American Heart Association | American Stroke Association

October 21, 2011

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
ATTN: CMS-9989-P
PO Box 8010
Baltimore, MD 21244-8010

RE: File Code CMS-9989-P (Patient Protection and Affordable Care Act; Proposed Rule Regarding Establishment of Exchanges and Qualified Health Plans)

Dear Sir or Madam:

On behalf of the American Heart Association (AHA), including its American Stroke Association (ASA) division, and more than 22 million volunteers and supporters, we appreciate the opportunity to offer our comments on key issues related to the establishment and operation of the new health insurance exchanges to be created under the Patient Protection and Affordable Care Act (ACA).

The creation of state-based health insurance exchanges is a central element of the ACA's provisions to make affordable, high-quality health insurance coverage available to American patients and consumers. We want to work with you to ensure that these exchanges fulfill this promise and meet the needs of the millions of Americans with heart disease and stroke and those at risk for cardiovascular disease. In our comments, there are 3 key priorities that resonate throughout: The federal rules should facilitate the good governance and stability of exchanges, help further protect against adverse selection, and make it simple and easy for patients and consumers to access high-quality, affordable coverage and care. We appreciate the opportunity to provide the following specific comments in response to the rule proposed for the establishment of insurance exchanges and qualified health plans (QHPs).

PART 155
SUBPART B—General Standards Related to the Establishment of an Exchange by a State

Approval of a State Exchange, §155.105

We appreciate the emphasis HHS has placed on ensuring that all states will have insurance exchanges operating in time to provide coverage to individuals and small businesses beginning on January 1, 2014. We agree that in order to meet this deadline, an exchange must be capable of beginning operations to support the initial open enrollment period set to begin on October 1, 2013 and to meet certain standards and be able to perform the required functions.

Approval Standards, §155.105(b)

As the rule proposes, we agree the state Exchange must be able to carry out the functions in subparts C, E, H, and K; agree to perform the responsibilities related to operation of a reinsurance program; and be capable of carrying out the information requirements related to the premium credits for low- and moderate-income participants in an individual exchange. We are particularly pleased to see that the rule makes the information requirements related to the premium credits an approval standard for states seeking to operate an Exchange. We believe this is an essential element to ensure the premium subsidies can be administered properly.

The rule proposes that, in order for a state to be approved to operate an exchange, the entire geographic area of the state be covered "by one or more exchanges." In accordance with the statute, each exchange in a state must operate in geographically distinct areas and no area should be served by more than one exchange. This is necessary to reduce confusion among consumers and to ensure that exchanges operate as efficiently as possible. The language of the proposed rule must be modified in this section so that it is clear that where there are multiple exchanges, each exchange serves a distinct geographic area.

Recommendation: Modify §155.105(b)(4) to read: "The entire geographic area of the State is covered by one or more State Exchanges, each serving a geographically distinct area."

Approval Process, §155.105(c)

HHS should ensure that states' Exchange Plans are made publicly available and subject to a comment period before they are approved, either by releasing the plans and taking comments at the federal level or by requiring states to make Exchange Plans in their final form available to the public and accept comments before they are approved. We believe this could be done within the 90-day timeline for HHS approval or denial of an Exchange Plan that the rule proposes.

Recommendation: Ensure that states' Exchange Plans are publicly available and subject to a comment period prior to approval.

HHS Operation of an Exchange, §155.105(f)

We agree that a federally operated exchange should have to meet the minimum standards the proposed rule sets out for a state operated exchange. The final rule, or future rulemaking, must go beyond this basic description to address a number of important details about how a federally operated exchange would work and coordinate the operational functions of the federal exchange with the insurance markets and Medicaid agency in each state, including by specifying how a federally-facilitated exchange would be financed. As with state operated exchanges, federally-facilitated exchanges require a stable source of funding that minimizes the potential for adverse selection between plans inside and outside the exchange.

Recommendation: Address in the final rule the details of how a federally facilitated exchange would work, particularly how such an exchange would differ in some respects from state to state and how a federally developed and operated exchange would coordinate the operational functions and meet individual state conditions and needs.

"Partnership Model," §155.105(f)
We understand the real need for state flexibility and applaud HHS for seeking creative ways for the federal and state governments to collaborate on developing robust exchanges. HHS recently provided greater detail about potential options for federal-state Partnerships at a State Exchange Grantee Meeting. We are continuing to analyze the options that were presented. Overall, however, we support HHS' effort to place clear parameters around the Partnership concept and to ensure that the experience for consumers is seamless. We also support the position, consistent with the statute, that HHS is ultimately responsible and accountable for "Partnership" Exchanges even if a state handles certain aspects of consumer assistance and/or health plan management functions.

