385 to comply with this requirement in the first year.

A State operating a risk adjustment program would be required to submit by December 31st of the first benefit year an interim summary report on the first 10 months of risk adjustment activities, in order to obtain re-certification for the third benefit year. The cost of complying with this provision is the time and effort to write the interim report and submit it to HHS. We estimate it would take an insurance management analyst 16 hours (at \$51 per hour) and a senior manager 2 hours (at \$77 per hour) to prepare the interim summary report. Therefore, we estimate it would cost each state operating risk adjustment \$970 to submit this report to HHS (an aggregate cost of \$970 in the 2014 benefit year). A State operating a risk adjustment program would submit and make public, a summary report of its risk adjustment program operations for each benefit year after the first benefit year for which the State operates the program. We propose that this summary report include the results of a programmatic and financial audit for each benefit year conducted by an independent qualified auditing entity. We believe the cost of this annual report would be the same as the cost of producing the interim first-year report above, except for the cost of audits required in subsequent years, and these annual audit costs are estimated later in this RIA. These estimates also include the administrative costs related to the requirement for State-operated risk adjustment programs to keep accurate accounting for each benefit year of all receipts and expenditures related to risk adjustment payments, charges, and administration of the program.

States would face a variety of costs due to the monitoring requirements in this proposed rule. Conducting oversight of the Exchanges, State-operated risk adjustment and reinsurance programs, administration of the advance payments of the premium tax credit or cost-sharing reductions, and other activities require independent external audits, investigations, rectification of errors, and the development of summary reports which would be submitted to HHS. The estimated total audit costs for State reinsurance, risk adjustment and Exchange programs are presented in Table V.2. It is expected that 18 States will establish State Exchanges in 2014 and we assume that number will stay the same during the period covered by the RIA. We also assume that each State would conduct a financial audit and a programmatic audit annually, which would encompass reinsurance and risk adjustment programs. Financial audit costs are estimated based on prices among the big four audit firms for governmental entities of similar size to those of the anticipated State Exchanges for a financial statement audit and Yellowbook Report (report on internal controls) that reflects different levels of cost for small, medium, and large entities, for entities with low, medium, and high risk. Programmatic audit estimates reflect the experience of Federal entitlement programs similar to Medicaid audited under an A-133 program compliance supplement, and vary only by the size of the program (small medium and large). For example, a small Exchange judged to have low risk would have a combined financial and programmatic audit cost of \$90,000; a large Exchange, in a State that also administers a reinsurance program (which implies a more complex, high risk operation) would have combined financial and programmatic audit costs of \$360,000. Audit prices are based on 2012 pricing and reflect an annual increase of 3 percent each year, based on recent industry experience.

Table V.2. Estimated Audit Costs for State Programs: Exchanges, Risk Adjustment and Reinsurance

	2014	2015	2016	2017
Mid-range point estimate	\$2,572,000	\$2,649,160	\$2,728,635	\$2,810,494
Range	\$2,320,000- \$2,820,000	\$2,389,600- \$2,904,600	\$2,461,288 - \$2,991,738	\$2,535,127 - \$3,081,490

Exchanges and non-Exchange entities associated with FFEs and agents and brokers permitted by States to assist consumers would incur costs to comply with the privacy and security standards for PII, informing individuals about related policies, procedures and technologies developing policies and procedures, executing training, posting privacy policies on Web sites and providing reports of any violations to HHS. Issuers would also incur expenses to provide privacy and security training to their customer service representatives. It is anticipated that Exchanges and issuers' IT systems will need minimal changes to comply with these provisions.

The proposed rule would require the enrollee satisfaction survey vendors engaged by issuers to meet HHS standards. Survey vendors would apply for approval annually in order to administer enrollee satisfaction surveys to QHP enrollees on behalf of a QHP issuer. Vendors would incur costs to submit the annual applications to HHS and to meet the requirements necessary to meet approval.

The proposed rule would also amend existing requirements so that SHOPS would no longer be required to accept paper applications and applications by telephone. This could reduce the cost of operating a SHOP. A SHOP would also incur costs to develop uniform standards for

the termination of a group's coverage in a QHP and to keep sufficient records of terminations and reasonable accommodations.

C. Regulatory Alternatives

Under the Executive Order, HHS is required to consider alternatives to issuing rules and alternative regulatory approaches. HHS considered the following alternatives while developing this proposed rule:

1. Increased uniformity of FFE and State Exchange standards

Under this alternative, HHS would require a single standard for Exchanges across the nation regardless of whether the Exchange was established and operated by a State or was Federally-facilitated. The proposed rule would defer to State discretion in oversight of QHPs. This element of State flexibility would be precluded if greater uniformity in operations and standards were to be imposed. Greater standardization would have an uncertain impact on Federal oversight activities but would likely impose greater costs of compliance on State operations and issuers of QHPs in those States.

2. Placing more responsibility on the States to oversee standards, including those for FFEs

Under this alternative, HHS would place more responsibility on States and State Exchanges to interpret and meet statutory requirements. This approach could create a number of problems. If every State developed its own monitoring standards, oversight of different Exchanges could be quite uneven, as States across the country have varying levels of fiscal resources with which to monitor activities. States currently have certain levels of responsibility under the Affordable Care Act to oversee standards for Exchanges, QHPs, and other programs. State Exchanges also have latitude in the number, type, and standardization of plans they certify and accept into the Exchange as QHPs.

There are a number of provisions in the Affordable Care Act that devolve responsibilities from the Federal government to States. Increased devolution could decrease the need of Federal oversight, while granting States increased flexibility to regulate Exchanges within their borders. There would also be a decrease in oversight-related activities for the Federal government such as HHS investigations or audits. On the other hand, States would likely face an increase in their own oversight activities and related costs.

HHS believes that the options adopted for this proposed rule strike the best balance of ensuring efficient operation and integrity of Exchanges and the reinsurance and risk adjustment programs while providing flexibility to the States and minimizing the burden on 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. HHS anticipates that the proposed rule would not have a significant economic impact on a substantial number of small entities.

As discussed in the Web Portal final rule 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” business established by the SBA (currently \$7 million in annual receipts for health issuers).³⁸ In addition, HHS used the data from Medical Loss Ratio (MLR) annual report submissions for the 2011 MLR reporting year to develop an estimate of the number of small entities that offer comprehensive major medical coverage. These estimates may overstate the actual number of small health insurance issuers that would be affected, since they do not include receipts from these companies’ other lines of business. It is estimated that out of 466 issuers nationwide, there are 22 small entities each with less than \$7 million in earned premiums that offer individual or group health insurance coverage and would therefore be subject to the requirements of this proposed regulation. Thirty six percent of these small issuers belong to larger holding groups, and many if not all of these small issuers are likely to have other lines of business that would result in their revenues exceeding \$7 million. It is uncertain how many of these 466 issuers would offer QHPs and be subject to the provisions of this proposed rule. Based on this analysis, however, HHS expects that this proposed rule will not affect small issuers.

Some of the agents and brokers affected by the provisions of this proposed rule may be small entities and would incur costs to comply with the provisions of this proposed rule. The size threshold for “small” business established by the SBA is currently \$7 million in annual receipts for insurance agencies and brokerages. We anticipate that agents and brokers will continue to be

³⁸ “Table of Size Standards Matched To North American Industry Classification System Codes,” effective January 7, 2013, U.S. Small Business Administration, available at <http://www.sba.gov>.

an important source of assistance for many consumers seeking access to health insurance coverage through an Exchange, including those who own and/or are employed by small businesses. Due to lack of data, HHS is unable to estimate how many agents and brokers permitted by States to assist consumers would be small entities. We invite comments on this issue.

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 proposed 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 2013, that threshold level is approximately \$141 million.

UMRA does not address the total cost of a proposed 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.

The proposed rule would direct States to undertake oversight activities for State Exchanges, State-operated reinsurance and risk adjustment programs. The costs related to oversight activities, recordkeeping, reporting and audits are estimated to be approximately \$2.8 million in 2014. There are no mandates on local or tribal governments. The private sector, for example, QHP issuers and agents and brokers, would incur costs to comply with the record maintenance and reporting requirements set forth in this proposed rule. The related costs are estimated to be approximately \$21.8 million in 2014. However, consistent with policy embodied

in UMRA, this proposed rule has been designed to be a low-burden 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 proposed rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

States are the primary regulators of health insurance coverage. States will continue to apply State laws regarding health insurance coverage. However, if any State law or requirement prevents the application of a Federal standard, then that particular State law or requirement would be preempted. State requirements that are more stringent than the Federal requirements would be not be preempted by this proposed rule. Accordingly, States have significant latitude to impose requirements with respect to health insurance coverage that are more restrictive than the Federal law.

States would continue to license, monitor and regulate all agents and brokers, both inside and outside of Exchanges. All State laws related to agents and brokers, including State laws related to appointments, contractual relationships with issuers, and licensing and marketing requirements, would continue to apply. Under the proposed rule, States would have the option to operate only a State-based SHOP while the Exchange is operated as an FFE. The proposed rule would also provide additional flexibility to States with respect to the operation of a SHOP-specific Navigator program when the State operates only a SHOP Exchange. The State Exchange oversight program builds on State oversight efforts, where possible, by coordinating with State authorities to address compliance issues and concerns. HHS would coordinate

enforcement actions for QHP issuers with State efforts in order to streamline the oversight of QHP issuers by States and to avoid inappropriate duplication of enforcement actions. Because QHPs are one of several commercial market insurance products operating in State markets, HHS would not seek to inappropriately duplicate or interfere with the traditional regulatory roles played by the State DOIs. HHS would generally confine its QHP oversight to Exchange-specific requirements and attributes. HHS would also seek to work collaboratively with State DOIs on topics of mutual concern, in the interest of efficiently deploying oversight resources and avoiding needlessly duplicative regulatory roles. HHS may consider the regulatory action taken by a State against a QHP issuer as a factor in determining whether to decertify a QHP. As mentioned earlier in the preamble, HHS recognizes that States play an important role in handling consumer cases related to health insurance and HHS anticipates that States will continue to assist consumers with these grievances and complaints. QHP issuers are expected to comply with standards established by State law and regulation for cases forwarded to an issuer by a State in which it offers QHPs.

The requirements specified in this proposed rule would impose direct costs on State and local governments and we seek comments on how to minimize those costs. State Exchanges and State-operated reinsurance and risk-adjustment programs would be required to undertake oversight, record maintenance and reporting activities.

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. Throughout the process of developing this proposed rule, HHS has attempted to balance the States' interests in regulating health insurance issuers, and the Congress' intent to provide

uniform protections to consumers in every State. 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 proposed rule in a meaningful and timely manner.

G. Congressional Review Act

This proposed rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to the Congress and the Comptroller General for review.

List of Subjects45 CFR Part 144

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

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 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 practice and procedure, Advertising, Advisory Committees, Brokers, Conflict of interest, Consumer protection, 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, Public assistance programs,

Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, and Youth.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 45 CFR parts 144, 147, 153, 155, and 156 as set forth below:

PART 144 – REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

1. The authority citation for part 144 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).

2. Section 144.102 is amended by revising the second sentence of paragraph (c) to read as follows:

§144.102 Scope and applicability.

* * * * *

(c) * * * If the coverage is offered to an association member other than in connection with a group health plan, the coverage is considered individual health insurance coverage for purposes of 45 CFR parts 144 through 148. * * *

* * * * *

3. Section 144.103 is amended by revising the definitions of “Group market,” “Individual market,” “Large employer,” “Policy year,” and “Small employer” to read as follows:

§144.103 Definitions.

* * * * *

Group market means the market for health insurance coverage offered in connection with a group health plan.

* * * * *

Individual market means the market for health insurance coverage offered to individuals other than in connection with a group health plan.

* * * * *

Large employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 101 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. In the case of plan years beginning before January 1, 2016, a State may elect to define large employer by substituting “51 employees” for “101 employees.”

* * * * *

Policy year means, with respect to—

(1) A grandfathered health plan offered in the individual health insurance market, the 12-month period that is designated as the policy year in the policy documents of the individual health insurance coverage. If there is no designation of a policy year in the policy document (or no such policy document is available), then the policy year is the deductible or limit year used under the coverage. If deductibles or other limits are not imposed on a yearly basis, the policy year is the calendar year.

(2) A non-grandfathered health plan offered in the individual health insurance market, or in a market in which the State has merged the individual and small group risk pools, beginning January 1, 2015, a calendar year for which health insurance coverage provides coverage for health benefits.

