

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 155 and 156

[CMS-9989-P]

RIN 0938-AQ67

Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans

AGENCY: Department of Health and Human Services.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement the new Affordable Insurance Exchanges (“Exchanges”), consistent with title I of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), referred to collectively as the Affordable Care Act. The Exchanges will provide competitive marketplaces for individuals and small employers to directly compare available private health insurance options on the basis of price, quality, and other factors. The Exchanges, which will become operational by January 1, 2014, will help enhance competition in the health insurance market, improve choice of affordable health insurance, and give small businesses the same purchasing clout as large businesses.

A detailed Preliminary Regulatory Impact Analysis associated with this proposed rule is available at <http://ccio.cms.gov> under “Regulations and Guidance.” A summary of the aforementioned analysis is included as part of this proposed rule.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. Eastern Standard Time (EST) on September 28, 2011.

ADDRESSES: In commenting, please refer to file code CMS-9989-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the “More Search Options” tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:*

CMS-9989-P, P.O. Box 8010, Baltimore, MD 21244-8010.

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

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS-9989-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

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

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

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

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document’s paperwork requirements by following the instructions at the end of the “Collection of Information Requirements” section in this document. For information on viewing public comments, see the beginning of the “**SUPPLEMENTARY INFORMATION**” section.

FOR FURTHER INFORMATION CONTACT: Laurie McWright at (301) 492-4372 for general information matters. Alissa DeBoy at (301) 492-4428 for general information and matters related to part 155. Michelle Strollo at (301) 492-4429 for matters related to enrollment.

Pete Nakahata at (202) 680-9049 for matters related to part 156.

SUPPLEMENTARY INFORMATION:

Abbreviations

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

- BHP Basic Health Program
- CAHPS Consumer Assessment of Healthcare Providers and Systems
- CHIP Children’s Health Insurance Program
- CMS Centers for Medicare & Medicaid Services
- DOL U.S. Department of Labor
- ERISA Employee Retirement Income Security Act (29 U.S.C. section 1001, et seq.)
- FEHBP Federal Employees Health Benefits Program
- HEDIS Healthcare Effectiveness Data and Information Set
- HHS U.S. Department of Health and Human Services
- HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)
- HMO Health Maintenance Organization
- IHS Indian Health Service
- IRS Internal Revenue Service
- NAIC National Association of Insurance Commissioners
- NCQA National Committee for Quality Assurance
- OMB Office of Management and Budget
- OPM Office of Personnel Management
- PBM Pharmacy Benefit Manager
- PHS Act Public Health Service Act
- PPO Preferred Provider Organization
- QHP Qualified Health Plan
- SHOP Small Business Health Options Program
- SSA Social Security Administration
- The Act Social Security Act
- The Code Internal Revenue Code of 1986

Executive Summary: Starting in 2014, individuals and small businesses will be able to purchase private health insurance through State-based competitive marketplaces called Affordable Insurance Exchanges, or “Exchanges.” Exchanges will offer Americans competition, choice, and clout. Insurance companies will compete for business on a level playing field, driving down costs. Consumers will have a choice of health plans to fit their needs. And Exchanges will give individuals and small businesses the same purchasing clout as big businesses. The Departments of Health and Human Services, Labor, and the Treasury (the Departments) are working in close coordination to release guidance related to Exchanges in several phases. The first in this series was a Request for Comment relating to Exchanges, published in the **Federal Register** on August 3, 2010 (75 FR 45584). Second,

Initial Guidance to States on Exchanges was issued on November 18, 2010. Third, a proposed rule for the application, review, and reporting process for waivers for State innovation was published in the **Federal Register** on March 14, 2011 (76 FR 13553). Fourth, two proposed regulations, including this one, are published in this issue of the **Federal Register** to implement components of the Exchange and health insurance premium stabilization policies in the Affordable Care Act.