As HHS continues to develop the partnership approach, we recommend that HHS:

- *Ensure through regulation that the Partnership approach is clearly defined.*
- *The overarching goal of an exchange should be to provide a seamless, one-stop shop for the consumer regardless of who actually operates it.*
- *Clarify through regulation that HHS has ultimate decision-making authority and responsibility for core functions of a Partnership exchange and that HHS is accountable for compliance with the ACA and the performance of its contractors.*

Entities eligible to carry out Exchange functions, §155.110

Eligible contracting entities, §155.110(a)
Some states will delegate specific exchange functions to outside contractors; however, the exchange must remain accountable for meeting all Federal and State requirements. There should be limits to the functions that can be contracted to outside parties and contracting entities should be required to meet conflict of interest and confidentiality standards. We support the inclusion of Medicaid as an eligible contracting entity.

Governing Board Structure, §155.110(c)
It is critical that CMS establish minimum requirements for all exchange governing boards. In particular, we support the requirement that any such governing bodies must be administered under a publicly-adopted charter or bylaws and must hold regular public meetings with advanced notice provided to the public.

We strongly recommend that HHS require that all exchange governing boards prohibit membership of individuals that possess a clear conflict of interest. It is detrimental to the goal of the exchange – to provide affordable health coverage to millions – and to taxpayers supporting premium tax credits if exchange boards are comprised of parties that have a conflict of interest with the responsibilities of the Exchange. If HHS ultimately permits conflicted parties to serve on exchange boards, there should be more representatives of consumer interests (as defined below) than conflicted voting members, and consumer interests should constitute an overall majority and a voting majority of the board. A precedent for such a requirement exists in 42 USCS § 254b(k)(3)(H) regarding requirements of governing boards for Federally Qualified Health Centers (FQHCs), where a majority of the board must be individuals being served by the health center.

We believe that HHS should clearly define representatives of consumer interests. Such a definition should include: individuals who purchase or are likely eligible to purchase coverage through the individual exchange; small business employees who purchase or are likely eligible to purchase coverage through the SHOP exchange; and non-profit organizations that represent members of or that advocate on behalf of the interests of the individuals that will be enrolled in the exchanges.

Governance principles, §155.110(d)

We also strongly recommend that HHS be more explicit in the standards that exchanges must meet in terms of policies on ethical practices and conflict of interest. Specifically, HHS should set a minimum benchmark standard for exchanges requiring board members and staff to:

- Disclose any affiliations (financial or otherwise) that may cause the appearance or presence of a conflict of interest with their role in an exchange;
- Recuse themselves from all discussion and votes associated with such conflict; and
- Refrain from accepting any gifts (or any gifts exceeding a reasonable limit) from any individual or entity that can be considered a conflicted party; and

Recommendations: HHS should prohibit conflicted parties from serving on an exchange governing board. Barring that, HHS should set explicit minimum standards for ethical conduct, conflict of interest, and disclosure of financial interest.

Stakeholder Consultation, §155.130

It will be important for the Exchange to consult with a variety of individuals, employers, advocates and others with specialized knowledge of the health care industry that can help facilitate enrollment and the seamless operation of the exchange. Section 1311(d)(6) of the statute lists several stakeholders that must be consulted and CMS proposes expanding that list to also include health care providers, health insurance issuers, and insurance agents and brokers, among others.

"Educated healthcare consumers" should include individuals of various ages and health status, including the disabled, those with chronic health conditions, and those who have been underserved, who are enrolled in the QHPs to encourage a balance in the viewpoints expressed by stakeholders.

Recommendation: Expand the definition of "educated healthcare consumers" that should be consulted to require diversity in the age, background, and health status of consumer stakeholders.

Financial Support for Continued Operations, §155.160

We support the codification of states' ability to charge assessments on participating issuers, as defined by §155.160, as well as the flexibility to adopt additional mechanisms for generating revenue to fund exchange operations. We believe that one of the best mechanisms for funding an exchange is to assess not just participating insurers, but all insurers in the state. While assessments on only issuers selling coverage inside the exchange is one allowable way to obtain funding for continued operations, if a state pursues this model it may result in an unlevel playing field, undermining the viability of the exchange. We recommend that states be required to include in their

Exchange plans their plans to mitigate the risk for adverse selection through their exchange-financing structure.

Recommendation: The preamble to the final rule should include assessments on all carriers, as well as assessments on TPAs and reinsurers, as examples of exchange-funding mechanisms. Further, the preamble should discuss the risks of assessing only participating issuers to fund exchange operations.

SUBPART C—General Functions of an Exchange

Functions of an Exchange, §155.200

We support ensuring that all exchanges perform a minimum set of functions. It is particularly important to consumers that the proposed rule requires exchanges to perform eligibility determinations across a variety of programs, including the premium tax credits and cost-sharing reductions available through exchanges, Medicaid and the Children's Health Insurance Program. We also support the preamble's statement that the eligibility and enrollment function of the exchanges should be consumer-oriented and should minimize administrative hurdles and unnecessary paperwork for applicants.

We further recommend that HHS establish objective ways to measure whether exchanges are successfully carrying out their required functions on an ongoing basis. For example, to ensure that exchanges are properly carrying out their eligibility and enrollment functions, HHS should review data such as the percentage of a state's population that has health insurance and the percentage of consumers coming to an exchange that successfully complete the enrollment process, whether in the exchange, Medicaid, or other state health programs. Another important element to review is the change in exchange premium costs over time, possibly in relation to the individual and small-group markets outside the exchange.

