Health Care Reform Review Committee Questions – 8/5/11 meeting

One or two risk pools

- The law provides for separate pools for individual and small group markets. All enrollees in the small group market must be treated as members of a single risk pool (Act Sec. 1312(c)(2)).
- The Act provides that a health insurance issuer shall consider all enrollees in all health plans (other than grandfathered plans) offered by that issuer in the individual market, including those enrollees who do not enroll in such plans through an Exchange, to be members of a single risk pool (Act Sec. 1312(c)(1)).
- But, a State may require the individual and small group insurance markets within a State to be merged if the State determines appropriate (Act Sec. 1312(c)(3)).
- Grandfathered health plans cannot be pooled with non-grandfathered plans (Act Sec. 1312(c)(4).
- If there are separate pools for individual and small group markets (two pools), it is easier to see the relatively higher costs for individual coverages than for small group coverages. Separate pools (versus one pool) reduce the credibility of experience due to smaller numbers in each pool.
- If there is one combined pool for both individual and small group markets, there would be a broader spread of risk, so claims could be expected to have less fluctuation. With one combined pool, it could be expected that individuals would pay slightly lower rates, and small groups would pay slightly higher rates than if the pools were kept separate. With one combined pool, small employers could be subsidizing individual rates.

Offering products inside and outside Exchange

- The law specifically allows for products to be sold inside and outside the Exchange; but a State could prohibit sales outside the Exchange. The Act specifically allows for a continued market outside the Exchange. Section 1312(d) provides:
    - Continued operation of market outside Exchanges Nothing in this title shall be construed to prohibit: a) a health insurance issuer from offering outside of an Exchange a health plan to a qualified individual or qualified employer; and b) a qualified individual from enrolling in, or a qualified employer from selecting for its employees, a health plan offered outside of an Exchange.
- Products sold within the Exchange must cover at least essential benefits and fall into one of four categories (bronze, silver, gold, platinum), each defined by a maximum cost-sharing percentage: 40%, 30%, 20%, 10%. If products are sold outside the Exchange, essential benefits must still be covered but higher cost-sharing (and lower premiums) would be possible.
- If products are allowed both within and outside an Exchange, there could be anti-selection. For example, it may be advantageous for healthier people to purchase policies outside the Exchange because they are willing to accept higher cost-sharing, resulting in a greater proportion of unhealthy people purchasing insurance within the Exchange. Allowing products inside and outside the Exchange can create less disruption to the market because it preserves benefit plan flexibility. (Companies could be required to offer fewer options within the Exchange.) Employers and individuals who buy coverage

sold outside the Exchange would not be eligible to receive tax credits or cost-sharing reductions (i.e., subsidies).

- If products are allowed to be sold only through the Exchange, the anti-selection concern may be lessened, but fewer products would be available due to the maximum cost-sharing requirements in the Exchange.

Allowing multiple products within each of the four levels

- The law provides for four levels of coverage that have to be provided by plans sold through an Exchange, distinguished by cost-sharing levels. (Bronze = 60/40; Silver = 70/30; Gold = 80/20; and Platinum = 90/10.) For example, in a 60/40 plan, the maximum a consumer would generally pay is 40 percent of medical costs.
- There is latitude within each of these coverage levels to satisfy the maximum policyholder costs, i.e., there are multiple combinations of deductibles, co-pays and coinsurance percentages that could result, for example, in a 30% cost-sharing. For example, a policy that offers maternity benefits could be offered at the silver level while another policy that has no maternity benefits but rich pharmacy benefits could also be offered at the silver level.
- Allowing multiple products within each level increases product choices available to consumers, but probably with increased confusion.
- Limiting the product choices available in each of the product categories reduces the confusion, but results in fewer product choices for the consumer.
- Plans offering catastrophic coverage may be offered in the individual market (generally only to those under age 30) (Act Sec. 1302(e)).

Health Insurance Exchange

State Legislation Activity

Governance Model in State

Sources: NAIC; Allied Hospital Association; Center for Budget and Policy Priorities

*Some states have more than one bill pending.

State:	
CA	Final bill establishes Exchange within state government as an independent public entity to be governed by a board Exchange is a quasi-governmental entity (free-standing)
CO	Nonprofit unincorporated public entity with a board Exchange is a quasi-governmental entity (free-standing)
CT	Political subdivision of the state, not to be considered a state department or agency Exchange is a quasi-governmental entity (free-standing)
DC	State legislation is pending Exchange is a quasi-governmental entity (administratively housed in or supervised by a state agency)
HI	Created a health Exchange council Exchange is a not-for-profit organization (free-standing)
IL	Adopted legislation to create a study commission or panel Exchange is a quasi-governmental entity (free-standing)
IN	Executive order establishes Exchange as nonprofit corporation
ME	Independent executive agency State legislation is pending Exchange is a quasi-governmental entity (free-standing)
MD	Bill passed establishing as public corporation, independent unit of state government Exchange is a quasi-governmental entity (free-standing)
MN	Nonprofit entity State agency governed by a board of directors State legislation is pending Exchange operated by state agency Health exchange as a not-for profit organization (free-standing)
MS	Adopted legislation to create a study commission or panel

NV	Exchange is a quasi-governmental entity (free-standing)
NH	Corporate body that is an instrumentality of state and a public corporation State legislation is pending Exchange is a quasi-governmental entity (free-standing)
NJ	State legislation is pending Exchange is a quasi-governmental entity (administratively housed in or supervised by a state agency) Health exchange as a not-for profit organization (free-standing)
NY	State legislation is pending Exchange is a quasi-governmental entity (free-standing)
NC	Nonprofit entity State legislation is pending Health exchange as a not-for profit organization (free-standing)
ND	Enacted legislation that expresses intent to create a state exchange
OR	Public corporation Exchange is a quasi-governmental entity (free-standing)
PA	State legislation is pending Exchange is a quasi-governmental entity (free-standing)
RI	Public corporation of the state State legislation is pending Exchange is a quasi-governmental entity (free-standing)
UT	Adopted legislation to create a study commission or panel
VT	Bill passed establishing within Division of the Department of Vermont health access Exchange operated by state agency
VA	Enacted legislation that expresses intent to create a state exchange
WA	Bill passed establishing public-private partnership separate and distinct from state, with a governing board Health exchange as a not-for profit organization (free-standing)
WV	Bill passed establishing as governmental entity of the state Exchange is a quasi-governmental entity (administratively housed in or supervised by a state agency)
WY	Adopted legislation to create a study commission or panel

Several states had Exchange-related legislation that did not pass.

EXCHANGE PROPOSED REGULATION

Comments Due: September 28, 2011

Governance Options:

1) State Agency
2) Independent State Agency
    a. Board must have majority who represent consumers and small employers
    b. Must have publicly-established chart/by-laws
    c. Must hold public meetings
3) Non-Profit Organization
    a. Board must have majority who represent consumers and small employers
    b. Must have publicly-established chart/by-laws
    c. Must hold public meetings

- May partner with other states (no need to be contiguous) or establish subsidiary Exchanges (no overlap)
- May contract with other eligible entities to carry out functions
- May partner with the Federal Government

Approval Process:

- Secretary will certify state Exchanges by January 1, 2013
    - State submits an application
    - HHS review of application (90-day review after complete application received)
    - State received written approval, conditional approval, or rejection
- A State may receive "conditional approval" if it is demonstrated that they will be operational by Oct 1, 2013 (the beginning of the initial open enrollment period)
- A State may set up an Exchange after 2014 if a qualified plan is sent to the Secretary, along with a 12-month strategy for transitioning from the federal Exchange to the State-operated Exchange.
- Significant modifications to an approved Exchange must receive written approval from the Secretary

Funding:

- State-based Exchanges must be self-funded by January 1, 2015. Funding mechanism left to the State.

Functions of the Exchange:

1) Implement procedures for certification, recertification and decertification of health plans
2) Operate a toll-free hotline
3) Maintain an Internet website with standardized plan information (categories and template to be provided)
4) Provide for enrollment by Internet, paper, or phone
5) Perform eligibility determinations for private coverage, subsidies, Medicaid, CHIP or Basic Health Plan
6) Process appeals of eligibility determinations
7) Post justifications for rate increases (may coordinate directly with Dept of Insurance)

8) Assign a quality rating to each plan
9) Oversee satisfaction surveys, information disclosures and data reporting
10) Comply with reporting and financial oversight requirements
11) Make available a calculator to determine the actual cost of coverage after subsidies (individual only)
12) Grant a certification attesting that the individual is not subject to the coverage mandate because –
    - There is no affordable option available, or
    - The individual is exempt from the mandate
13) Transfer to the Treasury a list of individuals exempt from the individual mandate and employees eligible for tax credit
14) Provide to each employer the names of employees eligible for tax credit
15) Establish a Navigator program

- A State may negotiate with plans; place additional requirements on plans; or accept "all comers"
- A State may add other functions as they see fit

Payment of Premiums

- The individual market Exchange may: 1) take no part in the payment of premiums; 2) facilitate payment as a "pass-through"; or, 3) aggregate premiums for the carriers. The Exchange is not responsible for an individual's failure to pay premiums
- The SHOP Exchange must aggregate premiums for small businesses, at a minimum.

Enrollment Periods:

- Initial Individual Market Open Enrollment Period: October 1, 2013 – February 28, 2014
- Initial SHOP Open Enrollment Period: Begins October 1, 2013 (does not end because Small Group has rolling enrollment)
- Annual Open Enrollment Period: Individual (Oct 15th – Dec 7th); SHOP (plan year enrollment)
- Special Enrollment Periods: too many to count!

Network Adequacy/Marketing/Service Areas

- Left to state law – comments requested

Navigators and Agents/Brokers

- Navigators must have some tie to a target group – consumers, small businesses, cultural/language groups
- Navigators may not be insurance companies or receive funds from insurance companies
- Agents/Brokers may be Navigators, but may not receive funds from insurance companies
- Navigators provide information to consumers about the Exchange, their coverage options and subsidies – states may develop standardized materials
- States may require Navigators to be certified and have flexibility on their role and training requirements. States also have flexibility on the role of agents and brokers. The Exchange may display information about agents and brokers

STATE OF NORTH DAKOTA
(7/2011)

North Dakota Insurance Department
600 E. Boulevard Ave.
Bismarck, ND 58505-0320

Request For Proposal (RFP)

RFP Title: North Dakota Health Benefit Exchange consultant

RFP Number: 401-11-001

Date of Issue: July 18, 2011

Purpose of RFP: The North Dakota Insurance Department, hereafter known as "purchasing agency," seeks a qualified and experienced firm to conduct background research, analyze data, identify options and recommend a viable plan for developing and sustaining a health benefit Exchange ("Exchange") in North Dakota.

Offerors are not required to return this form.

Procurement Officer: Melissa Hauer, General Counsel
North Dakota Insurance Department
600 E. Boulevard Ave.,
Bismarck, ND 58505-0320
701-328-2440
mahauer@nd.gov

TABLE OF CONTENTS

SECTION ONE
Introduction and Instructions
1.01 Purpose of the RFP
1.02 Contact Person, Telephone, Fax Numbers and E-mail
1.03 RFP Schedule
1.04 Return Mailing Address and Deadline for Receipt of Proposals
1.05 Assistance to Offerors with a Disability
1.06 Deadline for Receipt of Questions and Objections
1.07 Approved Vendor Registration Requirements
1.08 Pre-proposal Conference
1.09 Amendments to the RFP
1.10 News Releases
1.11 Notice Provided
1.12 Letter of Interest

SECTION TWO
Background Information
2.01 Background Information
2.02 Budget

SECTION THREE
Scope and Schedule
3.01 Scope of Work
3.02 Location of Work
3.03 Prior Experience
3.04 Required Licenses
3.05 Federal Requirements
3.06 Deliverables
3.07 Contract Schedule
3.08 Additional Services

SECTION FOUR
General Contract Information
4.01 Contract Term, Extension and Renewal Options
4.02 Contract Type
4.03 Standard Contract Provisions
4.04 Proposal as a Part of the Contract
4.05 Additional Terms and Conditions
4.06 Supplemental Terms and Conditions
4.07 Contract Approval
4.08 Contract Changes – Unanticipated Amendments
4.09 Indemnification and Insurance Requirements
4.10 Taxes and Taxpayer Tax Identification
4.11 F.O.B. Point and Freight
4.12 Proposed Payment Procedures
4.13 Contract Funding
4.14 Payment Terms
4.15 Contract Personnel
4.16 Right to Inspect Place of Business
4.17 Inspection & Modification - Reimbursement for Unacceptable Deliverables
4.18 Termination for Default
4.19 Confidentiality
4.20 Work Product, Equipment, and Material
4.21 Independent Entity

4.22 Assignment
4.23 Disputes - Applicable Law and Venue
4.24 Informal Debriefing

SECTION FIVE
Evaluation Criteria and Contractor Selection
5.01 Understanding of the Project
5.02 Management Plan for the Project
5.03 Experience and Qualifications
5.04 Contract Cost

SECTION SIX
Proposal Format and Content
6.01 Proposal Format and Content
6.02 Introduction
6.03 Understanding of the Project
6.04 Management Plan for the Project
6.05 Experience and Qualifications
6.06 Cost Proposal
6.07 Required Enclosures

SECTION SEVEN
Standard Proposal Information
7.01 Authorized Signature
7.02 State Not Responsible for Preparation Costs
7.03 Conflict of Interest
7.04 Offeror Certification
7.05 Offer Held Firm
7.06 Amendments to Proposals and Withdrawal of Proposals
7.07 Alternate Proposals
7.08 Subcontractors
7.09 Joint Ventures
7.10 Disclosure of Proposal Contents and Compliance with North Dakota Open Records Laws
7.11 Evaluation of Proposal
7.12 Right of Rejection
7.13 Clarification of Offers
7.14 Discussion and Best and Final Offers
7.15 Preference Laws
7.16 Contract Negotiation
7.17 Failure to Negotiate
7.18 Notice of Intent to Award – Offeror Notification of Selection
7.19 Protest and Appeal

SECTION EIGHT
Attachments
8.01 Attachments

1. Proposal Evaluation Form
2. Contract Form
3. Cost Proposal Format

SECTION ONE
INTRODUCTION AND INSTRUCTIONS

1.01
Purpose of the RFP
The North Dakota Insurance Department, hereafter known as "Insurance Department," "Department," and "State," seeks a qualified and experienced firm to conduct background research, analyze data, identify options and recommend a viable plan for developing and sustaining a health benefit Exchange ("Exchange") in North Dakota.

1.02
Contact Person, Telephone, Fax, E-mail
The procurement officer is the point of contact for this RFP. All vendor communications regarding this RFP must be directed to the procurement officer. Unauthorized contact regarding the RFP with other State employees of the purchasing agency may result in the vendor being disqualified, and the vendor may also be suspended or disbarred from the state bidders list.

PROCUREMENT OFFICER: Melissa Hauer
PHONE: 701-328-2440
FAX: 701-328-4880
TTY Users call: 1-800-366-6888
E-MAIL: mahauer@nd.gov

1.03
RFP Schedule
This schedule of events represents the State's best estimate of the schedule that will be followed for this RFP. If a component of this schedule, such as the deadline for receipt of proposals, is delayed, the rest of the schedule will be shifted by the same number of days.

The approximate RFP schedule is as follows:

- RFP Issued: July 18, 2011
- Deadline for receipt of questions and objections related to the RFP: July 25, 2011
- Responses to questions / RFP amendments (if required): July 29, 2011
- Proposals due by: August 10, 2011
- Proposal Evaluation Committee evaluation completed by approximately : August 17, 2011
- State issues Notice of Intent to Award a Contract approximately: August 18, 2011
- State issues contract approximately: August 25, 2011
- Contract start: August 26, 2011

1.04
Return Mailing Address and Deadline for Receipt of Proposals
Offeror must submit three paper copies of its proposal in a sealed envelope or package. Offeror must also submit a PDF of each proposal via email to mahauer@nd.gov.

Cost proposals are to be submitted in a separate sealed envelope or package, clearly labeled "cost proposal."

Envelopes or packages containing proposals must be clearly addressed as described below to ensure proper delivery and to avoid being opened by the State before the deadline for receipt. Envelopes or packages must be addressed as follows:

Melissa Hauer
North Dakota Insurance Department
RFP Number: 401-11-001
600 E Boulevard Avenue, Dept. 401
Bismarck, ND 58505

Proposals must be received by the purchasing agency at the location specified no later than ***2:00 P.M.,*** Central Time on ***August 10, 2011***. Proposals will not be publicly read at the opening.

Proposals may not be delivered orally, by facsimile transmission, by other telecommunication or electronic means. Offeror may fax or electronically transmit signed proposal to a third party who must deliver the proposal to the location indicated above by the date and time designated as the deadline for receipt of proposals.

Offeror assumes the risk of the method of dispatch chosen. The State of North Dakota ("State") assumes no responsibility for delays caused by any delivery service. Postmarking by the due date will not substitute for actual proposal receipt by the State. An offeror's failure to submit its proposal prior to the deadline will cause the proposal to be rejected. Late proposals or amendments will not be opened or accepted for evaluation.

1.05
Assistance to Offerors with a Disability
Offerors with a disability that need an accommodation should contact the procurement officer prior to the deadline for receipt of proposals so that reasonable accommodation can be made.

1.06
Deadline for Receipt of Questions and Objections
Offeror must carefully review this solicitation, the contract, risk management provisions, and all attachments for defects, questionable, or objectionable material. All questions must be in writing and directed to the purchasing agency, addressed to the procurement officer, and cite the subject RFP number. The procurement officer must receive these written requests by the deadline specified in the RFP Schedule of Events to allow issuance of any necessary amendments.

This will also help prevent the opening of a defective solicitation and exposure of offeror's proposals upon which an award could not be made. Protests based on the content of the solicitation will be disallowed if these faults have not been brought to the attention of the procurement officer, in writing, before the time indicated in the Schedule of Events.

If the question may be answered by directing the questioner to a specific section of the RFP, then the procurement officer may answer the question over the telephone. Other questions may be more complex and may require a written amendment to the RFP. The procurement officer will make this determination. Oral communications is considered unofficial and non-binding on the State. The offeror must confirm telephone conversations in writing.

1.07
Approved Vendor Registration Requirements
Proposals will be accepted from vendors that are not currently approved vendors on the State's bidders list; however, the successful offeror will be required to become approved prior to award.

To become an approved vendor, offeror must: 1) be registered with the North Dakota Secretary of State (fees apply), and 2) submit a completed Bidders List Application to the North Dakota Vendor Registry Office. Prospective offerors may access the Procurement Vendor Database on-line to verify whether its firm is currently on the bidders list. The bidders list that will be used for this solicitation are commodity codes: 956-05 business research services, 946-77 statistical services and 918 consulting services, business consulting small, human services consulting, insurance consulting, finance/economic consulting.

The Procurement Vendor Database, registration instructions and forms are available online at: http://www.nd.gov/spo/vendor/registry/. Contact the Vendor Registry Office at 701-328-2683 or infospo@nd.gov for assistance.

The successful offeror must register and become approved within **30 calendar days** from the date of the Notice of Intent to Award***.*** If an offeror fails to become approved by the time specified by the Procurement Officer, its proposal will be determined to be non-responsive, and its proposal will be rejected.

Registration can take more than 30 days to complete so offeror is encouraged to register early. All potential offerors are encouraged to visit the North Dakota State Procurement web site at www.nd.gov/spo for more information on registering.

1.08
Pre-proposal Conference
No pre-proposal conference will be held for this RFP. Offeror is advised to carefully review the RFP and all attachments and submit all questions to the procurement officer by the deadline indicated for submission of questions in the schedule of events.

1.09
Amendments to the RFP
If an amendment to this RFP is issued, it will be provided to all offerors that were mailed a copy of the RFP and to those that have requested a copy of the RFP from the procurement officer.

1.10
News Releases
News releases related to this RFP will not be made without prior approval of the procurement officer or project manager designated by the State.

1.11
Notice Provided
Notice of this solicitation has been provided in accordance with N.D.C.C. § 54-44.4-09.
The Request for Proposal and any amendments to the RFP will be posted on the following websites: www.nd.gov/spo/ and www.nd.gov/ndins .

1.12
Letter of Interest
Vendors interested in receiving any notices related to this RFP are invited to contact the procurement officer with the name of their firm, contact person, mailing address, telephone number, fax number, and e-mail address. The sole purpose of the letter of interest is to provide the purchasing agency with a contact person to receive any notices related to the RFP. Submission of a letter of interest is not a requirement for submitting a proposal.

SECTION TWO

BACKGROUND INFORMATION

2.01
Background Information

In March 2010, the Patient Protection and Affordable Care Act (PPACA) and the Health Care and Education Reconciliation Act of 2010 were signed into law. The two laws are collectively referred to as the Affordable Care Act (ACA). The ACA provides grant funding to assist states in planning, developing and implementing of parts of the ACA.

By January 1, 2014, PPACA requires each state to establish a state-based American Health Benefit Exchange and a Small Business Health Options Program (SHOP) Exchange. These Exchanges will be online marketplaces where individuals and small businesses can shop for health plans in a way that permits comparison of available plan options based on price, benefits and services, and quality. A state may elect to provide for only one state Exchange that would provide both American Health Benefit Exchange services and SHOP Exchange services. States may also choose to create a multi-state, regional Exchange.

If North Dakota elects to not operate its' own Exchange, the United States Department of Health and Human Services ("HHS") will. By January 1, 2013, HHS must determine whether the state will have a qualified Exchange in operation by January 1, 2014. If it determines that the state will not have an operational Exchange by then, HHS is required to establish and operate the Exchange within that state.

Exchanges will allow people to compare health plans and determine which one is best for them. Health plans will be placed in tiers based on out-of-pocket costs, which allows consumers to compare plans on an apples-to-apples basis. All plans sold in the Exchange are offered by private insurance companies. There is no government-run plan or public insurance option.

An Exchange must also assist eligible individuals to receive premium tax credits or coverage through other federal or state health care programs such as Medicaid and the Children's Health Insurance Program (CHIP). Individuals whose household income does not exceed 400 percent of the poverty line will receive subsidies through the Exchange according to a sliding scale. By providing one-stop shopping, Exchanges are theoretically supposed to increase competition in the marketplace and make purchasing health insurance easier and more understandable for consumers.

A contractor is being solicited to research several issues regarding Exchange planning in North Dakota, taking into consideration the unique characteristics of North Dakota's insurance market, including but not limited to the following issues:

- Who should run the Exchange in North Dakota—an existing state agency, a new state agency, a nonprofit entity or the federal government?
- What kind of governance should the Exchange have (e.g., board of directors, stakeholder group)?
- Determine the number of uninsured North Dakotans.
- Determine the number of people that would potentially access North Dakota's Exchange.
- Analyze the benefits of establishing one Exchange or two, including a cost-benefit analysis.
- Analyze the benefits of running a state Exchange vs. a regional Exchange.
- Analyze the impact on and changes needed in the external insurance market in North Dakota.
- Analyze the economic and social advantages and disadvantages of North Dakota running its own Exchange.
- How can the Exchange(s) finance itself after 2015?

Offerors are encouraged to propose additional questions, variables or factors to consider and provide an explanation of the program/policy relevance of their proposals.

2.02
Budget

The estimated budget for completion of this project is $250,000. Proposals priced at more than $250,000 will be considered non-responsive.

SECTION THREE
SCOPE OF WORK

3.01
Scope of Work

Overview
It is the mission of the North Dakota Insurance Department to protect the public good by fairly and effectively administering the laws of North Dakota. We are committed to vigorous consumer protection efforts while fostering a strong, competitive marketplace that provide consumers with choices and access to high-quality insurance products and services at competitive prices. In pursuit of our mission, we will treat all of our constituencies with the highest ethical standards and respect they deserve.

The North Dakota Insurance Department seeks a qualified and experienced firm to conduct background research, analyze data, identify options and recommend a viable plan for developing and sustaining a health benefit Exchange ("Exchange") in North Dakota. The proposed plan must be in compliance with PPACA, all related federal regulations and guidance, and address the needs of North Dakotans.

An Exchange must meet the following requirements as outlined in the Affordable Care Act:

- Inform individuals of eligibility requirements for Medicaid, the Children's Health Insurance Program (CHIP), or any other state or local public programs and enroll eligible individuals in such programs
- Provide a calculator to determine enrollee premiums and cost-sharing reduction
- Identify those individuals exempt from the individual mandate and notify the Secretary of the U.S. Department of the Treasury
- Implement procedures for the certification, recertification, and decertification of health plans as qualified health plans and provide standardized comparative information for consumers
- Require participating plans to provide justification for rate increases
- Provide for the operation of a toll-free telephone hotline to respond to assistance requests
- Assign a rating to each qualified health plan offered through the Exchange
- Grant a certification attesting that, for purposes of the individual responsibility penalty, an individual is exempt from the individual requirement or penalty
- Report to the Secretary of Health and Human Services and the Government Accounting Office on use of funds
- Develop a plan for working with navigators and agents
- Provide employee choice of plan in the small group Exchange
- Provide each employer with the name of each of its employees who ceases coverage under a qualified health plan during a plan year
- Establish a Navigator program
- Meet any other requirements of the ACA and any implementing regulations.

Definitions

State-Furnished Property/Services
The North Dakota Insurance Department will provide guidance as necessary to assist the successful offeror in carrying out the requirements of the contract. Specific staff will be assigned as primary contacts for the contractor.

The Department will also ensure the successful bidder is informed of primary contacts in other key state agencies such as the North Dakota Information Technology Department, the North Dakota Department of Health , and the North Dakota Department of Human Services among others.

Contractor-Furnished Property
Contractor will provide office space, supplies, telecommunications equipment, computer and any necessary software or other supplies to carry out the scope of work in this RFP.

Description of Specific, Results-Oriented Tasks
The successful offeror will produce an integrated planning document that combines background research with best practice models and innovation to describe alternatives, cost estimates, timelines and recommendations for implementing and sustaining an Exchange in North Dakota.

The completed planning document must provide viable options and recommendations for development, implementation and sustainability of the best possible Exchange for North Dakota. The document will also estimate costs, expenses and outlay for Exchange implementation and for annual budgets each year through 2019. Responders must include a detailed break-down of total cost.

The completed planning document must:

Governance model

- Assess the best organizational structure of an exchange—pros and cons of various structural options for North Dakota, including feasibility of state vs. multistate model
- Assess the advantages and disadvantages of state vs. federal Exchange and partnering with the federal government
- Assess the advantages and disadvantages of single vs. multiple Exchanges in state
- Recommend an agency or entity that will be responsible for operating the Exchange—quasi-governmental vs. state agency; if state agency, which one or a new one?
- Recommend the governance and oversight's relation to Insurance Department regulatory oversight
- Recommend procedures to insure public accountability, transparency, stakeholder inclusion

Marketplace demographics

- Assess the number of individuals covered by an employer plan—size of group, type of plans, percent of employees covered, insured vs. self insured
- Assess the number of individuals eligible for employer coverage but not enrolled (insured vs. self insured)
- Assess the number of small employers not offering coverage
- Assess the number of individuals covered by full-coverage and individual major medical plans
- Assess the number of individuals in self-insured plans
- Assess the number of individuals in mini-med or limited benefit plans
- Assess the number of individuals enrolled in Medicaid
- Assess the number of individuals enrolled in CHIP
- Assess the number of individuals enrolled in another public plan including dual eligibles
- Assess the number of individuals eligible for Medicaid or CHIP but not enrolled
- Assess the number of individuals not insured in North Dakota
- Forecast how many individuals will remain uninsured in North Dakota in 2014and provide demographics and reasons (not eligible, waiver, chose penalty, other).

Provide information about uninsured demographics in North Dakota including:

- Income
- Age
- Work status
- Health status
- Household size
- County of residence
- Education/literacy status
- Barriers to coverage
- Electronic communication access/use
- Incentives for being/not being insured

Provide information about the insurance marketplace in North Dakota both public and private including:

- Number of private carriers in each market and their market share
- Benefit structure—mandated benefits, premiums, out-of-pocket expenses
- Roles of brokers, producers and others
- Compensation structure for navigators, producers, brokers
- Claims information—targeted models for evaluation of claims data. Any state law changes needed?
- Estimate number of enrollees and premium levels for private plans in Exchange
- Estimate number of enrollees in Medicaid and CHIP through the Exchange
- What is projected "take up" rate for individual and SHOP coverage inside and outside the Exchange? What about Comprehensive Health Association of North Dakota (CHAND) to Exchange? Federal Pre-Existing Condition Insurance Plan (PCIP) to Exchange?
- What will influence carrier behavior? How might we facilitate expanded carrier participation and competition?
- What will influence employer behavior? How might we facilitate expanded carrier participation and competition?
- What will influence individual customer behavior? How might we provide incentives to participate in plans meeting perspectives of diverse customer bases?
- Pros and cons of merging individual and small group markets into one rating pool
- Integration and coordination for enrollment and other/services for individuals within one family but receiving coverage from multiple payers/carriers (e.g. child on Medicaid, mother temporarily Medicaid eligible while pregnant, father covered on employer plan)
- Projected customer mix relative to health status

<u>Provide information about program integration including:</u>

- Plan to integrate consumer outreach/education; eligibility determinations, verification, enrollment; premiums collections and plans payment; post-enrollment services including call centers, ombudsmen or other consumer advocacy programs
- Provide cost-benefit analysis of premium aggregation services for the state and small business
- Define formal agreements needed between the Exchange and the Insurance Department that defines roles and responsibilities relative to qualified health plans and strategies for limiting adverse selection
- Discussion of Exchange modeling options with explanation of methods, variables and assumptions

<u>Provide information about Exchange financial modeling including:</u>

- Based on ranges of enrollment and premium level estimates
    - Analyze and determine level of Exchange infrastructure required based on empirical modeling and gaps
    - Include potential revenue sources and expected amounts at various enrollment and premium levels
    - Given various design assumptions, estimate number and type of positions necessary to run an Exchange, salary levels and critical experience needed
    - Evaluate and recommend viable business models to include administrative and other fees required for Exchange break even and cash flow estimates for various revenue and expense estimates through 2019

<u>Provide communication and outreach including:</u>

- Provide update of work every two weeks to Insurance Department. Consider format that could be disseminated to staff, workgroups and posted online.
- Identify ways to continue to engage stakeholders in welcoming their input on the Exchange.
- Identify best practices to educate businesses, consumers and government leaders on the Exchange.

<u>Project understanding</u>

Vendor will describe in detail the plan for meeting the requirements and objectives in this request for proposal.

Directives
Federal laws and regulations, state laws and administrative rules, federal directives and guidance, and federal regulations or requirements concerning grants may influence the contract. These directives are contained in the Affordable Care Act (ACA), federal regulations implementing the ACA, state laws and the North Dakota Administrative Code title 45, as well as federal guidance and directives. ACA regulations are subject to change, and additional ACA regulations may be released during the time of this contract.

3.02
Location of Work
The purchasing agency will not provide workspace for the contractor. The contractor shall bear all costs involved with providing the services specified in the contract.

In- and out-of-state travel may be required. The contractor shall bear all cost of travel, lodging, and meals associated with the performance of the contract. The contractor should include in its price proposal: transportation, lodging, and per diem costs sufficient to pay for the number of person(s) the contractor deems appropriate to make the number of trip(s) to Bismarck, North Dakota deemed necessary in order to provide the services described.

3.03
Prior Experience
Offeror will demonstrate and provide evidence of at least five years experience with public health coverage programs and working within a governmental environment. Preference will be given to offerors with experience in statistical analysis, business planning, analyzing options and estimating necessary time and resources.

3.04
Required Licenses
At the time specified by the deadline for submission of proposals, the offeror must have and keep current any professional licenses and permits required by federal, state, and local laws for performance of this contract. Offerors that do not possess required licenses at the time proposals are due will be determined non-responsive.

3.05
Federal Requirements
The offeror must identify all known federal requirements that apply to the proposal, the evaluation, or the contract.

3.06
Deliverables
The contractor will be required to provide the following deliverables:

- Progress reports at least every two weeks outlining work accomplished
- Interim report and presentation for preparation of draft legislation
- Final report and presentation
- The contractor may also be required to present findings to the North Dakota Legislative Assembly at the Department's request.

3.07
Contract Schedule
This schedule of events represents the State's best estimate of the contract schedule that will be followed. If a component of this schedule, such as the award date, is delayed, the rest of the schedule will be shifted by the same number of days.

The approximate contract schedule is as follows:

- Contract start: August 26, 2011
- Kick-off meeting with Department and other state agencies approximately: Sept. 6, 2011
- Contractor begins providing bi-weekly progress reports: Sept. 9, 2011

- Contractor submits interim project report: Sept. 28, 2011
- State provides contractor with comments for revision of interim report as needed: Oct. 5, 2011
- Contractor submits revised interim report: October 10, 2011
- Contractor submits final report: December 2, 2011
- Informal debriefing approximately: December 9, 2011

3.08 Additional Services

The State may require additional services from the awarded offeror during the term of the contract (i.e. oversight and/or planning activities related to the implementation phase). Offeror is encouraged to include an hourly rate in the cost proposal. The State reserves the right to negotiate with the awarded offeror on any additional services.

SECTION FOUR
GENERAL CONTRACT INFORMATION

4.01 Contract Term, Extension, and Renewal Options

The State intends to enter into a contract with an effective date beginning August 26, 2011 and ending December 31, 2011.

Extension Option

The State reserves the right to extend the contract period for an additional period of time, not to exceed 12 months, beyond the normal expiration date of the contract, upon mutual written agreement by both parties.

Renewal Option

This contract may be renewed upon satisfactory completion of the initial contract term. The State reserves the right to execute up to one option to renew this contract annually under the same terms and conditions for a period of 12 months each. This contract will not automatically renew. The State will provide written notice to the contractor of its intent to renew this contract at least 30 days before the scheduled contract expiration date.

4.02 Contract Type

This contract is a firm fixed with adjustment contract.

4.03 Standard Contract Provisions

The successful offeror will be required to sign and submit the contract attached to this RFP (Appendix A). The contractor must comply with the contract provisions set out in this attachment. Any objections to the contract provisions must be set out in the offeror's proposal. No alteration of these provisions will be permitted without prior written approval from the purchasing agency.

Offeror is instructed to contact the procurement officer in writing by the deadline set for questions with any concerns regarding the contract provisions.

4.04 Proposal as a Part of the Contract

Part or all of this RFP and the successful proposal may be incorporated into the contract.

4.05 Additional Terms and Conditions

The State reserves the right to add, delete, or modify terms and conditions during contract negotiations. These terms and conditions will be within the scope of the RFP and will not affect the proposal evaluations.

4.06 Supplemental Terms and Conditions

Proposals including supplemental terms and conditions will be accepted, but supplemental conditions that conflict with those contained in this RFP or that diminish the State's rights under any contract resulting from the RFP will be considered null and void. The State is not responsible for identifying conflicting supplemental terms and conditions before issuing a contract award. After award of contract:

(a) if conflict arises between a supplemental term or condition included in the proposal and a term or condition of the RFP, the term or condition of the RFP will prevail; and
(b) if the State's rights would be diminished as a result of application of a supplemental term or condition included in the proposal, the supplemental term or condition will be considered null and void.

4.07 Contract Approval

This RFP does not, by itself, obligate the State. The State's obligation will commence when the purchasing agency approves the contract. Upon written notice to the contractor, the State may set a different starting date for the contract. The State will not be responsible for any work done by the contractor, even work done in good faith, if it occurs prior to the contract start date set by the State.

4.08 Contract Changes - Unanticipated Amendments
During the course of this contract, the contractor may be required to perform additional work. That work will be within the general scope of the initial contract. When additional work is required, the project manager designated by the State will provide the contractor a written description of the additional work and request the contractor to submit a firm time schedule for accomplishing the additional work and a firm price for the additional work. Cost and pricing data must be provided to justify the cost of amendments.

The contractor will not commence additional work until the project director has secured any required State approvals necessary for the amendment and issued a written contract amendment, approved by the purchasing agency.

4.09 Indemnification and Insurance Requirements
Offeror must review the attached contract for indemnification and insurance requirements. The indemnification and insurance provisions will be incorporated into the final contract.

Objections to any of the provisions of the Indemnification and Insurance Requirements must be made in writing to the attention of the procurement officer by the time and date set for receipt of questions. No alteration of these provisions will be permitted without prior written approval from the purchasing agency in consultation with the North Dakota Risk Management Division.

Upon receipt of the Notice of Intent to Award, the successful offeror must obtain the required insurance coverage and provide the procurement officer with proof of coverage prior to contract approval. The coverage must be satisfactory to the purchasing agency, in consultation with the North Dakota Risk Management Division. An offeror's failure to provide evidence of insurance coverage is a material breach and grounds for withdrawal of the award or termination of the contract.

4.10 Taxes and Taxpayer Identification
The contractor must provide a valid Vendor Tax Identification Number as a provision of the contract.

The State is not responsible for and will not pay local, state, or federal taxes. The State sales tax exemption number is E-2001, and certificates will be furnished upon request by the purchasing agency.

A contractor performing any contract, including service contracts, for the United States Government, State of North Dakota, counties, cities, school districts, park board, or any other political subdivisions within North Dakota, is not exempt from payment of sales or use tax on material and supplies used or consumed in carrying out contracts. In these cases, the contractor is required to file returns and pay sales and use tax just as required for contracts with private parties. Contact the North Dakota Tax Department at 701-328-3470 or visit its website at www.nd.gov/tax for more information.

A contractor performing any contract, including a service contract, within North Dakota is also subject to the corporation income tax, individual income tax, and withholding tax reporting requirements, whether the contract is performed by a corporation, partnership, or other business entity, or as an employee of the contractor. In the case of employees performing the services in the state, the contractor is required to withhold state income tax from the employees' compensation and remit to the state as required by law. Contact the North Dakota Tax Department at 701-328-3125 or visit its website for more information.

4.11 F.O.B. Point and Freight
All commodities purchased through this contract will be Free on Board ("F.O.B.") final destination, freight prepaid. Unless specifically stated otherwise, all prices offered must include the delivery costs to any location within the State of North Dakota. Title will pass to the State at destination, and the vendor will be responsible for any freight claims.

4.12 Proposed Payment Procedures
The State will make payments based on a negotiated payment schedule. Each billing must consist of an invoice and progress report. No payment will be made until the progress report and the project director has approved invoice.

The State will not make any advanced payments before performance by the contractor under this contract.

4.13 Contract Funding
Approval or continuation of a contract resulting from this solicitation is contingent upon continuing appropriation. The contract may be terminated by the State or modified by agreement of both parties in the event funding from federal, state, or other sources is not obtained and continued at sufficient levels.

4.14 Payment Terms
No payment will be made until the purchasing agency approves the contract.

Payment for commodities and services received under contracts will normally be made within 30 calendar days after receipt and acceptance by the purchasing agency or after receipt of a correct invoice, whichever is later. Payment inquiries must be directed to the purchasing agency.

Prompt Payment Discount Terms offered by the contractor may be taken by the purchasing agency if payment is made within the specified terms.

4.15 Contract Personnel
The project manager designated by the purchasing agency must approve any change of the contractor's project team members named in the proposal, in advance and in writing. Personnel changes that are not approved by the State may be grounds for the State to terminate the contract.

4.16 Right to Inspect Place of Business
At reasonable times, the State may inspect those areas of the contractor's place of business that are related to the performance of a contract. If the State makes an inspection, the contractor must provide reasonable assistance.

4.17 Inspection and Modification - Reimbursement for Unacceptable Deliverables
The contractor is responsible for the completion of all work set out in the contract. All work is subject to inspection, evaluation, and approval by the project manager designated by the State. The State may employ all reasonable means to ensure that the work is progressing and being performed in compliance with the contract. Should the project manager determine that corrections or modifications are necessary in order to accomplish its intent, the project manager may direct the contractor to make changes. The contractor will not unreasonably withhold changes.

Substantial failure of the contractor to perform the contract may cause the State to terminate the contract. In this event, the State may require the contractor to reimburse monies paid (based on the identified portion of unacceptable work received) and may seek associated damages.

4.18 Termination for Default
If the project manager designated by the purchasing agency determines that the contractor has refused to perform the work or has failed to perform the work with diligence as to ensure its timely and accurate completion, the State may, by providing written notice to the contractor, terminate the contractor's right to proceed with part or all or the remaining work.

This clause does not restrict the State's right to termination under the contract provisions of the Service Contract, attached.

4.19 Open Records Laws - Confidentiality
Any records that are obtained or generated by the contractor under this contract are subject to North Dakota open records law regarding public records and handling of confidential information.

4.20 Work Product, Equipment, and Material
All work product, equipment or materials created or purchased under this contract belong to the State and must be delivered to State at State's request upon termination of this contract, unless otherwise agreed in

writing by the purchasing agency.

4.21 Independent Entity
The contractor is an independent entity under this contract and is not a State employee for any purpose. The contractor retains sole and absolute discretion in the manner and means of carrying out the contractor's activities and responsibilities under the contract, except to the extent specified in the contract.

4.22 Assignment
Contractor may not assign or otherwise transfer or delegate any right or duty without the State's express written consent. However, the contractor may enter into subcontracts provided that the subcontract acknowledges the binding nature of this contract and incorporates this contract, including any attachments.

4.23 Disputes - Applicable Law and Venue
Any dispute arising out of this agreement will be resolved under the laws of the State of North Dakota.

4.24 Informal Debriefing
When the contract is completed, an informal debriefing may be performed at the discretion of the procurement officer or project manager designated by the State. If performed, the scope of the debriefing will be limited to the work performed by the contractor. The debriefing time and location will be negotiated between the purchasing agency and contractor.

SECTION FIVE
EVALUATION CRITERIA AND CONTRACTOR SELECTION

The total number of points used to score this contract is 100.

5.01
Understanding of the Project
Ten Percent (10%) of the total possible evaluation points will be assigned to this criterion.

Proposals will be evaluated against the questions set out below:

a. How well has the offeror demonstrated a thorough understanding of the purpose and scope of the project?
b. How well has the offeror identified pertinent issues and potential problems related to the project?
c. How well has the offeror demonstrated an understanding of the deliverables the State expects it to provide?
d. How well has the offeror demonstrated an understanding of the State's time schedule and can meet it?
e. Is the proposal submitted responsive to all material requirements in the RFP?

5.02
Management Plan for the Project
Twenty-Five Percent (25%) of the total possible evaluation points will be assigned to this criterion.

Proposals will be evaluated against the questions set out below:

a. How well does the management plan support all of the project requirements and logically lead to the deliverables required in the RFP?
b. How well is accountability completely and clearly defined?
c. Is the organization of the project team clear?
d. How well does the management plan illustrate the lines of authority and communication?
e. To what extent does the offeror already have the hardware, software, equipment, and licenses necessary to perform the contract?
f. Does it appear that offeror can meet the schedule set out in the RFP?
g. Has the contractor gone beyond the minimum tasks necessary to meet the objectives of the RFP?
h. Is the proposal practical, feasible, and within budget?

5.03
Experience and Qualifications
Thirty-Five Percent (35%) of the total possible points will be assigned to this criterion.

If the RFP required a minimum amount of experience or qualifications, no points will be awarded for meeting the minimum. Points will be awarded for experience and qualifications that exceed the stated minimums. Proposals will be evaluated against the questions set out below:

Questions regarding the personnel.

a. Do the individuals assigned to the project have experience on similar projects?
b. Are resumes complete and do they demonstrate backgrounds that would be desirable for individuals engaged in the work the RFP requires?
c. How extensive is the applicable education and experience of the personnel designated to work on the project?

Questions regarding the firm.
d. Has the firm demonstrated experience in completing similar projects on time and within budget?
e. How successful is the general history of the firm regarding timely and successful completion of projects?

f. Has the firm provided letters of reference from previous clients?
g. If a subcontractor will perform work on the project, how well does it measure up to the evaluation used for the offeror?

5.04
Contract Cost
Thirty Percent (30%) of the total possible evaluation points will be assigned to cost.
Any prompt payment discounts terms proposed by the offeror will not be considered in evaluating cost. The cost amount used for evaluation may be affected by the application of North Dakota preference laws (N.D.C.C. § 44-08-01). The lowest cost proposal will receive the maximum number of points allocated to cost. The point allocations for cost on the other proposals will be evaluated according to the method set forth in the Proposal Evaluation form attached to this RFP.

SECTION SIX

PROPOSAL FORMAT AND CONTENT

6.01
Proposal Format and Content
The State discourages overly lengthy and costly proposals; however, in order for the State to evaluate proposals fairly and completely, the offeror must follow the format set out in this RFP and provide all information requested.

6.02
Introduction
Proposals must include the complete name and address of offeror's firm and the name, mailing address, and telephone number of the person the State should contact regarding the proposal.

Proposals must confirm that the offeror will comply with all provisions in this RFP. The proposal must disclose any instances where the firm or any individuals working on the contract has a possible conflict of interest and, if so, the nature of that conflict (e.g. employed by the State of North Dakota).

Proposals must be signed by a company officer empowered to bind the company. An offeror's failure to include these items in the proposals may cause the proposal to be determined to be non-responsive and the proposal may be rejected.

6.03
Understanding of the Project
Offeror must provide comprehensive narrative statements that illustrate its understanding of the requirements of the project, deliverables, project schedule, and contract terms and conditions. Offeror must also identify any pertinent issues and potential problems related to the project.

Offeror must provide comprehensive narrative statements that set out the methodology it intends to employ. Offeror must illustrate how the methodology will serve to accomplish the work and provide the deliverables described in the scope of work within the State's project schedule.

Offeror must provide a comprehensive response to address how they will accomplish the tasks and deliverables specified in Sections 3.01 and 3.06. Responses must be in the same sequence as they appear in Sections 3.01 and 3.06.

6.04
Management Plan for the Project
Offeror must provide comprehensive narrative statements that set out the management plan it intends to follow and illustrate how the plan will serve to accomplish the work and furnish the deliverables described in the scope of work within the State's project schedule. Offeror must provide a narrative or organizational chart that describes the organization of the project team. The organizational chart must illustrate the lines of authority, designate the individual responsible and accountable for the completion of each component and deliverable of the RFP, and indicate where the work will be performed.

6.05
Experience and Qualifications
Offeror must describe the experience of its firm in completing similar projects. Additional, offeror must provide information specific to the personnel assigned to accomplish the work called for in this RFP.

Offeror shall present organizational details including date established, ownership, number of employees, full-time equivalents engaged in similar contracts and any similar contracts terminated for performance reasons including contracting entity and contact name and phone number.

The offeror must provide a narrative description of the organization of the project team and a personnel roster that identifies each person who will actually work on the contract and provide the following

information about each person listed:

a) title;
b) resume including number of years working on similar projects;
c) description of the type of work the individual will perform; and
d) the number of estimated hours for each individual named above.

