

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Part 170****Planning and Establishment of State-Level Exchanges; Request for Comments Regarding Exchange-Related Provisions in Title I of the Patient Protection and Affordable Care Act**

AGENCY: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services.

ACTION: Request for comments.

SUMMARY: This document is a request for comments regarding the Exchange-related provisions of the Patient Protection and Affordable Care Act (the Affordable Care Act), enacted on March 23, 2010. The Department of Health and Human Services (HHS) invites public comments in advance of future rulemaking and grant solicitations.

DATES: Submit written or electronic comments by **[insert date 60 days from date of publication in the Federal Register]**.

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

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

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

- By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: OCIIIO-9989-NC,
P.O. Box 8010
Baltimore, MD 21244-8010.

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

- By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: OCIIIO-9989-NC,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

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

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

200 Independence Avenue, SW.,
Washington, DC 20201

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

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

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

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

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT: Donna Laverdiere, Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, at (301)492-4100.

Customer Service Information: Individuals interested in obtaining information about the Patient Protection and Affordable Care Act may visit the Department of Health and Human Services' website (<http://www.HealthCare.gov>).

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments. All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all electronic comments received before the close of the comment period on the following public Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at Room 445-G, Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, call 1-800-743-3951.

I. Background

A. General

Title I of the Patient Protection and Affordable Care Act (Affordable Care Act, or the Act), Pub. L. 111-148, enacted on March 23, 2010, expands access to health insurance through the establishment of American Health Benefits Exchanges (“Exchanges”). Sections 1311(b) and 1321 (b) of the Affordable Care Act provide that each State may elect to establish an Exchange that would (consistent with definitions relating to the individual and group markets and employer size established in Section 1304 of the Act): 1) facilitate the purchase of qualified health plans (QHPs); 2) provide for the establishment of a Small Business Health Options Program (“SHOP Exchange”) designed to assist qualified employers in facilitating the enrollment of their employees in QHPs offered in the SHOP Exchange; and 3) meet other requirements specified in the Act. Additionally, Section 1321(c)(1) requires the Secretary to establish and operate an Exchange within States that do not elect to establish an Exchange, or if the Secretary determines, on or before January 1, 2013, that the State will not have an Exchange operable by January 1, 2014 or has not taken the actions necessary to meet required Exchange standards as defined by regulation or to implement other requirements in Subtitles A and C of the Affordable Care Act (relating to insurance market reforms). For purposes of the remainder of this notice, the term

"Exchange" will refer to State-operated Exchanges and the Exchange operated by the Federal government on behalf of States that do not elect to establish an Exchange.

B. Requirements for Establishing and Operating Exchanges

Section 1311(d) of the Affordable Care Act specifies certain requirements for Exchanges, and Section 1311(e) specifies the requirements for a plan to be certified by the Exchange as a QHP. Additionally, Section 1321 of the Affordable Care Act discusses State flexibility in the operation and enforcement of Exchanges and related requirements. The Secretary will issue regulations setting standards for meeting the requirements under Title I of the Act with respect to the establishment and operations of the Exchanges. Each State electing to establish and operate an Exchange must have in effect Federal standards or a State law or regulation that implements the Federal standards within the State. Also, Section 1311(k) specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations promulgated by the Secretary under Subtitle D of the Affordable Care Act.

Section 1321(c) of the Act provides the authority for the Secretary to establish and operate an Exchange on behalf of a State that does not elect to establish an Exchange or that the Secretary determines will not have an Exchange operable by January 1, 2014; or has not taken the necessary actions to

implement the requirements in 1321(a) or other market reforms specified in Subtitles A and C of Title I of the Affordable Care Act.

1. General Requirements for Exchanges

Section 1311(d)(1) requires that an Exchange must be a governmental agency or nonprofit entity established by a State. Section 1311(d)(2) requires Exchanges to make QHPs available to eligible individuals and employers. Section 1311(d)(6) requires Exchanges to consult with various stakeholders relevant to carrying out their responsibilities.

