

**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://cciio.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

### 3. Subpart C—General Functions of an Exchange

Subpart C outlines the minimum functions of an Exchange, with cross-references in some cases to more detailed standards that are described in subsequent subparts (E, H and K). The proposed minimum functions are designed to provide State flexibility. Uniform standards are proposed where required by the statute or where there are compelling practical, efficiency or consumer protection reasons.

#### a. Functions of an Exchange (§ 155.200)

Proposed § 155.200 identifies the minimum functions of an Exchange. These functions closely parallel sections 1311(d)(2), (4), and (6), and sections 1402 and 1411–13 of the Affordable Care Act.

In paragraph (a), we propose a general standard that an Exchange must perform the required functions set forth in this subpart and in subparts E, H, and K of this part.

In paragraph (b), we propose, consistent with our interpretation of section 1311(d)(4)(H) and section 1411 of the Affordable Care Act, that an Exchange must grant certifications of exemptions from the individual responsibility requirement and payment. The specific standards and eligibility criteria that apply to such certifications will be addressed in future rulemaking.

In paragraph (c), we propose that the Exchange must perform eligibility determinations. We intend to provide specific standards and eligibility criteria for this Exchange function in future rulemaking to implement sections 1311, 1411, 1412, and 1413 of the Affordable Care Act. Further, it will support and complement rulemaking conducted by the Secretary of the Treasury with respect to section 36B of the Code, as added by section 1401(a) of the Affordable Care Act, and by the Secretary of HHS with respect to several sections of the Affordable Care Act that create new law and amend existing law regarding Medicaid and CHIP.

We note that the aforementioned sections of the Affordable Care Act create a central role for the Exchange in the process of determining an individual's eligibility for enrollment in a QHP, advance payments of the premium tax credit, cost-sharing reductions, Medicaid, CHIP and the BHP, if a BHP is operating in the Exchange service area. We interpret Affordable Care Act sections 1311(d)(4)(F), and 1413, and section 1943 of the Act, as added by section 2201 of the Affordable Care Act, to

require the establishment of a system of streamlined and coordinated eligibility and enrollment through which an individual may apply for enrollment in a QHP, advance payments of the premium tax credit, cost-sharing reductions, Medicaid, and CHIP and receive a determination of eligibility for any such program. We also note that we interpret section 1413(b)(2) to mean that the eligibility and enrollment function should be consumer-oriented, minimizing administrative hurdles and unnecessary paperwork for applicants.

In paragraph (d), we propose that each Exchange establish a process for appeals of eligibility determinations. These requirements and the appeal process generally, including the requirements of section 1411(f) of the Affordable Care Act, will be addressed in future rulemaking.

In paragraph (e), we propose that an Exchange must perform required functions related to oversight and financial integrity requirements in order to comply with section 1313 of the Affordable Care Act.

In paragraph (f), we propose that the Exchange must evaluate quality improvement strategies and oversee implementation of enrollee satisfaction surveys, assessment and ratings of health care quality and outcomes, information disclosures, and data reporting pursuant to sections 1311(c)(1), 1311(c)(3), and 1311(c)(4) of the Affordable Care Act. We anticipate future rulemaking on these topics, but propose here the basic requirement that the Exchange will have a role in the implementation, oversight, and improvement of the quality and enrollee satisfaction initiatives required by the Affordable Care Act. This will include requirements for quality data collection, standards for assessing a QHP issuer's quality improvement strategies, and details on how Exchanges can assess and calculate ratings of health care quality and outcomes using methodologies made available by HHS or alternatives, if applicable.

The functions of an Exchange listed in proposed § 155.200 are important to the achievement of a more stable and accessible health insurance market for consumers and businesses and represent the minimum functions of an Exchange to meet that goal. We encourage States to consider supplemental standards or functionality for their Exchanges that benefit consumers and businesses, and we welcome comments regarding these and other functions that should be required of an Exchange.

#### b. Required Consumer Assistance Tools and Programs of an Exchange (§ 155.205)

In § 155.205, we outline the standards for a number of consumer assistance tools and activities that Exchanges must provide. In paragraph (a), we propose to codify section 1311(d)(4)(B) of the Affordable Care Act, which requires the Exchange to provide for the operation of a call center to respond to requests for assistance by consumers that is accessible via a toll-free telephone number.