If an offeror intends to use subcontractors, the offeror must identify in the proposal the names of the subcontractors and describe the experience of the entity or person in completing similar projects. The offeror must provide evidence as set out in the relevant section of this RFP that the subcontractor is registered, and, if applicable, holds a valid North Dakota business license and a written statement signed by each proposed subcontractor that clearly verifies that the subcontractor is committed to render the services required by the contract.

The offeror must provide a narrative description of the organization of the subcontractor project team and a personnel roster that identifies each person who will actually work on the contract. Include the following information about each person listed:

a) title;
b) resume including number of years working on similar projects;
c) description of the type of work the individual will perform; and
d) the number of estimated hours for each individual named above.

Offeror must provide at least three letters of recommendation from three clients from similar projects for whom they have done similar work within the last three years. Include contact person, phone number and email address. References will be asked to confirm:

- That the provider has, under previous agreement, successfully performed work of a similar nature to that detailed in this RFP.
- That the provider met all obligations under the aforementioned agreement with regard to the provision of services, quality of work and completion dates.
- That the provider and all staff conducted themselves in a highly professional and ethical manner.
- That the provider met all obligations to subcontractors.

If unfavorable information is obtained from a reference, the offeror may be deemed as non-responsible and the proposal may be rejected. The State reserves the right to contact any references provided by the offeror. Offeror is invited to provide letters of reference from previous clients.

If subcontractors are proposed, three letters of recommendation should also be submitted for each subcontractor to attest to their work experience. The North Dakota Insurance Department reserves the right to contact the references submitted as well as any other references that may attest to the offeror's work experience specific to the scope of work for this project. Be sure to include current contact information.

Any changes in key personnel will need Insurance Department approval.

6.06
Cost Proposal
Complete attachment three. All costs associated with the contract must be stated in U.S. currency.

6.07
Required Enclosures
Offeror must provide all documents, samples, or other information specifically required in this RFP.

SECTION SEVEN

STANDARD PROPOSAL INFORMATION

7.01
Authorized Signature
An individual authorized to bind the offeror to the provisions of the RFP must sign all proposals.

7.02
State Not Responsible for Preparation Costs
The State will not pay any cost associated with the preparation, submittal, presentation, or evaluation of any proposal.

7.03
Conflict of Interest
Offeror must disclose any instances where the firm or any individuals working on the contract has a possible conflict of interest and, if so, the nature of that conflict (e.g. employed by the State of North Dakota). The State reserves the right to cancel the award if any interest disclosed from any source could either give the appearance of a conflict or cause speculation as to the objectivity of the offeror's proposal. The State's determination regarding any questions of conflict of interest is final.

7.04
Offeror's Certification
By signature on the proposal, an offeror certifies that it complies with:

a) the laws of the State of North Dakota;
b) North Dakota Administrative Code;
c) all applicable local, state, and federal laws, code, and regulations;
d) the applicable portion of the Federal Civil Rights Act of 1964;
e) the Equal Employment Opportunity Act and the regulations issued by the federal government;
f) the Americans with Disabilities Act of 1990 and the regulations issued by the federal government;
g) all terms, conditions, and requirements set forth in this RFP;
h) a condition that the proposal submitted was independently arrived at, without collusion;
i) a condition that the offer will remain open and valid for the period indicated in this solicitation; and
j) a condition that the firm and any individuals working on the contract do not have a possible conflict of interest (e.g. employed by the State of North Dakota).

If any offeror fails to comply with the provisions stated in this paragraph, the State reserves the right to reject the proposal, terminate the contract, or consider the contractor in default.

7.05
Offer Held firm
Proposals must remain open and valid for at least ***90 DAYS*** from the deadline specified for submission of proposals. In the event award is not made within ***90 DAYS***, the State will send a written request to all offerors deemed susceptible for award asking offerors to hold their price firm for a longer specified period of time.

7.06
Amendments to Proposals and Withdrawals of Proposals
Offeror may amend or withdraw proposal prior to the deadline set for receipt of proposals. No amendments will be accepted after the deadline unless they are in response to the State's request. After the deadline, offeror may make a written request to withdraw proposal and provide evidence that a substantial mistake has been made. The procurement officer may permit withdrawal of the proposal upon verifying that a substantial mistake has been made.

7.07
Alternate Proposals
Offeror may submit only one proposal for evaluation.

Alternate proposals (proposals that offer something different than what is requested) will be rejected.

7.08
Subcontractors
Subcontractors may be used to perform work under this contract. If an offeror intends to use subcontractors, the offeror must identify in the proposal the names of the subcontractors and the portions of the work the subcontractors will perform.

Subcontractors may be used to perform work under this contract. If an offeror intends to use subcontractors, the offeror must identify in the proposal the names of the subcontractors and the portions of the work the subcontractors will perform and provide the following:

(a) Complete name of the subcontractor;
(b) Complete address of the subcontractor;
(c) Type of work the subcontractor will be performing;
(d) Percentage of work the subcontractor will be providing;
(e) Evidence, as set out in the relevant section of this RFP, that the subcontractor is registered and, if applicable, holds a valid North Dakota business license; and
(f) A written statement, signed by each proposed subcontractor, that clearly verifies that the subcontractor is committed to render the services required by the contract.

The substitution of one subcontractor for another may be made only at the discretion and prior written approval of the State's procurement officer or project manager designated by the State.

7.09
Joint Ventures
Joint ventures are acceptable. If submitting a proposal as a joint venture, the offeror must submit a copy of the joint venture agreement that identifies the principles involved and its rights and responsibilities regarding performance and payment.

7.10
Disclosure of Proposal Contents and Compliance with North Dakota Open Records Laws
All proposals and other material submitted become the property of the State and may be returned only at the State's option. All proposals and related information, including detailed cost information, are exempt records and will be held in confidence until an award is made, in accordance with N.D.C.C. § 54-44.4-10(2).

Offeror may make a written request that trade secrets and other proprietary data contained in its proposal be held confidential. Material considered confidential by the offeror must be clearly identified, and the offeror must include a brief statement that sets out the reasons for confidentiality. See the North Dakota Office of the Attorney General website for additional information.
http://www.ag.nd.gov/OpenRecords/ORM.htm

After award, proposals will be subject to the North Dakota open records law. Records are closed or confidential only if specifically stated in law. If a request for public information is received, the procurement officer, in consultation with the Office of the Attorney General, will determine whether the information is an exception to the North Dakota open records law, and the information will be processed appropriately.

7.11
Evaluation of Proposals
All proposals will be reviewed to determine if they are responsive to the requirements of this solicitation. The procurement officer or an evaluation committee will evaluate responsive proposals. The evaluation will be based solely on the evaluation factors set forth in this RFP. The evaluation will consider information obtained subsequent to any discussions with offeror determined to be reasonable for award and any demonstrations, oral presentations, or site inspections, if required in this RFP.

7.12
Right of Rejection
The State reserves the right to reject any proposals, in whole or in part. Proposals received from debarred or suspended vendors will be rejected. The procurement officer may reject any proposal that is not responsive to all of the material and substantial terms, conditions, and performance requirements of the RFP.

Offeror may not qualify the proposal nor restrict the rights of the State. If an offeror does so, the procurement officer may determine the proposal to be a non-responsive counter-offer and the proposal may be rejected.

The procurement officer may waive minor informalities that:

- Do not affect responsiveness;
- Are merely a matter of form or format;
- Do not change the relative standing or otherwise prejudice other offers;
- Do not change the meaning or scope of the RFP;
- Are insignificant, negligible, or immaterial in nature;
- Do not reflect a material change in the work; or
- Do not constitute a substantial reservation against a requirement or provision,

The State reserves the right to reject any proposal determined to be not responsive, and to reject the proposal of an offeror determined to be not responsible. The State also reserves the right to refrain from making an award if it determines it to be in its best interest.

7.13
Clarification of Offers
In order to determine if a proposal is reasonably susceptible for award, communications by the procurement officer or the proposal evaluation committee are permitted with an offeror to clarify uncertainties or eliminate confusion concerning the contents of a proposal and determine responsiveness to the RFP requirements. Clarifications may not result in a material or substantive change to the proposal. The initial evaluation may be adjusted because of a clarification under this section.

After receipt of proposals, if there is a need for any substantial clarification or material change in the RFP, an amendment will be issued. The amendment will incorporate the clarification or change, and a new date and time established for new or amended proposals. Evaluations may be adjusted as a result of receiving new or amended proposals.

7.14
Discussions and Best and Final Offers
The State may conduct discussions or request best and final offers with offerors that have submitted proposals determined to be reasonably susceptible for award. The State is not obligated to do so; therefore, vendors should submit their best terms (cost and technical). The purpose of these discussions is to ensure full understanding of the requirements of the RFP and the offeror's proposal. Discussions will be limited to specific sections of the RFP or proposal identified by the procurement officer. Discussions, if held, will be after initial evaluation of proposals by the proposal evaluation committee. If modifications to the proposal are made as a result of these discussions, the modifications must be put in writing.

Offerors with a disability needing accommodation should contact the procurement officer prior to the date set for discussions so that reasonable accommodation can be made.

7.15
Preference Laws
The preference given to a resident North Dakota offeror will be equal to the preference given or required by the state of the nonresident bidder. A "resident" North Dakota bidder, offeror, seller, or contractor is one that has maintained a bona fide place of business within this State for at least one year prior to the date on which a contract was awarded. For a listing of state preference laws, visit the following website:

http://www.oregon.gov/DAS/SSD/SPO/reciprocal_detail.shtml or contact the North Dakota State Procurement Office at 701-328-2740.

7.16
Contract Negotiation
After final evaluation, the procurement officer may negotiate with the offeror of the highest-ranked proposal. Negotiations, if held, will be within the scope of the request for proposals and limited to those items that would not have an effect on the ranking of proposals. If the highest-ranked offeror fails to provide necessary information for negotiations in a timely manner, or fails to negotiate in good faith, the State may terminate negotiations and negotiate with the offeror of the next highest-ranked proposal.

If contract negotiations are commenced, they will be held in Bismarck, North Dakota.

If contract negotiations are held, the offeror will be responsible for all cost including its travel and per diem expenses.

7.17
Failure to Negotiate
If the selected offeror:

- Fails to provide the information required to begin negotiations in a timely manner;
- Fails to negotiate in good faith;
- Indicates it cannot perform the contract within the budgeted funds available for the project; or
- If the offeror and the State, after a good faith effort, cannot come to terms,

the State may terminate negotiations with the offeror initially selected and commence negotiations with the next highest ranked offeror.

7.18
Notice of Intent to Award - Offeror Notification of Selection
After the completion of contract negotiation the procurement officer will issue a written Notice of Intent to Award and send copies to all offerors. The Notice of Intent Award will set out the names and addresses of all offerors and identify the proposal selected for award. The scores and placement of other offerors will not be part of the Notice of Intent to Award.

The successful offeror named in the Notice of Intent to Award is advised not to begin work, purchase materials, or enter into subcontracts relating to the project until both the successful offeror and the State sign the contract.

7.19
Protest and Appeal
North Dakota law provides that an interested party may protest a solicitation.
If an interested party wishes to protest the content of this RFP, the protest must be received, in writing, by the procurement officer at least seven calendar days before the deadline for receipt of proposals.

An interested party may protest the award or proposed award of a contract.
If an offeror wishes to protest the award of a contract or proposed award of a contract, the protest must be received, in writing, by the procurement officer within seven calendar days after the date the Notice of Intent to Award was issued.

SECTION EIGHT
ATTACHMENTS

8.01
Attachments

Attachments

1. Proposal Evaluation Form
2. Contract Form
3. Cost Proposal Format

ATTACHMENT 1

EVALUATION CRITERIA AND SCORING

Person or Firm Name _____

Name of Proposal Evaluation (PEC) Member _____

Date of Review _____

RFP Title/Number _____

THE TOTAL NUMBER OF POINTS USED TO SCORE THIS CONTRACT IS 100

6.03 Understanding of the Project

NOTE:REVISE OR DELETE AS NEEDED.

Weight ***10 Percent***. Maximum Point Value for this Section
100 Points x ***10 Percent*** = ***10 Points***

Rating Scale (***10 POINT*** Maximum)	
Point Value	Explanation
0	None. Not addressed or response of no value
1-3	Fair. Limited applicability
4-5	Good. Some applicability
6-8	Very Good. Substantial applicability
9-10	Excellent. Total applicability

Proposals will be evaluated against the questions set out below. Do not assign points to individual questions, instead, award a total score for each evaluation criterion.

[a] Has the offeror demonstrated a thorough understanding of the purpose and scope of the project?

EVALUATOR'S NOTES _____

_____

[b] How well has the offeror identified pertinent issues and potential problems related to the project?

EVALUATOR'S NOTES _____

_____

[c] Has the offeror demonstrated an understanding of the deliverables the State expects it to provide?

EVALUATOR'S NOTES _____

_____

[d] Has the offeror demonstrated an understanding of the State's time schedule and can meet it?

EVALUATOR'S NOTES _____

_____

[e] Is the proposal submitted responsive to all material requirements in the RFP?

EVALUATOR'S NOTES _____

_____

EVALUATOR'S POINT TOTAL FOR 6.03 _____

6.04 Management Plan for the Project

NOTE: REVISE OR DELETE AS NEEDED.

Weight ***25 Percent***. Maximum Point Value for this Section
100 Points x ***25 Percent*** = ***25 Points***

Rating Scale (***25 POINT*** Maximum)	
Point Value	Explanation
0	None. Not addressed or response of no value
1-6	Fair. Limited applicability
7-12	Good. Some applicability
13-18	Very Good. Substantial applicability
19-25	Excellent. Total applicability

Proposals will be evaluated against the questions set out below. Do not assign points to individual questions, instead, award a total score for each evaluation criterion.

[a] How well does the management plan support all of the project requirements and logically lead to the deliverables required in the RFP?

EVALUATOR'S NOTES _____

_____

[b] How well is accountability completely and clearly defined?

EVALUATOR'S NOTES _____

_____

[c] Is the organization of the project team clear?

EVALUATOR'S NOTES _____

_____

[d] How well does the management plan illustrate the lines of authority and communication?

EVALUATOR'S NOTES _____

_____

[e] To what extent does the offeror already have the hardware, software, equipment, and licenses necessary to perform the contract?

EVALUATOR'S NOTES _____

_____

[f] Does it appear that offeror can meet the schedule set out in the RFP?

EVALUATOR'S NOTES _____

_____

[g] Has the contractor gone beyond the minimum tasks necessary to meet the objectives of the RFP?

EVALUATOR'S NOTES _____

_____

[h] Is the proposal practical, feasible, and within budget?

EVALUATOR'S NOTES _____

_____

EVALUATOR'S POINT TOTAL FOR 6.04 _____

6.05 Experience and Qualifications

Weight ***35 Percent***. Maximum Point Value for this Section
100 Points x ***35 Percent*** = ***35 Points***

Rating Scale (***35 POINT*** Maximum)	
Point Value	Explanation
0	None. Not addressed or response of no value
1-8	Fair. Limited applicability
9-17	Good. Some applicability

18-26	Very Good. Substantial applicability
27-35	Excellent. Total applicability

Proposals will be evaluated against the questions set out below. Do not assign points to individual questions, instead, award a total score for each evaluation criterion.

Questions regarding the personnel.

[a] Do the individuals assigned to the project have experience on similar projects?

EVALUATOR'S NOTES _____

_____

[b] Are resumes complete and do they demonstrate backgrounds that would be desirable for individuals engaged in the work the RFP requires?

EVALUATOR'S NOTES _____

_____

[c] How extensive is the applicable education and experience of the personnel designated to work on the project?

EVALUATOR'S NOTES _____

_____

Questions regarding the firm.

[d] Has the firm demonstrated experience in completing similar projects on time and within budget?

EVALUATOR'S NOTES _____

_____

[e] How successful is the general history of the firm regarding timely and successful completion of projects?

EVALUATOR'S NOTES _____

_____

[f] If references were required, did the references provide information to verify the satisfactory performance of the vendor?

EVALUATOR'S NOTES _____

_____

[g] Has the firm provided letters of reference from previous clients?

EVALUATOR'S NOTES _____

_____

[h] If a subcontractor will perform work on the project, how well does it measure up to the evaluation used for the offeror?

EVALUATOR'S NOTES _____

_____

EVALUATOR'S POINT TOTAL FOR 6.05 _____

6.06 Contract Cost

Weight ***30 Percent***. Maximum Point Value for this Section
100 Points x ***30 Percent*** = ***30 Points***

Rating Scale (***30 POINT*** Maximum)	
Point Value	Explanation
0	None. Not addressed or response of no value
1-10	Fair. Limited applicability
11-20	Good. Some applicability
21-27	Very Good. Substantial applicability
28-30	Excellent. Total applicability

Applying Preference Laws

Any prompt payment discounts terms proposed by the offeror will not be considered in evaluating cost. The cost amount used for evaluation may be affected by the application of North Dakota preference laws (N.D.C.C. § 44-08-01). The preference given to a resident offeror will be equal to the preference given or required by the state of the nonresident offeror (i.e. reciprocal preference).

When evaluating cost proposals from nonresident (out-of-state) offerors, determine whether the offeror's state of residence has a preference law for vendors resident in that state. The cost proposal of the nonresident offeror will be increased by the same percentage of preference given to vendors resident in that state.

For example, if the state law of the nonresident offeror requires a 5% preference for vendors resident in that state, the procurement officer will increase that offeror's cost proposal by 5% before evaluation.

See http://www.oregon.gov/DAS/SSD/SPO/reciprocal_detail.shtml for a list of States Preference Laws or contact the North Dakota State Procurement Office at 701-328-2683.

Converting Cost to Points

After applying any reciprocal preference, the lowest cost proposal will receive the maximum number of points allocated to cost. The point allocations for cost on the other proposals will be determined as follows:

Price of Lowest Cost Proposal
Price of Proposal Being Rated X Total Points for Cost Available = Awarded Points

COST PROPOSAL EVALUATION

EVALUATOR'S POINT TOTAL FOR 6.06 _____

ATTACHMENT 2

SERVICE CONTRACT

SAMPLE PERSONAL SERVICE CONTRACT

The parties to this contract are the State of North Dakota, acting through its North Dakota Insurance Department (STATE) and [contractor's legal name] (CONTRACTOR);

1. SCOPE OF SERVICE

CONTRACTOR, in exchange for the compensation paid by STATE under this contract, agrees to provide the following services:

Analyze options, define requirements, and estimate the time and resources necessary and the price to implement an electronic system that will operate a State health insurance exchange and a Small Business Health Options Program (SHOP) exchange in North Dakota as required by the Patient Protection and Affordable Care Act of 2010 and the Health Care and Education Reconciliation Act of 2010 (collectively referred to as the "Affordable Care Act" or "ACA."

Deliverables

The CONTRACTOR will produce to the State an integrated planning document that combines background research with best practice models and innovation to describe alternatives, cost estimates, timelines and recommendations for implementing and sustaining an Exchange in North Dakota.

The completed planning document must provide viable options and recommendations for development, implementation and sustainability of the best possible Exchange for North Dakota. The document will also estimate costs, expenses and outlay for Exchange implementation and for annual budgets each year through 2019and include a detailed break-down of total cost.

The completed planning document must address:

<u>Governance model</u>

- Organizational structure recommendations including the pros and cons of various structural options for North Dakota, including the feasibility of a state vs. a multistate model
- The advantages and disadvantages of single vs. multiple Exchanges in the State
- The best location of the Exchange in North Dakota in either a quasi-governmental entity, an existing state agency; a new state agency, or a nonprofit entity
- The recommended governance and oversight of the Exchange and its relation to Insurance Department regulatory oversight
- Policies to insure public accountability, transparency, and stakeholder inclusion

<u>North Dakota marketplace demographics</u>

- Number of individuals covered by employer plans including the size of groups, type of plans, percent of employees covered, insured, self insured
- Number of individuals eligible for employer coverage but not enrolled broken down by insured and self insured
- Number of small employers not offering coverage
- Number of individuals covered by full-coverage and individual major medical plans
- Number of individuals in self-insured plans
- Number of individuals in mini-med or limited benefit plans
- Number of individuals enrolled in Medicaid
- Number of individuals enrolled in CHIP
- Number of individuals enrolled in another public plan including dual eligibles

- Number of individuals eligible for Medicaid or CHIP but not enrolled
- Number of individuals not insured
- Number of individuals that will remain uninsured in 2014including the demographics and reasons (such as: not eligible, waiver, chose penalty, other).

North Dakota uninsured demographics

- Income
- Age
- Work status
- Health status
- Household size
- County of residence
- Education/literacy status
- Barriers to coverage
- Electronic communication access/use
- Incentives for being/not being insured

North Dakota insurance marketplace—public and private

- Number of private carriers in each market (individual and small group) and their market share
- Benefit structure—mandated benefits, premiums, out-of-pocket expenses
- Roles of brokers, producers and others
- Compensation structure for navigators, producers, brokers
- Claims information including targeted models for evaluation of claims data and whether any state law changes are needed
- Estimate number of enrollees and premium levels for private plans in Exchange
- Estimate number of enrollees in Medicaid and CHIP through the Exchange
- Estimate the projected "take up" rate for individual and SHOP coverage inside and outside the Exchange, estimate the number of individuals that will cease to receive coverage through CHAND and will instead purchase it through the Exchange, and estimate the number of individuals that will cease to receive coverage through the Federal PCIP and will instead purchase it through the Exchange
- Describe the items or circumstances that will influence insurance carrier behavior and how the State might facilitate expanded insurance carrier participation and competition
- Describe the items or circumstances that will influence employer behavior and how the State might facilitate expanded insurance carrier participation and competition
- Describe the items or circumstances that will influence individual customer behavior and how the State might provide incentives to participate in plans meeting perspectives of diverse customer bases?
- Describe the pros and cons of merging individual and small group markets into one rating pool
- Recommend integration and coordination for enrollment and other/services for individuals within one family but receiving coverage from multiple payers/carriers (e.g. child on Medicaid, mother temporarily Medicaid eligible while pregnant, father covered on employer plan)
- Estimate the projected customer mix relative to health status in the Exchange

Program integration

- Recommend a plan to integrate consumer outreach/education; eligibility determinations, verification, enrollment; premiums collections and plans payment; post-enrollment services including call centers, ombudsmen or other consumer advocacy programs
- Provide cost-benefit analysis of premium aggregation services for the state and small business
- Define formal agreements needed between the Exchange and the Insurance Department that defines roles and responsibilities relative to qualified health plans and strategies for limiting adverse selection
- Provide an analysis of Exchange modeling options with explanation of methods, variables and assumptions

Exchange financial modeling

- Based on ranges of enrollment and premium level estimates
    - Analyze and determine the level of Exchange infrastructure required based on empirical modeling and gaps
    - Include potential revenue sources and expected amounts at various enrollment and premium levels
    - Given various design assumptions, estimate number and type of positions necessary to run an Exchange, salary levels and critical experience needed
    - Evaluate and recommend viable business models to include administrative and other fees required for Exchange break even and cash flow estimates for various revenue and expense estimates through 2019

Ongoing communication with Insurance Department and stakeholders

- Recommend plans for ongoing two-way communication with contractor performing early stakeholder involvement work and Department Exchange planning staff.
- Provide update of work every two weeks to Insurance Department. Consider format that could be disseminated to staff, workgroups and posted online.
- Identify ways to continue to engage stakeholders in welcoming their input on the Exchange
- Identify best practices to educate businesses, consumers and government leaders on the Exchange
- Ultimately make a recommendation to the North Dakota Insurance Department regarding the best way to meet the requirements of the ACA for the State's Exchange.

2. TERM OF CONTRACT

The term of this contract is approximately four (4) months, beginning on August 26, 2011, and ending December 31, 2011.

3. COMPENSATION

STATE will pay for the services provided by CONTRACTOR under this contract an amount not to exceed _____ per _____, to be paid _____.

4. TERMINATION OF CONTRACT

a. Termination without cause. This contract may be terminated by mutual consent of both parties.
b. Termination for lack of funding or authority. STATE, by written notice of default to CONTRACTOR, may terminate the whole or any part of this contract, under any of the following conditions:
    i. If funding from federal, state, or other sources is not obtained and continued at levels sufficient to allow for purchase of the services or supplies in the indicated quantities or term.
    ii. If federal or state laws or rules are modified or interpreted in a way that the services are no longer allowable or appropriate for purchase under this contract or are no longer eligible for the funding proposed for payments authorized by this contract.
    iii. If any license, permit, or certificate required by law or rule, or by the terms of this contract, is for any reason denied, revoked, suspended, or not renewed.

Termination of this contract under this subsection is without prejudice to any obligations or liabilities of either party already accrued prior to termination.

c. Termination for cause. STATE may terminate this contract effective upon delivery of written notice to CONTRACTOR, or any later date stated in the notice:
    i. If CONTRACTOR fails to provide services required by this contract within the time specified or any extension agreed to by STATE; or
    ii. If CONTRACTOR fails to perform any of the other provisions of this contract, or so fails to pursue the work as to endanger performance of this contract in accordance with its terms.

The rights and remedies of STATE provided in this subsection are not exclusive and are in addition to any other rights and remedies provided by law or under this contract.

5. FORCE MAJEURE

CONTRACTOR shall not be held responsible for delay or default caused by fire, flood, riot, acts of God or war if the event is beyond CONTRACTOR'S reasonable control and CONTRACTOR gives notice to STATE immediately upon occurrence of the event causing the delay or default or that is reasonably expected to cause a delay or default.

6. RENEWAL

This contract will not automatically renew. If STATE desires to renew, STATE will provide written notice to CONTRACTOR of its intent to renew this contract at least 60 days before the scheduled termination date.

7. MERGER AND MODIFICATION, CONFLICT IN DOCUMENTS

This Contract, including the following documents, constitutes the entire agreement between the parties. There are no understandings, agreements, or representations, oral or written, not specified within this Contract. This contract may not be modified, supplemented or amended, in any manner, except by written agreement signed by both parties. Notwithstanding anything herein to the contrary, in the event of any inconsistency or conflict among the documents making up this Contract, the documents must control in this order of precedence:

a) The terms of this Contract as may be amended;
b) Solicitation Amendment #__ to Request for Proposal ("RFP") number 401-11-001 dated _____;
c) Request for Proposal ("RFP") number 401-11-001, dated July 18, 2011;
d) CONTRACTOR's proposal dated _____ in response to RFP number 401-11-001.

Any automated end user license agreement is superseded by this contract.

8. SEVERABILITY

If any term of this contract is declared by a court having jurisdiction to be illegal or unenforceable, the validity of the remaining terms is unaffected, and, if possible, the rights and obligations of the parties are to be construed and enforced as if the contract did not contain that term.

9. ASSIGNMENT AND SUBCONTRACTS

CONTRACTOR may not assign or otherwise transfer or delegate any right or duty without STATE'S express written consent. However, CONTRACTOR may enter into subcontracts provided that any subcontract acknowledges the binding nature of this contract and incorporates this contract, including any attachments. CONTRACTOR is solely responsible for the performance of any subcontractor. CONTRACTOR does not have authority to contract for or incur obligations on behalf of STATE.

10. NOTICE

All notices or other communications required under this contract must be given by registered or certified mail and are complete on the date mailed when addressed to the parties at the following addresses:

CONTRACTOR
NAME(S)
ADDRESS
CITY, STATE ZIP CODE

And

Melissa Hauer
North Dakota Insurance Department
600 East Boulevard Avenue, Dept. 401

Bismarck ND 58505

Notice provided under this provision does not meet the notice requirements for monetary claims against the State found at N.D.C.C. § 32-12.2-04.

11. APPLICABLE LAW AND VENUE

This contract is governed by and construed in accordance with the laws of the State of North Dakota. Any action to enforce this contract must be adjudicated exclusively in the State District Court of Burleigh County, North Dakota.

12. SPOLIATION – NOTICE OF POTENTIAL CLAIMS

CONTRACTOR shall promptly notify STATE of all potential claims that arise or result from this contract. CONTRACTOR shall also take all reasonable steps to preserve all physical evidence and information that may be relevant to the circumstances surrounding a potential claim, while maintaining public safety, and grants to STATE the opportunity to review and inspect the evidence, including the scene of an accident.

13. INDEMNITY

CONTRACTOR agrees to defend, indemnify, and hold harmless the STATE of North Dakota, its agencies, officers and employees, from and against claims based on the vicarious liability of the STATE or its agents, but not against claims based on the STATE's contributory negligence, comparative and/or contributory negligence or fault, sole negligence, or intentional misconduct.

This obligation to defend, indemnify, and hold harmless does not extend to professional liability claims arising from professional errors and omissions. The legal defense provided by CONTRACTOR to the STATE under this provision must be free of any conflicts of interest, even if retention of separate legal counsel for the STATE is necessary. CONTRACTOR also agrees to defend, indemnify, and hold the STATE harmless for all costs, expenses and attorneys' fees incurred if the STATE prevails in an action against CONTRACTOR in establishing and litigating the indemnification coverage provided herein. This obligation shall continue after the termination of this agreement.

14. INSURANCE

CONTRACTOR shall secure and keep in force during the term of this agreement and CONTRACTOR shall require all subcontractors, prior to commencement of an agreement between CONTRACTOR and the subcontractor, to secure and keep in force during the term of this agreement, from insurance companies, government self-insurance pools or government self-retention funds, authorized to do business in North Dakota, the following insurance coverage:

a. Commercial general liability, including premises or operations, contractual, and products or completed operations coverage (if applicable), with minimum liability limits of $250,000 per person and $1,000,000 per occurrence.
b. Employer's liability or "stop gap" insurance of not less than $1,000,000 as an endorsement on the workers compensation or commercial general liability insurance.
c. Professional errors and omissions, including a three year "tail coverage endorsement," with minimum liability limits of $1,000,000 per occurrence and in the aggregate.
d. Automobile liability, including Owned (if any), Hired, and Non-Owned automobiles, with minimum liability limits of $250,000 per person and $500,000 per occurrence.
e. Workers compensation coverage meeting all statutory requirements. The policy shall provide coverage for all states of operation that apply to the performance of this contract.

The insurance coverage listed above must meet the following additional requirements:

a. Any deductible or self-insured retention amount or other similar obligation under the policies shall be the sole responsibility of the CONTRACTOR.
b. This insurance may be in policy or policies of insurance, primary and excess, including the so-called umbrella or catastrophe form and must be placed with insurers rated "A-" or better by A.M.

Best Company, Inc., provided any excess policy follows form for coverage. Less than an “A-” rating must be approved by the STATE. The policies shall be in form and terms approved by the STATE.

c. The duty to defend, indemnify, and hold harmless the STATE under this agreement shall not be limited by the insurance required in this agreement
d. The STATE of North Dakota and its agencies, officers, and employees (STATE) shall be endorsed on the commercial general liability policy, including any excess policies (to the extent applicable), as additional insured. The STATE shall have all the benefits, rights and coverage of an additional insured under these policies.
e. The insurance required in this agreement, through a policy or endorsement, shall include:
    i. “Waiver of Subrogation” waiving any right to recovery the insurance company may have against the STATE;
    ii. a provision that the policy and endorsements may not be canceled or modified without thirty (30) days’ prior written notice to the undersigned STATE representative;
    iii. a provision that any attorney who represents the STATE under this policy must first qualify as and be appointed by the North Dakota Attorney General as a Special Assistant Attorney General as required under N.D.C.C. § 54-12-08;
    iv. a provision that CONTRACTOR’s insurance coverage shall be primary (i.e. pay first) as respects any insurance, self-insurance or self-retention maintained by the STATE and that any insurance, self-insurance or self-retention maintained by the STATE shall be in excess of the CONTRACTOR’s insurance and shall not contribute with it;
    v. cross liability/severability of interest for all policies and endorsements;
    vi. The legal defense provided to the STATE under the policy and any endorsements must be free of any conflicts of interest, even if retention of separate legal counsel for the STATE is necessary;
    vii. The insolvency or bankruptcy of the insured CONTRACTOR shall not release the insurer from payment under the policy, even when such insolvency or bankruptcy prevents the insured CONTRACTOR from meeting the retention limit under the policy.
f. The CONTRACTOR shall furnish a certificate of insurance to the undersigned STATE representative prior to commencement of this agreement. All endorsements shall be provided as soon as practicable.
g. Failure to provide insurance as required in this agreement is a material breach of contract entitling the STATE to terminate this agreement immediately.

The insurance coverage listed above must meet the following additional requirements:

a. Any deductible or self-insured retention amount or other similar obligation under the policies shall be the sole responsibility of the CONTRACTOR. The amount of any deductible or self retention is subject to approval by the STATE.
b. This insurance may be in policy or policies of insurance, primary and excess, including the so-called umbrella or catastrophe form and must be placed with insurers rated “A-” or better by A.M. Best Company, Inc., provided any excess policy follows form for coverage. Less than an “A-” rating must be approved by the STATE. The policies shall be in form and terms approved by the STATE.
c. The insurance required in this agreement, through a policy or endorsement, shall include a provision that the policy and endorsements may not be canceled or modified without 30 days’ prior written notice to the undersigned STATE representative.
d. CONTRACTOR shall furnish a certificate of insurance to the undersigned STATE representative prior to commencement of this agreement.

e. Failure to provide insurance as required in this agreement is a material breach of contract entitling STATE to terminate this agreement immediately.

15. ATTORNEY FEES

In the event a lawsuit is instituted by STATE to obtain performance due under this contract, and STATE is the prevailing party, CONTRACTOR shall, except when prohibited by N.D.C.C. § 28-26-04, pay STATE'S reasonable attorney fees and costs in connection with the lawsuit.

16. ALTERNATIVE DISPUTE RESOLUTION – JURY TRIAL

STATE does not agree to any form of binding arbitration, mediation, or other forms of mandatory alternative dispute resolution. The parties have the right to enforce their rights and remedies in judicial proceedings. STATE does not waive any right to a jury trial.

17. CONFIDENTIALITY

CONTRACTOR shall not use or disclose any information it receives from STATE under this contract that STATE has previously identified as confidential or exempt from mandatory public disclosure except as necessary to carry out the purposes of this contract or as authorized in advance by STATE. STATE shall not disclose any information it receives from CONTRACTOR that CONTRACTOR has previously identified as confidential and that STATE determines in its sole discretion is protected from mandatory public disclosure under a specific exception to the North Dakota open records law, N.D.C.C. § 44-04-18. The duty of STATE and CONTRACTOR to maintain confidentiality of information under this section continues beyond the term of this contract.

18. COMPLIANCE WITH PUBLIC RECORDS LAW

CONTRACTOR understands that, except for disclosures prohibited in this contract, STATE must disclose to the public upon request any records it receives from CONTRACTOR. CONTRACTOR further understands that any records that are obtained or generated by CONTRACTOR under this contract, except for records that are confidential under this contract, may, under certain circumstances, be open to the public upon request under the North Dakota open records law. CONTRACTOR agrees to contact STATE immediately upon receiving a request for information under the open records law and to comply with STATE'S instructions on how to respond to the request.

19. WORK PRODUCT, EQUIPMENT AND MATERIALS

All work product, equipment or materials created or purchased under this contract belong to STATE and must be delivered to STATE at STATE'S request upon termination of this contract. CONTRACTOR agrees that all materials prepared under this contract are "works for hire" within the meaning of the copyright laws of the United States and assigns to STATE all rights and interests CONTRACTOR may have in the materials it prepares under this contract, including any right to derivative use of the material. CONTRACTOR shall execute all necessary documents to enable STATE to protect its rights under this section.

20. INDEPENDENT ENTITY

CONTRACTOR is an independent entity under this contract and is not a STATE employee for any purpose, including the application of the Social Security Act, the Fair Labor Standards Act, the Federal Insurance Contribution Act, the North Dakota Unemployment Compensation Law and the North Dakota Workforce Safety and Insurance Act. CONTRACTOR retains sole and absolute discretion in the manner and means of carrying out CONTRACTOR'S activities and responsibilities under this contract, except to the extent specified in this contract.

21. NONDISCRIMINATION AND COMPLIANCE WITH LAWS

CONTRACTOR agrees to comply with all laws, rules, and policies, including those relating to nondiscrimination, accessibility and civil rights. CONTRACTOR agrees to timely file all required reports, make required payroll deductions, and timely pay all taxes and premiums owed, including sales and use taxes and unemployment compensation and workers' compensation premiums. CONTRACTOR shall

have and keep current at all times during the term of this contract all licenses and permits required by law.

22. STATE AUDIT

All records, regardless of physical form, and the accounting practices and procedures of CONTRACTOR relevant to this contract are subject to examination by the North Dakota State Auditor or the Auditor's designee. CONTRACTOR shall maintain all such records for at least three years following completion of this contract.

23. PREPAYMENT

The STATE will not make any advance payments before performance by CONTRACTOR under this contract.

24. TAXPAYER ID

CONTRACTOR'S federal employer ID number is: _____.

25. PAYMENT OF TAXES BY STATE

The STATE is not responsible for and will not pay local, state, or federal taxes. State sales tax exemption number is E-2001, and certificates will be furnished upon request by the STATE.

26. EFFECTIVENESS OF CONTRACT

This contract is not effective until fully executed by both parties.

CONTRCTOR	STATE OF NORTH DAKOTA Acting through its North Dakota Insurance Department
_____ (Company Name)	
By:_____	By:_____
Title:_____	Title:_____
Date:_____	Date:_____

ATTACHMENT 3

COST PROPOSAL FORMAT

Cost proposals are to be submitted in a separate sealed envelope or package, clearly labeled “cost proposal.”

Offerors must use the following line items in the cost proposals submitted:

Personnel			
Staff Name/Title	**Hourly Rate**	**Estimated Hours**	**Amount**
1.			
2.			
3.			
4.			
5.		Personnel Total	
Other Expenses			
Item	**Quantity**	**Cost**	**Amount**
Direct			
		Total Direct Costs	
Indirect			
		Total Indirect Costs	
		Total Costs	

*Total costs must not exceed $250,000.

STATE OF NORTH DAKOTA

North Dakota Insurance Department
600 East Boulevard Avenue
Bismarck, ND 58505-0320

QUESTIONS AND ANSWERS

RFP Title: North Dakota Health Benefit Exchange Consultant
RFP No. 401-11-001
July 29, 2011

Section 1.03 of the solicitation established a deadline for receipt of questions. The responses to these questions are provided as addenda to the solicitation.

1. **Question:** Section 1.04 (p. 5) – This section indicates that an electronically transmitted signed proposal is acceptable by the State as long as it is received by the due date/time. This suggests that an original proposal document, signed in ink, is not required to be submitted. Please clarify.

   Answer: Section 1.04 states that "Proposals may not be delivered orally, by facsimile transmission, by other telecommunication or electronic means." No amendment is necessary.

2. **Question:** Section 2.02 (p. 8) and Section 3.02 (p. 12) – We have reviewed these sections along with RFP Attachment 3 and we understand that the cost proposal must include travel costs. Please clarify whether the maximum $250,000 budget amount is inclusive or exclusive of travel costs.

   Answer: As stated in Section 3.02, "The contractor should include in its price proposal: transportation, lodging, and per diem costs…" As stated in Section 2.02, "Proposals priced at more than $250,000 will be considered nonresponsive." The maximum budget includes travel costs. No amendment is necessary.

3. **Question:** Section 3.05 – Federal Requirements (p. 12) – This section states that, "The offeror must identify all known federal requirements that apply to the proposal, the evaluation, or the contract." Please clarify what is required for the bidder to include in their proposal relative to this RFP requirement.

Answer: The RFP states in Section 3.01 – Scope of Work on page 12:

> ***Directives***
> Federal laws and regulations, state laws and administrative rules, federal directives and guidance, and federal regulations or requirements concerning grants may influence the contract. These directives are contained in the Affordable Care Act (ACA), federal regulations implementing the ACA, state laws and the North Dakota Administrative Code Title 45, as well as federal guidance and directives. ACA regulations are subject to change, and additional ACA regulations may be released during the time of this contract.

Since Section 3.01 – Scope of Work already identifies the source of certain federal requirements, an offeror may exclude any federal requirements stated in Section 3.01 from its response to Section 3.05 – Federal Requirements. In addition, Section 21 of the contract Attachment 2 provides that Contractor agrees to comply with all laws, rules, and policies, including those relating to nondiscrimination, accessibility and civil rights, and to timely file all required reports, make required payroll deductions, and timely pay all taxes and premiums owed. An offeror may also exclude any federal requirements stated in the contract Attachment 2 from its response to Section 3.05 – Federal Requirements. No amendment is necessary.

4. **Question:** Section 4.03 – Standard Contract Provisions (p. 14) – This section states that, "Any objections to the contract provisions must be set out in the offeror's proposal." Should the bidder have any suggested contract language for the State to consider, please clarify where in the proposal this information should be placed.

   Answer: There is no specified place within the proposal that this information must be placed. There is no requirement beyond what is stated in Section 4.03. No amendment is necessary.

5. **Question:** According to RFP Section 3.07, the final planning document is due December 2, 2011. It is our understanding that Federal funding expires on September 30, 2011; is the State under the impression that it will get an extension from HHS?

   Answer: Section 3.07 says, in part, "The approximate contract schedule is as follows . . . Contractor submits final report: December 2, 2011." The North Dakota Insurance Department requested a No Cost Extension from HHS for the Exchange planning grant on July 19, 2011. No amendment is necessary.

6. **Question:** Does the State have the data necessary for the research analyses or will data collection be expected as part of this project: For example, the Marketplace Demographics list on page 10 of the RFP.

Answer: Any publicly available information that is available within the Insurance Department will be provided to the contracted entity. Contact information for other potential sources of information will be provided as available; however, the contracted entity will be responsible for searching for and collecting all data. See Section 3.01 – Scope of Work for RFP content addressing the undertakings of the offeror and the State. No amendment is necessary.

7. **Question:** Is an IT needs assessment or a gap analysis part of the scope of services under this RFP? If not, will that information be available for the contractor selected under this RFP?

   Answer: See Section 3.01 – Scope of Work. An information technology (IT) needs assessment or gap analysis is not an individually articulated part of the scope of this RFP. However, the successful offeror must take into account all relevant factors in recommendations for the governance model (RFP Section 3.01 page 10) and financial modeling (RFP Section 3.01 page 11). No amendment is necessary.

8. **Question:** Is the State anticipating a cost component model to be developed (as part of this project) that will provide the different alternatives of an Exchange to the State? For example, this model would provide the State the guidance to build, buy, or outsource Exchange functions.

   Answer: See Section 3.01 – Scope of Work. The successful offeror must take into account all relevant factors in recommendations for the governance model (RFP Section 3.01, p. 10) and financial modeling (RFP Section 3.01 page 11). No amendment is necessary.

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Part II

Department of Health and Human Services

45 CFR Parts 155 and 156

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

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.

Table of Contents

I. Background
A. Legislative Overview
1. Legislative Requirements for Establishing Exchanges
2. Legislative Requirements for Related Provisions
B. Request for Comment
C. Structure of the Proposed Rule
II. Provisions of the Proposed Regulation
A. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act
1. Subpart A—General Provisions
2. Subpart B—General Standards Related to the Establishment of an Exchange by a State
3. Subpart C—General Functions of an Exchange
4. Subpart D—Reserved
5. Subpart E—Exchange Functions in the Individual Market: Enrollment in Qualified Health Plans
6. Subpart F—Reserved
7. Subpart G—Reserved
8. Subpart H—Exchange Functions: Small Business Health Options Program (SHOP)
9. Subpart I—Reserved
10. Subpart J—Reserved
11. Subpart K—Exchange Functions: Certification of Qualified Health Plans
B. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges
1. Subpart A—General Provisions
2. Subpart B—Reserved
3. Subpart C—Qualified Health Plan Minimum Certification Standards
III. Collection of Information Requirements
IV. Summary of Regulatory Impact Analysis
V. Regulatory Flexibility Act
VI. Unfunded Mandates
VII. Federalism
VIII. Regulations Text

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

codify these requirements under this authority in part 156, subpart C.

B. Stakeholder Consultation and Input

On August 3, 2010, HHS published a Request for Comment (the RFC) inviting the public to provide input regarding the rules that will govern the Exchanges. In particular, HHS asked States, tribal representatives, consumer advocates, employers, insurers, and other interested stakeholders to comment on the types of standards Exchanges should be required to meet. The comment period closed on October 4, 2010. This proposed rule does not directly respond to comments from the RFC; however, the comments received are described at the beginning of each subpart and referred to, where applicable, when discussing specific regulatory proposals.

The public response to the RFC yielded comment submissions from consumer advocacy organizations, medical and health care professional trade associations and societies, medical and health care professional entities, health insurers, insurance trade associations, members of the general public, and employer organizations. The majority of the comments were related to the general functions and requirements for Exchanges, QHPs, eligibility and enrollment, and coordination with Medicaid. We intend to respond to comments from the RFC, along with comments received on this proposed rule, as part of the final rule.

In addition to the RFC, HHS has consulted with stakeholders through weekly meetings with the National Association of Insurance Commissioners (NAIC), regular contact with States through the Exchange grant process, and meetings with tribal representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties. This consultation will continue throughout the development of Exchange guidance.

C. Structure of the Proposed Rule

The regulations outlined in this notice of proposed rulemaking will be codified in the new 45 CFR parts 155 and 156. Part 155 outlines the proposed standards for States relative to the establishment of Exchanges and outlines the proposed standards required of Exchanges related to minimum Exchange functions. Part 156 outlines the proposed standards for health insurance issuers with respect to participation in an Exchange, including the minimum certification requirements for QHPs. Many provisions in part 155 have parallel requirements under part 156 because the Affordable Care Act creates complementary responsibilities for Exchanges and QHP issuers. Where possible, there are cross-references between parts 155 and 156 to avoid redundancy.

Subjects included in the Affordable Care Act to be addressed in separate rulemaking include but are not limited to: (1) Standards for individual eligibility for participation in the Exchange, advance payments of the premium tax credit, cost-sharing reductions, and related health programs and appeals of eligibility determinations; (2) standards outlining the Exchange process for issuing certificates of exemption from the individual responsibility requirement and payment under section 1411(a)(4); (3) defining essential health benefits, actuarial value and other benefit design standards; and (4) standards for Exchanges and QHP issuers related to quality.

We note that the health plan standards set forth under this proposed rule are, for the most part, strictly related to QHPs offered through the Exchange and not the entire individual and small group market. Various sections added to the Public Health Service (PHS) Act, and incorporated by reference into ERISA and the Code, by the Affordable Care Act extend some of the requirements in this proposed rule to the non-QHP market. Such requirements for the entire individual and small and large group markets already have been, and will continue to be, addressed in separate rulemaking issued by HHS, and the Departments of Labor and the Treasury.