Section 1311(d)(4) identifies the minimum functions that an Exchange must perform. These functions include, but are not limited to: implementing procedures for certification, recertification, and decertification of QHPs; providing for the operation of a toll-free telephone hotline to respond to requests for assistance; maintaining an Internet website containing standardized comparative information on QHPs; assigning ratings to each QHP offered through the Exchange on the basis of relative quality and price, in accordance with criteria as defined by the Secretary; utilizing a standardized format for presenting health benefits options in the Exchange; consistent with requirements in Section 1413 of the Act, informing individuals of eligibility requirements for the Medicaid and CHIP programs or any applicable State or local public program, and enrolling individuals in those

programs if the Exchange determines they are eligible through screening of the application by the Exchange; establishing and making available by electronic means a calculator to determine the actual cost of coverage after application of any premium tax credit and cost-sharing reduction; granting certifications to individuals relating to hardship or other exemptions; and establishing a Navigator program consistent with the requirements in Section 1311(i).

2. Requirements Relating to Plan Ratings and Internet Portals

Section 1311(c)(3) requires the Secretary to develop a rating system that would rate QHPs offered through an Exchange on the basis of the relative quality and price. Additionally, Section 1311(c)(4) requires the Secretary to develop an enrollee satisfaction system that would evaluate the level of satisfaction with QHPs that had more than 500 enrollees during the previous year that are offered through an Exchange. The Act requires Exchanges to include quality and enrollee satisfaction ratings in the information provided to individuals and employers through their Internet portals.

Section 1311(c)(5) directs the Secretary to make a model template available to Exchanges for an Internet portal that may be used to direct eligible individuals and employers to QHPs; assist individuals and employers in determining eligibility for participation in Exchanges, premium tax credits, or cost-sharing

reductions; and present standardized information (including plan ratings) to assist consumers in making health insurance choices. The Affordable Care Act also directs the Secretary to continue operating, maintaining and updating the Federal Internet portal developed under Section 1103(a) and to assist States in developing and maintaining their own portals.

3. Requirements Relating to Navigator Programs

Section 1311(i) provides that an Exchange shall establish a Navigator program under which it awards grants to eligible entities that meet the law's criteria, including demonstrating to the Exchange that they have existing relationships or could establish relationships with employers and employees, consumers, or self-employed individuals likely to be eligible to enroll in a qualified health plan. The duties of entities that serve as Navigators under such a grant include: conducting public education activities to raise awareness of the availability of QHPs; distributing fair and impartial information concerning enrollment in QHPs and the availability of premium tax credits and cost-sharing reductions; facilitating enrollment in QHPs; providing referrals to any applicable office of health insurance consumer assistance, health insurance ombudsman, or other State agency to address enrollee complaints and questions about their health plans and coverage determination; and providing information in a manner that is culturally and linguistically

appropriate to the needs of the population being served by the Exchange. The Affordable Care Act directs the Secretary, in collaboration with States, to develop standards to ensure that information made available by Navigators is fair, accurate and impartial.

4. Other Requirements Relating to Exchanges

Section 1311(c)(6) requires Exchanges to provide for an initial open enrollment period (as determined by the Secretary no later than July 1, 2012), annual open enrollment periods (as determined by the Secretary), and special enrollment periods.

Section 1311(d)(5)(A) specifies that States must ensure that their Exchanges are self-sustaining on or after January 1, 2015, including allowing Exchanges to charge assessments or user fees to participating health insurance issuers, or otherwise generate funding to support their operations. Section 1311(d)(5)(B) prohibits wasteful use of funds by Exchanges. Additionally, Section 1313 requires Exchanges to keep an accurate accounting of all activities, receipts, and expenditures, and annually submit to the Secretary a report concerning such accounting. Section 1313(a) also specifies that the Secretary has certain enforcement authority if an Exchange or a State has engaged in serious misconduct related to compliance with Title I of the Act.

