THE GEORGE WASHINGTON UNIVERSITY
SCHOOL OF PUBLIC HEALTH AND HEALTH SERVICES

THE DEPARTMENT OF HEALTH POLICY

MEMORANDUM

To: Interested Parties

From: Hirsh Health Law and Policy Program

Date: 18 July 2011

Subject: **Health Insurance Exchanges: Qualified Health Plans and Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment**

Introduction

On July 11, 2011, the U.S. Department of Health and Human Services (HHS) released for publication in the July 15th Federal Register two Notices of Proposed Rulemaking (NPRMs).

The first NPRM, related to Exchanges, implements PPACA §§1301-1321 and related provisions of the law. The rule proposes: (1) federal requirements that States must meet if they elect to establish and operate an Exchange, as well as standards related to selection and oversight of qualified health plans (QHPs); (2) standards that employers must meet to participate in the Small Business Health Options Program (SHOP); and (3) the minimum requirements that health insurance issuers selling qualified health plans (QHPs) must meet in order to have their products certified for sale in an Exchange.

The second NPRM implements PPACA §§1341-1343 and related provisions. This NPRM addresses standards related to state reinsurance programs, the temporary federal risk corridor program, and the ongoing requirement that Exchanges maintain a risk adjustment program to assure premium stability and mitigate the impact of potential adverse selection in the individual and small group markets, both during implementation and as a matter of ongoing operations.

The Exchange NPRM clarifies that the issues addressed only a partial listing of the matters to be addressed in Exchange regulations. Still to come are (1) standards for individual participation in the Exchange; advance payments of premium tax credits, dost sharing reductions, and related health programs and appeals of eligibility determinations; (2) standards outlining the Exchange process for issuing certificates of exemption from the individual responsibility requirement and payment under PPACA §1411; (3) the definition of essential health benefits, actuarial value and other benefit design standards; and (4) standards for Exchanges and QHP issuers related to quality. In addition, the NPRM notes that federal standards related to the entire individual and group market will be the subject of separate and forthcoming regulations.

The 75-day comment period closes September 28, 2010.

Top-Level Take

There are three notable points about the NPRMs. Point One is that, to a remarkable degree, the regulations are deferential to states – not only in terms of the pace at which states will be allowed to move in "standing up" their Exchanges and commencing operations, but also in the substantive manner in which state Exchanges operate and in the level of discretion given to states in determining QHP certification standards.

Point Two is that the level of deference given health insurance issuers is nearly as remarkable. Indeed, the Preamble states explicitly that "[t]he Exchanges should be an attractive market for health insurance issuers to achieve the goal of providing consumers and employers with access to a competitive choice of affordable high quality QHPs." At crucial points, the proposed rule leaves considerable discretion to issuers, unless and until the Exchange itself (or controlling state law) imposes a stricter standard. A tremendously important issue for state implementation will be how this considerable devolution of authority is exercised.

Point Three is a central issue related to QHP qualifications, entirely overlooked in our view by the Exchange rule. The rule appears to be predicated on the belief that the QHP individual and group markets will be plentiful, that competition will be fierce, and that in fact there will be more competition for business than what is needed to serve the Exchange population. In some states this may well be true, at least for the first year or so. But an important lesson from the Medicare Part D and Medicaid managed care experiences is that in the case of subsidized network plans (e.g., the Part D LIS program, the Medicaid system), capacity often falls well short of what is needed. In such situations, people can be eligible and literally have no means of enrolling, at least if the issuer is honest and indicates a capacity problem. As CMS points out, PHSA §2702(c) (guaranteed issue) explicitly allows plans to turn away people if they lack capacity[1] to serve enrollees. Despite this provision of the law, the NPRM does not address Exchange mechanisms for assuring that all persons seeking to enroll in a plan can do so, even if their initial choice cannot be honored.[2] Indeed, the NPRM obligates the Exchange to honor selection, even if (apparently) no selection can be made. Because this issue will be so serious in Exchanges covering populations at risk for medical underservice and disparities in health and health care, it is a matter that bears monitoring.

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[1] Section 2702(c) as amended by the ACA provides as follows: (c) SPECIAL RULES FOR NETWORK PLANS.— (1) IN GENERAL.—In the case of a health insurance issuer that offers health insurance coverage in the group and individual market through a network plan, the issuer may— (A) limit the employers that may apply for such coverage to those with eligible individuals who live, work, or reside in the service area for such network plan; and (B) within the service area of such plan, deny such coverage to such employers and individuals if the issuer has demonstrated, if required, to the applicable State authority that— (i) it will not have the capacity to deliver services adequately to enrollees of any additional groups or any additional individuals because of its obligations to existing group contract holders and enrollees, and (ii) it is applying this paragraph uniformly to all employers without regard to the claims experience of those employers and their employees (and their dependents) or any health status-related factor relating to such. and individuals 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

[2] Two options would be an open network requirement at that point or an auto-enrollment system so that individuals and groups can be matched to plans in the service area with capacity.

The Exchange NPRM

Part 155 Subparts A-C
Subpart A – General Provisions

Scope of the Regulation

The NPRM amends 45 C.F.R. When fully developed the rules will address minimum standards for the establishment of an Exchange, minimum Exchange functions, eligibility determinations, enrollment periods, minimum SHOP functions, certification of Qualified Health Plans (QHPs), and health plan quality improvement.[3]

Key Definitions

Many of the definitions duplicate the definitions set forth in the Exchange provisions of the *Affordable Care Act* (e.g. difference between small and large employer, definition of qualified health plan) or in subsequent regulations (e.g., regulations on grandfathered health plans) or elsewhere in the Public Health Service Act or ERISA (e.g. the definition of employer/employee, definition of a health plan). However, a few additional definitions are noted here: [4]

- Applicant: An individual who is seeking eligibility through an application to the Exchange for at least one of the following: (i) Enrollment in a QHP through the Exchange; (ii) Advance payments of the premium tax credit and cost-sharing reductions; or (iii) Medicaid, CHIP, and the Basic Health Plan (BHP), if applicable. Applicant can also mean an employer or employee seeking eligibility for enrollment in a QHP through the SHOP, where applicable.
- Eligible Employer-Sponsored Plan: With respect to any employee, a group health plan or group health insurance coverage offered by an employer to the employee which is: (1) A governmental plan (e.g. Federal Employees Health Benefits Plan); or (2) Any other plan or coverage offered in the small or large group market within a State. This term includes a grandfathered health plan offered in the group market.
- Exchange: Exchange means a governmental agency or non-profit entity that meets all applicable requirements and makes QHPs available to qualified individuals and qualified employers. Unless otherwise identified, the term "Exchange" refers to State Exchanges, regional Exchanges, subsidiary Exchanges, and a Federally-facilitated Exchange.
- Exchange Service Area: The area in which the Exchange is certified to operate (e.g. state Exchange, regional Exchange, subsidiary Exchange covering a geographically distinct area)
- Qualified Employee: An individual employed by a qualified employer who has been offered health insurance coverage by such qualified employer through the SHOP.
- Qualified Employer: A small employer that elects to make, at a minimum, all fulltime employees eligible for one or more QHPs in the small group market offered through a SHOP. Beginning in 2017, if a State allows large employers to purchase coverage

[3] §155.10(b)
[4] §155.20

through the SHOP, the term "qualified employer" will include large employers that elect to make all full-time employees eligible for one or more QHPs in the large group market offered through the SHOP.

- Qualified Individual: With respect to an Exchange, an individual who has been determined eligible to enroll in a QHP in the individual market offered through the Exchange.

Subpart B – General Standards Related to the Establishment of an Exchange by the State

State Options for Exchange Administration

- States may choose to establish a state Exchange by following the procedures established by HHS for obtaining federal approval and demonstrating operational readiness, as defined in future guidance.[5]
- States may choose to create an independent SHOP (Small Business Health Options Program) with separate governance and administrative structures. If the state chooses this option, it must ensure that the SHOP coordinates and shares information with the Exchange.[6]
- States may participate in a regional Exchange, which spans two or more states, instead of establishing a state Exchange.[7]
- States may establish one or more subsidiary Exchanges, which must serve geographically distinct areas and be at least as large as an HHS-approved rating area.[8]
- If a state does not elect to establish an Exchange, or its Exchange is not approved (or conditionally approved) by January 1, 2013, HHS must establish and operate an Exchange within the state.[9]

Federal Standards for Approval

Federal standards for approval require that:

- The Exchange be able to carry out the required functions of an Exchange—including enrollment, premium payments, navigator programs, consumer tools, a SHOP program, and plan certification and contracting.
- The Exchange can comply with IRS requirements related to advance payments of the premium tax credit (these requirements are not yet defined).
- The state agrees to operate a reinsurance program, per the requirements of the Affordable Care Act.
- The entire geographic area of the state is covered by one or more state Exchanges.[10]

Eligible Entities

- Exchanges must be a governmental agency or a non-profit entity with demonstrated experience in the individual and small group markets and in benefits coverage. Health insurance issuers are not eligible to serve as the Exchange, but state Medicaid agencies may function as the Exchange. Exchanges may also contract with Medicaid agencies to determine eligibility on behalf of the Exchange.[11]

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[5] §155.100, §155.105
[6] §155.110 (e)
[7] §155.140 (a)
[8] §155.140 (b)
[9] §155.105 (f)
[10] §155.105 (b)
[11] §155.110 (a)