This proposed rule: (1) Sets forth the Federal requirements that States must meet if they elect to establish and operate an Exchange; (2) outlines minimum requirements that health insurance issuers must meet to participate in an Exchange and offer qualified health plans (QHPs); and (3) provides basic standards that employers must meet to participate in the Small Business Health Options Program (SHOP). The intent of this proposed rule is to afford States substantial discretion in the design and operation of an Exchange. Greater standardization is proposed where required by the statute or where there are compelling practical, efficiency or consumer protection reasons. This proposed rule does not address all of the Exchange provisions in the Affordable Care Act; additional guidance on the establishment and operation of Exchanges will be provided in forthcoming proposed rules.

Submitting Comments: We welcome comments from the public on all issues set forth in this proposed rule to assist us in fully considering issues and developing policies. Comments will be most useful if they are organized by the section of the proposed rule to which they apply. You can assist us by referencing the file code [CMS-9989-P] and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all electronic comments received before the close of the comment period on the following public Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at Room 445-G, Department of Health

and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, Monday through Friday of each week from 8:30 a.m. to 4 p.m. to schedule an appointment to view public comments, call 1-800-743-3951.

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I. Background

A. Legislative Overview

1. Legislative Requirements for Establishing Exchanges

Section 1311(b) and section 1321(b) of the Affordable Care Act provide that each State has the opportunity to establish an Exchange(s) that: (1) Facilitates the purchase of insurance coverage by qualified individuals through qualified health plans (QHPs); (2) assists qualified employers in the enrollment of their employees in QHPs; and (3) meets other requirements specified in the Affordable Care Act.

Section 1321 of the Affordable Care Act discusses State flexibility in the

operation and enforcement of Exchanges and related requirements. In this proposed rule, we aim to encourage State flexibility within the boundaries of the law. Each State electing to establish an Exchange must adopt the Federal standards contained in this law and in this proposed rule, or have in effect a State law or regulation that implements these Federal standards. Section 1311(k) further specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations promulgated by the Secretary. Section 1311(d) describes the minimum functions of an Exchange, including the certification of QHPs.

Section 1321(c)(1) requires the Secretary to establish and operate such Exchange within States that either: (1) Do not elect to establish an Exchange, or (2) as determined by the Secretary on or before January 1, 2013, will not have an Exchange operable by January 1, 2014. Section 1321(a) also provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs, and other components of title I of the Affordable Care Act.

Unless otherwise specified, the provisions in this proposed rule related to the establishment of minimum functions of an Exchange are based on the general authority of the Secretary under section 1321(a)(1) of the Affordable Care Act. Section 1321(a)(2) requires the Secretary to engage in consultation to ensure balanced representation among interested parties. We describe the consultation activities the Secretary has undertaken later in this introduction.

2. Legislative Requirements for Related Provisions

Subtitle K of title II of the Affordable Care Act, Protections for American Indians and Alaska Natives, section 2901, extends special benefits and protections to Indians including limits on cost sharing and payer of last resort requirements for health programs operated by the Indian Health Service (IHS), Indian tribes, tribal organizations, and urban Indian organizations. We propose some provisions under this authority in subpart C of part 156, and we expect to address others in future rulemaking.

Section 6005 of the Affordable Care Act creates new section 1150A of the Act, which requires QHP issuers, and sponsors of certain plans offered under part D or title XVIII of the Act, to provide data on the cost and distribution of prescription drugs covered by the plan. We propose to

In paragraph (b), we propose a process to allow a State-operated Exchange to cease its operations after January 1, 2014 and to elect to have the Federal government establish and operate an Exchange within the State. If a State determines that it will no longer operate an Exchange after January 1, 2014, we propose in paragraph (b)(1) that the State must notify HHS of this determination 12 months prior to ceasing its operations. Also, we propose in paragraph (b)(2) that the Exchange must collaborate with HHS on the development and execution of a transition plan and process to facilitate operation of a Federally-facilitated Exchange. We estimate that we will need 12 months to establish a Federally-facilitated Exchange in a State due to the time required to set up the necessary information technology and QHP certification process.

d. Entities Eligible To Carry Out Exchange Functions (§ 155.110)

