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

July 15, 2011

On July 15, 2011, the Department of Health and Human Services (HHS) published in the *Federal Register* a notice of proposed rulemaking (NPRM) implementing the Affordable Insurance Exchange provisions of the Patient Protection and Affordable Care Act of 2010 (P.L. 111-148) as amended by the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152). Together, these laws are referred to as the Affordable Care Act (ACA). The Exchanges are designed to create a competitive marketplace for individuals and small employers to compare and purchase private health insurance coverage. Under the ACA, the Exchanges will become operational by January 1, 2014.

The proposed rule: (1) sets forth 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 standards for employers to meet to participate in the Small Business Health Options Program (SHOP). Throughout the proposed rule, HHS emphasizes its intent that States be offered substantial discretion in the design and operation of an Exchange. A separate proposed rule, also published on July 15th , implements the reinsurance, risk corridor and risk-adjustment provisions of the ACA. **The comment periods for both these proposed rules close on September 28, 2011.**

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I. Background

The statutory authority for the proposed regulation is cited, generally provided under sections 1311(b) and 1321(b) of the ACA. With respect to a few other related provisions (dealing with protections for American Indians and Native Americans and with requirements for QHPs and private plans under Medicare regarding prescription drug costs), separate specific authority from other parts of the ACA applies.

HHS discusses the August 3, 2010 Request for Comments (RFC) on rules governing the Exchanges, and indicates that comments were received from a wide range of organizations and individuals. While HHS refers generally to the comments received on the RFC in this proposed rule, it plans to respond directly to them in the final rule, along with comments received on this proposed rule.

The proposed requirements in the NPRM are codified in new sections 45 CFR Subtitle A, Chapter B, Parts 155 and 156. Part 155 outlines standards for the States in establishing Exchanges and the standards for minimum Exchange functions. Part 156 outlines the standards for participating health insurance issuers, including the minimum certification requirements for QHPs.

HHS indicates that this proposed rule does not address all the Exchange provision in the ACA. Subjects that HHS indicates will to be addressed in separate rulemaking include:

(1) eligibility for participation in the Exchange, advance payments of the premium tax credit, cost sharing subsidies, and related health programs, and appeals of eligibility determinations;
(2) the Exchange process for issuing certificates of exemption from the individual responsibility requirement or penalty;
(3) defining essential health benefits, actuarial value and other benefit design standards; and
(4) quality standards for Exchanges and QHP issuers.

In addition, HHS notes that QHP standards in the proposed rule for the most part are limited to QHPs offered through the Exchange. Requirements for the entire individual and small group markets will continue to be addressed in separate rulemaking issued by HHS and the Departments of Labor and 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 (§155.10 and §155.20)

These sections of the proposed regulation identify their basis and scope and provide definitions of terms. Section 155.10, on the basis and scope, lists the sections of the ACA on which the regulation is based and states that the scope is to establish minimum standards for establishment

of an Exchange, Exchange functions, eligibility determinations, enrollment periods, minimum SHOP functions, certification of QHPs and health plan quality improvement. As noted earlier, health plan quality requirements will be addressed in future rulemaking.

Various terms are defined in §155.20. Many of the definitions codify those specified in the ACA (e.g., "Exchange", "minimum essential coverage", "small employer"), others are drawn from existing regulations (e.g., "employer", "group health plan", "grandfathered plan"), yet others are newly defined (e.g., "special enrollment period", "plain language", "Exchange service area"). In the NPRM preamble, HHS discusses proposed definitions for which it believes more clarity is warranted. Some of these are highlighted here:

- "Exchange" includes both State-run Exchanges and those operated by the Federal government in the case of a State that does not establish an Exchange.
- "Cost sharing" is defined to apply to payments for deductibles, copayments, coinsurance or similar charges related to the essential health benefits only.
- The scope of the term "qualified employer" is expected to vary among States and over time. The ACA defines the term as a small employer, meaning not more than 100 employees, but allows States to limit small employers to those with no more than 50 employees until 2016. Also, beginning in 2017 the ACA provides States the option of allowing issuers to offer QHPs in the large group market through the SHOP.
- The term "qualified individual" is proposed to mean that an individual has been determined eligible to participate in an Exchange. "Qualified employer" and "qualified employee" are similarly defined as employers and employees, respectively, who have been determined to be eligible to participate in a SHOP.
- "Benefit year" refers to coverage that begins on January 1st and lasts for the duration of a calendar year, while "plan year" refers to any rolling 12-month period of coverage. The latter is typically used in reference to coverage in the small group market.

Regarding the term "health plan", HHS indicates that under the ACA, this term encompasses health insurance coverage and a group health plan, except that it does not include a group health plan or multiple employer welfare arrangement (MEWA) that is not subject to State insurance regulation. HHS notes that under section 514 of the Employee Retirement Income Security Act (ERISA), States may regulate MEWAs to the extent such regulation does not conflict with ERISA. **HHS solicits comments on how to reconcile this inconsistency regarding MEWAs. Additionally, having received comments on whether Taft-Hartley plans and church plans can participate in an Exchange, HHS seeks comments on how such plans could provide coverage opportunities through the Exchange.**

Noting that the term health plan is sometimes used colloquially as interchangeable with health insurance issuer, HHS clarifies that within this proposed rule it refers to the entity offering coverage as the issuer and the coverage being purchased as the health plan.

2. Subpart B – General Standards Related to the Establishment of an Exchange by a State (§155.100 through §155.160)

The ACA provides general standards for the establishment of a State Exchange, and in a number of areas provides States with discretion in making decisions about Exchange operations. States have choices regarding the structure and governance of Exchanges, including whether to establish the Exchange as a State agency or non-profit organization, whether to contract with other organizations to carry out various functions of the Exchange, whether to partner with other States to form a regional Exchange, and whether to establish one or more Exchanges within the State. In this Subpart, HHS proposes standards that would apply to State Exchanges and the process by which HHS would determine whether a State Exchange meets the standards.

Through its efforts to facilitate the establishment of an Exchange in every State, HHS has concluded that States may find it advantageous to combine State efforts with business services developed by other States and the Federal government. HHS indicates that some States have expressed preference for a flexible State-Federal partnership, and HHS is exploring different partnership models. Examples offered for possible shared business functions include eligibility and enrollment, financial management, and health plan management systems and services.

Establishment of a State Exchange (§155.100). HHS would codify the ACA provisions offering States the option to operate a State Exchange and requiring that a State Exchange be operated by a governmental or non-profit agency. Regarding the choice of government agency, HHS advises States to consider the costs and benefits of using the accountability structure of an existing agency compared with the need to establish a governing body for an independent agency. In response to comments received in response to the RFC expressing concerns about Exchanges operated by a non-profit entity, HHS does not propose to further restrict State choice of this option, which it says may permit Exchanges to operate more flexibly. However, HHS notes that an Exchange operated by an independent agency or a non-profit with a government body appointed and overseen by the State may address these concerns.

Approval of a State Exchange (§155.105). HHS proposes to codify the ACA requirement that sets January 1, 2013 as the deadline for the Secretary to approve a State Exchange for it to begin offering QHPs on January 1, 2014. HHS proposes that States apply for approval by submitting an Exchange Plan, to be described in separate guidance, which must demonstrate operational readiness after an assessment conducted by HHS. HHS states that this means an Exchange must be capable of operating the October 1, 2013 initial open enrollment period proposed elsewhere in this rule.

To receive approval States would have to meet several standards. First, they would need to be able to carry out the specified general functions of an Exchange and those regarding enrollment in QHPs, the SHOP, certification of QHPs, and requirements to be established in future rulemaking regarding advance payments of the premium tax credits for individuals. Second, the entire geographic area of a State would have to be covered by one or more State Exchanges, and HHS encourages States with more than one Exchange to ensure that consumers understand which Exchange they should use. Finally, States would be required to agree to operate a

reinsurance program. (State requirements regarding reinsurance are included in the separate proposed rule also published on July 15, 2011.)

The Exchange Plan would include detailed information on how the State plans to meet each of the applicable standards, and would include copies of agreements with other organizations to carry out Exchange responsibilities. HHS plans to issue a template outlining the requirements of the Exchange Plan, subject to the notice and comment process under the Paperwork Reduction Act.

HHS would evaluate whether a State is operationally ready to implement its Exchange Plans. HHS indicates that it would coordinate its readiness assessment process with the grants monitoring process under the State planning and establishment grants. The process may include meetings with State and Exchange officials, conference calls and on-site visits. HHS plans to issue additional guidance on the structure and schedule of the assessments.

Approval by HHS of a State Exchange Plan could be conditional. An approval would constitute an agreement between HHS and the Exchange. A conditional approval could be issued if a State cannot demonstrate complete readiness on January 1, 2013 but HHS believes the State is making progress towards being operational on January 1, 2014. HHS would continue to work with the State and monitor progress until approval was made or conditional approval revoked. HHS notes that even if a State receives approval by January 1, 2013, systems development and contracting activities would continue to occur in 2013.

HHS is considering, and seeks comments on, establishing a review process for the Exchange Plan that is similar to Medicaid and the State Children's Health Insurance Program (CHIP), providing for 90 days to review the plan for approval, denial or to request comment. If HHS requests additional information from the State, HHS would have 90 days from that time to approve or disapprove the plan.

A State would be required to notify HHS in writing before making significant changes to its Exchange Plan, and significant changes would require written approval from HHS before taking effect. Significant changes are described in the preamble as including changes to key Exchange functions or timeframes, Exchange governance, State laws or regulations, IT systems, QHP certification or enrollment processes. **HHS is considering, and seeks comments on, using for this purpose the State Plan Amendment process in place for Medicaid and CHIP.**

If a State does not elect to operate an Exchange or if it does not have an approved Exchange by January 1, 2013, HHS, either directly or through agreement with a not-for-profit entity, would establish or operate an Exchange in the State. Such a "Federally-facilitated" Exchange would be required to meet the regulatory requirements regarding functions of an Exchange, including stakeholder consultation. The proposed rule does not provide further details of how a Federally-facilitated Exchange would operate in a State.

Election to operate an Exchange after 2014 (§105.106). A State could seek approval to operate an Exchange after January 1, 2013, including a process for transitioning from a Federally-facilitated Exchange to a State Exchange. In order to comply with standardized open enrollment

periods, these changes would take effect on January 1st of a year, with approval required by January 1st of the previous year. Additionally, a process is proposed under which a State Exchange may cease to operate and be replaced by a Federally-established and operated Exchange. States would notify HHS of this election 12 months prior to ceasing operations.

Entities eligible to carry out Exchange functions (§155.110). Requirements are proposed regarding the entities eligible to carry out Exchange functions. A State would be permitted to elect to authorize an Exchange to contract with outside entities for one or more responsibilities. Specifically, this may be an entity that is incorporated under State law, has demonstrated experience in the individual and small group markets and in benefits coverage and is not a health insurance issuer. A State Medicaid agency may serve as an Exchange, and HHS additionally proposes that an exchange may contract with the Medicaid agency for eligibility determinations. **As noted earlier, HHS is also considering developing Federal-State partnership models for operating an Exchange, and welcomes comments on how to construct these.**

The proposed regulation would hold the Exchange responsible for meeting all standards including those applicable to functions for which the Exchange has contracted with other entities. **HHS seeks comments on the extent to which conflict of interest requirements should be placed on contracted entities.**

Governance rules are proposed with respect to an Exchange that is an independent State agency or a non-profit established by the State. The governing board would be clearly defined, operate under a formal, publicly-adopted charter or by-laws, hold regular meetings announced in advance, and could not have a majority of voting members with a conflict of interest, including health insurance issuers or brokers. This latter requirement is stated in the proposed regulation as a means of representing consumer interests. **HHS specifically seeks comments on whether the categories of representatives with potential conflicts of interest should be further specified, and notes that this is proposed as a minimum Federal standard so that a State could adopt more stringent or specialized conflict of interest requirements than those used in connection with regular government operations.**

The Exchange would also be required to have a majority of voting members with specified relevant experience, specifically health benefits administration, health 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. **HHS specifically invites comments on the types of representatives that should be on Exchange governing boards to ensure that consumer interests are well-represented and that the board as a whole has the necessary technical expertise.** HHS indicates that it considered additional options for regulating Exchange governance structures beyond what it refers to as the "minimal" proposed requirements, but elected to offer States discretion in selecting and appointing boards. HHS notes that States may include additional membership as long as the board meets the proposed minimum requirements

Guiding principles regarding ethics, conflict of interest, financial disclosure, accountability and transparency would be publicly available and procedures for financial disclosure by members of the Exchange board or governance structure would be required. **HHS invites comments on**

whether additional detail should be proposed regarding the financial disclosure requirement, and notes that it received numerous comments in response to the RFC on Exchange governance, some suggesting the adoption of minimum standards because of the limited statutory requirements, and others supporting more restrictive standards due to concerns about conflict of interest and non-governmental entities carrying out governmental functions.