- States must ensure that when independent state agencies and non-profit entities function as the Exchange, the Exchange has in place a governing board that represents consumer interests, holds regular, public meetings and operates under a formal operating charter or by-laws.[12]

Exchange Funding

- States must ensure that their Exchange or Exchanges have funding to support ongoing operations beginning January 1, 2015. States may charge assessments or user fees on participating issuers, or fund Exchange operations through other means.[13]

Other Requirements for State Exchanges

- Exchanges must have in place guiding principles that include ethics, conflict of interest standards, accountability and transparency standards, and disclosure of financial interest. The Exchange must disclose financial interests by members of the Exchange board or governance structure.[14]
- As they establish and operate their programs, Exchanges are required to consult with certain stakeholder groups, including:
    - Educated consumers who are enrolled in qualified health plans;
    - Individuals and entities with experience in facilitating enrollment in health coverage;
    - Advocates for enrolling hard-to-reach populations (including individuals with mental health or substance abuse disorders);
    - Small businesses and self-employed individuals;
    - State Medicaid and CHIP agencies;
    - Federally-recognized tribes;
    - Public health experts;
    - Health care providers (type not specified);
    - Large employers;
    - Health insurance issuers; and
    - Health insurance agents and brokers.[15]

  In the Preamble, HHS recommends that Exchanges also consult with individuals with disabilities, advocates for individuals with disabilities, advocates for individuals who need culturally and linguistically appropriate services, and Medicaid and CHIP beneficiaries, but the NPRM does not require Exchanges to consult with these groups.
- Exchanges may not establish rules that conflict with federal Exchange regulations, pre-empt insurance reforms established by the Affordable Care Act, or engage in discriminatory behavior with regard to marketing, outreach and enrollment.[16]

[12] §155.110 (c)
[13] §155.160
[14] §155.110 (d)
[15] §155.130
[16] §155.120

Changes to State Exchanges

- States that choose to establish Exchanges after January 1, 2014 must secure federal approval for the new Exchange, following the process established for initial Exchanges, and work with HHS to transition from the federally-facilitated Exchange to the state Exchange. The state would need to obtain federal approval for the new Exchange at least one year prior to the new Exchange beginning operations.[17]
- States that choose to terminate an existing Exchange after January 1, 2014, must notify HHS at least 12 months prior to the end of Exchange operations, and coordinate with HHS on a transition plan to the federally-facilitated Exchange.[18]

Subpart C – General Functions of an Exchange

The Preamble notes that the "proposed minimum functions are designed to provide State flexibility."[19]

Functions of an Exchange

An Exchange must perform the functions identified in this subpart and in subparts E, H, and K.[20] These functions include certification of exemptions from the individual responsibility requirement and payment[21], eligibility determinations[22], and establishing an appeals process for eligibility determinations[23]; details on these three functions are to be established in future rulemakings. An Exchange must also perform functions related to oversight and financial integrity requirements under §of the ACA.[24] Finally, an Exchange must "evaluate quality improvement strategies and assessments and ratings of healthcare quality and outcomes" – this function will also be detailed in future rulemakings.[25]

The Preamble "encourage[s] States to consider supplemental standards or functionality for their Exchanges that benefit consumers and businesses, and [] welcome comments regarding these and other functions that should be required of an Exchange."[26]

Required consumer assistance tools and programs of an Exchange

This section codifies ACA §1311 (d)(4)(b), which requires Exchanges to establish a toll-free call center for consumers. The Preamble states that while Exchanges will have "significant latitude" over how to operate the call center, it is suggested that they operate outside normal business

[17] §155.106 (a)
[18]§155.106 (b)
[19] Preamble pp. 36-7.
[20] §155.200(a)
[21] §155.200(b)
[22] §155.200(c)
[23] §155.200(d)
[24] §155.200(e)
[25] §155.200(f)
[26] Preamble, p. 39.

hours, as well as have the ability to inform consumers and business on a range of issues, including:

- types of QHPs;
- premiums, benefits, cost-sharing and quality;
- available assistance (tax credits, Medicaid or CHIP); and
- the application process.[27]

The proposed rule also requires that each Exchange have an internet website that:

- includes standardized comparative information on each QHP; premium and cost-sharing information; a summary of benefits and coverage; indication of whether each QHP is a bronze, silver, gold, platinum or catastrophic plan; results of enrollee satisfaction surveys; quality ratings; MLR information; transparency of coverage measures; and a provider directory[28];
- is accessible to people with limited English proficiency and to people with disabilities[29];
- includes financial information, including average licensing costs; any regulatory fees charged; any additional payments required; administrative costs; and money "lost to waste, fraud, and abuse"[30];
- gives information about Navigators and the call center[31];
- allows an eligibility determination[32]; and
- allows for enrollment in accordance with Subpart E.[33]

The proposal also requires an electronic calculator; a customer assistance function, including the Navigator program; and outreach and education activities.

Navigator program standards

The Preamble clarifies that these standards are to apply to both individual plans and SHOP.[34] Exchanges are required to make grants to public or private entities to serve as Navigators.[35] A Navigator must be able to carry out the following duties:

- "maintain expertise" on eligibility, program specs, and enrollment, and carry out education to raise awareness about Exchanges[36];
- give information that is "fair, accurate, and impartial"[37];
- facilitate enrollment in QHPs[38];
- give referrals to any ombudsman or other consumer assistance offered by offices of health insurance[39]; and

[27] Preamble, pp. 39-40.
[28] §155.205(b)(1).
[29] §155.205(b)(2).
[30] §155.205(b)(3).
[31] §155.205(b)(4).
[32] §155.205(b)(5).
[33] §155.205(b)(6).
[34] Preamble p. 45.
[35] §155.210(a).
[36] §155.210(d)(1).
[37] §155.210(d)(2).
[38] §155.210(d)(3).

- provide information that is "culturally and linguistically appropriate to the needs of the population being served by the Exchange," including people with disabilities and with limited English proficiency.[40]

Navigators must also be able to demonstrate existing relationships, or the ability to develop them, with employers, employees, consumers (including underinsured and uninsured) or self-employed individuals.[41] The Preamble notes that an entity does not have to be able to have relationships with *all* relevant groups.[42] Navigators must meet any applicable licensing or other standards set by the State or by the Exchange[43], and must not have conflicts of interest while serving as a Navigator.[44]

An Exchange must select Navigators from at least two of the following categories:

- community and consumer-focused nonprofits;
- trade, industry, and professional associations
- commercial fishing industry, ranching, and farming organizations;
- chambers of commerce;
- unions;
- resource partners of the Small Business Administration;
- licensed agents and brokers; and
- other public or private entities that meet the requirements of this section, including but not limited to Indian tribes, tribal organizations, urban Indian organizations, and State or local human service agencies.[45]

The Preamble notes that the Department is seeking comment as to whether "community and consumer-focused nonprofit groups" should be a required category, or whether it should be required that Navigators represent "a cross section of stakeholders."[46]

Navigators are prohibited from being issuers of health insurance and from receiving indirect or direct compensation from health insurance issuers based on enrollment.[47]

Navigators cannot be funded with federal Exchange operating dollars.[48] The Preamble notes that if a State opts to permit or require a Navigator to also perform Medicaid or CHIP administrative functions, the state agency can claim Federal funding for a share of those expenditures.[49]

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[39] §155.210(d)(4).
[40] §155.210(d)(5).
[41] §155.210(b)(1)(ii).
[42] Preamble p. 45.
[43] §155.210(b)(1)(iii).
[44] §155.210(b)(1)(iv).
[45] §155.210(b)(2).
[46] Preamble p. 46.
[47] §155.210(c).
[48] §155.210(e).
[49] Preamble p.48.

The Preamble also notes that the Department is considering a requirement that Navigators be operational no later than the first day of the open enrollment period.[50] This timeframe does not appear in the proposed regulation, but the Department is seeking comment.

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

This provision codifies the ACA provision (§1312(e)) that gives States the option to allow agents and brokers a) to enroll qualified individuals, employers or employees in QHPs as soon as they become available through Exchanges, and b) to assist individuals in applying for advance payment of tax payments and cost-sharing reductions.[51] It permits Exchanges to include information about licensed agents and brokers on the website.[52]

General standards for Exchange notices

Notices sent by Exchanges to applicants or to qualified individuals, employers, or employees must be in writing and include contact information for customer service resources; an explanation of appeal rights; and a reference to the regulation supporting the action.[53] All notices, as well as forms and applications, must be in plain language and accessible to people with disabilities and people with limited English proficiency.[54]

Payment of premiums

Exchanges *must* allow qualified individuals to pay premiums directly to the QHP issuer.[55] They *may* allow Indian tribes, tribal organizations, and urban Indian organizations to pay premiums on behalf of qualified individuals.[56] They *must* accept payment of aggregated premiums by qualified employers.[57] They *may* establish an electronic process to facilitate payments[58], using specified standards and operating rules.[59]

Privacy and security of information

An Exchange is prohibited from collecting, using, or disclosing personally identifiable information unless the use is specifically required or permitted by this provision, by other applicable law, while fulfilling responsibilities under §155.200(c), under subpart E of this part, or under data sharing arrangements related to eligibility between the Exchange and agencies administering Medicaid, CHIP, or BHP.[60] "Personally identifiable information" is defined as "information that there is a reasonable basis to believe, alone or when combined with other