II. Provisions of the Proposed Regulation

A. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act

1. Subpart A—General Provisions

a. Basis and Scope (§ 155.10)

Section 155.10 of subpart A specifies the general statutory authority for and scope of standards proposed in part 155 that establish minimum requirements for the State option to establish an Exchange, minimum Exchange functions, enrollment periods, minimum SHOP functions, and certification of QHPs. In general, this NPRM is based on the broad rulemaking authority of 1321(a)(1) as well as other specific statutory provisions identified in the preamble where appropriate.

b. Definitions (§ 155.20)

Under § 155.20, we set forth definitions for terms that are used throughout part 155. For the most part, the definitions presented in § 155.20 are taken directly from the Affordable Care Act or from existing regulations, unless otherwise specified. Some new definitions were created for the purposes of carrying out regulations proposed in part 155. When a term is defined in part 155 other than in subpart A, the definition of the term is applicable only to the relevant subpart or section. The application of the terms defined in this section is limited to this proposed rule.

Several terms are defined by the Affordable Care Act, including ''individual market'' (section 1304(a)(2)), ''small group market'' (section 1304(b)(2)), ''qualified employer'' (section 1312(f)(2)), ''qualified individual'' (section 1312(f)(1)), ''qualified health plan'' (section 1301(a)(1)), ''cost sharing'' (section 1302(c)(3)), ''Navigator'' (section 1311(i)), ''plain language'' (section 1311(e)(3)(B)), ''health plan'' (section 1301(b)(1)), ''eligible employer-sponsored plan'' and ''minimum essential coverage'' (section 5000A(f)(1) of the Code, as added by section 1501(f)), ''large employer'' and ''small employer'' (section 1304(b)), and ''State'' (section 1304(d)). The term ''Code'' refers to the Internal Revenue Code of 1986.

The definition for an ''Exchange'' in § 155.20 is drawn from the statutory text in section 1311(d)(1) and 1311(d)(2)(A). We interpret section 1321(c) of the Affordable Care Act to mean that this definition includes an Exchange established or operated by the Federal government if a State does not establish an Exchange. Also, pursuant to section 1311(b)(1)(B), we interpret the term ''Exchange'' to be inclusive of the operation of a SHOP, which we define based on that section as well.

Some definitions were taken from other interim final regulations issued previously pursuant to the Affordable Care Act, including the term ''lawfully present'' from § 152.2 of this chapter and the term ''grandfathered plan'' from § 147.140 of this chapter. The definitions for the terms ''group health plan,'' ''health insurance issuer,'' and ''health insurance coverage'' are cross-referenced to the definitions established in § 144.103. The definition for the term ''employee'' is taken from the PHS Act, which refers to section 3(6) of ERISA. Under ERISA, the term employee means any individual employed by an employer. The definition of ''employer'' is taken as well from the PHS Act, which refers to section 3(5) of ERISA. We note that coverage for only a sole proprietor, certain owners of S corporations, and certain relatives of

each of the above would not constitute a group health plan under ERISA section 732(a) (29 U.S.C. section 1191a(a)) and would not be entitled to purchase in the small group market under Federal law.

We create several definitions regarding eligibility and enrollment for the purpose of this proposed rule, including ''advance payments of the premium tax credit,'' ''annual open enrollment period,'' ''applicant,'' ''cost-sharing reductions,'' ''initial enrollment period,'' and ''special enrollment period.'' Several other definitions used throughout this proposed rule are established for various purposes, including the terms: ''agent or broker,'' ''benefit year,'' ''enrollee,'' ''plan year,'' and ''Exchange service area.''

In the following paragraphs, we discuss the proposed definitions where more clarity is warranted. We note that we interpret the term ''cost sharing'' as defined in section 1302(c)(3) of the Affordable Care Act to apply to payments for deductibles, copayments, coinsurance or similar charges related to the essential health benefits only. This is consistent with the definition of actuarial value in section 1302(d)(2) of the Affordable Care Act, which specifies that actuarial value shall apply only to the essential health benefits; section 1402(c)(4), which applies cost-sharing reductions only to essential health benefits; and section 1302(c)(3)(ii), which applies any other payments only to essential health benefits.

The term ''qualified employer'' is defined in section 1312(f)(2) of the Affordable Care Act as a small employer that elects to make, at a minimum, all full-time employees eligible for coverage in a qualified health plan. While the definition indicates that a qualified employer is a ''small employer,'' the Affordable Care Act provides that, beginning in 2017, States will have the option to allow issuers to offer QHPs in the large group market through the SHOP. The Affordable Care Act also defines a small employer, for the purposes of health coverage, as an employer with at least one but not more than 100 employees. Pursuant to 1304(b)(3), each State has the option to limit small employers to having no more than 50 employees until 2016. We clarify that the scope of the term qualified employer is expected to vary among States and over time. The term ''qualified employee'' refers to employees offered coverage through a SHOP by a qualified employer.

We propose several terms to define an individual's participation in an Exchange at different periods in the process for individuals, employers, or employees. The terms are ''applicant,'' ''qualified individual/qualified employer/qualified employee,'' and ''enrollee.'' An applicant is an individual who is seeking an eligibility determination to enroll in a QHP in the Exchange, to receive advance payments of the premium tax credit or cost-sharing reductions, or to receive benefits through other State health programs. In the context of a SHOP, the term applicant indicates an employer or employee. The term ''qualified individual'' is based on section 1312(f)(1) of the Affordable Care Act. Although the Affordable Care Act does not specifically indicate in section 1312(f)(1) that a qualified individual is one who has been determined eligible to participate in an Exchange, we have interpreted it and propose to use the term to mean that the individual has been determined eligible based on the context in which the term is used in other provisions. For example, section 1312(d)(3)(C) states that ''a qualified individual may enroll in any qualified health plan'' and section 1311(d)(2) states that ''an Exchange shall make available qualified health plans to qualified individuals and qualified employers.'' These provisions suggest that a qualified individual is one who is already determined eligible to participate in an Exchange. Similarly, ''qualified employee'' and ''qualified employer'' are terms to indicate an employee or employer that has been determined eligible to participate in a SHOP.

We propose to use the term ''enrollee'' to describe a qualified individual or qualified employee who has enrolled in a QHP. Although not a defined term, we use the word ''consumer'' throughout discussion in this NPRM. We generally use the term to mean qualified individuals, qualified employers, or qualified employees, as indicated by the context. In some places, the term may be used to generally describe any potential purchaser of health coverage.

For the purposes of this proposed rule, any reference to the term ''issuer,'' meaning a health insurance issuer, qualified health plan issuer, or QHP issuer, is used in making reference to requirements on or actions taken by the entity that offers health plans. A ''health plan,'' ''qualified health plan,'' or ''QHP'' is defined as a discrete combination of benefits and cost-sharing that is offered by a health insurance issuer and in which an individual or group can enroll.

We propose to define ''health plan'' in accordance with section 1301(b)(1) of the Affordable Care Act to encompass health insurance coverage and a group health plan. The Affordable Care Act specifies that, except to the extent specified, the term ''health plan'' shall not include a group health plan or multiple employer welfare arrangement (MEWA) to the extent the plan or arrangement is not subject to State insurance regulation under section 514 of ERISA. However, we recognize that section 514 of ERISA allows State regulations of MEWAs, provided that such regulation does not conflict with standards of ERISA. We request comment on how to reconcile this inconsistency. We have also received questions about whether Taft-Hartley plans and church plans can participate in the Exchange. We request comment on how such plans could potentially provide coverage opportunities through the Exchange.

We recognize that the term health plan is sometimes used colloquially in a way that is interchangeable with health insurance issuer, but for the sake of clarity we refer to the entity offering coverage as the issuer and the coverage being purchased as the health plan within this proposed rule.

For the purposes of this proposed rule, the term ''qualified health plan'' denotes a health plan that is certified to be offered through an Exchange as a QHP, while a ''qualified health plan issuer'' is an issuer that is subject to requirements in this proposed rule related to the offering of QHPs through the Exchange. We note that ''QHP issuer'' and ''health insurance issuer'' generally refer to the same entity, but the former is used to describe a health insurance issuer that is offering a QHP through an Exchange, and therefore, must meet the requirements set forth in this NPRM related to such offerings. As a general theme, we use the word ''qualified'' to denote an individual or an entity eligible to participate, where applicable, in an Exchange or a product eligible to be offered through the Exchange. In this proposed rule, ''qualified health plan'' only refers to those QHPs that are certified by and offered through an Exchange; however, a QHP issuer is not precluded from offering the certified QHP outside of an Exchange.

We include two separate terms related to defining the time an individual or family is covered by health insurance: ''Benefit year'' and ''plan year.'' Benefit year refers to coverage that begins on January 1 and lasts for the duration of a calendar year. This is typically used to refer to coverage in the individual market. ''Plan year'' is used to refer to any rolling consecutive 12-month period of coverage. This is typically used when referring to coverage through

the small group market, which becomes effective on a rolling basis depending on when the small employer first offers or purchases the health plan.

The terms ''eligible employer-sponsored plan'' and ''minimum essential coverage'' have the meaning provided in statute and applicable regulations. In accordance with section 36B(c)(2)(B) of the Code, as added by section 1401(a) of the Affordable Care Act, an individual is ineligible for advance payments of the premium tax credit if he or she is eligible for ''minimum essential coverage'' (other than coverage in the individual market), which includes coverage through an ''eligible employer-sponsored plan.'' However, section 36B(c)(2)(C) of the Code specifies exceptions under which an individual who is eligible for an ''eligible employer-sponsored plan'' is eligible for advance payments of the premium tax credit; specifically, if such coverage is unaffordable or does not meet a minimum value requirement.

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

The Affordable Care Act sets forth general standards related to the establishment of a State Exchange and provides a number of areas where States that choose to operate an Exchange may exercise discretion in making decisions about Exchange operations. Under the statute, States have choices regarding the structure and governance of their Exchanges. For example, a State may establish an Exchange as a State agency or as a non-profit organization, and may choose to contract with other eligible entities to carry out various functions of the Exchange. A State may also choose to partner with other States to form a regional Exchange, or may establish one or more subsidiary Exchanges within the State. This subpart sets forth approval standards for State Exchanges as well as the process by which HHS will determine whether a State Exchange meets those standards.

HHS has pursued various forms of collaboration with the States to facilitate, streamline and simplify the establishment of an Exchange in every State. These efforts have made it clear that for a variety of reasons including reducing redundancy, promoting efficiency, and addressing the tight implementation timelines authorized under the Affordable Care Act, States may find it advantageous to draw on a combination of their own work plus business services developed by other States and the Federal government as they move toward certification. Some States have expressed a preference for a flexible State partnership model combining State-designed and operated business functions with Federally-designed and operated business functions. Examples of such shared business functions might include eligibility and enrollment, financial management, and health plan management systems and services. We note that States have the option to operate an exclusively State-based Exchange. HHS is exploring different partnership models that would meet the needs of States and Exchanges.

In response to the RFC, we received numerous comments related to the establishment of State Exchanges. In general, the comments focused on how to balance the need for State flexibility against the need for consistency. We also received numerous comments related to the governance structure of the Exchanges and the establishment of regional or subsidiary Exchanges. We considered these comments as we developed the proposed rule.

a. Establishment of a State Exchange (§ 155.100)

Sections 1311(b) and 1321(b) of the Affordable Care Act provide each State with the option to elect to establish an Exchange for the individual and small group markets. We propose to codify this option in paragraph (a).

In paragraph (b), we propose to codify section 1311(d)(1) of the Affordable Care Act that an Exchange must be a governmental agency or non-profit entity established by the State. We also propose that the governance structure of the Exchange must be established and operated consistent with the requirements in § 155.110. A governmental agency could be an existing State executive branch agency or an independent public agency. When reviewing the types of governmental agencies that could serve as an Exchange, States should consider the costs and benefits of utilizing the accountability structure within an existing agency versus the need to establish a governing body for an independent public agency. Additionally, each State will need to follow its own laws related to the establishment of non-profit organizations. A State could operate an Exchange through an existing non-profit that was established by a State, or by establishing a new non-profit organization or corporation. Under any scenario, the management structure of the Exchange must be accountable for Exchange oversight and performance.

While a number of commenters on the RFC expressed concern over the operation of Exchanges by non-profit entities, we do not propose to limit the States' discretion to choose this type of entity beyond the minimum standards proposed in § 155.110. However, we note that States should consider the relative merits of operating an Exchange through a non-profit entity. Non-profit entities may be able to operate without some of the restrictions that can limit the flexibility of governmental agencies; however, non-profit entities may face limitations performing functions that are typically governmental in nature. In light of these concerns, we note suggestions by some commenters that States consider establishing independent public/governmental agencies with flexible hiring and operational practices or establishing non-profit entities with governing bodies that are appointed and overseen by States.

b. Approval of a State Exchange (§ 155.105)

In paragraph (a) of proposed § 155.105, we propose to codify section 1321(c)(1)(B) of the Affordable Care Act that directs the Secretary to determine by January 1, 2013 whether a State's Exchange will be fully operational by January 1, 2014. We believe that ''fully operational'' means that an Exchange is capable of beginning operations by October 1, 2013 to support the initial open enrollment period proposed in § 155.410. HHS will make this determination through applying the State Exchange approval standards and process established in this section.

In paragraph (b), we outline the standards upon which HHS will approve a State Exchange. First, an Exchange must be established consistent with this subpart and be capable of carrying out the required functions of an Exchange consistent with the subparts contained within this part, including: subpart C related to minimum Exchange functions; subpart E related to enrollment; subpart H related to the operation of a SHOP; and subpart K related to certification of QHPs. Second, an Exchange must be able to comply with the information requirements established pursuant to section 36B of the Code with respect to advance payments of the premium tax credit and in accordance with future rulemaking. Third, a State seeking approval of an Exchange must agree to perform its responsibilities related to the operation of a reinsurance program, set forth in the proposed rule, the Affordable Care Act; Standards Related to Reinsurance, Risk Corridors and Risk Adjustment published in this issue of the Federal Register. According to section 1341 of the Affordable Care Act, each State must

include in the standards it adopts under section 1321(b) related to the election to operate a State Exchange the Federal requirements for State reinsurance programs, and must also establish or enter into a contract with one or more applicable reinsurance entities to carry out the reinsurance program.

Finally, the entire geographic area of a State must be covered by one or more Exchanges. A State could meet this requirement by having a combination of a regional Exchange and one or more subsidiary Exchanges although to minimize consumer confusion, only one Exchange may operate in each geographically distinct area. To the extent that more than one Exchange is established in a State, we encourage each Exchange to ensure that consumers understand which Exchange they should utilize to access health insurance coverage.

In paragraph (c), we outline the process through which HHS will approve a State Exchange. In paragraph (c)(1), we propose that to initiate the State Exchange approval process, a State must elect to establish an Exchange by submitting an Exchange Plan to HHS, which constitutes the State's application for approval of its Exchange. The Exchange Plan will be submitted through a procedure to be described in additional guidance. As part of the Exchange Plan, the State will be asked to provide detailed information on how it will meet each of the standards described in paragraph (b) of this section. We expect that the Exchange Plan will include copies of any agreements into which the Exchange has entered to carry out one or more of the Exchange's responsibilities in accordance with § 155.110, as well as additional supporting documentation. We plan to issue a template outlining the required components of the Exchange Plan, subject to the notice and comment process under the Paperwork Reduction Act. States are encouraged to leverage the implementation plans that are required as part of reporting on State Exchange grant awards when preparing to submit an Exchange Plan.

In paragraph (c)(2), we propose that each State applying for approval of its Exchange be subject to an assessment to be carried out by HHS to evaluate a State's operational readiness to execute its Exchange Plan. HHS will coordinate the readiness assessment process with the grants monitoring process under the State planning and establishment grants. This process may include meetings with State and Exchange officials as well as conference calls and on-site visits. HHS will issue additional guidance on the structure for and schedule of these assessments.

In paragraph (d), we propose that each State must receive written approval or conditional approval of its Exchange Plan in order to be approved to operate. If approved, the Exchange Plan will constitute an agreement between HHS and the Exchange to adhere to the contents of the Exchange Plan. We also note that, although the statute requires HHS to approve State Exchanges no later than January 1, 2013, there will be systems development and contracting activities that continue to occur in 2013 after the statutory deadline for approval. In order to accommodate States that are making progress towards the operational date of January 1, 2014, HHS may issue a conditional approval. The conditional approval would presume that the State's Exchange would be operational by January 1, 2014 even if it cannot demonstrate complete readiness on January 1, 2013. HHS would continue to work with and monitor the progress of States with conditional approval until a determination of full approval is made, or until the conditional approval is revoked.

We also note that we are considering establishment of a review process for the Exchange Plan that is similar to Medicaid and CHIP for which there would be 90 days to review the plan for either approval or denial, or to request comment. If additional information is requested and received from the State, HHS would have 90 days to either approve or disapprove the plan. We seek comments on the appropriateness of this process and timeline.

In paragraph (e), we propose that a State must notify HHS before significant changes are made to the Exchange Plan and that an Exchange must receive written approval of significant changes from HHS before they may be effective. We are considering utilizing the State Plan Amendment process in place for Medicaid and CHIP. We seek comment on this approach. By establishing an ongoing dialogue with each State, HHS will be able to provide technical assistance and support to ensure that each Exchange is operating in compliance with Federal requirements. Significant changes could include altering a key function of the Exchange operations, changing a crucial timeframe for certain functions, or other changes to the Exchange Plan that would have an impact on the operation of the Exchange. While not exhaustive, changes within this scope could also include changes to: (1) Exchange governance structure, (2) State laws or regulations, (3) IT systems or functionality, (4) the QHP certification process, and (5) the process for enrollment into a QHP. We expect to issue further guidance on this process.

In paragraph (f), we propose to codify the statutory requirement in section 1321(c)(1) of the Affordable Care Act that if a State elects not to establish an Exchange, or if the State's Exchange is not approved, HHS, either directly or through agreement with a non-profit entity, must establish and operate an Exchange in that State. We also identify the standards in this proposed regulation that would apply to a Federally-facilitated Exchange, which generally include all requirements of this part except for Exchange approval requirements and other specific State Exchange requirements.

c. Election To Operate an Exchange After 2014 (§ 155.106)

In paragraph (a), we propose an approval process for a State that does not have in place an approved or conditionally approved Exchange Plan and operational readiness assessment by January 1, 2013. We propose to allow States the flexibility of seeking approval to operate an Exchange even if a State is not approved to operate by January 1, 2013. We propose in paragraph (a)(1) that a State electing to seek initial approval of its Exchange after January 1, 2013 must comply with the standards and process set forth in § 155.105. We propose in paragraph (a)(2) that a State electing to operate an Exchange after 2014 must have in effect an approved or conditionally approved Exchange Plan at least 12 months prior to the first effective date of coverage. We assume that the first effective date of coverage will fall on January 1 of any given year because of the standardized annual open enrollment periods, so the approval or conditional approval would have to be in effect by January 1 of the prior year; these dates would align future Exchange Plan approvals with the initial approval timeline set forth in statute. We note that we expect that an Exchange would have an open enrollment period prior to the first effective date of coverage.

In paragraph (a)(3), we propose that such a State must work with HHS to develop a plan to transition from a Federally-facilitated Exchange to a State Exchange. We anticipate that this would include the smooth transition of operational functions from the Federally-facilitated Exchange to the State Exchange, including transitioning enrollees from QHPs certified by the Federally-facilitated Exchange to QHPs certified by a State Exchange, which may or may not differ.

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.

We note that the Secretary will address the process for States requesting approval of rating areas in future rulemaking.

We invite comment on operational or policy concerns about the idea of subsidiary Exchanges that cover areas across State lines. We also request comment on the extent to which we should allow more flexibility in the structure of a subsidiary Exchange, for example, related to the combination of subsidiary Exchanges that would be allowed to operate in a State.

We note that several commenters suggested that we consider whether a tribal government could operate a regional or subsidiary Exchange or otherwise carry out some of the functions of an Exchange. Because an Exchange must be established by a State or by a Territory pursuant to sections 1311, 1321, and 1323 of the Affordable Care Act, or be operated by HHS consistent with 1321(c) of the Affordable Care Act, we do not believe that a tribal government itself could establish an Exchange. Instead, we believe that the tribal government could work with the State as the State establishes an Exchange.

In paragraph (c), we propose basic standards for a regional or subsidiary Exchange. First, in paragraph (c)(1), we propose that a regional or subsidiary Exchange must meet all requirements within this part. In paragraph (c)(2), we propose that a regional or subsidiary Exchange perform the functions of a SHOP consistent with subpart H of this part. If a regional or subsidiary Exchange chooses to operate a SHOP through separate governance than the individual market Exchange, we propose in paragraph (c)(2)(ii) that the geographic areas served must be the same. For example, if a State chooses to participate in a regional Exchange, it would need to do so for both the individual market and the small group market. We propose this standard as means to maximize administrative efficiency for the SHOP and to provide consistency for consumers. This consistency would also reduce the burden on entities such as QHPs that would otherwise operate in different service areas depending on whether they offer plans in the individual market or the small group market.

h. Transition Process for Existing State Health Insurance Exchanges (§ 155.150)

Some States have established operational health insurance exchanges that are currently providing access to health insurance coverage to certain individuals in their States. These State exchanges were established prior to passage of the Affordable Care Act and may not meet all the requirements set forth in the Affordable Care Act or this proposed rule. Section 1321(e) requires the establishment of a process for determining any areas in which the State may not be with Federal standards, which we propose in this section.

Consistent with section 1321(e)(1) of the Affordable Care Act, in paragraph (a), we propose that, unless determined to be non-compliant through the process below, a State operating an exchange is presumed to be in compliance with the standards set forth in this part if: (1) The exchange was operating before 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.

We are considering which data source to use to determine the applicable percentage of the national population projected to be insured after the implementation of the Affordable Care Act, which we propose to interpret to mean the year 2016. We consider 2016 to be the first full year after implementation of the Affordable Care Act in which health insurance coverage would achieve its steady state. We note that the CMS Office of the Actuary currently estimates that the coverage level of the U.S. population in 2016 will be 93.6 percent; the Congressional Budget Office estimates the coverage level at 95 percent.[1] We are considering the use of data from the CMS Office of the Actuary or the Congressional Budget Office to determine the applicable percentage. We invite comments on which proposed threshold should be used and on alternative numbers to be used.

In paragraph (b), we propose that any State that is currently operating a health insurance exchange that meets the description of such a State under paragraph (a) must work with HHS to identify areas of non-compliance with the requirements of this part.

i. Financial Support for Continued Operations (§ 155.160)

Section 1311(d)(5) of the Affordable Care Act provides that a State Exchange must be self-sustaining by January 1, 2015; the statute explicitly lists assessments and user fees on participating issuers as one potential means for a State to secure operational funding for Exchanges. In addition, section 1311(d)(5) places certain prohibitions on uses of the funds that are intended for Exchange administration and operations in order to prevent waste.

In paragraph (a), we incorporate the definition of ''participating issuer'' provided in § 156.50 to this section. In paragraph (b) of § 155.160, we propose to codify the statutory requirement that a State ensure its Exchange has sufficient funding to support ongoing operations beginning January 1, 2015. In addition, we propose that States must develop a plan for ensuring funds will be available. We note that the funding plan is a requirement of Exchange approval under subpart B of this part.

In paragraph (b)(1), we propose to codify the statutory flexibility in section 1311(d)(5)(A) of the Affordable Care Act that allows a State Exchange to fund its ongoing operations by charging user fees or assessments on participating issuers. In paragraph (b)(2), we propose that States may use other forms of funding for Exchange operations, consistent with the reference in section 1311(d)(5)(A) that allows States to ''otherwise generate funding.'' This language provides States with broad flexibility to generate funds beyond charging the ''assessments or user fees'' identified in the statute. States may use broad-based funding (which may include general State revenues, provider taxes, or other funding that spreads costs beyond imposing assessments or user fees on participating issuers), as long as the use of such funding does not violate other State or Federal laws.

In paragraph (b)(3), we propose to codify the implied statutory requirement established in section 1311(d)(5)(A) of the Affordable Care Act that a State Exchange must be self-sustaining starting on January 1, 2015. Federal funds may not be provided after that time to support its continued operations. This direction is also articulated in section 1311(a)(4)(B), which limits the duration of Federal grants to plan for and establish State Exchanges.

In paragraph (b)(4), we propose that the State Exchange announce the assessment of any user fees on health insurance issuers in advance of the plan year. We invite comment on whether the final regulation should otherwise limit how and when user fees may be charged, and whether such fees should be assessed on an annual basis.

[1] CMS Office of the Actuary, April 22, 2010: *https://www.cms.gov/ActuarialStudies/Downloads/PPACA_2010-04-22.pdf* (page 24); Congressional Budget Office, March 18, 2011: *http://www.cbo.gov/budget/factsheets/2011b/HealthInsuranceProvisions.pdf* (excluding unauthorized immigrants).

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) [2] 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 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.[3] 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; [4]

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 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 [5] 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

[2] 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.

[3] *http://cciio.cms.gov/resources/files/joint_cms_ociio_guidance.pdf.*

[4] *http://www.access-board.gov/sec508/guide/index.htm.*

[5] 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

issuer. We propose to codify this Exchange requirement in paragraph (a) of § 155.240. We interpret this to mean that while an Exchange may exercise any of the options listed above, pursuant to section 1312(b), it must always allow an individual to pay directly to the QHP issuer if he or she chooses, regardless of whether an Exchange has elected to establish another option for premium payment. This requirement does not preclude an Exchange from facilitating or aggregating premium payments, if it chooses to do so.

In paragraph (b), we propose that an Exchange may permit Indian tribes, tribal organizations and urban Indian organizations to pay the QHP premiums on behalf of qualified individuals, subject to the terms and conditions determined by the Exchange. Comments in response to the November 12, 2010 HHS tribal consultation letter and the RFC suggest that premiums may present an obstacle for Indians and suggested that we consider implementation of a process for a tribe to pay premiums on behalf of its members since premiums cannot be waived for Indians.

An Exchange may consider setting-up an upfront group payment mechanism similar to the mechanism currently used by some tribes to enroll members in the Medicare Prescription Drug Program. Under that program, tribes offer a selection of plans from which their members may choose, thus limiting the members' options. We seek comment on whether this approach would work in an Exchange and how such an approach might be tailored to fit the Exchange.

We note that section 402 of the Indian Health Care Improvement Act (IHCIA) permits Indian tribes, tribal organizations, and urban Indian organizations to purchase health benefits coverage for IHS beneficiaries. As a result, the payment of premiums that we propose under this section is more inclusive than other Exchange provisions (special enrollment periods and cost-sharing rules) that pertain to Indians. We invite comment on how to distinguish between individuals eligible for assistance under the Affordable Care Act and those who are not in light of the different definitions of ''Indian'' that apply for other Exchange provisions.

In paragraph (c), we propose that, in the operation of a SHOP, an Exchange must accept payment of an aggregate premium by a qualified employer pursuant to the standards set forth in § 155.705(b)(4).

In paragraph (d), we propose that an Exchange may facilitate through electronic means the collection and payment of premiums. This could include the Exchange acting as a simple pass-through or the Exchange collecting and distributing premiums to QHP issuers.

Additionally, we propose in paragraph (e) that an Exchange choosing to offer enrollees payment through electronic means must conform to any standards and protocols (including privacy and security) required under § 155.260 and § 155.270.

If an Exchange elects to facilitate the collection and payment of premiums, it must establish administrative protocols to ensure the integrity of the financial transactions. We clarify that premium collection by the Exchange does not make the Exchange liable for payment. For example, if an individual is late making a payment or misses a premium payment, the Exchange would not have to make a payment on behalf of the individual. We seek comments concerning Exchange flexibility in establishing the premium payment process and what standards would be appropriate for the Federal government to establish in regulations to ensure fiduciary accountability in the case of an Exchange that collects premiums.

g. Privacy and Security of Information (§ 155.260)

In § 155.260, we address the privacy and security standards Exchanges must establish and follow. Each Exchange will need to obtain applicants' personally identifiable information, such as names, social security numbers, addresses, dates of birth, and tax returns or other financial information during the application process discussed in § 155.405 as part of the eligibility determination process required by § 155.200(c) of this subpart. In addition to the proposals in this part, part 156 requires QHP issuers to provide personally identifiable information to the Exchange on a regular basis. We propose to require that the Exchange apply appropriate security and privacy protections when collecting, using, disclosing or disposing of personally identifiable information it collects. In addition, we propose to require contractual terms that impose these standards on contractors or sub-contractors that fulfill Exchange functions or access information from or on behalf of the Exchange.

In paragraph (a), we propose to define the term ''personally identifiable information'' in this context as information that, alone or when combined with other personal or identifying information which is linked or linkable to a specific individual, can reasonably be used to distinguish or trace an individual's identity. We propose that the term applies to information collected, received or used by the Exchange as part of its operations. Consistent with section 1411(g) of the Affordable Care Act, in paragraph (b), we propose limiting the collection, use, and disclosure of personally identifiable information to what is specifically required or permitted by § 155.260, other applicable law, subpart E of this part, the standards established in accordance with § 155.200(c) of this subpart, and section 1942(b) of the Act. We note that Exchanges may not collect, use, or disclose personally identifiable information if prohibited by another law. We invite comment as to whether and how we should restrict the method of disposal in this section as well.

The Affordable Care Act provides specific privacy and security standards at sections 1411(g), 1413(c)(2), and 1414(a)(1) for some, but not all, types of information flowing to and from the Exchange. Furthermore, we recognize that some or all of the Exchanges may be HIPAA covered entities (health plans, health care clearinghouses and health care providers that conduct certain electronic transactions covered by HIPAA) or business associates of HIPAA covered entities; in such cases, some or all exchange privacy and security responsibilities regarding individuals' health information may be governed by HIPAA. Therefore, in addition to other standards mentioned directly by the Affordable Care Act, HIPAA may dictate the appropriate privacy and security standards for some Exchanges, and may serve as guidance on appropriate privacy and security practices for others. Each Exchange should engage in an analysis of its operations and functions and determine its HIPAA status based on the definitions in § 160.103 in subchapter C of 45 CFR. That analysis will be fact-intensive and will depend heavily on the decisions of each State about how the Exchange will be set up and on the functions and services the Exchange performs, including those functions it performs with respect to QHPs, Medicaid and CHIP. Regardless of whether an Exchange is subject to HIPAA as a covered entity or as a business associate, we propose that the Exchanges implement safeguards to ensure that any and all personally identifiable information received, used, stored, transferred, or prepared for disposal by an Exchange is subject to adequate privacy and security protections. For an Exchange that is subject to HIPAA, the privacy and security standards imposed by HIPAA

must be followed with respect to information that is ''protected health information.''

Because each Exchange may have different needs and structures and work in different capacities, it is difficult to create a uniform set of detailed privacy and security standards that we could propose to apply to all Exchanges. That said, we believe that HIPAA provides certain universally appropriate security standards. We therefore propose to require that the security standards of the Exchange (and which the Exchange must contractually impose on contractors and subcontractors) are consistent with HIPAA security rules described at 45 CFR 164.306, 164.308, 164.310, 164.312, and 164.314. These rules provide tested and familiar guidelines that should ensure the proper handling of applicant and enrollee information. Again, and as explained below, we propose to require contractual requirements that apply these security standards to contractors or sub-contractors that receive information from the Exchange or fulfill Exchange functions.

Privacy policies for the Exchanges will need to allow for the appropriate collection, receipt, use, disclosure and disposal of the various kinds of information including health, financial and other types of personally identifiable information. For Exchanges not subject to HIPAA as covered entities or as business associates, while HIPAA may provide an appropriate model for the protection of the privacy of health information, we are concerned about its applicability to all data passing through Exchanges—specifically, tax return information protected by 6103 of the Code. As such, we are not proposing to adopt a selection of HIPAA privacy standards as the minimum protections for data at all Exchanges. Rather, we propose to provide States with the flexibility to create a more appropriate and tailored standard. We are considering requiring each Exchange to adopt privacy policies that conform to the Fair Information Practice Principles (FIPPs). We believe that FIPPs will afford an appropriate baseline of privacy protections regarding the use, disclosure and disposal of personally identifiable information.[6] The FIPPs have been incorporated into both the privacy laws of many States with regard to government-held records[7] and numerous international frameworks, including the OECD's privacy guidelines, the EU Data Protection Directive, and the APEC Privacy Framework.[8] Specifically, the principles include: (1) Individual Access; (2) Correction; (3) Openness and Transparency; (4) Individual Choice; and (5) Collection, Use, and Disclosure Limitations. We note that we plan to address collection limitations in the eligibility standards established pursuant to § 155.200(c) of this part. We welcome comments on the appropriateness of the FIPPs in this context and the best means to integrate FIPPs into the privacy policies and operating procedures of individual Exchanges while allowing for adaptability to each Exchange's particular structure and operations. We also solicit comment on the aptness of adopting the HIPAA privacy model for Exchanges. Again, we note that an Exchange that is subject to HIPAA must comply with both the privacy and security standards imposed by HIPAA with respect to protected health information.

We also propose in paragraph (b) to adopt several additional requirements for the privacy and security policies and procedures of Exchanges. We propose requiring that the policies and procedures be in writing and available to the Secretary of HHS, and that this writing identify any applicable laws that the Exchange will need to follow. We also propose to require that the Exchange must, in any contract or agreement with a contractor, require that information provided to, created by, received by, and subsequently disposed of by the contractor or any of its subcontractors be protected by the same or higher privacy and security standards than are applicable to the Exchange. We believe that this will ensure that all contractors and subcontractors that fulfill Exchange functions are subject to adequate privacy and security standards. Last, we are considering imposing a requirement that each Exchange implement some form of authentication procedure for ensuring that all entities interacting with Exchanges are who they claim. We are currently working with other Federal agencies to determine the best methods of authentication to ensure the identities of parties accessing information in or furnishing information to Exchanges.

In paragraph (c), we propose an additional requirement related to data matching arrangements that are made between the Exchange and agencies that administer Medicaid and CHIP in States for the exchange of eligibility information. The Exchange must participate in the data matching program required by section 1413(c)(2) of the Affordable Care Act consistent with the privacy and security standards described in section 1942(b) of the Act and in other applicable laws. We expect Exchanges and the Medicaid and CHIP agencies to execute data use agreements that prevent the unauthorized use or disclosure of personally identifiable information and prohibit the Exchange or State agency from seeking to obtain or provide information that it will not, or does not reasonably expect to, use. We propose to adopt these same requirements as data privacy and security requirements for Exchanges.

In paragraph (d), we also propose to require Exchanges to adopt privacy and security policies and procedures that meet the standards in section 6103 of the Code that protect the confidentiality of tax returns and tax return information. Section 1414(a)(1) of the Affordable Care Act added section 6103(l)(2) to the Code to authorize the disclosure of certain tax return information to carry out eligibility determinations for advance payments of the premium tax credit and certain other government-sponsored health programs, subject to the confidentiality and safeguarding requirements of section 6103 of the Code. We are currently working with the Secretary of the Treasury and States to ensure that Treasury-required safeguards for tax information will be met across the information technology architecture.

Finally, in paragraph (e), we propose to codify the requirement in section 1411(h)(2) of the Affordable Care Act that provides that any person that knowingly and willfully uses or discloses personally identifiable information in violation of section 1411(g) of the Affordable Care Act will be subject to a civil money penalty of not more than $25,000 per disclosure and be subject to any other applicable penalties that may be prescribed by law. We propose to interpret section 1411(h)

[6] In 1973, the Department of Health, Education, and Welfare (HEW) released its report, *Records, Computers, and the Rights of Citizens,* which outlined a Code of Fair Information Practices that would create ''safeguard requirements'' for certain ''automated personal data systems'' maintained by the Federal Government. This Code of Fair Information Practices is now commonly referred to as fair information practice principles (FIPPs) and established the framework on which much privacy policy would be built. There are many versions of the FIPPs; the principles described here are discussed in more detail in *The Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information,* December 15, 2008. *http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__privacy___security_framework/1173.*

[7] Pritts, J.L., Altered States: State Health Privacy Laws and the Impact of the Federal Health Privacy Rule (Spring 2002), 2 Yale J. Health Pol'y L. & Ethics 325.

[8] See Department of Commerce, Internet Policy Task Force, Commercial Data Privacy, and Innovation in the Internet Economy: A Dynamic Policy Framework, (Washington, D.C.: 2010).

to apply the civil money penalty of $25,000 to each violation of section 1411(g).

h. Use of Standards and Protocols for Electronic Transactions (§ 155.270)

In this section, we propose to apply certain standards and protocols to the operation of Exchanges. We consider these requirements to be important considerations in the development and operation of Exchange information technology systems, and as such, propose them here as requirements for Exchanges.

In paragraph (a), we propose to apply the HIPAA administrative simplification requirements. To the extent that the Exchange performs electronic transactions with a covered entity, including State Medicaid programs and QHP issuers, the Exchange must use standards and operating rules adopted by the Secretary pursuant to 45 CFR parts 160 and 162.

In paragraph (b), we propose to codify the HIT enrollment standards and protocols that were developed pursuant to section 3021 of the PHS Act, which was added by section 1561 of the Affordable Care Act, and that were adopted by the Secretary.[9] Such standards and protocols will be incorporated within Exchange information technology systems as required under the Exchange cooperative agreements awarded pursuant to section 1311(a) of the Affordable Care Act.

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

In subpart E, we outline the initial, annual, and special enrollment periods as well as the enrollment process and the termination of coverage process. The standards established by the Exchange in accordance with this subpart will facilitate the enrollment of qualified individuals into QHPs and the transfer of enrollees from one QHP to another. For the purposes of this subpart, any reference to enrollee means a qualified individual who enrolls in a QHP through the Exchange.

In response to the RFC, many commenters suggested that States should design systems for the Exchange by either building off of existing systems that are in place for Medicaid and CHIP or, alternatively, developing new systems that would serve the Exchange as well as advance payments of the premium tax credit, cost-sharing reductions, Medicaid and CHIP. Comments also focused on the importance of a streamlined enrollment process. In addition, many commenters recommended that the initial open enrollment period be longer and more flexible than subsequent annual open enrollment periods while others suggested enrollment periods be structured so as not to encourage migration in and out of the Exchange.

Commenters also suggested that we follow HIPAA and Medicare guidelines when establishing qualifying events that trigger special enrollment periods. Some suggested that there should not be a single open enrollment period for all eligible individuals but instead, a staggered open enrollment so as not to place excessive administrative burdens on Exchanges, States, and QHP issuers. We also received comments supporting a lag between enrollment periods and effective dates to provide time for enrollment, billing, and other information to be processed, as well as to allow time for QHP issuers to produce and mail consumer identification cards and any necessary start-up communications.

a. Enrollment of Qualified Individuals into QHPs (§ 155.400).

Section 155.400 addresses that the Exchange must: Accept a QHP selection from an applicant who is determined eligible for enrollment in a QHP, notify the issuer of the applicant's selected QHP, and transmit information necessary to enable the QHP issuer to enroll the applicant.

In paragraph (b), we propose that the Exchange must send QHP issuers enrollment information on a timely basis; we anticipate issuing further guidance on this timing. In addition, the Exchange will be required to develop a process by which QHP issuers can verify and acknowledge the receipt of enrollment information. While it would be ideal for information sharing to occur on a real-time basis, we are not certain that all parties will have the necessary functionality for real-time information sharing by 2014. As such, we encourage real-time processing and acknowledgement of enrollment information; we seek comment as to whether we should consider codifying a requirement for a specific frequency for enrollment transactions such as in real time or daily in our final rule.

To ensure that the Exchange and QHP issuers have identical plan enrollment records, we propose under paragraphs (c) and (d) that the Exchange maintain records of enrollment, submit enrollment information to HHS, and reconcile the enrollment files with the QHP issuers no less than on a monthly basis.

b. Single Streamlined Application (§ 155.405)

Section 1413(b)(1)(A) of the Affordable Care Act requires that the Secretary develop and provide to each State a single, streamlined form that may be used to apply for 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, and that must be structured to maximize an applicant's ability to complete the form satisfactorily, taking into account the characteristics of individuals who qualify for the programs. Section 1311(c)(1)(F) of the Affordable Care Act states that an issuer shall use a uniform enrollment form for qualified individuals and employers to enroll in QHPs through the Exchange, and that the enrollment form must take into account criteria developed by the NAIC. In § 155.405 we describe a single streamlined application and standards for any alternative application developed by the Exchange that incorporate both eligibility and enrollment, in order to facilitate an efficient process.

In paragraph (a), we propose that the Exchange use a single streamlined application to collect information necessary for QHP enrollment, advance payments of the premium tax credit, cost-sharing reductions, and Medicaid, CHIP, and the BHP, if a BHP is operating in the Exchange service area. We propose use of a single streamlined application to limit the amount of information and number of times an individual must make submissions to receive an eligibility determination and complete the enrollment process. HHS plans to create both a paper-based and web-based dynamic application. We anticipate that the electronic application will enable many applicants to complete the eligibility and QHP selection process in a single online session.

In paragraph (b), we propose that if the Exchange seeks to use an alternative application it must be approved by HHS. The alternative application should collect the information necessary to support an eligibility determination and to process enrollment through the programs described in paragraph (a). Our intent is to simplify the application process and reduce, if not eliminate, the collection of extraneous information. We seek comment regarding whether we should codify a requirement that applicants may not be required to answer questions that are not pertinent to the eligibility and enrollment process.

[9] *http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=3161.*

In paragraph (c), we propose that the Exchange must accept applications from multiple sources, including the applicant; an authorized representative (we propose this to be defined by State law); or someone acting responsibly for the applicant. In addition, section 1413(b)(1)(A)(ii) of the Affordable Care Act sets forth requirements regarding mechanisms by which an individual may file an application. In paragraph (c)(2), we propose that an individual must be able to file an application online, by telephone, by mail, or in person. We solicit comments on the requirement that an individual must be able to file an application in person.

We reserve paragraphs (d) and (e) for future rulemaking.

In regard to requests for personally identifiable information that the Exchange will collect during the application process, we are contemplating standards for the final rule for information collection based on the Fair Information Practices Principles (FIPPs) framework. For a more detailed discussion on FIPPs, see the preamble to 155.260. According to FIPPs, applicants should be given notice of an entity's information practices before any personal information is collected from them so that they are able to make an informed decision about whether and to what extent to disclose their personal information.

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

Section 1311(c)(6) of the Affordable Care Act directs the Secretary to establish an initial open enrollment period and an annual open enrollment period. In § 155.410, we propose standards for Exchanges related to the initial and annual open enrollment periods. Our proposed timeframes are informed by both the experience implementing Medicare Advantage and the Medicare Prescription Drug Benefit Program, as well as information from FEHBP.

In paragraph (a)(1), we propose that the Exchange adhere to the initial and annual open enrollment periods set forth in this section and indicate that qualified individuals and enrollees may begin or change coverage in a QHP at such times. In paragraph (a)(2), we propose that the Exchange may only permit a qualified individual to enroll in a QHP or an enrollee to change QHPs during the initial open enrollment period specified in paragraph (b), the annual open enrollment period specified in paragraph (e), or a special enrollment period described in § 155.420 for which the qualified individual or enrollee has been determined eligible.

In paragraph (b), we propose an initial open enrollment period that allows a qualified individual to enroll in a QHP from October 1, 2013 through February 28, 2014. We want to ensure that qualified individuals have sufficient time to learn about Exchange coverage, compare options, and ultimately enroll. In addition, we seek to provide the maximum flexibility for the information management system of the Exchange to be designed, built, tested, and ready for January 1, 2014 coverage in addition to the time needed to certify QHPs.

We believe that consumers should have an initial open enrollment period that extends beyond January 1, 2014 to allow for outreach and education beyond the first potential date of coverage. We recognize that extending the initial open enrollment period into 2014 will require flexibility on the part of QHPs because some enrollees will have fewer than 12 months of coverage in the first year. As such, we seek to balance the needs of consumers with the interest of QHPs to have individuals enrolled for as close to a full coverage year as possible. We seek comment on the duration of the initial open enrollment period.

In paragraph (c), we propose rules regarding the effective date of coverage for the initial open enrollment period based on the date on which the Exchange receives a QHP selection from an individual, in order to allow appropriate time for QHP issuers to process QHP selections. In paragraph (c)(1), we propose that for a QHP selection received by the Exchange on or before December 22, 2013, the Exchange must ensure an effective date of January 1, 2014. In paragraph (c)(2), we propose that for a QHP selection received by the Exchange between the first and twenty-second day of any subsequent month during the initial open enrollment period, the Exchange must ensure an effective date on the first day of the following month. In paragraph (c)(3), we propose that for a QHP selection received by the Exchange between the twenty-third and last day of the month for any month between December, 2013 and February 28, 2014, the Exchange must ensure an effective date of either the first day of the following month or the first day of the second following month.

In general, we propose to apply this approach to effective dates for the annual open enrollment period and for special enrollment periods as well. This proposal is designed to minimize the time between enrollment and coverage effective dates, while leaving sufficient time to ensure that QHP selections can be fully processed by QHP issuers. In addition, the proposal provides the Exchange with flexibility to work with QHP issuers to implement selections received between the twenty-third and last day of the month on either the first of the following month or the first of the second following month, which allows the Exchange and QHP issuers to choose to process enrollments more quickly to the extent possible.

We note that the coverage effective date may not be set or enrollment information sent from the Exchange to the QHP until the individual is determined eligible to purchase coverage through the Exchange. Section 36B(c)(2)(A)(i) of the Affordable Care Act specifies that advance payments of the premium tax credit may only be provided for an enrollee who is enrolled in a QHP on the first of the month. As such, in order to coordinate coverage in a QHP with the advance payments of the premium tax credit that support the purchase such coverage, we propose to establish that coverage in a QHP may only begin on the first of the month. However, we seek comment as to whether we should consider allowing at least twice-monthly effective dates of coverage or complete flexibility to allow for coverage to begin any day for individuals who forego receipt of such credit for their first partial month or who are not eligible to receive advance payments of the premium tax credit.

In paragraph (d), we propose that the Exchange must send written notification to enrollees about the annual open enrollment period. We are considering codifying the requirement that such notice must be sent no later than 30 days before the start of the annual open enrollment period in our final rule. Further, we believe the notice may require inclusion of specific information and we seek comment regarding whether we should codify such requirements for information pertaining to: (1) The date annual open enrollment begins and ends, (2) where individuals may obtain information about available QHPs, including the Web site, call center, and through Navigator assistance, and (3) other relevant information.

In paragraph (e), we propose an annual open enrollment period from October 15 through December 7 of each year, starting in October 2014 for coverage beginning January 1, 2015. As an alternative annual open enrollment period, we considered November 1 through December 15 of each year to provide a 45-day window close to the end of the year that would be easy to remember. We welcome comments

regarding our proposed and alternative approach for the annual open enrollment period.

In paragraph (f), we propose that the Exchange must ensure coverage is effective as of the first day of the following benefit year for a qualified individual who has made a QHP selection during the annual open enrollment period.

We seek comment regarding whether we should require Exchanges to automatically enroll individuals who received advance payments of the premium tax credit and are then disenrolled from a QHP because the QHP is no longer offered if such individual does not make a new QHP selection. We also seek comment regarding whether we should codify requirements in the final rule regarding automatic enrollment of individuals into new QHPs when there are mergers between issuers or when one QHP offered through a specific issuer is no longer offered but there are other options available to the individual through the same issuer. Further, if we were to provide for automatic enrollment, we seek comment as to how far such automatic enrollment should extend.