The requirement for an exchange to report the necessary data should be added to the approval standards, and HHS should propose specific measures of exchange success. Once exchanges are up and running, HHS should formulate specific standards on various data points that the exchanges must meet. The requirement to supply data to help monitor exchange performance should be place on state exchanges as well as federally facilitated exchanges, and the data should be publicly available.

Recommendation: Establish measures to evaluate and compare the exchanges performance of key operational functions such as eligibility and enrollment and over time, as exchanges become more established, set specific benchmarks that exchanges must meet and share the results with the public.

Quality Activities, §155.200(f)

The proposed rule codifies the statutory requirements that Exchanges must evaluate quality improvement strategies. Below we offer our recommendations on a number of these issues to inform HHS as it develops additional rulemaking on Exchange quality initiatives.

First and foremost, HHS should establish a standardized set of quality metrics to ensure comparability across plans. Standard measures are critical for making quality data meaningful and useful to consumers and purchasers. All QHPs, irrespective of product type (e.g. HMO, HMO/POS, PPO), should be required to report on the same measures in the same way. At a minimum, QHPs should be required to report on accreditation status (including level of accreditation if available, results from the Consumer Assessment of Healthcare Providers and Systems (CAHPS), and other nationally recognized and available health plan quality measures, such as HEDIS. Quality information should be presented to consumers who are shopping for QHPs in an easy-to-understand format so they can make value-based decisions on their coverage and care.

HHS should set out clear metrics for all quality improvement strategies and Exchanges should hold QHPs accountable for their results – with clear goals and benchmarks – so that consumers and employers will know whether plans are hitting the quality improvement and cost containment targets over time. In particular, plans should be required to stratify data by available demographic data, including race, ethnicity, primary language, sex, disability status, sexual orientation, and gender identity, to document reductions in health disparities.

As the federal government and states gain greater experience with Exchanges, the minimum thresholds for exchanges and QHPs should not be static; instead, they should evolve to more effectively confront the quality and cost challenges facing consumers. Strategies and standards must be updated on a regular basis to keep pace with advances in measurement, consumer education, medical science, and payment.

Consumer Assistance Tools, §155.205

Outreach and Education, §155.205(e)

Outreach and education will be critical to the success of the exchange, particularly during the initial enrollment period. To maximize the effectiveness of outreach and education in exchanges, outreach should broadly promote coverage for individuals, families, and small businesses in need of health coverage and care; target specific hard-to-reach populations; and be coordinated among the various entities, including navigators and other state-based and community assistors. An important lesson learned through Medicaid and CHIP is that outreach targeting the "uninsured"—or those in need of coverage or care—is more effective than promoting a single coverage option. When individuals hear about a specific option, they often assume it is not for them or that they are not eligible. Outreach that targets all those in need of coverage or care avoids self-selection away from certain services and is more likely to reach a wide range of individuals whose eligibility for all insurance affordability programs can be determined by the exchange.

Recommendations: Amend §155.205(e) to require the exchanges to conduct outreach and education activities to broadly promote access to coverage for the uninsured (without regard to a specific coverage option) and encourage participation. Outreach and education activities should target underserved populations and those who experience health disparities due to language barriers, low literacy, race, color, national origin, geography, or disability including mental illnesses and substance abuse disorders.

Navigator Program Standards, §155.210

We consider a robust, impartial Navigator program to be a critical component of exchange outreach and enrollment to exchange customers in their communities. We support the rule's requirement that each exchange's Navigators represent more than one type of eligible entity, and offer the following specific comments to strengthen section 155.210.

Entities eligible to be a Navigator, §155.210 (b)

The rule mirrors the statutory requirement that entities seeking a Navigator grant demonstrate to the exchange that they have, or could readily establish, relationships with likely exchange customers. We recommend that HHS include requirements, or at the very least examples, for how exchanges can comply with this provision to assess the capability of Navigator applicants to reach targeted populations. For example, exchanges could be required to solicit action plans from applicants for the Navigator program that would outline who the potential Navigators intend to assist (including estimates for how many people or businesses they intend to serve) and how they will reach those clients.

We strongly support the provision in 155.210(b)(2) that requires an exchange to include at least two different types of eligible entities in its Navigator program. This provision is critical to ensuring that Navigator programs meet the needs of diverse populations, instead of being comprised of just one type of entity that may reach only a narrow segment of the exchange-eligible population.

We recommend that HHS develop an online training and certification program for Navigators that exchanges may adapt to their needs. This will save states from duplicative efforts and will ensure that Navigators receive uniform information about federal requirements relative to their duties.

Recommendation: The final rule should maintain the requirement that each exchange have Navigators representing at least two different eligible entities. We recommend that HHS develop a model training and certification program for Navigators that exchanges can adapt to include state-specific information.