[50] Preamble pp. 48-9.
[51] §155.220(a).
[52] §155.220(b).
[53] §155.230(a).
[54] §155.230(b).
[55] §155.240(a).
[56] §155.240(b).
[57] §155.240(c).
[58] §155.240(d).
[59] §155.240(e).
[60] §155.260(b)(1) and (c).

personal or identifying information which is linked or linkable to a specific individual, can be used to distinguish or trace an individual's identity."[61] In addition, Exchanges must:

- Establish and follow security standards consistent with those required for certain covered entities under HIPPA[62];
- Establish and follow privacy standards consistent with applicable law[63];
- Maintain, in writing, policies and procedures on the use, disclosure and disposal of personally identifiable information[64];
- Include requirements at least as stringent as those in this section in any contract or agreement[65]; and
- Keep tax information private and secure.[66]

The Preamble notes that while some Exchange entities may be covered by HIPAA, the Department is not proposing that HIPAA privacy standards apply to all information under the Exchange.[67] The Department is proposing that States have flexibility, and is considering requiring Exchanges to adopt privacy policies that are consistent with the Fair Information Practice Principles.[68]

Finally, the rule establishes a penalty of not more than $25,000 for each knowing and willful use or disclosure of information in violation of §1411(g) of ACA.[69]

Use of standards and protocols for electronic transmissions

This provision requires that Exchanges performing electronic transactions with HIPAA-covered entities use existing HIPAA administrative simplification requirements.[70] Exchanges must also use HIT enrollment standards and protocols developed by the Secretary in their information technology systems.[71]

Subpart D – [Reserved]

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

Subpart E sets forth the requirements for enrollment of individuals in QHPs. Exchanges are required to accept an eligible applicant's QHP selection and must notify the issuer of the individual's selected QPH and transmit necessary enrollment information.[72] Enrollment information must be sent to QHP issuers in a timely manner and the Exchange must have a

[61] §155.260(a).
[62] §155.260(b)(2).
[63] §155.260(b)(3).
[64] §155.260(b)(4).
[65] §155.260(b)(5).
[66] §155.260(d).
[67] Preamble p.56.
[68] Preamble pp. 56-7.
[69] §155.260(e).
[70] §155.270(a).
[71] §155.270(b).
[72] § 155.400(a).

process for verifying the QHP's receipt of that information.[73] Records must be maintained and reconciled monthly, and enrollment information sent to HHS monthly.[74]

The Exchanges are required to use a single streamlined application for eligibility and enrollment. This application must be sufficient for QHP enrollment, advance payments of the premium tax credit, cost sharing reductions, and enrollment in Medicaid, CHIP, or BHP.[75] Exchanges can use an alternative application that requests the same information, if approved by HHS.[76] The Exchanges must accept the application from the applicant or applicant's agent, and must provide the tools for the application to be filed online, by telephone, by mail, and in person.[77]

The initial open enrollment period will be October 1, 2013, through February 28, 2014.[78] By December 22, 2013, Exchanges must ensure that QHP coverage will be effective as of January 1, 2014. During the initial enrolment period, if an individual enrolls between the 1st and 22nd of a month, coverage must be effective on the first day of the following month, and if enrollment occurs between the 23rd and the end of the month, the coverage may be effective either the first of the following month or the first of month after that.[79]

Exchanges must have annual open enrollment periods for qualified individuals to enroll in a QHP or change QHPs, and must give current enrollees advance written notice of the annual open enrollment.[80] Individuals may be restricted to these periods to enroll, unless they qualify for a special enrollment period as a result of a triggering event.[81] Effective coverage dates follow the same pattern as for new enrollees, except that coverage begins on the date of birth, adoption, or placement for adoption for those new dependents.[82] Exchanges must allow individuals to enroll in or change from one QHP to another as a result of the following triggering events with respect to a qualified individual or dependent:[83]

- Loss of minimum essential coverage (except as a result of failure to pay premiums on a timely basis, including COBRA premiums, or where a rescission is allowed);[84]
- Loss or gain of a dependent or change in dependent status through marriage, birth, adoption, or placement for adoption;
- Becoming a citizen, national, or lawfully present individual;
- Correction of enrollment status due to unintentional error, misrepresentation, or inaction by Exchange or HHS;
- Demonstration by enrollee that QHP of current enrollment substantially violated a material provision of its contract with respect to that enrollee;

[73] § 155.400(b).
[74] § 155.400(c) and (d).
[75] § 155.405(a).
[76] § 155.405(b).
[77] § 155.405(c).
[78] § 155.410(b).
[79] § 155.410(c).
[80] § 155.410(a) and (d).
[81] § 155.420(a).
[82] § 155.420(b).
[83] § 155.420(d).
[84] § 155.420(e).

- Determination of new eligibility or ineligibility for advance payments of premium tax credit or change in eligibility for cost-sharing reductions, even if already enrolled in a QHOP;
- A permanent move that results in access to new QHPs;
- Status as an Indian (under Section 4 of the Indian Health Care Improvement Act), which entitles the individual to enroll or change QHPs once per month; or
- Other exceptional circumstances as provided by the Exchange or HHS.

CMS proposes that an enrollee with a special enrollment period as a result of a triggering event, other than new eligibility or ineligibility for the premium tax credit or cost-sharing reductions, be restricted to moving to a different plan at the same level of coverage.[85] This policy is intended to reduce adverse selection, but CMS notes that it could present a challenge for an enrollee with a low level of coverage (such as a catastrophic plan) that becomes pregnant but cannot switch to a higher value plan. CMS requests comment on whether there should be an exception for such circumstances.[86]

Exchanges are required to determine the form and manner for termination of coverage, but must permit the enrollee to terminate coverage with appropriate notice to the Exchange or QHP (with termination effective either when specified by enrollee or after a reasonable amount of time after notice given).[87] The Exchange may terminate, and must permit a QHP issuer to terminate, an enrollee's coverage in the following circumstances:[88]

- Enrollee is no longer eligible for coverage in a QHP through the Exchange;
- Enrollee becomes covered by other minimum essential coverage (termination effective when other coverage becomes effective);
- Premium payments are not made, after the grace period has elapsed;
- Enrollee's coverage is rescinded;
- QHP terminates or is decertified; or
- Enrollee changes from one QHP to another during an open enrollment or special enrollment period (termination effective when new coverage begins).

Except as noted above, the effective date of termination of coverage is the 14th day of the month if notice of termination is given prior to the 14th day of the previous month, or the last day of the month if notice of termination is given prior to the last day of the previous month.

Subpart F – [Reserved]

Subpart G – [Reserved]

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

[85] § 155.420(f).
[86] P. 74.
[87] § 155.430.
[88] § 155.430(b).

- If a state chooses to operate an Exchange, it must establish a Small Business Health Options Program (SHOP), also known as a small business Exchange.[89] The SHOP will assist qualified employers and facilitate enrollment of qualified employees into QHPs. The SHOP must carry out all of the same required functions as an individual Exchange set forth in Subparts C, E, and K, which relate to general functions, enrollment in QHPs, certification of QHPs, with limited exceptions, as well as the SHOP requirements in Subpart H.[90] The exceptions proposed are that the SHOP does not need to meet requirements related to: 1) individual eligibility determinations; (2) enrollment of qualified individuals into QHPs; 3) provision of comparison calculator for QHPs after application of premium tax credits and cost sharing reductions; 4) certification of exemptions from individual coverage requirement; and 5) requirements related to premium payments by individuals and Indian organizations.[91]

- The SHOP has unique functions and eligibility requirements.[92] It must allow qualified employers to choose a level of coverage, under which all qualified employees have the choice of any available plan, but may also use a different method to allow qualified employers to offer plan choices to employees, such as allowing a choice from any level or allowing employers to designate a single QHP to offer employees.[93]

- CMS notes in the Preamble that the flexibility proposed may create potential for risk selection and invites comment on this as well as whether the SHOP should have a minimum participation requirement for QHPs. The SHOP must perform certain payment administration functions (i.e., provide qualified employers with a monthly bill, collecting the amount due, and making payments to QHP issuers for all qualified enrollees).[94] SHOPs must ensure that QHPs the same certification requirements as for the individual Exchange.[95] QHP rate changes must be made at a uniform time and not vary for a qualified employer during the QHP's plan year.[96] If the state merges the individual and small group market risk pools, the SHOP may permit a qualified employee to enroll in any QHP that meets minimum levels of coverage and maximum deductibles.[97] In unmerged markets, the SHOP must limit qualified enrollees to QHPs in the small group market.[98] If a state expands the SHOP to the large group market, it must allow issuers in the state market to offer QHPs through a SHOP beginning in 2017, provided that the large employer qualifies by making all full-time employees eligible for such coverage.[99]

[89] § 155.700.
[90] § 155.705.
[91] § 155.705(a).
[92] § 155.705(b).
[93] § 155.705(b)(2) and (3).
[94] § 155.705(b)(4).
[95] § 155.705(b)(5).
[96] § 155.705(b)(6).
[97] § 155.705(b)(7).
[98] § 155.705(b)(8).
[99] § 155.705(b)(9).