Section 1311(f)(3) of the Affordable Care Act provides an Exchange with the authority to contract with eligible entities to carry out one or more of the responsibilities of an Exchange, which we propose to codify in paragraph (a) of § 155.110. The minimum requirements set forth in the statute, and which are proposed in paragraph (a), specify that an eligible entity is one that: (1) Is incorporated under and subject to the laws of one or more States, (2) has demonstrated experience on a State or regional basis in the individual and small group markets and in benefits coverage, and (3) is not a health insurance issuer or treated as a health insurance issuer. An eligible entity also includes the State Medicaid agency. We also interpret this language as allowing an Exchange to contract with the State Medicaid agency through which the State Medicaid agency determines eligibility on behalf of the Exchange. This authority is also provided in section 1413(d)(2) of the Affordable Care Act. We note that there may be ways in which an Exchange and the Federal government can work in partnership to carry out certain activities. Underlying this NPRM and the cooperative agreement funding opportunities provided to States is a philosophy of Federal and State partnership. As States, and the Federal government in connection with the Federally-facilitated Exchange, develop expertise and implement the infrastructure for Exchange operations, we anticipate sharing of information and ideas. We welcome comment on how to implement or construct a partnership model consistent with sections

1311(f)(3) and 1311(d)(5) of the Affordable Care Act.

In paragraph (b), to the extent that the Exchange establishes contracting arrangements with outside entities, we propose that the Exchange remains responsible for meeting all Federal requirements related to contracted functions. Pursuant to these provisions, States have flexibility to determine appropriate contracting entities within legal limits. We invite comment on the extent to which we should place conflict of interest requirements on contracted entities.

In paragraph (c), we propose that if the Exchange is an independent State agency or not-for-profit entity established by the State and not an existing State agency, it must have a clearly defined governing board that meets certain minimum requirements outlined in paragraphs (c)(1) through (4). Further, the Exchange must submit detailed information on its accountability structure in its Exchange Plan, as described in § 155.105(c).

In paragraph (c)(1), we propose that the Exchange accountability structure be administered under a formal, publicly-adopted operating charter or by-laws. This provision ensures transparency of the governing board structure for the public. In paragraph (c)(2), we propose that the Exchange board must hold regular public meetings for which the public is provided advance notice to provide them with opportunities to observe and comment on Exchange policies and procedures.

In paragraphs (c)(3) and (c)(4), we propose standards on the membership of an Exchange governing board related to conflicts of interest and management qualifications. Exchanges are intended to support consumers, including small businesses, and as such, the majority of the voting members of governing boards should be individuals who represent their interests. We propose in paragraph (c)(3) that the voting members of an Exchange governing board represent consumer interests by ensuring that membership may not consist of a majority of representatives of health insurance issuers, agents, or brokers, or any other individual licensed to sell health insurance. We invite comment on the extent to which these categories of representatives with potential conflicts of interest should be further specified and on the types of representatives who have potential conflicts of interest. We propose these categories as a minimum Federal standard. A State may wish to adopt more stringent or specialized conflict of interest requirements than those used in connection with regular governmental operations.

In paragraph (c)(4), we propose that the Exchange governing body ensure that a majority of members have relevant experience in health benefits administration, health care finance, health plan purchasing, health care delivery system administration, public health, or health policy issues related to the small group and individual markets and the uninsured. We invite comment on the types of representatives that should be on Exchange governing boards to ensure that consumer interests are well-represented and that the Exchange board as a whole has the necessary technical expertise to ensure successful operations.

We considered additional options for regulating Exchange governance structures beyond the minimal requirements proposed herein. However, we propose to afford States discretion to select and appoint members of their Exchange boards. As such, a State may choose to include additional membership as long as composition of the board still meets the minimum Federal requirements.

In paragraph (d), we propose two requirements related to governance principles of an Exchange. First, in paragraph (d)(1), we propose that each Exchange publish a set of guiding governance principles that includes ethical and conflict of interest standards and disclosure of financial interests that are posted for public consumption. In paragraph (d)(2), we propose to require that an Exchange have in place procedures for disclosure of financial interest by members of the governing body or governance structure of the Exchange. We invite comment on this proposal and whether additional detail should be proposed. We note that we received numerous comments in response to the RFC on Exchange governance. Some commenters suggested that we establish minimum standards because of the limited statutory requirements in this area. In contrast, other commenters suggested that HHS establish more restrictive standards, citing concerns over conflicts of interest and non-governmental entities carrying out activities that are inherently governmental.