5. Establishment of Exchanges in the Territories

Section 1323 of the Affordable Care Act provides an opportunity for U.S. Territories to elect to establish Exchanges and appropriates a fixed amount of funds to reduce the cost of coverage provided through an Exchange in the Territories. The Act stipulates that Territories' elections related to establishing Exchanges must be consistent with Section 1321, relating to standards for establishing and operating Exchanges, and received not later than October 1, 2013.

II. Solicitation of Comments

Section 1321(a)(2) of the Affordable Care Act requires the Secretary to consult with stakeholders to ensure balanced representation among interested parties. HHS is inviting public comment to aid in the development of standards for establishment and operation of the Exchanges, to address other Exchange-related provisions in Title I of the Affordable Care Act, and to inform for the awarding of grants to the States to assist them in planning and developing Exchanges. The Department is interested in comments from all interested parties. To assist interested parties in responding, this request for comments describes specific areas in which the Department is particularly interested.

Commenters should use the questions below to provide the Department with relevant information for the development of regulations regarding the Exchange-related provisions in Title I

of the Affordable Care Act. However, it is not necessary for commenters to address every question below and commenters may also address additional issues under the Exchange-related provisions in Title I of the Affordable Care Act. Individuals, groups, and organizations interested in providing comments may do so at their discretion by following the above mentioned instructions.

Specific areas in which HHS is particularly interested include the following:

A. State Exchange Planning and Establishment Grants

Section 1311(a) directs the Secretary to make planning and establishment grant awards to States for activities related to establishing an Exchange. For each fiscal year, the Secretary must determine the total amount that will be made available to each State. Grants awarded under this Section may be renewed if a State is making sufficient progress toward establishing an Exchange, implementing other insurance market reforms, and meeting other benchmarks. The Secretary must make the initial grant awards under this Section no later than one year after enactment, and no grants shall be awarded after January 1, 2015.

1. What factors are States likely to consider in determining whether they will elect to offer an Exchange by January 1, 2014?

To what extent are States currently planning to develop their

own Exchanges by 2014 (e.g., become electing States) versus choosing to opt-in to an Exchange operated by the Federal government for their State? When will this decision be made? Can planning grants assist in identifying and assessing relevant factors and making this decision?

2. To what extent have States already begun to plan for establishment of Exchanges? What kinds of activities are currently underway (e.g., legislative, regulatory, etc.)? What internal and/or external entities are involved, or will likely be involved in this planning process?

a. What kinds of governance structures, rules or processes have States established or are they likely to establish related to operating Exchanges (e.g., legal structure (such as placement in State agency or nonprofit organization), governance structure, requirements relating to governing board composition, etc.)?

b. To what extent have States begun developing business plans or budgets relating to Exchange implementation?

3. What are some of the major factors that States are likely to consider in determining how to structure their Exchanges (e.g. separate or combined individual Exchanges and SHOP Exchanges; regional or interstate Exchanges; subsidiary Exchanges, State agency versus nonprofit entity)? What are the pros and cons of these various options?

4. What kinds of factors are likely to affect States' resource needs related to establishing Exchanges?

a. What is the estimated range of costs that States are likely to incur during the upcoming year (e.g., calendar 2010 through calendar 2011) for each of the major categories of Exchange activities? Which of these expenses are fixed costs, and which costs are variable?

b. To what extent do States have existing resources that could be leveraged as a starting point for Exchange operations (e.g. existing information technology (IT) systems, toll-free hotlines, websites, business processes, etc.)?

c. For what kinds of activities are States likely to seek funding using the Exchange establishment and planning grants?

5. What kinds of questions are States likely to receive during the initial planning and start-up phase of establishing Exchanges? How can HHS provide technical assistance, and in what forms, in helping States to answer these questions?