We note that an Exchange has significant latitude in how it structures the call center. To increase accessibility to the call center, we suggest that an Exchange consider operating it outside of normal business hours and adjusting staffing levels in anticipation of periods of higher call volumes (for example, the weeks leading up to and during open enrollment). We also believe that the Exchange call center should have the capability to provide assistance to consumers and businesses on a broad range of issues, including but not limited to:

- (1) The types of QHPs offered in the Exchange;
- (2) The premiums, benefits, cost-sharing, and quality ratings associated with the QHPs offered;
- (3) Categories of assistance available, including advance payments of the premium tax credit and cost-sharing reductions as well assistance available through Medicaid and CHIP;
- (4) The application process for enrollment in coverage through the Exchange and other programs (for example, Medicaid and CHIP).

The Affordable Care Act includes several programs that aid consumers through the process of acquiring and using health insurance, including the State-based consumer assistance programs (for example, health insurance ombudsman programs created under Section 1002 of the Affordable Care Act) and the Navigator program, which we describe more fully in § 155.210 below. We encourage Exchanges to use call centers as a conduit to these and any other State consumer programs, where appropriate. We also recognize there may be some instances where there is appropriate overlap between information provided by the Exchange call centers and information provided by customer service call centers operated by health insurance issuers, particularly in the area of health plan enrollment. We seek comments on ways to streamline and prevent duplication of effort by the Exchange call center and QHP issuers' customer call centers, but

ensure that consumers have a variety of ways to learn about their coverage options and receive assistance on other health insurance coverage issues.

In paragraph (b), we propose to codify section 1311(d)(4)(C) of the Affordable Care Act, which requires an Exchange to maintain an Internet Web site. The Affordable Care Act provides two key provisions related to the establishment of an Exchange Web site. First, section 1103(b) of the Affordable Care Act requires the Secretary to establish a standardized format for presenting coverage option information, which is utilized to present comparative health plan information on the current HealthCare.gov Web site. Second, section 1311(c)(5) requires the Secretary to make available to all Exchanges a model Exchange Web site template developed by the Secretary. We are currently evaluating the extent to which the Exchange Web site may satisfy the need to provide plan comparison functionality using HealthCare.gov, and invite comments on this issue.

Generally, we envision the Exchange Web site to be an easy-to-use access point that serves as a primary source of information about available QHPs, Exchange activities, and other sources of health coverage. We believe that the Exchange Web site is an appropriate venue to post QHP information as required by other sections of the Affordable Care Act that require disclosure of information that would be helpful for consumers in comparing QHPs, including the medical loss ratio (section 2718 of the PHS Act), transparency in coverage data (section 1311(e)(3) of the Affordable Care Act), summary of benefits and coverage (section 2715 of the PHS Act)<sup>2</sup> and levels of coverage (section 1302(d) of the Affordable Care Act).

We specifically propose in § 155.205(b)(1) through (6) that an Exchange must maintain an up-to-date Internet Web site that:

1. Presents standardized comparative information on each available QHP. Such information must include:
  - i. Premium and cost-sharing information;
  - ii. The summary of benefits and coverage required by section 2715 of the PHS Act. Exchanges may consider making this information available

<sup>2</sup> The proposal here to post the summary of benefits and coverage (SBC) on the Exchange Web site is in addition to, and not in lieu of, any requirements regarding the manner, timing, and format for the delivery of an SBC to individuals under PHS Act section 2715. The Departments of HHS, Labor, and the Treasury are developing proposed regulations to be issued in the near future that are expected to address section 2715.

through a link from their Web site to each QHP's Web site or Exchanges could require QHPs to submit this information in a manner that supports a searchable format;