* * * * *

Small employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. In the case of plan years beginning before January 1,

2016, a State may elect to define small employer by substituting “50 employees” for “100 employees.”

* * * * *

PART 147 – HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

4. 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.

5. Section 147.102 is amended by revising paragraph (a) introductory text and adding a sentence at the end of paragraph (a)(1)(ii) to read as follows:

§147.102 Fair health insurance premiums.

* * * * *

(a) In general. With respect to the premium rate charged by a health insurance issuer in accordance with §156.80 of this subchapter for health insurance coverage offered in the individual or group market—

(1) * * *

(ii) * * * For purposes of this paragraph (a)(1), rating area is determined in the small group market using the group policyholder’s principal business address and in the individual market using the primary policyholder’s address.

* * * * *

6. Section 147.104 is amended by revising paragraph (a), adding a sentence at the end of paragraph (b)(2), and revising paragraphs (c)(2), (d)(1)(ii), and (d)(2) introductory text to read as follows:

§147.104 Guaranteed availability of coverage.

(a) Guaranteed availability of coverage in the individual and group market. Subject to paragraphs (b) through (d) of this section, a health insurance issuer that offers health insurance coverage in the individual, small group, or large group market in a State must offer to any individual or employer in the State all products that are approved for sale in the applicable market, and must accept any individual or employer that applies for any of those products.

* * * * *

(b) * * *

(2) * * * As of January 1, 2015, health insurance coverage in the individual market or in a market in which the State has merged the individual and small group risk pools must be offered on a calendar year basis.

* * * * *

(c) * * *

(2) An issuer that denies health insurance coverage to an individual or an employer in any service area, in accordance with paragraph (c)(1)(ii) of this section, may not offer coverage in the individual, small group, or large group market, as applicable, for a period of 180 calendar days after the date the coverage is denied. This paragraph (c)(2) does not limit the issuer’s ability to renew coverage already in force or relieve the issuer of the responsibility to renew that coverage.

* * * * *

(d) * * *

(1) * * *

(ii) It is applying this paragraph (d)(1) uniformly to all employers or individual in the large group, small group, or individual market, as applicable, in the State consistent with

applicable State law and without regard to the claims experience of those individuals, employers and their employees (and their dependents) or any health status-related factor relating to such individuals, employees, and dependents.

(2) An issuer that denies health insurance coverage to any employer or individual in a State under paragraph (d)(1) of this section may not offer coverage in the large group, small group, or individual market, as applicable, in the State before the later of either of the following dates:

* * * * *

7. Section 147.106 is amended by revising paragraphs (a) and (d)(1) introductory text to read as follows:

§147.106 Guaranteed renewability of coverage.

(a) General rule. Subject to paragraphs (b) through (d) of this section, a health insurance issuer offering health insurance coverage in the individual, small group, or large group market is required to renew or continue in force the coverage at the option of the plan sponsor or the individual, as applicable.

* * * * *

(d) * * *

(1) An issuer may elect to discontinue offering all health insurance coverage in the individual, small group, or large group market, or all markets, in a State in accordance with applicable State law only if—

* * * * *

PART 153 – STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

8. The authority citation for part 153 continues to read as follows:

Authority: Secs. 1321, 1341-1343, Pub. L. 111-148, 24 Stat. 119.

9. Section 153.20 is amended by revising the definition of “contributing entity” to read as follows:

§153.20 Definitions.

* * * * *

Contributing entity means a health insurance issuer or a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage). A self-insured group health plan is responsible for the reinsurance contributions, although it may elect to use a third party administrator or administrative services-only contractor for transfer of the reinsurance contributions.

* * * * *

10. Section 153.240 is amended by revising paragraph (c) to read as follows:

§153.240 Disbursement of reinsurance payments.

* * * * *

(c) Maintenance of records. If a State establishes a reinsurance program, the State must maintain documents and records relating to the reinsurance program, whether paper, electronic, or in other media, for each benefit year for at least 10 years, and make them available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity. The documents and records must be sufficient to enable the evaluation of the State-operated reinsurance program’s compliance with Federal standards. The State must also ensure that its contractors, subcontractors, and agents similarly maintain and make relevant documents and

records available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity.

* * * * *

11. Section 153.260 is added to subpart C to read as follows:

§153.260 General oversight requirements for State-operated reinsurance programs.

(a) Accounting requirements. A State that establishes a reinsurance program must ensure that its applicable reinsurance entity keeps an accounting for each benefit year of:

(1) All reinsurance contributions received from HHS for reinsurance payments and for administrative expenses;

(2) All claims for reinsurance payments received from issuers of reinsurance-eligible plans;

(3) All reinsurance payments made to issuers of reinsurance-eligible plans; and

(4) All administrative expenses incurred for the reinsurance program.

(b) State summary report. A State that establishes a reinsurance program must submit to HHS and make public a report on its reinsurance program operations for each benefit year in the manner and timeframe specified by HHS. The report must summarize the accounting for the benefit year kept pursuant to paragraph (a) of this section.

(c) Independent external audit. A State that establishes a reinsurance program must engage an independent qualified auditing entity to perform a financial and programmatic audit for each benefit year of its State-operated reinsurance program in accordance with generally accepted auditing standards. The State must:

(1) Provide to HHS the results of the audit, in the manner and timeframe to be specified by HHS;

(2) Ensure that the audit addresses the prohibitions set forth in §153.265;

(3) Identify to HHS any material weakness or significant deficiency identified in the audit, and address in writing to HHS how the State intends to correct any such material weakness or significant deficiency; and

(4) Make public a summary of the results of the audit, including any material weakness or significant deficiency, in the manner and timeframe to be specified by HHS.

12. Section 153.265 is added to subpart C to read as follows:

§153.265 Restrictions on use of reinsurance funds for administrative expenses.

A State that establishes a reinsurance program must ensure that its applicable reinsurance entity does not use any funds for the support of reinsurance operations, including any reinsurance contributions provided under the national contribution rate for administrative expenses, for any of the following purposes:

- (a) Staff retreats;
- (b) Promotional giveaways;
- (c) Excessive executive compensation; or
- (d) Promotion of Federal or State legislative or regulatory modifications.

13. Section 153.310 is amended by adding paragraphs (c)(4), (d)(3) and (d)(4), and by removing paragraph (f) to read as follows:

§153.310 Risk adjustment administration.

* * * * *

(c) * * *

(4) Maintenance of records. A State operating a risk adjustment program must maintain documents and records relating to the risk adjustment program, whether paper, electronic, or in

other media, for each benefit year for at least 10 years, and make them available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity. The documents and records must be sufficient to enable the evaluation of the State-operated risk adjustment program's compliance with Federal standards. A State operating a risk adjustment program must also ensure that its contractors, subcontractors, and agents similarly maintain and make relevant documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity.

(d) * * *

(3) In addition to requirements set forth in paragraphs (d)(1) and (d)(2) of this section, to obtain recertification from HHS to operate risk adjustment for a third benefit year, the State must, in the first benefit year for which it operates risk adjustment, provide to HHS an interim report, in a manner specified by HHS, including a detailed summary of its risk adjustment activities in the first 10 months of the benefit year, no later than December 31 of the applicable benefit year.

(4) To obtain recertification from HHS to operate risk adjustment for each benefit year after the third benefit year, each State operating a risk adjustment program must submit to HHS and make public a detailed summary of its risk adjustment program operations for the most recent benefit year for which risk adjustment operations have been completed, in the manner and timeframe specified by HHS.

(i) The summary must include the results of a programmatic and financial audit for each benefit year of the State-operated risk adjustment program conducted by an independent qualified auditing entity in accordance with generally accepted auditing standards.

(ii) The summary must identify to HHS any material weakness or significant deficiency identified in the audit and address in writing to HHS how the State intends to correct any such material weakness or significant deficiency.

* * * * *

14. Section 153.365 is added to subpart D to read as follows:

§153.365 General oversight requirements for State-operated risk adjustment programs.

If a State is operating a risk adjustment program, it must keep an accounting of all receipts and expenditures related to risk adjustment payments and charges and the administration of risk adjustment-related functions and activities for each benefit year.

15. Section 153.400 is amended by revising paragraph (a)(1)(i) and by adding paragraph (a)(3) to read as follows:

§153.400 Reinsurance contribution funds.

(a) * * *

(1) * * *

(i) Such plan or coverage is not major medical coverage, subject to paragraph (a)(3) of this section.

* * * * *

(3) Notwithstanding paragraph (a)(1)(i) of this section, a health insurance issuer must make reinsurance contributions for lives covered by its group health insurance coverage even if the insurance coverage does not constitute major medical coverage, if –

(i) The group health plan provides health insurance coverage for those covered lives through more than one insurance policy that in combination constitute major medical coverage but individually do not;

(ii) The lives are not covered by self-insured coverage of the group health plan (except for self-insured coverage limited to excepted benefits); and

(iii) The health insurance coverage under the policy offered by the health insurance issuer represents a percentage of the total health insurance coverage offered in combination by the group health plan greater than the percentage offered under any of the other policies. For purposes of this paragraph, the percentage of coverage offered under various policies is determined based on the average premium per covered life for those policies. In the event that the percentage of coverage for two or more insurance policies is equal, the issuer of the policy that provides the greatest portion of in-network hospitalization benefits will be responsible for reinsurance contributions.

* * * * *

16. Section 153.405 is amended by adding paragraph (h) to read as follows:

§153.405 Calculation of reinsurance contributions.

* * * * *

(h) Maintenance of records. A contributing entity must maintain documents and records, whether paper, electronic, or in other media, sufficient to substantiate the enrollment count submitted pursuant to this section for a period of at least 10 years, and must make that evidence available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity, for purposes of verification, investigation, audit, or other review of reinsurance contribution amounts.

17. Section 153.410 is amended by adding paragraph (c) to read as follows:

§153.410 Requests for reinsurance payment.

* * * * *

(c) Maintenance of records. An issuer of a reinsurance-eligible plan must maintain documents and records, whether paper, electronic, or in other media, sufficient to substantiate the requests for reinsurance payments made pursuant to this section for a period of at least 10 years, and must make that evidence available upon request from HHS, the OIG, the Comptroller General, or their designees, or, in a State where the State is operating reinsurance, the State or its designee, to any such entity, for purposes of verification, investigation, audit, or other review of reinsurance payment requests.

18. Section 153.620 is amended by revising paragraph (b) to read as follows:

§153.620 Compliance with risk adjustment standards.

* * * * *

(b) Issuer records maintenance requirements. An issuer that offers risk adjustment covered plans must also maintain documents and records, whether paper, electronic, or in other media, sufficient to enable the evaluation of the issuer's compliance with applicable risk adjustment standards, and must make that evidence available upon request to HHS, OIG, the Comptroller General, or their designees, or in a State where the State is operating risk adjustment, the State or its designee to any such entity.

19. Section 153.740 is added to subpart H to read as follows:

§153.740 Failure to comply with HHS-operated risk adjustment and reinsurance data requirements.

(a) Enforcement actions. If an issuer of a risk adjustment covered plan or reinsurance-eligible plan fails to establish a dedicated distributed data environment in a manner and timeframe specified by HHS; fails to provide HHS with access to the required data in such environment in accordance with §153.700(a) or otherwise fails to comply with the requirements

of §153.700 through §153.730; fails to adhere to the reinsurance data submission requirements set forth in §153.420; or fails to adhere to the risk adjustment data submission and data storage requirements set forth in §153.610 through §153.630, HHS may impose civil money penalties in accordance with the procedures set forth in §156.805 of this subchapter.

(b) Default risk adjustment charge. If an issuer of a risk adjustment covered plan fails to establish a dedicated distributed data environment or fails to provide HHS with access to the required data in such environment in accordance with §153.610(a), §153.700, §153.710, or §153.730 such that HHS cannot apply the applicable Federally certified risk adjustment methodology to calculate the risk adjustment payment transfer amount for the risk adjustment covered plan in a timely fashion, HHS will assess a default risk adjustment charge.

PART 155 - EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

20. 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, 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).

21. Section 155.20 is amended by revising the definition for “Exchange” and by adding a definition for “Issuer customer service representative” in alphabetical order to read as follows:

§155.20 Definitions.

* * * * *

Exchange means a governmental agency or non-profit entity that meets the applicable standards of this part and makes QHPs available to qualified individuals and/or qualified employers. Unless otherwise identified, this term includes an Exchange serving the individual

market for qualified individuals and a SHOP serving the small group market for qualified employers, regardless of whether the Exchange is established and operated by a State (including a regional Exchange or subsidiary Exchange) or by HHS.