B. Implementation Timeframes and Considerations

Section 1321(b) requires each State that elects to establish an Exchange meeting the Secretary's requirements to have an Exchange operational by January 1, 2014. Section 1321(c) directs

the Secretary to establish and operate an Exchange within each State that: 1) does not elect to establish an Exchange; or 2) the Secretary determines will not have an Exchange operational by January 1, 2014, or has not taken the actions the Secretary determines necessary to implement the requirements in Section 1321(a) or the other insurance market reform requirements in Subtitles A and C of Title I of the Act.

Additionally, the Affordable Care Act includes several statutory deadlines for the Secretary related to establishment of Exchanges, including:

- Issuing regulations and/or guidance relating to requirements for Exchanges, requirements for QHPs, and risk adjustment as soon as practicable;
- Awarding State planning grants no later than one year after enactment (March 23, 2011);
- Determining the dates of the initial open enrollment period by July 1, 2012;
- No later than January 1, 2013, determining States' readiness to have Exchanges operational and implement required insurance market reforms by January 1, 2014;
- No later than July 1, 2013, issuing regulations for health choice compacts and the CO-OP program, and awarding CO-OP program grants; and
- Having in place additional insurance market reforms and

providing cost-sharing reductions beginning on January 1, 2014.

In order to carry out the Federal implementation activities to ensure Exchanges are fully operational on January 1, 2014, the Department is seeking comments from stakeholders relating to implementation timeframes.

1. What are the key implementation tasks that need to be accomplished to meet Exchange formation deadlines and what is the timing for such tasks? What kinds of business functions will need to be operational before January 1, 2014, and how soon will they need to be operational?
2. What kinds of guidance or information would be helpful to States, plans, employers, consumers, and other groups or sectors as they begin the planning process?
3. What potential criteria could be considered in determining whether an electing State is making sufficient progress in establishing an Exchange and implementing the insurance market reforms in Subtitles A and C of Title I of the Affordable Care Act? What are important milestones for States to show they are making steady and sufficient progress to implement reforms by the statutory deadlines?

4. What other terms or provisions require additional clarification to facilitate implementation and compliance? What specific clarifications would be helpful?

C. State Exchange Operations

Section 1311(b) requires an Exchange to be established in each State not later than January 1, 2014 that: facilitates the purchase of QHPs; provides for the establishment of a SHOP Exchange that assists small employers in facilitating the enrollment of their employees in QHPs offered in the small group market in the State; and meets additional requirements for Exchanges outlined in Section 1311(d). The Act requires the Secretary to publish regulations relating to the requirements for operating State Exchanges as soon as practicable, and provides various types of flexibility for States.

A number of additional programs established by the Act are closely related to the establishment of health insurance Exchanges, such as the Navigator program in Section 1311(i) and other consumer assistance programs. In addition, the insurance reforms, consumer protection provisions, and premium rating requirements will apply to plans both inside and outside the Exchanges.

1. What are some of the major considerations for States in planning for and establishing Exchanges?

2. For which aspects of Exchange operations or Exchange standards would uniformity be preferable? For which aspects of Exchange operations or Exchange standards is State flexibility likely to be particularly important?

3. What kinds of systems are States likely to need to enable important Exchange operational functions (e.g., eligibility determination, plan qualification, data reporting, payment flows, etc.), to ensure adequate accounting and tracking of spending, provide transparency to Exchange functions, and facilitate financial audits? What are the relative costs and considerations associated with building Exchange operational, financial, and/or IT systems off of existing systems, versus building new stand-alone Exchange IT systems?

4. What are the tradeoffs for States to utilize a Federal IT solution for operating their Exchanges, as compared to building their own unique systems to conform to the current State environment? For what kinds of functions would it make more sense for States to build their own systems, or modify existing systems?