- iii. The level of coverage of a QHP (that is, bronze, silver, gold, platinum, or catastrophic coverage consistent with section 1302(d) and 1302(e) of the Affordable Care Act);
- iv. The results of enrollee satisfaction surveys described in section 1311(c)(4) of the Affordable Care Act;
- v. Quality ratings assigned to QHPs described in section 1311(c)(3) of the Affordable Care Act;
- vi. The medical loss ratio as reported in accordance with interim final rule 75 FR 74921, December 1, 2010, amended 75 FR 82278, December 30, 2010;
- vii. Transparency of coverage measures reported to the Exchange as required under § 155.1040; and
- viii. The provider directory reported to the Exchange during certification pursuant to § 156.230;

2. Provides meaningful access to information for individuals with limited English proficiency. Such accessibility needs may be met by providing language assistance services, which may include translated information and "tag lines" directing individuals to translated materials and/or telephone numbers to call to reach interpreters for assistance. Web sites must also be accessible to people with disabilities in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act. HHS has issued guidance regarding the requirements of section 504 with respect to Web site accessibility.<sup>3</sup> The guidance states that at this time, the Department will consider a recipient's Web sites, interactive kiosks, and other information systems addressed by section 508 standards as being in compliance with section 504 if such technologies meet those standards. We encourage States to follow either the 508 guidelines or guidelines that provide greater accessibility to individuals with disabilities. States may wish to consult the latest section 508 guidelines issued by the U.S. Access Board or W3C's Web Content Accessibility Guidelines (WCAG) 2.0;<sup>4</sup>

3. Publishes the following financial information: the average cost of licensing required by the Exchange, any regulatory fees required by the Exchange, any other payments required by the Exchange, administrative costs of

<sup>3</sup> <http://cciio.cms.gov/resources/files/joint cms ociio guidance.pdf>.

<sup>4</sup> <http://www.access-board.gov/sec508/guide/index.htm>.

the Exchange, and monies lost to fraud, waste, and abuse in accordance with section 1311(d)(7) of the Affordable Care Act.

4. Provides contact information for Navigators and other consumer assistance services, including the telephone number of the Exchange call center;

5. Allows for an eligibility determination pursuant to the standards established in accordance with § 155.200(c) of this subpart; and

6. Allows for enrollment in coverage pursuant to subpart E of this part. We are considering a Web site requirement that would allow applicants and enrollees to store and access their personal account information and make changes, provided that the Web site complied with the standards developed by the Secretary pursuant to section 3021(b)(3) of the PHS Act, as added by section 1561 of the Affordable Care Act. The standards<sup>5</sup> address electronic enrollment systems for Federal and State health and human services, provide for the submission and storage of electronic documents, and permit reuse of stored information. To minimize administrative burden, we would encourage Exchanges to develop a feature whereby eligibility and enrollment experts, caseworkers, Navigators, agents and brokers, and other application assisters are able to maintain records of individuals they have assisted with the application process. We request comment on this proposal.

In paragraph (c), we propose to codify section 1311(d)(4)(G) of the Affordable Care Act that requires an Exchange to establish an electronic calculator to assist individuals in comparing the costs of coverage in available QHPs after the application of any advance payments of the premium tax credit and cost-sharing reductions. We invite comment on the extent to which States would benefit from a model calculator and suggestions on its design.

In paragraph (d), we propose that the Exchange have a consumer assistance function (including but not limited to a Navigator program described more fully in § 155.210) that provides assistance services to consumers. Exchanges will receive various types of requests for assistance from consumers, including assistance with eligibility and enrollment, appeals, and handling complaints, and must be able to direct consumers accordingly. We note that if an Exchange receives complaints of

<sup>5</sup> Standards accessible at: <http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=3161>.

race, color national origin, disability, age, or sex discrimination, it may refer these individuals to the HHS Office for Civil Rights (OCR).

In paragraph (e), we propose that the Exchange conduct outreach and education activities to educate consumers about the Exchange and to encourage participation, separate from the implementation of a Navigator program described in § 155.210. Exchanges should aim to maximize enrollment of eligible individuals into QHPs to increase QHP participation and competition which in turn increases consumer choice and purchasing clout. This will also reduce the number of individuals without health insurance coverage. We encourage Exchanges to conduct outreach broadly as well as in ways that are accessible to people with disabilities, individuals with low literacy, and those with limited English proficiency. In addition, we encourage Exchanges to target specific groups including hard to reach populations and populations that experience health disparities due to low literacy, race, color, national origin, or disability, including mental illnesses and substance use disorders.