Separate governance would be permitted for the SHOP if the State ensures that the SHOP coordinates and shares relevant information with the Exchange operating in the same service area. If the Exchange and SHOP are established under a single governance or administrative structure, the State would be required to ensure that the Exchange has adequate resources to assist individuals and small employers. In discussing this proposal, HHS indicates its view that a single governance structure would yield better policy and operational coordination and operational efficiencies.

HHS would be authorized to periodically review the accountability structure and governance principles of a State Exchange. **HHS specifically seeks comments on recommended frequency of these reviews.**

Non-interference with Federal law and non-discrimination standards (§155.120). An Exchange would be prohibited from establishing rules that are inconsistent with the ACA requirements (subtitle D of Title I), and nothing in the regulation pre-empts any State law that does not prevent application of Title I of the ACA. Compliance with non-discrimination statutes and a specific prohibition on discrimination would be required. HHS states that this standard applies to marketing, outreach and enrollment among other actions.

Stakeholder consultation (§155.130). Exchanges would be required to regularly consult on an ongoing basis with stakeholders, specified in the proposed regulation as: educated health consumers enrolled in QHPs, individuals/entities with experience in health insurance enrollment facilitation, advocates for enrolling hard-to-reach populations such as individuals with a mental health or substance abuse disorder, large employers, small businesses and self employed individuals, health care providers, Medicaid/CHIP agencies, Federally-recognized tribes located within the Exchange's geographic area, public health experts, health insurance issuers and agents/brokers. In discussing this proposed requirement, HHS recommends that Exchanges include individuals with disabilities as educated consumers, advocates for individuals with disabilities and those who need culturally linguistically appropriate services among advocates for hard-to-reach populations, and consumers who are Medicaid and CHIP beneficiaries. HHS notes that the first five proposed stakeholder groups were specified by the ACA while the others (beginning with tribes) were added by HHS after considering comments received in response to the RFC.

HHS discusses in particular its proposed requirement regarding tribal consultation, stating that each Exchange that has one or more Federally-recognized tribes located within its geographic area engage in regular and meaningful consultation and collaboration with those tribes on all Exchange policies that have tribal implications. HHS further recommends that Exchanges seek input from all tribal and urban Indian organizations, and that States should also have a role in the consultation process. HHS encourages States to have a tribal consultation policy that is approved

by the State, the Exchange and the tribe. Additional guidance to both States and the tribes on collaboration is anticipated.

Establishment of a regional Exchange or subsidiary Exchange (§155.140). A State would be permitted to participate in a regional Exchange if it spans two or more States (regardless of whether they are contiguous) and the regional Exchange submits a single Exchange Plan that is approved. HHS encourages States to consider a number of factors: how a regional Exchange would meet the standards, how to achieve the required cooperation between the Exchange and each State's insurance department, how to provide a consistent level of consumer protection, procedures by which a State could withdraw from the regional Exchange, and how each State would contribute to financing the Exchange.

The proposed regulation also codifies that a State could also establish one or more subsidiary Exchanges within the State if each serves a distinct geographic area and the area served by each subsidiary is at least as large as a rating area described in section 2701 of the Public Health Service Act (PHS) Act.[1] HHS notes that the Secretary will address the process for States requesting approval of rating areas in future rulemaking. **HHS specifically seeks comments on the idea of subsidiary Exchanges that cover areas across State lines, and on the extent to which more flexibility should be allowed in the structure of a subsidiary Exchange related to the combination of Exchanges operating in a State.** In response to comments received in response to the RFC regarding tribal governments operating a regional or subsidiary Exchange, HHS notes that it does not believe a tribal government could establish an Exchange, but it could work with the State as it establishes an Exchange.

A regional or subsidiary Exchange would be required to meet all the requirements for an Exchange and perform the functions of a SHOP for its area. If a State operates separate an individual market Exchange and SHOP, the geographic area for both must be the same. For example, a State participating in a regional Exchange would have to do so for both the individual and small group markets. HHS views this as maximizing administrative efficiency, providing consistency for consumers and reducing burden on QHPs.

Transition process for existing State health insurance exchanges (§155.150). Consistent with the ACA requirements, HHS proposes that a State Exchange is presumed to be in compliance with the standards if it was operating prior to January 1, 2010 and the State has insured a percentage of its population not less than the percentage projected to be covered nationally after implementation of the ACA. HHS proposes that "after implementation" refer to the year 2016, which it considers the first full year in which health insurance coverage would achieve its steady state**. Comments are specifically invited on the threshold HHS should use to determine whether a State meets the coverage percentage,** noting that for 2016 the CMS Office of the Actuary estimates coverage will reach 93.6 percent nationally, compared with an estimate of 95 percent by the Congressional Budget Office. HHS also proposes that a State meeting these criteria be required to work with HHS to identify areas of non-compliance with the Federal standards.

[1] Section 2701 of the PHSA says that each State shall establish one or more rating areas within the State and that the Secretary shall review the rating areas established by each State to ensure adequacy. If they are found inadequate or the State fails to establish them, the Secretary may do so.

Financial support for continued operations (§155.160). HHS proposes to codify the ACA requirement that by January 1, 2015 a State must ensure that its Exchanges has sufficient funding to support ongoing operations, and may charge assessments or user fees on participating issuers, which must be announced to participating issuers in advance of the plan year. **HHS seeks comment on whether the final regulation should limit how and when user fees may be charged and where such fees should be assessed on an annual basis.** HHS notes that the funding plan is a requirement of Exchange approval.

3. Subpart C – General Functions of an Exchange

This subpart outlines minimum functions for an Exchange. HHS reiterates that its intention is to provide State flexibility, providing for uniform standards where required by statute or for compelling practical, efficiency or consumer protection reasons.

Functions of an Exchange (§155.200). This section summarizes the minimum functions required of an Exchange. Exchanges would be required to meet requirements specified later pertaining to enrollment in QHPs, SHOP, and certification of QHPs. In addition, Exchanges would provide individuals with certificates of exemption from the ACA individual responsibility requirements, make eligibility determinations, establish an appeals process for eligibility determinations, perform functions related to ACA oversight and financial integrity requirements, and evaluate quality improvement strategies and oversee implementation of enrollee satisfaction surveys, assessment of ratings of health care quality and outcomes, information disclosures and data reporting. HHS anticipates future rulemaking on the enrollee satisfaction and quality requirements. **In discussing these requirements, HHS welcomes comments and encourages States to consider supplemental standards or functions for their Exchanges that benefit consumers and businesses,**

HHS notes that the ACA creates a central role for the Exchange in determining eligibility of individuals for enrollment in a QHP, advance payment of premium tax credits, cost sharing reductions, Medicaid, CHIP and the Basic Health Program where one is operating in the Exchange service area. Its interpretation is that the ACA calls for a system of streamlined and coordinated eligibility and enrollment for these programs, which should be consumer-oriented and minimize administrative barriers and unnecessary paper work for applicants.

Required consumer assistance tools and programs of an Exchange (§155.205). The Exchange would be required to provide for operation of a toll-free consumer assistance call center, maintain an up-to-date internet website, provide an electronic calculator for consumers, provide consumer assistance, and conduct outreach and education.

Call Center. In the preamble discussion, HHS indicates that under the proposed regulation the Exchange would have significant latitude in structuring the call center, and suggests that the Exchange consider operating it outside normal business hours and adjusting staffing levels to anticipate periods of higher call volume. HHS believes the call center should have the capacity for providing assistance on the types of QHPs offered in the Exchange; premiums, benefits, cost sharing, and quality ratings of the offered QHPs; premium tax credits, cost sharing reductions,

and other assistance; and the application process for enrollment in the Exchange, Medicaid and CHIP and other programs. HHS also encourages Exchanges to use call centers to link consumers to other assistance programs such as health insurance ombudsmen and the Navigator program (described below). **HHS seeks comments on ways to prevent duplication of effort by the Exchange call center and QHP issuers' customer call centers while ensuring that consumers have various ways to learn about coverage options and receive assistance.**

Website. The Exchange website would be required to provide standardized comparative information on each QHP, including at a minimum: premium and cost sharing information; a summary of benefits; whether the QHP is a bronze, silver, gold, platinum, or a catastrophic plan; enrollee satisfaction information; quality ratings; medical loss ratio information; transparency of coverage measures; and the provider directory. It would also be required to allow for an eligibility determination and enrollment in coverage. HHS suggests that Exchanges consider making information on benefits and coverage available through a link to each QHPs website or by requiring QHPs to submit information to provide for a searchable format.

The website would have to be accessible to people with disabilities and provide meaningful access for persons with limited English proficiency. HHS indicates in the preamble that it has issued guidance regarding the requirements of section 504 of the Rehabilitation Act with respect to website accessibility, available at http://cciio.cms.gov/resources/files/joint_cms_ociio_guidance.pdf.

The Exchange website would also be required to provide applicants with information about Navigators (described below) and other consumer assistance services, and to publish certain financial information on the average costs of licensing required by the Exchange; regulatory fees and other payments required by the Exchange; Exchange administrative costs; and monies lost to waste, fraud and abuse.

In discussing the website in the preamble, HHS indicates that the Exchange website is envisioned as an easy-to-use access point to serve as a primary source of information about available QHPs, Exchange activities and other sources of health insurance coverage. **HHS indicates that it is evaluating the extent to which the Exchange website may satisfy the need to provide plan comparisons using HealthCare.gov, and invites comments on the issue.**

Exchange Calculator. In addition to the website, the Exchange would be required to establish and make available by electronic means a calculator to facilitate comparison of available QHPs after application of any advance payments of premium tax credits and cost sharing reductions. **HHS seeks comments on the extent to which States would benefit from a model calculator and suggestions on its design.**

Consumer Assistance and Outreach and Education. The Exchange would be required to have a consumer assistance function, including the Navigator program, and to make referrals to other appropriate consumer assistance when available and appropriate as well as conduct outreach and education activities to inform consumes about the Exchange and encourage participation. In the preamble, HHS states that Exchanges should aim to maximize enrollment of eligible individuals into QHPs and to increase QHP competition.

Navigator program standards (§155.210). HHS proposes that Exchanges must establish a Navigator program awarding grants to eligible public or private entities. Eligible entities would be those capable of at least these requirements: 1) maintaining expertise in eligibility and enrollment and raising public awareness of the Exchange; 2) providing information and services in a fair, accurate and impartial manner; 3) facilitating enrollment in QHPs; 4) providing appropriate referrals for enrollees with a grievance or question regarding their health plan; 5) providing information that is culturally and linguistically appropriate and ensures the accessibility and usability of Navigator tools for individuals with disabilities. **HHS is considering standards for grant awards with regard to information content, referral strategies and training requirements, and specifically invites comments on potential standards to ensure that Navigators provide information that is fair, accurate, and impartial. More generally, HHS seeks comments with respect to any additional standards regarding Navigators to be considered in future rulemaking or additional guidance that may be developed.**

In addition to the capability to carry out the duties of a Navigator, an eligible entity would be required to demonstrate to the Exchange that it has or could readily have relationships with employers and individuals likely to be eligible for enrollment in a QHP, meets licensing or certification standards required by the State or the Exchange, and does not have a conflict of interest during the term as a Navigator. HHS indicates that this latter requirement would not exclude an organization from consideration if it formerly had a conflict of interest that no longer exists. An example offered is a nonprofit community organization that previously received a grant from a health insurance issuer. **HHS seeks comments on whether it should propose additional requirements on Exchanges to make determinations regarding conflict of interest.**

In awarding Navigator grants, an Exchange would be required to include entities from at least two of the following: community and consumer focused nonprofits; trade, industry and professional associations; commercial fishing, ranching and farming organizations; chambers of commerce; unions; resource partners of the Small Business Administration; licensed agents and brokers; an other public or private entities, including Indian tribes, tribal organizations, urban Indian organizations, and State or local human service agencies. **HHS seeks comments on whether it should require that at least one entity type be a community and consumer focused nonprofit, or whether the grantees of an Exchange should be required to reflect a cross section of stakeholders.**

As specified in the ACA, Navigators may not be a health insurance issuer or receive any consideration directly or indirectly from a health insurance issuer for enrollment of qualified individuals in a QHP. In the preamble, HHS notes that receiving consideration would include without limitation, any monetary or non-monetary commission, kickback, salary, wage or payment made directly or indirectly from the QHP. A Navigator could, however, receive compensation from a health insurance issuer in connection with enrollment of individuals or employers in a non-QHP. **HHS specifically seeks comments on this issue and ways to manage any potential conflicts of interest that may arise.**

The proposed regulation codifies the ACA requirement that Navigator grants may not be financed by funds received by the State to establish the Exchange. In the preamble, HHS notes that if a State chooses to permit its Navigator program to address Medicaid or CHIP administrative activities and these are performed under a contract or agreement that permits the costs to be separately identified, these costs would be eligible for Medicaid or CHIP Federal matching funds.