- SHOPs must permit all qualified employers to purchase coverage for qualified employees through the SHOP.[100] In order to be eligible, employers must be a small employer (100 or fewer employees, although a state may limit it to 50 or fewer employees up to 2016), chooses to offer all full-time employees coverage in a QHP through a SHOP, and either offers covers coverage through the SHOP for the Exchange service area in which it has its primary business address or offers coverage to each employee through the SHOP serving that employee's primary worksite.[101] In this last case, the employer might be participating in multiple SHOPs, so CMS proposes that a SHOP could establish a participation rule with respect to the number of employees within the service area of the SHOP.[102]

- The SHOP is required to determine eligibility for both employers and employees, using a single employer application form and a single employee application form, before permitting purchase of QHP coverage.[103] For employers, CMS proposes that the SHOP verify the size of the employer, that it meets all the standards for eligibility, and that at least one employee works in the SHOP's service area.[104] Besides relying on the application information, the SHOP may establish additional or alternate methods to verify application information. For an employer whose application information is in doubt, the SHOP must make a reasonable effort to identify and address any reason for doubt (such as a typographical error), notify the employer of the reason, and give the employer 30 days to resolve the issue or provide satisfactory documentary evidence in support of the application. If such evidence is not received after 30 days, the SHOP must notify the employer of its denial of eligibility and, if the employer is already participating, discontinue the employer's participation in the SHOP at the end of the following month.[105] The same procedure must be followed if the SHOP doubts information on an individual application.[106] Both employers and employees must be notified of their approval or denial of eligibility and right to appeal that determination.[107] CMS requests comments on this eligibility and notice process, specifically whether the notice must inform the employee about eligibility for special enrollment periods in the Exchange and for premium tax credit and cost-sharing reductions.[108] If a qualified employer stops purchasing coverage through the SHOP, the SHOP must ensure that participating QHPs terminate coverage of the employer's qualified employees and that employees are notified prior to that termination.[109]

- The SHOP is required to process employee applications for coverage and facilitate the enrollment of qualified employees in QHPs. [110] Specifically, it must establish a uniform

[100] § 155.710.
[101] § 155.710(b).
[102] P. 86.
[103] § 155.715(a).
[104] § 155.715(c); p. 87.
[105] § 155.715(d)(1).
[106] § 155.715(d)(2).
[107] § 155.715(e) and (f).
[108] P. 89.
[109] § 155.715(g).
[110] § 155.720.

enrollment timeline and process for all QHP issuers and employers to follow so that the following activities occur before employees' coverage begins:
  - Determination of employer eligibility for purchase of coverage through SHOP;
  - Employer selection of QHPs offered through the SHOP to employees;
  - Provision of specific timeframe for employer selection of level of coverage or QHP;
  - Provision of specific timeframe for employees to provide relevant application information;
  - Determination and verification of employee eligibility;
  - Processing enrollment of qualified employees into selected QHPs; and
  - Establishment of effective dates of coverage;

- SHOPs must also transmit enrollment information to QHPs, notify employees of the effective date of coverage, administer payments, terminate non-compliant employers, receive and maintain enrollment and participation records, reconcile information at least monthly, and notify the employer if an employee terminates coverage.

- The SHOP must administer enrollment periods, including the initial open enrollment period, and ensure that enrollment transactions are sent to QHP issuers, who must adhere to coverage effective dates. CMS proposes that the initial enrollment period for the SHOP begin October 1, 2013 for coverage effective January 1, 2014 (the same dates as the individual Exchange).[111] Employers can purchase coverage for small groups at any time ("rolling enrollment") and must be given a period prior to the completion of the employer's plan year and before the annual employee open enrollment period in which the employer may change the terms of its participation for the next year, including the method of making QHPs available to employees, amount of contribution to premium costs, the level of coverage, or the selected QHPs offered to employees.[112] Under this rolling enrollment, employers' 12-month plan year may not correspond to the calendar year, unlike the individual market. CMS invites comments on this issue.[113]

- The NPRM requires that employees be given an annual open enrollment period after the employer's annual election period, and newly hired employees may seek coverage beginning on the first day of employment, regardless of the open enrollment period. Coverage will be renewed for employees that remain eligible for coverage and employees will remain in the same plan as the previous year unless the employee terminates coverage, enrolls in another QHP, or the QHP is no longer available.[114]

- SHOPs are required to use a single application to determine eligibility for both employers and employees. From employers, the application must collect the employer name, address of employer's locations, number of employees, Employer Identification Number (EIN) and a list of qualified employees and their social security numbers. The SHOP may use

[111] Pp. 91-92.
[112] § 155.725.
[113] P. 92.
[114] § 155.725(h).

model employer and employee applications provided by HHS or an alternative application, if approved by HHS.[115]

Subpart I – [Reserved]

Subpart J – [Reserved]

Subpart K – Exchange Functions: Certification of Qualified Health Plans (QHPs)

Under the proposed rule, certification of QHPs is by and large consistent with what is set out in the ACA regarding requirements and responsibilities of an Exchange to certify, recertify and decertify QHPs and to ensure that only QHPs are offered in the Exchange[116]. In the Preamble HHS acknowledges that an Exchange may be in the best position to determine whether a particular health plan should be certified as a QHP based on the needs of the State's consumers.[117]

Certification standards for QHPs

- At a minimum, Exchanges must ensure health plans meet two basic requirements to be certified as a QHP: (1) the health insurance issuer must demonstrates compliance with the minimum certification requirements outlined in Subpart C of Part 156; and (2) the Exchange determines that the health plan is in the interest of qualified individuals and employers.[118]
- To determine whether a health plan is in the interest of qualified individuals and employers, an Exchange may choose from a variety of strategies (e.g. allow "any qualified plan", competitive bidding, or negotiation on a case-by-case basis), but HHS suggests that a competitive bidding strategy may allow the Exchange to achieve additional value and quality objectives.[119] Exchanges are also permitted to establish additional criteria to determine if a plan is in the "interest" of qualified consumers (e.g. quality improvement activities, reasonableness of premium costs, past performance etc...). An Exchange cannot exclude a health plan because it is fee-for-service, by imposing premium price controls, or because the health plan provides treatments necessary to prevent patient's death under circumstances the Exchange determines are costly or inappropriate.[120]
- Any reference to QHPs is deemed to include multi-State plans, as defined by the ACA, unless specifically excluded.[121]
- Certification process for QHPs
- The Exchange must complete certification of QHPs prior to open the enrollment period stated in §155.410.[122]

[115] § 155.730.
[116] §155.1000(b)
[117] Preamble p. 97
[118] §155.1000(c)
[119] Preamble p. 99
[120] §155.1000(c)
[121] §155.1000(b)
[122] §155.1010(c)

- An Exchange is required to accept multi-state plans (offered through OPM) as QHPs without additional certification processes.[123]
- The Exchange must monitor QHP issuers for evidence of ongoing compliance with certification requirements.[124]

QHP issuer rate and benefit information

- Exchanges must receive justification for a rate increase from the QHP issuer prior to the implementation of the increase.[125] Exchanges must consider the justification for the rate increase, recommendations provided by the State and any excess rate growth outside the Exchange vs. inside the Exchange when determining whether to certify a QHP.[126] To reduce duplication efforts, HHS suggests that an Exchange leverage their State's effective rate review program (if there is one) and notes that a bifurcated process for rate increase justifications is being considered as a standard for the final rule. [127]
- The Exchange must receive, at least annually, information from QHP issuers about rates, covered benefits, and cost-sharing requirements for each QHP.[128]

Transparency in Coverage

- The Exchange must collect information relating to coverage transparency as described in Subpart C §156.220(a). The Exchange must determine whether the information required to be submitted is provided in plain language.[129] The Secretaries of HHS and Labor will jointly issue guidance on "best practices of plain language writing".[130] The Exchange must monitor whether a QHP issuer has made cost-sharing information available in a timely manner upon an individual's request.[131]

Accreditation Timeline

- The Exchange must establish a consistent time period following certification of the QHP within which a non-accredited QHP issuer must become accredited.[132]

Establishment of Exchange network adequacy standards

- An Exchange must ensure QHP offers a sufficient choice of providers.[133] Exchanges are given discretion to establish such standards, with no minimum requirements specified. CMS requests comments on what minimum qualitative or quantitative standards

[123] §155.1010(b)
[124] §155.1010(d)
[125] §155.1020(a)
[126] §155.1020(b)
[127] Preamble p. 103
[128] §155.1020(c)
[129] §155.1040(b)
[130] Preamble p. 105
[131] §155.1040
[132] §155.1045
[133] §155.1050

Exchanges should use to determine whether the QHP provider network offers sufficient access to care (e.g. numbers and types of providers, proximity of providers to enrollees' residence or workplace, or cost of out-of-network provider).[134] In its Preamble, CMS notes the NAIC standards, which are considerably more robust than those established by the NPRM:

> "We also examined the NAIC Managed Care Plan Network Adequacy Model Act, from which a number of States have drawn in developing their network adequacy standards for health insurance issuers. We have sought to develop a standard that balances the need for a uniform level of protection with the level of variation across States and local markets. In particular, we seek comment on a potential additional requirement that the Exchange establish specific standards under which QHP issuers would be required to maintain the following: (1) sufficient numbers and types of providers to assure that services are accessible without unreasonable delay; (2) arrangements to ensure a reasonable proximity of participating providers to the residence or workplace of enrollees, including a reasonable proximity and accessibility of providers accepting new patients; (3) an ongoing monitoring process to ensure sufficiency of the network for enrollees; and (4) a process to ensure that an enrollee can obtain a covered benefit from an out-of-network provider at no additional cost if no network provider is accessible for that benefit in a timely manner. These standards are based in part on the NAIC Managed Care Plan Network Adequacy Model Act. This set of standards would create a baseline that each Exchange could interpret and apply in a manner appropriate to local market conditions and patterns of care. Consistent with these basic standards, an Exchange would be able to set quantitative requirements where possible to establish clear expectations of access to care."