#### c. Navigator Program Standards (§ 155.210)

In § 155.210, we propose the standards for the Navigator program, consistent with section 1311(i) of the Affordable Care Act. The Navigator standards apply to the Exchange including both the individual market and SHOP. In paragraph (a), we propose the general standard that Exchanges must award grant funds to public or private entities to serve as Navigators. In paragraph (b)(1), we propose the eligibility requirements for and the types of entities to which the Exchange may award Navigator grants. We propose that Navigators must be capable of carrying out those duties established in paragraph (d) of this subsection. In addition, a Navigator must demonstrate to the Exchange, as required by section 1311(i)(2)(A) of the Affordable Care Act, that the entity has existing relationships, or could readily establish relationships with employers and employees, consumers (including uninsured and underinsured consumers), or self-employed individuals likely to be eligible to enroll in a QHP through the Exchange. We note that an entity need not have the ability to form relationships with all relevant groups in order to be eligible for Navigator funding; for example, an entity that can effectively conduct outreach to rural areas may not be as effective in urban areas.

We further propose in paragraph (b)(1)(iii) that a Navigator must meet any licensing, certification or other standards prescribed by the State or Exchange, as appropriate, consistent with section 1311(i)(4)(A) of the Affordable Care Act. This will allow the State or Exchange to enforce existing licensure standards (such as verifying that agents who seek to be Navigators are licensed), certification standards, or regulations for selling or assisting with enrollment in health plans and to establish new standards or licensing requirements tailored to Navigators (such as participating in periodic trainings), as appropriate.

We further propose in paragraph (b)(1)(iv) that any entity that serves as a Navigator may not have conflict of interest during the term as Navigator. We specify “during the term as a Navigator” because we want to ensure that an entity that might have formerly had a conflict would not be excluded from consideration if that conflict no longer exists. We clarify that these standards would not exclude, for example, a non-profit community organization that previously received grant funding from a health insurance issuer from serving as a Navigator. We seek comment on whether we should propose additional requirements on Exchanges to make determinations regarding conflicts of interest.

Section 1311(i)(2)(B) of the Affordable Care Act identifies entities which may be eligible to serve as Navigators, including “other entities” pursuant to section 1311(i)(2)(B) insofar as they meet the requirements of section 1311(i)(4). In paragraph (b)(2), we propose that the Exchange include at least two of the types of entities listed in Section 1311(i)(2)(B) as Navigators. We seek comment as to whether we should require that at least one of the two types of entities serving as Navigators include a community and consumer-focused non-profit organization, or whether we should require that Navigator grantees reflect a cross section of stakeholders. We note that Indian tribes, tribal organizations, and urban Indian organizations may be eligible, along with State or local human service agencies.

In paragraph (c), we codify the statutory prohibitions on Navigator conduct in the Exchange. Consistent with 1311(i)(4) of the Affordable Care Act, health insurance issuers are prohibited from serving as Navigators and a Navigator must not receive any consideration directly or indirectly from any health insurance issuer in connection with the enrollment of any qualified individuals or qualified

employees in a QHP. Such consideration includes, without limitation, any monetary or non-monetary commission, kick-back, salary, hourly-wage or payment made directly or indirectly to the entity or individual from the QHP issuer. These provisions would not preclude a Navigator from receiving compensation from health insurance issuers in connection with enrolling individuals, small employers or large employers in non-QHPs. We seek comment on this issue and whether there are ways to manage any potential conflict of interest that might arise.

In paragraph (d), we set forth the minimum duties of a Navigator. The Exchange may require that a Navigator meet additional standards and carry out duties so long as such standards are consistent with requirements set forth herein. We clarify that as part of its obligation to establish the Navigator program and oversee the grants, the Exchange must ensure that Navigators are performing their duties as required. Duties include maintaining expertise in eligibility, enrollment, and program specifications and conducting public education activities to raise awareness of the availability of QHPs.

We also propose that the information and services provided by the Navigator be fair, accurate, and impartial and acknowledge other health programs. The Affordable Care Act requires the Secretary to collaborate with the States to develop standards related to this requirement. We are considering standards related to content of information shared, referral strategies, and training requirements to include in grant award conditions. We welcome comment on potential standards to ensure that information made available by Navigators is fair, accurate, and impartial.