In paragraph (e), we acknowledge a State's option to elect to establish a separate governance and administrative structure for the SHOP. Section 1311(b)(2) of the Affordable Care Act provides each State with flexibility to merge its individual market Exchange and SHOP under a single administrative or governance structure. We interpret this provision to also allow a State to operate these functions under separate governance or administrative structures.

However, we believe that a single governance structure for both the individual market Exchange functions and SHOP will yield better policy coordination, increased operational efficiencies, and improved operational coordination. In paragraph (e)(1), we propose to allow a State to operate its individual market Exchange and SHOP under separate governance or administrative structures and also require that if it chooses to do so, it must, where applicable, coordinate and share relevant information between the two Exchange bodies. Then, we propose in paragraph (e)(2) to codify the requirement in section 1311(b)(2) of the Affordable Care Act that if a State does choose to operate its individual market Exchange and SHOP under a single governance or administrative structure, it must ensure that the Exchange has adequate resources to assist individuals and small employers.

Finally, in paragraph (f), we propose that HHS may periodically review the accountability structure and governance principles of an Exchange. We request comment on recommended frequency of these reviews.

e. Non-Interference With Federal Law and Non-Discrimination Standards (§ 155.120)

Section 1311(k) of the Affordable Care Act requires that an Exchange may not establish rules that conflict with or prevent the application of Exchange regulations promulgated by HHS, which we propose to codify in paragraph (a).

Section 1321(d) of the Affordable Care Act establishes that nothing in title I may be construed to preempt any State law that does not prevent the application of the provisions set forth under title I of the Affordable Care Act, which we propose to codify and extend to this proposed rule in paragraph (b).

In paragraph (c), we propose that a State must comply with any applicable non-discrimination statutes. Specifically, pursuant to the authority provided in 1321(a)(1)(A) to regulate the establishment and operation of an Exchange, we propose that an Exchange and a State, when fulfilling or carrying out the requirements of this part, must not operate an Exchange in such a way as to discriminate on the basis of race, color, national origin, disability, age, sex, gender identity, or sexual orientation. Examples of actions to which this standard applies include marketing, outreach, and enrollment.

f. Stakeholder Consultation (§ 155.130)

According to section 1311(d)(6) of the Affordable Care Act, Exchanges are required to consult with certain groups

of stakeholders as they establish their programs and throughout ongoing operations. We propose that the Exchange consult on an ongoing basis with key stakeholders, including:

a. Educated health care consumers who are enrollees in QHPs; “educated” is the term used in Section 1311(d)(6)(A) of the Affordable Care Act to describe consumers who must be consulted. We recommend that Exchanges include in these consultations individuals with disabilities;

b. Individuals and entities with experience in facilitating enrollment in health coverage;

c. Advocates for enrolling hard-to-reach populations, which includes individuals with a mental health or substance abuse disorder. We also encourage Exchanges to include advocates for individuals with disabilities and those who need culturally and linguistically appropriate services;

d. Small businesses and self-employed individuals;

e. State Medicaid and CHIP agencies. We also encourage Exchanges to consult with consumers who are Medicaid or CHIP beneficiaries;

f. Federally-recognized tribe(s) as defined in the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a, located within the Exchange’s geographic area;

g. Public health experts;

h. Health care providers;

i. Large employers;

j. Health insurance issuers; and

k. Agents and brokers.

We note that the first five groups are identified in the Affordable Care Act under section 1311(d)(6). We proposed additional groups in response to numerous comments that we received to the RFC indicating that the views of such types of organizations and entities should be considered, which we propose in (f) through (k). We believe that the inclusion of these additional groups will provide diverse input and will be informative of the viewpoints of the various groups impacted by the Exchange.