HHS is considering, and seeks comments on, an additional requirement that Exchanges ensure that the Navigator program is operational in time to be of assistance to consumers at the start of the initial open enrollment period, proposed elsewhere in this rule to begin on October 1, 2013.

Ability of States to permit agents and brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs (§155.220). HHS codifies the ACA provisions allowing States to permit agents and brokers to enroll qualified individuals, employers and employees in any QHPs offered through the Exchange, and assisting individuals in applying for the advance payments of the premium tax credit and cost sharing reductions for QHPs. HHS also proposes that the Exchange may also provide information regarding licensed agents and brokers on its website. In the preamble, HHS reiterates that under §155.210, an agent or broker serving as a Navigator may not receive any financial compensation from an issuer for helping an individual or small employer select a specific QHP.

HHS indicates that some web-based entities and others with experience in health plan enrollment are interested in contracting with an Exchange to perform outreach and enrollment functions or by acting independently to the Exchange to do so. HHS states that while it recognizes that such entities may help raise public awareness of the QHPs, individuals may only access advance payment of tax credits and cost sharing reductions through the Exchange. **HHS seeks comments on what functions such entities could perform, the potential scope of their interaction with Exchanges, and what standards should apply to an entity performing functions in place of or on behalf of an Exchange. Additionally, comments are invited regarding the practical implications, costs and benefits of coordination between an Exchange and such entities, and any security and privacy implications.**

General standards for Exchange notices (§155.230). HHS proposes that notices sent by an Exchange as required under this part be in writing and include contact information for customer service, an explanation of any rights to appeal, and a citation to the specific regulation causing the notice to be sent. HHS further proposes that all applications, forms and notices be in plain language, which is defined in 155.20 as "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." In addition, notices would be provided in a manner that provides meaningful access to limited English proficient individuals and ensures effective communication for people with disabilities. The Exchange would be required to re-evaluate the appropriateness and usability of applications, forms, and notices annually and in consultation with HHS when changes are made.

Payment of premiums §155.240. The Exchange would be required to allow a qualified individual to pay any premium owed directly to the QHP issuer. Indian tribes, tribal organizations and urban Indian organizations could be permitted by the Exchange to pay QHP premiums on behalf of qualified individuals. Exchanges would be required to accept payment of an aggregate premium for a qualified employer. An electronic process for collecting premiums could be established by the Exchange, subject to the privacy and protocols required under §155.260 and §155.270. In discussing this section, HHS notes that an Exchange has three options regarding payment of premiums: 1) take no payments, so that enrollees pay directly to the QHP, 2) facilitate the payment of premiums by creating an electronic "pass-through" of premiums without retaining any payments, and 3) collect premiums from QHP enrollees and pay an aggregated sum to the QHP issuers. HHS states that under the ACA, individuals must be allowed to pay the QHP directly, so in all three Exchange options an enrollee must always have this option. HHS notes that if an Exchange elects to facilitate payment of premiums, the Exchange would not be liable for payment of premiums if an individual is late in making payment, for example. **HHS seeks comments regarding Exchange flexibility in the premium payment process and what Federal standards would be appropriate to ensure fiduciary accountability when an Exchange collects premiums.**

With respect to Indian tribes, tribal organizations and urban Indian organizations, HHS seeks comments on whether the mechanism used by some tribes to enroll members in the Medicare prescription drug program, under which tribes may limit members' options, would work in an Exchange. In addition, because the Indian Health Care Improvement Act provision permitting the purchase of health benefits coverage for IHS beneficiaries applies to a broader definition of Indian than the Exchange provisions, HHS seeks comment on how to distinguish individuals eligible under the ACA from others.

Privacy and security of information §155.260. HHS proposes to prohibit the Exchange from collecting, using, or disclosing personally identifiable information unless it is specifically required or permitted by law or is made pursuant to the required Exchange responsibilities. Exchanges would be required to follow security standards consistent with those required for covered entities under the Health Insurance Portability and Accountability Act (HIPAA) (specified sections of 45 CFR 164). They would also be required to establish and follow privacy standards for proper collection, use and disclosure and disposal of personally identifiable information, have written policies and require contractors to protect personally identifiable information. In addition, other applicable laws would apply regarding tax returns and data matching and sharing arrangements between an Exchange and agencies administering Medicaid, CHIP or a Basic Health Program. Civil penalties of up to $25,000 per disclosure are proposed for improper use and disclosure of information in addition to any other applicable penalties under the law.

In discussing these proposed requirements, HHS notes that some or all the Exchanges might be HIPAA covered entities or business associates of HIPAA covered entities, in which case privacy and security standards might be governed by the HIPAA. HHS encourages Exchanges to determine its HIPAA status. HHS notes that for those Exchanges which are not subject to HIPAA, the proposed regulation does not require the HIPAA privacy standards to be adopted as the minimum protection for all Exchanges, but instead provides Exchanges flexibility in

adopting a tailored standard. **HHS reports that it is considering requiring each Exchange to adopt privacy policies that conform to the Fair Information Practice Principles, and welcomes comments on this approach, or the application of the HIPAA privacy model to Exchanges.**

Use of standards and protocols for electronic transactions. (§155.270) HHS proposes that an Exchange performing electronic transactions with a covered entity (e.g., Medicaid programs and QHP issuers) is subject to HIPAA administrative simplification requirements. In addition, Exchanges would be required to incorporate health information technology enrollment standards and protocols adopted by the Secretary. HHS notes that this is required under the Exchange cooperative agreements awarded by HHS.

(Note: HHS is reserving Subpart D for future use.)

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

This subpart sets forth standards for Exchanges regarding enrollment periods and processes for enrolling individuals in QHPs. HHS reports on a range of comments received on these issues in response to the RFC.

Enrollment of qualified individuals into QHPs (§155.400). Exchanges would be required to accept a QHP selection from qualified individuals, notify the issuer of the applicant's selected QHP and transmit information necessary for the QHP to enroll the applicant. The Exchange would provide eligibility and enrollment information to QHPs on a timely basis and would establish a process by which the QHP would acknowledge receipt of the information. HHS indicates that although it would be ideal for information sharing to occur in real time, it is not certain that all parties will have the capacity for this by 2014. **HHS seeks comments on whether to codify in the final rule a requirement for enrollment transactions (e.g., real time, or daily).** The Exchange would also maintain records of all QHP enrollment and submit information to HHS each month. In addition, at least once a month the Exchange would reconcile enrollment information with QHP issuers.

Single streamlined application (§155.405). HHS proposes that an Exchange must use a single streamlined application to determine eligibility and collect the information necessary for enrollment in a QHP, advance payment of the premium tax credit, cost sharing reductions, and Medicaid, CHIP, or the Basic Health Program, where applicable. HHS intends to create a paper-based and web-based application, and anticipates that the electronic application will enable many applicants to complete the eligibility and QHP selection process in a single online session. If an Exchange seeks to use an alternative application, it must be approved by HHS and must request the minimum information necessary. **HHS seeks comments on whether to codify a requirement that applicants may not be required to answer questions that are not pertinent to the eligibility and enrollment process.** The Exchange would be required to accept applications from an applicant, an authorized representative, or from someone acting responsibly for the applicant, and would be required to provide for applications filed via an internet portal,

through a telephone call center, by mail, and in person. **HHS solicits comments on the requirement that an individual must be able to file an application in person.**

Initial and annual open enrollment periods (§155.410). HHS proposes to require Exchanges to provide open enrollment periods during which eligible individuals may enroll in a QHP or change QHPs. A qualified individual would only be permitted to enroll in a QHP during an the initial open enrollment period, an annual open enrollment period, or a special open enrollment period for which they are eligible.

The initial open enrollment period is proposed to be October 1, 2013 through February 28, 2014. QHP selections received by the Exchange prior to December 23, 2013 would be ensured a coverage effective date of January 1, 2014. Selections received between the first and 22nd day of any subsequent month would be ensured a coverage effective date of the first day of the following month, and those received between the 23rd and last day of the month for any month during the initial open enrollment period would be ensured a coverage effective date of either the first day of the following month or the first day of the second following month.

For benefit years beginning in 2015, the annual open enrollment period would be October 1st through December 7th of the preceding calendar year. For individuals making a QHP selection during an annual open enrollment period, the Exchange would be required to ensure that coverage take effect on January 1st of the following year. **HHS specifically seeks comments on an alternative 45-day period it considered, from November 1st through December 15th.**

In the preamble, HHS indicates that the proposed timeframes are informed by experience with the Medicare Advantage and Medicare Prescription Drug Benefit programs and information from the Federal Employees Health Benefits Program. **HHS acknowledges that extending the initial open enrollment period into calendar year 2014 would require flexibility on the part of QHPs because some enrollees would have coverage for fewer than 12 months. HHS believes the longer period is necessary to allow for outreach and education, and specifically seeks comment on the duration of the initial open enrollment period.**

In proposing that coverage always be effective on the first day of the month, HHS indicates that this is intended to coordinate with the advance payments of the premium tax credit, which the statute requires may only be provided for an enrollee who is enrolled in a QHP on the first of the month. **HHS seeks comments as to whether twice-monthly effective dates or complete flexibility in effective dates should be allowed for individuals who forego receipt of the credit for their first partial month or those who are not eligible for advance payment of the credit.**

Beginning in 2014, HHS proposes that Exchanges would be required to provide advance written notification to enrollees about annual open enrollment. **HHS is considering codifying in the final rule, and seeks comments on, a requirement that notice to enrollees about the open enrollment period be sent no later than 30 days before the start of the annual open enrollment period. Comment is also sought on requiring specifically in that notice inclusion of information on the date that annual open enrollment begins and ends and where individuals may obtain information about QHPs, including the website, call center and through Navigator and other relevant information.**

Special enrollment periods (§155.420). Exchanges would be required to allow qualified individuals and enrollees to enroll in or change a QHP during a 60-day special enrollment period if specified triggering events occur. The special enrollment period would begin on the date of the triggering event. Coverage would be effective on the first day of the month for QHP selections made by the 22nd of the previous month, and for QHP selections made after the 23rd, would be effective either on the first day of the month or the first day of the second following month. An exception would be made in the case of birth, adoption, or placement for adoption, for which coverage would be effective on the date of birth.

The proposed triggering events, many of which HHS modeled on those provided for with respect to Federal group health plan requirements or the Medicare Prescription Drug Benefit, are: 1) loss of minimum essential coverage by a qualified individual or dependent; 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 error, misrepresentation or inaction by the Exchange or HHS; 5) an enrollee adequately demonstrates to the Exchange that the QHP in which he or she is enrolled substantially violated a material provision of the 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 the individual is enrolled in a QHP. In the case of an individual whose existing coverage through an eligible employer-sponsored plan will no longer be affordable or provide minimum value would be permitted to access this special enrollment period prior to the end of coverage under the employer-sponsored plan; 7) A qualified individual or enrollee gains access to new QHPs as a result of a permanent move; 8) An Indian may enroll in a QHP or change from one QHP to another once a month; 9) A qualified individual or enrollee meets other exceptional circumstances as the Exchange or HHS may provide. HHS indicates that exceptional circumstances could include natural disasters or other circumstances that would impede an individual's ability to enroll on a timely basis through no fault of their own.

With respect to item 7, HHS seeks comments on whether to begin the special enrollment period on the date of the move or the date on which the individual provides notice of the move, whichever is later.

HHS provides numerous examples of situations that would be covered by these proposed triggering events, such as death or divorce leading to loss of coverage for a dependent, loss of coverage due to decertification of a QHP, release from incarceration, a household move to the jurisdiction of a different Exchange, relocating outside the service area of the QHP in which an individual is enrolled, loss of COBRA continuation coverage, reaching a lifetime limit on all benefits under a grandfathered plan, and termination of Medicaid or CHIP.