The Navigator must also facilitate enrollment in a QHP through the Exchange and provide referrals to any applicable office of health insurance consumer assistance or health insurance ombudsman, or any other appropriate State agency or agencies for any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under such plan or coverage. Further the Navigator must provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange. We seek comment regarding any specific standards we might issue through future rulemaking or additional guidance on these proposed requirements that we might further develop.

In paragraph (e), we codify the statutory restriction from section

1311(i)(5) of the Affordable Care Act that the Exchange is prohibited from supporting the Navigator program with Federal funds received by the State for the establishment of Exchanges. Thus, the Exchange must use operational funds generated through non-Federal sources (pursuant to section 1311(d)(5)) including general operating funds, to fund the Navigator program. If the State chooses to permit or require Navigator activities to address Medicaid and CHIP administrative functions, and such functions are performed under a contract or agreement that specifies a method for identifying costs or expenditures attributable to Medicaid and CHIP activities, the Medicaid or CHIP agencies may claim Federal funding for a share of expenditures incurred for such activities at the administrative Federal financial participation rate described in 42 CFR 433.15 for Medicaid and 42 CFR 457.618 for CHIP.

Finally, we are considering a requirement that the Exchanges ensure that the Navigator program is operational with services available to consumers no later than the first day of the initial open enrollment period. Since consumers will likely require significant assistance to understand options and make informed choices when selecting health coverage, we believe it is important that Exchanges begin the process of establishing the Navigator program by awarding grants and training grantees in time to ensure that Navigators can assist consumers in obtaining coverage throughout the initial open enrollment period. We seek comment on this timeframe under consideration.

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

Section 1312(e) of the Affordable Care Act gives States the option to permit agents or brokers to assist individuals enrolling in QHPs through the Exchange. This includes allowing agents and brokers to enroll qualified individuals, qualified employers, or qualified employees in QHPs and to assist individuals with applications for advance payments of the premium tax credit and cost-sharing reductions. We propose to codify this option under paragraph (a) of § 155.220.

We note that the standards described in this section would not apply to agents and brokers acting as Navigators. Any entity serving as a Navigator, including an agent or broker, may not receive any financial compensation

from an issuer for helping an individual or small group select a specific QHP, consistent with § 155.210. We also clarify that the statute permits agents and brokers to assist with applications for advance payments of the premium tax credit and cost-sharing reductions.

To ensure that individuals and small groups have access to information about agents and brokers should they wish to use one, in paragraph (b) we propose to permit an Exchange to display information about agents and brokers on its Web site or in other publicly available materials.

We recognize that there are web-based entities and other entities with experience in health plan enrollment that are seeking to assist in QHP enrollment in several ways, including: by contracting with an Exchange to carry out outreach and enrollment functions, or by acting independently of an Exchange to perform similar outreach and enrollment functions to the Exchange. To the extent that an Exchange contracts with such an entity, the Exchange would need to adhere to the requirements proposed for eligible contracting entities at § 155.110(a).

In the event that the Exchange contracts with such web-based entities, the Exchange would remain responsible for ensuring that the statutory and regulatory requirements pertinent to the relevant contracted functions are met. We understand that such entities may provide an additional avenue for the public to become aware of and access QHPs, but we also note that advance payments of the premium tax credit and cost-sharing reductions may only be accessed through an Exchange. We seek comment on the functions that such entities could perform, the potential scope of how these entities would interact with the Exchanges and what standards should apply to an entity performing functions in place of, or on behalf of, an Exchange. We also seek comment on the practical implications, costs, and benefits to an Exchange that coordinates with such entities, as well as any security- or privacy-related implications of such an arrangement.

e. General Standards for Exchange Notices (§ 155.230)

Notices are developed to ensure that applicants, qualified individuals, and enrollees understand their eligibility and enrollment status, including the reason for receipt of the notice and information about any subsequent action(s) they must take.