Each Exchange that has one or more Federally-recognized tribes, as defined in the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a, located within the Exchange’s geographic area must engage in regular and meaningful consultation and collaboration with such tribes and their tribal officials on all Exchange policies that have tribal implications. We encourage Exchanges to also seek input from all tribal organizations and urban Indian organizations. While the

Exchanges will be charged with the consultation, tribal consultation is a government-to-government process, and therefore the State should have a role in the process. We encourage States to develop a tribal consultation policy that is approved by the State, the Exchange, and tribe(s). We anticipate providing additional guidance to both the tribes and States on how the governments may collaborate and build a strong working relationship.

g. Establishment of a Regional Exchange or Subsidiary Exchange (§ 155.140)

Section 1311(f)(1) provides for the operation of an Exchange in more than one State if each State permits such operation and the Secretary approves such an Exchange. In paragraph (a) of § 155.140, we propose criteria that the Secretary will use to approve a regional Exchange. Although the statute uses the phrase “regional or interstate Exchange,” we use only the term “regional Exchange” to mean an Exchange that operates in two or more States for purposes of clarity. In paragraph (a)(1), we propose that a State may participate in a regional Exchange if the Exchange spans two or more States, noting that the States need not be contiguous. In paragraph (a)(2), we propose that a regional Exchange submit a single Exchange Plan for the regional Exchange and receive approval consistent with § 155.105 to demonstrate its readiness to operate an Exchange.

We encourage States to consider how a regional Exchange would meet the Exchange requirements and achieve the cooperation that must occur between the regional Exchange and each participating State’s department of insurance. States should also consider how to provide a consistent level of consumer protections across the States, procedures by which a State would withdraw from a regional Exchange, and how each State would contribute to the financing of the regional Exchange.

Section 1311(f)(2) provides that a State may establish one or more subsidiary Exchanges, which we propose to codify in paragraph (b). In paragraph (b)(1), we propose to codify the statutory language in section 1311(f)(2)(A) that a State may establish one or more subsidiary Exchanges if each such Exchange serves a geographically distinct area. In paragraph (b)(2), we propose to codify the statutory requirement that the area served by a subsidiary Exchange must be at least as large as a rating area described in section 2701(a) of the PHS Act, and referenced in section 1311(f)(2)(B) of the Affordable Care Act.

benefits. A plan year may be a calendar year or otherwise.

Qualified employee means an individual employed by a qualified employer who has been offered health insurance coverage by such qualified employer through the SHOP.

Qualified employer means a small employer that elects to make, at a minimum, all full-time employees of such employer 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 through the SHOP, the term “qualified employer” shall include a large employer that elects to make all full-time employees of such employer eligible for one or more QHPs in the large group market offered through the SHOP.

Qualified health plan or *QHP* means a health plan that has in effect a certification that it meets the standards described in subpart C of part 156 issued or recognized by each Exchange through which such plan is offered pursuant to the process described in subpart K of part 155.

Qualified health plan issuer or *QHP issuer* means a health insurance issuer that offers, pursuant to a certification from an Exchange, a QHP.

Qualified individual means, 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.

SHOP means a Small Business Health Options Program operated by an Exchange through which a qualified employer can provide its employees and their dependents with access to one or more QHPs.

Small employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. In the case of plan years beginning before January 1, 2016, a State may elect to define small employer by substituting “50 employees” for “100 employees.”

Small group market means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by a small employer (as defined in this section).

Special enrollment period means a period during which a qualified individual or enrollee who experiences certain qualifying events may enroll in,

or change enrollment in, a QHP through the Exchange outside of the initial and annual open enrollment periods.

State means each of the 50 States and the District of Columbia.

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

§ 155.100 Establishment of a State Exchange.

(a) *General requirements.* Each State may elect to establish an Exchange that facilitates the purchase of health insurance coverage in QHPs and provides for the establishment of a SHOP.

(b) *Eligible Exchange entities.* The Exchange must be a governmental agency or non-profit entity established by a State, consistent with § 155.110.

§ 155.105 Approval of a State Exchange.

(a) *State Exchange approval requirement.* Each State Exchange must be approved by HHS by no later than January 1, 2013 in order to begin offering QHPs on January 1, 2014.