Duties of a Navigator, §155.210 (d)

Section 155.210(d)(5) requires Navigators to provide information in a manner that is appropriate to culturally and linguistically diverse individuals and to individuals with disabilities. To ensure that individuals with limited-English proficiency can obtain adequate assistance, Navigator programs should have printed outreach materials available in certain threshold languages based on the service area. Navigator programs must have oral linguistic capacity, including bilingual staff and targeted outreach, in many more languages. Navigators should designate entities to provide language-specific outreach. Additionally, each Navigator entity must be able to assist callers in other languages through a language line.

Recommendation: Specific thresholds should be included in the final rule to ensure that Navigators provide adequate services to individuals with limited-English proficiency.

General Standards for Exchange Notices, §155.230

We appreciate CMS's recognition in the preamble and proposed regulatory language that applications, forms, and notices must be provided in plain language and provide meaningful access to limited English proficient ("LEP") individuals and persons with disabilities. The implementation of the various "health insurance affordability options" envisioned by the ACA presents a range of new options and operational changes that must be explained clearly to enrollees and potential enrollees for health reform to be successful. It is thus more critical than ever that all written materials be presented in a manner that will effectively communicate to the wide range of populations affected. "Plain language" is necessary not only to clearly notify enrollees of their rights, but to properly explain the various health insurance options that may be available to consumers. Communications geared toward LEP persons and persons with disabilities is not only desirable but required by various laws, including Section 2001 of the ACA (enacting Public Health Service Act § 2719, which requires group health plans and health insurance issuers to provide notice of appeal processes in a "culturally and linguistically appropriate manner"); Title VI -- 42 U.S.C. § 2000d, *et seq.*; ACA, Section 1557, 42 U.S.C. § 18116 (Nondiscrimination).

While the proposed regulation incorporates the basic critical "accessibility and readability" concepts of plain language, access for LEP persons and access for persons with disabilities, we make the following suggestions for improvements:

Recommendations: Require all notices of action to include a statement of the reasons for the action being taken. Require that a second notice of action be sent if the action will result in termination of coverage and the enrollee has not responded to the first notice. Expand regulatory requirement for accessibility and readability to include "any other documents."

SUBPART E—Individual Market Enrollment in QHPs

Single streamlined application, §155.405

A single, streamlined application and application process is central to the success of the No Wrong Door concept. An applicant should only be required go through the application process once in order to receive an eligibility determination for all insurance affordability programs.

Recommendation: The regulations should require that the online version of the simple streamlined application allow users to create an account and save their work, so that applicants can start and stop the application multiple times without losing their work, and so that they can begin an application on their own, but share with an application assistor if they need help (or vice versa; initially apply with an assistor, but later check the status of the application on their own through their online account).

To the extent that an application requests optional information, these fields should be clearly marked as optional. The applicant must be permitted to advance through an online application without completing optional fields. When optional information (such as a non-applicant parent's SSN) would

significantly streamline the application process and reduce paper documentation requirements, this should be communicated to the applicant in plain language.

Recommendation: Require in paragraphs (a) and (b) that any optional information requested be clearly marked as such, and require that applicants are informed that not completing such information will not affect their eligibility or ability to enroll in a qualified health plan or insurance affordability program.

Given that a large proportion of applicants will likely obtain assistance completing and submitting their application, we support the provision at paragraph (c) that exchanges accept applications from multiple sources and via multiple mechanisms. In addition to accepting applications online, over the phone, and via mail/fax, exchanges should also accept in-person applications (consistent with section 1413(b)(1)(A)(ii) of the ACA). These in-person applications might be submitted to a Medicaid eligibility office or and exchange office, if such a site exists in the state. Regardless of the method of application, however, all applicants should be able to obtain assistance with the application and enrollment process that is culturally and linguistically appropriate from an unbiased and knowledgeable source.

Recommendations: Maintain the requirement at paragraph (c)(2)(iv) that individuals be permitted to apply in person. Include in paragraph (c)(2) that the tools an applicant needs to file an application should include culturally and linguistically appropriate assistance from an unbiased and knowledgeable source.

Special enrollment, §155.420

Special enrollment periods, §155.420 (d)

This section provides special enrollment periods for people and households losing other coverage or gaining a dependent and for Indians, consistent with the statute. It also appropriately lists other reasons that may arise midyear and should allow a person to enroll in a QHP, including when a person gains citizenship or lawfully present status, when errors or misrepresentations about exchange eligibility caused the non-enrollment, when a person moves into a new plan's service area, when a QHP violates a material provision of its contract, when a person newly becomes eligible for premium credits or there is a change in a person's eligibility for cost-sharing reductions, or in other exceptional circumstances provided by the exchange or HHS. The preamble mentions national disasters as one exceptional circumstance, and we agree that emergency temporary relocations due to storms have necessitated plan changes in the past. We support this broad language in (d)(9), which could also allow for special enrollment if there were major changes in an insurance market or if an exchange needed an additional period to encourage enrollments.