- Advance Notice NPRM, pp. 108-109.

<u>Service area of a QHP</u>

- An Exchange must have a process to establish or evaluate the service area of a QHP to ensure that: (1) the service area covers at least an area of a county or group of counties unless the QHP issuer can show that serving a smaller area is necessary, nondiscriminatory and in the best interest of qualified individuals and employers; and (2) the service area is established without regard to racial, ethnic, language, health status related factors listed in §2705(a) of PHS Act.[135]

<u>Stand-alone dental plans</u>

[134] Preamble p. 108
[135] §155.1055

- This section codifies the ACA §1302(b), which allows an Exchange to offer a limited scope dental benefits plan as defined in the ACA §1302(b)(1)(J) (essential health benefits).[136] An Exchange may allow the dental plan to be offered as stand-alone plan or in conjunction with QHP.[137] Health plans that do not offer a limited scope dental benefits plan can be certified as a QHP as long as a stand-alone dental plan is offered through the Exchange.[138]
- HHS is requesting comments on whether any of the requirements on QHP issuers should apply as minimum standards to stand-alone dental plans and what limits an Exchange may face is setting such requirements.[139] Comments are also requested on whether all dental benefit plans be offered and priced separately.

Recertification of QHPs

- An Exchange must establish a process for recertification of a QHP that includes a review of general certification criteria and must be completed on or before September 15 of the applicable year.[140] HHS allows the Exchange to determine recertification periods.[141]

Decertification of QHPs

- Decertification is defined as the termination of the certification status and offering of a QHP by the Exchange.[142] An Exchange must establish a decertification process which, at a minimum, includes decertifying a health plan if the Exchange determines a QHP is no longer in compliance with the general certification criteria[143], an appeals process[144], and notice of decertification to all affected parties[145].

Part 156 – Subparts A-C

Subpart A – General Provisions

Statutory Authority for Qualified Health Plan Standards

- Section 1311(c) of the ACA provides statutory authority to establish standards for health plans and health insurance issuers offering Qualified Health Plans (QHPs) through an Exchange.

Key Definitions

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[136] §155.1065(a)
[137] §155.1065(b)
[138] §155.1065
[139] Preamble p. 111
[140] §155.1075
[141] Preamble p. 113
[142] §155.1080(a)
[143] §155.1080(b) and (c)
[144] §155.1080(d)
[145] §155.1080

- Definitions used in this part are the same as those used in earlier sections. The terms "applicant, benefit year, cost-sharing, cost-sharing reductions, plan year, qualified employer, qualified health plan, qualified health plan issuer, and qualified individual" are cross-referenced to §155.20. The terms "group health plan, health insurance coverage, and health insurance issuer or issuer" are cross-referenced to §144.103.

Definitions applying solely to Part 156:

- Benefit design standards – Coverage that provides "essential health benefits," under §1302(b) of the ACA, cost-sharing limits described in §1302(c), and the level of coverage (bronze, silver, gold, platinum) defined under §1302(d) and a catastrophic plan described in §1302(e) of the Affordable Care Act.[146] Preamble notes that the term is used in lieu of "essential health benefits package," as defined in §1302(a) to avoid confusion with the term "essential health benefits" in §1302(b) of the ACA.[147]
- Level of coverage – One of four standardized actuarial values as defined in §1302 of the Affordable Care Act.[148]

Financial Support

- Requires a participating insurer to pay user fees if required by an Exchange. The Preamble notes that Exchanges must be self-sustaining by January 1, 2015. For the purposes of this section (156.50), a participating insurer is defined as an issuer offering plans that participate in the specific function that is funded by user fees. The term may include health insurance issuers, issuers of multi-State plans (§155.1000(a)), stand-alone dental plans (§155.1065), or other issuer identified by an Exchange.[149]

Subpart B – [Reserved]

Subpart C – Qualified Health Plan Minimum Certification Standards

QHP Issuer Participation Standards

- General Requirement – Issuer participation in the Exchange is conditioned on each plan offered in the Exchange being certified by the Exchange as a QHP.[150] The Preamble notes that Section 1311(c)(1) authorizes the Secretary to issue regulation to establish criteria for the certification of QHPs, and that the minimum standards are intended to foster direct competition on the basis of price and quality to increase access to high qualify affordable care for individuals and small employers.[151] Exchanges will be responsible for determining whether plans seeking to participate meet the minimum

[146] §156.20.
[147] Proposed rule at 116.
[148] §156.20.
[149] §156.50.
[150] §156.200(a).
[151] Proposed rule at p. 117.

requirements, and the Exchange will have the discretion to set additional standards.[152] Unless otherwise noted, standards do not supersede state law, and do not exempt health insurance issuers from any state law or regulation generally applicable to health insurance issuers. Further, states may establish more stringent standards than outlined in this subpart.[153]

- QHP Issuer Requirements
  - Each QHP must meet all the requirements of this subpart on an ongoing basis (the Preamble notes that this applies to both initial certification and periodic recertification);[154]
  - Issuers must comply with the Exchange processes, procedures and requirements under subpart K of part 155 in the small group market;
  - Each QHP must comply with benefit design standards;
  - Issuers must be licensed and in good standing in each state in which coverage is offered (the agency interprets the term "good standing" to mean that the issuer has no outstanding sanctions imposed by a State's department of insurance"[155];
  - Issuers must comply with quality improvement standards under the ACA; §1311(g) quality improvement strategies, §1311(c)(1)(H) and (I) disclosure and reporting of quality and outcomes measures, and §1311(c)(4) enrollee satisfaction surveys (the agency will address specific requirements in future rulemaking[156]);
  - Issuers must pay user fees under §156.60; and
  - Comply with risk adjustment program. [157]
- Offering requirements – Issuers must offer:
  - 1 silver and 1 gold level QHP;
  - A child only QHP for individuals under 21 (same level of coverage as any other QHP offered through the Exchange)
  - Offer a QHP at the same premium rate as is offered outside the Exchange.[158]
- State requirements – Issuers must comply with Exchange or state requirements that condition participation on compliance.[159]
- Non-discrimination – Bans issuer discrimination (with re: each QHP) on the basis of race, color, national origin, disability, age, sex, gender identity or sexual orientation.[160] Non-discrimination practices include, but are not limited to marketing, outreach and enrollment.[161]

<u>QHP Rate and Benefit Information</u>

Issuers must:

- Set rates for an entire benefit year, or in the case of a SHOP, for a plan year;

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[152] *Id.*
[153] Preamble at 118.
[154] Preamble at 119.
[155] Preamble at 119.
[156] Preamble at 120.
[157] §156.200(b).
[158] §156.200(c).
[159] §156.200(d).
[160] §156.200(e).
[161] Preamble at 120-121.

- Submit rate and benefit information to the Exchange; and
- Submit a justification for a rate increase before implementing the increase, and must prominently post the justification in the issuer's website. [162] Exchanges may leverage the preliminary justification collected as part of the rate review process, and the agency is considering a standard in which the issuers will submit rate justification in the form and manner determined by the Exchange.[163]

Transparency in coverage

- Issuers must provide information (in plain language) to the Exchange, HHS, the State insurance commissioner, and make available to the public. The information must include claims payment and practices, periodic financial disclosures, data on enrollment, data on disenrollment, data on the number of claims that are denied, data on rating practices, information on cost-sharing and payments with respect to out-of-network coverage and information on enrollee rights.[164] The agency notes that it includes participants in the definition of enrollee, and seeks comment on whether issuers should be required to *submit* the information to the Exchange and other entities, or to *make the information available* [emphasis added] to the Exchange and other entities.[165]
- Issuers must make available the amount of enrollee cost-sharing under the individual's plan or coverage by item or service, and by participating provider, in a timely manner upon the request of the individual. At a minimum, the information must be made available to such individual through an Internet website and other means for individuals without Internet access.[166]

Marketing of QHPs

- Issuers, including officials, employees, agents and representatives must comply with state laws and regulations relating to marketing of health insurance, and are prohibited from employing practices that discourage enrollment of individuals with significant health needs.[167] In the Preamble, the agency notes that the Exchange should consider a QHP issuer's marketing practices in determining whether offering a QHP is in the best interest of consumers, and the agency seeks comments on the best means for an Exchange to monitor QHP issuers' marketing practices to determine whether issuers have discouraged enrollment of individuals with significant health needs, as well as on a broad prohibition against unfair or deceptive marketing practices by all QHP issuers, and there officials, agents and representatives. This would permit Exchanges to take action to address practices if State agencies do not have the authority to do so under state law.