* * * * *

Issuer customer service representative means an employee, contractor, or agent of a QHP issuer that provides assistance to applicants and enrollees, but is not licensed as an agent, broker, or producer under State law.

* * * * *

22. Section 155.100 is amended by revising paragraph (a) to read as follows:

§155.100 Establishment of a State Exchange.

(a) General requirements. Each State may elect to establish:

(1) An Exchange that facilitates the purchase of health insurance coverage in QHPs in the individual market and that provides for the establishment of a SHOP; or

(2) An Exchange that provides only for the establishment of a SHOP.

(3) Timing. For plan years beginning before January 1, 2015, only States with a conditionally approved Exchange Blueprint may elect to establish an Exchange that provides only for the establishment of a SHOP, pursuant to the process in §155.105(e). For plan years beginning on or after January 1, 2015, any State may elect to establish an Exchange that provides only for the establishment of a SHOP, pursuant to the process in §155.106(a).

* * * * *

23. Section 155.105 is amended by revising paragraphs (b)(1), (b)(2) and (f) to read as follows:

§155.105 Approval of a State Exchange.

* * * * *

(b) * * *

(1) The Exchange is able to carry out the required functions of an Exchange consistent with subparts C, D, E, H, and K of this part unless the State is approved to operate only a SHOP by HHS pursuant to §155.100(a)(2), in which case the Exchange must perform the minimum functions described in subpart H and all applicable provisions of other subparts referenced therein;

(2) The Exchange is capable of carrying out the information reporting requirements in accordance with section 36B of the Code, unless the State is approved to operate only a SHOP by HHS pursuant to §155.100(a)(2); and

* * * * *

(f) HHS operation of an Exchange. (1) If a State does not elect to operate an Exchange under §155.100(a)(1) or an electing State does not have an approved or conditionally approved Exchange pursuant to §155.100(a)(1) by January 1, 2013, HHS must (directly or through agreement with a not-for-profit entity) establish and operate such Exchange within the State. In this case, the requirements in §155.120(c), §155.130 and subparts C, D, E, H, and K of this part will apply.

(2) If an electing State has an approved or conditionally approved Exchange pursuant to §155.100(a)(2) by January 1, 2013, HHS must (directly or through agreement with a not-for-profit entity) establish and operate an Exchange that facilitates the purchase of health insurance coverage in QHPs in the individual market and operate such Exchange within the State. In this case, the requirements in §155.120(c), §155.130 and subparts C, D, E, and K of this part will apply to the Exchange operated by HHS.

24. Section 155.140 is amended by revising paragraph (c)(2)(ii) to read as follows:

§155.140 Establishment of a regional Exchange or subsidiary Exchange.

* * * * *

(c) * * *

(2) * * *

(ii) Encompass the same geographic area for its regional or subsidiary SHOP and its regional or subsidiary Exchange except:

(A) In the case of a regional Exchange established pursuant to §155.100(a)(2), the regional SHOP must encompass a geographic area that matches the combined geographic areas of the individual market Exchanges established to serve the same set of States establishing the regional SHOP; and

(B) In the case of a subsidiary Exchange established pursuant to §155.100(a)(2), the combined geographic area of all subsidiary SHOPS established in the State must encompass the geographic area of the individual market Exchange established to serve the State.

25. Section 155.200 is amended by revising paragraph (a) to read as follows:

§155.200 Functions of an Exchange.

(a) General requirements. The Exchange must perform the minimum functions described in this subpart and in subparts D, E, H, and K of this part unless the State is approved to operate only a SHOP by HHS pursuant to §155.100(a)(2), in which case the Exchange operated by the State must perform the minimum functions described in subpart H and all applicable provisions of other subparts referenced therein while the Exchange operated by HHS must perform the minimum functions described in this subpart and in subparts D, E, and K of this part.

* * * * *

26. Section 155.220 is amended by revising paragraph (c)(3)(i); by adding paragraphs (c)(3)(vii), (c)(4), (d)(4), (f), (g), and (h); by removing the word “and” from the end of paragraph (c)(3)(v); and by removing the period at the end of paragraph (c)(3)(vi) and by adding “; and” in its place to read as follows:–

§155.220 Ability of States to permit agents and brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(c) * * *

(3) * * *

(i) Disclose and display all QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of §155.205(b)(1) and §155.205(c), and display a Web link to the Exchange Web site;

* * * * *

(vii) For the Federally-facilitated Exchange, prominently display language notifying consumers that the agent’s or broker’s Web site is not the Exchange Web site, that the agent or broker’s Web site might not display all QHP data available on the Exchange Web site, that the agent or broker has entered into an agreement with HHS pursuant to paragraph (d) of this section, and that the agent or broker agrees to conform to the standards specified in paragraph (c) and (d) of this section.

(4) When an Internet Web site of an agent or broker is used to complete the QHP selection in the Federally-facilitated Exchange, and an agent or broker permits another agent or broker to access or use the Web site pursuant to an arrangement, the agent or broker who makes the Web site available must provide a list of agents and brokers who enter into such an

arrangement to the Federally-facilitated Exchange, and must ensure that any agent or broker accessing or using the Web site pursuant to the arrangement:

(i) Complies with paragraphs (c) and (d) of this section; and

(ii) Complies with the policies and procedures that the agent or broker making the Web site available has established pursuant to paragraph (d)(4) of this section.

(d) * * *

(4) In the Federally-facilitated Exchange, comply with the following standards:

(i) Establish policies and procedures to ensure compliance with paragraph (d)(3) of this section;

(ii) Train its employees, representatives, contractors and agents with respect to the policies and procedures established pursuant to paragraph (d)(3) of this section on a periodic basis; and

(iii) Ensure as a condition of contract or agreement that its employees, representatives, contractors, agents comply with the policies and procedures established pursuant to paragraph (d)(3) of this section.

* * * * *

(f) Termination notice to HHS. (1) An agent or broker may terminate its agreement with HHS by sending to HHS a written notice at least 30 days in advance of the date of intended termination.

(2) The notice must include the intended date of termination, but if it does not specify a date of termination, or the date provided is not acceptable to HHS, HHS may set a different termination date that will be no less than 30 days from the date on the agent or broker's notice of termination.

(3) When termination becomes effective, the agent or broker will not be able to assist any individual through the Federally-facilitated Exchange, but the agent or broker must continue to protect PII created, collected, use or disclosed during the term of the agreement with the Federally-facilitated Exchange.

(g) Standards for termination for cause from the Federally-facilitated Exchange. (1) If, in HHS's determination, a specific finding of noncompliance or pattern of noncompliance is sufficiently severe, HHS may terminate an agent's or broker's agreement with the Federally-facilitated Exchange for cause.

(2) An agent or broker may be determined noncompliant if HHS finds that the agent or broker violated –

(i) Any standard specified under this section;

(ii) Any term or condition of its agreement with the Federally-facilitated Exchange required under paragraph (d) of this section, including but not limited to compliance with Federally-facilitated Exchange privacy and security standards;

(iii) Any State law applicable to agents or brokers, as required under paragraph (e) of this section, including but not limited to State laws related to confidentiality and conflicts of interest;
or

(iv) Any Federal law applicable to agents or brokers.

(3) HHS will notify the agent or broker of the of the specific finding of noncompliance or pattern of noncompliance, and after 30 days from the date of the notice, may terminate the agreement for cause if the matter is not resolved to the satisfaction of HHS.

(4) After the period in paragraph (f)(3) of this section has elapsed, the agent or broker will no longer be registered with the Federally-facilitated Exchange or able to transact data through a secure connection with HHS.

(h) Request for reconsideration of termination for cause from the Federally-facilitated Exchange. (1) Request for reconsideration. An agent or broker whose agreement with the Federally-facilitated Exchange has been terminated may request reconsideration of such action in the manner and form established by HHS.

(2) Timeframe for request. The agent or broker must submit a request for reconsideration to the HHS reconsideration entity within 30 calendar days of the date of the written notice from HHS.

(3) Notice of reconsideration decision. The HHS reconsideration entity will provide the agent or broker with a written notice of the reconsideration decision within 30 calendar days of the date it receives the request for reconsideration. This decision will constitute HHS's final determination.

27. Section 155.270 is amended by revising paragraph (a) to read as follows:

§155.270 Use of standards and protocols for electronic transactions.

(a) HIPAA administrative simplification. To the extent that the Exchange performs electronic transactions with a covered entity, the Exchange must use standards, implementation specifications, operating rules, and code sets that are adopted by the Secretary in 45 CFR parts 160 and 162 or that are otherwise approved by HHS.

* * * * *

28. Section 155.280 is added to subpart C to read as follows:

§155.280 Oversight and monitoring of privacy and security requirements.

(a) General. HHS will oversee and monitor the Federally-facilitated Exchanges and non-Exchange entities associated with Federally-facilitated Exchanges which are required to comply with the privacy and security standards established and implemented by a Federally-facilitated Exchange pursuant to §155.260 for compliance with those standards. HHS will oversee and monitor State Exchanges for compliance with the standards State Exchanges establish and implement pursuant to §155.260. State Exchanges will oversee and monitor non-Exchange entities associated with the State Exchanges for compliance with the standards established and implemented by the State Exchange pursuant to §155.260.

(b) Audits and investigations. HHS may conduct oversight activities that include but are not limited to the following: audits, investigations, inspections, and any reasonable activities necessary for appropriate oversight of compliance with the Exchange privacy and security standards. HHS may also pursue civil, criminal or administrative proceedings or actions as determined necessary.

(c) Security and privacy incidents and breaches. (1) The following definitions apply to privacy and security incidents and breaches:

(i) Incident means the act of violating an explicit or implied security policy, which includes attempts (either failed or successful) to gain unauthorized access to a system or its data, unwanted disruption or denial of service, the unauthorized use of a system for the processing or storage of data; and changes to system hardware, firmware, or software characteristics without the owner's knowledge, instruction, or consent.

(ii) Breach means the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, unauthorized access, or any similar term referring to situations where persons other

than authorized users and for an other than authorized purpose have access or potential access to personally identifiable information, whether physical or electronic.

(2) Incident or breach management. The entity where an incident or breach occurs is responsible for managing the incident or breach in accordance with the entity’s documented incident handling and breach notification procedures.

(3) Reporting. Federally-facilitated Exchanges, non-Exchange entities associated with the Federally-facilitated Exchange, and State Exchanges must report all privacy and security incidents and breaches to HHS within one (1) hour of discovering the incident or breach. A non-Exchange entity associated with a State Exchange must report all privacy and security incidents and breaches to the State Exchange with which they are associated.

29. Section 155.310 is amended by adding and reserving paragraph (j) and adding paragraph (k) to read as follows:

§155.310 Eligibility process.

* * * * *

(j) [Reserved]

(k) Incomplete application. If an application filer submits an application that does not include sufficient information for the Exchange to conduct an eligibility determination for enrollment in a QHP through the Exchange or for insurance affordability programs, if applicable, the Exchange must --

(1) Provide notice to the applicant indicating that information necessary to complete an eligibility determination is missing, specifying the missing information, and providing instructions on how to provide the missing information; and

(2) Provide the applicant with a period of no less than 15 days and no more than 90 days from the date on which the notice described in paragraph (k)(1) of this section is sent to the applicant to provide the information needed to complete the application to the Exchange.

(3) During the period described in paragraph (k)(2) of this section, the Exchange must not proceed with an applicant's eligibility determination or provide advance payments of the premium tax credit or cost-sharing reductions, unless an application filer has provided sufficient information to determine his or her eligibility for enrollment in a QHP through the Exchange, in which case the Exchange must make such a determination for enrollment in a QHP.

30. Section 155.320 is amended by revising the section heading; by redesignating paragraphs (b)(1) and (b)(2) as paragraph (b)(1)(i) and (b)(1)(ii), by revising newly designated paragraph (b)(1), and by adding paragraph (b)(2) to read as follows:

§155.320 Verification of eligibility for minimum essential coverage other than through an eligible employer-sponsored plan.

* * * * *

(b) * * *

(1) (i) The Exchange must verify whether an applicant is eligible for minimum essential coverage other than through an eligible employer-sponsored plan, Medicaid, CHIP, or the BHP, using information obtained by transmitting identifying information specified by HHS to HHS for verification purposes.

