

Proposed Rules for State Insurance Exchanges

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This document provides a summary of the Department of Health and Human Services (HHS) proposed rule (CMS-9989-P) to implement state insurance exchanges and qualified health plans. Sections directly related to managed care pharmacy are highlighted in yellow. The proposed rule is available at: <http://www.gpo.gov/fdsys/pkg/FR-2011-07-15/pdf/2011-17610.pdf>

Comments on the proposed rule are due September 28, 2011.

Highlights of the proposed rule:

This proposed rule (page 41867):

- Sets forth federal requirements that states must meet if they elect to establish and operate an exchange;
- Outlines minimum requirements that health insurance issuers must meet to participate in an exchange and offer qualified health plans (QHPs); and
- Provides basic standards that employers must meet to participate in the small business health options program (SHOP).

Health plan standards set forth under this proposed rule are related to QHPs offered through the exchange and not the entire individual and small group market. (41868)

Each state electing to establish an exchange must adopt the federal standards contained in this law and this proposed rule, or have in effect a state law or regulation that implements these federal standards. (41867)

The HHS Secretary is responsible to establish and operate exchanges in states that either (41867, 41870):

- Do not elect to establish an exchange; or
- As determined by the Secretary on or before January 1, 2013, will not have an exchange operable by January 1, 2014. ("Fully operational" refers to operations being capable by October 1, 2013 to support initial open enrollment period.)

The ACA requires QHP issuers and sponsors of certain plans offered under Medicare Part D or title XVIII of the Act to provide data on the cost and distribution of prescription drugs covered by the plan. (41867-8)

Part 155: Exchange Establishment Standards and Other Related Standards Under the ACA

States may establish an exchange as a state agency or as a non-profit organization, and may choose to contract with other eligible entities to carry out various functions of the exchange. A state may also choose to partner with other states to form a regional exchange, or may establish one or more subsidiary exchanges within the state. (41870)

A state electing to operate an exchange after 2014 must have in effect an approved or conditionally approved exchange plan at least 12 months prior to the first effective date of coverage. (41871)

To the extent that the exchange establishes contracting arrangements with outside entities, it is proposed that the exchange remains responsible for meeting all federal requirements related to contracted functions. Pursuant to these provisions, states have flexibility to determine appropriate contracting entities within legal limits. Inviting comments on the extent to which conflict of interest requirements should be placed on contracted entities. (41872)

Proposed rules on exchange governance. (41872)

A state exchange must be self-sustaining by January 1, 2015; assessments and user fees on participating issuers a possibility for funding exchange operations. (41874)

An exchange must perform required functions related to oversight and financial integrity requirements and evaluate quality improvement strategies and oversee implementation of enrollee satisfaction surveys, assessment and ratings of health care quality and outcomes, information disclosures, and data reporting. (41875)

An exchange must provide a call center to respond to requests for consumer assistance that is accessible via toll-free telephone number. HHS seeking comment on ways to streamline and prevent duplication of effort by the exchange call center and QHP issuers' customer call centers. (41875)

Exchange must maintain an up-to-date internet web site that (41876):

1. Is an easy-to-use access point that serves as a primary source of information about available QHPs, exchange activities, and other sources of health coverage, including disclosure of information that would be helpful for consumers to compare QHPs with standardized comparative information, including:
 - Premium and cost-sharing information;
 - Summary of benefits and coverage;
 - The level of coverage (e.g. bronze, silver, gold, platinum or catastrophic coverage);
 - The results of enrollee satisfaction surveys;
 - Quality ratings assigned to QHPs;
 - The medical loss ratio;
 - And transparency of coverage.
2. Provides meaningful access to information for individuals with limited English proficiency.
3. Publishes financial information, such as the average cost of licensing required by the exchange, regulatory fees required by the exchange, administrative costs of the exchange, and monies lost to FWA.
4. Provides contact information for Navigators and other consumer assistance services.
5. Allows for eligibility determinations.
6. Allows for enrollment in coverage.