5. What are the considerations for States as they develop web portals for the Exchanges?

6. What factors should Exchanges consider in reviewing justifications for premium increases from insurers seeking certification as QHPs? How will States leverage/coordinate the work funded by the rate review grants to inform the decisions about which plans will be certified by QHPs?

7. To what extent are Territories likely to elect to establish their own Exchanges? What specific issues apply to establishing Exchanges in the Territories?

8. What specific planning steps should the Exchanges undertake to ensure that they are accessible and available to individuals from diverse cultural origins and those with low literacy, disabilities, and limited English proficiency?

9. What factors should the Secretary consider in determining what constitutes as wasteful spending (as outlined in Section 1311 (d) (5) (B))?

D. Qualified Health Plans (QHPs)

Section 1311(d) (2) (A) requires Exchanges to make QHPs

available to qualified individuals and employers, and Section 1311(d) (4) (A) requires Exchanges to implement procedures for the certification, recertification, and decertification of health plans as QHPs, consistent with criteria developed by the Secretary under Section 1311(c). This certification criteria include, at a minimum: meeting marketing requirements; ensuring a sufficient choice of providers and providing information on the availability of providers; including essential community providers within health insurance plan networks; receiving appropriate accreditation; implementing a quality improvement strategy; utilizing a uniform enrollment form and a standard format to present health benefit plan options; and providing quality information to enrollees and prospective enrollees.

1. What are some of the major considerations involved in certifying QHPs under the Exchanges, and how do those considerations differ in the context of individual and SHOP State Exchanges, subsidiary Exchanges, regional or interstate Exchanges, or an Exchange operated by the Federal government on behalf of States that do not elect to establish an Exchange?

2. What factors should be considered in developing the Section 1311(c) certification criteria? To what extent do States currently have similar requirements or standards for plans in the individual and group markets?

a. What issues need to be considered in establishing appropriate standards for ensuring a sufficient choice of providers and providing information on the availability of providers?

b. What issues need to be considered in establishing appropriate minimum standards for marketing of QHPs and enforcement of those standards? What are appropriate Federal and State roles in marketing oversight?

3. What factors are needed to facilitate participation of a sufficient mix of QHPs in the Exchanges to meet the needs of consumers?

a. What timeframes and key milestones will be most important in assessing plans' participation in Exchanges?

b. What kinds of factors are likely to encourage or discourage competition among plans in the Exchanges based on price, quality, value, and other factors?

4. What health plan standards and bidding processes would help to facilitate getting the best value for consumers and taxpayers?

5. What factors are important in establishing minimum requirements for the actuarial value/level of coverage?

6. What factors, bidding requirements, and review/selection

practices are likely to facilitate the participation of multiple plans in Exchanges? To what extent should the Exchanges accept all plans that meet minimum standards or select and negotiate with plans?

7. What are some important considerations related to establishing the program to offer loans or grants to foster the promotion of qualified nonprofit health plans under CO-OP plans? How prevalent are these organizations today? What is the likely demand for these loans and grants? What kinds of guidance are they likely to need from HHS and what legislative or regulatory changes are they likely to need from States?

8. Are there any special factors that are important for consideration in establishing standards for the participation of multi-State plans in Exchanges?

9. To what extent are States considering setting up State Basic Health Plans under Section 1331 of the Act?

E. Quality

The Affordable Care Act requires the Secretary to develop a health plan rating system on the basis of quality and prices that would be used by the Exchanges and to establish quality

improvement criteria that health plans must meet in order to be qualified plans for Exchanges.

1. What factors are most important for consideration in establishing standards for a plan rating system?

a. How best can Exchanges help consumers understand the quality and cost implications of their plan choices?

b. Are the measures and standards that are being used to establish ratings for health plans in the Medicare Advantage program appropriate for rating QHPs in the Exchanges? Are there other State Medicaid or commercial models that could be considered?

c. How much flexibility is desirable with respect to establishing State-specific thresholds or quality requirements above the minimum Federal thresholds or quality requirements?