(ii) The Exchange must verify whether an applicant has already been determined eligible for coverage through Medicaid, CHIP, or the BHP, if a BHP is operating in the service area of the Exchange, within the State or States in which the Exchange operates using information obtained from the agencies administering such programs.

(2) Consistent with §164.512(k)(6)(i) of this subchapter, a health plan that is a government program providing public benefits, is expressly authorized to disclose protected health information, as that term is defined at §160.103 of this subchapter, that relates to eligibility for or enrollment in the health plan to HHS for verification of applicant eligibility for minimum essential coverage as part of the eligibility determination process for advance payments of the premium tax credit or cost-sharing reductions.

* * * * *

31. Section 155.340 is amended by adding paragraph (h) to read as follows:

§155.340 Administration of advance payments of the premium tax credit and cost-sharing reductions.

* * * * *

(h) Failure to reduce enrollee’s premiums to account for advance payments of the premium tax credits. If the Exchange discovers that it did not reduce an enrollee’s premium by the amount of the advance payment of the premium tax credit, then the Exchange must refund to the enrollee any excess premium paid by or for the enrollee and notify the enrollee of the improper reduction no later than 30 calendar days after discovery of the improper reduction

32. Section 155.415 is added to read as follows:

§155.415 Allowing issuer customer service representatives to assist with eligibility applications.

(a) Exchange option. An Exchange, to the extent permitted by State law, may permit issuer customer service representatives who do not meet the definition of agent or broker at §155.20 to assist individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange and insurance affordability

programs, and to facilitate selection of a QHP offered by the issuer represented by the customer service representative, provided that such issuer customer service representatives meet the requirements set forth in §156.1230(a)(2) of this subchapter.

(b) [Reserved]

33. Section 155.420 is amended by removing the period at the end of paragraph (d)(9) and by adding “; and” in its place, and by adding paragraph (d)(10) to read as follows:

§155.420 Special enrollment periods.

* * * * *

(d) * * *

(10) It has been determined by the Exchange that a qualified individual was not enrolled in QHP coverage, was not enrolled in the QHP selected by the individual, or is eligible for but is not receiving advance payments of the premium tax credit or cost-sharing reductions as a result of misconduct on the part of a non-Exchange entity providing enrollment assistance or conducting enrollment activities. For purposes of this provision, misconduct includes, but is not limited to, the failure of the non-Exchange entity to comply with applicable standards under this part, part 156 of this subchapter, or other applicable Federal or State laws, as determined by the Exchange.

* * * * *

34. In §155.700, paragraph (b) is amended by adding the definition of “SHOP application filer” in alphabetical order to read as follows:

§155.700 Standards for the establishment of a SHOP.

* * * * *

(b) * * *

SHOP application filer means an applicant, an authorized representative, an agent or broker of the employer, or an employer filing for its employees where not prohibited by other law.

35. Section 155.705 is amended by revising paragraphs (b)(6)(i), and (b)(6)(ii), and by adding paragraphs (c) and (d) to read as follows:

§155.705 Functions of a SHOP.

* * * * *

(b) * * *

(6) * * *

(i) Require all QHP issuers to make any change to rates at a uniform time that is no more frequently than quarterly.

(ii) In the FF-SHOP, rates may be updated quarterly with effective dates of January 1, April 1, July 1, or October 1 of each calendar year, beginning with rates effective no sooner than July 1, 2014. The updated rates must be submitted to HHS at least 60 days in advance of the effective date of the rates.

* * * * *

(c) Coordination with individual market Exchange for eligibility determinations. A SHOP must provide data related to eligibility and enrollment of a qualified employee to the individual market Exchange that corresponds to the service area of the SHOP, unless the SHOP is operated pursuant to §155.100(a)(2).

(d) Duties of Navigators in the SHOP. In States that have elected to operate only a SHOP pursuant to §155.100(a)(2), at State option and if State law permits the Navigator duties

described in §155.210(e)(3) and §155.210(e)(4) may be fulfilled through referrals to agents and brokers.

36. Section 155.730 is amended by revising paragraph (f) to read as follows:

§155.730 Application standards for SHOP.

* * * * *

(f) The SHOP must:

- (1) Accept applications from SHOP application filers; and
- (2) Provide the tools to file an application via an Internet Web site.

* * * * *

37. Section 155.735 is added to subpart H to read as follows:

§155.735 Termination of coverage.

(a) General requirements. The SHOP must determine the timing, form, and manner in which coverage in a QHP may be terminated.

(b) Termination of employer group health coverage at the request of the employer. (1)
The SHOP must establish policies for advance notice of termination required from the employer and effective dates of termination.

(2) In the FF-SHOP, an employer may terminate coverage for all enrollees covered by the employer group health plan effective on the last day of any month, provided that the employer has given notice to the FF-SHOP on or before the 15th day of any month. If notice is given after the 15th of the month, the FF-SHOP may terminate the coverage on the last day of the following month.

(c) Termination of employer group health coverage for non-payment of premiums. (1)
The SHOP must establish policies for termination for non-payment of premiums, including but

not limited to policies regarding due dates for payment of premiums to the SHOP, grace periods, employer and employee notices, and reinstatement provisions.

(2) In an FF-SHOP–

(i) For a given month of coverage, premium payment is due by the first day of the coverage month.

(ii) If premium payment is not received 31 days from the first of the coverage month, the FF-SHOP may terminate the qualified employer for lack of payment.

(iii) If a qualified employer is terminated due to lack of premium payment, but within 30 days following its termination the qualified employer requests reinstatement, pays all premiums owed including any prior premiums owed for coverage during the grace period, and pays the premium for the next month's coverage, the FF-SHOP must reinstate the qualified employer in its previous coverage.

(d) Termination of employee or dependent coverage. (1) The SHOP must establish consistent policies regarding the process for and effective dates of termination of employee or dependent coverage in the following circumstances:

(i) The employee or dependent is no longer eligible for coverage under the employer's group health plan;

(ii) The employee requests that the SHOP terminate the coverage of the employee or a dependent of the employee under the employer's group health plan;

(iii) The QHP in which the employee is enrolled terminates or is decertified as described in §155.1080;

(iv) The enrollee changes from one QHP to another during the employer's annual open enrollment period or during a special enrollment period in accordance with §155.725(j); or

(v) The enrollee's coverage is rescinded in accordance with §147.128 of this subchapter.

(2) In the FF-SHOP, termination is effective on the last day of the month in which the FF-SHOP receives notice of an event described in paragraph (d)(1) of this section, and notice must have been received by the FF-SHOP prior to the proposed date of termination.

(e) Termination of coverage tracking and approval. The SHOP must comply with the standards described in §155.430(c).

(f) Effective date. The provisions of §155.735 apply to coverage –

(1) Beginning on or after January 1, 2015; and

(2) In any SHOP providing qualified employers with the option described in §155.705(b)(2) or the option described in §155.705(b)(4) before January 1, 2015, beginning with the date that option is offered.

38. Subpart M is added to read as follows:

Subpart M - Oversight and Program Integrity Standards for State Exchanges

Sec.

155.1200 General program integrity and oversight requirements.

155.1210 Maintenance of records.

Subpart M - Oversight and Program Integrity Standards for State Exchanges

§155.1200 General program integrity and oversight requirements.

(a) General requirement. A State Exchange must:

(1) Keep an accurate accounting of Exchange receipts and expenditures in accordance with generally accepted accounting principles (GAAP).

(2) Monitor and report to HHS on Exchange related activities.

(3) Collect and report to HHS performance monitoring data.

(b) Reporting. The State Exchange must, at least annually, provide to HHS, in a manner specified by HHS, the following data and information:

- (1) A financial statement presented in accordance with GAAP by April 1 of each year,
- (2) Eligibility and enrollment reports, and
- (3) Performance monitoring data.

(c) External audits. The State Exchange must engage an independent qualified auditing entity which follows generally accepted governmental auditing standards (GAGAS) to perform an annual independent external financial and programmatic audit and must make such information available to HHS for review. The State must:

- (1) Provide to HHS the results of the annual external audit; and
- (2) Inform HHS of any material weakness or significant deficiency and any intended corrective action identified in the audit;

(d) External audit standard. The State Exchange must ensure that independent audits of State Exchange financial statements and program activities in paragraph (c) of this section address:

- (1) Compliance with paragraph (a)(1) of this section;
- (2) Compliance with requirements under subparts D, E, and K of this part;
- (3) Processes and procedures designed to prevent improper eligibility determinations and enrollment transactions; and
- (4) Identification of errors that have resulted in incorrect eligibility determinations.

§155.1210 Maintenance of records.

(a) General. The State Exchange must maintain and must ensure its contractors, subcontractors, and agents maintain for 10 years, documents and records (whether paper,

electronic, or other media) and other evidence of accounting procedures and practices, which are sufficient to do the following:

- (1) Accommodate periodic auditing of the State Exchange's financial records; and
- (2) Enable HHS or its designee(s) to inspect facilities, or otherwise evaluate the State-Exchange's compliance with Federal standards.

(b) Records. The State Exchange and its contractors, subcontractors, and agents must ensure that the records specified in paragraph (a) of this section include, at a minimum, the following:

- (1) Information concerning management and operation of the State Exchange's financial and other record keeping systems;
- (2) Financial statements, including cash flow statements, and accounts receivable and matters pertaining to the costs of operations;
- (3) Any financial reports filed with other Federal programs or State authorities;
- (4) Data and records relating to the State Exchange's eligibility verifications and determinations, enrollment transactions, appeals, and plan variation certifications; and
- (5) Qualified health plan contracting (including benefit review) data and consumer outreach and Navigator grant oversight information.

(c) A State Exchange must make all records and must ensure its contractors, subcontractors, and agents must make all records in paragraph (a) of this section available to HHS, the OIG, the Comptroller General, or their designees, upon request.

PART 156 – HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

39. The authority citation for part 156 continues to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301–1304, 1311–1313, 1321, 1322, 1324, 1334, 1342–1343, and 1401–1402, Pub. L. 111-148, 124 Stat. 119 (42 U.S.C. 18042).

40. Section 156.20 is amended by adding definitions for “Delegated entity,” “Downstream entity,” “Enrollee satisfaction survey vendor,” “Exchange,” and “Registered user of the enrollee satisfaction survey data warehouse,” in alphabetical order to read as follows:

§156.20 Definitions

* * * * *

Delegated entity means any party, including an agent or broker, that enters into an agreement with a QHP issuer to provide administrative services or health care services to qualified individuals, qualified employers, or qualified employees and their dependents.

Downstream entity means any party, including an agent or broker, that enters into an agreement with a delegated entity or with another downstream entity for purposes of providing administrative or health care services related to the agreement between the delegated entity and the QHP issuer. The term “downstream entity” is intended to reach the entity that directly provides administrative services or health care services to qualified individuals, qualified employers, or qualified employees and their dependents.

Enrollee satisfaction survey vendor means an organization has relevant survey administration experience (e.g., CAHPS[®] surveys), organizational survey capacity, and quality control procedures for survey administration.

* * * * *

Exchange has the meaning given to the term in §155.20 of this subchapter.

* * * * *

Registered user of the enrollee satisfaction survey data warehouse means enrollee satisfaction survey vendors, QHP issuers, and Exchanges authorized to access CMS’s secure data warehouse to submit survey data and to preview survey results prior to public reporting.

41. Section 156.80 is amended by adding paragraph (d)(3) to read as follows:

§156.80 Single risk pool.

* * * * *

(d) * * *

(3) Frequency of index rate and plan-level adjustments. A health insurance issuer may make the market-wide index rate adjustment described in paragraph (d)(1) of this section or the plan-level adjustments described in paragraph (d)(2) of this section—

(i) With respect to the individual market or markets in which the individual and small group risk pools were merged by the State pursuant to paragraph (c) of this section, on an annual basis.

(ii) With respect to the small group market, on an annual basis, and beginning the quarter after HHS issues notification that the FF-SHOP can process quarterly rate updates, on a quarterly basis.

* * * * *

42. Section 156.285 is amended by revising paragraphs (d)(1)(i) and (iii) to read as follows:

§156.285 Additional standards specific to SHOP.

* * * * *

(d) * * *

(1) * * *

(i) (A) Effective in plan years beginning on or after January 1, 2015, requirements regarding termination of coverage established in §155.735 of this subchapter, if applicable to the coverage being terminated; otherwise

(B) General requirements regarding termination of coverage established in §155.270 of this subchapter.