An exchange to establish an electronic calculator to assist individuals in comparing the costs of coverage in available QHPs after the application of any advance payments of the premium tax credit and cost-sharing reductions. (41876)

Exchange to conduct outreach and education activities to educate consumers about the exchange and to encourage participation. (41877)

General standard that exchanges must award grant funds to public or private entities to serve as Navigators with duties that include maintaining eligibility, enrollment, and program specification expertise and conducting public education activities to raise awareness of the availability of QHPs. (41877-8)

While contracted entities of exchanges may provide an additional avenue for the public to become aware of and access QHPs, advance payments of the premium tax credit and cost-sharing reductions may only be accessed through an exchange. Seeking comment on functions such entities can perform and scope of their interaction with exchanges. (41878)

An exchange has three options for the payment of premiums (41878):

1. To take no part in the payment of premiums (and the enrollee pays premium directly to the QHP);
2. To facilitate payment of premiums by enrollees by creating an electronic “pass-through” of premiums without directly retaining any of the payments; or
3. To establish a payment option where exchanges collect premiums from enrollees and pay an aggregated sum to the QHP issuers.

While HIPAA may provide an appropriate model for the protection of health information privacy, states are provided flexibility to create a more appropriate and tailored standard for all data, including tax return information. (41880)

Seeking comment on the duration of the initial enrollment period to allow for outreach and education beyond the first potential date of coverage. (41882)

Similar to when an individual is newly eligible for Medicare and has a period of time to begin coverage in Medicare and to select a Medicare Prescription Drug Plan, a qualified individual qualifies for may qualify for a special enrollment period. (41884)

Termination of enrollee coverage. (41885)

Exchange Functions for Small Business Health Options Program, SHOP, will offer set coverage level options (bronze, silver, gold or platinum plans) for employees to select plans within that coverage level option. (41885-90)

SHOP must process applications for enrollment from employees and facilitate enrollment of qualified employees into QHPs. (41889)

Proposing a rolling qualified employer enrollment process for the SHOP to match the enrollment process for the small group market outside of the SHOP. Qualified employees will only be able to enroll or change plans once a year unless such employees qualify for a special enrollment period. (41889)

Seeking comment on approach in differentiating the individual and small group market enrollment as well as specific comments concerning the proposed structure for initial, rolling, and annual open enrollment through the SHOP. (41890)

SHOP will use a single employer application to determine employer eligibility and to collect the information necessary for the employer to purchase coverage through the SHOP. (41890)

Exchange functions: Certification of qualified health plans. Proposal to set specific requirements to ensure QHPs in all exchanges meet a consistent minimum standard of quality and value while in other instances, proposal to allow each exchange the discretion to set standards for QHPs tailored to local market conditions. (41891-5)

- Exchanges have discretion on how to determine whether offering health plans is in the interest of individuals and employers. Exchange may elect to allow for any QHP to be in an exchange, a competitive bidding process, or decide on a case-by-case basis. (41891)
- Exchanges are prohibited from excluding a plan on the basis that it is a fee-for-service plan; through the imposition of premium price controls; or on the basis that the plan provides treatments necessary to prevent patient deaths in circumstances determined to be inappropriate or too costly. (41892)
- Multi-state plans will need to meet all the requirements of a QHP and each exchange must accept multi-state plans as QHPs without applying an additional certification process to such plans. (41892)
- Exchanges to have a process to establish or evaluate the QHP service areas, guarding against practices that would specifically exclude high-utilizing or high-cost populations. (41894)
- QHP recertification by September 15, prior to annual open enrollment period. (41895)
- Exchanges to determine decertification process and allow for plans to appeal. (41895)

Part 156: Health Insurance Issuer Standards Under the ACA, Including Standards Related to Exchanges