- CMS notes that it considered setting detailed and uniform Federal standards, but was concerned about the interaction with current State rules or unintentionally creating "safe

[162] §156.210.
[163] Preamble at 122.
[164] §156.220(a),(b),(c).
[165] Preamble at 123.
[166] §156.220(d).
[167] 156.225.

harbors." Exchanges may choose to apply additional requirements, but should work closely with State insurance departments to create a level playing field inside and outside the Exchange. In addition CMS is concerned that QHPs may be marketed to Medicare beneficiaries, and seek comment on a standard that issuers do not represent benefits, advantages, conditions, exclusions, limitations or terms.[168]

Network Adequacy Standards

- Issuers must ensure that provider networks of each QHP includes essential community providers (§155.1050) and complies with network adequacy standards established under §2702(c) of the PHSA, which CMS notes requires issuers to furnish coverage unless the individual resides outside the plan's service area or unless the plan is at capacity for enrollment, which provides an exception to guarantee issue requirements if there will be an insufficient number of providers to serve all potential enrollees. In such cases, the exception must be applied uniformly across all employees or individuals without regard to claims experience or health status.[169] In addition, issuers must make a QHP provider directory available to the Exchange for online publication, must make hard copies available to potential enrollees upon request. The provider directory must identify providers that are not accepting new patients.[170] CMS seeks comments on standards that the agency might set to ensure that issuers maintain up-to-date provider directories.[171]

Essential Community Providers

CMS' Preamble is lengthy and noteworthy here, because it puts the proposed essential community provider rule into greater perspective and illustrates the agency's thinking about how to approach the issue:

> "In §156.235, we propose to codify section 1311(c)(1)(C) of the Affordable Care Act, which requires that a health plan's network include essential community providers who provide care to predominantly low-income and medically-underserved populations to be certified as a QHP. As specified in section 1311(c)(1)(C), essential community providers include entities specified under section 340B(a)(4) of the PHS Act and section 1927(c)(1)(D)(i)(IV) of the Act as set forth by section 211 of Public Law 111-8.
>
> We received a number of comments in response to the RFC regarding essential community providers. In general, respondents to the RFC offered recommendations on the types of entities that might be included in the definition of an essential community provider, and essential community provider inclusion in QHP provider networks. We considered these comments in developing the standards related to essential community providers. In paragraph (a) of this section, we require that QHP issuers include in their provider networks a

[168] Preamble at 124.
[169] Preamble at 124.
[170] §156.230.
[171] Preamble at 126.

> sufficient number of essential community providers, where available, that serve low income, medically-underserved individuals.
>
> We also propose to codify the provision that nothing in this requirement shall be construed to require any QHP to provide coverage for any specific medical procedure. We interpret this to mean that while a QHP issuer must contract with essential community providers, coverage of specific services or procedures performed by an essential community provider is not required. An important issue with respect to implementing section 1311(c)(1)(C) is establishing a sufficient level of essential community provider participation in QHPs. Although the Affordable Care Act requires inclusion of essential community providers in QHP networks, the Act does not require QHP issuers to contract with or offer contracts to all essential community providers. The statute refers to "those essential community providers, where available," and "that serve predominantly low-income and medically-underserved," which suggests a requirement that QHP issuers contract with a subset of essential community providers.
>
> We considered establishing broad contracting requirements where QHP issuers would have to offer a contract to all essential community providers in each QHP's service area, or establishing a requirement for issuers to contract with essential community providers on an any willing provider basis. Requiring issuers to offer contracts to all essential community providers would allow continuity of service for enrollees with existing relationships especially in communities where the essential community provider has been the only reliable source of care. However, such a requirement may inhibit attempts to use network design to incentivize higher quality, cost effective care by tiering networks and driving volume towards providers that meet certain quality and value goals. We note that "sufficiency" could be interpreted to mean that the QHP issuer would have to demonstrate to the Exchange that it has a sufficient number and geographic distribution of essential community providers to ensure timely access for low-income, medically underserved individuals in its health plan service area, pursuant to the Exchange's applicable network adequacy and access requirements. We solicit comment on how to define a sufficient number of essential community providers. We note that States may elect to establish more stringent participation requirements, including adoption of a blanket contracting requirement. Similarly, a potential safe-harbor strategy for QHP issuers would be to offer contracts to all essential community providers or accept any-willing essential community provider in its service area."[172]

- Thus, under the proposed rule, issuers must include a "sufficient number" of essential community providers (ECPs) that serve predominantly low-income, medically-underserved individuals, in the provider network.
- The statute itself provides the full range of "essential community providers" as entities described under section 340B(a)(4) of the Public Health Service Act. These entities qualify for special pricing from prescription drug manufacturers, and include among

[172] Preamble pp. 126-128.

others, federally qualified health centers (FQHCs), community health center grantees, Title X family planning grantees, Ryan White grantees, State-operated AIDS drug purchasing programs, black lung clinics, hemophilia diagnostic treatment centers, Native Hawaiian Health Center grantees, Indian Health Service grantees, and certain hospitals that treat predominantly low-income individuals (public hospitals, certain children's hospitals, critical access hospitals and rural referral centers). Essential community providers also include certain entities that qualify for the nominal pricing structure under the Medicaid drug rebate program (entities that meet all the requirements of certain grant funding, but who do not receive grant dollars).[173] CMS seeks comment on whether other types of providers should be included.[174] CMS also clarifies that the ECP requirement does not require plans to cover any specific medical procedure provided by the essential community provider.[175]

- CMS leaves the special FQHC payment rules in the ACA unaddressed. The agency notes that two provisions of the ACA regarding payment of FQHC's may conflict. Section 1311(c)(2) states that QHPs are not required to contract with ECPs if the provider refuses to accept the generally applicable payment rates of the plan, while 1302(g) requires QHPs to reimburse FQHCs at each facilities Medicaid prospective payment rate.[176] The agency suggests two possible solutions, one of which is to require QHPs to pay at least the Medicaid PPS rate to each participating FQHC, and the other proposes allowing plans and providers to negotiate mutually agreed-upon payment rates. CMS suggests pros and cons to each approach and invites comments on these or other approaches.[177]
- In a similar vein, CMS also seeks comments on requirements regarding reimbursement of Indian health providers under Section 206 of the Indian Health Care Improvement Act, which provides that all Indian health providers have the right to recover from third part payers, including insurance companies up to the reasonable charges billed for providing health care services, or if higher, the highest amount an insurer would pay to other providers. Section 206 also provides that no law of any state or provision of contract shall prevent or hinder this right of recovery. CMS believes that this would require a QHP issuer, employee benefit plan or third party payer to pay on this basis, regardless of whether there is a contract between the insurer and the provider. CMS invites comment on a standard contracting addendum for QHPs contracting with Indian health providers to address other provisions of federal law that require special accommodation when contracting with Indian health providers, including but not limited to the Anti-Deficiency Act, the Indian Self-Determination and Education Act, the Federal Tort Claims Act and the Federal Medical Care Recovery Act.[178]

<u>Treatment of Direct Primary Care Medical Homes</u>

The rule permits issuers to offer coverage through a direct primary care medical home so long as the QHP meets all other requirements and that services provided by the medical home are

[173] §156.235.
[174] Preamble at 129.
[175] §156.235(a).
[176] Preamble at 129.
[177] Preamble at 131-132.
[178] *Id.*

coordinated with the issuer.[179] CMS states that commenters highlighted the direct primary care medical home model in the State of Washington, and considered allowing an individual to purchase a direct primary care medical home plan and separately acquire wrap-around coverage. CMS ultimately rejected this approach, however since these medical homes are providers, not insurers, Exchanges would be required to develop a separate accreditation and certification process, and would require consumers to make two payments for full medical coverage, adding a complication in implementation of the premium tax credit.[180]

Health Plan Applications and Notices

Issuers must meet application and notice requirements described in §155.230(b).

Rating Variations

- Issuers may vary premiums for a QHP or multi-state QHP by geographic rating area established under section 2701(a)(2) of the Public Health Service Act.[181]
- Issuers must charge the same premium rate for a plan, regardless of whether the plan is offered through the Exchange, directly to a consumer, or through an agent.[182]
- Issuers must cover all of the following groups using one or more combinations including, individuals, two-adult families, one-adult families with a child or children, and all other families.[183] CMS notes that 2701(a)(4) of the PHS Act requires that any family premium using age or tobacco rating may only apply those rates to the portion of the premium that is attributable to each family member, and seeks comment on how to structure the family rating categories to comply with this requirement, and on how to balance the number of categories to reduce consumer confusion, while maintaining plan offerings and rating structures. In addition, CMS is considering whether to require issuers to cover an enrollee's tax household, because of the potential administrative challenge of administering the premium tax credit for families filing with non-spousal adult dependents, and seeks comment.[184]

[179] §156.245.
[180] Preamble at 133.
[181] §156.255(a).
[182] §156.255(b).
[183] §156.255(c).
[184] Preamble at 136.

Enrollment of Qualified Individuals

- Issuers must meet the initial enrollment, annual enrollment, special enrollment requirements, and notification of coverage requirements described in §155.410 and §155.420.[185]
- If an applicant initiates enrollment directly with the issuer for enrollment in a QHP, the issuer must collect enrollment information using the uniform application, must transmit enrollment information to the Exchange to facilitate an eligibility determination process, and must enroll the individual only after receiving confirmation that the eligibility process is complete and applicant is eligible, consistent with requirements outlined in §§155.405, 155.260.