We reserve paragraph (g) for future rulemaking.

d. Special Enrollment Periods (§ 155.420)

In accordance with section 1311(c)(6)(C) of the Affordable Care Act, the Secretary must establish special enrollment periods. The statute requires use of the special enrollment periods in section 9801 of the Code and, where relevant, special enrollment periods similar to those in the Medicare Prescription Drug Program. In § 155.420, we propose standards to address this statutory requirement. In paragraph (a) of this section, we specify that the Exchange must allow a qualified individual or enrollee to enroll in a QHP or change from one QHP to another outside of the annual open enrollment period, if such individual qualifies for a special enrollment period.

In paragraph (b), we propose that, in general, the effective dates for QHP selections based on special enrollment periods follow the proposed effective dates for QHP selections during the initial or annual open enrollment periods described in § 155.410(c) of this subpart. First, in paragraph (b)(1), we propose that once determined eligible for a special enrollment period, the Exchange must ensure that a qualified individual or enrollee's effective date is on the first day of the following month for all QHP selections made by the 22nd of the previous month, and on either the first day of the following month or the first day of the second following month for all QHP selections made between the 23rd and last day of a given month. We provide an exception in the case of birth, adoption or placement for adoption, for which coverage must be effective on the date of birth, adoption, or placement for adoption.

In paragraph (c), we propose a standard length of 60 days for each special enrollment period from the date of the triggering event unless the applicable regulation provides otherwise. We believe that having a standardized length for special enrollment periods will simplify administrative processes and accommodate the needs of individuals undergoing significant life changes, although we note that we raise alternatives for the special enrollment periods proposed in paragraphs (d)(6) and (d)(7) of this section in the preamble associated with those paragraphs. We request comment on the alternatives raised for the special enrollment periods described in paragraphs (d)(6) and (d)(7) and whether others, such as (d)(4), should have an alternate start date.

In paragraph (d), we propose specific special enrollment periods. We note that all requests for special enrollment periods must be evaluated by the Exchange as part of the eligibility determination process established pursuant to § 155.200(c) of this part. For purposes of special enrollment periods provided herein, we interpret dependent to mean any individual who is or may become eligible for coverage under the terms of a QHP because of a relationship to an enrollee (including the enrollee's spouse). In paragraph (d)(1), we propose that the Exchange permit a qualified individual and any dependents to enroll in a QHP due to loss of other minimum essential coverage. We interpret loss of coverage to include any event that triggers a loss of eligibility for other minimum essential coverage. We further propose that a dependent of a current enrollee in a QHP and the enrollee are each eligible for a special enrollment period if the dependent loses other minimum essential coverage. Examples of loss of coverage include decertification of a QHP that occurs outside of the annual open enrollment period. In such cases, an enrollee would be allowed to select and enroll in a new QHP upon notification of plan decertification. If the enrollee does not select a new QHP before the effective date of plan termination, he or she would be provided 60 days from the date of plan termination, which is the triggering event, to select a new QHP.

Other examples of events that would qualify as loss of coverage include but are not limited to the following: legal separation or divorce ending eligibility of a spouse or step-child enrolled in other minimum essential coverage as a dependent; end of dependent status (such as attaining the maximum age to be eligible as a dependent child under the plan); death of an individual enrolled in minimum essential coverage ending eligibility for covered dependents; termination of employment or reduction in the number of hours of employment necessary to maintain coverage; or relocation outside of the service area of the QHP. Examples of relocation include relocation to the United States (US) in the case of a US citizen, national, or lawfully present individual who was not previously eligible for Exchange participation while residing outside of the US; release from incarceration; moving from the jurisdiction of one Exchange to another; or relocating outside of the individual's QHP's service area.

In accordance with section 9801(f) of the Code, we propose that loss of coverage also include: termination of employer contributions for a qualified individual or dependent who has coverage that is not COBRA continuation coverage by any current or former employee, exhaustion of COBRA continuation coverage, reaching a lifetime limit on all benefits in a grandfathered plan, and termination of Medicaid or CHIP. We vary from the Code for this first special enrollment period by specifying only loss of minimum essential coverage rather than loss of any coverage because of the requirement in section 5000A of the Affordable Care Act that qualified individuals and their dependents must maintain essential coverage. If otherwise qualified individuals who maintained less than minimum essential coverage were granted a special enrollment period based on termination of such coverage, such individuals might wait until experiencing a significant health care need to enroll in a QHP through the Exchange by using a special enrollment period. Such allowance could create a problem of adverse selection; we solicit comment on this provision.

Similar to the provisions outlined in section 9801 of the Code, we propose in paragraph (d)(2) a special enrollment period for a qualified individual who gains a dependent or becomes a dependent through marriage, birth, adoption or placement for adoption. We welcome comment as to whether States might consider expanding the special

enrollment period to include gaining dependents through other life events.

Similar to when an individual is newly eligible for Medicare and has a period of time to begin coverage in Medicare and to select a Medicare Prescription Drug Plan, we propose in paragraph (d)(3) that upon gaining status as a citizen, national, or lawfully present individual in the US, a qualified individual qualifies for a special enrollment period because the individual is newly eligible to purchase coverage. We view this initial enrollment period as the functional equivalent of a special enrollment period since it occurs outside of the annual open enrollment period and provides an opportunity for eligible individuals to gain access to coverage through a QHP.

The special enrollment periods that are proposed in paragraphs (d)(4) through (d)(7) are also patterned on the Medicare Prescription Drug Program. In paragraph (d)(4), we propose that qualified individuals who experience an error in enrollment receive a special enrollment period. This applies in any case where the Exchange finds that a qualified individual's enrollment or non-enrollment in a QHP is unintentional, inadvertent, or erroneous and is the result of the error, misrepresentation, or inaction of an officer, employee, or agent of the Exchange or HHS, or its instrumentalities as evaluated and determined by the Exchange.

In paragraph (d)(5), we propose a special enrollment period for an individual enrolled in a QHP who adequately demonstrates to the Exchange that the QHP in which he or she is enrolled substantially violated a material provision of its contract in relation to such individual and their dependents. One example of such a violation is material misrepresentation by the QHP issuer (or its agent, representative, or plan provider) when marketing the plan to the individual.

In paragraph (d)(6), we propose a special enrollment period for individuals who are newly eligible or newly ineligible for advance payments of the premium tax credit or have a change in eligibility for cost-sharing reductions. This proposal allows new enrollment or movement from one QHP to another. This special enrollment period would be granted for individuals who receive an eligibility determination for the first time for coverage through the Exchange or for individuals who experience a mid-year change in circumstance that changes their eligibility, including a change that ends their eligibility for advance payments of the premium tax credit. We propose this special enrollment period because we anticipate that individuals will decide whether to enroll in a QHP and choose a specific plan based in part on financial status and how financial status impacts eligibility. Additionally, qualified individuals and enrollees may wish to enroll in or change plans to take advantage of different benefit designs and plan cost structures as their eligibility changes. We seek comment as to whether the start of the 60 day special enrollment period, as discussed in 155.420(c), should be based on the date on which an individual experiences a change in eligibility or based upon the date of the eligibility determination.

In addition, sections 36B(c)(2)(C)(i) and (ii) of the Code specify that an individual may be determined eligible for advance payments of the premium tax credit or cost-sharing reductions in situations in which minimum essential coverage offered through an eligible employer-sponsored plan, as defined in section 5000A(f)(2) of the Code, is determined to no longer meet the minimum value requirement or be affordable for the upcoming plan year. We note that even if there is a special enrollment period, advance payments of the premium tax credit only apply if the individual is not enrolled in employer coverage. The proposal in paragraph (d)(6) would allow an individual in this situation to be determined eligible for this special enrollment period during the open enrollment period for the employer-sponsored health coverage or when the employee learns of the change in his or her eligible employer-sponsored plan, even if he or she is still covered by the eligible employer-sponsored plan at the time of eligibility determination. This is designed to ensure that such individuals will not be required to be uninsured prior to receiving a determination of eligibility for a special enrollment period. We request comment on the timing of the special enrollment period in this situation and whether the 60 day period should begin when the employee learns of the change(s) in the employer-sponsored coverage or when the employee terminates coverage by the employer-sponsored plan.

In paragraph (d)(7), we propose that if new QHPs offered through the Exchange are available to a qualified individual or enrollee as a result of a permanent move, such enrollee receives a special enrollment period. We propose that the special enrollment period begin on either the date of the permanent move or on the date the individual provides notification of such move and request comment on these alternatives. Individuals who move and have new QHP available to them as a result of the move, but continue to reside in the current plan service area, may use this special enrollment period to enroll in any QHP for which they are newly eligible in their new place of residence. It is the individual's responsibility to notify the Exchange or QHP that he/she is permanently moving.

We considered several options with respect to the start date for the special enrollment period proposed in paragraph (d)(7) regarding an individual or enrollee who gains access to new QHPs as a result of a permanent move. One option that we considered for the start date of this special enrollment period was either the date of the individual's permanent move, or the date on which the individual provides notice of the move, if an individual provides notice of his or her move within a reasonable timeframe. Under this option, we could establish the length of this special enrollment period either as 60 days from the start date or as 60 days from the date of the move or his or her notice of the move, whichever is later. We solicit comments on these options.

In paragraph (d)(8), we propose to codify the statutory special enrollment period that Indians receive a monthly special enrollment period as specified in section 1311(c)(6)(D) of the Affordable Care Act. We interpret the monthly special enrollment period to allow for an Indian to join or change plans one time per month. For purposes of this special enrollment period, section 1311(c)(6)(D) defines an Indian as specified in section 4 of the Indian Health Care Improvement Act (IHCIA). Section 4 of the IHCIA defines ''Indian'' as a member of a Federally-recognized tribe. We solicit comment on the potential implications on the process for verifying Indian status.

In paragraph (d)(9) we propose a special enrollment period for exceptional circumstances, as determined by the Exchange or HHS. This special enrollment period could be used for a variety of situations, including natural disasters such as hurricanes or floods. Exceptional circumstances include circumstances that would impede an individual's ability to enroll on a timely basis, through no fault of his or her own.

In paragraph (e), similar to section 9801 of the Code, we propose that loss of coverage does not include failure to pay premiums on a timely basis, including COBRA premiums prior to expiration of COBRA coverage, or situations allowing for a rescission as specified in 45 CFR § 147.128.

In paragraph (f) we propose that upon qualifying for a special enrollment period, the Exchange may only allow an existing enrollee of a QHP to change plans within levels of coverage as defined by 1302(d) of the Affordable Care Act. As an example, if an enrollee is in a silver level plan and gives birth to a child outside of the annual open enrollment period, the enrollee may add the child to her existing plan or change from one silver level plan to another; however, she may not move to a gold level plan. We propose this limitation to maintain a single level of coverage throughout the year to avoid adverse selection. We propose a single exception for new eligibility for advance payments of the premium tax credit or change in eligibility for cost-sharing reductions. We recognize that limiting enrollees such that they must stay within a specific coverage level during a special enrollment period could pose a challenge for an enrollee in a catastrophic plan that becomes pregnant. We request comment as to whether we should provide an exception for such circumstances.

We clarify that the Exchange will provide information, accept applications, perform eligibility determinations, and accept enrollments and send enrollment information to QHPs for individuals year round to accommodate special enrollment periods, and coverage through Medicaid and CHIP. Although most individuals will likely approach the Exchange during initial and annual open enrollment periods, individuals may approach the Exchange at all times. Further, the special enrollment periods that are required and set forth in § 155.420 are not the only applicable enrollment requirements. To the extent other law applies to require a special enrollment right from issuers, such law continues to apply. The Exchange special enrollment periods are a minimum requirement for the Exchange to permit enrollment outside of the initial and annual open enrollment periods.

e. Termination of Coverage (§ 155.430)

Pursuant to section 1321(a)(1) of the Affordable Care Act, in paragraph (a), we propose that the Exchange must determine the form and manner in which coverage in a QHP may be terminated.

In paragraph (b), we propose a set of events that would cause an enrollee's coverage in a QHP to be terminated. In paragraph (b)(1), we propose that the Exchange must permit an enrollee to terminate his or her coverage in a QHP with appropriate notice to the Exchange or the QHP. We anticipate that these voluntary termination requests will generally occur in situations in which an enrollee in a QHP has obtained other minimum essential coverage. In paragraph (b)(2), we propose that the Exchange may terminate an enrollee's coverage in a QHP, and must permit a QHP issuer to terminate such coverage in the following circumstances: (1) The enrollee is no longer eligible for coverage in a QHP through the Exchange; (2) the enrollee becomes covered in other minimum essential coverage; (3) payments of premiums for coverage of the enrollee cease, provided that the grace period for enrollees receiving advance payments of the premium tax credit, as specified in § 156.270(d) of this chapter, has elapsed; (4) the enrollee's coverage is rescinded in accordance with § 147.128 of this chapter; (5) the QHP terminates or is decertified by the Exchange as described in § 155.1080; or (6) the enrollee changes from one QHP to another during the annual open enrollment period, or a special enrollment period in accordance with § 155.410 or § 155.420.

To ensure the Exchange oversees the actions related to termination of coverage undertaken by QHPs, in paragraph (c), we propose that the Exchange must establish maintenance of records procedures for termination of coverage, track the number of individuals for whom coverage has been terminated and submit that information to HHS on a monthly basis, establish terms for reasonable accommodations, and retain records in order to facilitate audit functions.

In paragraph (d), we propose standards for the effective dates for termination of coverage. In paragraph (d)(1), we propose that in the case of a termination requested by an enrollee, the last day of coverage for an enrollee is the termination date specified by the enrollee, if the Exchange and QHP have a reasonable amount of time from the date on which the enrollee provides notice to terminate his or her coverage. We also propose that if the Exchange or the QHP do not have a reasonable amount of time from the date on which the enrollee provides notice to terminate his or her coverage, the last day of coverage is the first day after such reasonable amount of time has passed.

In paragraph (d)(2), we propose that in the case of a termination by the Exchange or a QHP as a result of an enrollee obtaining new minimum essential coverage, the last day of coverage is the day before the effective date of the new coverage. We solicit comments regarding how Exchanges can work with QHP issuers to implement this proposal, which is intended to ensure that an enrollee is not covered under two forms of minimum essential coverage simultaneously. Among the concerns about double coverage is that it makes an individual ineligible for the premium tax credit in accordance with section 36B(c)(2)(B) of the Code. We also note that as the Exchange establishes procedures for termination of coverage notification to enrollees, it should consider how it will also notify the issuer about effective dates of coverage termination.

In paragraph (d)(3), we propose that in the case of a termination by the Exchange or a QHP as a result of an enrollee changing QHPs, the last day of coverage in the enrollee's prior QHP is the day before the effective date of coverage in his or her new QHP. Lastly, in paragraph (d)(4), we propose that for a termination that is not described in paragraphs (d)(1)–(3), the last day of coverage is the fourteenth day of the month if the notice of termination is sent by the Exchange or termination is initiated by the QHP no later than the fourteenth day of the previous month or, the last day of the month if the notice of termination is sent by the Exchange or termination is initiated by the QHP no later than the last day of the previous month. As an example, if the Exchange notifies an enrollee of his or her termination on September 12, his or her coverage will terminate on October 14.

f. Reserved (§ 155.440)

5. Subpart H—Exchange Functions: Small Business Health Options Program (SHOP)

Section 1311(b)(1)(B) of the Affordable Care Act directs each State that chooses to operate an Exchange to establish insurance options for small businesses through a Small Business Health Options Program (SHOP). This program will enable small employers to offer affordable health plans to their employees. Subpart H of this part contains the proposed standards for Exchanges with respect to a SHOP. States that choose to operate an Exchange may also merge SHOP with the individual market Exchange.

We note that participation in a SHOP is strictly voluntary for small employers. Like the Exchange generally, the SHOP will improve access to information about plan benefits, quality, and premiums. It gives small businesses the types of choices and purchasing power that large businesses typically enjoy. Purchasing employer-sponsored coverage through the SHOP will also qualify certain small employers to receive a small business tax credit for

up to 50 percent of the employer's premium contributions toward employee coverage pursuant to section 45R of the Code. The requirements for the small business tax credit applicable for calendar years 2014 and beyond are not within the scope of this rule, but will be addressed in separate rulemaking by the Secretary of the Treasury.

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

In § 155.700, we propose that an Exchange must provide for the establishment of a SHOP that meets the requirements of this subpart, and is designed to assist qualified employers and facilitate the enrollment of qualified employees into qualified health plans.

b. Functions of a SHOP (§ 155.705)

In § 155.705, we propose the required functions of a SHOP. In paragraph (a), we propose that the SHOP must carry out all the required functions of an Exchange described in this subpart and in subparts C, E, H, and K of this part. As some of the requirements contained in those subparts are specific to the individual market, we propose the SHOP exceptions from those requirements in (a)(1) through (a)(5).

In paragraph (a)(1), we propose that the SHOP does not need to meet the requirements related to individual eligibility determinations described in § 155.200(c) and the appeals of such determinations described in § 155.200(d). In paragraph (a)(2) we clarify that the SHOP does not need to comply with the requirements related to enrollment of qualified individuals into QHPs, as described in subpart E. The enrollment requirements specific to SHOP are outlined in § 155.720 of this subpart.

In paragraph (a)(3), we propose that the SHOP does not need to include the calculator described in § 155.205(c) given that individuals eligible for affordable employer sponsored coverage are not eligible for advance payments of the premium tax credit. Because of the employee choice provisions of the Affordable Care Act, we encourage a SHOP to consider options to calculate and display the net employee contribution to the premium for different plans and different family compositions, after any employer contribution has been subtracted from the full premium amount. Because conveying net premium to the employee for coverage is current market practice and is important to informed employee choice, we encourage SHOPs to use this practice.

In paragraph (a)(4), we clarify that the SHOP does not need to certify exemptions from the individual coverage requirement as described in § 155.200(b), as the Exchange will fulfill this requirement. In paragraph (a)(5), we clarify that requirements related to the payment of premiums by individuals, Indian tribes, tribal organizations and urban Indian organizations under § 155.240 do not apply to the SHOP.

In paragraph (b), we propose unique functions of the SHOP. In paragraph (b)(1), we clarify that a SHOP must adhere to unique enrollment and eligibility requirements that are further described in §§ 155.710, 155.715, 155.720, 155.725, and 155.730. In addition, the SHOP must at a minimum facilitate the special enrollment periods described in § 156.285(b)(2). We note that in the context of a SHOP, a special enrollment period allows a qualified employee to join or change plans in certain circumstances during a period other than the employer's annual open enrollment period. In paragraph § 156.285(b)(2), we propose that all of the special enrollment periods that apply in the Exchange in connection with individual market coverage apply in the SHOP, with two exceptions:

(1) Because non-lawfully present individuals employed by a small business are not eligible for the SHOP, there would be no special enrollment period associated with becoming a new citizen, national, or lawfully present individual for the SHOP;

(2) There would be no special enrollment period in the SHOP to reflect a change in eligibility or new eligibility for advance payments of the premium tax credit or cost-sharing reductions since neither is available to qualified employees in the SHOP.

We recognize that other laws (including, but not limited to HIPAA (Pub.L. 104–191)) may require additional special enrollment periods and this proposed rule in no way eliminates those requirements. We also clarify that the two exceptions described above also apply to qualified employees in a SHOP with merged risk pools. We invite comment on special enrollment periods for the SHOP and how they might differ from those that would apply to the Exchange for the individual market.

In paragraph (b)(2) of this section, we propose to codify section 1312(a)(2) of the Affordable Care Act, which specifically provides that a qualified employer may choose a level of coverage under 1302(b), under which a qualified employee may choose an available plan at that level of coverage. We interpret the statute as requiring a SHOP to offer this specific consumer choice option to qualified employers and qualified employees.

In paragraph (b)(3), we provide flexibility for Exchanges and their SHOPs to choose additional ways for qualified employers to offer one or more plans to their employees. For example, an Exchange may (1) allow employees to choose any QHP offered in the SHOP at any level; (2) allow employers to select specific levels from which an employee may choose a QHP; (3) allow employers to select specific QHPs from different levels of coverage from which an employee may choose a QHP; or (4) allow employers to select a single QHP to offer employees. With respect to the fourth potential option, we believe that section 1312(f)(2)(B) of the Affordable Care Act may allow a qualified employer to select only a single QHP to make available to qualified employees. We welcome comments on the statutory interpretation of section 1312(a)(2)(A), which speaks to employer specification of a level of coverage and section 1312(f)(2)(B), which may permit a single QHP selection by an employer.

We note that allowing a qualified employee to purchase any plan across levels raises some potential for risk selection. A portion of any risk selection among plans and issuers due to employee choice of QHPs as defined in § 155.705(b)(2) may be mitigated through the risk adjustment program established pursuant to section 1343 of the Affordable Care Act. We also address this by only proposing a requirement for employee choice within a level of cost sharing, while providing SHOPs the option to offer broader employee choices among plans. We invite comment on this proposed flexibility.

A common practice in the small group market is the issuers' use of minimum participation rules, as defined in 42 U.S.C. 300gg–11(e)(2). The purpose of minimum participation rules is to protect the issuer against adverse selection related to healthy employees either remaining uninsured or obtaining coverage in the individual market. The first concern is mitigated by the coverage expansion provisions in the Affordable Care Act, and the second is mitigated by the market reform provisions of the Act. Nonetheless, there may still be advantages to establishing a minimum participation rule for participation in the SHOP. Methods for calculating the participation rate may vary across States. For example, in some States, carriers may exclude certain non-participating qualified employees from the calculation if they have certain types of coverage, such as Medicare,

Medicaid, or employer-sponsored health insurance obtained through a spouse. We invite comment about whether QHPs offered in the SHOP should be required to waive application of minimum participation rules at the level of the QHP or issuer; whether a minimum participation rule applied at the SHOP level is desirable; and if so, how the rate should be calculated, what the rate should be, and whether the minimum participation rate should be established in Federal regulation.

In paragraph (b)(4), we propose standards related to premium aggregation by the SHOP. To simplify the administration of health benefits among small employers, we propose that the SHOP allow qualified employers to receive a single monthly bill for all QHPs in which their employees are enrolled and to pay a single monthly amount to the SHOP. If this option were not available, a qualified employer may have to pay multiple bills from different QHP issuers each month. Therefore, we propose in paragraph (b)(4)(i) to require that the SHOP provide a monthly bill to a qualified employer that identifies the total premiums owed. We anticipate that most SHOPs will also include the employer and employee contribution for the QHP selected by each employee as a service to employers. Employers will have selected their contribution at the time of initial enrollment or renewal, and employees will have based their plan choices in part on the net cost of the QHPs they select. In paragraph (b)(4)(ii), we propose that the SHOP collect from employers offering multiple coverage options a single cumulative premium payment for all of a qualified employer's qualified employees enrolled through the employer in the SHOP. We note that the SHOP, itself, may aggregate these premium payments from employers and distribute these payments to the appropriate QHP issuers or contract with a third party to perform this function.

In paragraph (b)(5), we clarify that with respect to QHP certification, QHPs must meet the requirements described in § 156.285. As described further in subpart C of part 156, the minimum Federal certification criteria for health plans participating in the SHOP are nearly identical to the certification criteria for the Exchange. However, QHP certification criteria for the SHOP do not include adherence to requirements related to the administration of advance payments of the premium tax credit and cost-sharing reductions, which are specific to the Exchange for the individual market. Additionally, there are a few certification criteria that are specific to the SHOP, including:

- Health plan rate setting and premium payment standards for the SHOP,
- Enrollment period requirements for the SHOP, and
- Enrollment process requirements for the SHOP.

In paragraph (b)(6), we propose standards for rates and rate changes. In paragraph (b)(6)(i), we propose that the SHOP require all QHPs to make any change to rates at a uniform time that is either quarterly, monthly, or annually. As described in § 155.725, we propose to permit rolling enrollment in a SHOP, which allows qualified employers to purchase coverage in QHPs at any point during the year. Because employers will purchase coverage through the SHOP at different times during the year, employers will be subject to different rates based on the month or quarter during which they purchase coverage. Although QHPs may change rates during the year, those rates only apply to new coverage and to annual renewals. Additionally, such rate changes are still subject to rate increase consideration as described in § 155.1020. Paragraph (b)(6)(ii) proposes to require that the rate for a given employer not change during the employer's plan year. By providing uniform intervals for rate setting, SHOPs will experience less administrative burden and qualified employers and qualified employees will have more useful rate comparison information. We note that if an employee is hired during the plan year or changes coverage during the plan year during a special enrollment period, the rates set at the beginning of the plan year must be the rates quoted to the employee. We invite comment on whether we should allow a more permissive or restrictive timeframe than monthly, quarterly, or annually. We also invite comment on what rates should be used to determine premiums during the plan year.

In paragraph (b)(7), we propose that if a State merges the individual and small group risk pools, the Exchange may only offer employers and employees QHPs that meet the SHOP requirements for QHPs, such as the deductible maximums described in section 1302(c) of the Affordable Care Act and the employer choice requirements described in § 155.705(b)(2) of the Affordable Care Act. QHPs sold in a merged market must still meet the general standards defined in § 156.20. Similarly, employee choices among QHPs within and across levels may be limited or expanded by policies of the Exchange or by choices made by the employer.

In paragraph (b)(8), we propose that if a State does not merge the individual and small group risk pools described in (b)(7), a SHOP may only make small group QHPs available to qualified employees. We note that if risk pools are not merged, allowing those in the SHOP to purchase health plans outside of the small group risk pool could result in adverse selection.

In paragraph (b)(9), we propose to codify section 1312(f)(2)(B) of the Affordable Care Act, which permits States to allow insurers in the large group market to offer health plans inside of the SHOP beginning in 2017. In States that elect this option, large employers could make an employee eligible for the SHOP if it provides all full-time employees with the opportunity to enter the SHOP. Section 2794(b)(2)(B) of the PHS Act requires the State to consider excess premium growth outside of the SHOP when considering whether to allow large employers to purchase coverage inside of the SHOP.

c. Eligibility Standards for SHOP (§ 155.710)

In § 155.710, we propose the eligibility standards for qualified employers and qualified employees seeking to purchase coverage through a SHOP. In paragraph (a), we propose to codify section 1311(d)(2) of the Affordable Care Act, which specifies that the SHOP make QHPs available to qualified employers. Paragraph (b) describes the eligibility criteria for qualified employers. We limit the scope of these standards to maximize the accessibility of the SHOP, streamline the enrollment process, and to minimize the burden on employers and employees.

In paragraph (b)(1), we propose that the SHOP ensure that an entity is a small employer. Specifically, the employer must employ no more than 100 employees, with the exception that a State may elect to limit enrollment in the small group market to employers with no more than 50 employees until January 1, 2016.

Section 1304 of the Affordable Care Act defines the calculation of an employer's size based upon the average number of employees employed on business days during the preceding calendar year. The terms ''employer,'' ''small employer,'' and ''large employer'' are defined in § 155.20, and are based on the definitions from the PHS Act. The PHS Act determines employer size by counting all employees, including part-time and seasonal employees, to determine an employer's size. Part-time workers

would be counted in the same manner as full-time workers, while seasonal employees would be counted proportionately to the number of days they work in a year, as discussed in more detail later in this preamble. The PHS Act is in turn consistent with the definition of an employee in section 3(6) of ERISA. Because the PHS Act definition of employer and ERISA definition of group health plan refer to at least 1 employee, they exclude sole proprietors, certain owners of S corporations, and certain relatives of each of the above. The definition of ''employer'' in § 155.20 also requires that all persons treated as a single employer under subsections (b), (c), (m) or (o) of section 414 of the Code must be treated as one employer when determining employer size. We note that States use a variety of methods to determine employer size with regard to eligibility for participation in the small group market, and that these State methods may, in turn, add a level of specificity not described in this method of determining employer size. We solicit comment on this approach.

In paragraph (b)(2), pursuant to section 1312(f)(2)(A) of the Affordable Care Act, we propose to codify the requirement that the SHOP ensure a qualified employer provides an offer of coverage through a SHOP to all full-time employees. In paragraph (b)(3), we propose that the employer can elect to cover all employees through the SHOP serving the employer's principal business address. An employer with worksites in different SHOP service areas can elect to offer each eligible employee coverage through the SHOP serving the employee's primary worksite.

In paragraph (c), we propose to require a SHOP to accept the application of an employer to provide coverage to eligible employees whose worksite is in the SHOP service area, if the employer elects to cover all employees through the SHOPs serving their worksites. This standard provides qualified employers with the flexibility to cover qualified employees in areas in which such employees work, and provides those employees with access to local QHPs that may best meet their needs. If a qualified employer opts to provide coverage through SHOPs in different service areas, SHOPs could establish a participation rule with respect to the number of employees employed by the employer within the service area of the SHOP.

In paragraph (d), we propose to codify section 1304(b)(4)(D) of the Affordable Care Act which allows an employer participating in the SHOP to continue participating in the SHOP if the number of workers employed exceeds the level specified by the definition of a qualified employer after the employer's initial eligibility determination. This provision seeks to minimize potential disruption to qualified employees who work for growing employers. However, this provision would not apply to an employer that otherwise fails to meet the eligibility criteria for participation in the SHOP.

In paragraph (e), we propose eligibility criteria for a qualified employee. Only employees that receive an offer of coverage through the SHOP from a qualified employer may be a qualified employee.

d. Eligibility Determination Process for SHOP (§ 155.715)

In paragraph (a), we propose the eligibility determination process for employers seeking to offer qualified employees health coverage through a SHOP. We propose that a SHOP determine eligibility consistent with the standards described in § 155.710. For both employers and employees, the information proposed to be collected is limited to the minimum information needed to determine eligibility to participate in the SHOP. One way for SHOPs to determine the size of the employer is to allow employers to self-report the size of its workforce and attest to the report's accuracy; however, SHOPs are permitted to require a more stringent determination of employer size and may require other information.

In addition to verifying the size of an employer, we propose that a SHOP must verify that a qualified employer has fulfilled all of the standards specified in § 155.710, including offering all full-time employees access to health coverage through the SHOP, as well as verifying that at least one employee employed by the employer works in the SHOP's service area. We believe that a self-reported address and an attestation by the employer that it is offering coverage should be considered sufficient for verification purposes.

In paragraph (b), we propose that the SHOP use only two application forms: one for qualified employers and one for qualified employees; this is based on our interpretation of section 1413(b)(1)(A), which requires that the Secretary develop and provide to each State a single, streamlined form, and section 1311(c)(1)(F), which provides that an issuer shall use a uniform enrollment form for qualified individuals and employers to enroll in QHPs through the Exchange.

In paragraph (c), we propose that for the purpose of determining eligibility in the SHOP, the SHOP may use the information attested to by the employer or employee on the applicable application. However, the SHOP must, at a minimum, verify that an individual attempting to enter the SHOP as an employee is listed on the qualified employer's roster of employees to whom coverage is offered. Additionally, the SHOP may deny applications for which, through its verification process, it has reason to doubt the veracity of the information provided by the applicant. A SHOP may establish additional methods to verify information beyond reliance on the single employer application and the single employee application. Methods of additional verification that may lead to instances in which a SHOP may have a reason to doubt information provided by employers or employees include, but are not limited to: (1) Review of quarterly wage reports suggesting the employer does not meet the State's definition of a small employer; and (2) attempts by an employer to enroll a number of employees that is greater than allowed under the State's definition of small employer, contrary to attestations made on the application. Appeals related to this process will be addressed in future rulemaking.

In paragraph (d), we propose that the SHOP have processes to resolve occasions when the SHOP has a reason to doubt the information provided through the employer and employee applications. In such cases, the employer or employee must be notified by the SHOP. Further, the SHOP must make a reasonable effort to identify and address the cause of the doubt; contact the employee or employer to confirm the accuracy of relevant information and provide the employee or employer with a 30-day period to correct the possible error. At the end of this period, the SHOP must notify the employee or employer of its eligibility determination and in the case of the employer, if the employer was enrolled in a plan before the completion of this verification process, discontinue the employer's participation in the SHOP (and the enrollment of any employees of that employer) at the end of the month following the month in which the notice was sent.

In paragraph (e), we propose that the SHOP notify an employer of the SHOP's eligibility determination and the employer's right to appeal. In paragraph (f) we propose that the SHOP notify an employee of the SHOP's eligibility determination and the employee's right to appeal.

In paragraph (g), we propose that if a qualified employer ceases to purchase

any coverage through the SHOP, the SHOP must ensure that: (1) Each QHP terminates the coverage of the employer's qualified employees enrolled in QHPs through the SHOP; and (2) each of the employer's qualified employees enrolled in a QHP through the SHOP is notified of the employer's withdrawal and their termination of coverage prior to such withdrawal and termination. We are considering whether this notice must inform the employee about his or her eligibility for special enrollment periods in the Exchange and about the process of being determined eligible for advance payments of the premium tax credit and cost-sharing reductions, Medicaid and CHIP. We solicit comments regarding this eligibility and notification process.

e. Enrollment of Employees into QHPs Under SHOP (§ 155.720)

In § 155.720 we address enrollment of employees into QHPs under SHOPs. In paragraph (a), we propose a general standard that the SHOP must process applications for enrollment from employees and facilitate enrollment of qualified employees into QHPs.

In paragraph (b), we propose that the SHOP establish a uniform enrollment timeline and process to be followed by all employers and QHPs in the SHOP. Such timeline is for the following activities: (1) Determination of employer eligibility to purchase coverage in the SHOP as described in § 155.715; (2) qualified employer selection of QHPs offered through the SHOP to qualified employees, consistent with § 155.705(b)(2) and (3); (3) provision of a specific timeframe during which qualified employers may select the level of coverage or QHP offering, as appropriate; (4) provision of a specific timeframe for qualified employees to complete the employee application process; (5) determination and verification of employee eligibility for enrollment through the SHOP; (6) enrollment processing of qualified employees into selected QHPs; and (7) establishment of effective dates of qualified employee coverage. We note that, pursuant to the rolling enrollment requirements of § 155.725(b), the timeframe for these activities should be standardized relative to a plan year as opposed to a calendar year; while the enrollment dates qualified for employers will differ depending on when they join, the period they have to complete the steps along this process will be consistent among all employers. Ultimately, we believe that to provide a competitive shopping experience for qualified employees, it is important to have similar enrollment processes across QHPs, so qualified employees are not excluded from some QHPs due to inconsistent timing requirements.

In paragraph (c), we propose that the SHOP must process applications in accordance with the timeline described in paragraph (b) and adhere to the requirements specified in § 155.400(b) regarding relevant standards for enrollment and timing of data exchange between the SHOP and QHPs. In paragraph (d), we propose that the SHOP must adhere to standards set forth in § 155.705(b)(4) regarding payment administration.

In paragraph (e), we propose that the SHOP must ensure that qualified employees who select a QHP are notified of the effective date of coverage. The SHOP may require QHPs to officially make such notice, but we propose to make the SHOP responsible for ensuring that such notification occurs.

In paragraphs (f) and (g), we address maintenance of enrollment records and reconciliation of enrollment information with QHPs. We propose that information maintained must include records of qualified employer participation and qualified employee enrollment in the SHOP. Such information must also be reported to HHS, consistent with the standards of § 155.400(d). We propose that reconciliation of enrollment information with QHPs occur at least monthly. We provide SHOPs with discretion to conduct enrollment reconciliation processes on a more frequent basis, depending upon the technical capabilities of the SHOP and participating QHPs. We welcome comments about whether we should establish target dates or guidelines so that multi-State qualified employers are subject to consistent rules.

In paragraph (h), we propose that if a qualified employee voluntarily terminates coverage from a QHP, the SHOP must notify the individual's employer. This ensures that the employer has the proper information for administration of the benefits provided to its employees and the payment for those benefits. Terminations by qualified employees will also be subject to requirements and limitations identified in other laws and the employer's plan; for example, cafeteria plan restrictions on mid-year changes based on the Code will remain applicable.

f. Enrollment Periods Under SHOP (§ 155.725)

In § 155.725, we address enrollment periods under SHOPs consistent with section 1311(c)(6) of the Affordable Care Act. In paragraph (a), we propose that the SHOP: (1) Adhere to the start of the initial open enrollment period for the Exchange; and (2) ensure that enrollment transactions are sent to QHP issuers and that such issuers adhere to coverage effective dates in accordance with § 156.260. We propose that the initial open enrollment for the SHOP begins on October 1, 2013 for coverage effective January 1, 2014, which is the same as the Exchange serving the individual market. However, unlike the initial open enrollment period that closes after a certain date, in the SHOP, the initial open enrollment date represents the starting point for which qualified employers may begin participating in the SHOP.

In paragraph (b), we propose a rolling enrollment process in the SHOP whereby qualified employers may begin participating in the SHOP at any time during the year. We are proposing a rolling enrollment process for the SHOP to match the enrollment process for the small group market outside of the SHOP. We believe that qualified employers will only join the SHOP if it is convenient to do so. Further, employers may be less likely to choose coverage through the SHOP if they can only enroll in the SHOP during a single annual open enrollment period.

We clarify that while a qualified employer may enter the SHOP at any time, the qualified employees will only be able to enroll or change plans (to the extent multiple QHPs are available) once a year unless such employees qualify for a special enrollment period. Additionally, we note that, consistent with current market practice, an employer's plan year may not necessarily align with the calendar year. Instead, plan years inside the SHOP must consist of the twelve-month period beginning with the employer's effective date of coverage. This is different from the open enrollment period for the individual market, where a full plan year will always begin on January 1 and terminate on December 31. We invite comments on these provisions.

In paragraph (c), we propose an annual employer election period in advance of the annual open enrollment period, during which time a qualified employer may, among other things, modify the employer contribution towards the premium cost of coverage and plan offerings. To ensure timely renewal, the qualified employer must work within the confines of the uniform enrollment timeline established by the SHOP and described in § 155.720(b) to make such changes. This requires the employer to make its election before the conclusion of its current plan year and

before the annual employee enrollment period for the following plan year. Because of rolling enrollment and the non-alignment of plan years and calendar years in the SHOP, this annual election period may be specific to each qualified employer and therefore must occur at a fixed point in the plan year, for example two months before its completion, and not at a fixed point in the calendar year.

In paragraph (d), we propose that the SHOP must notify participating employers that their annual election period is approaching. We are considering whether to require the participating employer receive 30 days advance notice that the election period is approaching. During this time, the participating employer will have the time to compare the options available and can then make any changes during the election period. We solicit comment on this notice requirement.

In paragraph (e), we propose to require the SHOP to establish an annual employee open enrollment period for qualified employees. We note that if the SHOP were to allow a qualified employer to offer only one plan to its employees, a qualified employee will not be able to change plans during the annual open enrollment period, but could still change who is enrolled by adding and dropping dependents. As previously stated, small group markets are unique and we believe that the annual employee open enrollment period should be established by the SHOP in order to accommodate the markets that it serves. Such period must occur prior to the completion of the employer's plan year and after the employer's annual election period. Similar to the annual employer election period, because of rolling enrollment in the SHOP, the annual employee enrollment period should occur at a fixed point in the plan year and not at a fixed point in the calendar year. We solicit comment on this provision.

In paragraph (f), we propose that the SHOP ensure a qualified employee who is hired outside of the initial or annual open enrollment period would have a specified window set by the SHOP to seek coverage in a QHP beginning on the first day of employment. Much like the Federal Employees Health Benefit program (which has a 60-day window), the coverage for such an employee would continue through the qualified employer's plan year. At the time of the annual open enrollment period, the employee would have the option to renew or change coverage on a similar basis as the other employees of that qualified employer covered through the SHOP. We solicit comments on these proposed notices and their interaction with existing law and regulation.

In paragraph (g), we propose that the SHOP establish effective dates of coverage for qualified employees. In paragraph (h), we propose that if an enrollee remains eligible for coverage in a QHP through the SHOP, such individual will remain in the QHP selected during the previous plan year with limited exceptions. Exceptions would include: (1) Employee termination of coverage in accordance with the standards of § 155.430 for the individual market: (2) enrollment in another QHP if such option exists: or, (3) the qualified health plan in which the enrollee was enrolled is no longer available to the enrollee. In all such cases, an individual would be disenrolled from the QHP in which he or she was enrolled at the end of the coverage year.

We welcome comments about our approach in differentiating the individual and small group market enrollment as well as specific comments concerning the proposed structure for initial, rolling, and annual open enrollment through the SHOP.

g. Application Standards for SHOP (§ 155.730)

Section 155.730 outlines the specific application-related standards for participation in the SHOP, consistent with the authority under section 1311(b)(1)(B) of the Affordable Care Act. In paragraph (a), we propose a general requirement that SHOP applications must adhere to the application standards set forth in this section. Many of the standards in this section are quite similar to the standards of § 155.405 and in places we directly reference those standards. However, we do not require that the SHOP use the same, single streamlined application as the Exchange uses in the individual market, as the SHOP is not responsible for determining eligibility for advance payments of the premium tax credit, cost-sharing reductions, Medicaid or CHIP.

In paragraph (b), we propose that the SHOP use a single employer application to determine employer eligibility and to collect the information necessary for the employer to purchase coverage through the SHOP. We also propose the minimum employer information that SHOPs must collect on the single employer application. This information includes (1) the employer name and address of employer's; (2) number of employees; (3) Employer Identification Number (EIN); and (4) a list of qualified employees and their social security numbers. Such application may be submitted by other individuals or organizations on behalf of the employer. We welcome comments regarding other employer information we should consider requiring a SHOP to collect.

In paragraph (c), we propose that the SHOP must use a single employee application for each employee to collect eligibility and QHP selection and enrollment information from employees seeking to enroll in a QHP. The amount of information that will be collected about employees will be significantly less than that which is collected for applicants to the individual Exchange making the wholesale reuse of the individual application burdensome. However the single, streamlined application completed by an individual seeking to enroll in the individual market may be modified and reduced to meet the needs of an employee in the SHOP. A SHOP applicant applying online should only be asked questions relevant to an employee application. Similarly, an employee applying through the paper application should receive a paper application containing only the portion relevant to eligibility and enrollment of a qualified employee in the SHOP. Using the same application foundation for employees and individuals will further streamline processes of developing applications and information sharing among the individual Exchange, SHOP, QHP issuers, and HHS. Such application may be submitted by other individuals or organizations on behalf of the employee.

In paragraph (d), we specify that SHOPs may use a model single employer application and model single employee application created by HHS. Model applications will be proposed by HHS, after consultation with the NAIC. This process mirrors the standards in the Exchange serving the individual market. In paragraph (e), we permit a SHOP to use an alternative employer application with approval by HHS. Such application should support the information described in paragraph (b) and information relevant to determine eligibility for the programs for which the employer is applying and plan selection, where relevant. The SHOP may also use an alternative employee application, the approval by HHS. Such application requests the information necessary to establish eligibility of the employee as a qualified employee and to complete the enrollment of a qualified employee, such as a plan selection and identification of dependents to be enrolled.

In paragraph (f), we propose that the SHOP must allow employers and employees to submit their eligibility and enrollment information consistent with § 155.405(c).

6. Subpart K—Exchange Functions: Certification of Qualified Health Plans

This subpart codifies section 1311(d)(4)(A) of the Affordable Care Act, which requires that Exchanges, at a minimum, implement procedures for the certification, recertification, and decertification of health plans as QHPs, consistent with guidelines developed by HHS. This subpart also distinguishes the Exchanges' responsibility related to the inclusion in the Exchange of certain multi-State plans. Standards for health insurance issuers with respect to QHP certification are contained in subpart C of part 156 of this regulation, and we cross-reference those standards where applicable in this subpart.

When developing this subpart, we considered comments to the RFC recommending that Exchange certification of QHPs be structured in one of two ways: Establish QHP certification standards that would be uniform across Exchanges, or provide each Exchange the discretion to determine certification standards and whether or not a health plan should be certified. While we recognize the importance of setting consistent consumer protections which may ensure equitable treatment across States, we also acknowledge that an Exchange may be best positioned to identify whether a particular health plan should be certified as a QHP based on the needs of consumers within the State and local market conditions. In this subpart, we seek to strike a balance between the approaches suggested by RFC commenters. In some cases, we propose setting specific requirements to ensure QHPs in all Exchanges meet a consistent minimum standard of quality and value, and in other instances, we propose allowing each Exchange the discretion to set standards for QHPs tailored to local market conditions.

a. Certification Standards for QHPs (§ 155.1000)

In § 155.1000, we describe the overall responsibility and requirements of an Exchange to certify QHPs, and to ensure that only QHPs are offered. In paragraph (a), we define a multi-State plan. Section 1334(a) of the Affordable Care Act establishes multi-State plans; the Office of Personnel Management (OPM) will enter into contracts with health insurance issuers to offer at least two multi-State QHPs through each Exchange in each State. Section 1334(c)(1) of the Affordable Care Act further specifies that multi-State QHP requirements are satisfied if the OPM Director determines the plan offers a benefits package that is uniform in each State and consists of the benefit design standards described in section 1302, meets all requirements for QHPs, and meets Federal rating requirements pursuant to section 2701 of the PHS Act, or a State's more restrictive rating requirements, if applicable.

In paragraph (b), we propose to codify section 1311(d)(2)(B)(i) of the Affordable Care Act, which requires that an Exchange may not make available any health plan that is not a QHP. Offering only QHPs through an Exchange will assure consumers that the coverage options presented through the Exchange meet minimum standards. Also, consistent with the definition of QHP in § 155.20, we propose to codify section 1301(a)(1)(A) of the Affordable Care Act, in which QHPs must have in effect a certification issued or recognized by the Exchange as QHPs. Finally, we propose to codify section 1301(a)(2) of the Affordable Care Act, which requires any reference to QHPs to include the multi-State plans, unless specifically provided for otherwise.

In paragraph (c), we propose to codify the two basic sets of requirements that an Exchange must ensure that a health plan meets to be certified as a QHP issuer by an Exchange pursuant to section 1311(e) of the Affordable Care Act. In paragraph (c)(1), we propose to codify section 1311(c)(1) of the Affordable Care Act, which provides for the minimum QHP certification requirements to be applied by an Exchange; these requirements are outlined in subpart C of part 156. In developing a process to certify QHPs, the Exchange should identify those standards from subpart C of part 156 with which a health insurance issuer should demonstrate compliance as a condition of certification of QHPs, as well as those standards with which a health insurance issuer should agree to comply as an ongoing condition of offering QHPs.

In paragraph (c)(2), we propose to codify section 1311(e)(1)(B) of the Affordable Care Act, which allows an Exchange to certify a health plan if it determines it is in the interest of qualified individuals and qualified employers in the State. We received RFC comments regarding the extent to which Exchanges should implement an ''any-willing plan'' model, or implement active purchasing approaches, such as selective contracting or price negotiation. Some commenters argued that active purchasing approaches would minimize costs, improve health outcomes, and increase enrollment and coordination with other programs. Of these comments, many recommended that at a minimum, HHS should not require the Exchanges to accept all eligible plans. In contrast, advocates of the any-willing plan approach noted that State insurance departments already review and approve rates and regulate insurer solvency, and that negotiation would result in de facto premium price controls for the entire market, reduce consumer choice and competition, and result in duplicative regulatory structures.