HHS notes that it specifies the loss of minimum essential coverage, not the loss of any coverage, and seeks comments on this provision. HHS believes making this distinction avoids adverse selection that would occur if individuals with less than minimum essential coverage

could maintain that coverage until they had significant health needs that led them to elect the special enrollment period into a QHP in the Exchange.

Loss of coverage would not include termination or loss due to failure to timely pay premiums, including COBRA premiums, or situations allowing for a rescission under Federal regulations.

As required under the ACA, enrollees who are permitted to change plans during a special enrollment period could only move to a different plan at the same level of coverage (e.g., bronze, silver, gold, platinum). **HHS indicates that requiring individuals to maintain coverage during a special enrollment period could pose challenges to an enrollee of a catastrophic plan who becomes pregnant and requests comments on whether an exception should be provided for such circumstances.**

HHS clarifies that the Exchange is required to provide information, accept applications, perform eligibility determinations and provide for enrollments into QHPs throughout the year to accommodate special enrollment periods. In addition, HHS notes that the special enrollment periods are a minimum requirement for the Exchange to permit enrollment outside of the initial and annual open enrollment periods, and that other laws requiring a special enrollment period right from issuers would continue to apply.

Termination of coverage (§155.430). HHS proposes that the Exchange must determine the form and manner in which coverage in a QHP may be terminated. Termination of coverage by an enrollee would be permitted with appropriate notice to the Exchange or QHP. Termination of an individual's coverage by the Exchange or the QHP would be permitted if: 1) the enrollee is no longer eligible for coverage in a QHP through the Exchange, 2) the enrollee becomes covered by other minimum essential coverage, 3) payments of premiums for coverage of the enrollee cease and the grace period (see §156.270) has expired, 4) the coverage is rescinded as permitted under Federal regulations, 5) the QHP is terminated or decertified, or 6) the enrollee switches QHPs during an annual or special open enrollment period.

The Exchange would be required to establish procedures for QHPs to maintain records of terminations of coverage and would track and submit monthly to HHS the number of coverage terminations. In addition, the Exchange would establish standards that require 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. Other standards would require QHPs to retain records to facilitate audits.

In the case of a termination requested by an enrollee, the effective date would be the date specified by the enrollee if a reasonable amount of time is provided from the enrollee's notice. Otherwise, the last day of coverage would be the first day after such reasonable amount of time has passed. In the case of a termination because the enrollee becomes eligible for other minimum essential coverage or switches to another QHP, the coverage would terminate the day before the new coverage is effective. For all other cases, the termination would be effective the 14th day of the month if the notice of termination is sent by the Exchange or initiated by the QHP before the 14th day of the previous month, or the last day of the month if the termination is initiated no later than the last day of the previous month.

(Note: HHS is reserving Subparts F and G for future use.)

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

In this subpart HHS proposes standards for the SHOP. HHS proposes in §155.700 that an Exchange must provide for establishment of a SHOP that meets all the requirements of this subpart and facilitates the enrollment of qualified employees into qualified health plans.

HHS notes that participation in the SHOP is voluntary for small employers, highlighting potential advantages. Notably, beginning in 2014, the small business tax credit will only be available to eligible small employers purchasing coverage through the SHOP, to be addressed in separate rulemaking by the Secretary of the Treasury.

Functions of a SHOP (§155.705). The functions of a SHOP would include all the functions of an Exchange set forth in the proposed regulation except for the requirements related to individual eligibility determinations, enrollment of qualified individuals into QHPs (as opposed to enrollment of employees), and requirements related to the premium tax credit, certifying exemptions from the individual mandate, and payment of premiums.

The SHOP would also be required to provide functions not required of the Exchange. These involve eligibility and enrollment into the SHOP and certification of QHPs in the small group market, employer choice, premium aggregation, rates and rate changes. Specific additional requirements regarding special enrollment periods for SHOPs are discussed in §156.285 below.

Employer Choice. Regarding employer choice, the SHOP would be required to allow a qualified employer to select a level of coverage within which all qualified QHPs would be made available to the qualified employees of that employer. HHS believes this is required under the statute, and proposes to provide additional flexibility for SHOPs to choose additional ways for qualified employers to offer plans to their employees. Examples of alternatives offered in the preamble are allowing employees to choose any QHP in the SHOP at any level, allowing employers to select a menu of specific QHPs from different levels from which employees may choose, or allowing employers to select a specific QHP to offer employees. **Specific to the employer choice issue, HHS welcomes comments on the statutory interpretation of §1312(a)(2)(A) and 1312(f)(2)(B) of the ACA.** HHS notes that allowing employees to choose QHPs across levels raises potential for risk selection. In addition to the risk adjustment program proposed elsewhere, HHS would address this requiring only that a SHOP provide for employee choice within a level of coverage, while providing SHOPs the option to offer broader employee choices among plans. **HHS also invites comments on this proposed flexibility.**

Premium aggregation. HHS proposes that for the premium aggregation function, the SHOP each month would bill each qualified employer for the aggregate premiums due to the QHP issuers from the employer, collect those funds from the employer, and make the payments to the QHPs. HHS expects that the monthly bill sent to employers would include both the employer and employee contribution for the QHP as a service to employers.

Rates and rate changes. The SHOP would have to require that all QHP issuers make any change to rates at a uniform time that is quarterly, monthly, or annually, and rates could not vary for a qualified employer during its plan year. HHS believes that this proposal is necessary because elsewhere it proposes that the SHOP provide for rolling enrollment in a SHOP, under which employers would be able to purchase coverage at any time during the year. Proving a uniform interval for rate changes would allow for more useful rate comparison and less administrative burden for the SHOP. If an employee is hired during the plan year or changes coverage during the plan year during a special enrollment period, the rate set at the beginning of the plan year would still apply. **HHS seeks comments on whether the proposed timeframes should be more permissive, and what rates should be used to determine premiums during the plan year.**

Merged markets. If a State merges the individual and small group market pools, the SHOP would permit a qualified employer to enroll in any QHP that meets the ACA small group market requirements regarding the maximum deductible and which meets the employer choice requirements. If the markets are not merged, the SHOP could only permit qualified employees to enroll QHPs in the small group market.

SHOP expansion to large group market. If a State elects to expand the SHOP to the large group market beginning in 2017, a SHOP would be required to allow large group market issuers to offer QHPs to large employers through a SHOP provided that the large employer makes all full time employees eligible for coverage through the SHOP.

In the preamble, HHS discusses two issues that are not included in the proposed regulation:

- SHOPs are encouraged to consider options for calculating and displaying the net employee contribution to the premium for different plans and family compositions after any employer contribution is taken into account. HHS believes that because conveying net premium is current market practice and important to informed employee choice, SHOPs should use this practice.
- The common practice of small group issuers to require minimum participation of employees is discussed, and **HHS invites comments about whether QHPs 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 a minimum participation rate should be established in Federal regulation.**

Eligibility standards for SHOP (§155.710). HHS proposes that an employer be a qualified employer eligible to purchase coverage through the SHOP if it is a small employer who elects to offer coverage at a minimum to all full-time employees through the SHOP, and either has a principal business address in the Exchange service area and offers coverage to all its employees through that SHOP or offers coverage to each eligible employee through the SHOP serving that employee's primary worksite. If an employer participates in multiple SHOPs, the SHOP would offer coverage to an employee whose primary worksite is in the SHOP service area. The SHOP would be required to continue eligibility for an employer who is no longer a small employer because the number of employees increases but otherwise meets the eligibility requirements. A

"qualified employee" would be one who receives an offer of coverage from a qualified employer. HHS notes that it proposes a limited scope of requirements for eligibility to maximize accessibility of the SHOP, streamline the eligibility process, and minimize burden on employers and employees.

HHS discusses the definitions of small employer and large employer, which in this proposed regulation are based on definitions in the PHS Act, where size is determined by counting all employees. Part time workers count the same as full time workers and seasonal employees are counted proportionately to the number of days they work in the year. **HHS seeks comments on this approach.**

Eligibility determination process for SHOP (§155.715). HHS proposes that the SHOP be required to provide for a single application form for employers and one for employees. HHS is required under the ACA to provide States with a single streamlined form, and will propose model applications after consultation with the National Association of Insurance Commissioners. The SHOP would have to verify that an employee applicant is an employee to whom the qualified employer has offered coverage and to accept the other information provided unless the SHOP has reason to doubt its veracity. A SHOP may establish other methods of verifying information. HHS suggests that these may include review of quarterly wage reports suggesting the employer is not a small employer and attempts by an employer to enroll more employees than allowed under the definition of small employer. HHS intends to address appeals related to this process in future rulemaking.

If a SHOP has reason to doubt the information provided by an employer or individual applying for coverage through the SHOP, it must make a reasonable effort to identify the causes for concern, notify the employer and provide 30 days for the employer to document its eligibility. Notification of denial or discontinuation of participation would be required. A right to appeal an eligibility determination would be required. If an employer terminates participation in the SHOP, the SHOP would be required to ensure that QHP coverage was terminated and employees were notified prior to termination. **HHS seeks comments on whether this notice should include information about special enrollment period in the Exchange and the availability of advance payment of premium tax credits, cost sharing reductions, Medicaid and CHIP.**

Enrollment of employees into QHPs under SHOP (§155.720). The SHOP would be required to establish a uniform enrollment timeline and process that all QHP issuers and qualified employers comply with so that prior to the effective date of coverage for qualified employees, certain activities are accomplished. These are determination of employer eligibility to purchase coverage in the SHOP, employer choice of QHPs to be made available to its employees, the timeframe during which employer selection of QHPs occurs, the timeframe for employees to apply, verification of employee eligibility, processing enrollment of qualified employees into chosen QHPs and establishment of effective dates of employee coverage. The SHOP would be required to transmit enrollment information to QHP issuers, provide for collection and distribution of payments, terminate employers that do not comply with premium payment requirements, notify employees of the effective date of coverage, maintain records of enrollment in QHPs, reconcile enrollment and employer participation files and notify the employer when an employee terminates coverage in a QHP.

Enrollment periods under SHOP (§155.725). The SHOP would be required to adhere to the start of the Exchange initial open enrollment period (proposed as October 1, 2013) and ensure that enrollment transactions are sent to QHP issuers and that issuers adhere to effective dates specified under §156.260. The SHOP would be required to provide for rolling enrollment so that any qualified employer could purchase coverage at any time during the year. The employer's plan year would be required to be a 12 month period, which may or may not be a calendar year. Employees would only be able to enroll in or change a QHP during an open enrollment period, unless they qualify for a special enrollment period.

The SHOP would provide for an annual employer election period to occur prior to completion of the employer's plan year and before the annual employee open enrollment period during which the employer would be able to change its participation in the SHOP for the next plan year. Changes could involve the QHP choices available to employees or the employer contribution toward the premium. The SHOP would notify participating employers that their annual election is approaching. **HHS is considering, and solicits comments on, whether to require 30-days notice.**

The SHOP would also provide for an annual open enrollment period for qualified employees prior to completion of the employer's plan year. **HHS notes that it believes the SHOP should establish the annual open enrollment period in o**rder to accommodate its marketplace, and solicits comments on this proposal.

Further, HHS proposes automatic renewal of coverage so that if a qualified employee enrolled in a QHP through the SHOP remains eligible for coverage, they would remain enrolled in that QHP unless they choose to disenroll, enroll in another QHP or the QHP is no longer available to the qualified employer.

Employees who are hired outside of the initial or annual open enrollment period would have a specified amount of time, beginning on the first day of employment, to seek coverage in a QHP. HHS proposes that this timeframe be established by the SHOP. Coverage for that employee would continue through the rest of the employer's plan year.

Application standards for the SHOP (§155.730). The proposed SHOP application standards are similar to those proposed for the Exchange. The SHOP would be required to use a single employer application for eligibility that includes the employer's name and address of locations, number of employees, employer identification number and list of qualified employees and their social security numbers. A separate single application would be required for employee eligibility. These applications may be the models to be provided by HHS or an alternative approved by HHS that collects specified information. HHS notes that the information that needed from employee applicants would be significantly less than that collected for individual applicants to the Exchange, so use of the individual Exchange application for this purpose would be overly burdensome. However, the Exchange application could be modified for use as the SHOP employee application, and HHS suggests that using the same application platform could help streamline information sharing between the Exchange, SHOP, QHP issuers and HHS. **HHS**

welcomes comments on other employer information that it should consider requiring a SHOP to collect.