* * * * *

(iii) (A) Effective in plan years beginning on or after January 1, 2015, requirements regarding termination of coverage effective dates as set forth in §155.735 of this subchapter, if applicable to the coverage being terminated; otherwise

(B) Requirements regarding termination of coverage effective dates as set forth in §156.270(i).

* * * * *

43. Subpart D is added to read as follows:

Subpart D – Federally-facilitated Exchange Qualified Health Plan Issuer Standards

Sec.

156.330 Changes of ownership in a Federally-Facilitated Exchange.

156.340 Standards for downstream and delegated entities.

Subpart D – Federally-facilitated Exchange Qualified Health Plan Issuer Standards

§156.330 Changes of ownership in a Federally-Facilitated Exchange.

When a QHP issuer that offers one or more QHPs in a Federally-facilitated Exchange undergoes a change of ownership as recognized by the State in which the issuer offers the QHP, the QHP issuer must notify HHS of the change in a manner to be specified by HHS, and provide the legal name and Taxpayer Identification Number (TIN) of the new owner and the effective

date of the change at least 30 days prior to the effective date of the change of ownership. The new owner must agree to adhere to all applicable statutes and regulations.

§156.340 Standards for downstream and delegated entities.

(a) General requirement. Effective October 1, 2013, notwithstanding any relationship(s) that a QHP issuer may have with delegated and downstream entities, a QHP issuer maintains responsibility for its compliance and the compliance of any of its delegated or downstream entities, as applicable, with all applicable standards, including —

(1) Standards of subpart C of part 156 with respect to each of its QHPs on an ongoing basis;

(2) Exchange processes, procedures, and standards in accordance with subparts H and K of part 155 and, in the small group market, §155.705 of this subchapter;

(3) Standards of §155.220 of this subchapter with respect to assisting with enrollment in QHPs; and

(4) Standards of §156.705 and §156.715 for maintenance of records and compliance reviews for QHP issuers operating in a Federally-facilitated Exchange or FF-SHOP.

(b) Delegation agreement specifications. If any of the QHP issuer's activities or obligations, in accordance with paragraph (a) of this section, are delegated to other parties, the QHP issuer's agreement with any delegated or downstream entity must—

(1) Specify the delegated activities and reporting responsibilities;

(2) Provide for revocation of the delegated activities and reporting standards or specify other remedies in instances where HHS or the QHP issuer determines that such parties have not performed satisfactorily;

(3) Specify that the delegated or downstream entity must comply with all applicable laws and regulations relating to the standards specified under paragraph (a) of this section;

(4) Specify that the delegated or downstream entity must permit access by the Secretary and the OIG or their designees in connection with their right to evaluate through audit, inspection, or other means, to the delegated or downstream entity’s books, contracts, computers, or other electronic systems, including medical records and documentation, relating to the QHP issuer’s obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the final date of the agreement period; and

(5) Contain specifications described in paragraph (b) of this section by no later than January 1, 2015, for existing agreements; and no later than the effective date of the agreement for agreements that are newly entered into as of October 1, 2013.

44. Section 156.400 is amended by revising the definition of “Most generous or more generous” to read as follows:

§156.400 Definitions.

* * * * *

Most generous or more generous means, as between a QHP (including a standard silver plan) or plan variation and one or more other plan variations of the same QHP, the standard plan or plan variation designed for the category of individuals last listed in §155.305(g)(3) of this subchapter. Least generous or less generous has the opposite meaning.

* * * * *

45. Section 156.410 is amended by adding paragraphs (c) and (d) to read as follows:

§156.410 Cost-sharing reductions for enrollees.

* * * * *

(c) Improper cost-sharing reductions. (1) If a QHP issuer fails to ensure that an individual assigned to a plan variation receives the cost-sharing reductions required under the applicable plan variation, taking into account §156.425(b) concerning continuity of deductibles and out-of-pocket amounts (if applicable), then the QHP issuer must, no later than 30 calendar days after discovery of the application of the cost-sharing reduction, refund any resulting excess cost sharing paid by or for the enrollee and notify the enrollee of the improper application.

(2) If a QHP issuer provides an individual assigned to a plan variation more cost-sharing reductions than required under the applicable plan variation, taking into account §156.425(b) concerning continuity of deductibles and out-of-pocket amounts (if applicable), then the QHP issuer will not be eligible for reimbursement of any excess cost-sharing reductions provided to the enrollee, and may not seek reimbursement from the enrollee or the applicable provider for any of the excess cost-sharing reductions.

(d) Improper assignment. If a QHP issuer does not assign an individual to the applicable plan variation (or standard plan without cost-sharing reductions) in accordance with §156.410(b) and §156.425(a) based on the eligibility and enrollment information or notification provided by the Exchange, then the QHP issuer must, no later than 30 calendar days after discovery of the improper assignment, reassign the enrollee to the applicable plan variation (or standard plan without cost-sharing reductions) and notify the enrollee of the improper assignment such that –

(1) If, pursuant to a reassignment under this paragraph (d), a QHP issuer reassigns an enrollee from a more generous plan variation to a less generous plan variation of a QHP (or a standard plan without cost-sharing reductions), the QHP issuer will not be eligible for reimbursement for any of the excess cost-sharing reductions provided to the enrollee following

the effective date of eligibility required by the Exchange, and may not seek reimbursement from the enrollee or the applicable provider for any of the excess cost-sharing reductions.

(2) If, pursuant to a reassignment under this paragraph (d), a QHP issuer reassigns an enrollee from a less generous plan variation (or a standard plan without cost-sharing reductions) to a more generous plan variation of a QHP, the QHP issuer must recalculate the enrollee's liability for cost sharing paid between the effective date of eligibility required by the Exchange and the date the issuer effectuated the change, and must refund any excess cost sharing paid by or for the enrollee during such period, no later than 30 calendar days after discovery of the improper assignment.

46. Section 156.460 is amended by adding paragraph (c) to read as follows:

§156.460 Reduction of enrollee's share of premium to account for advance payments of the premium tax credit.

* * * * *

(c) Refunds to enrollees for improper reduction of enrollee's share of premium to account for advance payments of the premium tax credit. If a QHP issuer discovers that it did not reduce the portion of the premium charged to or for an enrollee for the applicable month(s) by the amount of the advance payment of the premium tax credit in accordance with paragraph (a)(1) of this section, the QHP issuer must refund to the enrollee any excess premium paid by or for the enrollee and notify the enrollee of the improper reduction no later than 30 calendar days after the QHP issuer's discovery of the improper reduction.

47. Section 156.480 is added to subpart E to read as follows:

§156.480 Oversight of the administration of the cost-sharing reductions and advance payments of the premium tax credit programs.

(a) Maintenance of records. An issuer that offers a QHP in the individual market through a State Exchange must adhere to, and ensure that any relevant delegated entities and downstream entities adhere to, the standards set forth in §156.705 concerning maintenance of documents and records, whether paper, electronic, or in other media, by issuers offering QHPs in a Federally-facilitated Exchange, in connection with cost-sharing reductions and advance payments of the premium tax credit.

(b) Annual reporting requirements. For each benefit year, an issuer that offers a QHP in the individual market through an Exchange must report to HHS, in the manner and timeframe required by HHS, summary statistics specified by HHS with respect to administration of cost-sharing reduction and advance payments of the premium tax credit programs.

(c) Audits. HHS or its designee may audit an issuer that offers a QHP in the individual market through an Exchange to assess compliance with the requirements of this subpart.

Subpart G – [Added and Reserved]

48. Subpart G is added and reserved.

49. Subpart H is added to read as follows:

Subpart H– Oversight and Financial Integrity Standards for Issuers of Qualified Health Plans in Federally-facilitated Exchanges

Sec.

156.705 Maintenance of records for the Federally-facilitated Exchange.

156.715 Investigations and compliance reviews in Federally-facilitated Exchanges.

Subpart H– Oversight and Financial Integrity Standards for Issuers of Qualified Health Plans in Federally-facilitated Exchanges

§156.705 Maintenance of records for the Federally-facilitated Exchange.

(a) General standard. Issuers offering QHPs in a Federally-facilitated Exchange must maintain all documents and records (whether paper, electronic, or other media) and other evidence of accounting procedures and practices, necessary for HHS to do the following:

(1) Periodically audit financial records related to QHP issuers' participation in a Federally-facilitated Exchange, and evaluate the ability of QHP issuers to bear the risk of potential financial losses; and

(2) Conduct compliance reviews or otherwise monitor QHP issuers' compliance with all Exchange standards applicable to issuers offering QHPs in a Federally-facilitated Exchange as listed in this part.

(b) Records. The records described in paragraph (a) of this section include the sources listed in §155.1210(b)(2), (b)(3), and (b)(5) of this subchapter.

(c) Record retention timeframe. Issuers offering QHPs in a Federally-facilitated Exchange must maintain all records referenced in paragraph (a) of this section for 10 years.

(d) Record availability. Issuers offering QHPs in a Federally-facilitated Exchange must make all records in paragraph (a) of this section available to HHS, the OIG, the Comptroller General, or their designees, upon request.

§156.715 Investigations and compliance reviews in Federally-facilitated Exchanges.

(a) General standard. Issuers offering QHPs in the Federally-facilitated Exchange may be subject to compliance reviews to ensure ongoing compliance with Exchange standards applicable to issuers offering QHPs in the Federally-facilitated Exchange.

(b) Records. In preparation for or in the course of the compliance review, a QHP issuer must make available for HHS to review the records of the QHP issuer that pertain to its activities

within the Federally-facilitated Exchange. Such records may include, but are not limited to the following:

(1) The QHP issuer's books and contracts, including the QHP issuer's policy manuals and other QHP plan benefit information provided to the QHP issuer's enrollees;

(2) The QHP issuer's policies and procedures, protocols, standard operating procedures, or other similar manuals related to the QHP issuer's activities in the Federally-facilitated Exchange;

(3) Any other information reasonably necessary for HHS to—

(i) Evaluate the QHP issuer's compliance with QHP certification standards and other Exchange standards applicable to issuers offering QHPs in the Federally-facilitated Exchange;

(ii) Evaluate the QHP's performance, including its adherence to an effective compliance plan, within the Federally-facilitated Exchange;

(iii) Verify that the QHP issuer has performed the duties attested to as part of the QHP certification process; and

(iv) Assess the likelihood of fraud or abuse.

(c) Interest of qualified individuals and qualified employers. HHS's findings from the compliance reviews under this section may be in conjunction with other finds related to the QHP issuers' compliance with certification standards, used to confirm that permitting the issuer's QHPs to be available through the Federally-facilitated Exchange is in the interest of the qualified individuals and qualified employers as provided under §155.1000(c)(2) of this subchapter.

(d) Onsite and desk reviews. The QHP issuer will make available, for the purposes listed in paragraph (c) of this section, its premises, physical facilities and equipment (including

computer and other electronic systems), for HHS to conduct a compliance review as provided under this section.

(1) A compliance review under this section will be carried out as an onsite or desk review based on the specific circumstances.

(2) Unless otherwise specified, nothing in this section is intended to preempt Federal laws and regulations related to information privacy and security.

(e) Compliance review timeframe. A QHP issuer may be subject to a compliance review up to 10 years from the last day of that plan benefit year, or 10 years from the last day that the QHP certification is effective if the QHP is no longer available through a Federally-facilitated Exchange; provided, however, that if the 10 year review period falls during an ongoing compliance review, the review period would be extended until the compliance review is completed.

50. Subpart I is added to read as follows:

Subpart I - Enforcement Remedies in Federally-facilitated Exchanges

Sec.

156.800 Available remedies; Scope.

156.805 Bases and process for imposing civil money penalties in Federally-facilitated Exchanges.

156.810 Bases and process for decertification of a QHP offered by an issuer through a Federally-facilitated Exchange.

Subpart I - Enforcement Remedies in Federally-facilitated Exchanges

§156.800 Available remedies; Scope.

(a) Kinds of sanctions. HHS may impose the following types of sanctions on QHP issuers in a Federally-facilitated Exchange that are not in compliance with Exchange standards applicable to issuers offering QHPs in the Federally-facilitated Exchange:

(1) Civil money penalties as specified in §156.805; and

(2) Decertification of a QHP offered by the non-compliant QHP issuer in a Federally-facilitated Exchange as described in §156.810.

(b) Scope. Sanctions under this subpart are applicable only for non-compliance with QHP issuer participation standards and other standards applicable to issuers offering QHPs in a Federally-facilitated Exchange.