We provide Exchanges with discretion on how to determine whether offering health plans is in the interest of individuals and employers. An Exchange may want to choose among one of several strategies for making this determination. An Exchange may choose to utilize an ''any qualified plan'' strategy for certifying QHPs in its Exchange. Under this approach, an Exchange would certify all health plans as QHPs solely on the basis that such plans meet and agree to comply with the minimum certification requirements in paragraph (c)(1) of this section.

Alternatively, an Exchange could undertake a competitive bidding or selective contracting process, and limit QHP participation to only those plans that ranked highest in terms of certain Exchange criteria. With competitive bidding, an Exchange may be able to achieve additional value and quality objectives by limiting participation and through plan competition. Since many State Medicaid programs employ selective contracting models today and have experience negotiating with health insurance issuers on Medicaid managed care plans, some State Exchanges may want to pursue similar competitive strategies when certifying QHPs.

An Exchange may also choose to negotiate with health insurance issuers on a case-by-case basis. Under this strategy, the Exchange would request a health insurance issuer, upon meeting the minimum certification standards, to amend one or more specific health plan offerings to further the interest of qualified individuals and qualified employers served by the Exchange. Unlike the previous options, the Exchange would not need to undertake a competitive bidding process to accomplish this negotiation. Rather, it could choose to negotiate with issuers on certain criteria based on the unique market conditions within the State or region served by that same Exchange.

An Exchange may also implement selection criteria beyond the minimum certification standards in determining whether a plan is in the interests of the qualified individuals and employers. Some examples of such selection criteria include: (1) Reasonableness of the estimated costs supporting the

calculation of the health plan's premium and cost-sharing levels; (2) past performance of the health insurance issuer; (3) quality improvement activities; (4) enhancements of provider networks including the availability of network providers to new patients; (5) service area of the QHPs (the size of a service area and the amount of choice afforded to the consumers within that service area); and (6) premium rate increases from years preceding the Exchange operation and proposed rate increases, consistent with § 155.1020.

Some of these approaches are not mutually exclusive and may be implemented in combination. How an Exchange elects to implement the ''interest'' determination may vary based upon a number of factors, including the size and risk profile of the Exchange's potential enrollees, concentration of the health insurance market in the area served by the Exchange, and the applicable State insurance rules. Each Exchange will likely need to assess these factors in selecting an approach that will promote value and quality for its enrollees.

In paragraph (c)(2) we propose to codify section 1311(e)(1)(B) of the Affordable Care Act, which outlines the prohibitions on the Exchange when it is making the determination that a health plan is in the interest of qualified individuals and qualified employers. Under this authority, an Exchange is prohibited from excluding a plan: (1) On the basis that the plan is a fee-for-service plan; (2) through the imposition of premium price controls; or (3) on the basis that the health plan provides treatments necessary to prevent patients' deaths in circumstances the Exchange determines are inappropriate or too costly.

b. Certification Process for QHPs (§ 155.1010)

In § 155.1010, we propose the required process that Exchanges must use when certifying health plans, and identify which health plans are not subject to Exchange certification. Specifically, in paragraph (a) we propose to codify section 1311(d)(4)(A) of the Affordable Care Act, which requires the Exchange to establish procedures for the certification of QHPs. We further propose that the procedures must be consistent with the certification criteria outlined in § 155.1000(c).

In paragraph (b), we propose to codify section 1334(d) of the Affordable Care Act which requires a multi-State plan offered through OPM to be deemed as certified by an Exchange for the purposes of section 1311(d)(4)(A). We note that, pursuant to section 1334(c)(1)(B), multi-State plans will need to meet all the requirements of a QHP, as determined by OPM. We believe that the intent of the statute is that each Exchange must accept multi-State plans as QHPs without applying an additional certification process to such plans. In paragraph (c), we propose that the Exchange complete the certification of QHPs prior to the open enrollment periods established in § 155.410. We believe this is necessary to ensure that consumers will have a robust market from which to select QHPs when the open enrollment period begins.

In paragraph (d), we propose that the Exchange must monitor the QHP issuers for demonstration of ongoing compliance with the certification requirements in § 155.1000(c). If the QHP issuers or their QHPs cease to demonstrate ongoing compliance, the Exchange may be inclined to seek actions against the issuers or try to remedy the situation.

c. QHP Issuer Rate and Benefit Information (§ 155.1020)

Section 1311(e)(2) of the Affordable Care Act establishes standards on Exchanges regarding the transparency of justifications for rate increases submitted by QHP issuers. In accordance with this section, in paragraph (a) of § 155.1020, we propose that Exchanges must receive a QHP issuer's justification for a rate increase prior to the implementation of such an increase, and ensure that the QHP issuer posts the justification on its Web site. We recognize that QHP issuers may already submit rate increase justifications as part of the rate review process, and note that an Exchange may receive this information from the State department of insurance (or HHS, if applicable), to satisfy its obligation to receive such a justification.

Section 1311(e)(2) of the Affordable Care Act also requires an Exchange to consider rate increases in determining whether to make a health plan available on the Exchange. Several comments in response to the RFC recommended a range of purposes for the Exchange consideration of rate increases, including adequacy of claims payment, reasonableness for benefits offered based upon actuarial analysis, discriminatory practices, and unsupported excessive rate increases. Other comments noted the interaction between the State rate review process and Exchange review of premiums for QHP certification purposes. Finally, some commenters recommended transparency in review of rate justifications as well as consistent criteria of ''reasonableness'' of increases inside and outside Exchanges.

In paragraph (b) we propose to codify the statutory requirement that an Exchange must consider the following factors related to health plan rates when determining whether to certify QHPs: (1) The justification of a rate increase prior to the implementation of the increase; (2) the recommendations provided to the Exchange by the State under section 2794(b)(1)(B) of the PHS Act; and (3) any excess rate growth outside the Exchange as compared to the rate of growth inside the Exchange, including information reported by the States. We clarify that the obligation to consider rate increases justifications is an ongoing requirement, beginning with the plan year 2014.

We seek to avoid duplicating the State rate review process in section 2794 of the PHS Act. We recognize that many States already operate an effective rate review program, collect information from issuers in the rate filing process and make a determination if the rate complies with State law. This process, when available, should be leveraged by the Exchange to avoid any duplication. For example, Exchanges may consider the preliminary justification already collected through the rate review process, and use the same format for the rate justification from health plans issuers under § 154.215. Establishing consistency between the rate justification described in § 154.215 and the justification required from QHP issuers by § 156.210 would reduce duplication of effort for issuers and Exchanges and promote greater transparency.

We are considering a standard for the final rule in which there would be a bifurcated process for the rate increase justifications. Where section 2794 of the PHS Act applies (rates are subject to review), the Exchange may rely on the justification submitted pursuant to section 2794 of the PHS Act. Where section 2794 of the PHS Act does not apply, the Exchange could develop a less burdensome rate justification to satisfy section 1311(e)(2) of the Affordable Care Act. We are cognizant of existing State regulatory authorities; thus, we encourage the Exchange and the State department of insurance to collaborate in this process. Collaboration may include determining the form, manner, and timing of the submission of the rate justifications. We solicit comment on how to best align section 2794 of the PHS Act and section 1311(e)(2) of the Affordable Care Act.

Separate and apart from the consideration of a rate increase

justification, Exchanges will need to receive rate and benefit information from QHP issuers for specific operational purposes. In paragraph (c) of § 155.1020, we propose that the Exchange must at least annually receive the following information from the QHP issuers' for each QHP: Rates, covered benefits and cost-sharing requirements. HHS will provide the form and manner for the submission of this information. We note that the Exchange will need to receive rate information from QHP issuers in order to determine premium amounts for Exchange applicants as well as for the determination of the second lowest cost silver plan benchmark for advance payments of the premium tax credit. Additionally, benefit information is needed to determine whether a QHP complies with the benefit design standards defined in § 156.20 and with the actuarial value requirements for cost-sharing reductions as well as to display plan options on the Exchange Web site. Furthermore, rate information is needed to support HHS' administration of the risk corridor program.

In establishing the required rate and benefit data elements, HHS will seek to align this reporting requirement with information available through the State rate review process or through State rate filings, to the extent possible, so that an Exchange may consider leveraging already available sources.

d. Transparency in Coverage (§ 155.1040)

In § 155.1040, we propose to codify section 1311(e)(3) of the Affordable Care Act, which establishes that Exchanges must require health plans seeking certification as QHPs to submit transparency information to the Exchange, HHS, and other entities. In paragraph (a), we require Exchanges to collect information from QHP issuers relating to coverage transparency as described in § 156.220(a).

While the transparency reporting requirements in § 156.220 apply specifically to QHPs, we note that these same requirements will also apply to all group health plans and health insurance issuers in the individual and group markets under section 2715A of the PHS Act as amended by the Affordable Care Act. As section 2715A of the PHS Act is implemented, we anticipate working closely with the Department of Labor and the Department of the Treasury in order to ensure that these reporting standards are applied appropriately across the insurance market. In addition, HHS is soliciting comments under this proposed rule as part of the process of planning for the implementation of section 1311(e)(3)(D) of the Affordable Care Act. Any comments received related to section 1311(e)(3)(D) will be shared with the Department of Labor so that it can update and harmonize its rules for group health plan disclosures.

In paragraph (b), we require the Exchange to monitor the use of plain language by QHP issuers when making available QHP transparency data pursuant to § 156.220. Section 1311(e)(3)(B) requires the Secretary of HHS and the Secretary of Labor to jointly develop and issue guidance on best practices of plain language writing. Exchanges will need to ensure that QHP issuers' use of plain language is consistent with the definition provided in § 155.20 and the guidance set forth as required by section 1311(e)(3)(B).

In paragraph (c), we propose to codify section 1311(e)(3)(C) of the Affordable Care Act which specifies that the Exchange require QHP issuers make available cost-sharing information to enrollees. This requirement on QHP issuers is described in § 156.220(c).

We note that the information provided by QHP issuers pursuant to this section may be used by Exchanges during the certification process when determining if the health plan is in the interest of the qualified individuals served by the Exchange. Information reported under this section may inform Exchanges when considering the past performance of the health insurance issuers.

e. Accreditation Timeline (§ 155.1045)

In § 155.1045, we propose to codify the Exchange responsibility, required by section 1311(c)(1)(D)(ii) of the Affordable Care Act, to establish the time period within which any QHP issuer that is not already accredited must become accredited following certification of a QHP. Accreditation acts as a ''seal of approval'' to indicate to individuals and employers seeking coverage that a health insurance issuer meets minimum standards of quality and consumer protection. We note that, although section 1311(c)(1)(D)(i) of the Affordable Care Act requires a health plan to be accredited to be certified as a QHP, we interpret this to mean that QHP issuers must be accredited, because accrediting entities accredit issuers, not plans. In § 156.275, we propose that all QHP issuers must be accredited with respect to their QHPs.

The Affordable Care Act does not set the deadline by which a health insurance issuer must be accredited to have a health plan certified as a QHP, nor does it establish a time period after certification of a QHP during which a QHP issuer must become accredited if it is not already accredited. A grace period may be necessary since a typical accreditation process for a health insurance issuer may take twelve to eighteen months to complete, and could be even longer for health insurance issuers seeking accreditation for the first time. We encourage the Exchanges to establish a timeline for accreditation that accommodates the length of the accreditation process, particularly for issuers seeking first-time accreditation.

We propose to require the Exchange to establish the length of time following initial certification of a QHP within which a QHP issuer must become accredited. The Exchange must establish a consistent deadline for accreditation with respect to each QHP issuer's initial participation in the Exchange; the deadline, for example, may be two years following certification of a QHP. This proposal is consistent with section 1311(c)(1)(D)(ii) of the Affordable Care Act which specifies that the time period established by the Exchange must be ''applicable to all QHPs.'' We believe this interpretation, as opposed to a single date by which all QHP issuers must be accredited in order to participate or continue participating in the Exchange, will allow for inclusion of a wider variety of QHP issuers in the Exchange.

f. Establishment of Exchange Network Adequacy Standards (§ 155.1050)

The Exchanges will make health insurance available to a variety of consumers, including those who reside or work in rural or urban areas where it may be challenging to access health care providers. Network adequacy requirements will help ensure that QHP enrollees can readily obtain services. Under section 1311(c)(1)(B) of the Affordable Care Act, HHS is required to establish network adequacy requirements for health insurance issuers seeking certification of QHPs.

We recognize that network adequacy standards should be appropriate to States' particular geography, demographics, local patterns of care, and market conditions. Therefore, to ensure that Exchange network adequacy requirements are appropriate for QHP issuers and reflect local patterns of care, we propose in § 155.1050 that each Exchange ensure that enrollees of QHPs have a sufficient choice of providers. This broad standard affords the Exchange significant flexibility to apply this standard to QHPs in a manner appropriate to the State's existing patterns of care, establishing specific standards where necessary and leveraging existing State oversight and

enforcement mechanisms in this area. We propose at § 156.230 that QHP issuers adhere to standards set by the Exchange, as well as several statutorily required standards that would apply to all QHP issuers.

We solicit comment on additional minimum qualitative or quantitative standards for the Exchange to use in evaluating whether the QHP provider networks provide sufficient access to care. When considering our options for establishing network adequacy standards for QHP issuers, we examined typical standards employed in the existing insurance market by State departments of insurance, Medicare Advantage, TRICARE Prime and States that contract with Medicaid managed care organizations. We also examined the NAIC Managed Care Plan Network Adequacy Model Act, from which a number of States have drawn in developing their network adequacy standards for health insurance issuers. We have sought to develop a standard that balances the need for a uniform level of protection with the level of variation across States and local markets.

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

We also seek comment on an additional standard that the Exchange ensure that QHPs' provider networks provide sufficient access to care for *all* enrollees, including those in medically underserved areas. Such a requirement would protect against a network design that does not serve all enrollees' medical needs.

The standard proposed here would allow an Exchange to set standards appropriate to local patterns of care. We urge the Exchanges to consider the needs of enrollees in isolated geographic areas in particular; for example, an Exchange may want to consider the needs of American Indians and Alaska Natives residing in remote locations, given that they may often have a limited choice of providers from which to select. We also clarify that a QHP issuer's provider network must ensure reasonable access to care for all enrollees enrolled through the Exchange regardless of an enrollee's medical condition.

We recognize that primary care access is a challenge in many communities nationally, and that more consumers may seek routine primary care services in 2014 given improved access to health insurance coverage. Consistent with the goals and policies of the Affordable Care Act in supporting primary care, in establishing provider networks that ensure broad access to care, we encourage States, Exchanges and health insurance issuers to consider broadly defining the types of providers that furnish primary care services (e.g., nurse practitioners).

g. Service Area of a QHP (§ 155.1055)

In § 155.1055, we propose that Exchanges have a process to establish or evaluate the service areas of QHPs. Under this proposed rule, an Exchange would maintain discretion to pre-determine service areas for plans to cover, permit plans to propose coverage of certain service areas, or negotiate with issuers over service areas during the certification process. This provision is intended to promote greater choice and competition as consistently as possible across a State, and to guard against discrimination, ''cherry picking,'' ''red-lining,'' or other similar efforts to offer health plans only in areas of low risk. We also seek to recognize that the capacity of health insurance issuers varies by region due to some factors that are outside of their control.

In paragraph (a), we propose that an Exchange must ensure that the service area of a QHP covers at least a county, or a group of counties if the Exchange designates such a group, unless the QHP issuer demonstrates that serving a partial county is necessary, nondiscriminatory, and in the interest of qualified individuals and employers. The requirement outlined here parallels the ''county integrity rule'' established in Medicare Advantage, which also outlines examples for determining whether serving a partial county would fall under the ''necessary'' or ''nondiscriminatory'' standards.

In paragraph (b), we propose that an Exchange must ensure that QHP service areas be established without regard to racial, ethnic, language and health status factors outlined in section 2705(a) of the PHS Act. This provision is intended to guard against redlining and other practices that would specifically exclude high-utilizing or high-cost populations.

h. Stand-Alone Dental Plans (§ 155.1065)

In § 155.1065(a), we propose to codify the requirement in section 1311(d)(2)(B)(ii) of the Affordable Care Act that an Exchange allow limited scope stand-alone dental plans to be offered provided that the plan furnishes at least the pediatric essential dental benefit required in section 1302(b)(1)(J) of the Affordable Care Act. We also propose to codify the requirement that the stand-alone dental plan comply with section 9832(c)(2)(A) of the Code and section 2791(c)(2)(A) of the PHS Act.

In paragraph (b), we propose to codify the option for a dental plan to be offered as a stand-alone plan or in conjunction with a QHP. In paragraph (c), we propose to codify section 1302(b)(4)(F) of the Affordable Care Act that allows a health plan be certified as a QHP if it does not offer the pediatric essential dental benefit, provided that a stand-alone dental plan is offered through the Exchange. We also note that dental plan issuers would be considered participating issuers subject to any user fees specified by the Exchange, as established under § 156.50 and § 155.160.

We are considering interpreting this provision such that an Exchange may require issuers of stand-alone dental plans to comply with any QHP certification requirements and consumer protections that the Exchange determines to be relevant and necessary. Potential QHP issuer standards that might be applied to stand-alone dental plans might include: Quality reporting, transparency measures, summary of coverage information, provider network standard, and standards regarding the consumer's experience in comparing and purchasing dental plans. While we provide significant latitude to Exchanges regarding requirements for stand-alone dental plans, we request comment on whether some of the requirements on QHP issuers should also apply to stand-alone dental plans as a Federal minimum and what limits Exchanges may face on placing

requirements on dental plans given that they are excepted benefits.

We also request comment on whether we should set specific operational minimum standards. Substantial operational issues exist with allocating advance payments of the premium tax credit and calculating actuarial value (as defined by section 1302(d)(2) of the Affordable Care Act) when stand-alone dental plans segment coverage of the essential health benefits (as defined in 1302(b) of the Affordable Care Act). Also, a QHP issuer will have to know far enough in advance of the QHP certification process whether it needs to include pediatric dental coverage.

Lastly, some commenters to the RFC requested that we require all dental benefits to be offered and priced separately from medical coverage, even when offered by the same issuer. Such a requirement would preclude QHP issuers from offering a ''bundled'' QHP that covers all essential health benefits, including the pediatric dental benefit, under one premium. While we recognize that requiring a QHP to price and offer dental benefits separately could promote comparison of dental coverage offerings, we have significant concerns about the administrative burden this could impose on Exchanges and QHP issuers. We request comment on whether either option should be required.

i. Recertification of QHPs (§ 155.1075)

In § 155.1075, we propose to codify section 1311(d)(4)(A) of the Affordable Care Act, which requires the Exchange to implement procedures for the recertification of health plans as QHPs. While the Exchange must continuously ensure that QHPs are in compliance with the certification standards, recertification provides a process for an Exchange to conduct a comprehensive review of its QHPs. This process also allows for QHPs and Exchanges to terminate their relationship if intended. In paragraph (a), we provide that the Exchange must establish a process for recertification of QHPs that includes a review of the general certification criteria outlined in § 155.1000(c). We note that the recertification process for the QHPs should be less intensive than the initial certification process, given that the Exchange will have an established relationship with the QHP issuer. An Exchange may also consider using this process to make modifications to any agreements between the Exchange and its QHP issuers.

We permit the Exchange to determine the frequency for recertifying QHPs. The Affordable Care Act does not require an Exchange to recertify QHPs on an annual basis. Therefore, an Exchange has the discretion to decide to recertify QHPs annually, or on a less frequent basis, such as every other year or every three years. Some Exchanges may choose to develop longer recertification periods to reduce the administrative costs associated with such an evaluation. By operation of § 156.200, each QHP must still adhere to the requirements listed in § 155.1000(c) on an ongoing basis. We invite comment as to whether we should require more specific requirements associated with the term length for recertification.

We note that an Exchange that elects to conduct multi-year recertification will need to review certain information on a more frequent basis. For example, the Exchange will need to consider rate increase information and ensure compliance with benefit design standards annually, since issuers may alter rate and benefit design on an annual basis.

We also propose that, after reviewing all relevant information and determining whether to recertify a QHP, the Exchange notify a QHP issuer of its recertification status. If the Exchange determines that a plan should be denied recertification, the Exchange would then proceed decertifying the plan as described in § 155.1080.

In paragraph (b), we propose that the Exchange must complete the recertification process on or before September 15 of the applicable calendar year. We chose this date so that the recertification process is completed in advance of the annual open enrollment period, which begins on October 15 of each year. By providing a September 15 deadline, we allow the Exchanges discretion to determine a recertification timeframe that is most suitable for its consumers and QHPs. The Exchange may choose to complete its recertification process well in advance of the September 15 deadline. We solicit comments on the appropriateness of this recertification deadline.

j. Decertification of QHPs (§ 155.1080)

In § 155.1080, we propose to codify section 1311(d)(4)(A) of the Affordable Care Act, which requires the Exchange to implement procedures for the decertification of health plans as QHPs. In paragraph (a), we define decertification as the termination by the Exchange of the certification status and offering of a QHP. We note that decertification is an action taken by the Exchange in response to the most severe actions of a QHP, or as a result of a determination not to recertify a plan. In paragraph (b), we propose to codify section 1311(d)(4)(A) of the Affordable Care Act, which requires the Exchange to implement procedures for the decertification of health plans as QHPs.

In paragraph (c), we propose that the Exchange may at any time decertify a QHP if the Exchange determines that the QHP issuer or the QHP is no longer acting in accordance with the general certification criteria outlined in § 155.1000(c), including that the QHP participation is no longer in the interest of its enrollees. Similar to the certification and recertification processes, the Exchange has the ability to tailor the decertification process, within the confines of the aforementioned standards, to meet the needs of the market it serves.

The Exchange will have discretion in determining how to implement the decertification process. We recommend that Exchanges solicit input from a broad range of stakeholders, including issuers, when determining how to implement the decertification procedures. We request comments on the creation of the decertification process and what other authorities could be extended to the Exchange to make the process more efficient.

In paragraph (d), we propose to require that the Exchange establish an appeals process for health plans that have been decertified by the Exchange. A health plan that has been decertified should have that ability to request a second evaluation if the issuer believes that its health plan has been unjustly decertified. This appeal process could be implemented in conjunction with the State department of insurance, by the Exchange on its own, or through a third party entity.

In paragraph (e), we propose that if a QHP is decertified, the Exchange must provide notice of the decertification to parties who may be affected. The decertification of a QHP will have an impact on the Exchange market, including the QHP issuer, enrollees of the decertified QHP, who must receive information about a special enrollment period as described in § 155.420, HHS, and the State department of insurance.

B. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

The Exchanges should be an attractive market for health insurance issuers to achieve the goal of providing consumers and employers with access to a competitive choice of affordable, high quality QHPs. Part 156 contains the proposed standards for QHPs and QHP issuers that are intended to promote robust and meaningful consumer

choice. Many provisions in this part have parallel standards in part 155, because certain standards for States and Exchanges have complementary standards for health insurance issuers seeking to offer, or offering, QHPs through an Exchange. We cross-reference to minimize redundancy and avoid confusion with respect to certain proposed policies. To the extent possible, this approach to drafting is designed to avoid gaps between the minimum standards we propose for Exchanges and QHPs.

1. Subpart A—General Provisions

a. Basis and Scope (§ 156.10)

Proposed § 156.10 of subpart A specifies the general statutory authority for the ensuing proposed regulation and indicates that the scope of part 156 is to establish standards for health plans and health insurance issuers related to the benefit design standards and in regard to offering QHPs through an Exchange. Under § 156.20, we propose definitions for terms used in part 156. Section 156.50 proposes the user fees that participating issuers may pay to contribute to the operations of a State Exchange, and Exchange-related operations.

b. Definitions (§ 156.20)

Many definitions presented in § 156.20 are taken directly from the Affordable Care Act or from existing regulations. The definitions set forth in subpart A reflect general meanings for the terms as they are used in part 156 unless otherwise indicated; the definitions apply strictly for the purposes of part 156. When a term is defined in part 156 other than in subpart A, the definition of the term is limited to a specified purpose in the relevant subpart or section.

Many of the terms defined in this section refer to those defined in § 155.20, including ''applicant,'' ''benefit year,'' ''cost sharing,'' ''cost-sharing reductions,'' ''plan year,'' ''qualified employer,'' ''qualified individual,'' ''qualified health plan or QHP,'' and ''qualified health plan issuer or QHP issuer.'' We define ''benefit design standards'' for the purposes of the requirements related to the benefit packages outlined in the Affordable Care Act. The terms ''group health plan,'' ''health insurance coverage,'' and ''health insurance issuer'' are defined in section § 144.103 of this chapter.

We propose to use the term ''benefit design standards'' to mean the ''essential health benefits package'' defined in section 1302(a) of the Affordable Care Act. To avoid confusion with the term ''essential health benefits,'' which refers only to the definition in section 1302(b) of the Affordable Care Act, we instead refer to the set of health plan requirements as benefit design standards for the purposes of clarity within this proposed rule.

c. Financial Support (§ 156.50)

Section 156.50 contains requirements on participating issuers to pay user fees to support ongoing operations of an Exchange, if a State chooses to impose fees. A State-operated Exchange must be self-sustaining by January 1, 2015, under section 1311(d)(5)(A), which also allows State user fee assessments on participating health insurance issuers, or other methods of funding, to support State Exchange operations.

In paragraph (a), we define the term ''participating issuer'' to mean an issuer offering plans that participate in the specific function that is funded by the user fee. Under this definition, a participating issuer would encompass different segments of issuers of health plans or other benefit plans depending on the Exchange function being funded by the user fee. As this term is used in section 1311(d)(5)(A), it provides an Exchange with the flexibility to collect user fees from issuers that benefit in some way from an Exchange and Exchange-related operations. We note that the term ''participating issuer,'' for the purposes of this section, may include: health insurance issuers, QHP issuers, issuers of multi-State plans (as defined in § 155.1000(a)), issuers of stand-alone dental plans (as described in § 155.1065), or other issuers identified by an Exchange. In paragraph (b), we propose that participating issuers pay any fees assessed by a State Exchange, consistent with Exchange authority outlined in § 155.160.

2. Subpart C—Qualified Health Plan Minimum Certification Standards

Section 1311(c)(1) authorizes the Secretary, by regulation, to establish criteria for the certification of health plans as QHPs, which are described in this subpart. The statute outlines several minimum QHP standards to be established by the Secretary that will foster direct competition on the basis of price and quality and which will increase access to high quality, affordable health care for individuals and small employers. Each Exchange will be responsible for determining whether a health plan seeking to participate meets these minimum requirements to be a QHP and will have the discretion to set additional standards to ensure that offering the plan through that Exchange is in the best interest of consumers.

We received many comments in response to the RFC on minimum QHP certification requirements, which we describe in the preamble to subpart K of part 155 and which we considered as we developed the proposed rule. We highlight that, unless otherwise noted, the standards for QHPs proposed in this subpart do not supersede existing State laws or regulations applicable to health insurance issuers. While this subpart addresses health plan standards that States traditionally set, either through the process of granting licensure or otherwise, the standards proposed here apply specifically to the certification of QHPs for participation in the Exchange and do not exempt health insurance issuers from any State laws or regulations that generally apply to health insurance issuers in that State. We note that if a State establishes a higher standard for licensure than what we outline here as a minimum Federal requirement for health plan certification, such standard would apply.

a. QHP Issuer Participation Standards (§ 156.200)

Section 156.200 outlines the requirements on QHP issuers as a condition of participation in the Exchange. States may choose to establish additional conditions for participation beyond the minimum requirements established by the Secretary.

In paragraph (a), we propose to codify section 1301(a)(1)(A) of the Affordable Care Act. To participate in an Exchange, a health insurance issuer must have in effect a certification issued or recognized by the Exchange to demonstrate that each health plan it offers in the Exchange is a QHP and that the issuer meets all requirements on QHP issuers. We clarify that some requirements in this proposed rule apply to the design of the specific QHPs offered. Other requirements are placed on the issuers related to the offering of QHPs.

In paragraph (b), we outline the set of standards with which a QHP issuer must comply related to the offering of a QHP. We propose in paragraph (b)(1) that the QHP issuer must comply with the requirements set forth in this subpart on an ongoing basis. We expect the Exchange to take into account compliance with the requirements in this subpart not only when determining whether to initially certify a health plan as a QHP, but also when reviewing QHPs for recertification.

In paragraph (b)(2), we propose that QHP issuers must comply with any Exchange processes, procedures, and standards set forth under subpart K of part 155 and § 155.705 for the small group market. We include the requirement to adhere to this certification process as a condition of participation so that the Exchange has the ability to conduct certification processes in a way that best meets the needs of the market it serves. This includes the process in which a health insurance issuer seeking initial certification of a QHP must demonstrate that it complies with the standards listed under paragraph § 155.1000(c).

In paragraph (b)(3), we propose to require that a QHP issuer ensures that each QHP it offers complies with the benefit design standards defined in § 156.20. Benefit design standards relate to the requirement in section 1301(a)(1)(B) of the Affordable Care Act that requires that QHPs offer the essential health benefits, adhere to cost-sharing limits, and meet the levels of coverage described in 1302(a) which will be the subject of future rulemaking.

In paragraph (b)(4), we propose to codify the requirement in section 1301(a)(1)(C)(i) that a QHP issuer be licensed and in good standing to offer health insurance coverage in each State in which such issuer offers health insurance coverage. We interpret the term ''good standing'' to mean that the issuer has no outstanding sanctions imposed by a State's department of insurance. We seek comment on this interpretation. Licensure could also mean a ''certificate of authority,'' or any other State method of approving a health insurance issuer to offer health insurance coverage in the State.

In paragraph (b)(5), we propose that QHP issuers comply with quality standards established in and pursuant to sections 1311(c)(1), 1311(c)(3), 1311(c)(4), and 1311(g) of the Affordable Care Act. We intend to address specific requirements in future rulemaking, such as requirements for QHP issuers related to quality data reporting, quality improvement strategies, and enrollee satisfaction surveys described in these statutory provisions.

In paragraph (b)(6) and (b)(7), we propose that QHP issuers adhere to additional proposed requirements including user fees described in subpart A of part 156, if applicable, and the risk adjustment participation requirements as described in 45 CFR part 153.

In paragraph (c), we outline the requirements on QHP issuers related to the offering of QHPs. In paragraph (c)(1), we propose to codify section 1301(a)(1)(C)(ii), which requires that each QHP issuer offer at least one QHP in the silver coverage level and at least one QHP in the gold coverage level; the levels of coverage are defined in section 1302(d)(1) of the Affordable Care Act. In paragraph (c)(2), we propose to codify section 1302(f) of the Affordable Care Act, which specifies that any QHP issuer offering a non-catastrophic health plan in the Exchange must offer the identical plan as a child-only health plan. Child-only plans are only available to individuals under the age of 21. In paragraph (c)(3), we require the QHP issuer to offer a QHP at the same premium rate consistent with the requirements described in § 156.255(b).

In paragraph (d), we require that QHP issuers adhere to the requirements of this subpart and any additional participation standards that may be applied by the Exchange or the State.

In paragraph (e), pursuant to the authority to set QHP standards in section 1321(a)(1)(B), we propose that QHP issuers must not discriminate based on race, color, national origin, disability, age, sex, gender identity and sexual orientation. Such practices would include, but not be limited to marketing, outreach, and enrollment.

b. QHP Rate and Benefit Information (§ 156.210)

In § 156.210, we propose the requirements for QHP issuers to submit QHP rate and benefit information to the Exchange, including rate justifications. The Exchange will be responsible for ensuring that issuers adhere to this requirement during initial certification and on an annual basis, as specified in § 155.1020.

In paragraph (a), we propose that a QHP's rates must be applicable for an entire benefit year or, for the SHOP, plan year. We propose this requirement since the Exchange will have an annual open enrollment period during which qualified individuals will be able to change their QHP selection. This requirement would shield consumers from rate increases during the benefit year or, for the SHOP, the plan year. For the SHOP, the timing of the rate changes will vary by employer, since the annual open enrollment periods differ by employer. We discuss this in greater detail in § 156.285.

In paragraph (b), we require the QHP issuer to submit rate and benefit information to the Exchange as described in § 155.1020(c). As noted in § 155.1020(c), to the extent possible, HHS seeks to align the required data elements with information already collected as part of the rate review program and State rate filing processes. This will allow both Exchanges and QHPs to leverage already existing information collections for this purpose.

In paragraph (c), we propose to codify the general requirement that a QHP issuer submit a justification for a rate increase prior to implementation of the rate increase as required by section 1311(e)(2) of the Affordable Care Act. As noted in § 155.1020, Exchanges may leverage the preliminary justification collected as part of the rate review process as described in 45 CFR part 154, and consider the rate justification, as appropriate. We are considering a standard in which the issuers will submit a rate justification in the form and manner determined by the Exchange.

We also propose to codify the rate transparency requirement under section 1311(e)(2) of the Affordable Care Act, which requires that issuers post the rate increase justifications on their Web sites so they can be viewed by consumers, enrollees, and prospective enrollees. To promote consistency in how the rate increase justifications are posted on issuer Web sites, and to assist the consumers in understanding the rate increase justifications, we are considering whether we should develop standards for ''prominently posting'' rate increase justifications. Again, to avoid duplication of effort, we intend to leverage the rate increase justification provided by QHP issuers as part of the rate review process.

c. Transparency in Coverage (§ 156.220)

In § 156.220(a) and (b), we propose to codify section 1311(e)(3)(A) of the Affordable Care Act, which establishes a transparency standard as a condition for certification of QHPs. To receive and maintain certification, health insurance issuers must make available to the public and submit to the Exchange, the Secretary, and the State insurance commissioner a broad range of information relevant to the plan's quality and cost. The statutorily required disclosures include: (1) Claims payment policies and practices; (2) periodic financial disclosures; (3) data on enrollment; (4) data on disenrollment; (5) data on the number of claims that are denied; (6) data on rating practices; (7) information on cost-sharing and payments with respect to any out-of-network coverage; and (8) information on enrollee rights under title I of the Affordable Care Act. We clarify that, while the statute refers to ''enrollee and participant rights,'' we believe our definition of enrollee is inclusive of those who may be considered ''participants.'' We seek comment on whether issuers should be required to submit this information to

the Exchange and other entities, or to make such information available to the Exchange and other entities.

Under paragraph (c), we propose to require QHP issuers to provide the information described in paragraph (a) in plain language. Section 1311(e)(3)(B) calls for the Secretary of HHS and the Secretary of Labor to jointly develop and issue guidance on best practices of plain language writing. QHP issuers' use of plain language should be consistent with the definition provided in § 155.20 and the forthcoming guidance.

In paragraph (d) and pursuant to section 1311(e)(3)(C), we propose that QHP issuers make available to the enrollee information on cost-sharing responsibilities for a specific service by a participating provider under that enrollee's particular plan. The information must be provided upon request from the enrollee in a timely manner through a Web site or through other means for individuals without access to the internet.

d. Marketing of QHPs (§ 156.225)

Section 1311(c)(1)(A) of the Affordable Care Act requires that the Secretary establish marketing requirements for QHP issuers seeking to participate in an Exchange, which we propose in § 156.225.

To ensure that an Exchange's oversight of marketing by QHP issuers is consistent with those standards applied in the non-Exchange market and leverages existing State oversight mechanisms, we propose in paragraph (a) to require QHP issuers to comply with any applicable State laws and regulations regarding marketing by health insurance issuers. Though QHP issuers are not exempt from otherwise applicable State law by participating in the Exchange, we propose to apply compliance with State law as a certification standard to reinforce the coordinated efforts of the Exchange and the State department of insurance and to ensure that the Exchange considers a QHP issuer's marketing practices in determining whether offering a QHP is in the best interest of consumers.

In paragraph (b), we propose to codify section 1311(c)(1)(A), which prohibits QHP issuers from employing marketing practices that have the effect of discouraging enrollment of individuals with significant health needs. We seek comment on the best means for an Exchange to monitor QHP issuers' marketing practices to determine whether they have discouraged enrollment of individuals with significant health needs.

We seek comment on also applying a broad prohibition against unfair or deceptive marketing practices by all QHP issuers and their officials, agents and representatives. Such a requirement would protect consumers from deceptive and misleading marketing practices and allow an Exchange to take action to address such practices if the State's department of insurance or applicable State agency did not have the authority or capacity to do so under applicable law.

We considered setting detailed and uniform Federal standards prohibiting specific marketing practices across all QHP issuers, but were concerned about the interaction with current State marketing rules or unintentionally creating ''safe harbors'' that might allow issuers to technically comply with specific requirements without meeting the spirit of the broader marketing protections. We permit States and Exchanges to adopt additional requirements for the marketing of health plans that are most appropriate to the unique market dynamics in that State, both inside and outside the Exchange. Any Exchange that chooses to apply additional marketing requirements to QHP issuers should consider working closely with State insurance departments to ensure that all health insurance issuers in the State are subject to the same minimum marketing requirements in order to create a level playing field with equal consumer protections inside and outside the Exchange.

One particular area of concern in regulating marketing practices of health insurance issuers is ensuring that individuals understand the coverage options made available under the Affordable Care Act. For those individuals already covered by Medicare or other third-party coverage, enrollment in a QHP could be duplicative and/or unnecessary. We are particularly concerned that QHPs may be marketed towards certain vulnerable populations, such as Medicare beneficiaries, for whom coverage from a QHP would not be necessary. We seek comment on a standard that QHP issuers do not misrepresent the benefits, advantages, conditions, exclusions, limitations or terms of a QHP.

e. Network Adequacy Standards (§ 156.230)

In § 156.230, we describe the minimum criteria for network adequacy that health plans must meet to be certified as QHPs, pursuant to section 1311(c)(1)(B) of the Affordable Care Act. We propose in paragraph (a)(1) of this section that QHP issuers must maintain networks for QHPs that include essential community providers in accordance with § 156.235. We propose in paragraph (a)(2) that QHP issuers must maintain networks that comply with any network adequacy standards established by the Exchange consistent with § 155.1050. We propose under paragraph (a)(3) that a QHP issuer must ensure that the provider network of its QHPs must be consistent with the provisions of 2702(c) of the PHS Act as amended by the Affordable Care Act, consistent with section 1311(c)(1)(B) of the Affordable Care Act. Section 2702(c) of the PHS Act requires that health insurance issuers furnish coverage to any individual who applies for a group, small group or individual health plan, with exceptions only if the individual resides outside the plan's service area or if the health insurance issuer does not have the capacity to serve the individual because of its existing obligations to enrollees. This allows QHP issuers an exception to the guaranteed issue requirement if their provider network would not be sufficient to serve additional potential enrollees. In such cases, an issuer must apply such an exception uniformly across all employees or individuals without regard to their claims experience or health status. We note that these standards would be applied to all QHP issuers along with any standards established by the Exchange.

As a condition of certification of the QHP, a health insurance issuer must also provide information to potential enrollees on the availability of in-network and out-of-network providers. We propose in paragraph (b) that a QHP issuer must make its health plan provider directory available to the Exchange electronically and to potential enrollees and current enrollees in hard copy upon request. Exchanges will have discretion to determine the best way to give potential enrollees access to the provider directory for each QHP, including through a link from the Exchange's Web site to the issuer's Web site, or by establishing a consolidated provider directory through which a consumer may search for a provider across QHPs. Under paragraph (b), we also propose that the QHP issuer note providers in the directory that are no longer accepting new patients. We seek comment on standards we might set to ensure that QHP issuers maintain up-to-date provider directories.

f. Essential Community Providers (§ 156.235)

In § 156.235, we propose to codify section 1311(c)(1)(C) of the Affordable Care Act, which requires that a health plan's network include essential community providers who provide care

to predominantly low-income and medically-underserved populations to be certified as a QHP. As specified in section 1311(c)(1)(C), essential community providers include entities specified under section 340B(a)(4) of the PHS Act and section 1927(c)(1)(D)(i)(IV) of the Act as set forth by section 211 of Public Law 111–8.

We received a number of comments in response to the RFC regarding essential community providers. In general, respondents to the RFC offered recommendations on the types of entities that might be included in the definition of an essential community provider, and essential community provider inclusion in QHP provider networks. We considered these comments in developing the standards related to essential community providers.

In paragraph (a) of this section, we require that QHP issuers include in their provider networks a sufficient number of essential community providers, where available, that serve low-income, medically-underserved individuals. We also propose to codify the provision that nothing in this requirement shall be construed to require any QHP to provide coverage for any specific medical procedure. We interpret this to mean that while a QHP issuer must contract with essential community providers, coverage of specific services or procedures performed by an essential community provider is not required.

An important issue with respect to implementing section 1311(c)(1)(C) is establishing a sufficient level of essential community provider participation in QHPs. Although the Affordable Care Act requires inclusion of essential community providers in QHP networks, the Act does not require QHP issuers to contract with or offer contracts to all essential community providers. The statute refers to ''those essential community providers, where available,'' and ''that serve predominantly low-income and medically-underserved,'' which suggests a requirement that QHP issuers contract with a subset of essential community providers.

We considered establishing broad contracting requirements where QHP issuers would have to offer a contract to all essential community providers in each QHP's service area, or establishing a requirement for issuers to contract with essential community providers on an any-willing provider basis. Requiring issuers to offer contracts to all essential community providers would allow continuity of service for enrollees with existing relationships especially in communities where the essential community provider has been the only reliable source of care. However, such a requirement may inhibit attempts to use network design to incentivize higher quality, cost effective care by tiering networks and driving volume towards providers that meet certain quality and value goals.

We note that ''sufficiency'' could be interpreted to mean that the QHP issuer would have to demonstrate to the Exchange that it has a sufficient number and geographic distribution of essential community providers to ensure timely access for low-income, medically underserved individuals in its health plan service area, pursuant to the Exchange's applicable network adequacy and access requirements.

We solicit comment on how to define a sufficient number of essential community providers. We note that States may elect to establish more stringent participation requirements, including adoption of a blanket contracting requirement. Similarly, a potential safe-harbor strategy for QHP issuers would be to offer contracts to all essential community providers or accept any-willing essential community provider in its service area.

We are considering whether to provide separate consideration for integrated delivery network health plans where services are provided solely ''in-house.'' This could include plans where all providers are employees of the plan (''staff model'') and plans where the providers are part of an entity that furnishes all of the plan's services on an exclusive basis. We understand that the essential community provider requirements may not be compatible with the operating model of ''staff model'' plans and exclusive integrated delivery network plans. We seek comment on whether we should create an exemption to the essential community provider requirements for such plans. If such organizations were exempt from the essential community provider requirement, the exemption could be contingent upon the organizations meeting other criteria, such as: evidence of services provided to low-income populations; compliance with national standards for provision of culturally and linguistically appropriate services (CLAS); or implementation of a plan to address health disparities.

In paragraph (b), we specify the types of providers included in the definition of an essential community provider. We include in the definition of essential community providers those providers specifically referenced in statute. In paragraphs (b)(1) and (b)(2) of this section, we define essential community providers to include all health care providers defined in section 340B(a)(4) of the PHS Act and providers described in section 1927(c)(1)(D)(i)(IV) of the Act. We continue to look at other types of providers that may be considered essential community providers to ensure that we are not overlooking providers that are critical to the care of the population that is intended to be covered by this provision. We solicit comment on the extent to which the definition should include other similar types of providers that serve predominantly low-income, medically-underserved populations and furnish the same services as the providers referenced in section 340B(a)(4) of the PHS Act.

We acknowledge that two provisions of the Affordable Care Act regarding payment of essential community providers and payment of Federally Qualified Health Centers (FQHCs) may conflict. Section 1311(c)(2) of the Affordable Care Act states that nothing shall be construed to require a QHP to contract with an essential community provider if such provider refuses to accept the generally applicable payment rates of the plan. This requirement may conflict with section 1302(g) of the Affordable Care Act, which requires that a QHP issuer reimburse FQHCs at each facility's Medicaid prospective payment system (PPS) rate. The FQHC Medicaid PPS rates are facility specific rates paid on a per encounter basis, and they may be higher than the rates that a QHP issuer pays to other contracted providers for similar services.

One approach to reconciling these provisions would be to require QHP issuers to pay at least the Medicaid PPS rate to each FQHC that participates in the issuer's QHP network. This approach would enable FQHCs to be paid their Medicaid PPS rates for services provided to QHP enrollees. However, if FQHC Medicaid PPS rates are greater than comparable amounts paid to other providers, and if many of the enrollees in a QHP receive care at FQHCs, the costs of these QHPs may be greater than the costs of QHPs that do not have many enrollees who are seen at the centers. Also, if Medicaid prospective payment rates exceed QHPs' generally applicable payment rates, requiring QHP issuers to pay the full FQHC Medicaid PPS rate could lead insurers to minimally contract with FQHCs.

We note that there are other practical considerations regarding how issuers would pay the Medicaid PPS rate. For example, it is not clear how QHP issuers would administer the FQHC Medicaid PPS rate, since it is a facility specific rate paid on a per encounter basis for a

pre-determined set of covered services. Issuers would need to replicate each FQHC's Medicaid PPS rate, which may be complicated since Medicaid covered services vary by State and rates vary by FQHC.

Another potential approach to reconciling these two payment provisions would be to permit issuers to negotiate mutually agreed-upon payment rates with FQHCs, as long as they are at least equal to the issuer's generally applicable payment rates. Such an interpretation may furnish FQHCs with a degree of negotiating leverage with issuers to obtain payment rates higher than the issuer's generally applicable payment rates but not tie issuers to the full Medicaid PPS rate for in-network FQHCs. This approach would decrease the incentive to drive patients away from providers that may be best suited to their needs, while providing FQHCs with leverage to be able to negotiate payments that will allow them to continue providing the comprehensive services that are particularly valuable to the individuals they serve. However, this approach may result in FQHCs receiving less than their Medicaid PPS rates for in-network participation. We invite comment on the issue of FQHC payment and solicit other potential approaches for resolving these potentially conflicting provisions.

We also invite comment on establishing requirements regarding reimbursement of Indian health providers qualifying under 340B(a)(4) of the PHS Act. Section 206 of the Indian Health Care Improvement Act (IHCIA) provides that all Indian health providers have the right to recover from third party payers, including insurance companies up to the reasonable charges billed for providing health services or, if higher, the highest amount the insurer would pay to other providers to the extent that the patient or another provider would be eligible for such recoveries. This section also states that no law of any State or provision of any contract shall prevent or hinder this right of recovery. Therefore, this requirement applies whether or not there is a contract between the insurance company and the Indian health provider. We believe that payment requirements under section 206 of IHCIA apply to QHP issuers, as well as to any insurer, employee benefit plan or other third party payer. We invite comment on the payment requirement under section 206 of IHCIA, and how it might be reconciled with the essential community provider payment requirement described in section 1311(c)(2) of the Affordable Care Act.