The SHOP would be required to allow an employer or employee to apply in the same manner that application can be made to the Exchange. Specifically, applications would be accepted from an applicant, an authorized representative, or from someone acting responsibly for the applicant, and would be required to provide for applications filed via an internet portal, through a telephone call center, by mail, and in person.

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

In this subpart HHS proposes procedures for Exchanges to follow in certifying health plans as QHPs. Part 156 which follows, (and which is at times referenced in this section of the summary), presents the standards that health insurance issuers must meet for QHP certification. HHS reports that it considered the varied comments it received in response to the RFC regarding how to certify QHPs, and that it seeks a balance between providing for consistent consume protections and providing Exchange with flexibility to tailor standards for QHPs taking into account local market conditions.

Certification standards for QHPs (§155.1000). In this section, HHS proposes that Exchanges offer only QHPs as certified by the Exchange, and that any reference to QHPs include multi-State plans under contract with the Office of Personnel Management unless specifically provided for otherwise. The Exchange would certify a health plan as a QHP in the Exchange if the issuer provides evidence of compliance with the applicable requirements in subpart C of part 156, and the Exchange determines that making the plan available is in the best interest of qualified individuals and employers. As required under the ACA, the Exchange could not exclude a health plan because it is a fee-for-service plan, through the imposition of price controls, or on the basis that the plan provides treatments necessary to prevent patient deaths in circumstances the Exchange determines are inappropriate or too costly.

HHS discusses comments it received regarding to extent to which Exchanges should implement an "any willing plan" model or use of active purchaser approaches such as selective contracting or price negotiation. HHS proposes to provide Exchanges with discretion that could involve certifying all qualified plans or establishing additional criteria to determine whether a plan is in the best interest of consumers. For example, HHS indicates that Exchanges could employ competitive bidding, selective contracting, case-by-case negotiation, or other selection criteria such as 1) reasonableness of the estimated costs supporting the calculation of the plan's premium and cost-sharing levels, 2) past performance, 3) quality improvement activities, 4) provider networks, 5) service area and 6) prior and proposed premium rate increases.

Certification process for QHPs (§155.1010). Exchanges would be required to establish procedures for certifying QHPs under which multi-State plans would be exempt and deemed to meet the certification process. Certification would be required to be completed prior to the open enrollment period. The Exchange would monitor QHP issuers for ongoing compliance with the certification requirements.

QHP issuer rate and benefit information (§155.1020). Exchanges would be required to receive a justification for a rate increase prior to its implementation, and would ensure that the QHP prominently posted the justification on its website (see §156.210). HHS notes that Exchanges may receive this information from the State department of insurance or HHS. HHS proposes to codify the ACA requirement that rate increases would be considered in accordance with the ACA requirements that Exchanges consider a justification prior to implementation of the rate increase, recommendations provided to the Exchange by the State under section 2794 of the Public Health Service Act, and any excess rate of growth outside the Exchange compared to the rate of growth inside the Exchange.[2] At least annually, the Exchange would receive from QHP issuers information on rates, covered benefits and cost sharing requirements. HHS would specify the form and manner of the information to be provided by QHPs. HHS notes that information on rates is needed for a variety of purposes: to determine and display premium amounts for Exchange applicants, to determine the second lowest cost silver plan benchmark for advance payments of the premium tax credit, and to determine whether the QHP complies with benefit design and actuarial value requirements.

HHS indicates that it seeks to avoid duplication of the State rate review process in section 2794, and that where States are operating an effective rate review program, that process should be leveraged by the Exchange to avoid duplication. For example, the Exchange might consider the rate justification format from issuers under §154.215. HHS is considering for the final rule a bifurcated process under which the Exchange may rely on the justification submitted under section 2794 of the PHS Act for rates subject to that review, and develop a less burdensome rate justification when section 2794 does not apply. Exchanges would be encouraged to collaborate with the State insurance department for this purpose. **HHS solicits comments on how best to align the requirements of section 2794 of the PHS Act and section 1311(e)(2) of the ACA, which requires an Exchange to consider rate increases in determining whether to make a health plan available on the Exchange.**

Transparency in coverage (§155.1040). The Exchange would be required to receive from QHPs information related to coverage transparency required under §156.220(s) below. The Exchange would determine whether the information provided was in plain language and monitor whether the QHP issuer has made cost-sharing information available to enrollees. HHS notes that it proposes to codify ACA requirements which will also apply to all group health plans and health plan issuers in the individual and small group markets, and it anticipates working closely with the Departments of Treasury and Labor. HHS will share comments received regarding section 1311(e)(3)(D) of the ACA involving transparency regarding group health plans with the Department of Labor so that it can harmonize rules for group health plan disclosures.

Accreditation timeline (§155.1045). The Exchange would be required to establish a uniform period following certification of the QHP within which a QHP issuer that is not accredited must become accredited as under §156.275. HHS notes that this codifies requirements of the ACA, which it interprets to require that QHP issuers must be accredited for a QHP to be certified. HHS notes that the ACA does not establish a deadline for accreditation, and believes that a grace period may be necessary because the typical accreditation process may take 12 to 18 months or

[2] On May 23, 2011 HHS has finalized regulations related to section 2794 rate review in 45 CFR 154. See 76 FR 29964.

longer to complete. Thus, HHS encourages Exchanges to establish an accreditation timeline that accommodates the length of the accreditation process, particularly for issuers seeking accreditation for the first time. HHS believes that by establishing a uniform period for accreditation following certification rather than a single date by which all QHP issuers must be accredited will allow for inclusion of a wider variety of QHP issuers in the Exchange.

Establishment of Exchange network adequacy standards (§155.1050). The Exchange would be required to ensure that the provider network of each QHP offers a sufficient choice of providers for enrollees. HHS believes that this broad standard would afford Exchanges the ability to ensure that network adequacy requirements reflect State patterns of care and leveraging existing State standards and enforcement mechanisms. HHS solicits comments on additional qualitative or quantitative standards for the Exchange to use in evaluating network adequacy**. In particular, HHS seeks comments on specific potential standards based in part on the NAIC Managed Care Plan Network Adequacy Model Act.** Under these potential standards, Exchanges would be required to establish standards under which QHP issuers would be required to maintain: 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 proximity to providers accepting new patients, 3) an ongoing monitoring process to ensure network sufficiency 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. HHS notes that these standards would provide a baseline that each Exchange could interpret and apply to local market conditions and patterns of care, and could establish quantitative requirements where possible to establish clear expectations of access to care.

In addition, HHS seeks comments on an additional standard that the Exchange ensure that QHPs provider networks provide sufficient care for all enrollees, including those in medically underserved areas. HHS further encourages Exchanges to consider the needs of enrollees in isolated areas, and consider broadly defining the types of providers that furnish primary care services. HHS clarifies that a QHP issuer's provider network must ensure reasonable access to care for all enrollees enrolled through the Exchange regardless of medical condition.

Service area of a QHP (§155.1055). An Exchange would be required to have a process for establishing or evaluating the service areas for QHPs, subject to requirements that 1) the service area cover at least the entire geographic area of a county or group of counties unless the Exchange determines that serving a smaller area is necessary, nondiscriminatory and in the best interest of qualified individuals and employers and 2) the service area has been established without regard to factors regarding race, ethnicity, language and health status factors listed in section 2705(a) of the PHS Act[3], or other factors that exclude specific high utilizing, high cost or medically underserved populations. HHS indicates that the first requirement follows the "county integrity rule" established for Medicare Advantage.

[3] These are medical condition (including both physical and mental illnesses), claims experience, receipt of health care, medical history, genetic information, evidence of insurability (including conditions arising out of acts of domestic violence, disability and other health status-related factor determined appropriate by the Secretary.

HHS notes that the Exchange would have discretion to pre-determine service areas, permit plans to propose coverage of certain service areas, or negotiate with issuers over service areas during the certification process. HHS intends this to provide choice and competition while guarding against discrimination, cherry-picking and red-lining, and to recognize that the capacity of issuers varies by region due to some factors outside their control.

Stand-alone dental plans (§155.1065). Exchanges would be required to allow the offering of a limited scope dental health benefits plan through the Exchange if the plan is an excepted benefits limited scope dental plan under the tax code and the PHS Act and it covers at least the pediatric dental essential health benefit. The Exchange may allow the plan to be offered as a stand-alone dental plan or in conjunction with a QHP. If a stand-alone dental plan is offered through the Exchange, a plan could be certified as a QHP if it does not offer the pediatric dental essential health benefit. HHS is considering an interpretation of this provision that would allow an Exchange to require issuers of stand-alone dental plans to comply with QHP certification requirements and consumer protections that the Exchange determines to be relevant and necessary. These might include requirements regarding quality reporting, transparency, summary of coverage information, provider networks, and standards regarding consume experience in comparing and purchasing dental plans. **HHS seeks comments on whether some of the requirements of QHPs should also apply to stand-alone dental plans as a Federal minimum and what limits Exchanges may face in placing requirements on dental plans given that they are excepted benefits. Comments are also sought on whether specific operational minimum standards should be set**. HHS notes that substantial operational issues exist with allocating advance payments of tax credits and determining actuarial value when stand-alone dental plans segment coverage of the essential benefits. Additionally, QHPs will need sufficient notice as to whether they must include pediatric dental benefits. **HHS also seeks comment on whether to, as suggested by some commenters in response to the RFC, require that all pediatric dental benefits be offered and priced separately from medical coverage even when offered by the same issuer.**

Recertification of QHPs. (§155.1075). The Exchange would be required to provide a process for recertification and notification of QHPs that includes a review of the general certification criteria. The recertification process would be required to be completed by the Exchange on or before September 15th. No frequency is proposed; the Exchange would determine the frequency of recertification, which could be annually or less frequently. **HHS seeks comments on whether to require a more specific term length for recertification, and the appropriateness of the September 15th deadline.** HHS notes that as specified elsewhere, some Exchange review requirements would be required annually, such as rate information and benefit design, regardless of whether recertification was annual.

Decertification of QHPs. (§155.1080). A decertification process would be required of the Exchange under which the Exchange may decertify a QHP at any time if the issuer is no longer in compliance with the general certification criteria. The process would include an appeals process and notices to the issuer; Exchange enrollees in the QHP, who would receive information about a special enrollment period; HHS; and the State department of insurance. HHS notes that the Exchange would have discretion in determining how to implement this requirement, and recommends that Exchanges seek input from a broad range of stakeholders,

including issuers, and suggests that the appeals process could be implemented in conjunction with the State insurance department. **HHS seeks comments on the creation of the decertification process and authorities that could be extended to the Exchange to make the process more efficient.**

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

This part contains proposed standards for QHPs and QHP issuers. Many provisions cross-reference parallel standards proposed in part 155 for States and Exchanges.

1. Subpart A - General Provisions

Basis and scope (§156.10). HHS specifies the statutory authorities under the ACA for the proposed regulation and states that the scope of the proposal is to establish standards for QHPs under the Exchanges, and address other health insurance issuer requirements.

Definitions (§156.20). HHS proposes definitions, many of which are taken directly from the ACA. The proposal notes that the definitions apply to this part (Part 156) unless otherwise indicated. Some of the definitions cross reference the definitions previously summarized in §155.20 (proposed definitions for Part 155, Exchange Establishment Standards) and 45 CFR §144.103 (current Federal regulations defining health coverage.)

- Benefit design standards: coverage that provides for all of the following:
  - The essential health benefits as described in section 1302(b) of the ACA;
  - Cost sharing limits as described in section 1302(c) of the ACA;
  - A bronze, silver, gold, or platinum level of coverage, or a catastrophic plan, as described in sections 1302(d) and (e) of the ACA.
- Level of coverage: one of the four standardized actuarial values as defined by section 1302(d)(2) of the ACA.
- Applicant, benefit year, cost sharing, cost sharing reductions, plan year, qualified employer, qualified health plan, qualified health plan issuer, qualified individual: same meaning as in §155.20.
- Group health plan, health insurance coverage, health insurance issuer or issuer: same meaning as in §144.103.

Financial support (§156.50). HHS proposes that participating issuers must remit any user fee payments that are assessed by an Exchange under §155.160 to support ongoing operations. It defines a participating issuer as any issuer participating in the functions funded by that fee, including health insurance issuers, QHP issuers, issuers of multi-State plans, issuers of stand-alone dental plans, or other issuers identified by an Exchange.