Under (d)(6) special enrollment is available to people "determined newly eligible or newly ineligible for advance payments of the premium tax credit….." We assume that this means the special enrollment right is triggered by the exchange making a determination, and request that you clarify this in guidance. It would be an unnecessary burden on exchanges and plans to have to calculate special enrollment periods based on when the person's income actually changed sufficiently to alter their credits. Further, the intent of the Affordable Care Act is to provide affordable health care for all Americans. We anticipate that it will take time to reach people who previously could not afford coverage and inform them of the availability of premium credits in the

exchange, and continuous enrollment for that population will help to get them into the program. Tax penalties for failure to maintain coverage should dissuade people from intentionally delaying enrollment, making any further restrictions on enrollment unnecessary for the credit-eligible population.

Recommendations: Clarify that the date that the exchange completes an eligibility determination regarding premium or cost sharing credits begins the special enrollment period for someone qualifying that way.

Information about special enrollment rights
The rules do not provide for any notices about special enrollment rights. We are therefore not sure how people would find out that they are entitled to special enrollment prior to the expiration of the 60-day period.

Recommendations: Add a new subsection on notice. Exchanges should be required to notify people of their special enrollment rights when they report an income change or other life change that would trigger special enrollment. They should also provide all new enrollees and applicants with general information about special enrollment periods, and maintain information about special enrollment rights on their websites.

SUBPART K—Exchange Functions: Certification of Qualified Health Plans

Certification Standards for QHPs, §155.1000

General certification criteria, §155.1000(c)
Section 155.1000(c)(2) codifies the statutory requirement that an exchange must determine that making a health plan available is "in the interest of qualified individuals and qualified employers" in order to certify it as a QHP. As described in the preamble, the proposed rule gives exchanges discretion on how to determine whether a plan meets this standard.

Neither the preamble nor the rule itself make it clear that, in order for a state to have an Exchange that is compliant with the ACA, the Exchange must have the discretionary ability to certify a QHP based on a determination that the QHP is in the interests of qualified individuals and qualified employers in the State. By the same token, state policymakers need to provide their Exchange leadership with the authority and flexibility they need to meet the needs of consumers and provide a meaningful range of affordable insurance products to individuals and employers.
Unfortunately, there are currently bills pending in state legislatures that would require the Exchange to take any qualified plan. Some also prohibit "active purchasing." Such provisions, if enacted, would be in conflict with § 1311(e)(1)(B) of the ACA because they effectively take away an Exchange's ability to make a determination of whether a particular QHP's participation is in the interests of enrollees. State laws that curtail Exchanges' authority to be selective in the products offered, or to prohibit purchasing practices that encourage value defeat the goals of the ACA and are contrary to the intent of Congress. HHS should clarify that state statutory or regulatory provisions that take away the ability of an Exchange to make a determination that a QHP is or is not in the interests of participants are in conflict with the ACA.

Recommendation: The final rule should clarify that exchanges must both certify that a health plan meets the minimum QHP certification standards *and* independently determine that offering the plan is in the interests of qualified individuals and employers before certifying it as a QHP.

Certification Process for QHPs, §155.1010

We are concerned about the implications of §155.1010(b) of the proposed rule, which requires each Exchange to accept multi-State plans (MSPs) as QHPs without applying an additional certification process to such plans. While we appreciate that this rule is an interpretation of §1334(d) of the ACA, it could create an unlevel playing field between the state Exchange QHPs and multi-state QHPs. We support allowing state Exchanges to require MSPs to meet the same certification requirements as the state QHP plans to assure that enrollees are offered comparable health plans and can make their insurance selection based on their own health needs. We do recognize that there are numerous reasons why MSPs may be particularly attractive to some enrollees (such as those who travel extensively, live in other areas of the country for a portion of the year, or want access to nationally recognized centers of excellence not available in their state), and we support their inclusion in the state QHPs, provided that the above concerns are addressed.

We recognize that it is the U.S. Office of Personnel Management (OPM) that is charged with the responsibility for certifying MSPs. We urge you to work with officials at OPM to ensure that MSPs meet not only the minimum federal requirements for the program, but also any additional requirements that a state Exchange may establish to avoid placing the state QHPs at a competitive disadvantage.

Recommendation: Work with the U.S. Office of Personnel Management to ensure that MSPs must meet the QHP certifications of the state Exchanges.

QHP rate and benefit information, §155.1020

The cost of insurance is still the top concern of many families. This will be especially true in the exchange where families may face significant premiums and cost-sharing and taxpayers will bear the balance of premium hikes through premium tax credits.

The rate review process is important to overall cost containment. Improvements made under the ACA ensure that states have the resources to conduct a more thorough, professional, and public review of rates. States' laws on rate review vary. Some states have the authority to reject or modify rate increases or actively negotiate with plans to achieve a better value for consumers. Insurance departments will continue this work on plans offered inside and outside the exchange and should continue applying the same rules that are used outside the exchange to maintain a level playing field and comparison of similar products inside and outside the exchange. Mid-year rate increases should not be supported. Tax credits would be impacted by mid-year rate increases that could change the amount of tax credits and would make managing premiums and rates more difficult for all parties involved. The MLR, rate review and reinsurance are all based on annual rates.