We also invite comment on other special accommodations that must be made when contracting with Indian health providers. Indian health providers operate under or are governed by numerous federal authorities, including but not limited to the Anti-Deficiency Act, the Indian Self-Determination and Education Assistance Act, the Indian Health Care Improvement Act, the Federal Tort Claims Act, and the Federal Medical Care Recovery Act. Indian health providers serve a specific population in accordance to these and other federal laws. Some RFC commenters recommended that we consider developing a standard contract addendum containing all conditions that would apply to QHP issuers when contracting with Indian health providers. Such an addendum may be similar to the special Indian Health Addendum currently used in the Medicare Prescription Drug Program, which CMS requires all plans to use when contracting with Indian Health Service, tribal organization, and urban Indian organization (I/T/U) pharmacies and serve as a safe-harbor for all issuers contracting with Indian health providers, which would minimize potential disputes and legal challenges between Indian health providers and issuers. We invite comment on the applicability of these special requirements to QHP issuers, and the potential use of a standardized Indian heath provider contract addendum.

g. Treatment of Direct Primary Care Medical Home (§ 156.245)

In § 156.245, we propose to codify section 1301(a)(3) of the Affordable Care Act, which permits a QHP issuer to provide coverage through a direct primary care medical home that meets the requirements established by HHS, provided that the QHP meets all requirements otherwise applicable. We request comment on what standards HHS should establish under this section.

Commenters to the RFC noted that the direct primary care medical home model in the State of Washington has benefited providers by providing predictable income without added administrative costs, while consumers gain access to an affordable and reliable source of primary services that decreases reliance on emergency rooms as a source of routine care.

We interpret the phrase ''direct primary care medical home plan'' to mean an arrangement where a fee is paid by an individual, or on behalf of an individual, directly to a medical home for primary care services, consistent with the program established in Washington. We generally consider primary care services to mean routine health care services, including screening, assessment, diagnosis, and treatment for the purpose of promotion of health, and detection and management of disease or injury.

We considered allowing an individual to purchase a direct primary care medical home plan and separately acquire wrap-around coverage. However, direct primary care medical homes are providers, not insurance companies, which would require the Exchange to develop an accreditation and certification process that is inherently different from certifying health plans and that would significantly depart from the role of an Exchange. Furthermore, allowing a separate offering would require consumers to make two payments for full medical coverage, adding complexity to the process of acquiring health insurance, ensuring enrollee have access to the full complement of the essential health benefits to which they are entitled, and complicating the allocation of advance payments of the premium tax credit.

h. Health Plan Applications and Notices (§ 156.250)

In § 156.250, we establish basic standards for the format of applications and notices provided by the QHP issuer to the enrollee. QHP issuers will be required to provide enrollees with a variety of applications and notices in accordance with the standards for enrollment and termination of coverage. Since these notices will be provided to all enrollees, it is important to ensure that those enrollees with limited English proficiency (LEP) have access to translated materials and enrollees with disabilities can obtain materials in alternate formats.

We propose that QHP issuers must adhere to the standards established for notices in § 155.230(b). The incorporated standard requires QHP issuers to provide meaningful access to LEP individuals and ensure effective communication for people with disabilities. This may include providing information about the availability and means to obtain oral interpretation services, languages in which written materials are available, and the availability of materials in alternate formats for persons with disabilities.

i. Rating Variation (§ 156.255)

Section 2701(a)(1)(A) of the PHS Act, as revised by section 1201 of the Affordable Care Act, limits the variation in premium rating to four factors:

Whether the coverage is for an individual or family; rating area; age; and tobacco use. The specific rating rules will be issued through separate regulation, but this section discusses several rate-related provisions for QHPs.

Consistent with the rating rules provision, section 1301(a)(4) of the Affordable Care Act allows QHP issuers to vary premiums by the rating areas established under section 2701(a)(2), which we propose to codify in § 156.255(a). Section 2701(a)(2) of the PHS Act requires that States establish one or more rating areas within a State, subject to the Secretary's approval. Permitting premium variation by geographic rating area enables health insurance issuers to account for regional variation in health care costs. Because section 1302(a)(4) of the Affordable Care Act directly references the rating areas outlined in section 2701(a)(2) of the PHS Act, we interpret that the rating areas will be applied consistently inside and outside of the Exchange.

In paragraph (b), we codify section 1301(a)(1)(C)(iii) of the Affordable Care Act, which specifies that each QHP issuer must offer a QHP at the same premium rate without regard to whether the plan is offered through an Exchange or whether the plan is offered directly from the issuer or through an agent. We interpret this provision to mean that an issuer must charge a premium that uses underlying rating assumptions that account for all expected enrollees of a QHP, including individuals that enroll in the QHP outside of an Exchange, and for all methods of enrollment, including through an Exchange, an agent or broker, or the issuer itself. Thus, the resulting premium for a QHP would vary only by the rating factors listed in 2701(a) of the PHS Act.

We believe that the rating factor related to family size has significant implications for Exchanges. Pursuant to the Secretary's authority to regulate QHPs under section 1311(c)(1), we are considering options on how to structure family rating for QHPs that are offered in the Exchange. Offering uniform family rating categories will maximize competition between health plans based on price and quality. Our understanding is that issuers currently use multiple rating tiers in the individual market.

In paragraph (c), we propose issuers vary premiums among no more than four different types of family composition that are commonly used among health insurance issuers currently: individual; two adults; adult plus child or children; and a catch-all ''family'' category for two-adult families with a child or children and other family compositions that do not fit in the other categories. QHP issuers must cover all of these four groups, but in doing so may combine some of the identified categories; for example, a QHP issuer may combine the second and third categories to include both two-adult families and families with one adult plus child or children. We believe that such a rating structure would be beneficial to the market because it would limit premium variation within families of similar types.

We recognize that section 2701(a)(4) of the PHS Act requires that any family premium using age or tobacco rating may only apply those rates to the portion of the premium that is attributable to each family member. As a result, calculating a family premium by determining the age and tobacco rated premium for one member of the family and applying a multiplier to set the rating for the entire family is not permitted. We seek comment on how we might structure family rating categories while adhering to Section 2701(a)(4) of the PHS Act. Additionally, we request comment on how to apply four family categories when performing risk adjustment. We also invite comment on alternatives to four categories for defining family composition. We seek comment on how to balance the number of categories offered by QHP issuers in order to reduce potential consumer confusion, while maintaining plan offerings and rating structures that are similar to those that are currently available in the health insurance market.

We are also considering whether to require QHP issuers to cover an enrollee's tax household, including for purposes of applying individual and family rates. We are considering this approach because of the potential challenge of administering the premium tax credit, particularly for families filing with non-spousal adult dependents. We note that QHP issuers would not be required to cover dependents living outside of the Exchange service area. We recognize that such an approach would add non-spousal adult dependents to the family risk pool, but the impact of this configuration may be offset through risk adjustment. We seek comment on the potential considerations of this approach.

j. Enrollment Periods for Qualified Individuals (§ 156.260)

In § 156.260, we propose that QHP issuers comply with the enrollment periods as a condition of offering a QHP. In paragraph (a), we propose that QHP issuers accept and enroll qualified individuals in QHPs only during the enrollment periods described in § 155.410 and § 155.420.

In paragraph (a)(1), we specify that QHP issuers must accept and enroll qualified individuals during the initial enrollment period, described in § 156.410(b), and during the annual open enrollment period thereafter, described in § 156.410(e). In paragraph (a)(2), we propose that QHP issuers accept and enroll qualified individuals in QHPs if they are granted a special enrollment period described in § 155.420. QHP issuers must also abide by all other State laws that may provide an individual with an enrollment period outside of those described in § 155.410 and § 155.420.

For the initial, annual open, and special enrollment periods, we propose to require QHP issuers to adhere to the effective dates of coverage established in § 155.410(c), § 155.410(f), and § 155.420. We propose that qualified individuals who make QHP selections on or before December 22, 2013 would have a coverage effective date of January 1, 2014 and qualified individuals who make a QHP selection between the twenty-third and last day of the month for any month between December of 2013 and February 2014 would have coverage effective the first day of the month immediately following the next month.

In paragraph (b) we propose to require QHP issuers to provide enrollees with notice of their effective date of coverage, and such notice must correspond with the effective dates established in § 155.410(c), § 155.410(f) and § 155.420(b) as applicable.

k. Enrollment Process for Qualified Individuals (§ 156.265)

In § 156.265, we propose that QHP issuers must accept and process enrollment of qualified individuals enrolling in a QHPs. In paragraph (a), we propose that QHP issuers must adhere to the Exchange's process for enrollment in QHPs, which includes standards for the collection and transmission of enrollment information. As a general principle, both the Exchange and the QHP issuer must use a common set of enrollment information for an enrollment to be successful.

We propose in paragraph (b)(1) that QHP issuers use the application adopted pursuant to § 155.405 when accepting applications from individuals seeking to enroll in a QHP through the Exchange enrollment process. We interpret section 1413(b)(1)(A), which requires that the Secretary develop and provide to each State a single, streamlined form, together with section 1311(c)(1)(F), which states that an issuer shall use a

uniform enrollment form for qualified individuals and employers to enroll in QHPs through the Exchange, to require that one single streamlined application developed by HHS with recommendations from the NAIC be used for enrollment in QHPs.

In paragraph (b)(2), we propose that after collecting the uniform enrollment information from an applicant, the QHP issuer must send the information to the Exchange, in accordance with the standards established in § 155.260 and, as applicable, § 155.270. We clarify that the term ''applicant'' is used here as defined in § 155.20. In paragraph (b)(3), we permit the QHP issuer to enroll the individual in a QHP only after it has received confirmation from the Exchange that the eligibility determination is complete and the applicant is a qualified individual.

We propose in paragraph (c) that QHP issuers receive enrollment information electronically from the Exchange in a format and manner that is consistent with the standards established pursuant to § 155.260 and in § 155.270. We seek comment on the frequency with which plans should receive electronic enrollment information.

In paragraph (d), we propose that QHP issuers abide by the premium payment process established by the Exchange and described in § 155.240.

In paragraph (e), we propose to require QHP issuers provide enrollees in the Exchange with an enrollment packet. We plan to issue standards for the content of the enrollment information package, which may include an enrollment card, information on how to access care, the summary of benefit and coverage document, and information on how to access the provider directory and drug formulary and submit a request for a hard copy. We solicit comment on the appropriateness of these documents and any other documents or information that should be included in an enrollment information package.

In paragraph (f), we propose to require QHP issuers provide the summary of benefits and coverage document to qualified individuals, similar to the requirement in section 2715 of the PHS Act. We note that all health insurance issuers must provide such document on several occasions to potential or current enrollees as required under section 2715 of the PHS Act, for which HHS, the Department of Labor and the Treasury will issue implement regulations in the near future; this requirement is consistent with that PHS Act provision.

In paragraph (g), we propose that QHP issuers reconcile enrollment files with the Exchange no less than once a month, consistent with the proposed standard in § 155.400(d). In paragraph (h), we propose that QHP issuers acknowledge the receipt of enrollment information in accordance with Exchange standards established in § 155.400(b)(2). These provisions will protect consumers from potential gaps in coverage that might occur due to errors in communication.

l. Termination of Coverage for Qualified Individuals (§ 156.270)

A key function of an Exchange, described in § 155.430, will be to verify a QHP issuer's standard operating procedures for the termination of coverage for enrollees enrolled in a QHP through the Exchange. In § 156.270, we propose standards for QHP issuers regarding the termination of coverage of enrollees enrolled in QHPs through the Exchange. We propose in paragraph (a) that a QHP issuer may only terminate coverage as permitted by the Exchange in accordance with § 155.430(b), which includes non-payment of premium, fraud and abuse, and relocation outside of the service area, among other situations.

In paragraph (b), we propose that QHP issuers must provide a notice of termination of coverage to the enrollee and the Exchange that is consistent with the standards for effective dates in § 155.430(d). We plan to issue standards for the termination of coverage notice which may include content such as reason for termination and termination effective date. We solicit comment on other information that should be included in the termination notice.

In paragraph (c), we propose that QHP issuers develop a uniform policy as permitted by the Exchange for the termination of coverage due to non-payment of premium in accordance with § 155.430(b)(2)(iii). Section 1412(c)(2)(B)(iv)(II) of the Affordable Care Act requires QHP issuers to provide enrollees receiving advance payments of the premium tax credit with a three-month grace period for non-payment of premium prior to coverage termination, which we propose to codify in paragraph (d). This standard applies only to those enrollees receiving advance payments of the premium tax credit. There is no Federal standard requiring QHP issuers to extend this grace period to enrollees who are not receiving advance payments of the premium tax credit, although the Exchange could choose to require QHP issuers to provide all enrollees with such a grace period, regardless of advance payment status. However, QHP issuers must apply non-payment of premium policies, irrespective of Exchange standards, uniformly to all enrollees in similar circumstances.

In paragraph (d), we propose standards for the application of the three-month grace period for enrollees receiving advance payments of the premium tax credit. We interpret that the three-month grace period only applies to enrollees who have paid at least one month's worth of premiums to establish coverage to ensure that this period applies only when there is a lapse in an enrollee's payment.

During the three-month grace period, we propose that the QHP issuer continue to pay all appropriate claims submitted on behalf of the enrollee. This standard ensures that providers will be reimbursed for care provided to such enrollees during the grace period. In addition, in paragraph (d)(2), we specify how payments received during the grace period would be applied. If an eligible enrollee is more than one month behind on payments, any payment paid to the QHP issuer will be applied to amounts associated with the first billing cycle in which the enrollee was delinquent. The grace period will reset only when the individual has fully paid all outstanding premiums. In paragraph (d)(3), we propose that, during the grace period, the issuer would continue to receive a portion of the premium payment from the advance payments of the premium tax credit from the Department of the Treasury.

In paragraph (e), we propose QHP issuers to provide notice to all enrollees who are delinquent on premium payments. We plan to issue standards for content and timing of the notice. We seek comment on the potential required elements of such a notice, such as the total amount of delinquent payment, possible date of coverage termination and payment options, and the timing and frequency with which such a notice should be provided to enrollees, such as bi-weekly beginning with the first missed payment or more frequently.

In paragraph (f), we propose that if an enrollee receiving advance payments of premium tax credit exhausts the grace period, as provided in paragraph (d), without submitting any premium payment, the QHP issuer may terminate coverage effective at the completion of the three-month period. This termination must be preceded by the appropriate notice as referenced in paragraph (e).

In paragraph (g), we propose to require QHP issuers to maintain records of termination of coverage in accordance with Exchange standards as established in § 155.430(c). In paragraph (h), we propose that QHP issuers abide by the

effective dates for termination of coverage as described in § 155.430(d).

m. Accreditation of QHP Issuers (§ 156.275)

In § 156.275, we describe the accreditation standards for QHP issuers. In paragraph (a)(1), we propose to codify the statutory requirement that a QHP issuer be accredited on the basis of local performance in each of the nine categories listed under section 1311(c)(1)(D)(i) of the Affordable Care Act. We clarify that we interpret ''local performance'' to mean the performance of the QHP issuer in the State in which it is licensed. We note that, although Section 1311(c)(1)(D)(i) of the Affordable Care Act requires a health plan to be accredited in order to be certified as a QHP, we interpret this to mean that QHP issuers must be accredited, since accrediting entities accredit issuers, not plans.

We also further specify that a QHP issuer must be accredited by an entity recognized by HHS. We intend to provide the standards by which HHS will recognize accrediting entities in future rulemaking. Section 1311(c)(1)(D)(i) of the Affordable Care Act requires that QHP issuers be accredited by entities recognized by the Secretary with ''transparent and rigorous methodological and scoring criteria.'' We seek comment on the standards by which HHS should recognize accrediting bodies. We may model this process in part on a similar process used by CMS to identify accrediting organizations for Medicare Advantage plans; this process can be found at 42 CFR 422.157–422.158. We anticipate addressing this issue and identifying recognized accrediting entities as early as possible to give health insurance issuers seeking to participate in the Exchange the time necessary to seek accreditation from appropriate accrediting entities.

In paragraph (a)(2), we propose to require a QHP issuer to authorize the accrediting entity to release certain materials related to the QHP issuer's accreditation (e.g., a copy of its most recent accreditation survey) to the Exchange and to HHS.

In paragraph (b), we propose to codify the requirement that a QHP issuer must obtain its accreditation within a time period established by the Exchange under § 155.1045. Allowing these issuers extra time to meet the standards proposed in this section may encourage a wider variety of health insurance issuers to seek to offer QHPs through the Exchange.

n. Segregation of Funds for Abortion Services (§ 156.280)

Federal funds cannot be used for abortion services (except in the cases of rape or incest, or when the life of the woman would be endangered). The Affordable Care Act is fully consistent with this policy and includes additional provisions to enforce it. Section 156.280 of this proposed rule codifies section 1303 of the Affordable Care Act. This codification includes the non-discrimination clause for providers and facilities, a voluntary choice clause for issuers with respect to abortion services, the standards for the segregation of funds for QHP issuers that elect to cover abortion services for which public funding is prohibited, and the associated communication requirements related to such services. In addition, the Office of Management and Budget and HHS jointly issued ''Pre-Regulatory Model Guidelines Under Section 1303 of the Affordable Care Act'' on September 20, 2010.[10] This pre-regulatory guidance furnishes potential standards to meet the segregation requirements of the Affordable Care Act. We are soliciting comment on the model guidelines; we intend that the model guidelines may serve as the basis for the final rule in connection with the provisions included in section 1303 of the Affordable Care Act.

We note that, to maintain consistency with the definitions and terminology used in this part, we have substituted the term ''QHP'' in the regulation where ''plan'' is used in the statute and ''QHP issuer'' in the regulation where ''issuer of a qualified health plan'' is used in the statute.

o. Additional Standards Specific to the SHOP (§ 156.285)

In § 156.285, we establish requirements for QHP issuers as a condition of participating in the SHOP. In general, QHP issuers must meet the same requirements for the SHOP as the Exchange, along with the additional requirements prescribed in this section.

In paragraph (a), we propose rating and premium payment requirements for QHP issuers in the SHOP. In paragraph (a)(1), we specify that the QHP issuer must accept payment of premiums from the SHOP in accordance with § 155.705(b)(4). We note that this proposed requirement reduces complexity by ensuring the issuer receives all payments from a single source. In paragraph (a)(2), we propose that QHP issuers abide by the rate setting timeline established by the SHOP in § 155.705(b)(5). Since the SHOP allows qualified employers to enter the SHOP on a rolling basis, QHP issuers may establish new rates on a quarterly or monthly basis in accordance with SHOP standards. In paragraph (a)(3) we propose that QHP issuers charge the same contract rate for a plan year.

In paragraph (b), we propose requirements for QHP issuers consistent with SHOP enrollment periods. QHP issuers must accept and enroll applicants during the rolling initial enrollment period, the qualified employer's annual employee open enrollment period, and special enrollment periods for a SHOP as established in § 155.725 and in § 155.420 with the exception of (d)(3) and (d)(6). In addition to the enrollment periods, we propose that QHP issuers abide by the effective dates of coverage established in § 155.410(c). We are considering whether to require QHPs in the SHOP to allow employers to offer dependent coverage. We solicit comment on this potential requirement.

In paragraph (c), we propose QHP issuers abide by the SHOP enrollment process requirements and timeline, established pursuant to § 155.720(b). In paragraph (c)(2), we propose that QHP issuers accept electronic transmission of enrollment information frequently from the SHOP in accordance with the requirements pursuant to § 155.260 and § 155.270. In paragraph (c)(3), we propose that QHP issuers provide all new enrollees with the enrollment information package as described in § 156.265(e). In paragraph (c)(4), we proposed to require QHP issuers to provide qualified employers and employees with the summary of cost and coverage document in accordance with the standards described in § 156.265(f).

In paragraph (c)(5), we propose QHP issuers reconcile enrollment files with the SHOP at least monthly. In paragraph (c)(6), we propose that the QHP issuers abide by the SHOP standards for acknowledgement of the receipt of enrollment information. In paragraph (c)(7), we propose that the QHP issuers must issue qualified employees a policy that aligns with the qualified employer's plan year and contract established in paragraph (a)(3). For example, if an employee is hired mid-plan year, the QHP issuer would issue an abbreviated policy for the duration of the employer's plan year so the enrollee will be eligible for an annual open enrollment period at the completion of the qualified employer's plan year.

[10] OMB and HHS Pre-Regulatory Guidance: *http://www.whitehouse.gov/sites/default/files/omb/assets/financial_pdf/segregation_2010–09–20.pdf.*

In paragraph (d)(1), we propose general standards related to termination of coverage in the SHOP that are largely similar to the standards for the Exchange with respect to their enrollees from the individual market. However, in paragraph (d)(1)(ii), we propose to require the QHP issuer to provide the qualified employers and employees with a notice of termination of coverage of enrollees and QHP non-renewal, as described in § 156.270(a) and § 156.290(b). This will ensure that the qualified employer is aware of the changes in coverage for its employees and the availability of coverage in the SHOP.

In paragraph (d)(2), we propose that a QHP issuer terminate all enrolled qualified employees of the withdrawing employer if the employer chooses to stop participating in the SHOP since the enrollee will no longer be eligible for SHOP coverage.

p. Non-Renewal and Decertification of QHPs (§ 156.290)

In § 156.290(a), we propose requirements on QHP issuers that elect to not seek recertification with the Exchange. In paragraph (a)(1), the QHP issuer must notify the Exchange of its decision prior to the beginning of the recertification process adopted by the Exchange pursuant to § 155.1075. This notification will allow time for the Exchange to determine if it is in the best interest of the qualified individuals and employers to begin modifying the certification process to increase the number of QHPs offered in the Exchange. In paragraph (a)(2), we propose that QHP issuers must continue covering benefits for each enrollee until the completion of the benefit year or plan year for the SHOP. It is critical that enrollees' coverage remain unaffected during the benefit or plan year due to an issuer's decision to withdraw from the Exchange.

In paragraph (a)(3), we propose that a QHP issuer must continue providing the Exchange with reporting information for the benefit or plan year even after withdrawing its QHP from the Exchange. We recognize that a time lag often exists in the collection of data and include this requirement to ensure the Exchange is able to compile a complete set of data records for the QHP.

In paragraph (a)(4), we propose that a QHP issuer provide notice of the non-renewal to enrollees of the QHP, as described in paragraph (b) of this section. In paragraph (a)(5), we propose that a QHP issuer must terminate coverage for enrollees in accordance with the applicable requirements in § 156.270.

In paragraph (b), we propose to require QHP issuers that elect not to seek recertification to provide a written notice to each enrollee. HHS will issue future guidance on the timing and content of the notice. In developing this notice, we may adopt some of the concepts from the Medicare Advantage non-renewal notice, in which the issuer must provide notice at least 90 days prior to the effective date of non-renewal and include information on the enrollee transition process and alternatives for other coverage through the Exchange. We solicit comment on the potential content of the non-renewal notice and any other information we should consider including.

In paragraph (c), we propose that if an Exchange decertifies a QHP, the QHP issuer must terminate coverage for the QHP enrollees only after the Exchange has notified the QHP's enrollees as described in § 155.1080 and enrollees have had the opportunity to enroll in other coverage. We seek comment on the extent to which enrollees should continue to receive coverage from a decertified plan, even if it is for only a short period of time.

q. Prescription Drug Distribution and Cost Reporting (§ 156.295)

Section 6005 of the Affordable Care Act added section 1150A to the Act, which requires a QHP issuer to provide to HHS information on the distribution of prescription drugs, pharmacy benefit management activities, the collection of rebates and other monies in conducting these activities, and costs incurred to provide those drugs. We propose to codify the requirements contained in section 6005 here in § 156.295.

In paragraph (a), we propose to codify the elements specified in section 1150A(b) of the Act that a QHP issuer must report to HHS in a form and manner to be determined by HHS. Specifically, we propose that the QHP issuer must provide the following information: (1) The percentage of all prescriptions that were provided under the contract through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed compared to all drugs dispensed, broken down by pharmacy type, that is paid by the QHP issuer or pharmacy benefit manager (PBM) under the contract; (2) the aggregate amount, and the type of rebates, discounts, or price concessions, with certain exceptions, that the PBM negotiates that are attributable to patient utilization under the plan, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed; and (3) the aggregate amount of the difference between the amount the QHP issuer pays the PBM and the amounts that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed. We anticipate issuing guidance on these reporting requirements. We seek comment on how a QHP issuer whose contracted PBM operates its own mail order pharmacy can meaningfully report on the aggregate difference between what the QHP issuer pays the PBM and the PBM pays the mail order pharmacy.

We clarify that, for the purposes of this section, we interpret ''generic drug'' to have meaning given to the term in 42 CFR 423.4, which is used in the Medicare Prescription Drug Benefit Program. We seek comment on potential definitions for ''rebates,'' ''discounts'' and ''price concessions''; we are considering using the term ''direct and indirect remuneration,'' a term used in regulations related to the Medicare Prescription Drug Benefit Program, to encompass these various arrangements.

The statute refers to PBMs, entities with which health insurance issuers often contract to perform activities such as prescription drug claims processing, negotiation with prescription drug manufacturers, the development and maintenance of pharmacy networks, or the distribution of prescription drugs on behalf of the health insurance issuer. We interpret the statutory references to PBMs to include any entity that performs such activities on behalf of a QHP issuer; we seek comment on this interpretation and whether we should define PBMs as such in this section. We seek comment on how to minimize the burden of these reporting requirements.

In paragraph (c) we propose to codify the confidentiality requirements to ensure that this information is not disclosed by either HHS or the QHP issuer except under specific circumstances described in the Affordable Care Act. The exceptions allow HHS to de-identify and aggregate prescription drug pricing, rebate and distribution information to report it to the Comptroller General or the Congressional Budget Office.

Finally, we propose under paragraph (c) to codify the penalties for noncompliance. Specifically, a QHP issuer that does not provide HHS the information required under paragraph (b) or knowingly provides false information would be subject to the provisions of subsection (b)(3)(C) of section 1927 of the Act. Under this subsection, if the information is not

provided at all, the QHP issuer would be subject to a fine that would increase $10,000 each day that the information is not provided. If the information is not reported within 90 days of the set deadline, the QHP issuer would lose its contract with the Exchange. If the QHP issuer provides false information, it would be subject to a fine not to exceed $100,000 for each piece of false information provided.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

Below is a partial summary of the proposed information collection requirements outlined in this regulation. Any information collection requirements in this regulation which are not outlined below will be subject to a separate notice and comment process under the Paperwork Reduction Act. We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding General Standards Related to the Establishment of an Exchange (§ 155.105 and § 155.110)

Within Part 155, subpart B of this proposed rule, we describe reporting requirements for a State to receive approval of its Exchange Plan by January 1, 2013. For purposes of presenting an estimate of paperwork burden in Part 155, we reflect full participation of all States and the District of Columbia in operating an Exchange. However, we recognize that not all States will elect to operate their own Exchanges, so these estimates should be considered an upper bound of burden estimates. These estimates may be adjusted proportionally in the final rule based upon additional information as States progress in their Exchange development processes.

As discussed in § 155.105, States are required to submit an Exchange plan to HHS. As noted above, we plan to issue a template outlining the required components of the Exchange Plan, subject to the notice and comment process under the Paperwork Reduction Act. We estimate that it will take a State approximately 160 hours (approximately one month) for the time and effort needed to develop the plan and submit to HHS. We estimate minimal burden requirements for developing the Exchange plan as States will be gathering most of the information needed for the plan through the planning grants provided by HHS. States are also required to make the governance principles available to the public. We estimate that it will take States 40 hours for the time and effort to develop these principles and disclose this information to the public. This estimate is similar to estimates provided for reporting requirements for Medicare Part D as described in § 423.514.

We estimate that all 50 States and the District of Columbia will establish an Exchange and will be subject to meeting these requirements. Again, this estimate should be considered an upper bound, and we may revise these estimates in the final rule based upon additional information as States progress in their Exchange development processes. We estimate that it will take 200 hours for a State to meet these provisions. The total burden for all States and the District of Columbia is 10,200 hours. For the purposes of this estimate, we assume that meeting these requirements will take a health policy analyst 120 hours (at an average wage rate of $43 an hour) and a senior manager 80 hours (at $77 an hour). The wage rate estimates include a 35% fringe benefit estimate for state employees, which is based on the March 2011 Employer Costs for Employee Compensation report by U.S Bureau of Labor Statistics. This fringe benefit estimate will be used throughout this section for all presumed state personnel. The estimated cost burden for each State is $11,320 with a total estimated burden of $577,320.

As described in § 155.105, States must also notify CMS of any changes to its Exchange proposal. We estimate that 5 States submit changes and that it will take each state 12 hours to develop the notification and submit to CMS for a total burden of 60 hours. We presume that it will take a health policy analyst 12 hours (at $43 an hour) to meet this requirement. The estimated burden cost per State is $516 for a total cost burden estimate of $2,580 for five States.

B. ICRs Regarding General Functions of an Exchange (§ 155.205)

In Part 155, subpart C we describe the information and reporting requirements that Exchanges are required to perform. According to provisions spelled out in this subpart, Exchanges are required to collect and populate the Web site they develop with information on qualified health plans, premium and cost-sharing information, benefits and coverage of qualified health plans, levels of plan coverage, medical loss ratio information, transparency of coverage, and a provider directory.

The burden estimate related to the Web site reflects the time and effort needed to collect the information described above and disclose this information on a Web site; however, we understand that overall administrative burden and costs will be higher for Web site development and testing. These costs are reflected in the impact analysis for Exchanges. Assuming that all States and the District of Columbia establish Exchanges, an upper bound estimate, we estimate that it will take 320 hours (approximately 2 months) for each State to meet this requirement for a total estimate of 16,320 hours. We presume that it will take a health policy analyst 40 hours (at $43 an hour), a financial analyst 90 hours (at $62 an hour), a senior manager 50 hours (at $77 an hour), and various network/computer administrators or programmers 140 hours (at $54 an hour) to meet the reporting requirements for this subpart. We estimate the total cost burden for an Exchange to be $18,710 for a total estimated burden of $954,210 for all 50 States and the District of Columbia.

C. ICRs Regarding Exchange Functions: Enrollment in Qualified Health Plans (§ 155.400–§ 155.430)

Within Part 155 subpart E of this proposed rule, we describe the requirements of Exchanges in the enrollment of qualified individuals and disenrollment. As discussed in § 155.400, Exchanges are required to maintain records of enrollment annually. We estimate that this will take an exchange 52 hours annually to maintain these records. This estimate is similar to Medicare Part D, where is was estimated that it will take 52 hours on an annual basis for plan sponsors to maintain books, records, and documents on accounting procedures and practices as described in § 423.505. Estimates related specifically to the maintenance of records for enrollment were not provided in Medicare Part D.

Exchanges are also required to submit enrollment information to HHS on a monthly basis, and reconcile enrollment information on at least a monthly basis. We estimate that it will take an Exchange 12 hours submit this information and 12 hours to reconcile this information on a monthly basis. Exchanges are also required submit the number of coverage terminations to HHS. We estimated that it will take 12 hours for an Exchange to submit this information. These estimates are similar to estimates provided in Medicare Part D rule for data submission. For example, Medicare Part D estimated that it would take plan sponsors approximately 10 hours annually for plan sponsors to submit data on aggregated negotiated drug pricing from pharmaceutical companies described in § 423.104. We provide a slightly higher estimate for the submission of data due to the complexity of the Exchange program.

Exchanges are also required to provide a notice of eligibility to the applicant and a notice of the annual open enrollment period to the applicant. Estimates related to notices in this subpart and throughout the proposed rule for Exchanges take into account the time and effort needed to develop the notice and make it an automated process to be sent out when appropriate. As such, we estimate that it will take approximately 16 hours annually for the time and effort to develop and submit a notice when appropriate. Again, this estimate is slightly higher than the 8 hours estimated for notices discussed in the Medicare Part D rule and reflects the overall complexity of the Exchange program.

States are required to maintain records of termination coverage. Again, we estimate that this will take an exchange 52 hours annually to maintain these records. We estimate that all 50 States and the District of Columbia will establish an Exchange subject to these reporting requirements. This estimate is an upper bound of burden as a result of the reporting requirements in this subpart; we will revise these estimates in the final rule as States progress in their Exchange development. We estimate that it will take 436 hours for an Exchange to meet these reporting requirements for a total of 22,236 hours. We presume that it will take an operations analyst 224 hours (at $55 an hour), a health policy analyst 119 hours (at $43 an hour), and a senior manager 93 hours (at $77 an hour) to meet the reporting requirements for a burden cost estimate of $24,598 for an Exchange and total estimated burden costs of $1,254,498 for all 50 States and the District of Columbia.

D. ICRs Regarding Exchange Functions: Small Business Health Options Program (SHOP) (§ 155.715–§ 155.725)

Part 155, subpart H of this proposed rule describes reporting requirements for SHOP. As described in § 155.715 through § 155.725, the SHOP is required to provide the following notices:

- Notice to employer of reason to doubt information submitted;
- Notice to employer of non-resolution for reason to doubt;
- Notice to individual of inability to substantiate employee status;
- Notice of employer eligibility;
- Notice of employee eligibility;
- Notice of employer withdrawal from SHOP;
- Notification of effective date to employees;
- Notice of employee termination of coverage to employer;
- Notice of annual employer election period; and
- Notice to employee of open enrollment period.

As discussed previously, we estimate that it will take 16 hours annually for a SHOP to provide each notice as described in this subpart. The SHOP is also required to maintain records for SHOP enrollment and reconcile SHOP enrollment files on a monthly basis. Again, we estimate that this will take 52 hours annually for a SHOP to maintain SHOP enrollment records. This estimate is similar to Medicare Part D, where it was estimated that it will take 52 hours on an annual basis for plan sponsors to maintain books, records, and documents on accounting procedures and practices as described in § 423.505. Estimates related specifically to the maintenance of records for enrollment were not provided in Medicare Part D. We also estimate that it will take 12 hours for a SHOP to reconcile this information on a monthly basis.

We estimate that that all 50 States and the District of Columbia will establish a SHOP subject to meeting these reporting requirements. This estimate is an upper bound of burden as a result of the reporting requirements in this subpart; we will revise these estimates in the final rule as States progress in their Exchange development. We estimate that it will take each SHOP 356 hours to meet these requirements for a total of 18,156 hours. We presume that it will a health policy analyst 132 hours (at $43 an hour), a senior manager 80 hours (at $77 an hour), and an operations analyst 144 hours (at $55 an hour) to meet these reporting requirements for an estimated cost burden of $19,756 for each Exchange. The total estimated cost burden is $1,007,556 for all 50 States and the District of Columbia.

E. ICRs Regarding Exchange Functions: Certification of Qualified Health Plans (§ 155.1020, § 155.1040, and § 155.1080)

Within Part 155, subpart K, we describe data collection and reporting requirements for Exchanges related to the certification of qualified health plans. As described in § 155.1020, § 155.1040, and § 155.1080, Exchanges are required to collect qualified health plan issuer reports on covered benefits, rates, and cost-sharing requirements. We estimate that it will take 12 hours for an Exchange to collect this information from issuers annually. This estimate is similar to estimates for data collection described in the Medicare Part D rule. Exchanges are also required to collect information on coverage transparency from issuers. Again, we estimate that it will take 12 hours for an Exchange to collect this information. Finally, Exchanges are required to provide a notice of the decertification, if applicable, of a QHP to the QHP issuer, Exchange enrollees, HHS, and the State insurance department. This burden was estimated at 16 hours for an Exchange to provide notice.

For this burden exercise, we estimate that all 50 States and the District of Columbia will establish an Exchange subject to these reporting requirements, an upper bound estimate. We further estimate that it will take 40 hours for an Exchange to meet the provisions discussed, with a total burden estimate of 2,040 hours for all 50 States and the District of Columbia. We presume that it will take an operations analyst 32 hours (at $55 an hour) and a senior manager 8 hours (at $77 an hour) to carry out the requirements in this subpart. HHS estimates that the cost burden for an Exchange to meet the reporting requirements in subpart K to be $2,376 with a total cost burden estimate of $121,176 for all 50 States and the District of Columbia.

F. ICRs Regarding Qualified Health Plan Minimum Certification Standards (§ 156.210–§ 156.290)

Part 156, subpart C describes reporting requirements for issuers. Each qualified health plan issuer is required to report annually to the Exchange information on benefits and rates, justification of rate increases, coverage transparency, and a summary of cost and coverage documents, including notice of coverage of abortion provided by a QHP plan. Issuers are also required to make available enrollee cost sharing information, provide information to applicants and enrollees, provide enrollment packages, collect enrollment information and submit this information

to the Exchange, reconcile enrollment files on a monthly basis, and maintain records related to termination of coverage. There are also several notices that issuers must provide to enrollees related to the effective date of coverage, non-renewal of coverage, termination of coverage, and payment delinquency; and to the Exchange for non-renewal of recertification.

As described in § 156.285, for the SHOP program, issuers must provide an enrollment package to SHOP enrollees and a summary of benefits and coverage to employers and employees; reconcile enrollment files for SHOP on a monthly basis; and provide notice to SHOP enrollees of termination of coverage. As discussed previously, estimates related the collection and submission of data; maintenance of records, notices are similar to estimates provided in the Medicare Part D rule.

Qualified health plan issuers must also submit to the Exchange and HHS on an annual basis information on drug distribution and costs. We estimate that it will take an issuer 24 hours to submit this data. This estimate is a slight increase from the Medicare Advantage estimate of 15 hours for submitting data for drug claims as described for § 423.329 for Medicare Part D and reflects the complexity of reporting this data for the Exchange program.

For the purpose of this estimate and whenever we refer to burden requirements for issuers, we utilize estimates of the number of issuers provided by the Healthcare.gov Web site as this site provides the best estimate of possible issuers at this time. Based on preliminary findings there are approximately 1827 issuers in the individual and small group markets. While we recognize that not all issuers will offer QHPs, we use the estimate of 1827 issuers as the upper bound of participation and burden.

We estimate that it will take an issuer 588 hours to meet these reporting requirements for a total burden estimate of 1,074,276 hours for all 1827 issuers. We presume that it will take at least two health policy analysts 80 hours (at an average private industry rate of $50 an hour), a financial analyst 124 hours (at $57 an hour), an operations analyst 352 hours (at $51 an hour), and a senior manager 32 hours (at $72 an hour) to meet these reporting requirements. These wage estimates include a 30% fringe benefit rate for the private sector as reported by the U.S. Bureau of Labor Statistics in the March 2011 Employer Costs for Employee Compensation report. The estimated burden cost for each issuer is $31,324. The total estimated burden cost for all issuers is $57.2 million.

Regulation section(s)	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($)	Total labor cost of reporting ($)
155.105–155.110	51	1	200	10,200	11,320	577,320
155.105	5	1	12	60	516	2,580
155.205	51	1	320	16,320	18,710	954,210
155.400–155.430	51	1	436	22,236	24,598	1,254,498
155.715–155.725	51	1 Exception: Monthly for SHOP enrollment reconciliation	356	18,156	19,756	1,007,556
155.1020–155.1080	51	1	40	2,040	2,376	121,176
156.210–156.290	1827	1 Exception: monthly for enrollment and SHOP enrollment reconciliation	588	1,074,276	31,324	57.2 million

Salaries and fringe benefit estimates were taken from the Bureau of Labor Statistics Web site: (*http://www.bls.gov/oco/ooh_index.htm*).

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

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

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

Attention: CMS Desk Officer, [CMS–9989–P],

Fax: (202) 395–5806; or

E-mail: OIRA_submission@omb.eop.gov.

IV. Summary of Preliminary Regulatory Impact Analysis

The summary analysis of benefits and costs included in this proposed rule is drawn from the detailed Preliminary Regulatory Impact Analysis, available at *http://cciio.cms.gov* under ''Regulations and Guidance.'' That preliminary impact analysis evaluates the impacts of this proposed rule and a second proposed rule, ''Patient Protection and Affordable Care Act; Standards Related to Reinsurance, Risk Corridors and Risk Adjustment.'' The second proposed rule is published elsewhere in this **Federal Register**. The following summary focuses on the benefits and costs of this proposed rule.

A. Introduction

HHS has examined the impacts of the proposed rule under Executive Orders 12866 and 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits (both quantitative and qualitative) of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of

reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an ''economically'' significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Using the Small Business Administration (SBA) definitions of small entities for agents and brokers, providers, and employers, HHS tentatively concludes that a significant number of firms affected by this proposed rule are not small businesses.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is approximately $136 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. HHS does not expect this proposed rule to result in one-year expenditures that would meet or exceed this amount.

B. Need for This Regulation

This proposed rule would implement standards for States related to the Establishment of Exchanges and Qualified Health Plans consistent with 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 business the same purchasing power as large businesses.

C. Summary of Costs and Benefits of the Proposed Requirements

Two proposed regulations are being published simultaneously to implement components of the Exchange and health insurance premium stabilization policies in the Affordable Care Act. The detailed PRIA, available at *http://cciio.cms.gov* under ''Regulations and Guidance,'' evaluates the impacts of both proposed rules, while this summary focuses on the benefits and costs of the proposed requirements in this Exchange NPRM.

Benefits in response to the proposed regulation:

Research has consistently noted that health insurance coverage improves health outcomes. For example, individuals without health insurance are significantly more likely to be at risk of mortality.[11] Secondly, lack of health insurance significantly increases financial risk for individuals. Thirdly, increases in health insurance results in a decrease in uncompensated care costs. This proposed regulation is expected to decrease the level of uninsurance and therefore should produce a benefit in the form of improved health outcomes, decreased fiscal risk, and decrease in uncompensated care costs. In addition, we estimate that for individuals and some employers, risk pooling and economies of scale will reduce the administrative cost of health insurance, and competition may increase insurers' incentive to lower payments to health care providers, reducing premiums and potentially national health expenditures.

The Exchanges and policies associated with them, according to CBO, are expected to reduce premiums for the same benefits compared to prior law. It estimated that, in 2016, people purchasing non-group coverage through the Exchanges would pay 7 to 10 percent less due to the healthier risk pool that results from the coverage expansion. An additional 7 to 10 percent in savings would result from gains in economies of scale in purchasing insurance and lower administrative costs from elimination of underwriting, decreased marketing costs, and the Exchanges' simpler system for finding and enrolling individuals in health insurance plans.[12]

Costs in Response to the Proposed Regulation

Meeting the proposed requirements will have costs on Exchanges and on issuers of qualified health plans (QHPs). The administrative costs of operating an Exchange will almost certainly vary by the number of enrollees in the Exchange due to economies of scale, variation in the scope of the Exchange's activities, and variation in average premium in the Exchange service area. However, we believe major cost components for Exchanges will include: IT infrastructure, Navigators, notifications, enrollment standards, application process, SHOP, certification of QHPs, and quality reporting. The major costs on issuers of QHPs will include: Accreditation, network adequacy standards, and quality improvement strategy reporting. CBO estimates that the administrative costs to QHP issuers would be more than offset by savings resulting from lower overhead due to new policies to limit benefit variation, prohibit ''riders,'' and end under-writing.

Methods of Analysis

This preliminary impact analysis references the estimates of the CMS Office of the Actuary (OACT) (CMS, April 22, 2010), but primarily uses the underlying assumptions and analysis done by the Congressional Budget Office (CBO) and the staff of the Joint Committee on Taxation. Their modeling effort accounts for all of the interactions among the interlocking pieces of the Affordable Care Act including its tax policies, and estimates premium effects that are important to assessing the benefits of the NPRM. A description of CBO's methods used to estimate budget and enrollment impacts is available.[13] The CBO estimates are not significantly different than the comparable components produced by OACT. Based on our review, we expect that the requirements in these NPRMs will not substantially alter CBO's estimates of the budget impact of Exchanges or enrollment. The proposed requirements are well within the parameters used in the CBO modeling of the Affordable Care Act and do not diverge from assumptions embedded in the CBO model. Our review and analysis of the proposed requirements indicate that the impacts are within the model's margin of error.

Summary of Costs and Benefits

CBO estimated program payments and receipts for outlays related to grants for Exchange startup. States' initial costs to the creation of Exchanges will be funded by these grants.

[11] Franks, Peter et al. ''Health Insurance and Mortality.'' Journal of American Medical Associates. 6(737–741) 1993.

[12] Congressional Budget Office, ''Letter to the Honorable Evan Bayh: An Analysis of Health Insurance Premiums Under the Patient Protection and Affordable Care Act.'' (Washington2009).

[13] CBO, ''CBO's Health Insurance Simulation Model: A Technical Description.'' (2007, October).

TABLE 1—ESTIMATED OUTLAYS FOR THE AFFORDABLE INSURANCE EXCHANGES FY 2012–FY 2016

[In billions of dollars]

Year	2012	2013	2014	2015	2016
Grant Authority for Exchange Start up	0.6	0.8	0.4	0.2	0.0

SOURCE: CBO.

Regulatory Options Considered

In addition to a baseline, HHS has identified two regulatory options for this proposed rule as required by Executive Order 12866.

(1) Have a uniform Standard for Operations of an Exchange.

Under this alternative HHS would require a single standard for State operations of Exchanges. The proposed regulation offers States the choice of whether to establish an Exchange, how to structure governance of the Exchange, whether to join with other States to form a regional Exchange, and how much education and outreach to engage in, among other factors. This alternative model would restrict State flexibility to some extent, requiring a more uniform standard that States must enact in order to achieve approval of an Exchange.

(2) Uniform Standard for Health Insurance Coverage.

Under this alternative, there would be a single uniform standard for certifying QHPs. QHPs would need to meet a single standard in terms of benefit packages, network adequacy, premiums, etc. HHS would set these standards in advance of the certification process and QHPs would either meet those standards and thereby be certified or would fail to meet those standards and therefore would not be available to enrollees.

Summary of Costs for Each Option

HHS notes that Option 1, which promotes uniformity, could produce a benefit of reduced Federal oversight cost; however this option would reduce innovation and therefore limit diffusion of successful policies and furthermore interfere with Exchange functions and needs. HHS also notes that while Option 2 could produce administrative burdens on Exchanges, this approach could reduce Exchanges' and QHP issuers' ability to innovate. These costs and benefits are discussed more fully in the detailed PRIA.

D. Accounting Statement

For full documentation and discussion of these estimated costs and benefits, see the detailed PRIA, available at *http://cciio.cms.gov* under ''Regulations and Guidance.''

Category	Primary estimate	Year dollar	Units discount rate	Period covered
Benefits				
Annualized Monetized ($millions/year)	Not estimated	2011	7%	2012–2016
	Not estimated	2011	3%	2012–2016
Qualitative	The Exchanges, combined with other actions being taken to implement the Affordable Care Act, will improve access to health insurance, with numerous positive effects, including earlier treatment and improved morbidity, fewer bankruptcies and decreased use of uncompensated care. The Exchange will also serve as a distribution channel for insurance reducing administrative costs as a part of premiums and providing comparable information on health plans to allow for a more efficient shopping experience.			
Costs				
Annualized Monetized ($millions/year)	424	2011	7%	2012–2016
	410	2011	3%	2012–2016
Qualitative	These costs include grant outlays to States to establish Exchanges.			

V. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The Act generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of ''small entity.'' HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

As discussed above, this proposed rule is necessary to implement standards related to the Establishment of Exchanges and Qualified Health Plans as authorized by the Affordable Care Act. For purposes of the Regulatory Flexibility Analysis, we expect the following types of entities to be affected by this proposed rule: (1) QHP issuers; (2) agents and brokers; and (3) employers. We believe that health insurers and agents and brokers would be classified under the North American Industry Classification System (NAICS) Codes 524114 (Direct Health and Medical Insurance Carriers) and 524210 (Insurance Agencies and Brokers). According to SBA size standards, entities with average annual receipts of $7 million or less would be considered small entities for both of these NAICS codes. Health issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be $10 million or less.

As discussed in the Web Portal interim final rule (75 FR 24481), HHS examined the health insurance industry in depth in the Regulatory Impact

Analysis we prepared for the proposed rule on establishment of the Medicare Advantage program (69 FR 46866, August 3, 2004). In that analysis we determined that there were few, if any, insurance firms underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) that fell below the size thresholds for ''small'' business established by the SBA (currently $7 million in annual receipts for health insurers, based on North American Industry Classification System Code 524114).[1]

Additionally, as discussed in the Medical Loss Ratio interim final rule (75 FR 74918), the Department used a data set created from 2009 National Association of Insurance Commissioners (NAIC) Health and Life Blank annual financial statement data to develop an updated estimate of the number of small entities that offer comprehensive major medical coverage in the individual and group markets. For purposes of that analysis, the Department used total Accident and Health (A&H) earned premiums as a proxy for annual receipts. The Department estimated that there were 28 small entities with less than $7 million in accident and health earned premiums offering individual or group comprehensive major medical coverage; however, this estimate may overstate the actual number of small health insurance issuers offering such coverage, since it does not include receipts from these companies' other lines of business.

As discussed earlier in this summary of the PRIA, the Department is seeking comments on the potential impacts of the requirements in this proposed regulation on issuers' administrative costs. The Department is also seeking comments relating to potential impacts on small issuers.

This rule proposes Exchange standards related to offering the QHPs. These standards and the associated certification process will impose costs on issuers, but these costs will vary depending on a number of factors, including the operating model chosen by the Exchange, their current accreditation status, and the variation between the proposed standards and current practice. Some QHP issuers will be more prepared to meet the standards than others and will incur fewer costs. For example, if data reporting functions required for certification already exist at the QHP issuer, there would be no additional cost. Exchanges also have the flexibility in some cases to set requirements. For example, the rule proposes discretion for Exchanges in setting network adequacy standards for participating health insurance issuers. The cost to the issuer will depend on whether the Exchange determines that compliance with relevant State law and licensure requirements is sufficient for a QHP issuer to participate in the Exchange or whether they decide to set additional standards in accordance with current provider market characteristics and consumer needs.

The cost of participating in an Exchange is an investment for QHP issuers, with benefits expected to accrue to QHP issuers. The Exchange will function as an important distribution channel for QHPs. QHP issuers currently fund their own sales and marketing efforts. As a centralized outlet to attract and enroll consumers, the Exchanges will supplement and reduce incremental health plan sales and marketing costs with their consumer assistance, education and outreach functions.

We anticipate that the agent and broker industry, which is comprised of large brokerage organizations, small groups, and independent agents, will play a critical role in enrolling qualified individuals in QHPs. We are proposing to codify Section 1312(e) of the Affordable Care Act, which gives States the option to permit agents or brokers to assist individuals enrolling in QHPs through the Exchange. Agents and brokers must meet any condition imposed by the State and, as a result, could incur costs. In addition, agents and brokers who become Navigators will also agree to comply with associated requirements and are likely to incur some costs. Because the States and the Exchanges will make these determinations, we cannot provide an estimate of the potential number of small entities that will be affected or the costs associated with these decisions.

This rule proposes requirements on employers that choose to participate in a SHOP. As discussed above, the SHOP is limited by statute to employers with at least one but not more than 100 employees. For this reason, we expect that many employers would meet the SBA Standard for Small entities. We do not believe that the proposed regulation imposes requirements on employers offering health insurance through SHOP that are more restrictive than the current requirements on employers offering employer sponsored health insurance. For this reason, we also believe the processes that we have proposed constitute the minimum amount of requirements necessary to implement statutory mandates and accomplish our policy goals, and that no appropriate regulatory alternatives could be developed to lessen the compliance burden. We also expect that for some employers, risk pooling and economies of scale will reduce the administrative cost of offering coverage through the SHOP and that they will, therefore, benefit from participation.

We request comment on whether the small entities affected by this rule have been fully identified. We also request comment and information on potential costs for these entities and on any alternatives that we should consider.

VI. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing proposed rule (and subsequent final rule) that includes any Federal mandate that may result in expenditures in any one year by a State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. Because States are not required to set up an Exchange, and because grants are available for funding of the establishment of an Exchange by a State, we anticipate that this proposed rule would not impose costs above that $136 million UMRA threshold on State, local, or tribal governments.

VII. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, pre-empts State law, or otherwise has Federalism implications. Because States have flexibility in designing their Exchange, State decisions will ultimately influence both administrative expenses and overall premiums. States are not required to certify an Exchange. For States electing to create an Exchange, much of the initial costs to the creation of Exchanges will be funded by Exchange Planning and Establishment Grants. After this time, Exchanges will be financially self-sustaining with revenue sources at the discretion of the State. Current State Exchanges charge user fees to issuers.

In the Department's view, while this proposed rule does not impose substantial direct requirement costs on State and local governments, this

[1] ''Table of Size Standards Matched to North American Industry Classification System Codes,'' effective November 5, 2010, U.S. Small Business Administration, available at *http://www.sba.gov.*

proposed regulation has Federalism implications due to direct effects on the distribution of power and responsibilities among the State and Federal governments relating to determining standards relating to health insurance coverage (i.e., for QHPs) that is offered in the individual and small group markets. Each State electing to establish an Exchange must adopt the Federal standards contained in the Affordable Care Act and in this proposed rule, or have in effect a State law or regulation that implements these Federal standards. However, the Department anticipates that the Federalism implications (if any) are substantially mitigated because under the statute, States have choices regarding the structure and governance of their Exchanges. Additionally, the Affordable Care Act does not require States to certify an Exchange; if a State elects not to establish an Exchange or the State's Exchange is not approved, HHS, either directly or through agreement with a non-profit entity, must establish and operate an Exchange in that State.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the States, the Department has engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with State insurance officials on an individual basis.

Throughout the process of developing this NPRM, the Department has attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide access to Affordable Insurance Exchanges for consumers in every State. By doing so, it is the Department's view that we have complied with the requirements of Executive Order 13132.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to this regulation, the Department certifies that CMS has complied with the requirements of Executive Order 13132 for the attached proposed regulation in a meaningful and timely manner.

List of Subjects

45 CFR Part 155

Administrative practice and procedure, Advertising, Brokers, Conflict of interest, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs-health, Organization and functions (Government agencies), Medicaid, Public assistance programs, Reporting and recordkeeping requirements, Safety, State and local governments, Technical assistance, Women, and Youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interest, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs-health, Organization and functions (Government agencies), Medicaid, Public assistance programs, Reporting and recordkeeping requirements, Safety, State and local governments, Sunshine Act, Technical Assistance, Women, and Youth.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 45 CFR subtitle A, subchapter B, as set forth below:

SUBTITLE A—DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER B—REQUIREMENTS RELATING TO HEALTH CARE ACCESS

1. Part 155 is added as follows:

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

Subpart A—General Provisions

Sec.

155.10 Basis and scope.
155.20 Definitions.

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

155.100 Establishment of a State Exchange.
155.105 Approval of a State Exchange.
155.106 Election to operate an Exchange after 2014.
155.110 Entities eligible to carry out Exchange functions.
155.120 Non-interference with Federal law and non-discrimination standards.
155.130 Stakeholder consultation.
155.140 Establishment of a regional Exchange or subsidiary Exchange.
155.150 Transition process for existing State health insurance exchanges.
155.160 Financial support for continued operations.

Subpart C—General Functions of an Exchange

155.200 Functions of an Exchange.
155.205 Required consumer assistance tools and programs of an Exchange.
155.210 Navigator program standards.
155.220 Ability of States to permit agents and brokers to assist qualified individuals, qualified employers or qualified employees enrolling in QHPs.
155.230 General standards for Exchange notices.
155.240 Payment of premiums.
155.260 Privacy and security of information.
155.270 Use of standards and protocols for electronic transactions.

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

155.400 Enrollment of qualified individuals into QHPs.
155.405 Single streamlined application.
155.410 Initial and annual open enrollment periods.
155.420 Special enrollment periods.
155.430 Termination of coverage.
155.440 [Reserved]

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

155.700 Standards for the establishment of a SHOP.
155.705 Functions of a SHOP.
155.710 Eligibility standards for SHOP.
155.715 Eligibility determination process for SHOP.
155.720 Enrollment of employees into QHPs under SHOP.
155.725 Enrollment periods under SHOP.
155.730 Application standards for SHOP.

Subpart K—Exchange Functions: Certification of Qualified Health Plans

155.1000 Certification standards for QHPs.
155.1010 Certification process for QHPs.
155.1020 QHP issuer rate and benefit information.
155.1040 Transparency in coverage.
155.1045 Accreditation timeline.
155.1050 Establishment of Exchange network adequacy standards.
155.1055 Service area of a QHP.
155.1065 Stand-alone dental plans.
155.1075 Recertification of QHPs.
155.1080 Decertification of QHPs.

Authority: Title I of the Affordable Care Act, sections 1301, 1302, 1303, 1304, 1311, 1312, 1313, 1321, 1322, 1331, 1334, 1341, 1342, 1343, 1402, 1411, 1412–1413.

Subpart A—General Provisions

§ 155.10 Basis and scope.

(a) *Basis.* This part is based on the following sections of title I of the Affordable Care Act:

1301. Qualified health plan defined.
1302. Essential health benefits requirements
1303. Special rules
1304. Related definitions
1311. Affordable choices of health benefit plans.
1312. Consumer choice.

1313. Financial integrity.
1321. State flexibility in operation and enforcement of Exchanges and related requirements.
1322. Federal program to assist establishment and operation of nonprofit, member-run health insurance issuers.
1331. State flexibility to establish Basic Health Programs for low-income individuals not eligible for Medicaid.
1334. Multi-State plans.
1342. Establishment of risk corridors for plans in individual and small group markets.
1343. Risk adjustment.
1402. Reduced cost-sharing for individuals enrolling in QHPs.
1411. Procedures for determining eligibility for Exchange participation, advance premium tax credits and reduced cost sharing, and individual responsibility exemptions.
1412. Advance determination and payment of premium tax credits and cost-sharing reductions.
1413. Streamlining of procedures for enrollment through an exchange and State Medicaid, CHIP, and health subsidy programs.

(b) *Scope.* This part establishes minimum standards for the establishment of an Exchange, minimum Exchange functions, eligibility determinations, enrollment periods, minimum SHOP functions, certification of QHPs, and health plan quality improvement.

§ 155.20 Definitions.

The following definitions apply to this part:

Advance payments of the premium tax credit means payment of the tax credits specified in section 36B of the Code (as added by section 1401 of the Affordable Care Act) which are provided on an advance basis to an eligible individual of a QHP through an Exchange pursuant to sections 1402 and 1412 of the Affordable Care Act.

Affordable Care Act means 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).

Agent or broker means a person or entity licensed by the State as an agent, broker or insurance producer.

Annual open enrollment period means the period each year during which a qualified individual may enroll or change coverage in a QHP through the Exchange.

Applicant means:

(1) An individual who is seeking eligibility through an application to the Exchange for at least one of the following:

(i) Enrollment in a QHP through the Exchange;

(ii) Advance payments of the premium tax credit and cost-sharing reductions; or

(iii) Medicaid, CHIP, and the BHP, if applicable.

(2) An employer or employee seeking eligibility for enrollment in a QHP through the SHOP, where applicable.

Benefit year means a calendar year for which a health plan provides coverage for health benefits.

Code means the Internal Revenue Code of 1986.

Cost sharing means any expenditure required by or on behalf of an enrollee with respect to essential health benefits; such term includes deductibles, coinsurance, copayments, or similar charges, but excludes premiums, balance billing amounts for non-network providers, and spending for non-covered services.

Cost-sharing reductions means reductions in cost sharing for an eligible individual enrolled in a silver level plan in the Exchange or for an individual who is an Indian who is enrolled in a QHP in the Exchange.

Eligible employer-sponsored plan means, with respect to any employee, a group health plan or group health insurance coverage offered by an employer to the employee which is—

(1) A governmental plan (within the meaning of section 2791(d)(8) of the PHS Act); or

(2) Any other plan or coverage offered in the small or large group market within a State.

Such term shall include a grandfathered health plan offered in the group market.

Employee has the meaning given to the term in section 2791 of the PHS Act.

Employer has the meaning given to the term in section 2791 of the PHS Act, except that such term must include employers with one or more employees. All persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 of the Code must be treated as one employer.

Employer contributions means any financial contributions towards an employer sponsored health plan, or other eligible employer-sponsored benefit made by the employer including those made by salary reduction agreement that is excluded from gross income.

Enrollee means a qualified individual or qualified employee enrolled in a QHP.

Exchange means a governmental agency or non-profit entity that meets the applicable requirements of this part and makes QHPs available to qualified individuals and qualified employers. Unless otherwise identified, this term refers to State Exchanges, regional Exchanges, subsidiary Exchanges, and a Federally-facilitated Exchange.

Exchange service area means the area in which the Exchange is certified to operate, in accordance with the requirements specified in subpart B of this part.

Grandfathered health plan means coverage provided by a group health plan, or a health insurance issuer as provided in accordance with requirements under § 147.140.

Group health plan has the meaning given to the term in § 144.103.

Health insurance coverage has the meaning given to the term in § 144.103.

Health insurance issuer or *issuer* has the meaning given to the term in § 144.103.

Health plan means health insurance coverage and a group health plan. It does not include a group health plan or multiple employer welfare arrangement to the extent the plan or arrangement is not subject to State insurance regulation under section 514 of the Employee Retirement Income Security Act of 1974.

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

Initial enrollment period means the period during which a qualified individual may enroll in coverage through the Exchange for coverage during the 2014 benefit year.

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

Lawfully present has the meaning given the term in § 152.2 of this subtitle.

Minimum essential coverage has the meaning given in section 5000A(f) of the Code.

Navigator means a private or public entity or individual that is qualified, and licensed, if appropriate, to engage in the activities and meet the requirements described in § 155.210.

Plain language means language that the intended audience, including individuals with limited English proficiency, can readily understand and use because that language is concise, well organized, and follows other best practices of plain language writing.

Plan year means a consecutive 12 month period during which a health plan provides coverage for health

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.

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.

(b) *HIT enrollment standards and protocols.* The Exchange must incorporate interoperable and secure standards and protocols developed by the Secretary pursuant to section 3021 of the PHS Act. Such standards and protocols must be incorporated within Exchange information technology systems.

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

§ 155.400 Enrollment of qualified individuals into QHPs.

(a) *General requirements.* The Exchange must accept a QHP selection from an applicant who is determined eligible for enrollment in a QHP in accordance with the standards established in accordance with § 155.200(c) of this subpart, and must—

(1) Notify the issuer of the applicant's selected QHP; and

(2) Transmit information necessary to enable the QHP issuer to enroll the applicant.

(b) *Timing of data exchange.* The Exchange must:

(1) Send eligibility and enrollment information to QHP issuers on a timely basis; and

(2) Establish a process by which a QHP issuer verifies and acknowledges the receipt of such information.

(c) *Records.* The Exchange must maintain records of all enrollments in QHPs through the Exchange and submit enrollment information to HHS on a monthly basis.

(d) *Reconcile files.* The Exchange must reconcile enrollment information with QHP issuers no less than on a monthly basis.

§ 155.405 Single streamlined application.

(a) *The application.* The Exchange must use a single streamlined application to determine eligibility and to collect information necessary for enrollment for—

(1) QHPs;

(2) Advance payments of the premium tax credit;

(3) Cost-sharing reductions; and

(4) Medicaid, CHIP, or the BHP, where applicable.

(b) *Alternative application.* If the Exchange seeks to use an alternative application, such application, as approved by HHS, must request the minimum information necessary for the purposes identified in paragraph (a) of this section.

(c) *Filing the single streamlined application.* The Exchange must—

(1) Accept the single streamlined application from

(i) An applicant;

(ii) An authorized representative; or,

(iii) Someone acting responsibly for the applicant.

(2) Provide the tools to allow for an applicant to file an application—

(i) Via an Internet portal;

(ii) By telephone through a call center;

(iii) By mail; and

(iv) In person.

(d) [Reserved]

(e) [Reserved]

§ 155.410 Initial and annual open enrollment periods.

(a) *General requirements.*

(1) The Exchange must provide an initial open enrollment period and annual open enrollment periods consistent with this section, during which qualified individuals may enroll in a QHP or enrollees may change QHPs.

(2) The Exchange may only permit a qualified individual to enroll in a QHP or an enrollee to change QHPs during the initial open enrollment period specified in paragraph (b) of this section, the annual open enrollment period specified in paragraph (e) of this section, or a special enrollment period described in § 155.420 of this subpart for which the qualified individual or enrollee has been determined eligible.

(b) *Initial open enrollment period.* The initial open enrollment period begins October 1, 2013 and extends through February 28, 2014.

(c) *Effective coverage dates for initial open enrollment period.* For QHP selections received by the Exchange from a qualified individual—

(1) On or before December 22, 2013, the Exchange must ensure a coverage effective date of January 1, 2014; and

(2) Between the first and twenty-second day of any subsequent month during the initial open enrollment period, the Exchange must ensure a coverage effective date of the first day of the following month; and

(3) Between the twenty-third and last day of the month for any month between December 2013 and February 28, 2014, the Exchange must ensure a coverage effective date of either the first day of the following month or the first day of the second following month.

(d) *Notice of annual open enrollment period.* Starting in 2014, the Exchange must provide advance written notification to each enrollee about annual open enrollment.

(e) *Annual open enrollment period.* For benefit years beginning on or after January 1, 2015, the annual open enrollment period begins October 15 and extends through December 7 of the preceding calendar year.

(f) *Effective date for coverage after the annual open enrollment period.* The Exchange must ensure coverage is effective as of the first day of the following benefit year for a qualified individual who has made a QHP selection during the annual open enrollment period.

(g) [Reserved]

§ 155.420 Special enrollment periods.

(a) *General requirements.* The Exchange must provide special enrollment periods consistent with this section, during which qualified individuals and enrollees may enroll in QHPs or change enrollment from one QHP to another.

(b) *Effective dates.* Once a qualified individual is determined eligible for a special enrollment period, the Exchange must ensure that the qualified individual's effective date of coverage is:

(1) On the first day of the following month for all QHP selections made by the 22nd of the previous month,

(2) On either the first day of the following month or the first day of the second following month for all QHP selections made between the 23rd and last day of a given month, or

(3) In the case of birth, adoption or placement for adoption effective on the date of birth, adoption, or placement for adoption.

(c) *Length of special enrollment periods.* Unless specifically stated otherwise herein, a qualified individual or enrollee has 60 days from the date of a triggering event to select a qualified health plan.

(d) *Special enrollment periods.* The Exchange must allow qualified individuals and enrollees to enroll in or change from one QHP to another as a result of the following triggering events:

(1) A qualified individual or dependent loses minimum essential coverage;

(2) A qualified individual gains a dependent or becomes a dependent through marriage, birth, adoption or placement for adoption;

(3) An individual, who was not previously a citizen, national, or lawfully present individual gains such status;

(4) A qualified individual's enrollment or non-enrollment in a QHP is unintentional, inadvertent, or erroneous and is the result of the error, misrepresentation, or inaction of an officer, employee, or agent of the Exchange or HHS, or its instrumentalities as evaluated and determined by the Exchange. In such cases, the Exchange may take such action as may be necessary to correct or

eliminate the effects of such error, misrepresentation, or inaction;

(5) An enrollee adequately demonstrates to the Exchange that the QHP in which he or she is enrolled substantially violated a material provision of its contract in relation to the individual;

(6) An individual is determined newly eligible or newly ineligible for advance payments of the premium tax credit or has a change in eligibility for cost-sharing reductions, regardless of whether such individual is already enrolled in a QHP. The Exchange must permit an individual whose existing coverage through an eligible employer-sponsored plan will no longer be affordable or provide minimum value for his or her employer's upcoming plan year to access this special enrollment period prior to the end of his or her coverage through such eligible employer-sponsored plan;

(7) A qualified individual or enrollee gains access to new QHPs as a result of a permanent move;

(8) An Indian, as defined by section 4 of the Indian Health Care Improvement Act, may enroll in a QHP or change from one QHP to another 1 time per month; and

(9) A qualified individual or enrollee meets other exceptional circumstances as the Exchange or HHS may provide.

(e) *Loss of coverage.* Loss of coverage does not include termination or loss due to—

(1) Failure to pay premiums on a timely basis, including COBRA premiums prior to expiration of COBRA coverage, or

(2) Situations allowing for a rescission as specified in 45 CFR 147.128, Rules Regarding Rescissions.

(f) *Limits on special enrollment periods.* An enrollee may only move to a different plan at the same level of coverage, as described in section 1302(d)(1) of the Affordable Care Act, excluding paragraph (d)(6) of this section.

§ 155.430 Termination of coverage.

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

(b) *Termination events.*

(1) The Exchange must permit an enrollee to terminate his or her coverage in a QHP with appropriate notice to the Exchange or the QHP.

(2) The Exchange may terminate an enrollee's coverage in a QHP, and must permit a QHP issuer to terminate such coverage, in the following circumstances:

(i) The enrollee is no longer eligible for coverage in a QHP through the Exchange;

(ii) The enrollee becomes covered in other minimum essential coverage;

(iii) Payments of premiums for coverage of the enrollee cease, provided that the grace period required by § 156.270 of this subtitle has expired;

(iv) The enrollee's coverage is rescinded in accordance with § 147.128 of this subtitle;

(v) The QHP terminates or is decertified as described in § 155.1080; or

(vi) The enrollee changes from one QHP to another during an annual open enrollment period or special enrollment period in accordance with § 155.410 or § 155.420.

(c) *Termination of coverage tracking and approval.* The Exchange must—

(1) Establish mandatory procedures for issuers of QHPs to maintain records of termination of coverage;

(2) Track number of coverage terminations and submit that information to HHS on a monthly basis;

(3) Establish standards for termination of coverage that require issuers of QHPs to provide reasonable accommodations to individuals with mental or cognitive conditions, including mental and substance use disorders, Alzheimer's disease, and developmental disabilities before terminating coverage for such individuals; and

(4) Retain records in order to facilitate audit functions.

(d) *Effective dates for termination of coverage.*

(1) In the case of a termination in accordance with paragraph (b)(1) of this section, the last day of coverage is the termination date specified by the enrollee, if the Exchange and QHP have a reasonable amount of time from the date on which the enrollee provides notice to terminate his or her coverage. If the Exchange or the QHP do not have a reasonable amount of time from the date on which the enrollee provides notice to terminate his or her coverage, the last day of coverage is the first day after such reasonable amount of time has passed.

(2) In the case of a termination in accordance with paragraph (b)(2)(ii) of this section, the last day of coverage is the day before the effective date of an enrollee's coverage for new minimum essential coverage.

(3) In the case of a termination in accordance with paragraph (b)(2)(vi) of this section, the last day of coverage in an enrollee's prior QHP is the day before the effective date of coverage in his or her new QHP.

(4) In cases other than those described in paragraphs (d)(1)–(3) of this section, the last day of coverage is:

(i) The fourteenth day of the month if the notice of termination is sent by the Exchange or termination is initiated by the QHP no later than the fourteenth day of the previous month; or

(ii) The last day of the month if the notice of termination is sent by the Exchange or termination is initiated by the QHP no later than the last day of the previous month.

§ 155.440 [Reserved]

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

§ 155.700 Standards for the establishment of a SHOP.

General requirement. An Exchange must provide for the establishment of a SHOP that meets the requirements of this subpart and is designed to assist qualified employers and facilitate the enrollment of qualified employees into qualified health plans.

§ 155.705 Functions of a SHOP.

(a) *Exchange functions that apply to SHOP.* The SHOP must carry out all the required functions of an Exchange described in this subpart and in subparts C, E, H, and K of this part, except:

(1) Requirements related to individual eligibility determinations in § 155.200(c) and appeals of such determinations in § 155.200(d).

(2) Requirements related to enrollment of qualified individuals described in subpart E of this part;

(3) The requirement to create a premium tax credit calculator pursuant to § 155.205(c);

(4) The requirement to certify exemptions from the individual coverage requirement pursuant to § 155.200(b);

(5) Requirements related to the payment of premiums by individuals, Indian tribes, tribal organizations and urban Indian organizations under § 155.240.

(b) *Unique functions of a SHOP.* The SHOP must also provide the following unique functions:

(1) *Enrollment and eligibility functions.* The SHOP must adhere to the requirements outlined in §§ 155.710, 155.715, 155.720, 155.725, and 155.730. In addition, the SHOP must at a minimum facilitate the special enrollment periods described in § 156.285(b)(2) of this subtitle.

(2) *Employer choice requirements.* With regard to QHPs offered through the SHOP, the SHOP must allow a qualified

employer to select a level of coverage as described in section 1302(d)(1) of the Affordable Care Act, in which all QHPs within that level are made available to the qualified employees of the employer.

(3) *SHOP options with respect to employer choice requirements.* With regard to QHPs offered through the SHOP, the SHOP may allow a qualified employer to make one or more QHPs available to qualified employees by a method other than the method described in paragraph (b)(2) of this section.

(4) *Premium aggregation.* The SHOP must perform the following functions related to premium payment administration:

(i) Provide each qualified employer with a bill on a monthly basis that identifies the total amount that is due to the QHP issuers from the qualified employer; and

(ii) Collect from each employer the total amount due and make payments to QHP issuers in the SHOP for all qualified enrollees.

(5) *QHP Certification.* With respect to certification of QHPs in the small group market, the SHOP must ensure QHPs meet the requirements specified in § 156.285 of this subtitle.

(6) *Rates and rate changes.* The SHOP must—

(i) Require all QHP issuers to make any change to rates at a uniform time that is either quarterly, monthly, or annually; and

(ii) Not vary rates for a qualified employer during its plan year.

(7) *QHP availability in merged markets.* If a State merges the individual market and the small group market risk pools pursuant to section 1312(c)(3) of the Affordable Care Act, the SHOP may permit a qualified employee to enroll in any QHP meeting the following requirements of the small group market:

(i) Deductible maximums described in section 1302(c) of the Affordable Care Act; and

(ii) Levels of coverage described in § 155.705(b)(2).

(8) *QHP availability in unmerged markets.* If a State does not merge the individual and small group market risk pools, the SHOP must permit each qualified employee to enroll only in QHPs in the small group market.

(9) *SHOP expansion to large group market.* If a State elects to expand the SHOP to the large group market, a SHOP must allow issuers of health insurance coverage in the large group market in the State to offer QHPs in such market through a SHOP beginning in 2017, provided that a large employer meets the qualified employer requirements by electing to make all full-time employees of such employer eligible for one or more QHPs offered in the large group market through a SHOP.

§ 155.710 Eligibility standards for SHOP.

(a) *General requirement.* The SHOP must permit qualified employers to purchase coverage for qualified employees through the SHOP.

(b) *Employer eligibility requirements.* An employer is a qualified employer eligible to purchase coverage through a SHOP if such employer—

(1) Is a small employer;

(2) Elects to offer, at a minimum, all full-time employees coverage in a QHP through a SHOP; and

(3) Either—

(i) Has its principal business address in the Exchange service area and offers coverage to all its employees through that SHOP; or

(ii) Offers coverage to each eligible employee through the SHOP serving that employee's primary worksite.

(c) *Participating in multiple SHOPs.* If an employer meets the criteria in (b) above and makes the election described in paragraph (b)(3)(ii) of this section, a SHOP shall allow the employer to offer coverage to those employees whose primary worksite is in the SHOP's service area.

(d) *Continuing eligibility.* The SHOP must treat a qualified employer which ceases to be a small employer solely by reason of an increase in the number of employees of such employer as a qualified employer until the qualified employer otherwise fails to meet the eligibility criteria of this section or elects to no longer purchase coverage for qualified employees through the SHOP.

(e) *Employee eligibility requirements.* An employee is a qualified employee eligible to enroll in coverage through a SHOP if such employee receives an offer of coverage from a qualified employer.

§ 155.715 Eligibility determination process for SHOP.

(a) *General requirement.* Before permitting the purchase of coverage in a QHP, the SHOP must determine that the employer or individual who requests coverage is eligible in accordance with the requirements of § 155.710.

(b) *Applications.* The SHOP must accept a SHOP single employer application form from employers and the SHOP single employee application form from employees wishing to elect coverage through the SHOP in accordance with the relevant standards of § 155.730.

(c) *Verification of application.* For the purpose of verifying information within the employer and employee applications, the SHOP—

(1) Must verify that an individual applicant is identified by the employer as an employee to whom the qualified employer has offered coverage and must otherwise accept the information attested to within the application unless the SHOP has a reason to doubt the information's veracity; and

(2) May establish, in addition to or in lieu of reliance on the application, additional methods to verify the information provided by the applicant on the applicable application.

(d) *Eligibility adjustment period.*

(1) For an employer requesting to purchase coverage through the SHOP for which the SHOP has a reason to doubt the information on the application submitted by the employer, the SHOP must—

(i) Make a reasonable effort to identify and address the causes of such reason to doubt, including through typographical or other clerical errors;

(ii) Notify the employer of the reason;

(iii) Provide the employer with a period of 30 days from the date on which the notice described in paragraph (d)(1)(i) of this section is sent to the employer to either present satisfactory documentary evidence to support the employer's application, or resolve the inconsistency; and

(iv) If, after the 30-day period described in paragraph (d)(1)(iii) of this section, the SHOP has not received satisfactory documentary evidence, the SHOP must—

(A) Notify the employer of its denial of eligibility pursuant to paragraph (e) of this section; and

(B) If the employer was enrolled pending the confirmation or verification of eligibility information, discontinue the employer's participation in the SHOP at the end of the month following the month in which the notice is sent.

(2) For an individual requesting eligibility to enroll in a QHP through the SHOP for whom the SHOP has a reason to doubt the information on the application submitted by the individual, the SHOP must—

(i) Make a reasonable effort to identify and address the causes of such inconsistency, including through typographical or other clerical errors;

(ii) Notify the individual of the inability to substantiate his or her employee status;

(iii) Provide the employee with a period of 30 days from the date on which the notice described in paragraph (d)(2)(ii) of this section is sent to the employee to either present satisfactory documentary evidence to support the

employee's application, or resolve the inconsistency; and

(iv) If, after the 30-day period described in paragraph (d)(2)(iii) of this section, the SHOP has not received satisfactory documentary evidence, the SHOP must notify the employee of its denial of eligibility pursuant to paragraph (f) of this section.

(e) *Notification of employer eligibility.* The SHOP must provide an employer requesting eligibility to purchase coverage with a notice of approval or denial of eligibility and the employer's right to appeal such eligibility determination.

(f) *Notification of employee eligibility.* The SHOP must notify an employee seeking to enroll in a QHP offered through the SHOP of the determination by the SHOP whether the individual is eligible in accordance with § 155.710 and the employee's right to appeal such determination.

(g) *Notification of employer withdrawal from SHOP.* If a qualified employer ceases to purchase coverage through the SHOP, the SHOP must ensure that—

(1) Each QHP terminates the coverage of the employer's qualified employees enrolled in the QHP through the SHOP; and

(2) Each of the employer's qualified employees enrolled in a QHP through the SHOP is notified of the termination of their coverage prior to such termination.

§ 155.720 Enrollment of employees into QHPs under SHOP.

(a) *General requirements.* The SHOP must process the SHOP single employee applications of qualified employees to the applicable QHP issuers and facilitate the enrollment of qualified employees in QHPs. All references to QHPs in this section refer to QHPs offered through the SHOP.

(b) *Enrollment timeline and process.* The SHOP must establish a uniform enrollment timeline and process that all QHP issuers and qualified employers comply with for the following activities to occur before the effective date of coverage for qualified employees:

(1) Determination of employer eligibility for purchase of coverage in the SHOP as described in § 155.715;

(2) Qualified employer selection of QHPs offered through the SHOP to qualified employees, consistent with § 155.705(b)(2) and (3);

(3) Provision of a specific timeframe during which the qualified employer can select the level of coverage or QHP offering, as appropriate;

(4) Provision of a specific timeframe for qualified employees to provide relevant information to complete the application process;

(5) Determination and verification of employee eligibility for enrollment through the SHOP;

(6) Processing enrollment of qualified employees into selected QHPs; and

(7) Establishment of effective dates of employee coverage.

(c) *Transfer of enrollment information.* In order to enroll qualified employees of a qualified employer participating in the SHOP, the SHOP must—

(1) Transmit enrollment information on behalf of qualified employees to QHP issuers in accordance with the timeline described in paragraph (b) of this section; and

(2) Follow requirements set forth in § 155.400(c) of this part.

(d) *Payment.* The SHOP must—

(1) Adhere to requirements set forth in § 155.705(b)(4); and

(2) Terminate qualified employers that do not comply with the process established in § 155.705(b)(4).

(e) *Notification of effective date.* The SHOP must ensure that a qualified employee enrolled in a QHP is notified of the effective date of coverage consistent with § 156.260(b) of this subtitle.

(f) *Records.* The SHOP must receive and maintain records of enrollment in QHPs, including identification of—

(1) Qualified employers participating in the SHOP, and

(2) Qualified employees enrolled in QHPs.

(g) *Reconcile files.* The SHOP must reconcile enrollment information and employer participation information with QHPs on no less than a monthly basis in accordance with standards established in § 155.400(d).

(h) *Employee termination of coverage from a QHP.* If any employee terminates coverage from a QHP, the SHOP must notify the individual's employer.

§ 155.725 Enrollment periods under SHOP.

(a) *General requirements.* The SHOP must—

(1) Adhere to the start of the initial open enrollment period set forth in § 155.410; and

(2) Ensure that enrollment transactions are sent to QHP issuers and that such issuers adhere to coverage effective dates in accordance with § 156.260 of this subtitle.

(b) *Rolling enrollment in the SHOP.* The SHOP must permit a qualified employer to purchase coverage for its small group at any point during the year. The employer's plan year must consist of the 12-month period beginning with the qualified employer's effective date of coverage.

(c) *Annual employer election period.* The SHOP must provide qualified employers with a period prior to the completion of the employer's plan year and before the annual employee open enrollment period, in which the qualified employer may change its participation in the SHOP for the next plan year, including—

(1) The method by which qualified employer makes QHPs available to qualified employees pursuant § 155.705(b)(2) and (3);

(2) The employer contribution towards the premium cost of coverage;

(3) The level of coverage offered to qualified employees as described in § 155.705(b)(2) and (3); or

(4) The QHP or plans offered to qualified employees pursuant to § 155.705.

(d) *Annual employer election period notice.* The SHOP must provide notification to a qualified employer of the annual election period in advance of such period.

(e) *Annual employee open enrollment period.* The SHOP must establish an annual open enrollment period for qualified employees prior to the completion of the applicable qualified employer's plan year and after that employer's annual election period.

(f) *Employees hired outside of the initial or annual open enrollment period.* The SHOP must provide an employee hired outside of the initial or annual open enrollment period a specified period to seek coverage in a QHP beginning on the first day of employment.

(g) *Effective dates.* The SHOP must establish effective dates of coverage for qualified employees consistent with the effective dates of coverage described in § 155.720.

(h) *Renewal of coverage.* If a qualified employee enrolled in a QHP through the SHOP remains eligible for coverage, such individual will remain in the plan selected the previous year unless—

(1) He or she disenrolls from such plan in accordance with standards identified in § 155.430;

(2) He or she enrolls in another QHP if such option exists; or

(3) The QHP is no longer available to the qualified employee.

§ 155.730 Application standards for SHOP.

(a) *General requirements.* Application forms used by the SHOP must meet the requirements set forth in this section.

(b) *Single employer application.* The SHOP must use a single application to determine employer eligibility and to collect information necessary for purchasing coverage. Such application must collect the following—

(1) Employer name and address of employer's locations;

(2) Number of employees;

(3) Employer Identification Number (EIN); and

(4) A list of qualified employees and their social security numbers.

(c) *Single employee application.* The SHOP must use a single application for eligibility determination, QHP selection and enrollment for qualified employees.

(d) *Model application.* The SHOP may use the model single employer application and the model single employee application provided by HHS.

(e) *Alternative employer application.* The SHOP may use an alternative application if such application is approved by HHS and collects the following—

(1) In the case of the employer application, the information described in paragraph (b) of this section; and

(2) In the case of the employee application, the information necessary to establish eligibility of the employee as a qualified employee and to complete the enrollment of a qualified employee, such as plan selection and identification of dependents to be enrolled.

(f) *Filing.* The SHOP must allow an employer to file the SHOP single employer application and employees to file the single employee application in the form and manner described in § 155.405(c).

Subpart K—Exchange Functions: Certification of Qualified Health Plans

§ 155.1000 Certification standards for QHPs.

(a) *Definition.* The following definition applies in this subpart:

Multi-State plan is a health plan offered by a health insurance issuer under contract with the U.S. Office of Personnel Management (OPM) to offer a multi-State QHP through the Exchange. The plan must offer a benefits package that is uniform in each State and consists of the benefit design standards described in section 1302 of the Affordable Care Act; meets all requirements for QHPs; and meets Federal rating requirements pursuant to section 2701 of the PHS Act, or a State's more restrictive rating requirements, if applicable.

(b) *General requirement.* The Exchange must offer only QHPs which have in effect a certification issued or recognized by the Exchange as QHPs. Any reference to QHPs must be deemed to include multi-State plans, unless specifically provided for otherwise.

(c) *General certification criteria.* The Exchange may certify a health plan as a QHP in the Exchange if—

(1) The health insurance issuer provides evidence during the certification process in § 155.1010 that it complies with the minimum certification requirements outlined in subpart C of part 156 of this subtitle, as applicable; and

(2) The Exchange determines that making the health plan available is in the interest of the qualified individuals and qualified employers, except that the Exchange must not exclude a health plan—

(i) On the basis that such plan is a fee-for-service plan;

(ii) Through the imposition of premium price controls; or

(iii) On the basis that the health plan provides treatments necessary to prevent patients' deaths in circumstances the Exchange determines are inappropriate or too costly.

§ 155.1010 Certification process for QHPs.

(a) *Certification procedures.* The Exchange must establish procedures for the certification of QHPs consistent with § 155.1000(c).

(b) *Exemption from certification process.* Notwithstanding paragraph (a) of this section, a multi-State plan is exempt from the certification process established by the Exchange and deemed as meeting the certification requirements for QHPs.

(c) *Completion date.* The Exchange must complete the certification of the QHPs prior to the open enrollment period as outlined in § 155.410.

(d) *Ongoing compliance.* The Exchange must monitor the QHP issuers for demonstration of ongoing compliance with the certification requirements in § 155.1000(c).

§ 155.1020 QHP issuer rate and benefit information.

(a) *Receipt and posting of rate increase justification.* The Exchange must receive a justification for a rate increase for a QHP prior to the implementation of such an increase. The Exchange must ensure that the QHP issuer has prominently posted the justification on its Web site as required under § 156.210 of this subtitle.

(b) *Rate increase consideration.* The Exchange must consider rate increases in accordance with section 1311(e)(2) of the Affordable Care Act, which includes consideration of the following:

(1) A justification for a rate increase prior to the implementation of the increase;

(2) Recommendations provided to the Exchange by the State pursuant to section 2794(b)(1)(B) of the PHS Act; and

(3) Any excess of rate growth outside the Exchange as compared to the rate of such growth inside the Exchange.

(c) *Benefit and rate information.* The Exchange must receive the following information, at least annually, from QHP issuers for each QHP in a form and manner to be specified by HHS:

(1) Rates;

(2) Covered benefits; and

(3) Cost-sharing requirements.

§ 155.1040 Transparency in coverage.

(a) *General requirement.* The Exchange must collect information relating to coverage transparency as described in § 156.220(a) of this subtitle from QHP issuers.

(b) *Use of plain language.* The Exchange must determine whether the information required to be submitted and made available under paragraph (a) of this section is provided in plain language.

(c) *Transparency of cost-sharing information.* The Exchange must monitor whether a QHP issuer has made cost-sharing information available in a timely manner upon the request of an individual as required by § 156.220(d) of this subtitle.

§ 155.1045 Accreditation timeline.

The Exchange must establish a uniform period following certification of the QHP within which a QHP issuer that is not already accredited must become accredited as required by § 156.275 of this subtitle.

§ 155.1050 Establishment of Exchange network adequacy standards.

An Exchange must ensure that the provider network of each QHP offers a sufficient choice of providers for enrollees.

§ 155.1055 Service area of a QHP.

The Exchange must have a process to establish or evaluate the service areas of QHPs to determine whether the following minimum criteria are met:

(a) The service area of a QHP covers a minimum geographical area that is at least the entire geographic area of a county, or a group of counties defined by the Exchange, unless the Exchange determines that serving a smaller geographic area is necessary, nondiscriminatory, and in the best interest of the qualified individuals and employers.

(b) The service area of a QHP has been established without regard to racial, ethnic, language, health status-related factors listed in section 2705(a) of the PHS Act, or other factors that exclude specific high utilizing, high cost or medically-underserved populations.

§ 155.1065 Stand-alone dental plans.

(a) *General requirements.* The Exchange must allow the offering of a limited scope dental benefits plan through the Exchange if—

(1) The plan meets the requirements of section 9832(c)(2)(A) of the Code and 2791(c)(2)(A) of the PHS Act; and

(2) The plan covers at least the pediatric dental essential health benefit as defined in section 1302(b)(1)(J) of the Affordable Care Act.

(b) *Offering options.* The Exchange may allow the dental plan to be offered—

(1) As a stand-alone dental plan; or

(2) In conjunction with a QHP.

(c) *Certification standards.* If a plan described in paragraph (a) is offered through an Exchange, another health plan offered through such Exchange must not fail to be treated as a QHP solely because the plan does not offer coverage of benefits offered through the stand-alone plan that are otherwise required under section 1302(b)(1)(J) of the Affordable Care Act.

§ 155.1075 Recertification of QHPs.

(a) *Recertification process.* The Exchange must establish a process for recertification of QHPs that includes a review of the general certification criteria as outlined in § 155.1000(c). Upon determining the recertification status of a QHP, the Exchange must notify the QHP issuer.

(b) *Timing.* The Exchange must complete the QHP recertification process on or before September 15 of the applicable calendar year.

§ 155.1080 Decertification of QHPs.

(a) *Definition.* The following definition applies to this section:

Decertification means the termination by the Exchange of the certification status and offering of a QHP.

(b) *Decertification process.* The Exchange must establish a process for the decertification of QHPs which, at a minimum, meet the requirements in this section.

(c) *Decertification by the Exchange.* The Exchange may at any time decertify a health plan if the Exchange determines that the QHP issuer is no longer in compliance with the general certification criteria as outlined in § 155.1000(c).

(d) *Appeal of decertification.* The Exchange must establish a process for the appeal of a decertification of a QHP.

(e) *Notice of decertification.* Upon decertification of a QHP, the Exchange must provide notice of decertification to all affected parties, including:

(1) The QHP issuer;

(2) Exchange enrollees in the QHP who must receive information about a special enrollment period, as described in § 155.420;

(3) HHS; and

(4) The State department of insurance.

3. Part 156 is added as follows:

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

Subpart A—General Provisions

Sec.
156.10 Basis and scope.
156.20 Definitions.
156.50 Financial support.

Subpart B—[Reserved]

Subpart C—Qualified Health Plan Minimum Certification Standards

156.200 QHP issuer participation standards.
156.210 QHP rate and benefit information.
156.220 Transparency in coverage.
156.225 Marketing of QHPs.
156.230 Network adequacy standards.
156.235 Essential community providers.
156.245 Treatment of direct primary care medical homes.
156.250 Health plan applications and notices.
156.255 Rating variation.
156.260 Enrollment periods for qualified individuals.
156.265 Enrollment process for qualified individuals.
156.270 Termination of coverage for qualified individuals.
156.275 Accreditation of QHP issuers.
156.280 Segregation of funds for abortion services.
156.285 Additional standards specific to the SHOP.
156.290 Non-renewal and decertification of QHPs.
156.295 Prescription drug distribution and cost reporting.

Authority: Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321, 1322, 1324, 1334, 1342–1343, and 1401–1402.

Subpart A—General Provisions

§ 156.10 Basis and scope.

(a) *Basis.*

(1) This part is based on the following sections of title I of the Affordable Care Act:

1301. QHP defined.
1302. Essential health benefits requirements.
1303. Special rules.
1304. Related definitions.
1311. Affordable choices of health benefit plans.
1312. Consumer choice.
1313. Financial integrity.
1321. State flexibility in operation and enforcement of Exchanges and related requirements.
1322. Federal program to assist establishment and operation of nonprofit, member-run health insurance issuers.
1331. State flexibility to establish Basic Health Programs for low-income individuals not eligible for Medicaid.
1334. Multi-State plans.
1402. Reduced cost-sharing for individuals enrolling in QHPs.
1411. Procedures for determining eligibility for Exchange participation, advance premium tax credits and reduced cost sharing, and individual responsibility exemptions.
1412. Advance determination and payment of premium tax credits and cost-sharing reductions.
1413. Streamlining of procedures for enrollment through an Exchange and State, Medicaid, CHIP, and health subsidy programs.

(2) This part is based on the following sections of title I of the Act:

1150A. Pharmacy Benefit Managers Transparency Requirements

(b) *Scope.* This part establishes standards for QHPs under Exchanges, and addresses other health insurance issuer requirements.

§ 156.20 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Applicant has the meaning given to the term in § 155.20 of this subtitle.

Benefit design standards means coverage that provides for all of the following:

(1) The essential health benefits as described in section 1302(b) of the Affordable Care Act;

(2) Cost-sharing limits as described in section 1302(c) of the Affordable Care Act; and

(3) A bronze, silver, gold, or platinum level of coverage as described in section 1302(d) of the Affordable Care Act, or is a catastrophic plan as described in section 1302(e) of the Affordable Care Act.

Benefit year has the meaning given to the term in § 155.20 of this subtitle.