In paragraph (a), we propose that any notice sent by an Exchange pursuant to this part must be in writing and include (1) contact information for customer

service resources, which might include web-based information, call center, Navigators, or consumer assistance programs; (2) an explanation of rights to appeal, if applicable; and (3) a citation to the specific regulation serving as the cause for notice.

In paragraph (b), we propose all applications, forms, and notices must be provided in plain language. In addition, applications, forms and notices should be written in a manner that meets the needs of diverse populations by providing meaningful access to limited English proficient individuals and ensuring effective communication for people with disabilities. As such, there are a number of ways that the Exchange may provide such access including provision of information about the availability and steps to obtain oral interpretation services, information about the languages in which written materials are available, and the availability of materials in alternate formats for persons with disabilities. We seek comment regarding whether we should codify these examples as requirements in the final rule as well as any other requirements we might consider to provide meaningful access to limited English proficient individuals and to ensure effective communication for people with disabilities.

In paragraph (c), we propose that the Exchange annually re-evaluate the appropriateness and usability of the applications, forms, and notices and in consultation with HHS in instances when changes are made. As the program evolves, we anticipate that the Exchange may be able to improve the tools used to collect information and inform individuals about their eligibility and coverage options.

f. Payment of Premiums (§ 155.240)

The Affordable Care Act includes some references to payment of premiums through an Exchange. While we do not require or limit the methods of premium payment in connection with individual market coverage, we note that an Exchange generally has three options: (1) Take no part in payment of premiums, which means that enrollees must pay premiums directly to a QHP issuer; (2) facilitate the payment of premiums by enrollees by creating an electronic "pass-through" of premiums without directly retaining any of the payments; or (3) establish a payment option where the Exchange collects premiums from enrollees and pays an aggregated sum to the QHP issuers.

Section 1312(b) of the Affordable Care Act states that a qualified individual enrolled in a QHP may pay any applicable premium directly to the

**Subpart C—General Functions of an Exchange****§ 155.200 Functions of an Exchange.**

(a) *General requirements.* The Exchange must perform the minimum functions described in this subpart and in subparts E, H, and K of this part.

(b) *Certificates of exemption.* The Exchange must issue certificates of exemption consistent with section 1311(d)(4)(H) and 1411 of the Affordable Care Act.

(c) *Eligibility determinations.* The Exchange must perform eligibility determinations.

(d) *Appeals of individual eligibility determinations.* The Exchange must establish an appeals process for eligibility determinations.

(e) *Oversight and financial integrity.* The Exchange must perform required functions related to oversight and financial integrity requirements in accordance with section 1313 of the Affordable Care Act.

(f) *Quality Activities.* The Exchange must evaluate quality improvement strategies and oversee implementation of enrollee satisfaction surveys, assessment and ratings of health care quality and outcomes, information disclosures, and data reporting pursuant to sections 1311(c)(1), 1311(c)(3), and 1311(c)(4) of the Affordable Care Act.

**§ 155.205 Required consumer assistance tools and programs of an Exchange.**

(a) *Call center.* The Exchange must provide for operation of a toll-free call center that addresses the needs of consumers requesting assistance.

(b) *Internet Web site.* The Exchange must maintain an up-to-date Internet Web site that:

(1) Provides standardized comparative information on each available QHP, including at a minimum:

(i) Premium and cost-sharing information;

(ii) The summary of benefits and coverage established under section 2715 of the PHS Act;

(iii) Identification of whether the QHP is a bronze, silver, gold, or platinum level plan as defined by section 1302(d) of the Affordable Care Act, or a catastrophic plan as defined by section 1302(e) of the Affordable Care Act;

(iv) The results of enrollee satisfaction survey, described in section 1311(c)(4) of the Affordable Care Act;

(v) Quality ratings assigned pursuant to section 1311(c)(3) of the Affordable Care Act;

(vi) Medical loss ratio information as reported to HHS in accordance with 45 CFR 158;

(vii) Transparency of coverage measures reported to the Exchange during certification in § 155.1040; and

(viii) The provider directory made available to the Exchange pursuant to § 156.230.

(2) Is accessible to people with disabilities in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act and provides meaningful access for persons with limited English proficiency.