2. What are some minimum standards or other factors that could be considered with respect to establishing quality measurement and improvement thresholds or quality requirements that should be met by QHPs? What other strategies, including payment structures, could be used by plans to improve the practices of plan providers?

F. An Exchange for Non-Electing States

Section 1321(c) requires that in the case of States that do not elect to establish Exchanges, or that the Secretary determines will not have Exchanges operational by January 1, 2014 or have not taken the necessary actions to implement the requirements in Section 1321(a) or other insurance market reforms specified in Subtitles A and C of Title I of the Act, the Secretary shall establish (directly or through agreement with a not-for-profit entity) and operate an Exchange within the State.

1. How can the Federal government best work to implement an Exchange in States that do not elect to establish or are unable to establish their own Exchanges?

2. Are there considerations for an Exchange operated by the Federal government on behalf of States that do not elect to establish an Exchange that would be different from the State-run Exchanges?

G. Enrollment and Eligibility

Section 1411 of the Affordable Care Act requires the Secretary to establish a program for determining whether an individual meets certain eligibility requirements for Exchange participation, premium tax credits and cost-sharing reductions, and individual responsibility exemptions. Additionally, Sections

1412, 1413 and 2201 contain additional requirements to assist Exchanges by making advance determinations regarding income eligibility and cost-sharing reductions; providing for residents of each State to apply for enrollment in, receive a determination of eligibility for participation in, and continue participation in applicable State health subsidy programs; and simplifying and coordinating enrollment in the Exchanges, Medicaid and the Children's Health Insurance Program (CHIP).

1. What are the advantages and issues associated with various options for setting the duration of the open enrollment period for Exchanges for the first year and subsequent years? What factors are important for developing criteria for special enrollment periods?
2. What are some of the key considerations associated with conducting online enrollment?
3. How can eligibility and enrollment be effectively coordinated between Medicaid, CHIP, and Exchanges? How could eligibility systems be designed or adapted to accomplish this? What steps can be taken to ease consumer navigation between the programs and ease administrative burden? What are the key considerations related to States using Exchange or Medicaid / CHIP application information to determine eligibility for all three programs?

4. What kinds of data linkages do State Medicaid and CHIP agencies currently have with other Federal and State agencies and data sources? How can the implementation of Exchanges help to streamline these processes for States, and how can these linkages be leveraged to support Exchange operations?

5. How do States or other stakeholders envision facilitating the requirements of Section 1411 related to verification with Federal agencies of eligibility for enrollment through an Exchange?

6. What are the verification and data sharing functions that States are capable of performing to facilitate the determination of Exchange eligibility and enrollment?

7. What considerations should be taken into account in establishing procedures for payment of the cost-sharing reductions to health plans?

H. Outreach

Section 1311(i) provides that Exchanges shall establish grant programs for Navigators, to conduct public education activities, distribute enrollment information, facilitate enrollment, and provide referrals for grievances, complaints, or

questions.

1. What kinds of consumer enrollment, outreach, and educational activities are States and other entities likely to conduct relating to Exchanges, insurance market reforms, premium tax credits and cost-sharing reductions, available plan choices, etc., and what Federal resources or technical assistance are likely to be beneficial?

2. What resources are needed for Navigator programs? To what extent do States currently have programs in place that can be adapted to serve as patient Navigators?

3. What kinds of outreach strategies are likely to be most successful in enrolling individuals who are eligible for tax credits and cost-sharing reductions to purchase coverage through an Exchange, and retaining these individuals? How can these outreach efforts be coordinated with efforts for other public programs?

I. Rating Areas

Section 2701(a)(2) of the Public Health Service Act, as added by Section 1201 of the Affordable Care Act requires each

State to establish one or more rating areas within the State for purposes of applying the requirements of Title I of the Affordable Care Act (including the Exchange provisions), subject to review by the Secretary.