Proposed standards for QHPs and QHP issuers intended to promote robust and meaningful consumer (41895-905)

A QHP in an exchange must:

- Offer at least on QHP in the silver and gold coverage levels and offer child-only health plans to individuals under 21. (41897)
- Apply rates for an entire benefit year or, for the SHOP, by plan year - the timing of the rate changes will vary by employer. (41897)
- Meet quality and cost transparency standards. (41897)
- Make available to enrollees cost-sharing requirements for specific services. (41898)
- Meet provider network adequacy standards. (41898)
- Meet essential community provider standards that provide service to low-income and medically-underserved populations. (41899-900)
 - Proposal for standard contract addendum to be created for QHP issuers contracting with Indian health providers, similar to the special Indian Health Addendum currently used in the Medicare Prescription Drug Program. (41899)
- Receive enrollment information electronically from the Exchange (41902)
- Provide enrollees in the exchange with an enrollment package, to include information on how to access the provider directory and drug formulary and to submit a request for a hard copy. (41902)
- Verify procedures for the termination of coverage for enrollees enrolled in a QHP through the exchange. QHP issuers are required to provide enrollees receiving advance payments of the premium tax credit with a three-month grace period for non-payment of premium prior to coverage termination. (41902)

- Be accredited with an HHS approved entity and release certain materials related to the QHP's accreditation (e.g., a copy of its most recent accreditation survey) to the exchange and to HHS. (41903)
- Be required to provide HHS information on the distribution of prescription drugs, pharmacy benefit management activities, the collection of rebates and other monies in conducting these activities, and the costs incurred to provide these drugs. HHS and QHP issuer to uphold disclosure confidentiality. The exceptions allow HHS to de-identify and aggregate prescription drug pricing, rebate and distribution information to report it to the Comptroller General or the Congressional Budget Office. If the information is not provided at all, the QHP issuer would be subject to a fine that would increase \$10,000 each day that the information is not provided. If the information is not provided in 90 days of the set deadline, the QHP issuer would lose its contract with the exchange. If false information is provided, a fine not to exceed \$100,000 for each piece of false information provided. HHS seeking comment on how a QHP issuer whose contracted PBM operates its own mail order pharmacy can meaningfully report on the aggregate difference between what the QHP issuer pays the PBM and the PBM pays the mail order pharmacy. Reporting would include: (41904)
 - The percentage of all prescriptions that were provided under the contract through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug is available and dispensed compared to all drugs dispensed, broken down by pharmacy type, that is paid by the QHP issuer or PBM under the contract.
 - The aggregate amount, and the type of rebates, discounts or price concessions, with certain exceptions that the PBM negotiates that are attributable to patient utilization under the plan, and the aggregate amount of rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed.
 - The aggregate amount of the difference between the amount the QHP issuer pays the PBM and the amounts that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.

HHS seeks comment on potential definitions for "rebates," "discounts," and "price concessions," and on its proposed definition for "PBM."

ACA subjects for future rulemaking include, but are not limited to:

- Standards for individual eligibility for participation in the exchange, advance payments of the premium tax credit, cost-sharing reductions, and related health programs and appeals of eligibility determinations;
- Standards outlining the exchange process for issuing certificates of exemption from the individual responsibility requirement and payment; and
- Defining essential health benefits, actuarial value and other benefit design standards; and
- Standards for exchanges and QHP issuers related to quality. (41868)
- Specific standards that an exchange must grant certifications of exemptions from the individual responsibility requirement and payment.
- Specific standards and eligibility criteria for an exchange to perform eligibility determinations.
- Requirements for exchange to establish a process for appeals of eligibility determinations. (41875)
- Standards will be provided by which HHS will recognize entities that accredit QHP issuers. (41903)

- Providing HHS information required by QHP issuer on the distribution of prescription drugs, pharmacy benefit management activities, the collection of rebates and other monies in conducting these activities, and the costs incurred to provide these drugs. (41904)