§156.805 Bases and process for imposing civil money penalties in Federally-facilitated Exchanges.

(a) Grounds for imposing civil money penalties. Civil money penalties may be imposed on an issuer in a Federally-facilitated Exchange by HHS if, based on credible evidence, HHS has reasonably determined that the issuer has engaged in one or more of the following actions:

(1) Misconduct in the Federally-facilitated Exchange or substantial non-compliance with the Exchange standards applicable to issuers offering QHPs in the Federally-facilitated Exchange under subparts C through G of part 153 of this subchapter;

(2) Limiting the QHP's enrollees' access to medically necessary items and services that are required to be covered as a condition of the QHP issuer's ongoing participation in the Federally-facilitated Exchange, if the limitation has adversely affected or has a substantial likelihood of adversely affecting one or more enrollees in the QHP offered by the QHP issuer;

(3) Imposing on enrollees premiums in excess of the monthly beneficiary premiums permitted by Federal standards applicable to QHP issuers participating in the Federally-facilitated Exchange;

(4) Engaging in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment into a QHP offered by the issuer (except as permitted by this part) by qualified individuals whose medical condition or history indicates the potential for a future need for significant medical services or items;

(5) Intentionally or recklessly misrepresenting or falsifying information that it furnishes—

(i) To HHS; or

(ii) To an individual or entity upon which HHS relies to make its certifications or evaluations of the QHP issuer's ongoing compliance with Exchange standards applicable to issuers offering QHPs in the Federally-facilitated Exchange;

(6) Failure to remit user fees assessed under §156.50(c); or

(7) Failure to comply with the cost-sharing reductions and advance payments of the premium tax credit standards of subpart E of this part.

(b) Factors in determining the amount of civil money penalties assessed. In determining the amount of civil money penalties, HHS may take into account the following:

(1) The QHP issuer's previous or ongoing record of compliance;

(2) The level of the violation, as determined in part by—

(i) The frequency of the violation, taking into consideration whether any violation is an isolated occurrence, represents a pattern, or is widespread; and

(ii) The magnitude of financial and other impacts on enrollees and qualified individuals;
and

(3) Aggravating or mitigating circumstances, or other such factors as justice may require, including complaints about the issuer with regard to the issuer's compliance with the medical loss ratio standards required by the Affordable Care Act and as codified by applicable regulations.

(c) Maximum penalty. The maximum amount of penalty imposed for each violation is \$100 for each day for each QHP issuer for each individual adversely affected by the QHP issuer's non-compliance; and where the number of individuals cannot be determined, HHS may estimate the number of individuals adversely affected by the violation.

(d) Notice of intent to issue civil money penalty. If HHS proposes to assess a civil money penalty in accordance with this part, HHS will send a written notice of this decision to—

(1) The QHP issuer against whom the civil money penalty is being imposed, whose notice must include the following:

- (i) A description of the basis for the determination;
- (ii) The basis for the penalty;
- (iii) The amount of the penalty;
- (iv) The date the penalty is due;
- (v) An explanation of the issuer's right to a hearing under subpart J of this part ; and
- (vi) Information about where to file the request for hearing.

(e) Failure to request a hearing. (1) If the QHP issuer does not request a hearing within 30 days of the issuance of the notice described in paragraph (d)(1) of this section , HHS may assess the proposed civil money penalty.

(2) HHS will notify the QHP issuer in writing of any penalty that has been assessed and of the means by which the responsible entity may satisfy the judgment.

(3) The QHP issuer has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with subpart J of this part unless the QHP issuer can show good cause, as determined under §156.905(b), for failing to timely exercise its right to a hearing.

§156.810 Bases and process for decertification of a QHP offered by an issuer through a Federally-facilitated Exchange.

(a) Bases for decertification. A QHP may be decertified on one or more of the following grounds:

(1) The QHP issuer substantially fails to comply with the Federal laws and regulations applicable to QHP issuers participating in the Federally-facilitated Exchange;

(2) The QHP issuer substantially fails to comply with the standards related to the risk adjustment, reinsurance, or risk corridors programs under 45 CFR part 153, including providing HHS with valid risk adjustment, reinsurance or risk corridors data;

(3) The QHP issuer substantially fails to comply with the transparency and marketing standards in §§156.220 and 156.225;

(4) The QHP issuer substantially fails to comply with the standards regarding advance payments of the premium tax credit and cost-sharing in subpart E of this part;

(5) The QHP issuer is operating in the Federally-facilitated Exchange in a manner that hinders the efficient and effective administration of the Exchange;

(6) The QHP no longer meets the conditions of the applicable certification criteria;

(7) Based on credible evidence, the QHP issuer has committed or participated in fraudulent or abusive activities, including submission of false or fraudulent data;

(8) The QHP issuer substantially fails to meet the requirements under §156.230 related to network adequacy standards or, §156.235 related to inclusion of essential community providers;

(9) The QHP issuer substantially fails to comply with the law and regulations related to internal claims and appeals and external review processes; or

(10) The State recommends to HHS that the QHP should no longer be available in a Federally-facilitated Exchange.

(b) State sanctions and determinations. (1) State sanctions. HHS may consider regulatory or enforcement actions taken by a State against a QHP issuer as a factor in determining whether to decertify a QHP offered by that issuer.

(2) State determinations. HHS may decertify a QHP offered by an issuer in a Federally-facilitated Exchange based on a determinations or actions by a State as it relates to the issuer offering QHPs in a Federally-facilitated Exchange, including when a State places an issuer or its parent organization into receivership or when the State recommends to HHS that the QHP no longer be available in a Federally-facilitated Exchange.

(c) Standard decertification process. For decertification actions on grounds other than those described in §156.810(a)(7), (a)(8), or (a)(9), HHS will provide written notices to the QHP issuer, enrollees in that QHP, and the State department of insurance in the State in which the QHP is being decertified. The written notice must include the following:

(1) The effective date of the decertification, which will be a date specified by HHS that is no earlier than 30 days after the date of issuance of the notice;

(2) The reason for the decertification, including the regulation or regulations that are the basis for the decertification;

(3) For the written notice to the QHP issuer, information about the effect of the decertification on the ability of the issuer to offer the QHP in the Federally-facilitated Exchange and must include information about the procedure for appealing the decertification by making a hearing request; and

(4) The written notice to the QHP enrollees must include information about the effect of the decertification on enrollment in the QHP and about the availability of a special enrollment period, as described in §155.420 of this subchapter.

(d) Expedited decertification process. For decertification actions on grounds described in §156.810(a)(7), (a)(8), or (a)(9), 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:

- (1) The effective date of the decertification, which will be a date specified by HHS; and
- (2) The information required by paragraphs (c)(2) through (c)(4) of this section.

(e) Appeals. An issuer may appeal the decertification of a QHP offered by that issuer under paragraph (c) or (d) of this section by filing a request for hearing under subpart J of this part.

(1) Effect of request for hearing. If an issuer files a request for hearing under this paragraph,

(i) If the decertification is under paragraph (c) of this section, the decertification will not take effect prior to the issuance of the final administrative decision in the appeal, notwithstanding the effective date specified in the notice under paragraph (c)(1) of this section.

(ii) If the decertification is under paragraph (d) of this section, the decertification will be effective on the date specified in the notice of decertification, but the certification of the QHP

may be reinstated immediately upon issuance of a final administrative decision that the QHP should not be decertified.

(2) [Reserved]

51. Subpart J is added to read as follows:

Subpart J – Administrative Review of QHP Issuer Sanctions in Federally-facilitated Exchanges

Sec.

156.901 Definitions.

156.903 Scope of Administrative Law Judge’s (ALJ) authority.

156.905 Filing of request for hearing.

156.907 Form and content of request for hearing.

156.909 Amendment of notice of assessment or decertification request for hearing.

156.911 Dismissal of request for hearing.

156.913 Settlement.

156.915 Intervention.

156.917 Issues to be heard and decided by ALJ.

156.919 Forms of hearing.

156.921 Appearance of counsel.

156.923 Communications with the ALJ.

156.925 Motions.

156.927 Form and service of submissions.

156.929 Computation of time and extensions of time.

156.931 Acknowledgment of request for hearing.

156.935 Discovery.

156.937 Submission of briefs and proposed hearing exhibits.

156.939 Effect of submission of proposed hearing exhibits.

156.941 Prehearing conferences.

156.943 Standard of proof.

156.945 Evidence.

156.947 The record.

156.949 Cost of transcripts.

156.951 Posthearing briefs.

156.953 ALJ decision.

156.955 Sanctions.

156.957 Review by Administrator.

156.959 Judicial review.

156.961 Failure to pay assessment.

156.963 Final order not subject to review.

Subpart J – Administrative Review of QHP Issuer Sanctions in Federally-facilitated

Exchanges

§ 156.901 Definitions.

In this subpart, unless the context indicates otherwise:

ALJ means administrative law judge of the Departmental Appeals Board of HHS.

Filing date means the date postmarked by the U.S. Postal Service, deposited with a carrier for commercial delivery, or hand delivered.

Hearing includes a hearing on a written record as well as an in-person or telephone hearing.

Party means HHS or the respondent.

Receipt date means five days after the date of a document, unless there is a showing that it was in fact received later.

Respondent means an entity that received a notice of proposed assessment of a civil money penalty issued pursuant to §156.805 or a notice of decertification pursuant to §156.810(c) or §156.810(d).

§156.903 Scope of Administrative Law Judge's (ALJ) authority.

(a) The ALJ has the authority, including all of the authority conferred by the Administrative Procedure Act (5 U.S.C. 554a), to adopt whatever procedures may be necessary or proper to carry out in an efficient and effective manner the ALJ's duty to provide a fair and impartial hearing on the record and to issue an initial decision concerning the imposition of a civil money penalty or the decertification of a QHP offered in a Federally-facilitated Exchange.

(b) The ALJ's authority includes the authority to modify, consistent with the Administrative Procedures Act (5 U.S.C. 552a), any hearing procedures set out in this subpart.

(c) The ALJ does not have the authority to find invalid or refuse to follow Federal statutes or regulations.

§156.905 Filing of request for hearing.

(a) A respondent has a right to a hearing before an ALJ if it files a request for hearing that complies with §156.907(a), within 30 days after the date of issuance of either HHS' notice of proposed assessment under § 156.805, notice of decertification of a QHP under §156.810(c) or §156.810(d). The request for hearing should be addressed as instructed in the notice of proposed

determination. “Date of issuance” is five (5) days after the filing date, unless there is a showing that the document was received earlier.

(b) The ALJ may extend the time for filing a request for hearing only if the ALJ finds that the respondent was prevented by events or circumstances beyond its control from filing its request within the time specified above. Any request for an extension of time must be made promptly by written motion.

§156.907 Form and content of request for hearing.

(a) The request for hearing must do the following:

(1) Identify any factual or legal bases for the assessment or decertifications with which the respondent disagrees.

(2) Describe with reasonable specificity the basis for the disagreement, including any affirmative facts or legal arguments on which the respondent is relying.

(b) Identify the relevant notice of assessment or decertification by date and attach a copy of the notice.

§156.909 Amendment of notice of assessment or decertification request for hearing.

The ALJ may permit CMS to amend its notice of assessment or decertification, or permit the respondent to amend a request for hearing that complies with §156.907(a), if the ALJ finds that no undue prejudice to either party will result.

§156.911 Dismissal of request for hearing.

An ALJ will order a request for hearing dismissed if the ALJ determines that:

(a) The request for hearing was not filed within 30 days as specified by §156.905(a) or any extension of time granted by the ALJ pursuant to §156.905(b).

(b) The request for hearing fails to meet the requirements of §156.907.

- (c) The entity that filed the request for hearing is not a respondent under §156.901.
- (d) The respondent has abandoned its request.
- (e) The respondent withdraws its request for hearing.

§156.913 Settlement.

HHS has exclusive authority to settle any issue or any case, without the consent of the ALJ at any time before or after the ALJ's decision.

§156.915 Intervention.

(a) The ALJ may grant the request of an entity, other than the respondent, to intervene if all of the following occur:

- (1) The entity has a significant interest relating to the subject matter of the case.
- (2) Disposition of the case will, as a practical matter, likely impair or impede the entity's ability to protect that interest.
- (3) The entity's interest is not adequately represented by the existing parties.
- (4) The intervention will not unduly delay or prejudice the adjudication of the rights of the existing parties.