(b) *State Exchange approval standards.* HHS will approve the operation of an Exchange established by a State provided that it meets the following standards:

(1) The Exchange is able to carry out the required functions of an Exchange consistent with subparts C, E, H, and K of this part;

(2) The Exchange is capable of carrying out the information requirements pursuant to section 36B of the Code;

(3) The State agrees to perform the responsibilities related to the operation of a reinsurance program pursuant to standards set forth in part 153 of this chapter; and

(4) The entire geographic area of the State is covered by one or more State Exchanges.

(c) *State Exchange approval process.* In order to have its Exchange approved, a State must:

(1) Elect to establish an Exchange by submitting, in a form and manner specified by HHS, an Exchange Plan that sets forth how the Exchange meets the standards outlined in paragraph (b) of this section; and

(2) Demonstrate operational readiness to execute its Exchange Plan through a readiness assessment conducted by HHS.

(d) *State Exchange approval.* Each Exchange must receive written approval or conditional approval of its Exchange Plan and its performance under the operational readiness assessment consistent with paragraph (c) of this

section in order to be considered an approved Exchange.

(e) *Significant changes to Exchange Plan.* The State must notify HHS in writing before making a significant change to its Exchange Plan; no significant change to an Exchange Plan may be effective until it is approved by HHS in writing.

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

§ 155.106 Election to operate an Exchange after 2014.

(a) *Election to operate an Exchange after 2014.* A State electing to seek initial approval of its Exchange later than January 1, 2013 must:

(1) Comply with the State Exchange approval requirements and process set forth in § 155.105;

(2) Have in effect an approved, or conditionally approved, Exchange Plan and operational readiness assessment at least 12 months prior to the Exchange’s first effective date of coverage; and

(3) Develop a plan jointly with HHS to facilitate the transition from a Federally-facilitated Exchange to a State Exchange.

(b) *Transition process for State Exchanges that cease operations.* A State that ceases operations of its Exchange after January 1, 2014 must:

(1) Notify HHS that it will no longer operate an Exchange at least 12 months prior to ceasing operations; and

(2) Coordinate with HHS on a transition plan to be developed jointly between HHS and the State.

§ 155.110 Entities eligible to carry out Exchange functions.

(a) *Eligible contracting entities.* The State may elect to authorize an Exchange established by the State to enter into an agreement with an eligible entity to carry out one or more responsibilities of the Exchange. Eligible entities are:

(1) An entity:

(i) Incorporated under, and subject to the laws of, one or more States;

(ii) That has demonstrated experience on a State or regional basis in the individual and small group health insurance markets and in benefits coverage; and

(iii) Is not a health insurance issuer or treated as a health insurance issuer

under subsection (a) or (b) of section 52 of the Code of 1986 as a member of the same controlled group of corporations (or under common control with) as a health insurance issuer; or

(2) The State Medicaid agency.

(b) *Responsibility.* To the extent that an Exchange establishes such arrangements, the Exchange remains responsible for ensuring that all Federal requirements related to contracted functions are met.

(c) *Governing board structure.* If the Exchange is an independent State agency or a non-profit entity established by the State, the State must ensure that the Exchange has in place a clearly-defined governing board that:

(1) Is administered under a formal, publicly-adopted operating charter or by-laws;

(2) Holds regular public governing board meetings that are announced in advance;

(3) Represents consumer interests by ensuring that overall governing board membership is not made up of a majority of voting representatives with a conflict of interest, including representatives of health insurance issuers or agents or brokers, or any other individual licensed to sell health insurance; and

(4) Ensures that a majority of the voting members on its governing board have relevant experience in health benefits administration, health care finance, health plan purchasing, health care delivery system administration, public health, or health policy issues related to the small group and individual markets and the uninsured.

(d) *Governance principles.*

(1) The Exchange must have in place and make publicly available a set of guiding governance principles that include ethics, conflict of interest standards, accountability and transparency standards, and disclosure of financial interest.

(2) The Exchange must implement procedures for disclosure of financial interests by members of the Exchange board or governance structure.