Termination of Coverage for Qualified Individuals

Except as provided, issuers may not terminate coverage:

- Plans must provide notice of termination of coverage, and must develop a uniform policy for termination of coverage which includes, a grace period for enrollees receiving advance payments of the premium tax credits. The grace period for recipients of advance payments of the premium tax credit must be at least three consecutive months.
- During the grace period, the enrollee must pay all claims, apply all payments to the first billing cycle in which payment was delinquent, continue to collect advance payments of the tax credits. If an enrollee is delinquent, issuer must provide notice of delinquency, and may terminate coverage at the end of the grace period, must maintain records and abide by the termination period described in §155.430.[186] CMS notes plans to issue standards for the termination of coverage which may include content such as a reason for termination and termination effective date, and seeks comments on other information that should be included in the notice.[187]

Accreditation of QHP Issuers

- Issuers must be accredited by HHS on the basis of local performance based on clinical quality measures, patient experience rating, consumer access, quality assurance, provider credentialing, complaints and appeals, network adequacy and access, and patient information programs.[188]
- Issuers must authorize the accrediting entity to release a copy of the most recent accreditation survey to the Exchange and HHS, together with any survey information that HHS may require, such as corrective action plans and summaries of findings.[189]

[185] §156.260.
[186] §156.270.
[187] Preamble at 139.
[188] §156.275(a).
[189] §156.275(b).

Segregation of funds for abortion services

- Unless prohibited by state law, issuers must determine whether a QHP covers abortion services.[190] QHPs are not required to cover abortion services as essential health benefits for any plan year.[191]
- The rule distinguishes between those abortion services for which federal funding prohibited,[192] and those abortion services for which federal funding is permitted (rape, incest or life of the mother would be endangered).[193] If a QHP provides services for which federal funding is not permitted, the issuer must not use any amount of funding attributable to the premium and cost sharing tax credits paid under section 1412 of the ACA.[194]
- Issuers must collect a separate payment from enrollees for the actuarial value of services for which federal funding is prohibited and deposit those payments in a separate account. The issuer must estimate the basic per enrollee, per month cost, and may not estimate the cost at less than one dollar per enrollee, per month. Issuers must provide notice to enrollees only as part of the summary of benefit s and coverage explanation.[195]
- QHP issuers may not discriminate against health care providers or facilities because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions.[196]
- Nothing in the ACA shall be construed to have any effect on State laws regarding the abortion coverage, funding of, or procedural requirements (including parental notification or consent), or on federal laws relating to provider conscience laws or federal civil rights law.[197]
- Nothing in the ACA alters requirements under the Emergency Medical Treatment and Active Labor Act.[198]

Additional Standards Specific to the SHOP

- Issuers offering QHPs through a SHOP must accept payment from the SHOP on behalf of a qualified employer or enrollee, adhere to the timeline for rate setting, and charge the same contract rate for a plan year.[199]
- Issuers must enroll a qualified employee during the qualified employer's annual employee open enrollment period, provide special enrolments, and establish effective dates in accordance with §155.[200]
- Issuers must adhere to the enrollment process timeline, receive enrollment information in electronic format, provide enrollees with enrollment information, provide the summary of benefits and coverage documents, reconcile enrollment files with the Exchanges at least

[190] §156.280(b) and (c)(2).
[191] §156.280(c)(1).
[192] §156.280(d)(1).
[193] §156.280(d)(2).
[194] §156.280(e)(1).
[195] §156.280(e) and (f).
[196] §156.280(g).
[197] §156.280(h).
[198] §156.280(i).
[199] §156.285(a).
[200] §156.285(b).

monthly, acknowledge receipt of enrollment information, and enroll all qualified employees.[201]

- Issuers must comply with requirements related to termination of coverage and notice to enrollees and qualified employers, and must terminate coverage for all employees if the employer chooses to withdraw from participation in the SHOP.[202]
- Issuers seeding to withdraw from QHP certification must comply with notification, coverage of benefits through end of plan or benefit year, fulfill data reporting obligations, provide notice to enrollees, comply with termination requirements, and may terminate coverage only after notification and after enrollees have the opportunity to enroll in other coverage.[203] CMS will provide further guidance on the timing and content of the notice, and may adopt concepts from the Medicare Advantage non-renewal notice, and seeks comments on the content of the non-renewal notice.[204]

Non-renewal and Decertification of QHPs

- QHPs that elect not to seek recertification with the exchange must: notify the Exchange of its decision prior to the beginning of the recertification process; fulfill its obligation to cover benefits for each enrollee through the end of the plan or benefit year; fulfill data reporting obligations from the last plan or benefit year; provide written notice to each enrollee;[205]and follow the requirements of the termination rule (§156.270)[206]
- If a QHP is decertified by the Exchange, then the QHP issuer must terminate coverage for enrollees only after the Exchange has made notification as specified in the rules (§155.1080) and enrollees have the chance to enroll in other coverage.[207]

Prescription Drug Distribution and Cost Reporting

QHP Issuers must provide the following information to the Secretary of HHS:

- Percentage of all prescriptions provided under the QHP through retail and mail order pharmacies, and the percentage for which generic drugs were available and dispensed as a percentage of all drugs by type of pharmacy.
- The aggregate amount of types of rebates, discounts or price concessions that are attributable to patient utilization under the QHP and the aggregate amount of rebates, discounts or concessions passed through the QHP issuer and number of prescriptions dispensed.
- The aggregate amount of the difference between the amount the issuer pays it's pharmacy benefit manager (PBM) and the amount the PBM pays retail and mail order pharmacies, and the total number of prescriptions dispensed, as well as other reporting requirements.[208] CMS anticipates providing guidance on the reporting requirements, and

[201] §156.285(c).
[202] §156.285(d).
[203] §156.290.
[204] Preamble at 147.
[205] No time frame for a written notice or whether the notice is an advance notice is specified.
[206] §156.290(a) and (b)
[207] While an involuntary termination thus is subject to an alternative enrollment timeframe requirement, QHPs apparently can voluntarily quit the market without safeguards.
[208] §156.295.

seeks comments on how an issuer whose contracted PBM operates its own mail order pharmacy can meaningfully report on the aggregate differences. CMS anticipates providing guidance on the reporting requirements, and seeks comments on how an issuer whose contracted PBM operates its own mail order pharmacy can meaningfully report on the aggregate differences.[209]

Standards Related to Reinsurance, Risk Corridors and Risk Adjustment

Subpart A – General Provisions

- This subpart states the statutory authority under the ACA for the promulgation of regulations that set forth the federal standards for three programs designed to avoid adverse selection and stabilized insurance premiums in the individual and small group markets: (1) the transitional state-based reinsurance program (designed to reduce the uncertainly of insurance risk in the individual market by paying for high-cost cases); (2) the temporary federally-administered risk corridor program (designed to protect against the uncertainty of the insurance market inside the Exchanges by limiting insurer losses and gains); and (3) the ongoing state-based risk adjustment program (designed to provide adequate payments to health insurers attracting high-risk populations).[210]
- Each state must establish a transitional reinsurance program for the first three years of Exchange operation (2014-2016). The Secretary must establish a transitional risk corridor program that will apply to the qualified health plans in the individual and small group markets for the first three years of Exchange operation (2014-2016). And, each state may establish an ongoing program for risk adjustment for all non-grandfathered plans in the individual and small group markets both inside and outside of an Exchange.[211]
- This subpart includes fourteen definitions, cross referencing language from the ACA itself, from existing regulations, from the NPRM entitled "Establishment of Exchanges and Qualified Health Plans," and in some cases newly defining some terms for the purposes of this NPRM only.[212]

Subpart B – State Notice of Insurance Benefits and Payment Parameters

- For states operating an Exchange or establishing a reinsurance program, this subpart proposes a process that states must follow to provide adequate annual notice to insurance issuers and other stakeholders about requirements to support payment-related functions. Because certain payment and benefit factors may change annually, such as reinsurance contribution rates, this update notice must come from the state every year.
- The annual federal notice of benefit and payment parameters serves as the baseline, and the state notice requirements described in this subpart are only triggered if the state intends to utilize any reinsurance or risk adjustment parameters that differ from those in the annual federal notice.[213] If the state does intend to deviate from the annual federal

[209] Preamble at 148.
[210] § 153.10).
[211] Preamble at 7.
[212] §153.20).
[213] §153.100(a)).

parameters, then the state notice to insurers and stakeholders must describe the specific reinsurance or risk adjustment parameters that the state intends to employ.[214]

- This subpart proposes specific deadlines for the state notice, which generally must occur one year in advance of the benefit year. Specifically, states must issue their notice by early March in the calendar year before the effective date.[215] In states that do not provide public notice in accordance with this subpart of their intent to have state-specific parameters regarding reinsurance and risk adjustment, the federal parameters in the annual federal notice of benefit and payment parameters will serve as the state parameters.[216]
- For states providing this public notice, the reinsurance parameters must include: data requirements and data collection frequency for insurers to receive the reinsurance payment; the attachment point, reinsurance cap, and coinsurance rate; and geographic boundaries of each applicable reinsurance entity and estimates of enrollees, payments and premiums available for contributions in each region.[217]
- Additionally, for states providing this public notice, the risk adjustment parameters must include: a description and rationale for modifying the federal risk adjustment parameters; a description of the modification including the methodology for determining the average actuarial risk; and the state's risk adjustment data validation methodology.[218]

Subpart C – State Standards for the Transitional Reinsurance Program for the Individual Market

- The ACA requires that a transitional reinsurance program be established in each state for the years 2014 –2016 to stabilize premiums for coverage in the individual market.[219] The ACA mandates that all health insurers (and 3rd party administrators on behalf of self-insured group health plans) make contributions to a not-for-profit reinsurance entity that in turn support the payments to individual market insurers covering high-cost individuals. This subpart offers several new definitions and explains the federal standards that states must follow in setting up their reinsurance programs.
- Each state that operates an Exchange must also establish a reinsurance program and enter into a contract with a reinsurance entity, or more than one reinsurance entity so long as the state publishes a public notice regarding the geographic divisions between the entities.[220] The reinsurance entity(ies) must cover the entire individual market in the state, and the reinsurance entity is permitted to contract out administrative functions approved by the state. The same reinsurance entity may conduct operations in more than one state; however, such an entity must have separate contracts with each state and maintain separate risk pools for each state's reinsurance program.[221] A state that does not elect to operate an Exchange may still nonetheless establish a reinsurance program in accordance