(b) A request for intervention must specify the grounds for intervention and the manner in which the entity seeks to participate in the proceedings. Any participation by an intervenor must be in the manner and by any deadline set by the ALJ.

(c) The Department of Labor (DOL) or the Internal Revenue Service (IRS) may intervene without regard to paragraphs (a)(1) through (a)(3) of this section.

§156.917 Issues to be heard and decided by ALJ.

- (a) The ALJ has the authority to hear and decide the following issues:
 - (1) Whether a basis exists to assess a civil money penalty against the respondent.

(2) Whether the amount of the assessed civil money penalty is reasonable.

(3) Whether a basis exists to decertify a QHP offered by the respondent in the Federally-facilitated Exchange.

(b) In deciding whether the amount of a civil money penalty is reasonable, the ALJ—

(1) Will apply the factors that are identified in §156.805 for civil money penalties.

(2) May consider evidence of record relating to any factor that HHS did not apply in making its initial determination, so long as that factor is identified in this subpart.

(c) If the ALJ finds that a basis exists to assess a civil money penalty, the ALJ may sustain, reduce, or increase the penalty that HHS assessed

§156.919 Forms of hearing.

(a) All hearings before an ALJ are on the record. The ALJ may receive argument or testimony in writing, in person, or by telephone. The ALJ may receive testimony by telephone only if the ALJ determines that doing so is in the interest of justice and economy and that no party will be unduly prejudiced. The ALJ may require submission of a witness' direct testimony in writing only if the witness is available for cross-examination.

(b) The ALJ may decide a case based solely on the written record where there is no disputed issue of material fact the resolution of which requires the receipt of oral testimony.

§156.921 Appearance of counsel.

Any attorney who is to appear on behalf of a party must promptly file, with the ALJ, a notice of appearance.

§156.923 Communications with the ALJ.

No party or person (except employees of the ALJ's office) may communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for both parties to

participate. This provision does not prohibit a party or person from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§156.925 Motions.

(a) Any request to the ALJ for an order or ruling must be by motion, stating the relief sought, the authority relied upon, and the facts alleged. All motions must be in writing, with a copy served on the opposing party, except in either of the following situations:

(1) The motion is presented during an oral proceeding before an ALJ at which both parties have the opportunity to be present.

(2) An extension of time is being requested by agreement of the parties or with waiver of objections by the opposing party.

(b) Unless otherwise specified in this subpart, any response or opposition to a motion must be filed within 20 days of the party's receipt of the motion. The ALJ does not rule on a motion before the time for filing a response to the motion has expired except where the response is filed at an earlier date, where the opposing party consents to the motion being granted, or where the ALJ determines that the motion should be denied.

§156.927 Form and service of submissions.

(a) Every submission filed with the ALJ must be filed in triplicate, including one original of any signed documents, and include:

(1) A caption on the first page, setting forth the title of the case, the docket number (if known), and a description of the submission (such as "Motion for Discovery").

(2) The signatory's name, address, and telephone number.

(3) A signed certificate of service, specifying each address to which a copy of the submission is sent, the date on which it is sent, and the method of service.

(b) A party filing a submission with the ALJ must, at the time of filing, serve a copy of such submission on the opposing party. An intervenor filing a submission with the ALJ must, at the time of filing, serve a copy of the submission on all parties. Service must be made by mailing or hand delivering a copy of the submission to the opposing party. If a party is represented by an attorney, service must be made on the attorney.

§156.929 Computation of time and extensions of time.

(a) For purposes of this subpart, in computing any period of time, the time begins with the day following the act, event, or default and includes the last day of the period unless it is a Saturday, Sunday, or legal holiday observed by the Federal government, in which event it includes the next business day. When the period of time allowed is less than seven days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal government are excluded from the computation.

(b) The period of time for filing any responsive pleading or papers is determined by the date of receipt (as defined in §156.901) of the submission to which a response is being made.

(c) The ALJ may grant extensions of the filing deadlines specified in these regulations or set by the ALJ for good cause shown (except that requests for extensions of time to file a request for hearing may be granted only on the grounds specified in §156.905(b)).

§156.931 Acknowledgment of request for hearing.

After receipt of the request for hearing, the ALJ assigned to the case or someone acting on behalf of the ALJ will send a letter to the parties that acknowledges receipt of the request for hearing, identifies the docket number assigned to the case, provides instructions for filing submissions and other general information concerning procedures, and sets out the next steps in the case.

§156.935 Discovery.

(a) The parties must identify any need for discovery from the opposing party as soon as possible, but no later than the time for the reply specified in §156.937(c). Upon request of a party, the ALJ may stay proceedings for a reasonable period pending completion of discovery if the ALJ determines that a party would not be able to make the submissions required by §156.937 without discovery. The parties should attempt to resolve any discovery issues informally before seeking an order from the ALJ.

(b) Discovery devices may include requests for production of documents, requests for admission, interrogatories, depositions, and stipulations. The ALJ orders interrogatories or depositions only if these are the only means to develop the record adequately on an issue that the ALJ must resolve to decide the case.

(c) Each discovery request must be responded to within 30 days of receipt, unless that period of time is extended for good cause by the ALJ.

(d) A party to whom a discovery request is directed may object in writing for any of the following reasons:

- (1) Compliance with the request is unduly burdensome or expensive.
- (2) Compliance with the request will unduly delay the proceedings.
- (3) The request seeks information that is wholly outside of any matter in dispute.

(4) The request seeks privileged information. Any party asserting a claim of privilege must sufficiently describe the information or document being withheld to show that the privilege applies. If an asserted privilege applies to only part of a document, a party withholding the entire document must state why the nonprivileged part is not segregable.

(5) The disclosure of information responsive to the discovery request is prohibited by law.

(e) Any motion to compel discovery must be filed within 10 days after receipt of objections to the party's discovery request, within 10 days after the time for response to the discovery request has elapsed if no response is received, or within 10 days after receipt of an incomplete response to the discovery request. The motion must be reasonably specific as to the information or document sought and must state its relevance to the issues in the case.

§156.937 Submission of briefs and proposed hearing exhibits.

(a) Within 60 days of its receipt of the acknowledgment provided for in §156.931, the respondent must file the following with the ALJ:

(1) A statement of its arguments concerning CMS's notice of assessment or decertification (respondent's brief), including citations to the respondent's hearing exhibits provided in accordance with paragraph (a)(2) of this section. The brief may not address factual or legal bases for the assessment or decertification that the respondent did not identify as disputed in its request for hearing or in an amendment to that request permitted by the ALJ.

(2) All documents (including any affidavits) supporting its arguments, tabbed and organized chronologically and accompanied by an indexed list identifying each document.

(3) A statement regarding whether there is a need for an in-person hearing and, if so, a list of proposed witnesses and a summary of their expected testimony that refers to any factual dispute to which the testimony will relate.

(4) Any stipulations or admissions.

(b) Within 30 days of its receipt of the respondent's submission required by paragraph (a) of this section, CMS will file the following with the ALJ:

(1) A statement responding to the respondent's brief, including the respondent's proposed hearing exhibits, if appropriate. The statement may include citations to CMS's proposed hearing exhibits submitted in accordance with paragraph (b)(2) of this section.

(2) Any documents supporting CMS's response not already submitted as part of the respondent's proposed hearing exhibits, organized and indexed as indicated in paragraph (a)(2) of this section (CMS's proposed hearing exhibits).

(3) A statement regarding whether there is a need for an in-person hearing and, if so, a list of proposed witnesses and a summary of their expected testimony that refers to any factual dispute to which the testimony will relate.

(4) Any admissions or stipulations.

(c) Within 15 days of its receipt of CMS's submission required by paragraph (b) of this section, the respondent may file with the ALJ a reply to CMS's submission.

§156.939 Effect of submission of proposed hearing exhibits.

(a) Any proposed hearing exhibit submitted by a party in accordance with §156.937 is deemed part of the record unless the opposing party raises an objection to that exhibit and the ALJ rules to exclude it from the record. An objection must be raised either in writing prior to the prehearing conference provided for in §156.941 or at the prehearing conference. The ALJ may require a party to submit the original hearing exhibit on his or her own motion or in response to a challenge to the authenticity of a proposed hearing exhibit.

(b) A party may introduce a proposed hearing exhibit following the times for submission specified in §156.937 only if the party establishes to the satisfaction of the ALJ that it could not have produced the exhibit earlier and that the opposing party will not be prejudiced.

§156.941 Prehearing conferences.

An ALJ may schedule one or more prehearing conferences (generally conducted by telephone) on the ALJ's own motion or at the request of either party for the purpose of any of the following:

(a) Hearing argument on any outstanding discovery request.

(b) Establishing a schedule for any supplements to the submissions required by §156.937 because of information obtained through discovery.

(c) Hearing argument on a motion.

(d) Discussing whether the parties can agree to submission of the case on a stipulated record.

(e) Establishing a schedule for an in-person hearing, including setting deadlines for the submission of written direct testimony or for the written reports of experts.

(f) Discussing whether the issues for a hearing can be simplified or narrowed.

(g) Discussing potential settlement of the case.

(h) Discussing any other procedural or substantive issues.

§156.943 Standard of proof.

(a) In all cases before an ALJ—

(1) CMS has the burden of coming forward with evidence sufficient to establish a prima facie case;

(2) The respondent has the burden of coming forward with evidence in response, once CMS has established a prima facie case; and

(3) CMS has the burden of persuasion regarding facts material to the assessment or decertification; and

(4) The respondent has the burden of persuasion regarding facts relating to an affirmative defense.

(b) The preponderance of the evidence standard applies to all cases before the ALJ.

§156.945 Evidence.

(a) The ALJ will determine the admissibility of evidence.

(b) Except as provided in this part, the ALJ will not be bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate; for example, to exclude unreliable evidence.

(c) The ALJ excludes irrelevant or immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence is excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement made in this action will be inadmissible to the extent provided in the Federal Rules of Evidence.

(g) Evidence of acts other than those at issue in the instant case is admissible in determining the amount of any civil money penalty if those acts are used under § 156.805 of this part to consider the entity's prior record of compliance, or to show motive, opportunity, intent, knowledge, preparation, identity, or lack of mistake. This evidence is admissible regardless of whether the acts occurred during the statute of limitations period applicable to the acts that constitute the basis for liability in the case and regardless of whether HHS' notice sent in accordance with §156.805 referred to them.

(h) The ALJ will permit the parties to introduce rebuttal witnesses and evidence.

(i) All documents and other evidence offered or taken for the record will be open to examination by all parties, unless the ALJ orders otherwise for good cause shown.

(j) The ALJ may not consider evidence regarding the willingness and ability to enter into and successfully complete a corrective action plan when that evidence pertains to matters occurring after HHS' notice under §156.805(d) or §156.810(c) or §156.810(d).

§156.947 The record.

(a) Any testimony that is taken in-person or by telephone is recorded and transcribed. The ALJ may order that other proceedings in a case, such as a prehearing conference or oral argument of a motion, be recorded and transcribed.

(b) The transcript of any testimony, exhibits and other evidence that is admitted, and all pleadings and other documents that are filed in the case constitute the record for purposes of an ALJ decision.

(c) For good cause, the ALJ may order appropriate redactions made to the record.

§156.949 Cost of transcripts.

Generally, each party is responsible for 50 percent of the transcript cost. Where there is an intervenor, the ALJ determines what percentage of the transcript cost is to be paid for by the intervenor.

§156.951 Posthearing briefs.

Each party is entitled to file proposed findings and conclusions, and supporting reasons, in a posthearing brief. The ALJ will establish the schedule by which such briefs must be filed. The ALJ may direct the parties to brief specific questions in a case and may impose page limits on posthearing briefs. Additionally, the ALJ may allow the parties to file posthearing reply briefs.

§156.953 ALJ decision.

The ALJ will issue an initial agency decision based only on the record and on applicable law; the decision will contain findings of fact and conclusions of law. The ALJ's decision is final and appealable after 30 days unless it is modified or vacated under § 156.957.

§156.955 Sanctions.

(a) The ALJ may sanction a party or an attorney for failing to comply with an order or other directive or with a requirement of a regulation, for abandonment of a case, or for other actions that interfere with the speedy, orderly or fair conduct of the hearing. Any sanction that is imposed will relate reasonably to the severity and nature of the failure or action.

(b) A sanction may include any of the following actions:

(1) In the case of failure or refusal to provide or permit discovery, drawing negative fact inferences or treating such failure or refusal as an admission by deeming the matter, or certain facts, to be established.