(3) Publishes the following financial information:

(i) The average costs of licensing required by the Exchange;

(ii) Any regulatory fees required by the Exchange;

(iii) Any payments required by the Exchange in addition to fees under (i) and (ii) of this paragraph;

(iv) Administrative costs of such Exchange; and

(v) Monies lost to waste, fraud, and abuse.

(4) Provides applicants with information about Navigators as described in § 155.210 and other consumer assistance services, including the toll-free telephone number of the Exchange call center required in paragraph (a) of this section.

(5) Allows for an eligibility determination to be made pursuant to § 155.200(c) of this subpart.

(6) Allows for enrollment in coverage in accordance with subpart E of this part.

(c) *Exchange calculator.* The Exchange must establish and make available by electronic means a calculator to facilitate the comparison of available QHPs after the application of any advance payments of the premium tax credit and any cost-sharing reductions.

(d) *Consumer assistance.* The Exchange must have a consumer assistance function, including the Navigator program described in § 155.210, and must refer consumers to consumer assistance programs in the State when available and appropriate.

(e) *Outreach and education.* The Exchange must conduct outreach and education activities to educate consumers about the Exchange and to encourage participation.

**§ 155.210 Navigator program standards.**

(a) *General Requirements.* The Exchange must establish a Navigator program consistent with this section through which it awards grants to eligible public or private entities described in paragraph (b) of this section.

(b) *Entities eligible to be a Navigator.*

(1) To receive a Navigator grant, an entity must—

(i) Be capable of carrying out at least those duties described in paragraph (d) of this section;

(ii) Demonstrate to the Exchange that the entity has existing relationships, or could readily establish relationships, with employers and employees, consumers (including uninsured and underinsured consumers), or self-employed individuals likely to be eligible for enrollment in a QHP;

(iii) Meet any licensing, certification or other standards prescribed by the State or Exchange, if applicable; and

(iv) Not have a conflict of interest during the term as Navigator.

(2) The Exchange must include entities from at least two of the following categories for receipt of a Navigator grant:

(i) Community and consumer-focused nonprofit groups;

(ii) Trade, industry, and professional associations;

(iii) Commercial fishing industry organizations, ranching and farming organizations;

(iv) Chambers of commerce;

(v) Unions;

(vi) Resource partners of the Small Business Administration;

(vii) Licensed agents and brokers; and

(viii) Other public or private entities that meet the requirements of this section. Other entities may include but are not limited to Indian tribes, tribal organizations, urban Indian organizations, and State or local human service agencies.

(c) *Prohibition on Navigator conduct.* The Exchange must ensure that a Navigator must not—

(1) Be a health insurance issuer; or

(2) Receive any consideration directly or indirectly from any health insurance issuer in connection with the enrollment of any qualified individuals or qualified employees in a QHP.

(d) *Duties of a Navigator.* An entity that serves as a Navigator must carry out at least the following duties:

(1) Maintain expertise in eligibility, enrollment, and program specifications and conduct public education activities to raise awareness about the Exchange;

(2) Provide information and services in a fair, accurate and impartial manner. Such information must acknowledge other health programs;

(3) Facilitate enrollment in QHPs;

(4) Provide referrals to any applicable office of health insurance consumer assistance or health insurance ombudsman established under section 2793 of the PHS Act, or any other appropriate State agency or agencies, for any enrollee with a grievance,

complaint, or question regarding their health plan, coverage, or a determination under such plan or coverage; and

(5) Provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange, including individuals with limited English proficiency, and ensure accessibility and usability of Navigator tools and functions for individuals with disabilities in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act.

(e) *Funding for Navigator grants.* Funding for Navigator grants may not be from Federal funds received by the State to establish the Exchange.

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

(a) *General rule.* A State may choose to permit agents and brokers to—

(1) Enroll qualified individuals, qualified employers or qualified employees in any QHPs in the individual or small group market as soon as the QHP is offered through an Exchange in the State; and

(2) Assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs.

(b) *Web site disclosure.* The Exchange may elect to provide information regarding licensed agents and brokers on its Web site for the convenience of consumers seeking insurance through that Exchange.