Recommendation: Reaffirm in the regulation that state insurance commissioners continue to have the ability to carry out their state authority on rate review, including denying or

modifying proposed rate increases and continue to apply the same rating requirements for all insurance products inside and out-side the exchange.

Accreditation Timeline, §155.1045

The rule proposes that Exchanges must establish a uniform period following certification of the QHP within which a QHP issuer that is not already accredited must become accredited. We support the statutory requirement that QHP issuers must be accredited. We do, however, appreciate the concern that some leeway may be necessary to allow new issuers that are seeking accreditation to be certified by and sold in Exchanges.

To reconcile these competing needs, first, we strongly urge HHS to establish a federal accreditation timeline rather than rely on states to individually establish processes. A federal accreditation timeline would minimize burden on all parties and QHP issuers operating in multiple states would not be subject to competing timelines.

Second, we recommend that HHS adopt a maximum grace period of two years after certification of a QHP during which a QHP issuer must become accredited if it is not already accredited. We believe a two year timeline is sufficient to accommodate the length of time needed to implement and demonstrate that the policies and procedures are in place and meeting the performance requirements to successfully complete the accreditation process. If a QHP issuer cannot complete the accreditation process within two years, they should be required to document extenuating circumstances causing the delay and Exchanges should have the authority to make limited extensions to the grace period.

Recommendation: HHS should require Exchanges to adopt a two year timeline after certification of a QHP during which a QHP issuer must become accredited if it is not already.

Establishment of Exchange Network Adequacy Standards, §155.1050

The rule proposes that Exchanges make health insurance and therefore health care available to a variety of consumers, including those who reside or work in rural or urban areas where it may be challenging to access health care providers, by requiring Exchanges to "ensure that the provider network of each QHP offers a sufficient choice of providers for enrollees." We support this goal and agree that network adequacy standards need to be appropriate to States' particular geography, demographics, local patterns of care, and market conditions. At the same time, however, national network adequacy requirements should serve as a floor to ensure that the enrollees of QHPs have a sufficient choice of primary care, specialty care and tertiary care providers to have meaningful, timely, and affordable access to the services they need.

Network adequacy requirements

The ACA requires the HHS Secretary to establish network adequacy requirements for health insurance issuers seeking certification of QHPs. However, the rule proposes to delegate this responsibility to each Exchange. We believe that the final rule should establish national standards that will serve as a minimum level of protection for network adequacy across the country. Such standards can be broad enough to ensure that they are appropriate to each state's needs.

In particular, we believe that the NAIC's Managed Care Plan Network Adequacy Model Act (NAIC Model Act) provides and appropriate and balanced framework for national network adequacy requirements. In addition, the NAIC Mode Act has already been adopted by a number of states and is used for all managed care plans in a given state which would provide a level playing field between plans offered inside the exchange and outside the exchange and avoid the risk of adverse selection based on provider participation in a given plans.

In addition, private national accreditation programs that currently accredit plans throughout the country using the same standards can serve as an added oversight and enforcement mechanism, provided that accreditation requirements for availability of practitioners, access to services, and other related requirements are aligned with the national network adequacy requirements that HHS should include in the final rule. This approach has the advantage of building on existing federal and state network adequacy regulations and guidance and private accreditation standards in defining the national minimum standards and leveraging state and private oversight and enforcement mechanisms. It also simplifies the certification process, avoids duplication of effort and reduces the administrative burden on the Exchange, QHPs and States.

Within the framework of the NAIC's Managed Care Plan Network Adequacy Model Act requirements, states would still have flexibility to ensure that they meet the geographic, demographic and other needs of their residents. For example, rural states may wish to allow licensed and credentialed telemedicine providers be included as network providers.

We note that the law requires all QHPs -- which will include both managed care plans and health indemnity plans -- to meet the minimum national network adequacy standards. Health indemnity plans are defined by the NAIC Model Act as "a health benefit plan that is not a managed care plan". As a result, these plans may not currently be subject to the same requirements regarding network adequacy. Health indemnity plans that seek to be QHPs should also be required to meet the same or similar minimum national network adequacy requirements as QHPs that are managed care plans.

Recommendations: HHS should adopt the NAIC Managed Care Plan Network Adequacy Model Act as the minimum national network adequacy requirements for QHP certification and add provisions to require QHPs that are health indemnity plans to demonstrate that they have a sufficient choice of providers accepting their health plan to meet the minimum national network adequacy standards. QHPs that are accredited by a national accreditation entity that HHS has determined uses standards at least equivalent to the NAIC Model Act should be given "deemed" status as meeting the national minimum network adequacy standards.

Out-Of Network Providers

A formalized 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 would be of significant value to enrollees. In a number of situations the provider is not willing to be a participating provider in a health plan network. In other situations, the provider may not be willing to accept the health plan reimbursement and the enrollee is required to pay the full cost of the services and submit the bill for payment to the health plan. To add to the confusion, the enrollee's physician or surgeon and the hospital may be participating providers, but other providers involved in the enrollee's treatment are not and the enrollee finds out after the treatment that certain providers are not participating. The end result is that enrollees incur significant unplanned financial costs

because a participating practitioner or facility is not available. A health plan process to assist enrollees prospectively in identifying the participation of providers and either finding accessible participating providers or helping to negotiate the fees from non-participating providers would be extremely helpful.