2. Subpart B - [Reserved]

3. Subpart C - Qualified Health Plan Minimum Certification Standards

HHS notes that the ACA calls for minimum QHP standards that will foster direct competition based on price and quality and will increase access to high quality, affordable health care for individuals and small employers. Each Exchange will have the discretion to set additional standards to ensure that offering the plan is in the best interest of consumers.

HHS states that, unless otherwise noted, the QHP standards proposed apply specifically to the certification of QHPs for participation in the Exchange. They do not supersede existing State laws or regulations applicable to health insurance issuers, and do not exempt health insurance issuers from State laws or regulations that generally apply to health insurance issuers in that State. If a State establishes a higher standard for licensure, such standard would apply.

QHP issuer participation standards (§156.200) General requirement (§156.200(a)). HHS proposes that health insurance issuers must have in effect a certification recognized or issued by an Exchange to demonstrate that each plan it offers in the Exchange is a QHP.

QHP issuer requirement (§156.200(b)). HHS proposes that a QHP issuer must comply with standards that are set forth in the proposed rules or that will be the subject of further rulemaking.

(1) It must comply with all minimum certification standards on an ongoing basis, not just on initial certification.
(2) It must comply with any Exchange processes, procedures, and standards under subpart K of part 155, and §155.705 (for the small group market).
(3) It must t ensure that each QHP complies with benefit design standards in §156.20.
(4) It must be licensed (which can include a certificate of authority, or any other method of State approval) and in good standing in each State in which the issuer offers health insurance coverage. HHS interprets "good standing" to mean that the issuer has no outstanding sanctions imposed by a State's department of insurance, and seeks comments on that interpretation.
(5) It must implement the quality improvement standards and reporting required under section 1311 of the ACA (which HHS notes will be addressed in future rulemaking).
(6) It must pay any applicable user fees under §156.50.
(7) It must comply with standards for the risk adjustment program under part 153.

QHP offering requirements (§156.200(c)). HHS proposes that QHP issuers must offer at least one QHP at the silver coverage level and one at the gold coverage level; a child-only plan at the same levels of coverage the issuer offers in the Exchange (except for catastrophic coverage); and at premium rates consistent with §156.255.

State requirements (§156.200(d)). HHS proposes that QHP issuers must meet any additional standards applied by the Exchange or the State.

Non-discrimination (§156.200(e)). HHS proposes that QHP issuers must not discriminate based on race, color, national origin, disability, age, sex, gender identity or sexual orientation. HHS

notes that such practices would include, but not be limited to, marketing, outreach and enrollment.

QHP rate and benefit information (§156.210). HHS proposes that QHP issuers set rates for an entire benefit year, or, in the case of the SHOP Exchange, a plan year. HHS proposes that issuers must submit rate and benefit information to an Exchange as required in §155.1020, and notes its intent to align the required data elements with information already collected as part of the rate review program and State rate filing process

HHS proposes that QHP issuers must submit to the Exchange justification for a rate increase prior to implementation. HHS notes that Exchanges may leverage the information and consider the justification described in 45 CFR 154, as appropriate, and that it is considering a standard in which the issuers will submit a rate justification in a form and manner determined by the Exchange.

HHS proposes that QHP issuers prominently post the justification for a rate increase on their websites, and notes that it is considering standards for "prominently posting."

Transparency in coverage (§156.220). Required information (§156.220(a)): HHS proposes that QHP issuers comply with statutorily required disclosures on claims payment policies and practices; periodic financial disclosures; data on enrollment, disenrollment, the number of claims denied, and rating practices; information on cost-sharing and payments for any out-of-network coverage; and information on enrollee rights under title I of the ACA.

Reporting requirement (§156.220(b)): HHS proposes that the information be submitted in an accurate and timely manner, to be determined by HHS, to the Exchange, HHS, and the State Insurance Commissioner, and made available to the public. **HHS seeks comment on whether issuers should be required to "submit" or to "make such information available" to the Exchange and other entities.**

Plain language (§156.220(c)): HHS proposes that the information be provided in "plain language" and notes that the ACA calls for the Secretaries of HHS and Labor to jointly develop and issue guidance on best practices for plain language writing, which is forthcoming.

Enrollee cost-sharing transparency (§156.220(d)): HHS proposes that QHP issuers make available to enrollees on a timely basis, on request, information on cost sharing for a specific service by a participating provider. The information must be available through an Internet website and other means for those without access to the Internet.

Marketing of QHPs (§156.225). HHS proposes that QHP issuers, and their officials, agents, employees and representatives must comply with any applicable State laws and regulations regarding marketing, and that the issuers not employ marketing practices that discourage the enrollment of individuals with significant health needs in QHPs.

HHS discusses and seeks comments in a number of areas regarding marketing. It notes that it considered setting detailed and uniform Federal standards, but was concerned about

the interaction with current State marketing rules, or unintentionally creating "safe harbors." It permits States and Exchanges to adopt additional requirements most appropriate to that State, and encourages Exchanges to work closely with State insurance departments to ensure that all health insurance issuers in the State are subject to the same minimum marketing requirements with equal consumer protections inside and outside the Exchange.

HHS is particularly concerned about marketing toward vulnerable populations, such as Medicare beneficiaries, for whom coverage under a QHP is not necessary, **and seeks comments on defining a standard under which QHP issuers would not misrepresent benefits, advantages, conditions, exclusions, limitations or terms of a QHP.**

HHS also seeks comments on the best means for an Exchange to monitor marketing practices to determine if an issuer has discouraged enrollment of individuals with significant health needs. It also seeks comments on applying a broad prohibition against unfair or deceptive marketing practices, noting that such a requirement would protect consumers from deceptive and misleading marketing practices and allow an Exchange to take action if the State's department of insurance or applicable State agency did not have the authority or capacity to do so.

Network adequacy standards (§156.230). HHS proposes that each QHP must ensure that its provider network: (1) includes essential community providers in accordance with §156.235; (2) complies with network adequacy standards set by the Exchange, and (3) is consistent with the Public Health Service Act's special rules for network plans (Sec. 2702(c) of the PHS Act), which provide for exceptions if a provider network does not have the capacity to serve additional enrollees, or in the case of an enrollee residing outside the network service area. HHS proposes that a QHP issuer make its provider directory available for publication online by the Exchange, and available to enrollees in hard copy upon request. The issuer must identify providers that are not accepting new patients. **HHS seeks comments on standards it might set to ensure that issuers maintain up-to-date provider directories.**

Essential community providers (§156.235). HHS proposes that QHP issuers included a sufficient number of essential community provides, where available, that serve predominantly low-income, medically-underserved individuals. The proposed rule specifies that it is not to be construed as requiring any health plan to provide coverage for any specific medical procedure provided by the essential community provider. HHS proposes to define essential community providers as those defined in section 340B(a)(4) of the PHS Act (covered entities for purposes of the 340B drug discount program) and in section 1927(c)(1)(D)(i)(IV) of the Social Security Act.

HHS discusses and seeks comments on its proposal for essential community providers. It notes that, while the ACA requires inclusion of essential community providers in QHP networks, HHS believes that it does not require that QHP issuers contract with all essential community providers. HHS considered establishing broad contracting requirements requiring that QHP issuers offer a contract to all essential community providers, or contract with such providers on an "any willing provider" basis. It notes that such a requirement would allow for continuity of

service for some enrollees in some communities, but that such a requirement may inhibit network design to incentivize higher quality, cost effective care through tiered networks.

HHS notes that "sufficiency" could be interpreted to mean that a QHP issuer would have to demonstrate to the Exchange that it has a sufficient number and distribution of essential community providers to ensure timely access for low-income, medically underserved individuals in the service area, and HHS solicits comments on how to define a "sufficient" number. It notes that States may elect more stringent requirements, including adoption of a blanket contracting agreement, and that a safe-harbor strategy for QHP issuers would be to offer contracts to all essential community providers, or to accept any willing essential community provider.

HHS notes that it is considering whether to provide separate consideration for integrated delivery network health plans where services are provided solely "in-house," including staff model plans and plans where the providers furnish services on an exclusive basis to members of the plan. **It seeks comments on whether it should create an exemption for such plans, and notes that such an exemption could be contingent on criteria such as evidence of services provided to low-income populations, compliance with national standards for culturally and linguistically appropriate services, or implementation of a plan to address health disparities.**

HHS notes that it continues to look at and seeks comments on the extent to which the definition of essential community providers should include other similar types of providers.

HHS also seeks comments on several payment provisions related to essential community providers. First, it discusses at length two potentially conflicting provisions in the ACA regarding payment of essential community providers and Federally Qualified Health Centers (FQHCs). Section 1311(c)(2) of the ACA states that nothing requires a QHP to contract with an essential community provider if the provider refuses to accept the generally applicable payment rates under the plan. This provision may conflict with section 1302(g) of the ACA which requires that QHP issuers pay FQHCs at the FQHC Medicaid payment system rate. HHS notes several approaches to reconciling these provisions. The potential approaches include requiring QHP issuers to pay at least the Medicaid rate for each FQHC participant, or permitting issuers to negotiate mutually agreed-upon payments with FQHCs as long as they are at least equal to the issuer's generally applicable payment rates. **HHS seeks comments on these or other potential approaches for resolving the potentially conflicting provisions.**

HHS also invites comments on payment for Indian health service providers qualifying as essential community providers. Here again, as noted above, section 1311(c)(2) of the ACA, which refers to generally applicable payment rates under the plan, must be reconciled with provisions in section 206 of the Indian Health Care Improvement Act, under which all Indian health providers have rights to recover amounts up to reasonable charges billed, or, if higher, the highest amount the insurer would pay to other providers**. HHS invites comments on how these provisions could be reconciled. HHS also invites comments on other special accommodations necessary when QHPs contract with Indian health providers, including the possibility a standardized provider contract addendum for such providers.**

Treatment of direct primary care medical homes (§156.245). HHS proposes that QHP issuers may provide coverage through a direct primary care medical home meeting criteria established by HHS. HHS interprets "direct primary care medical home" to be an arrangement where a fee is paid by or on behalf of an individual directly to a medical home for primary care services. It specifically notes that it would be consistent with the program established in Washington State. HHS notes that it considered allowing an individual to purchase a direct primary care medical home plan, with separate wrap-around coverage, but did not adopt this option.

Health plan applications and notices (§156.250). HHS proposes that QHP issuers provide all applications and notices to enrollees in accordance with the standards described in §155.230(b) (i.e. available to the Exchange for publication online, and hard copies on request).

Rating variations (§156.255). HHS notes that the ACA limits variation in premium rating to four factors: whether coverage is for an individual or family; the rating area; age; and tobacco use. HHS notes that specific rating rules will be set in a separate regulation, but proposes several rate-related provisions for QHPs in this proposed rule.

HHS proposes that a QHP issuer, including a multi-State QHP, may vary premiums by the rating areas set under section 2701 of the PHS Act. HHS further proposes that a QHP issuer must charge the same premium rate without regard to whether the plan is offered through an Exchange, directly from the issuer or through an agent.

HHS proposes that premiums vary among no more than four categories related to family size: (1) individuals; (2) two-adult families; (3) one-adult families with a child or children; and (4) all other families. HHS notes that issuers may combine the categories (for example, combining the 2nd and 3rd groups into one rating category.)

HHS notes that the rating factors related to family size have significant implications, and seeks comments in several areas. It notes that the statutory provision for age and tobacco rating may apply only to the portion of the premium attributable for each family member, **and seeks comments on how to apply those rating provisions to the family premiums. HHS also seeks comments on how to apply the four family categories when performing risk adjustment. Finally, HHS seeks comments on the four family size categories, seeking to balance the need to reduce consumer confusion while maintaining structures that are similar to those currently available.**

HHS also notes that it is considering whether to require QHP issuers to cover an enrollee's tax household, because of the challenge of administering the premium tax credit, particularly for households with non-spousal adult dependents**, and seeks comments on this approach.**

Enrollment periods for qualified individuals (§156.260). HHS proposes that QHP issuers must accept and enroll qualified individuals during the initial and annual open enrollment periods described in §155.410(b) and (e), and, at a minimum, the special enrollment periods described in §155.420(d), and abide by the effective dates of coverage under those provisions. QHP issuers must provide enrollees with notice of their effective dates of coverage.

HHS notes that it proposes that individuals who make QHP selections on or before December 22, 2013 would have a coverage effective date of January 1, 2014, and individuals who make a QHP selection between the twenty-third and last day of the month for any month through February, 2014 would have coverage effective on the first day of the month immediately following the next month.