**§ 155.230 General standards for Exchange notices.**

(a) *General requirement.* Any notice required to be sent by an Exchange to applicants, qualified individuals, qualified employees, qualified employers, and enrollees must be in writing and include:

(1) Contact information for available customer service resources;

(2) An explanation of appeal rights, if applicable; and

(3) A citation to or identification of the specific regulation supporting the action.

(b) *Accessibility and readability requirements.* All applications, forms, and notices must be written in plain language and provided in a manner that:

(1) Provides meaningful access to limited English proficient individuals; and

(2) Ensures effective communication for people with disabilities.

(c) *Re-evaluation of appropriateness and usability.* The Exchange must re-

evaluate the appropriateness and usability of applications, forms, and notices on an annual basis and in consultation with HHS in instances when changes are made.

**§ 155.240 Payment of premiums.**

(a) *Payment by individuals.* The Exchange must allow a qualified individual to pay any applicable premium owed by such individual directly to the QHP issuer.

(b) *Payment by tribes, tribal organizations, and urban Indian organizations.* The Exchange may permit Indian tribes, tribal organizations and urban Indian organizations to pay QHP premiums on behalf of qualified individuals, subject to terms and conditions determined by the Exchange.

(c) *Payment by qualified employers.* The Exchange must accept payment of an aggregate premium by a qualified employer pursuant to § 155.705(b)(4).

(d) *Payment facilitation.* The Exchange may establish a process to facilitate through electronic means the collection and payment of premiums.

(e) *Required standards.* In conducting an electronic transaction with a QHP that involves the payment of premiums or an electronic funds transfer, the Exchange must use the standards and operating rules referenced in § 155.260 and § 155.270.

**§ 155.260 Privacy and security of information.**

(a) *Definitions.* For purposes of this section, the following term has the following meaning:

*Personally identifiable information* means information that there is a reasonable basis to believe, alone or when combined with other personal or identifying information which is linked or linkable to a specific individual, can be used to distinguish or trace an individual's identity. Specifically, the term applies to information collected, received or used by the Exchange as part of its operations.

(b) *Use and disclosure.*

(1) The Exchange must not collect, use, or disclose personally identifiable information unless:

(i) The collection, use, or disclosure is specifically required or permitted by this section or by other applicable law; or

(ii) The collection, use, or disclosure is made pursuant to subpart E of this part, while the Exchange is fulfilling its responsibilities in accordance with § 155.200(c) of this subpart, or pursuant to section 1942(b) of the Act as described in paragraph (c) of this section.

(2) Exchanges must establish and follow security standards for collection,

use, disclosure and disposal of personally identifiable information that provide administrative, physical, and technical safeguards for the information that are consistent with the security standards required for covered entities by 45 CFR 164.306, 164.308, 164.310, 164.312 and 164.314.

(3) Exchanges must establish and follow privacy standards consistent with applicable law and that establish acceptable parameters for proper collection, use, disclosure and disposal of personally identifiable information.

(4) Policies and procedures regarding the use, disclosure and disposal of personally identifiable information must, at minimum:

(i) Be in writing, and available to the Secretary of HHS upon request;

(ii) Identify applicable law governing use, disclosure and disposal of personally identifiable information; and

(5) In any contract or agreement with a contractor, require that personally identifiable information provided to, created by, received by, used by, or subsequently disposed of by a contractor of the Exchange or any of its subcontractors, pursuant to an agreement with the Exchange or on behalf of the Exchange, be protected by privacy and security standards that are the same as or more stringent than those described in this section.

(c) *Other applicable law.* Data matching and sharing arrangements made between the Exchange and agencies administering Medicaid, CHIP or the BHP for the exchange of eligibility information must be consistent with other applicable laws, including section 1942 of the Act.

(d) *Compliance with the Code.* Tax returns and return information must be kept confidential and disclosed only in accordance with section 6103(l)(21) of the Code.

(e) *Improper use and disclosure of information.* Any person who knowingly and willfully uses or discloses information in violation of section 1411(g) of the Affordable Care Act will be subject to a civil penalty of not more than \$25,000 per person or entity, per disclosure, in addition to other penalties that may be prescribed by law.

**§ 155.270 Use of standards and protocols for electronic transactions.**

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