Exchanges should also incorporate provisions in their network adequacy requirements to address access to centers of excellence for certain tertiary or specialized care that may not be available within the geographic service area of the QHP or the Exchange. For example, a child born with severe congenital heart defects may need access to a pediatric cardiologist and a children's hospital that may not be available within the area of the Exchange. Such a requirement is included in the NAIC's Managed Care Plan Network Adequacy Model Act, as well as in the Contract Year 2012 Medicare Advantage Health Services Delivery Guidance.

Recommendation: 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 should be adopted.

Service area of a QHP, §155.1055

The service areas established by an exchange should be consistent with those in a state's insurance markets outside the exchange. If they are not, the exchange plans may be at risk of adverse selection, because their competitors in the outside markets could have greater ability to pick and choose the areas where they will offer their products, possibly in ways that help avoid sicker, high-cost enrollees. If a state is operating its exchange, it should apply the service areas for QHPs to the outside market.

Recommendation: QHPs offered in the Exchange should have the same service area inside and outside of the exchange.

PART 156
SUBPART C—Qualified Health Plan Minimum Certification Standards

QHP issuer participation standards, §156.200

This section sets out the requirements for the issuers of qualified health plans in an exchange. In several specific areas, such as marketing and network adequacy, we believe there should be minimum federal standards for QHPs. To build on the existing state laws and regulation (such as market conduct examinations), avoid additional unneeded regulation and ensure that QHPs inside and outside of the exchange are subject to the same requirements, we support providing states operating their own exchanges with significant flexibility to enforce their current laws as part of the process for certifying QHPs and other related requirements. The federal rules must ensure that QHPs are held to certain minimum standards no matter where in the country they operate, but should avoid adding regulations that are not needed. This approach will minimize the risk of adverse selection that may result if the rules are different inside and outside the exchange and avoid confusion for both the QHPs and Exchanges if there are different rules for the same activity in the same state.

Transparency in coverage, §156.220

The proposed rule requires that a QHP issuer must make available the amount of enrollee cost-sharing under the individual's plan or coverage with respect to the furnishing of a specific item or service by a participating provider in a timely manner upon request of the individual. At a minimum, such information must be made available to such individual through an Internet website and such other means for individuals without access to the Internet.

HHS should elaborate on this requirement to define "timely manner" and the format in which this information should be provided (e.g. paper vs. electronic) to align with the final requirements for providing summary of benefits and coverage and the uniform glossary upon request. Any penalties for non-compliance should also align with the penalties put in place for non-compliance with the summary of benefits and coverage requirements.

Recommendation: HHS should align cost-sharing requirements with similar requirements in the proposed rule on Summary of Benefits and Coverage and the Uniform Glossary.

Network Adequacy Standards, §156.230

Network adequacy criteria for QHPs

§156.230(a) of the proposed rule requires QHPs to comply with "any network adequacy standards established by the Exchange consistent with §155.1050. In our comments pertaining to §155.1050, we made a number of recommendations for ensuring that these requirements are meaningful network adequacy standards for QHPs, and we reiterate those recommendations here.

Recommendations: HHS should adopt the NAIC Managed Care Plan Network Adequacy Model Act as the minimum national network adequacy requirements for QHP certification and add provisions to require QHPs that are health indemnity plans to demonstrate that they have a sufficient choice of providers accepting their health plan to meet the minimum national network adequacy standards. QHPs that are accredited by a national accreditation entity that has standards at least equivalent to the NAIC Model Act (as determined by HHS) should be given "deemed" status as meeting the national minimum network adequacy standards.

Access to QHP directories

We strongly agree that a QHPs provider directory should be accessible to enrollees and potential enrollees, and we support allowing Exchanges to have discretion to determine the best way to give potential enrollees access to the provider directory for each QHP as part of the minimum national standard.

When determining how best to make provider directories available to enrollees and potential enrollees, Exchanges should be required to comply with Title VI of the Civil Rights Act, Section 508 of the Rehabilitation Act, and Section 1557 of the ACA. As such, they should be required to ensure that information is available in a variety of ways and formats to meet the needs of enrollees and potential enrollees with disabilities and limited English proficiency.

Recommendations: We support the requirement that a QHP issuer must make its health plan directory available to the Exchange electronically and to potential and current enrollees in

hard copy upon request. In allowing Exchanges to have discretion in determining the best way to give potential enrollees access to the provider directory for each QHP, the final rule should ensure that they be required to address the needs of enrollees and potential enrollees with diverse cultural and ethnic backgrounds, limited English proficiency, and physical and mental disabilities.