Enrollment process for qualified individuals (§156.265). HHS proposes a set of standards for QHP issuers enrolling qualified individuals. HHS notes a general principal that the Exchange and the QHP issuer must use a common set of enrollment information, with one streamlined application.

If an individual initiates enrollment with the issuer, the QHP must collect enrollment information using the application adopted under §155.405; transmit the enrollment information to the Exchange as described in §155.260 and §155.270; and enroll an individual only after receiving confirmation from the Exchange in accordance with §155.200(c).

A QHP must accept enrollment information in an electronic format from the Exchange consistent with §155.260 and §155.270. **HHS seeks comments on how frequently plans should receive such information.**

A QHP issuer must follow the premium payment process established by the Exchange under §155.240, and provide an enrollment information package to new enrollees. HHS suggests several items that might be included, and **seeks comments on standards for the content of the enrollment information package.** QHPs also must provide a summary of benefits and coverage as specified in section 2715 of the PHS Act.

A QHP issuer must reconcile enrollment files with the Exchange at least once a month, and acknowledge receipt of enrollment information, in accordance with standards under §155.400.

Termination of coverage for qualified individuals (§156.270). HHS notes that a key function for Exchanges is to verify a QHP issuer's procedures for terminating coverage, and proposes standards for QHP issuers terminating coverage.

A QHP issuer may terminate coverage only as permitted under §155.430(b). The QHP issuer must provide the enrollee and the Exchange with a notice of termination of coverage consistent with the effective date under §155.430(d). HHS notes that it plans to issue standards for the termination notice, and solicits comment on what should be included.

A QHP issuer must establish a standard policy, that must be applied uniformly to enrollees in similar circumstances, for termination of coverage due to non-payment of premiums consistent with §155.430(b)(2)(iii), including provision for a grace period for enrollees receiving premium tax credits. The grace period must be at least three consecutive months if the enrollee receiving advance payments of the premium tax credit previously paid at least one-month's premium. During the grace period, the QHP issuer must pay all appropriate claims, apply all payments received to the first billing cycle in which payment was delinquent, and continue to collect advance payments of the premium tax credit from the Department of the Treasury. HHS notes

that the grace period will reset only when the individual has fully paid all outstanding premiums. If a grace period is exhausted without the enrollee submitting any premium payment, the QHP issuer may terminate the enrollee's coverage effective at the end of the grace period. The QHP issuer must abide by the termination of coverage effective dates in §155.430(d).

A QHP issuer must provide notice to enrollees who are delinquent on premium payment. HHS plans to issue standards for such notice, and **seeks comment on the potential required elements of such a notice.**

A QHP issuer must maintain records of termination of coverage in accordance with §155.430(c).

Accreditation of QHP issuers (§156.275). HHS proposes that QHP issuers must be accredited on the basis of local performance (performance in the State in which the QHP is licensed) by an accrediting entity recognized by HHS. HHS notes that it intends to establish standards by which HHS will recognize accrediting entities in future rulemaking, and **seeks comments on those standards**. HHS notes that it may model the process in part on similar processes it uses to identify accrediting organizations for Medicare Advantage plans, which are found at 42 CFR §§422.157-158.

QHP issuers must be accredited in the following categories identified in statute: clinical quality measures such as the Healthcare Effectiveness Data and Information Set, patient experience ratings on a standardized CAHPS survey, consumer access, utilization management, quality assurance, provider credentialing, complaints and appeals, network adequacy and access, and patient information programs.

A QHP issuer must authorize the accrediting agency to release to the Exchange and HHS a copy of its most recent survey, along with survey-related information that HHS may require, such as a corrective action plan and summaries of findings.

A QHP issuer must be accredited within the timeframe established under §155.1045, and must maintain accreditation so long is it offers QHPs.

Segregation of funds for abortion services (§156.280). HHS notes that 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), and that the ACA includes provisions to enforce this policy. HHS proposes in §156.280 the codification of section 1303 of the ACA. In addition, HHS notes that 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, which may serve as the basis for final rules, and **HHS is soliciting comments on the model guidelines as well.**

HHS proposes the following:

State opt-out of abortion coverage (§156.280(a)). QHP issuers must comply with State law if a State enacts a law that prohibits coverage of abortions in QHPs.

Termination of opt out (§156.280(b)). A QHP issuer may provide coverage of abortion services through the Exchange in a State described in (a) if the State repeals such law.

Voluntary choice of coverage of abortion services (§156.280(c)). Nothing in the ACA shall be construed to require a QHP issuer to provide coverage of abortion services as part of its essential health benefits. The QHP issuer must determine whether or not the QHP provides such coverage.

Abortion services (§156.280(d)). (1) The abortion services for which public funding is prohibited are abortion services for which the expenditure of Federal funds appropriated for HHS is not permitted based on the law in effect as of the date that is 6 months before the beginning of the plan year involved.

(2) The abortion services for which public funding is allowed are abortion services for which the expenditure of Federal funds appropriated for HHS is permitted based on the law in effect as of the date that is 6 months before the beginning of the plan year involved.

Prohibition on use of Federal funds (§156.280(e)). (1) if a QHP issuer covers abortion services described in (d)(1) (i.e. abortion services for which public funding is prohibited), it must not use any amount attributable to any of the following for purposes of paying for such service: (i) the tax credit under section 36B of the Internal Revenue Code, and the amount (if any) of the advance payment of the credit under section 1412 of the ACA; (ii) any cost sharing reduction under section 1402 of the ACA and the amount (if any) for the advance payment of the reduction under section 1412 of the ACA.

(2) in the case of a QHP issuer described in (e)(1) (immediately above), the 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 paid directly by the enrollee for coverage under the QHP of services other than the abortion services described in (d)(1), after reductions for credits and cost-sharing reductions described in (e)(1); and
> (B) An amount equal to the actuarial value of the abortion services described in (d)(1).

(ii) deposit all such separate payments into separate allocation accounts is provided in section (e)(3) (immediately below). In the case of an enrollee whose premium is paid through an employee payroll deposit, the separate payments shall each be paid by a separate deposit.

(3) Segregation of funds: the QHP issuer must establish separate allocation accounts for the funds collected under (e)(2)(i)(A) and (B) that are used exclusively for those purposes.

(4) Actuarial value: the QHP issuer must estimate the basic per enrollee, per month cost, on an average actuarial basis, for coverage of the abortion services under (d)(1). The issuer may take into account the impact on overall costs of the inclusion of such coverage, but may not take into account any cost reduction resulting from such services, including prenatal care, delivery, or

postnatal care. The issuer must estimate such costs as if the coverage were included for the entire population covered, and may not estimate a cost at less than $1 per enrollee per month.

(5) Ensuring compliance with segregation requirements: the QHP must comply with the State health insurance commissioner to ensure compliance with the segregation of QHP funds in accordance with generally accepted accounting principles, circulars on funds management by the OMB and guidance on accounting from the GAO. Nothing prohibits the right of an individual or QHP issuer to appeal such action in a court of competent jurisdiction.

Rules relating to notice (§156.280(f)). A QHP providing coverage of abortion services under (d)(1) must provide notice to enrollees only as part of the summary of benefits and coverage at the time of enrollment. The notice, any advertising, any information provided by the Exchange, and any other information specified by HHS must provide information only with respect to the total amount of combined payment for services described in (d)(1) and other services covered by the QHP.

No discrimination on basis of provision of abortion (§156.280(g). No QHP offered through an Exchange may discriminate against any health care provider or facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions.

Application of State and Federal laws regarding abortions (§156.280(h)). Nothing in the ACA is to be construed as preempting or otherwise having an effect on State laws regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions, including parental notification or consent for minors. Nothing in the ACA is to be construed as having any effect on Federal laws regarding conscience protection, willingness or refusal to provide abortion, and discrimination on the basis of willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion. Nothing in section 103(c) of the ACA alters the rights and obligations of employees and employers under Title VII of the Civil Rights Act of 1964.

Application of emergency services laws (§156.280(i)). Nothing in the ACA is to be construed to relieve any health care provider from providing emergency services as required under State or Federal law, including "EMTALA."

Additional standards specific to the SHOP (§156.285). In general, HHS proposes that QHP issuers meet the same requirements for the SHOP Exchange as for the non-group Exchange, and proposes several additional requirements proposed in this subsection that generally link the QHP provisions to previously noted SHOP Exchange requirements.

SHOP rating and premium payment requirements (§156.285(a)). HHS proposes that QHP issuers in a SHOP must accept payment from the SHOP and adhere to the SHOP timeline for rating. HHS notes that QHP issuers may establish new rates on quarterly or monthly basis, but HHS proposes that QHP issuers charge the same contract rate for a plan year.

Enrollment periods (§156.285(b)). HHS proposes that QHP issuers in a SHOP must enroll a qualified employee in accordance with the employer's annual open enrollment period and

provide for special enrollment periods described in §155.420, excluding (d)(3) and (d)(6). The first exclusion, (d)(3), is because non-lawfully present individuals employed by a small business are not eligible for SHOP, there would be no special enrollment period associated with becoming a new citizen, national or lawfully present for SHOP. The second exclusion, (d)(6), is that there is no special enrollment period in the SHOP to reflect change in eligibility for advance payments of the premium tax credits or cost sharing, since neither subsidy is available to individuals in the SHOP Exchange. QHP issuers must also establish an effective date for coverage as provided in §155.410(c). HHS notes that it is considering whether to require QHPs in a SHOP to allow employers to offer dependent coverage, and **solicits comments on that requirement.**

Enrollment process (§156.285(c)). HHS proposes that QHP issuers in a SHOP abide by the enrollment process and timeline set under §155.720(b), and abide by standards set out related to receipt of enrollment information in an electronic format from the SHOP, the enrollment information package, the summary of benefits and coverage document, reconciliation of enrollment files with the Exchange at least monthly, acknowledgement of receipt of enrollment information, and enrollment of qualified employers consistent with the plan year of the employer.

Termination of coverage in the SHOP (§156,285(d)). HHS proposes that QHP issuers abide by the previously noted general requirements for termination of coverage, including requirements for notices to employees, and HHS adds notice to employers. HHS proposes that if a qualified employer withdraws from participation in the SHOP, the QHP must terminate coverage for all enrollees of that employer.

Non-renewal and decertification of QHPs (§156.290). HHS proposes requirements for a QHP that elects not to seek recertification with the Exchange. It must notify the Exchange prior to the beginning of the recertification period, which HHS notes will allow time for the Exchange to determine if it should modify its certification process to increase the number of QHPs in the Exchange. The QHP must continue covering benefits until the completion of the benefit year (or plan year for the SHOP), fulfill data reporting obligations, and provide written notice of non-renewal to enrollees. HHS notes that it will issue future guidance on the content and timing of the notice, and that it may adopt some of the concepts from the Medicare Advantage non-renewal notice. **HHS solicits comments on the notice.**

HHS proposes, in the event that a QHP is decertified by an Exchange, that the QHP issuer must terminate coverage only after the Exchange has made the notification required under §155.1080, and the enrollees have an opportunity to enroll in other coverage. **HHS seeks comments on whether enrollees should continue to receive coverage from a decertified plan, even if only for a short period of time.**

Prescription drug distribution and cost reporting (§156.295). HHS proposes that a QHP issuer provide specified information on prescription drug distribution and costs. That includes detailed information on percentages of prescriptions through retail and mail order pharmacies, and data on generic dispensing broken down by pharmacy type. Further, it includes the aggregate amount and type of rebates, discounts, and price concessions, with specified exceptions, negotiated by the QHP issuer or its contracted pharmacy benefit manager (PBM)

attributable to patient utilization under the plan, the aggregate amount passed through to the QHP issuer, and total prescriptions dispensed. Finally, it includes the difference between the amount the QHP issuer pays its contracted PBM, the amount that the PBM pays pharmacies, and total prescriptions dispensed.

HHS proposes confidentiality and disclosure requirements, so that the information is not disclosed by HHS or the QHP issuer except under specific circumstances, which would allow HHS to de-identify and aggregate prescription drug pricing for reporting to the GAO, the CBO, or the States as well as for carrying out the PBM Transparency Program under section 1150A of the SSA and the Medicare Part D Voluntary Prescription Drug Program.

HHS proposes penalties for noncompliance as set out in the statute.