(e) *SHOP independent governance.*

(1) A State may elect to create an independent governance and administrative structure for the SHOP, consistent with this section, if the State ensures that the SHOP coordinates and shares relevant information with the Exchange operating in the same service area.

(2) If a State chooses to operate its Exchange and SHOP under a single governance or administrative structure, it must ensure that the Exchange has adequate resources to assist individuals and small employers in the Exchange.

(f) *HHS review.* HHS may periodically review the accountability structure and governance principles of a State Exchange.

§ 155.120 Non-interference with Federal law and non-discrimination standards.

(a) *Non-interference with Federal law.* An Exchange must not establish rules that conflict with or prevent the application of regulations promulgated by HHS under subtitle D of title I of the Affordable Care Act.

(b) *Non-interference with State law.* Nothing in parts 155 or 156 of this subtitle shall be construed to preempt any State law that does not prevent the application of the provisions of title I of the Affordable Care Act.

(c) *Non-discrimination.* In carrying out the requirements of this part, the State and the Exchange must:

(1) Comply with applicable non-discrimination statutes; and

(2) Not discriminate based on race, color, national origin, disability, age, sex, gender identity or sexual orientation.

§ 155.130 Stakeholder consultation.

The Exchange must regularly consult on an ongoing basis with the following stakeholders:

(a) Educated health care consumers who are enrollees in QHPs;

(b) Individuals and entities with experience in facilitating enrollment in health coverage;

(c) Advocates for enrolling hard to reach populations, which include individuals with a mental health or substance abuse disorder;

(d) Small businesses and self-employed individuals;

(e) State Medicaid and CHIP agencies;

(f) Federally-recognized Tribes, as defined in the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a, that are located within such Exchange's geographic area;

(g) Public health experts;

(h) Health care providers;

(i) Large employers;

(j) Health insurance issuers; and

(k) Agents and brokers.

§ 155.140 Establishment of a regional Exchange or subsidiary Exchange.

(a) *Regional Exchange.* A State may participate in a regional Exchange if:

(1) The Exchange spans two or more States, regardless of whether the States are contiguous; and

(2) The regional Exchange submits a single Exchange Plan and is approved to operate consistent with § 155.105(c).

(b) *Subsidiary Exchange.* A State may establish one or more subsidiary Exchanges within the State if:

(1) Each such Exchange serves a geographically distinct area; and

(2) The area served by each subsidiary Exchange is at least as large as a rating area described in section 2701(a) of the PHS Act.

(c) *Exchange standards.* Each regional or subsidiary Exchange must:

(1) Otherwise meet the requirements of an Exchange consistent with this part; and

(2) Meet the following standards for SHOP:

(i) Perform the functions of a SHOP for its area in accordance with subpart H of this part; and

(ii) If a State elects to operate its individual market Exchange and SHOP under two governance or administrative structures as described in § 155.110(e), the SHOP must encompass a geographic area that matches the geographic area of the regional or subsidiary Exchange.

§ 155.150 Transition process for existing State health insurance exchanges.

(a) *Presumption.* Unless an exchange is determined to be non-compliant through the process in paragraph (b) of this section, HHS will otherwise presume that an existing State Exchange meets the standards under this part if:

(1) The Exchange was in operation prior to January 1, 2010; and

(2) The State has insured a percentage of its population not less than the percentage of the population projected to be covered nationally after the implementation of the Affordable Care Act.

(b) *Process for determining non-compliance.* Any State described in paragraph (a) must work with HHS to identify areas of non-compliance with the standards under this part.

§ 155.160 Financial support for continued operations.

(a) *Definition.* For purposes of this section, participating issuers has the meaning provided in § 156.50.

(b) *Funding for ongoing operations.* A State must ensure that its Exchange has sufficient funding in order to support its ongoing operations beginning January 1, 2015, as follows:

(1) The State may fund Exchange operations by charging assessments or user fees on participating issuers;

(2) States may otherwise generate funding for Exchange operations;

(3) No Federal funds will be provided for State Exchange operations after January 1, 2015; and

(4) The State Exchange must announce the user fees to participating issuers in advance of the plan year.