Identification of providers not accepting new patients and updating of directory

We support requiring the QHP issuer to identify providers that are not accepting new patients or are no longer part of the network on a quarterly basis as a minimum standard. QHPs that are indemnity health plans should similarly be required to update the names of providers and facilities accepting their coverage on a quarterly basis. In addition, the electronic and paper provider directories should include educational language advising an enrollee or potential enrollee to call the provider or facility to confirm that the provider is still participating in the QHP and accepting new patients before seeking care to avoid potential situations where the care will be out-of-network with higher cost sharing.

QHPs should also be required to notify enrollees under active treatment with a provider or with scheduled procedures or hospital admissions if their provider has submitted a termination notice to the QHP so that the enrollee can make alternative plans for treatment services with a participating provider or the QHP can work with the terminating provider to make sure the services are still treated as covered services and enrollees are not subject to out-of-network cost sharing requirements.

Recommendation: We support requiring QHP issuers to update their directory on a quarterly basis to identify providers that are not accepting new patients or are no longer part of the network as a minimum national standard.

Treatment of direct primary care medical homes, §156.245

The implementation of the patient-centered medical home concept could profoundly advance health care in this country, both by improving the quality of care patients receive and experience and by reducing costs. A patient-centered medical home provides care in a different way than most primary care practices do. The practice organizes care around the patient and his or her care, and emphasizes care coordination, patient self-management support, and continuous quality measurement and improvement. This results in better patient experiences with care and bring significant health and cost benefits, including greater attention to prevention and wellness, more care coordination, reduced health disparities, and fewer hospitalizations. As we have previously recommended to CMS, we do urge CMS to consider adopting an approach to patient-centered medical homes that would allow those specialists who are willing to take on the role of primary care physician to be designated as the primary provider of the beneficiary. We believe that allowing this flexibility will foster the development of creative ACO structures, perhaps spurring some specialists to become more oriented to comprehensive care and some generalists to develop specific skills in certain chronic diseases.

We support the integration of patient-centered medical homes into QHPs. Exchanges should leverage a range of tools to encourage use of patient-centered medical homes, such as reporting requirements that call for the percentage of primary care providers in a plan's network that are part of a recognized patient-centered medical home and, eventually, the percentage of primary care

services provided by a patient-centered medical home. QHPs should be allowed and encouraged to use payment incentives such as a network tiering policy that makes patient-centered medical homes available at a lower level of cost-sharing or tying payment rates to providers to their performance on measures relevant to patient-centered care. Consumers should be educated about the benefits afforded by a patient-centered medical home.

Recommendation: Exchanges should leverage a range of tools to encourage the integration of recognized patient-centered medical homes into QHP networks and not be limited to the direct payment arrangement described in the proposed rule.

Accreditation of QHP Issuers, §156.275

General requirements, §156.275(a)

The proposed rule requires QHP issuers to be accredited on the basis of local performance of its QHPs in a number of categories by an accrediting entity recognized by HHS. In the preamble, HHS solicits comments on the standards by which HHS should recognize accrediting bodies. To ensure that accreditation is meaningful for consumers, we recommend that HHS include the following as minimum standards for recognizing accrediting bodies:

- The accreditor must publicly report accreditation results, including performance on patient experience through CAHPS and on clinical quality measures, such as HEDIS, so that consumers and purchasers are informed about both quality as well as cost when picking a QHP.
- The accreditor must review a number of health plan processes important to consumers, including but not limited to those related to marketing practices, appeals processes, utilization management, quality improvement, network adequacy, patient information programs, member privacy, and language access services.
- The accreditor must maintain network adequacy standards that are equivalent to or more robust than the National Association of Insurance Commissioner's (NAIC's) Managed Care Plan Network Adequacy Model Act.

Recommendations: HHS-recognized accrediting bodies must require plans to publicly report accreditation and quality results; review health plan processes related to marketing practices, appeals processes, utilization management, quality improvement, network adequacy patient information programs, member privacy, and language access services; and maintain network adequacy standards that are at least equivalent to the NAIC's Managed Care Plan Network Adequacy Model Act. Exchanges should be required to publish consumer-friendly accreditation and quality information on their Internet Web sites for all accredited QHPs. If QHPs are not yet accredited, this should be reported.

Time frame for accreditation, §156.275(b)

The proposed rule requires a QHP issuer to be accredited within the timeframe established by the Exchange in which they are operating. Instead, we encourage HHS to set a universal timeframe for all Exchanges to minimize burden on states, as well as QHP issuers operating across jurisdictions.

This grace period should be no longer than two years, unless QHP issuers can document extenuating circumstances for the delay.

Recommendation: QHP issuers must be accredited no later than two years after certification.

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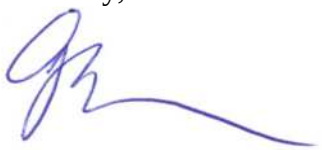
Thank you again for the opportunity to share our comments on these issues related to the establishment and operation of exchanges and certification of QHPs. If you have any questions, please feel free to contact Stephanie Mohl, Government Relations Manager, at Stephanie.Mohl@heart.org or 202-785-7909.

Sincerely,



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