1. To what extent do States currently utilize established premium rating areas? What are the typical geographical boundaries of these premium rating areas (e.g., Statewide, regional, county, etc.)? What are the pros and cons associated with interstate, statewide, and sub-State premium rating areas? What insurance markets are typically required to utilize these premium rating areas?

2. To the extent that States utilize premium rating areas, how are they established? What kinds of criteria do States and other entities typically consider when determining the adequacy of premium rating areas? What other criteria could be considered?

J. Consumer Experience

1. What kinds of design features can help consumers obtain coverage through the Exchange? What information are consumers likely to find useful from Exchanges in making plan selections? Which kinds of enrollment venues are likely to be most helpful in facilitating individual enrollment in Exchanges and QHPs?

2. What kinds of information are likely to be most useful to consumers as they determine whether to enroll in an Exchange and which plans to select (within or outside of an Exchange)? What are some best practices in conveying information to consumers relating to health insurance, plan comparisons, and eligibility for premium tax credits, or eligibility for other public health insurance programs (e.g., Medicaid)? What types of efforts could be taken to reach individuals from diverse cultural origins and those with low literacy, disabilities, and limited English proficiency?

3. What are best practices in implementing consumer protections standards?

4. Given that consumer complaints can be an important source of information in identifying compliance issues, what are the pros and cons of various options for collecting and reporting Exchange-related complaints (e.g., collecting complaints at the Federal level, versus at the State or Exchange level)?

K. Employer Participation

Section 1311(b)(1)(B) provides for the establishment of Small Business Health Options Programs, referred to as SHOP

Exchanges, which are designed to assist qualified employers in the State who are small employers in facilitating the enrollment of their employees in QHPs offered in the small group market in the State. Section 1304(b) provides that for plan years beginning before January 1, 2016, States have the option to define "small employers" as those with (1) 100 or fewer employees, or (2) 50 or fewer employees. Section 1312(f)(2)(B) specifies that beginning in 2017, States may elect to include issuers of health insurance coverage in the large group market to offer QHPs through the Exchange, and for large employers to purchase coverage through the Exchange.

In addition, employers that do not offer affordable coverage to their employees will also interact with the Exchanges including where their employees purchase coverage through the Exchange.

1. What Exchange design features are likely to be most important for employer participation, including the participation of large employers in the future? What are some relevant best practices?
2. What factors are important for consideration in determining the employer size limit (e.g., 50 versus 100) for participation in a given State's Exchange?
3. What considerations are important in facilitating coordination

between employers and Exchanges? What key issues will require collaboration?

4. What other issues are there of interest to employers with respect to their participation in Exchanges?

L. Risk Adjustment, Reinsurance, and Risk Corridors

Sections 1341, 1342, and 1343 of the Act provide for the establishment of transitional reinsurance programs, risk corridors, and risk adjustment systems for the individual and small group markets within States.

1. To what extent do States and other entities currently risk-adjust payments for health insurance coverage in order to counter adverse selection? In what markets (e.g., Medicaid, CHIP, government employee plans, etc.) are these risk adjustment activities currently performed? To the extent that risk adjustment is or has been used, what methods have been utilized, and what are the pros and cons of such methods?

2. To what extent do States currently collect demographic and other information, such as health status, claims history, or medical conditions under treatment on enrollees in the individual and small group markets that could be used for risk adjustment?

What kinds of resources and authorities would States need in order to collect information for risk adjustment of plans offered inside and outside of the Exchanges?

3. What issues are States likely to consider in carrying out risk adjustment for health plans inside and outside of the Exchanges? What kinds of technical assistance might be useful to States and QHPs?

4. What are some of the major administrative options for carrying out risk adjustment? What kinds of entities could potentially conduct risk adjustment or collect and distribute funds for risk adjustment? What are some of the options relating to the timing of payments, and what are the pros and cons of these options?