[214] Id.
[215] §153.100(b)).
[216] §153.100(c)).
[217] §153.110(a)).
[218] §153.110(b)).
[219] §153.210(a)).
[220] §153.210(a)).
[221] §153.210(b)).

with this regulation.[222] For states that do not elect to operate an Exchange or establish a reinsurance program, HHS will run the reinsurance program.[223]

- The reinsurance entity is in charge of collecting all reinsurance contribution funds from all health insurance issuers and 3rd party administrators on behalf of self-insured plans. These funds are limited to covering the reinsurance payments and the administrative costs of the reinsurance entity, but no other activities. Using a national uniform contribution rate (determined by a percent of premium amount applied to all contributing entities),[224] HHS has calculated the aggregate contribution funds for the purpose of making reinsurance payments as follows: $10 billion in 2014; $6 billion in 2015; and $4 billion in 2016.[225] All contribution funds collected by a state will stay in that state and be used to make reinsurance payments on valid claims.
- Additionally, the ACA requires the reinsurance entity to collect specified additional contribution funds for deposit in the US Treasury, in the amount of $2 billion for calendar years 2014 and 2015, and $1 billion in 2016.[226]
- A health insurance issuer of an individual market plan (not grandfathered) becomes eligible for a reinsurance payment when its expenses for items and services within the essential health benefits package for an individual enrollee exceed an "attachment point" (threshold dollar amount after which reinsurance payments kick-in).[227] States may use the annual federal notice of benefit and payment parameters for the payment formula and values for the attachment point, reinsurance cap (threshold dollar amount of expenses for an individual after which reinsurance payments cease), and coinsurance rate (rate at which the reinsurance entity will reimburse the health insurer for costs incurred after the attachment point and before the reinsurance cap) for the years 2014-2016, or states may modify the reinsurance payment formula to other values with proper notice and explanation as set forth above.[228] For both approaches, the state must ensure that the reinsurance payment equals the product of the coinsurance rate times the insurer's costs for an individual's essential health benefits between the attachment point and the reinsurance cap.[229]
- The state must ensure that the reinsurance entity collects from all reinsurance-eligible plans the data necessary to calculate the reinsurance payments.[230] Once they have the data, the reinsurance entities must make the reinsurance payments to the health insurers in the event of a valid claim,[231] and the state must ensure that reinsurance payments to the health insurers do not exceed overall contributions.[232] The payments are to be made in accordance with the annual federal notice of benefit and payment parameters, or as

[222] §153.210(c)).
[223] §153.210(d)).
[224] §153.220(b)).
[225] §153.220(a)(1)).
[226] §153.220(a)(2)).
[227] §153.230(a)).
[228] §153.230(b)).
[229] §153.230(b)(1)).
[230] §153.240(a)).
[231] §153.240(b)(3)).
[232] §153.240(b)).

modified by the state with proper notice and explanation.[233] And, payments may be reduced on a pro rata basis to match the amount of contributions received by the state.[234]

- The state must maintain documentation of accounting procedures and practices of the reinsurance program for each benefit year for at least 10 years.[235] Moreover, the state is required eliminate or modify any state-based high-risk pool if necessary to comply with these reinsurance provisions, or coordinate the reinsurance program with its high risk pool if possible under these regulations.[236]

Subpart D – State Standards for the Risk Adjustment Program

- A state that elects to establish an HHS-approved Exchange is eligible to operate a risk adjustment program. In states that do not establish an HHS-approved Exchange, or do establish one but do not create a risk adjustment program, HHS will carry out all the provisions of this risk adjustment regulation on their behalf.[237] A state must be ready to begin calculating payment and charges for the 2014 benefit year, and a state is permitted to have another entity besides the Exchange itself perform these risk adjustment functions.[238]
- Any risk adjustment methodology used by a state must be federally-certified by HHS.[239] To obtain certification, a state must submit to HHS information including: the applicable risk pools, a description of the model, factors to be employed in the proposed methodology, qualifying criteria, weights assigned to each factor, and a schedule for the collection of risk adjustment data, among other information.[240]
- The state, or HHS on behalf of the state, must collect risk-related data to determine individual risk scores that form the basis for risk adjustment.[241] The state may vary the amount and type of data it collects, but the state must use the following minimum standards for its risk adjustment data collection:
    - NCPDP claims transaction – or – HIPAA standard ASC X12N 837 Health Care Claim transaction, for all claims and encounter data; and
    - HIPAA standard ASC X12N 834 Benefit Enrollment and Maintenance transaction for all demographic and enrollment data; and
    - The use of individually identifiable information only as specifically required or permitted under this part.[242]

- In addition, the state must implement both privacy and security standards for the protection of individually identifiable information.[243] However, any state with an all-

[233] §153.240(b)(1)).
[234] §153.240(b)(2)).
[235] §153.240(c)).
[236] §153.250).
[237] §153.310(a)).
[238] §153.310(b), (c)).
[239] § 153.320(a)).
[240] §153.330).
[241] §153.340(a)).
[242] §153.340(b)).
[243] §153.340(b)).

payer claims database that is operational by January 1, 2013 may request an exemption from HHS from the data collection minimum standards.[244]

- To support its claims-related activities, the state must make available relevant claims and encounter data collected under its risk adjustment program, including: (1) to HHS, de-identified claims and encounter data for use in recalibrating federally-certified risk adjustment models; (2) to HHS, summarized claims cost for use in verifying risk corridor submissions; and (3) to the reinsurance entity, summarized claims and encounter data from reinsurance-eligible plans for payment verification purposes.[245]
- Finally, the state must validate a statistically valid sample of risk adjustment data from each insurer that offers at least one risk-adjusted covered plan in that state. The state may adjust the average actuarial risk for covered plans offered by an insurer based on a risk score error if there is one, and then adjust the charges and payments accordingly. The state must also provide an administrative process of appeal for data validation findings.[246]

Subpart E – Health Insurance Issuer Standards Related to the Transitional Reinsurance Program

- Each health insurer and third party administrator of a self-insured group health plan ("contributing entities") must make payments of contributions to the applicable reinsurance entity. Each contributing entity must submit to the applicable reinsurance entity data required to substantiate the contribution amounts for the contributing entity, and each contributing entity in the individual and fully insured market must also submit enrollment and premium data. For the self-insured market, each contributing entity must submit data on covered lives and total expenses.[247] A reinsurance-eligible plan may make a request for a reinsurance payment when the enrollee's claims have met the criteria for a payment.[248]

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

- Any insurance issuer of a qualified health plan must adhere to both this subpart and the annual federal notice of benefits and payment parameters regarding the establishment of a federal program of risk corridors for calendar years 2014, 2015 and 2016.[249] Designed to protect against uncertainty in setting premium rates in the Exchanges by limiting insurance issuer losses and gains, insurance issuers of qualified health plans will receive payments from HHS under the risk corridor program when a qualified health plan's allowable costs for any benefit year are more than 103% but not more than 108% of the target amount. The amount of this payment will be equal to 50% of the target amount in excess of 103% of the target amount. When the qualified health plan's allowable costs

[244] §153.340(c)).
[245] §153.340(d)).
[246] §153.350).
[247] §153.400).
[248] §153.410).
[249] §153.510(a)).

are more than 108% of the target amount, the HHS payment equals the sum of 2.5% of the target amount plus 80% of allowable costs in excess of 108% of the target amount.[250]

- Conversely, insurance issuers of qualified health plans must send payments to HHS if their projected gains are too high. If the qualified health plan's allowable costs for any benefit year are less than 97% but not less than 92% of the target amount, the plan must submit to HHS a payment equal to 50% of the difference between 97% of the target amount and the allowable costs. If a plan's allowable costs are less than 92% of the target amount, the plan must to HHS a payment equal to the sum of 2.5% of the target amount plus 80% of the difference between 92% of the target amount and allowable costs.[251]
- In order to verify the payment amounts, issuers of qualified health plans must submit to HHS data on the premiums collected for each QHP offered by the issuer. These reported premium amounts must be adjusted for any payments made or received for risk adjustment, reinsurance, and user fees paid.[252] Also, all QHP issuers must submit to HHS the allowable costs incurred for each QHP that the issuer offers.[253]

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

- All insurance issuers offering risk-adjustment covered plans must submit all the required risk adjustment data (all data that were used in the application of a risk adjustment payment model) for those covered plans to the state, including:
  - Claims and encounter data for items and services rendered; and
  - Enrollment and demographic information; and
  - Prescription drug utilization data.[254]

- Insurers are permitted to include in their contracts with providers, suppliers, etc. provisions requiring the submission of specific risk adjustment data in a manner established by the state, and these contracts may include penalties for non-compliance. Plans owing risk adjustment payments will be notified by the state of the amount and must remit those risk adjustment payments to the state.[255]

[250] §153.510(b)).
[251] §153.510(c)).
[252] §153.520(a)).
[253] §153.520(b)).
[254] §153.610(a)).
[255] §153.610(c)).