Cost-sharing has the meaning given to the term in § 155.20 of this subtitle.

Cost-sharing reductions has the meaning given to the term in § 155.20 of this subtitle.

Group health plan has the meaning given to the term in § 144.103 of this subtitle.

Health insurance coverage has the meaning given to the term in § 144.103 of this subtitle.

Health insurance issuer or issuer has the meaning given to the term in § 144.103 of this subtitle.

Level of coverage means one of four standardized actuarial values as defined by section 1302(d)(2) of the Affordable Care Act of plan coverage.

Plan year has the meaning given to the term in § 155.20 of this subtitle.

Qualified employer has the meaning given to the term in § 155.20 of this subtitle.

Qualified health plan has the meaning given to the term in § 155.20 of this subtitle.

Qualified health plan issuer has the meaning given to the term in § 155.20 of this subtitle.

Qualified individual has the meaning given to the term in § 155.20 of this subtitle.

§ 156.50 Financial support.

(a) *Definitions.* The following definitions apply for the purposes of this section:

Participating issuer means any issuer offering plans that participates in the specific function that is funded by user fees. This term may include: health insurance issuers, QHP issuers, issuers of multi-State plans (as defined in § 155.1000(a) of this subtitle), issuers of stand-alone dental plans (as described in § 155.1065 of this subtitle), or other issuers identified by an Exchange.

(b) *Requirement for State Exchanges.* A participating issuer must remit user fee payments assessed by an Exchange under § 155.160 of this subtitle.

Subpart B—[Reserved]

Subpart C—Qualified Health Plan Minimum Certification Standards

§ 156.200 QHP issuer participation standards.

(a) *General requirement.* In order to participate in an Exchange, a health insurance issuer must have in effect a certification issued or recognized by the Exchange to demonstrate that each health plan it offers in the Exchange is a QHP.

(b) *QHP issuer requirement.* A QHP issuer must—

(1) Comply with the requirements of this subpart with respect to each of its QHPs on an ongoing basis;

(2) Comply with Exchange processes, procedures, and requirements set forth pursuant to subpart K of part 155 and, in the small group market, § 155.705 of this subtitle;

(3) Ensure that each QHP complies with benefit design standards, as defined in § 156.20;

(4) Be licensed and in good standing to offer health insurance coverage in each State in which the issuer offers health insurance coverage;

(5) Implement and report on a quality improvement strategy or strategies consistent with the standards of section 1311(g) of the Affordable Care Act, disclose and report information on health care quality and outcomes described in sections 1311(c)(1)(H) and (I) of the Affordable Care Act, and implement appropriate enrollee satisfaction surveys consistent with section 1311(c)(4) of the Affordable Care Act; and

(6) Pay any applicable user fees assessed under § 156.50; and

(7) Comply with the standards related to the risk adjustment program under 45 CFR part 153.

(c) *Offering requirements.* A QHP issuer must offer through the Exchange:

(1) At least one QHP in the silver coverage level and at least one QHP in the gold coverage level as described in section 1302(d)(1) of the Affordable Care Act;

(2) A child-only plan at the same level of coverage, as described in section 1302(d)(1) of the Affordable Care Act, as any QHP offered through the Exchange to individuals who, as of the beginning of the plan year, have not attained the age of 21; and

(3) A QHP at the same premium rate consistent with § 156.255(b).

(d) *State requirements.* A QHP issuer participating in the Exchange must adhere to the requirements of this subpart and any provisions imposed by the Exchange, or a State in connection with its Exchange, that are conditions of participation with respect to each of its QHPs.

(e) *Non-discrimination.* A QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, sex, gender identity or sexual orientation.

§ 156.210 QHP rate and benefit information.

(a) *General rate requirement.* A QHP issuer must set rates for an entire benefit year, or for the SHOP, plan year.

(b) *Rate and benefit submission.* A QHP issuer must submit rate and benefit information to the Exchange pursuant to § 155.1020.

(c) *Rate justification.* A QHP issuer must submit a justification for a rate increase prior to the implementation of the increase. A QHP issuer must prominently post the justification on its Web site.

§ 156.220 Transparency in coverage.

(a) *Required information.* A QHP issuer must provide the following information in accordance with the standards in paragraph (b) of this section:

(1) Claims payment policies and practices;

(2) Periodic financial disclosures;

(3) Data on enrollment;

(4) Data on disenrollment;

(5) Data on the number of claims that are denied;

(6) Data on rating practices;

(7) Information on cost-sharing and payments with respect to any out-of-network coverage; and

(8) Information on enrollee rights under title I of the Affordable Care Act.

(b) *Reporting requirement.* A QHP issuer must submit, in an accurate and timely manner, to be determined by HHS, the information described in paragraph (a) of this section to the Exchange, HHS and the State insurance commissioner, and make the information described in paragraph (a) of this section available to the public.

(c) *Use of plain language.* A QHP issuer must make sure that the information submitted under paragraph (b) of this section is provided in plain language as defined under § 155.20 of this subtitle.

(d) *Enrollee cost-sharing transparency.* A QHP issuer must make available the amount of enrollee cost sharing under the individual's plan or coverage with respect to the furnishing of a specific item or service by a participating provider in a timely manner upon the request of the individual. At a minimum, such information must be made available to such individual through an Internet Web site and such other means for individuals without access to the Internet.

§ 156.225 Marketing of QHPs.

A QHP issuer and its officials, employees, agents and representatives must—

(a) *State law applies.* Comply with any applicable State laws and regulations regarding marketing by health insurance issuers; and

(b) *Non-discrimination.* Not employ marketing practices that discourage the enrollment of individuals with significant health needs in QHPs.

§ 156.230 Network adequacy standards.

(a) *General requirement.* A QHP issuer must ensure that the provider network of each of its QHPs, as available to all enrollees, meets the following standards—

(1) Includes essential community providers in accordance with § 156.235;

(2) Complies with any network adequacy standards established by the Exchange consistent with § 155.1050 of this section; and

(3) Is consistent with the network adequacy provisions of section 2702(c) of the PHS Act.

(b) *Notice to applicants and enrollees.* A QHP issuer must make its provider

directory for a QHP available to the Exchange for publication online pursuant to guidance from the Exchange and to potential enrollees in hard copy upon request. In the provider directory, a QHP issuer must identify providers that are not accepting new patients.

§ 156.235 Essential community providers.

(a) *General requirement.* A QHP issuer must include within the provider network of the QHP a sufficient number of essential community providers, where available, that serve predominantly low-income, medically-underserved individuals. Nothing in this requirement shall be construed to require any health plan to provide coverage for any specific medical procedure provided by the essential community provider.

(b) *Inclusion.* Essential community providers under paragraph (a) of this section include:

(1) Health care providers defined in section 340B(a)(4) of the PHS Act; and

(2) Providers described in section 1927(c)(1)(D)(i)(IV) of the Act as set forth by section 221 of Pub. L. 111–8.

§ 156.245 Treatment of direct primary care medical homes.

A QHP issuer may provide coverage through a direct primary care medical home that meets criteria established by HHS, so long as the QHP meets all requirements that are otherwise applicable and the services covered by the direct primary care medical home are coordinated with the QHP issuer.

§ 156.250 Health plan applications and notices.

QHP issuers must provide all applications and notices to enrollees in accordance with the standards described in § 155.230(b) of this subtitle.

§ 156.255 Rating variations.

(a) *Rating areas.* A QHP issuer, including an issuer of a multi-State QHP, may vary premiums for a QHP or a multi-State QHP by the geographic rating area established under section 2701(a)(2) of the PHS Act.

(b) *Same premium rates.* A QHP issuer must charge the same premium rate without regard to whether the plan is offered through an Exchange, or whether the plan is offered directly from the issuer or through an agent.

(c) *Rating categories.* A QHP issuer must cover all of the following groups using some combination of the following categories:

(1) Individuals;

(2) Two-adult families;

(3) One-adult families with a child or children; and

(4) All other families.

§ 156.260 Enrollment periods for qualified individuals.

(a) *Individual market requirement.* A QHP issuer must:

(1) Enroll a qualified individual during the initial and annual open enrollment periods described in § 155.410(b) and § 155.410(e) of this subtitle, and abide by the effective dates of coverage established by the Exchange pursuant to the requirements described in § 155.410(c) and § 155.410(f) of this subtitle; and

(2) Make available, at a minimum, special enrollment periods described in § 155.420(d), for QHPs and abide by the effective dates of coverage established by the Exchange pursuant to the requirements described in § 155.420(b) of this subtitle.

(b) *Notification of effective date.* A QHP issuer must notify the qualified individual of his or her effective date of coverage in coordination with the standards established in § 155.410(c), § 155.410(f) and § 155.420(b) of this subtitle.

§ 156.265 Enrollment process for qualified individuals.

(a) *General requirement.* A QHP issuer must adhere to the following requirements for individuals seeking enrollment in a QHP.

(b) *Enrollment information collection and transmission.* If an applicant initiates enrollment directly with the issuer for enrollment in a QHP, the QHP issuer must—

(1) Collect enrollment information using the application adopted pursuant to § 155.405 of this subtitle;

(2) Transmit the enrollment information to the Exchange consistent with the standards described in § 155.260 and § 155.270 of this subtitle to facilitate the eligibility determination process; and

(3) Enroll an individual only after receiving confirmation that the eligibility process is complete and the applicant has been determined eligible for enrollment in a QHP, in accordance with the standards established in § 155.200(c) of this subtitle.

(c) *Acceptance of enrollment information.* A QHP issuer must accept enrollment information in an electronic format from the Exchange that is consistent with the requirements of § 155.260 and § 155.270 of this subtitle.

(d) *Premium payment.* A QHP issuer must follow the premium payment process established by the Exchange pursuant to § 155.240 of this subtitle.

(e) *Enrollment information package.* A QHP issuer must provide new enrollees an enrollment information package.

(f) *Summary of benefits and coverage document.* A QHP issuer must provide the summary of benefits and coverage document to enrollees as specified in 2715 of the PHS Act and prior to the start of the open enrollment period.

(g) *Enrollment reconciliation.* A QHP issuer must reconcile enrollment files with the Exchange no less than once a month in accordance with § 155.400(d) of this subtitle.

(h) *Enrollment acknowledgement.* A QHP issuer must acknowledge receipt of enrollment information in accordance with Exchange standards established in § 155.400(b)(2) of this subtitle.

§ 156.270 Termination of coverage for qualified individuals.

(a) *General requirement.* A QHP issuer may only terminate coverage as permitted by the Exchange pursuant to § 155.430(b) of this subtitle.

(b) *Termination of coverage notice requirement.* If an enrollee's coverage with a QHP is terminated for any reason, the QHP issuer must provide the Exchange and the enrollee with a notice of termination of coverage which is consistent with the effective date established by the Exchange pursuant to § 155.430(d) of this subtitle.

(c) *Termination of coverage due to non-payment of premium.* A QHP issuer must establish a standard policy for the termination of coverage of enrollees due to non-payment of premium as permitted by the Exchange in § 155.430(b)(2)(iii) of this subtitle. This policy for the termination of coverage:

(1) Must include the grace period for enrollees receiving advance payments of the premium tax credits as described in paragraph (d) of this section; and

(2) Must be applied uniformly to enrollees in similar circumstances.

(d) *Payment grace period for recipients of advance payments of the premium tax credit.* A QHP issuer must provide a grace period of at least three consecutive months if an enrollee receiving advance payments of the premium tax credit has previously paid at least one month's premium. During the grace period, the QHP issuer must:

(1) Pay all appropriate claims submitted on behalf of the enrollee;

(2) Apply all payments received during such period to the first billing cycle in which payment was delinquent; and

(3) Continue to collect advance payments of the premium tax credit on behalf of the enrollee from the Department of the Treasury.

(e) *Notice of non-payment of premiums.* If an enrollee is delinquent on premium payment, the QHP issuer must provide the enrollee with notice of such payment delinquency.

(f) *Exhaustion of grace period.* If an enrollee receiving advance payments of the premium tax credit exhausts the grace period in paragraph (d) of this section without submitting any premium payment, the QHP issuer may terminate the enrollee's coverage effective at the end of the payment grace period.

(g) *Records of termination of coverage.* QHP issuers must maintain records in accordance with Exchange standards established pursuant to § 155.430(c) of this subtitle.

(h) *Effective date of termination of coverage.* QHP issuers must abide by the termination of coverage effective dates described in § 155.430(d) of this subtitle.

§ 156.275 Accreditation of QHP issuers.

(a) *General requirement.* A QHP issuer must:

(1) Be accredited on the basis of local performance of its QHPs in the following categories by an accrediting entity recognized by HHS:

(i) Clinical quality measures, such as the Healthcare Effectiveness Data and Information Set;

(ii) Patient experience ratings on a standardized CAHPS survey;

(iii) Consumer access;

(iv) Utilization management;

(v) Quality assurance;

(vi) Provider credentialing;

(vii) Complaints and appeals;

(viii) Network adequacy and access; and

(ix) Patient information programs, and

(2) Authorize the accrediting entity that accredits the QHP issuer to release to the Exchange and HHS a copy of its most recent accreditation survey, together with any survey-related information that HHS may require, such as corrective action plans and summaries of findings.

(b) *Time frame for accreditation.* A QHP issuer must be accredited within the timeframe established by the Exchange pursuant to § 155.1045 of this subtitle. The QHP issuer must maintain accreditation so long as the QHP issuer offers QHPs.

§ 156.280 Segregation of funds for abortion services.

(a) *State opt-out of abortion coverage.* QHP issuers must comply with State law, if such State enacts a law that prohibits abortion coverage in QHPs.

(b) *Termination of opt out.* A QHP issuer may provide coverage of abortion services through the Exchange in a State described in paragraph (a) of this section if the State repeals such law.

(c) *Voluntary choice of coverage of abortion services.* Notwithstanding any other provision of title I of the Affordable Care Act (or any other amendment made under that title):

(1) Nothing in title I of the Affordable Care Act (or any amendments by that title) shall be construed to require a QHP issuer to provide coverage of services described in paragraph (d) of this section as part of its essential health benefits, as described in 1302(b) of the Affordable Care Act, for any plan year.

(2) Subject to paragraphs (a) and (b) of this section, the QHP issuer must determine whether or not the QHP provides coverage of services described in paragraph (d) of this section as part of such benefits for the plan year.

(d) *Abortion services.*

(1) Abortions for which public funding is prohibited—The services described in this paragraph (d)(1) are abortion services for which the expenditure of Federal funds appropriated for HHS is not permitted, based on the law as in effect as of the date that is 6 months before the beginning of the plan year involved.

(2) Abortions for which public funding is allowed—The services described in this paragraph (d)(2) are abortion services for which the expenditure of Federal funds appropriated for HHS is permitted, based on the law as in effect as of the date that is 6 months before the beginning of the plan year involved.

(e) *Prohibition on the use of Federal funds.*

(1) If a QHP provides coverage of services described in paragraph (d)(1) of this section, the QHP issuer must not use any amount attributable to any of the following for the purposes of paying for such services:

(i) The credit under section 36B of the Code and the amount (if any) of the advance payment of the credit under section 1412 of the Affordable Care Act;

(ii) Any cost-sharing reduction under section 1402 of the Affordable Care Act and the amount (if any) of the advance payments of the reduction under section 1412 of the Affordable Care Act.

(2) *Establishment of allocation accounts.* In the case of a QHP to which paragraph (e)(1) of this section applies, the QHP issuer must:

(i) Collect from each enrollee in the QHP (without regard to the enrollee's age, sex, or family status) a separate payment for each of the following:

(A) An amount equal to the portion of the premium to be paid directly by the enrollee for coverage under the QHP of services other than services described in paragraph (d)(1) of this section (after reductions for credits and cost-sharing reductions described in paragraph (e)(1) of this section); and

(B) An amount equal to the actuarial value of the coverage of services described in paragraph (d)(1) of this section.

(ii) Deposit all such separate payments into separate allocation accounts as provided in paragraph (e)(3) of this section. In the case of an enrollee whose premium for coverage under the QHP is paid through employee payroll deposit, the separate payments required under this subparagraph shall each be paid by a separate deposit.

(3) *Segregation of funds.*

(i) The QHP issuer to which paragraph (e)(1) of this section applies must establish allocation accounts described in paragraph (e)(3)(ii) for enrollees receiving the amounts described in paragraph (e)(1) of this section.

(ii) *Allocation accounts.* The QHP issuer to which paragraph (e)(1) of this section applies must deposit:

(A) All payments described in paragraph (e)(2)(i)(A) of this section into a separate account that consists solely of such payments and that is used exclusively to pay for services other than the services described in paragraph (d)(1);

(B) All payments described in paragraph (e)(2)(i)(B) of this section into a separate account that consists solely of such payments and that is used exclusively to pay for services described in paragraph (d)(1) of this section.

(4) *Actuarial value.* The QHP issuer must estimate the basic per enrollee, per month cost, determined on an average actuarial basis, for including coverage under the QHP of services described in paragraph (d)(1) of this section. In making such an estimate, the QHP issuer:

(i) May take into account the impact on overall costs of the inclusion of such coverage, but may not take into account any cost reduction estimated to result from such services, including prenatal care, delivery, or postnatal care;

(ii) Must estimate such costs as if such coverage were included for the entire population covered; and

(iii) May not estimate such a cost at less than one dollar per enrollee, per month.

(5) *Ensuring compliance with segregation requirements.*

(i) Subject to paragraph (e)(5)(ii) of this section, the QHP issuer must comply with the efforts or direction of the State health insurance commissioner to ensure compliance with this section through the segregation of QHP funds in accordance with applicable provisions of generally accepted accounting requirements, circulars on funds management of the Office of

Management and Budget and guidance on accounting of the Government Accountability Office.

(ii) Nothing in this clause shall prohibit the right of an individual or QHP issuer to appeal such action in courts of competent jurisdiction.

(f) *Rules relating to notice.*

(1) *Notice.* A QHP that provides for coverage of services in paragraph (d)(1) of this section, must provide a notice to enrollees, only as part of the summary of benefits and coverage explanation, at the time of enrollment, of such coverage.

(2) *Rules relating to payments.* The notice described in paragraph (f)(1) of this section, any advertising used by the QHP issuer with respect to the QHP, any information provided by the Exchange, and any other information specified by HHS must provide information only with respect to the total amount of the combined payments for services described in paragraph (d)(1) of this section and other services covered by the QHP.

(g) *No discrimination on basis of provision of abortion.* No QHP offered through an Exchange may discriminate against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions.

(h) *Application of State and Federal laws regarding abortions.*

(1) *No preemption of State laws regarding abortion.* Nothing in the Affordable Care Act shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions, including parental notification or consent for the performance of an abortion on a minor.

(2) *No effect on Federal laws regarding abortion.* Nothing in the Affordable Care Act shall be construed to have any effect on Federal laws regarding:

(i) Conscience protection;

(ii) Willingness or refusal to provide abortion; and

(iii) Discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.

(3) *No effect on Federal civil rights law.* Nothing in section 1303(c) of the Affordable Care Act shall alter the rights and obligations of employees and employers under Title VII of the Civil Rights Act of 1964.

(i) *Application of emergency services laws.* Nothing in the Affordable Care Act shall be construed to relieve any health care provider from providing emergency services as required by State or Federal law, including section 1867 of the Act (popularly known as ''EMTALA'').

§ 156.285 Additional standards specific to the SHOP.

(a) *SHOP rating and premium payment requirements.* QHP issuers offering QHPs through a SHOP must:

(1) Accept payment from the SHOP on behalf of a qualified employer or an enrollee in accordance with § 155.705(b)(4) of this subtitle;

(2) Adhere to the SHOP timeline for rate setting as established in § 155.705(b)(5) of this subtitle; and

(3) Charge the same contract rate for a plan year.

(b) *Enrollment periods for the SHOP.* QHP issuers must:

(1) Enroll a qualified employee in accordance with the qualified employer's annual employee open enrollment period described in § 155.725 of this subtitle;

(2) QHP issuers must provide special enrollment periods described in § 155.420 of this subtitle excluding paragraphs (d)(3) and (d)(6).

(3) Establish an effective date of coverage in accordance with § 155.410(c) of this subtitle.

(c) *Enrollment process for the SHOP.* A QHP issuer offering a QHP in the SHOP must:

(1) Adhere to the enrollment process timeline for SHOP Exchanges as described in § 155.720(b) of this subtitle;

(2) Receive enrollment information in an electronic format, in accordance with the requirements in § 155.260 and § 155.270, from the SHOP frequently as described in § 155.720(c) of this subtitle;

(3) Provide new enrollees with the enrollment information package as described in § 156.265(f) of this subtitle;

(4) Provide the summary of benefits and coverage document to qualified employers and qualified employees as described in § 156.265(g) of this subtitle;

(4) Reconcile enrollment files with the Exchange at least monthly;

(5) Acknowledge receipt of enrollment information in accordance with Exchange standards; and

(6) Enroll all qualified employees consistent with the plan year of the applicable qualified employer.

(d) *Termination of coverage in the SHOP.* QHP issuers must:

(1) Abide by the following requirements with respect to coverage termination of enrollees in the SHOP:

(i) General requirements regarding termination of coverage established in § 156.270(a);

(ii) Requirements for notices to be provided to enrollees and qualified employers in § 156.270(b) and § 156.290(b).

(iii) Requirements regarding termination of coverage effective dates as set forth in § 156.270(g).

(2) If a qualified employer chooses to withdraw from participation in the SHOP, the QHP issuer must terminate coverage for all enrollees of the withdrawing qualified employer.

§ 156.290 Non-renewal and decertification of QHPs.

(a) *Non-renewal of recertification.* If a QHP issuer elects not to seek recertification with the Exchange, the QHP issuer, at a minimum, must—

(1) Notify the Exchange of its decision prior to the beginning of the recertification process and procedures adopted by the Exchange pursuant to § 155.1075 of this subtitle;

(2) Fulfill its obligation to cover benefits for each enrollee through the end of the plan or benefit year;

(3) Fulfill data reporting obligations from the last plan or benefit year;

(4) Provide notice to enrollees as described in paragraph (b) of this section; and

(5) Terminate coverage for enrollees in the QHP in accordance with § 156.270, as applicable.

(b) *Notice of QHP non-renewal.* If a QHP issuer elects not to seek recertification with the Exchange for its QHP, the QHP issuer must provide written notice to each enrollee.

(c) *Decertification.* If a QHP is decertified by the Exchange, the QHP issuer must terminate coverage for enrollees only after:

(1) The Exchange has made notification as described in § 155.1080 of this subtitle; and

(2) Enrollees have an opportunity to enroll in other coverage.

§ 156.295 Prescription drug distribution and cost reporting.

(a) *General requirement.* In a form and manner specified by HHS, a QHP issuer must provide to HHS the following information:

(1) The percentage of all prescriptions that were provided under the QHP through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed compared to all drugs dispensed, broken down by pharmacy type, which includes an independent pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public), that is paid by the QHP issuer or the QHP issuer's contracted PBM;

(2) The aggregate amount, and the type of rebates, discounts or price concessions (excluding bona fide service fees, which include but are not limited to distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs)) that the QHP issuer or its contracted PBM negotiates that are attributable to patient utilization under the QHP, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the QHP issuer, and the total number of prescriptions that were dispensed.

(3) The aggregate amount of the difference between the amount the QHP issuer pays its contracted PBM and the amounts that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.

(b) *Confidentiality.* Information disclosed by a QHP issuer or a PBM under this section is confidential and shall not be disclosed by HHS or by a QHP receiving the information, except that HHS may disclose the information in a form which does not disclose the identity of a specific PBM, QHP, or prices charged for drugs, for the following purposes:

(1) As HHS determines to be necessary to carry out section 1150A or part D of title XVIII of the Act;

(2) To permit the Comptroller General to review the information provided;

(3) To permit the Director of the Congressional Budget Office to review the information provided; or

(4) To States to carry out section 1311 of the Affordable Care Act.

(c) *Penalties.* A QHP issuer that fails to report the information described in paragraph (a) of this section to HHS or knowingly provides false information will be subject to the provisions of subsection (b)(3)(C) of section 1927 of the Act.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 29, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 7, 2011.

Kathleen Sebelius,

Secretary.

[FR Doc. 2011–17610 Filed 7–11–11; 11:15 am]

BILLING CODE 4120–01–P

NAMD
National Association of Medicaid Directors

To: All Medicaid Directors

From: NAMD Staff

Date: July 18, 2011

Re: Analysis of Medicaid related provisions in the proposed Exchange regulation

On July 11, 2011, the U.S. Department of Health and Human Services (HHS) released two proposed regulations addressing the development and implementation of health insurance Exchanges.[1] Enclosed with this memo is a summary of some of the major provisions of the regulation which was produced by the National Governors Association.

NAMD builds on the NGA summary to provide you with additional information of interest to Medicaid directors. NAMD's analysis focuses on the proposed rule for establishing Exchanges and Qualified Health Plans (QHPs). It examines issues in four categories: timelines, requirements, options and issues for further consideration.

Comment period: Comments are due by 5 pm ET on September 28, 2011. The 75-day comment period is longer than typically provided for a proposed regulation. HHS officials have indicated they plan to release related regulations on eligibility during this period, thus allowing public comments to incorporate both sets of regulations. NAMD's Policy Committees will engage in further dialogue about the Exchange and the forthcoming eligibility regulations.

The text of the regulation is posted at: http://www.ofr.gov/OFRUpload/OFRData/2011-17610_PI.pdf

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[1] The proposed rule, "Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans," (CMS-9989-P) was published in the *Federal Register* on July 15, 2011, at 76 FR 41866: http://frwebgate1.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=4itq1W/0/2/0&WAISaction=retrieve and the proposed rule, "Patient Protection and Affordable Care Act; Standards Related to Reinsurance, Risk Corridors and Risk Adjustment," (CMS–9975–P) was published July 15, 2011, at 76 FR 41930: http://frwebgate1.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=4itq1W/2/2/0&WAISaction=retrieve

NAMD
National Association of Medicaid Directors

Deadlines and Timelines

- A state Exchange must be approved or "conditionally approved" by no later than January 1, 2013, in order to begin offering qualified health plans (QHPs) on January 1, 2014.
- The Exchange must complete certification of QHPs prior to the open enrollment period and recertification of QHPs prior to September 15 of each applicable year.
- After January 1, 2014, a state may choose to operate an Exchange or end operation of an Exchange, but the state must provide HHS at least 12 months notice in either situation.
- A state must be able to support the ongoing operations of its Exchange by January 1, 2015, since no federal funding for operations is available after that date.
- ***155.410 Enrollment periods***. There is a five month initial open enrollment period from October 1, 2013 through February 28, 2014. Thereafter, annual enrollment periods are from October 15 through December 7, beginning with the 2015 benefit/calendar year.
- ***155.420 Special enrollment periods***. A 60-day special enrollment period is available to individuals because of a triggering event. The forthcoming CMS regulation addressing Medicaid eligibility is expected to provide additional guidance to states. Medicaid directors will need to evaluate both sets of regulations in order to obtain a comprehensive picture of how changes in an individual's income and eligibility will be handled in the Medicaid and the Exchange subsidy programs. Specifically, states will need to evaluate the level of "churn" that is expected to occur between the public programs and policies to minimize administrative burden and related costs for states as well as for consumers.
    - The "loss of coverage" is a triggering event. While not explicitly defined in the text of the proposed regulation, the Preamble defines the termination of Medicaid or CHIP coverage as a loss of coverage that triggers a special enrollment period for the individual/dependent. (See page 69 of the public display version[2])

[2] References to page numbers in this document refer to the version of the regulation that was put on public display July 11, 2011: http://www.ofr.gov/OFRUpload/OFRData/2011-17610_PI.pdf

- A special enrollment period is provided to an individual/dependent who is determined newly eligible or newly ineligible for the premium tax credit or has a change in eligibility for cost-sharing reductions. This applies to individuals/dependents who receive an eligibility determination for the first time for coverage through the Exchange or who experience a mid-year change in circumstance that changes their eligibility, including a change that ends their eligibility for advance payments of the premium tax credit.
- Coverage is effective the first day of the following month, provided the individual selects a QHP selection by the 22nd. If made after the 22nd, coverage is effective either the first day of the following or the second following month.

Requirements

- ***155.200 Eligibility determinations***. The regulation states that an Exchange must perform eligibility determinations. As noted below, this responsibility could be delegated to a state Medicaid agency. At a minimum, coordination between the Medicaid and the Exchange systems will be needed to perform this function. HHS plans to provide specific standards and eligibility criteria in future rulemaking.
- ***155.400 Enrollment records.*** An Exchange must keep records of all enrollments in QHPs and submit the enrollment reports to HHS monthly. The regulation does not specifically address whether or how enrollment reports about Medicaid, CHIP or the Basic Health Program (BHP), if applicable, are required. This is an issue states will need to explore since either the Exchange entity could perform eligibility determinations and enrollments or the state Medicaid agency could assume this responsibility.
- ***155.405 Enrollment forms.*** An Exchange is required to use a standardized form for eligibility determinations and to process enrollment in a QHP and Medicaid, CHIP and the BHP, if applicable. The Exchange may use an alternative application form, but it must be approved by HHS and must collect the information necessary for enrollment. In the Preamble, HHS states that the electronic application process will allow eligibility determination and plan selection to occur in a single on-line session. Medicaid agencies will need to coordinate with the state Exchange entity and HHS officials as well as other stakeholders on the format, content and systems related issues of the standardized or alternative form.

- ***155.260 Use and disclosure of personal data***. The regulation defines personally identifiable information and establishes privacy and security standards for such information that is collected, received or used by the Exchange as part of its operations. Exchanges also must have data matching and sharing arrangements with the Medicaid and CHIP agencies to facilitate exchange of eligibility information. Policies and procedures for data use and sharing must be consistent with all other applicable laws, for example HIPAA. According to the Preamble, HHS expects these agreements to prevent the unauthorized use or disclosure of personally identifiable information.

- ***156.230 and 156.235 Network adequacy standards.*** The regulation discusses essential community providers in two separate sections. Section 156.230 requires a QHP include essential community providers that are available to all enrollees and any other network adequacy standards the Exchange establishes. Section 156.235 goes on to say that a QHP must have a provider network with a "sufficient number" of essential community providers, where available, to serve low-income, medically underserved individuals. However, this section also states that QHPs are *not* required to provide coverage for any specific medical procedure provided by an essential community provider. In part, this addresses the Medicaid all-inclusive facility-based PPS rate and the comprehensive services offered by federally qualified health centers and similar clinic-based Medicaid providers.

- ***155.130 Consultation***. The regulation requires the Exchange to consult regularly with certain stakeholders, including state Medicaid and CHIP agencies. While not explicitly included in the text of the regulation, the Preamble explanation "encourages" Exchanges to consult with Medicaid and CHIP enrollees.

- ***156.295 Prescription drug data.*** The regulation requires that QHPs provide HHS with utilization and pricing information about prescription drugs, including the aggregate amount and type of rebates, discounts, or price concessions that the QHP or its PBM negotiates for its enrollees and the aggregate amount of the difference between the amount the QHP pays its PBM and the amount the PBM pays retail and mail order pharmacies. The regulation states that this information will remain confidential except that HHS may release information in a way that does not reveal pricing information or the identity of the PBM or QHP. HHS and states may wish to explore how this information could be leveraged by Medicaid agencies.

Options involving Medicaid

- ***155.110 Medicaid agency role***. An Exchange may contract with the state Medicaid agency to carry out some or all of the responsibilities of an Exchange.
- ***155.210 Navigator program***. A state Exchange must establish a Navigator program to award grants to eligible entities that will provide assistance to consumers. An Exchange must award grants to at least two entities from the eight categories specified in the regulation, one of which is state or local human service agencies. The regulation lists five required duties of a Navigator.
    - ***Cost allocation***—The state Exchange may contract with Navigators to allow or require these entities to address Medicaid and CHIP administrative functions. The Medicaid and CHIP agencies may claim FFP at the administration rate for these expenditures, consistent with federal cost allocation rules. The Preamble to the regulation states that cost allocation policies will apply to the Navigator program when Navigator entities also perform Medicaid eligibility and outreach activities.
- ***155.205 Call centers***. The regulation provides flexibility in how an Exchange structures its call center. However, in the Preamble HHS states it believes that the call center should have the capability to provide assistance to callers on assistance available through and the application process for enrollment in Medicaid and CHIP.

Issues for further consideration

The Preamble provides guidance for interpreting the text of the proposed rule and raises topics for Medicaid directors to consider. CMS also requests comments on provisions and policies still under consideration. The following are some of the key topics relevant for Medicaid directors.

- ***State-HHS partnerships***. The Preamble states that HHS is exploring different partnership models to allow states and the federal government to share responsibility for business functions. Some of the potential shared business functions cited include eligibility and enrollment, financial management, and health plan management systems and services. HHS is exploring different partnership models that would meet the needs of states. For example, this could allow the federal government to operate the eligibility and enrollment function and the state Exchange would retain

responsibility for health plan management activities like certification, rate review and monitoring. (See page 19).

- ***Conditional approval of Exchange***. The Preamble provides further background on "conditional approval" of a state Exchange. HHS must approve a state Exchange by January 1, 2013, but the rule offers some flexibility to states as they continue systems development and contracting activities after this deadline. Conditional approval will be granted to states that HHS determines are making progress towards the operational date of January 1, 2014. The conditional approval would presume that the state's Exchange would be operational by January 1, 2014, even if it cannot demonstrate complete readiness on January 1, 2013. (See page 23)

- ***Use of the Medicaid SPA process.*** HHS states it is considering a review process for the Exchange plan that is similar to the Medicaid and CHIP state plan amendment process. HHS requested comment on the use of Medicaid's "90 day clock" for approval or denial of the plan or to request comment. Regardless of whether or not the Medicaid process is ultimately used, Medicaid agencies in many states may be called upon to help Exchange entities navigate and manage the federal review process. (See page 23)

- ***Establishment of "steady state" coverage.*** HHS states that it considers 2016 to be the first full year after implementation of the Affordable Care Act in which health insurance coverage would achieve its "steady state." (See page 35)

- ***Provider taxes.*** States may use various means to generate funding for Exchange operations, including charging user fees or assessments on participating issuers. In addition, states may use broad-based funding mechanisms, including general state revenues, provider taxes and other funding that spread costs beyond imposing assessments or user fees on participating issuers. This is noteworthy for Medicaid directors given that many states are establishing or expanding provider taxes and assessments as a source of revenue for their state Medicaid program. Medicaid directors will likely need to participate in these discussions and evaluate the potential pressure on stakeholders as a source to generate revenues for a state-operated Exchange and Medicaid. (see page 36)

- ***Eligibility determinations***. As noted above, a state Medicaid agency could be delegated responsibility for performing the Exchange eligibility determination. HHS plans to provide specific standards and eligibility criteria for this function in future rulemaking. This is information is a component of state decision making on where to house this function.

- ***Qualified Health Plans (QHPs) and Medicaid plans.*** The Preamble and regulation provide information on the certification, accreditation, plan-document and other QHP requirements and processes. Health plans are evaluating business decisions for participating in both Medicaid and CHIP and the Exchange. There will likely be significant overlap in some states. State Medicaid agencies may wish to compare and contrast the QHP policies and requirements with those for Medicaid and CHIP plans. States may wish to align these policies and/or leverage requirements across the programs to drive value, quality and robust provider participation. (see page 98)

- ***Network adequacy standards.*** In light of CMCS' recently proposed regulation on access and provider payment, directors may wish to review in further detail the explanation of the Exchange network adequacy standards. HHS provides the Exchange flexibility to tailor network adequacy standards to the state's existing patterns of care -- establishing specific standards where necessary and leveraging existing state oversight and enforcement. HHS requests comments on whether the Department should set minimum standards for Exchanges to use to evaluate the sufficiency of QHP networks.

- ***Essential community providers***. While QHPs are required to contract with essential community providers, HHS reiterates in the Preamble that QHPs are not required to contract with *all* such providers. HHS indicates this is intended to help preserve the ability of QHPs to use network design to incentivize higher quality, cost effective care through the use of tiering networks and driving volume towards providers that meet certain quality and value goals. (See page 126)

    - ***FQHC PPS payment***. HHS also points out the statutory conflict in payment policies for essential community providers and FQHCs. QHPs are not required to contract with an essential community provider if that provider refuses to accept the generally applicable payment rates of the plan. However, QHPs are also required to reimburse FQHCs at each facility's Medicaid

prospective payment system (PPS) rate. The FQHC Medicaid PPS rates may be higher than the rates that a QHP issuer pays to other contracted providers for similar services. HHS then raises other practical challenges with how QHPs are to pay the Medicaid PPS rate. For example, it is not clear how QHP issuers would administer the FQHC Medicaid PPS rate, since it is a facility specific rate paid on a per encounter basis for a pre- determined set of covered services. Issuers would need to replicate each FQHC's Medicaid PPS rate, which may be complicated given the state or county variation by FQHC. Medicaid directors may wish to examine this issue further as they consider innovations in delivery and payment system reforms that involve FQHCs.

Health Insurance Exchange Proposed Regulation: A Summary by the National Governors Association[3]

Establishment of Exchanges and Qualified Health Plans

I. Requirements for certification of health plans to be sold in Exchanges

Exchanges must only offer Qualified Health Plans (QHPs) in Exchanges. They must ensure that QHP:

- Comply with Exchange processes, procedures, and requirements set forth pursuant to data collection and reporting described in subpart K of part 155 (covered benefits, rates, and cost-sharing requirements);
- Comply with benefit design standards, including essential health benefits (section 1302(b) of ACA), cost-sharing limits (Section 1302 of ACA), a bronze, silver, gold or platinum level of coverage (Section 1302 (d) of ACA) or is a catastrophic plan (Section 1302 (e) of ACA);

[3] This summary was produced by the National Governors Association and distributed via email to governors' health policy advisors on July 11, 2011.

- Be licensed and in good standing to offer health insurance coverage in each State in which the issuer offers health insurance coverage;

- Implement and report on a quality improvement strategy or strategies consistent with the standards of section 1311(g) of the Affordable Care Act, disclose and report information on health care quality and outcomes described in sections 1311(c)(1)(H) and (I) of the Affordable Care Act, and implement appropriate enrollee satisfaction surveys consistent with section 1311(c)(4) of the Affordable Care Act;

- Pay any applicable user fees assessed under §156.50;

- Comply with the standards related to the risk adjustment program under 45 CFR part 153; and

- Submit to the Exchange and HHS on annual basis information on drug distribution and costs.

Among the other requirements discussed (this is not intended to be exhaustive):

- ***Accreditation (§156.275)***A QHP issuer must obtain its accreditation within a time period established by the Exchange under §155.1045. CMS states, "Allowing these issuers extra time to meet the standards proposed in this section may encourage a wider variety of health insurance issuers to seek to offer QHPs through the Exchange." CMS seeks comment on the standards by which HHS should recognize accrediting bodies.

- ***Network adequacy (§156.230):*** The rule proposes discretion for Exchanges in setting network adequacy standards for participating health insurance issuers.

- ***Enrollment information (§156.265):*** CMS proposes to require that QHP issuers receive enrollment information electronically from the Exchange. CMS seeks comment on the frequency with which plans should receive electronic enrollment information.

- ***Termination of Coverage (§156.270):*** QHP issuers must develop a policy that is uniform as permitted by the Exchange for the termination of coverage due to non-payment of premium, irrespective of Exchange standards, uniformly to all enrollees in similar circumstances.

- **QHPs leaving Exchanges (§156.290):** QHP issuers must continue covering benefits for each enrollee until the completion of the benefit year or plan year for the SHOP.

- **Decertifying Plans (§156.290):** If an Exchange decertifies a QHP, the QHP issuer must terminate coverage for the QHP's enrollees only after the Exchange has notified the those enrollees and enrollees have had the opportunity to enroll in other coverage. CMS seeks comment on the extent to which enrollees should continue to receive coverage from a decertified plan.

- **Essential Community Providers (§156.235):** QHP issuers include in their provider networks a sufficient number of essential community providers, where available, that serve low income, medically underserved individuals. CMS seeks comment on how to define a sufficient number of essential community providers.

II. Governance and conflict of interest provisions

Summary:

- Governance and conflict of interest guidance is spelled out in §155.110

- The voting members of an Exchange governing board will 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.

- A State may wish to adopt more stringent or specialized conflict of interest requirements than those used in connection with regular governmental operations.

- Each Exchange shall 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.

- An Exchange must have in place procedures for disclosure of financial interest by members of the governing body or governance structure of the Exchange.

- SHOP exchange governance: A state may operate its individual market Exchange and SHOP under separate governance or administrative structures and if it chooses to do so, it must, where applicable, coordinate and share relevant information between the two Exchange bodies. 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. (paragraph (e)

Comment is invited as to 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.

III. Federally-operated Exchanges

The NPRM describes the potential for states to pursue "a flexible State partnership model combining State-designed and operated business functions with Federally-designed and operated business functions. Examples of such shared business functions might include eligibility and enrollment, financial management, and health plan management systems and services. We note that States have the option to operate an exclusively State-based Exchange. HHS is exploring different partnership models that would meet the needs of States and Exchanges." (Page 19)

"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." (Page 26)

There is no further detailed information about how a federally-run Exchange would operate in a state, or a timeline for implementation.

IV. Changes to requirements set forth in the original timeline

Conditional Approval: CMS proposes to add an option for Conditional Approval of exchanges. 155.105 paragraph (d) notes that "although the statute requires HHS to approve State Exchanges no later than January 1, 2013, there will be systems development and contracting activities that continue to occur in 2013 after the statutory deadline for approval. In order to accommodate States that are making progress towards the operational date of January 1, 2014, HHS may issue a conditional approval."

Establishment of Exchanges After 2014: CMS proposes to allow states to elect to operate an Exchange after 2014. §155.106 paragraph proposes to "allow States the flexibility of seeking approval to operate an Exchange even if a State is not approved to operate by January 1, 2013. A state electing to operate an Exchange after 2014 must have in effect an approved or conditionally approved Exchange Plan at least 12 months prior to the first effective date of coverage. It is assumed that first effective date of coverage will fall on January 1 of any given

year because of the standardized annual open enrollment periods, so the approval or conditional approval would have to be in effect by January 1 of the prior year.

V. Navigator program

Summary:

- The requirements for Navigators are described in §155.210.
- To be eligible for a Navigator grant an entity must:
  - Be capable of carrying out at least those duties described below;
  - 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;
  - Meet any licensing, certification or other standards prescribed by the State or Exchange, if applicable; and
  - Not have a conflict of interest during the term as Navigator.

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

- Community and consumer-focused nonprofit groups;
- Trade, industry, and professional associations;
- Commercial fishing industry organizations, ranching and farming organizations;
- Chambers of commerce;
- Unions;
- Resource partners of the Small Business Administration;
- Licensed agents and brokers; and

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

An entity that serves as a Navigator must carry out at least the following duties:

- Maintain expertise in eligibility, enrollment, and program specifications and conduct public education activities to raise awareness about the Exchange;
- Provide information and services in a fair, accurate and impartial manner. Such information must acknowledge other health programs;
- Facilitate enrollment in Qualified Health Plans;
- Provide referrals to any applicable office of health insurance consumer assistance or trusted state agency or organization for any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under such plan or coverage; and
- 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.

Other key points:

- The 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.
- The Exchange is prohibited from supporting the Navigator program with Federal funds received by the State for the establishment of Exchanges.
- The federal government is 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. ** CMS seeks comment on this timeframe.
- The Exchange must ensure that a Navigator must not be a health insurance issuer, or 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 qualified health plan.

VI. State Plan Amendment Process

CMS is considering the establishment of a review process for states' Exchange Plans that is similar to Medicaid and CHIP for which there would be 90 days to review the plan for either approval or denial, or to request comment. If additional information is requested and received from the State, HHS would have 90 days to either approve or disapprove the plan. **Comments are sought on the appropriateness of this process and timeline.

VII. Interaction with Medicaid agencies

Exchanges and the Medicaid and CHIP agencies are expected to execute data use

agreements that prevent the unauthorized use or disclosure of personally identifiable information and prohibit the Exchange or State agency from seeking to obtain or provide information that it will not, or does not reasonably expect to, use. CMS proposes to adopt these same requirements as data privacy and security requirements for Exchanges.

Standards Related to Reinsurance, Risk Corridors and Risk Adjustment

The proposed regulation on standards related to reinsurance, risk corridors, and risk adjustment routinely solicits comments on program design options arising from implementing the health reform statute. While the proposed regulation indicates a preferred approach in some cases, in many other instances the preamble discusses alternatives and seeks comment, leaving states the option to vary reinsurance or risk adjustment from what would be the Federal standard. The specifics of the Federal standard approaches, however, will be specified in subsequent regulatory guidance, such as annual notices that will be issued after a final rule is promulgated.

Some of the key provisions addressed in the proposed rule include:

- States that choose not to establish an Exchange may operate their own reinsurance program. For states that opt out of Exchanges and reinsurance, HHS will establish

the programs. However, states that choose to operate an Exchange must operate the reinsurance program.

- HHS proposes to create a nationally uniform rate, rather than state-by-state rates, for the $20 billion reinsurance program. All contributions collected by a state would stay within that state – and can only be used for reinsurance claims within that state. HHS proposes to set contributions on a percentage basis, rather than a flat, per capita amount. The details would be specified in a forthcoming (annual) notice laying out benefit and payment parameters, that would be issued pursuant to the final regulation.

- States may choose to increase reinsurance collections above the Federal rate to provide added reinsurance or finance associated administrative costs. States may also reduce on a *pro rata* basis payments to have them match contributions.

- States may alter the reinsurance attachment point, the reinsurance "cap", or the coinsurance rate, if they have sufficient funds and have published the modifications. There alterations would not require HHS approval.

- States may continue their high risk plans after 1/1/2014, although the continuation plans must be coordinated with the reinsurance program.

- Risk pools must be aggregated at the state level, even if there are regional exchanges because "risk many not be combined across state lines, but must be pooled at the individual state level."

- States running an Exchange may establish the risk adjustment program. Where states are not running an Exchange, HHS would run the risk adjustment program. Where a state is running an Exchange but has declined to run the risk adjustment program, HHS would administer the risk adjustment program (and all of its functions).

- HHS seeks comments on the appropriate schedule for starting and completing the risk adjustment program, as well as the schedule for reporting results.

- HHS provides an option for states to submit an alternative risk adjustment approach, or for state-specific values in the Federal risk adjustment model, with such state modifications requiring Federal approval. The proposed rule highlights several monographs as examples of the kind of detail that the Federal approval might require.

- The Federal risk adjustment system will be detailed "in a forthcoming annual Federal notice of benefit and payment parameters", presumably to be issued after final regulations are promulgated.

- HHS considered three options for data collection associated with risk adjustment. The rule proposes "an intermediate State-level approach in which issuers submit raw claims data sets to the State government, or the entity responsible for administering the risk adjustment process at the State level", rather than a centralized HHS approach or a fully distributed approach.