HHS notes that it anticipates issuing guidance on these reporting requirements, and **seeks comment on how a contracted PBM that operates its own mail order pharmacy can meaningfully report on the difference between what a QHP pays the PBM and what the PBM pays the pharmacy.** HHS further clarifies that it defines generic drug as the meaning given the term in the Medicare Prescription Drug Benefit Program**. It seeks comments on potential definitions for "rebates," "discounts," and "price concessions" and notes that it is considering using the term "direct and indirect remuneration", which is used in the Medicare Prescription Drug Benefit Program. HHS further seeks comments on how it should define PBMs, as well as on how to minimize the burden of the reporting requirements.**

III. Collection of Information Requirements

HHS is required, under the Paperwork Reduction Act of 1995**, to solicit comment on information collection requirements (ICRs), and identifies four areas for comment.**

- **The need for the information collection and its usefulness in carrying out the proper functions of the agency.**
- **The accuracy of the estimates of the 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.**

Those interested in commenting on these issues should submit the information electronically as noted in the introduction to the rule, or submit them to:

Office of Information and Regulatory Affairs
Office of Management and Budget
Attention: CMS Desk Officer, [CMS-9989-P]
Fax: 202-395-5806, or
Email: OIRA_submission@omb.eop.gov

HHS estimates that all 50 States and the District of Columbia will establish an Exchange, and a SHOP Exchange, and notes that this should be considered an upper bound, and subject to revised estimates in the final rule.

A. ICRs Regarding General Standards Related to the Establishment of an Exchange (§155.105 and §155.110). The proposed rule sets out reporting requirements for a State to establish an Exchange. HHS notes that most of the information needed for the plan will be gathered through the planning grants provided by HHS. HHS estimates that it will take about 160 hours to prepare and submit a plan to HHS, and another 40 hours to make governance principles available to the public. The estimated cost burden for each State for those 200 hours is $11,320, with a total burden of $577,320. HHS also estimates that five States will submit changes to the plans, which will take 12 hours per State, at a per State cost of $516 and total burden of $2,580 for those five States.

B. ICRs Regarding General Functions of an Exchange (§155.205). The proposed rule sets out information and reporting requirements for Exchanges, and in particular the collection and dissemination of information through the website. HHS notes that the cost of development and testing of the website is included in the impact analysis for the Exchanges. HHS estimates that it will take 320 hours for each State to fulfill these ongoing ICRs, with a total cost burden per State of $18,710, and a total estimated burden of $954,210.

C. ICRs Regarding Exchange Functions; Enrollment in Qualified Health Plans (§155.400-§155.430). The proposed rule sets out information and reporting requirements for Exchanges for the enrollment and disenrollment of qualified individuals. HHS estimates that it will take 436 hours for each Exchange to maintain the required records, submit and reconcile the required monthly information to HHS, and provide required notices to applicants and enrollees. The cost burden per State would be $24,598, with a total estimated burden of $1,254,498.

D. ICRs Regarding Exchange Functions. Small Business Health Options Program (SHOP) (§155.715 - §155.725). The proposed rule sets out reporting requirements for SHOP Exchanges. HHS estimates that it will take each SHOP Exchange 356 hours to meet the requirements, for an estimated cost burden of $19,756 per Exchange, and a total estimated burden of $1,007,556.

E. ICRs Regarding Exchange Functions. Certification of Qualified Health Plans (§155.1020, §155.1040, and §155.1080). The proposed rule sets out ICRs for Exchanges related to the certification of QHPs. HHS estimates that it will take each Exchange 40 hours to meet the requirements, with an estimated cost burden of $2,376 per Exchange, and a total estimated burden of $121.176.

F. ICRs Regarding Qualified Health Plan Minimum Certification Standards (156.210 - §156.290). The proposed rule sets out reporting requirements for issuers of QHPs. HHS estimates approximately 1,827 issuers in the small group and individual market. HHS estimates that it will take each issuer 588 hours to meet the requirements, with a cost burden of $31,324 per issuer, and a total estimated burden for the 1,827 issuers of $57.2 million.

IV. Regulatory Impact Analysis and Other Requirements

The Regulatory Impact Analysis is provided as Attachment A to this summary.

Regulatory Flexibility Act. The Regulatory Flexibility Act (RFA) requires agencies to prepare an initial regulatory flexibility analysis of the impact on small entities, unless the agency head certifies that the rule will not have a significant impact on a substantial number of small entities. HHS reviews the potential entities impacted, and **requests comments on whether the small entities have been fully identified, potential costs for these entities, and any alternatives it should consider**.

Unfunded Mandates. Section 202 of the Unfunded Mandates Reform Act requires agencies to assess anticipated costs and benefits in the case of any Federal mandate that will result in costs on States, local, or tribal governments in excess of a threshold that is approximately $136 million in 2011. Because States are not required to set up an Exchange, and grants are available for those that choose to, HHS anticipates that the proposed rule would not impose costs above that $136 million threshold.

Federalism. Executive Order 13132 establishes requirements on agencies when proposed rules have Federalism implications. HHS certifies that it has complied with the requirements, which include close cooperation.

ATTACHMENT:
PRELIMINARY REGULATORY IMPACT ANALYSIS

The Centers for Medicare and Medicaid Services (CMS) prepared a "Preliminary Regulatory Impact Analysis" of the two proposed rules, on the Establishment of Exchanges and Qualified Health Plans, and on Standards Related to Reinsurance, Risk Corridors and Risk Adjustment. That combined analysis is available at http://cciio.cms.gov/resources/files/cms-9989-p2.pdf, and each of the proposed rules includes a brief summary of the impact analysis.

I. Executive Orders

OMB has determined that the proposed rules are "economically significant" under the executive orders that govern regulatory review, because it is likely to have an annual effect of more than $100 million in any one year. As a result, CMS prepared the Regulatory Impact Analysis (RIA) to present the costs and benefits. CMS reviews briefly the provisions in the two notices of proposed rulemaking and their statutory basis.

II. Estimates of the Impact of Exchanges

CMS notes that the RIA references estimates of the CMS Office of the Actuary (April 22, 2010), but primarily uses the underlying assumptions and analysis conducted by the Congressional Budget Office (CBO) and the staff of the Joint Committee on Taxation (JCT), because that modeling accounted for all of the interactions among the interlocking pieces of the ACA.

CMS presents in Tables 1 and 2 estimates of outlays and receipts for the insurance Exchanges, based on the CBO data, and those tables are summarized below.

Estimated Outlays and Receipts for the Insurance Exchanges, FY 2012-2016, in billions of dollars					
	2012	**2013**	**2014**	**2015**	**2016**
Outlays					
Grant authority for Exchange Start-up	$0.6	$0.8	$0.4	$0.2	$0.0
Reinsurance and risk adjustment program payments	--	--	$11	$18	$18
Receipts					
Reinsurance and risk adjustment program receipts	--	--	$12	$16	$18
Source: Tables 1, 2 in CMS RIA Note: Risk adjustment payments lag receipts by one fiscal quarter					

CMS notes that the start-up funding for Exchanges is funded through a separate grant program.

CMS also presents in Table 3 the estimated number of people enrolled in Exchanges, based on the CBO data.

Estimated Number of People Enrolled in Exchanges, CY 2012-2016, in millions					
	2012	**2013**	**2014**	**2015**	**2016**
Total Exchange Enrollment	--	--	9	14	22
Exchange Enrollees Receiving Tax Credits	--	--	8	12	18
Employment-Based Coverage Purchased Through Exchanges	--	--	3	2	3
Change to Uninsured Coverage	-3	-3	-21	-26	-32
Source: Table 3 in CMS RIA					

III. Benefits

CMS notes that it is difficult to assess benefits of the various provisions of the ACA in isolation, as different elements work together to achieve the goal of making affordable health insurance available to individuals without access to affordable employer-sponsored coverage. CMS describes benefits in four areas.

- Utilization and outcomes: CMS cites studies that show that health insurance coverage improves utilization and health outcomes.
- Financial security: CMS cites studies showing the insecurity associated with a lack of insurance, and the mitigation of financial risk provided by health insurance.
- Uncompensated care: CMS cites studies showing that insurance coverage reduces uncompensated care.
- Premiums: CMS cites CBO's estimates that the Exchange policies would reduce premiums for the same benefits compared with prior law, in particular in the individual market Those savings come from a healthier risk pool resulting from the coverage expansion, as well as lower administrative costs

IV. Costs

CMS presents a review of the impact of Exchanges and on Qualified Health Plans.

Exchanges: CMS notes that the start-up of the Exchanges will be funded through the State Planning and Establishment Grants, with total grant outlays estimated at $2 billion through 2014. Starting in 2015, Exchanges must be self-sustaining and require another source of funding.

CMS reviews a number of functional areas of potential costs: developing and maintaining the Exchange plan; information technology and IT infrastructure, implementation of the Navigators provisions, notifications to applicants, enrollees, and employers, enrollment standards, the applications process, certification of QHPs, and implementation of the SHOP provisions. CMS does not provide cost estimates (apart from those noted in the summary for the information

collection requirements) because States have a great deal of flexibility in how they will set up their Exchanges, and must finance these costs on a self-sustaining basis through user fees or other such mechanisms.

Requirements on QHP Issuers: CMS notes that the cost of participating in the Exchange is an investment for QHP issuers, with substantial benefits expected for the issuer. The Exchange is a centralized outlet to attract and enroll consumers, coupled with market reforms and administrative efficiencies, which can lower sales, marketing and administrative costs, reduce premiums and help attract consumers.

CMS reviews a number of functional areas of potential costs for QHP issuers: securing accreditation, meeting network adequacy standards, and complying with premium rating rules. CMS does not provide cost estimates.

V. Impacts of the Proposed Rule on Standards Related to Reinsurance, Risk Corridors and Risk Adjustment

CMS reviews the impact of the proposed rules for the three risk sharing programs: transitional reinsurance, transitional risk corridors, and the permanent risk adjustment program. CMS notes that insurers charge premiums for expected costs plus a "risk premium. These programs reduce the risk of financial loss that issuers might otherwise expect in 2014, and the issuer can pass on a reduced risk premium to enrollees.

Reinsurance: The reinsurance pool is, by statute, $10 billion in 2014, declining to $6 billion in 2015 and $4 billion in 2016, plus an additional contribution of $2 billion in 2014 and $2015 and $1 billion in 2016. CMS notes that the funds are collected from all issuers, including insured and self-insured markets, but only issuers in the individual market are eligible for payments, so it is redistributive from the non-individual market to the individual market in order to stabilize and limit premium increases in that market in the initial years. CMS estimates that the cost of contributions to the pool will be passed on to enrollees through premium increases of about one percent in the total market, and the benefits of reinsurance will result in premium decreases in the individual market of 10-15 percent. As the reinsurance contributions decrease, their impact on the market will decline, which CMS notes tracks with decreased uncertainty in the market as experience is gained.

Risk corridors: CMS describes the risk corridor program as one that protects against rate setting uncertainty by limiting the amount of insurer losses and gains in the initial three years. It is an "after the fact adjustment to premiums" based on experience. Risk corridors are designed to shift cost from plans that overestimate their risk to plans that underestimate their risk. CMS provides no estimate of the impact.

Risk adjustment: CMS describes the permanent risk adjustment program as one that transfers dollars from health plans with the lowest risk to health plans with the highest risk. CMS estimates, based on CBO analyses, that $22 billion will be transferred among issuers. CMS states that this protects against overall adverse selection by allowing insurers to set premiums according to average actuarial risk. CMS notes that this should lower the risk premium and

allow insurers to price their products conservatively, and mitigate the incentive for health plans to avoid unhealthy members.

VI. Alternatives Considered

CMS notes the significant State flexibility provided under the proposed rules. That flexibility includes the governance structure of the Exchanges, the number of Exchanges in a State, whether to establish combined or separate individual and small business (SHOP) Exchanges, determination of the number and type and standardization of QHPs serving the exchange, and how to implement the requirement that the Exchanges be self-sustaining starting in 2015.

CMS reviews two alternatives it considered calling for less State flexibility: a uniform standard for operations of Exchanges, and a uniform standard for certifying QHPs. CMS sets out the advantages and disadvantages of those alternatives, and its rationale for rejecting them in favor of the proposed rule.

VII. Limitations of Analysis

CMS notes that the estimates are based on the CBO microsimulation model, and are both fair and realistic, but that there is fundamental uncertainty to the modeling: " ... there is greater uncertainty in estimating the impacts of implementing the Affordable Car Act and the Exchanges than in estimating implications of modifying a previously existing program." CMS notes uncertainty in any predictive model for a new program, along with uncertainty about external changes to the economy.