5. To what extent do States currently offer reinsurance in the health insurance arena (e.g. Medicaid, State employee plans, etc.) or in other arenas? How is that reinsurance typically structured in terms of contributions, coverage levels, and eligibility? How much is typically taken in and paid out? Is the reinsurance fund capped in any way?

6. What kinds of non-profit entities currently exist in the marketplace that could potentially fulfill the role of an "applicable reinsurance entity" as defined in the Act?

7. What methods are typically used to determine which individuals are deemed high-risk or high cost for the purposes of reinsurance?

8. What challenges are States likely to face in implementing the temporary reinsurance program?

9. How do other programs (e.g., Medicaid) use risk corridors to share profits and losses with health plans or other entities? How are the corridors defined and monitored under these programs? What mechanisms are used to collect and disburse payments?

10. Are there non-Federal instances in which reinsurance and/or risk corridors and/or risk adjustment were used together? What kinds of special considerations are important when implementing multiple risk selection mitigation strategies at once?

M. Comments Regarding Economic Analysis, Paperwork Reduction Act, and Regulatory Flexibility Act

Executive Order 12866 requires an assessment of the anticipated costs and benefits of a significant rulemaking action and the alternatives considered, using the guidance provided by the Office of Management and Budget. These costs and benefits

are not limited to the Federal government, but pertain to the affected public as a whole. Under Executive Order 12866, a determination must be made whether implementation of the Exchange-related provisions in Title I of the Affordable Care Act will be economically significant. A rule that has an annual effect on the economy of \$100 million or more is considered economically significant.

In addition, the Regulatory Flexibility Act may require the preparation of an analysis of the economic impact on small entities of proposed rules and regulatory alternatives. An analysis under the Regulatory Flexibility Act must generally include, among other things, an estimate of the number of small entities subject to the regulations (for this purpose, plans, employers, and in some contexts small governmental entities), the expense of the reporting, recordkeeping, and other compliance requirements (including the expense of using professional expertise), and a description of any significant regulatory alternatives considered that would accomplish the stated objectives of the statute and minimize the impact on small entities.

The Paperwork Reduction Act requires an estimate of how many "respondents" will be required to comply with any "collection of information" requirements contained in regulations and how much time and cost will be incurred as a result. A collection of information includes recordkeeping, reporting to governmental

agencies, and third-party disclosures.

Furthermore, Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$135 million.

The Department is requesting comments that may contribute to the analyses that will be performed under these requirements, both generally and with respect to the following specific areas:

1. What policies, procedures, or practices of plans, employers and States may be impacted by the Exchange-related provisions in Title I of the Affordable Care Act?

a. What direct or indirect costs and benefits would result?

b. Which stakeholders will be affected by such benefits and costs?

c. Are these impacts likely to vary by insurance market, plan type, or geographic area?

2. Are there unique effects for small entities subject to the Exchange-related provisions in Title I of the Affordable Care Act?

3. Are there unique benefits and costs affecting consumers? How will these consumer benefits be affected by States' Exchange design and flexibilities and the magnitude and substance of provisions mandated by the Act? Please discuss tangible and intangible benefits.

4. Are there paperwork burdens related to the Exchange-related provisions in Title I of the Affordable Care Act, and, if so, what estimated hours and costs are associated with those additional burdens?

N. Comments Regarding Exchange Operations

The Exchange-related provisions in Title I of the Affordable Care Act may affect/will involve various stakeholders. HHS wants to ensure receipt of all comments pertaining to the operations of the Exchanges.

1. What other considerations related to the operations of Exchanges should be addressed? If your questions related to the operations of Exchanges have not been asked, or you would like to add additional comments, you may do so here.

Signed at Washington, DC this 27th day of July, 2010.

Jay Angoff,
Director,
Office of Consumer Information and Insurance Oversight.
Department of Health and Human Services.

BILLING CODE 4150-65

[FR Doc. 2010-18924 Filed 07/29/2010 at 11:15 am; Publication
Date: 08/03/2010]