(2) Prohibiting a party from introducing certain evidence or otherwise advocating a particular claim or defense.

(3) Striking pleadings, in whole or in part.

(4) Staying the case.

(5) Dismissing the case.

(6) Entering a decision by default.

(7) Refusing to consider any motion or other document that is not filed in a timely manner.

(8) Taking other appropriate action.

§156.957 Review by Administrator.

(a) The Administrator of CMS (which for purposes of this section may include his or her delegate), at his or her discretion, may review in whole or in part any initial agency decision issued under §156.953.

(b) The Administrator may decide to review an initial agency decision if it appears from a preliminary review of the decision (or from a preliminary review of the record on which the initial agency decision was based, if available at the time) that:

(1) The ALJ made an erroneous interpretation of law or regulation.

(2) The initial agency decision is not supported by substantial evidence.

(3) The ALJ has incorrectly assumed or denied jurisdiction or extended his or her authority to a degree not provided for by statute or regulation.

(4) The ALJ decision requires clarification, amplification, or an alternative legal basis for the decision.

(5) The ALJ decision otherwise requires modification, reversal, or remand.

(c) Within 30 days of the date of the initial agency decision, the Administrator will mail a notice advising the respondent of any intent to review the decision in whole or in part.

(d) Within 30 days of receipt of a notice that the Administrator intends to review an initial agency decision, the respondent may submit, in writing, to the Administrator any arguments in support of, or exceptions to, the initial agency decision.

(e) This submission of the information indicated in paragraph (d) of this section must be limited to issues the Administrator has identified in his or her notice of intent to review, if the Administrator has given notice of an intent to review the initial agency decision only in part. A copy of this submission must be sent to the other party.

(f) After receipt of any submissions made pursuant to paragraph (d) of this section and any additional submissions for which the Administrator may provide, the Administrator will affirm, reverse, modify, or remand the initial agency decision. The Administrator will mail a copy of his or her decision to the respondent.

(g) The Administrator's decision will be based on the record on which the initial agency decision was based (as forwarded by the ALJ to the Administrator) and any materials submitted pursuant to paragraphs (b), (d), and (f) of this section.

(h) The Administrator's decision may rely on decisions of any courts and other applicable law, whether or not cited in the initial agency decision.

§156.959 Judicial review.

(a) Filing of an action for review. Any responsible entity against whom a final order imposing a civil money penalty or decertification of a QHP is entered may obtain review in the United States District Court for any district in which the entity is located or in the United States District Court for the District of Columbia by doing the following:

- (1) Filing a notice of appeal in that court within 30 days from the date of a final order.
- (2) Simultaneously sending a copy of the notice of appeal by registered mail to HHS.

(b) Certification of administrative record. HHS promptly certifies and files with the court the record upon which the penalty was assessed.

(c) Standard of review. The findings of HHS and the ALJ may not be set aside unless they are found to be unsupported by substantial evidence, as provided by 5 U.S.C. 706(2)(E).

§156.961 Failure to pay assessment.

If any entity fails to pay an assessment after it becomes a final order, or after the court has entered final judgment in favor of CMS, CMS refers the matter to the Attorney General, who

brings an action against the entity in the appropriate United States district court to recover the amount assessed.

§156.963 Final order not subject to review.

In an action brought under § 156.961, the validity and appropriateness of the final order described in § 156.945 is not subject to review.

52. Subpart K is added to read as follows:

Subpart K– Cases Forwarded to Qualified Health Plans and Qualified Health Plan Issuers in Federally-facilitated Exchanges

§156.1010 Standards.

(a) A case is a communication brought by a complainant that expresses dissatisfaction with a specific person or entity subject to State or Federal laws regulating insurance, concerning the person or entity's activities related to the offering of insurance, other than a communication with respect to an adverse benefit determination as defined in §147.136(a)(2)(i) of this subchapter. Issues related to adverse benefit determinations are not addressed in this section and are subject to the provisions in §147.136 of this subchapter governing internal claims appeals and external review.

(b) QHP issuers operating in a Federally-facilitated Exchange must investigate and resolve, as appropriate, cases from the complainant forwarded to the issuer by HHS. Cases received by a QHP issuer operating in a Federally-facilitated Exchange directly from a complainant or the complainant's authorized representative will be handled by the issuer through its internal customer service process.

(c) Cases may be forwarded to a QHP issuer operating in a Federally-facilitated Exchange through a casework tracking system developed by HHS or other means as determined by HHS.

(d) Cases received by a QHP issuer operating in a Federally-facilitated Exchange from HHS must be resolved within 15 calendar days of receipt of the case. Urgent cases as defined in §156.1010(e) that do not otherwise fall within the scope of §147.136 of this subchapter must be resolved no later than 72 hours after receipt of the case. Where applicable State laws and regulations establish timeframes for case resolution that are stricter than the standards contained in this paragraph, QHP issuers operating in a Federally-facilitated Exchange must comply with such stricter laws and regulations.

(e) For cases received from HHS by a QHP issuer operating in a Federally-facilitated Exchange, an urgent case is one in which there is an immediate need for health services because the non-urgent standard could seriously jeopardize the enrollee's or potential enrollee's life, or health or ability to attain, maintain, or regain maximum function.

(f) For cases received from HHS, QHP issuers operating in a Federally-facilitated Exchange are required to notify complainants regarding the disposition of the as soon as possible upon resolution of the case, but in no event later than seven (7) business days after the case is resolved. Notification may be by verbal or written means as determined most appropriate by the QHP issuer.

(g) For cases received from HHS, QHP issuers operating in a Federally-facilitated Exchange must use the casework tracking system developed by HHS, or other means as determined by HHS, to document, no later than seven (7) business days after resolution of the case, that the case has been resolved. The record must include a clear and concise narrative

explaining how the case was resolved including information about how and when the complainant was notified of the resolution.

(h) Cases received by a QHP issuer operating in a Federally-facilitated Exchange from a State in which the issuer offers QHPs must be investigated and resolved according to applicable State laws and regulations. With respect to cases directly handled by the State, HHS or any other appropriate regulatory authority, QHP issuers operating in a Federally-facilitated Exchange must cooperate fully with the efforts of the State, HHS, or other regulatory authority to resolve the case.

53. Subpart L is added to read as follows:

Subpart L – Quality Standards

§156.1105 Establishment of standards for HHS-approved enrollee satisfaction survey vendors for use by QHP issuers in Exchanges.

(a) Application for approval. An enrollee satisfaction survey vendor must be approved by HHS, in a form and manner to be determined by HHS, to administer, on behalf of a QHP issuer, enrollee satisfaction surveys to QHP enrollees. HHS will approve enrollee satisfaction survey vendors on an annual basis, and each enrollee satisfaction survey vendor must submit an application for each year that approval is sought.

(b) Standards. To be approved by HHS, an enrollee satisfaction survey vendor must meet each of the following standards:

(1) Sign and submit an application form for approval in accordance with paragraph (a) of this section;

(2) Ensure, on an annual basis, that appropriate staff participate in enrollee satisfaction survey vendor training and successfully complete a post-training certification exercise as established by HHS;

(3) Ensure the accuracy of their data collection, calculation and submission processes and attest to HHS the veracity of the data and these processes;

(4) Sign and execute a standard HHS data use agreement, in a form and manner to be determined by HHS, that establishes protocols related to the disclosure, use, and reuse of HHS data;

(5) Adhere to the enrollee satisfaction survey protocols and technical specifications in a manner and form required by HHS;

(6) Develop and submit to HHS a quality assurance plan and any supporting documentation as determined to be relevant by HHS. The plan must describe in adequate detail the implementation of and compliance with all required protocols and technical specifications described in paragraph (b)(5) of this section;

(7) Adhere to privacy and security standards established and implemented under §155.260 of this subchapter by the Exchange with which they are associated;

(8) Comply with all applicable State and Federal laws;

(9) Become a registered user of the enrollee satisfaction survey data warehouse to submit files to HHS on behalf of its authorized QHP contracts;

(10) Participate in and cooperate with HHS oversight for quality-related activities, including, but not limited to: review of the enrollee satisfaction survey vendor's quality assurance plan and other supporting documentation; analysis of the vendor's submitted data and sampling procedures; and site visits and conference calls; and,

(11) Comply with minimum business criteria as established by HHS.

(c) Approved list. A list of approved enrollee satisfaction survey vendors will be published on an HHS Web site.

54. Subpart M is added to read as follows:

Subpart M – Qualified Health Plan Issuer Responsibilities

Sec.

156.1210 Confirmation of HHS payment and collections reports.

156.1230 Direct enrollment with the QHP issuer in a manner considered to be through the Exchange.

156.1240 Enrollment process for qualified individuals.

Subpart M – Qualified Health Plan Issuer Responsibilities

§156.1210 Confirmation of HHS payment and collections reports.

Within 15 calendar days of the date of a payment and collections report from HHS, the issuer must, in a format specified by HHS, either:

(a) Confirm to HHS that the amounts identified in the payment and collections report for the timeframe specified in the report accurately reflects applicable payments owed by the issuer to HHS and the payments owed to the issuer by HHS; or

(b) Describe to HHS any inaccuracy it identifies in the payment and collections report.

§156.1230 Direct enrollment with the QHP issuer in a manner considered to be through the Exchange.

(a) A QHP issuer that is directly contacted by a potential applicant may, at the Exchange's option, enroll such applicant in a QHP in a manner that is considered through the Exchange. In order for the enrollment to be made directly with the issuer in a manner that is

considered to be through the Exchange, the QHP issuer needs to comply with at least the following requirements:

(1) QHP issuer general requirements. (i) The QHP issuer follows the enrollment process for qualified individuals consistent with §156.265.

(ii) The QHP issuer's Web site provides applicants the ability to view QHPs offered by the issuer with the data elements listed in §155.205(b)(1)(i) through (viii) of this subchapter.

(iii) The QHP issuer's Web site clearly distinguishes between QHPs for which the consumer is eligible and other non-QHPs that the issuer may offer, and indicate that APTC and CSRs apply only to QHPs offered through the Exchange.

(iv) The QHP issuer informs all applicants of the availability of other QHP products offered through the Exchange and displays the Web link to or describes how to access the Exchange Web site.

(v) The QHP issuer's Web site allows applicants to select and attest to an APTC amount, if applicable, in accordance with §155.310(d)(2) of this subchapter.

(2) QHP issuer customer service representative eligibility application assistance requirements. If permitted by the Exchange pursuant to §155.415 of this subchapter, and to the extent permitted by State law, a QHP issuer may permit its issuer customer service representatives who do not meet the definition of agent or broker at §155.20 of this subchapter to assist individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange and for insurance affordability programs, and to facilitate selection of a QHP offered by the issuer represented by the customer service representative, provided that such issuer customer service representatives comply with the terms

of an agreement between the issuer and the Exchange under which the issuer customer service representative at least-

(i) Receives training on QHP options and insurance affordability programs, eligibility, and benefits rules and regulations;

(ii) Complies with the Exchange's privacy and security standards adopted consistent with §155.260 of this subchapter; and

(iii) Complies with applicable State law related to the sale, solicitation, and negotiation of health insurance products, including applicable State law related to agent, broker, and producer licensure; confidentiality; and conflicts of interest.

(3) Premium accuracy requirements. A QHP issuer must ensure that

(i) The premium it charges to an enrollee is the same amount as was accepted by the Exchange in its certification of the QHP issuer after accounting for any applicable APTC.

(ii) No later than 30 calendar days after discovery of an incorrect amount it has charged an enrollee, retroactively correct any incorrect amounts collected.

(iii) For issuers of QHPs in a Federally-facilitated Exchange, it allows HHS to review the premiums charged to qualified individuals through compliance reviews as set forth in §156.715(a).

(b) Direct enrollment in a Federally-facilitated Exchange. The individual market Federally-facilitated Exchanges will permit issuers of QHPs in each Federally-facilitated Exchange to directly enroll applicants in a manner that is considered to be through the Exchange, pursuant to paragraph (a) of this section, to the extent permitted by applicable State law.

§156.1240 Enrollment process for qualified individuals.

(a) Premium payment. A QHP issuer must –

(1) Follow the premium payment process established by the Exchange in accordance with §155.240.

(2) Offer method of payment options that do not discriminate against individuals without bank accounts or credit cards.

(b) [Reserved]

Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)
(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance;
and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: May 28, 2013

Marilyn Tavenner,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: May 31, 2013

Kathleen Sebelius,

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