



September 28, 2011

Donald M. Berwick
Administrator, Centers for Medicare and Medicaid Services

Secretary Sebelius,
Secretary

U.S. Department of Health and Human Services
Attention: CMS-9989-P
P.O. Box 8010,
Baltimore, MD, 21244-8013

Submitted electronically to [Http://www.regulations.gov](http://www.regulations.gov)

Re: Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans CMS-9989-P: RIN 0938-AQ67; 45 Fed. Reg. Part 155 and 156. July 15, 2011.

The Nursing Alliance for Quality Care (NAQC) welcomes the opportunity to offer comments on this proposed rule. NAQC is a partnership among the nation's leading nursing organizations to advance the highest quality, safety and value of consumer-centered health care for all individuals-patients, their families, and their communities. NAQC works to ensure that: patients receive the right care at the right time by the right professional; nurses actively advocate and are accountable for consumer-centered, high quality health care; and that policy makers recognize the contributions of nurses in advancing consumer-centered, high quality health care.

NAQC recognizes the importance of codification of this important legislation, and the necessary bureaucracy it will create. We also appreciate the challenges of balancing individual states' needs with Federal requirements. In the interests of simplicity, cost containment and clarity for consumers, however, we support all reasonable efforts at standardization, and all possible utilization of existing structures and systems. For example, we applaud the proposed use as described of structures similar to those successful in Medicare, Medicaid and CHIP, and incorporation of existing standards established by HIPAA and other Federal regulations.

The Federal government is required to establish and operate an exchange on behalf of any state unable to do so, and must therefore design the necessary infrastructure. We strongly support the described options for states to utilize Federally-designed business functions. We recommend expedited public distribution of that design

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and all associated details including document templates. To the extent that States elect to adopt this common structure, there is potential for significant cost reduction overall, and improved cohesiveness for consumers. Likewise, the options for regionalization or multi-state exchanges represent potentially improved efficiency. NAQC supports this flexibility. The agency seeks comments and suggestions on how best to construct partnership models to implement segments of section 1311 of the Affordable Care Act. We suggest consideration of a model for dissemination of best practices similar to that offered by the Institute for Healthcare Improvement (IHI) Map for Improvement (<http://app.ihl.org/imap/tool/>).

II. Provisions of the Proposed Regulation

155-Exchange Establishment Standards and Other Related Standards under the Affordable Care Act
105 and 155.106

Timelines seem appropriate. Good flexibility in provisions for States who don't meet the deadlines to continue the application process while protecting consumer interests by initiation of a Federal program, and likewise by allowing States a mechanism to opt in or out of the Federal program in an orderly manner.

155.110

The proposed transparency in operations of the exchange is commendable. NAQC supports exclusion of health insurance issuers from eligibility to carry out the responsibilities of the Exchange. We applaud the recognition of the many potential conflicts of interest in this proposed rule, including the limitations on health insurance issuers participation in Exchange governing boards. Further, we **recommend** strengthening this section. The rule as currently drafted states that "...governing board membership is not made up of a majority of voting representatives with a conflict of interest, including representatives of health insurance issuers or agents or brokers, or any other individual licensed to sell health insurance...". In view of the reality of group dynamics and the relative power of industry representatives vs. consumer representatives, NAQC requests consideration of a higher standard of exclusion to define a specific percentage of governing board members who may have such a conflict of interest, such as 10% - 20%.

155.130

NAQC applauds the specific requirement that Exchange stakeholders must include advocates for vulnerable populations, including those with mental health or substance abuse disorders. We **recommend** language to require inclusion of advocates for individuals with disabilities, and those who need culturally and linguistically appropriate services. The description of the rule indicates this will be "encouraged" but no provision is provided in the rule itself.

155.150

Existing exchanges in operation prior to 2010 are presumed to meet the standard if "The State has insured a percentage of its population not less than the percentage

of the population projected to be covered nationally after the implementation of the Affordable Care Act". Unfortunately, there is no provision to assure that this includes members of vulnerable populations as described elsewhere in the document. Further requirements for existing programs to meet Federal standards are vague (affected States must "work with" HHS to identify non-compliance) which might allow an inequity to continue indefinitely. We **recommend** clarification of the requirement of pre-existing Exchanges in regard to equitable distribution of coverage.

155.160

The agency should clarify that any user fee assessed to the issuer is a portion of the insurance issuers' administrative cost, reported to consumers via medical loss ratio data, and that this cost cannot otherwise be passed to the consumer.

Section (b)(2) is of concern, as it provides very broad authority to states to collect fees for maintenance of the Exchange, including the described "provider taxes". Efforts to provide maximal State autonomy should not be permitted to defeat the fundamental intent of the legislation, which did not include passing costs of Exchanges to health care providers.

155.200

The current rule does not provide specific language regarding the role of the Exchange in evaluating quality improvement strategies and implementation of "assessment and ratings of healthcare quality and outcomes". The Department notes that this will be addressed further in future rulemaking. NAQC strongly **recommends** that this be conducted within the framework of existing quality improvement structures whenever possible. While it is critical for consumers to have access to this information through the Exchange, the Exchange should not create an additional layer of data collection to providers or facilities if sufficient assessment of quality is conducted through other venues.

155.205

As noted on page one, we support all opportunities for Federal models for optional state adoption, including the model calculator described in this segment of the proposed rule.

155.210

Conflict of interest exclusions should be strengthened better precludes those with historical employment in insurance sales from the role of Navigator. The current provision to exclude only those with conflict of interest during the term of navigator is sufficient for *other* entities. We support the requirement that Navigator grantees must reflect a cross section of stakeholders. Whenever possible, we **recommend** the development of standardized online training and evaluation tools to assist Navigators in meeting the requirements for maintenance of expertise. We **recommend** an earlier mandatory start date for Navigator program availability than the proposed first day of open enrollment. Consumers are likely to be investigating options well before that date and would benefit from the guidance of Navigators.

155.220

NAQC appreciates the consumer support of allowing brokers and agents to enroll participants in QHPs. However, we **recommend** that agents and brokers be required to disclose that no such support is required, that individuals or employers may enroll directly through the Exchange, and where to locate the Exchange website.

155.260

NAQC supports the critically important provision for privacy and security of personal information of consumers, including any information provided to Exchange contractors or sub-contractors. We **recommend** that data also be collect in a manner which allows de-identification, so that appropriate data might more easily be made available for research and analysis through independent institutions (in compliance with formal Institutional Review Board approval).

155.405

While we are in favor of the general concept that Exchanges not be permitted to require application responses unless pertinent to eligibility and enrollment, States should not be precluded from gathering data which will assist them in research and quality efforts. Consider a provision for states to apply to the Secretary for consent to add items to the application with good cause.

155.410

NAQC supports the greatest reasonable flexibility for allowing consumers options regarding enrollment periods. Proposed timelines including that for initial enrollment seem reasonable. We agree with the annual enrollment date concluding on December 15 for the reasons outlined in the proposal. Streamlined enrollment and implementation of existing guidelines (such as those utilized by Medicare) for triggering events represents good use of resources.

155.420

Definitions of special enrollment periods are well thought out. For circumstances in which employees become eligible in response to changes in an employer plan, NAQC finds concerns with both options discussed for timing to initiate the special enrollment period. We suggest centering the special enrollment period on the event of termination of employer-sponsored coverage. With regard to individuals who move, the option for a 60 day window beginning with notice of the move makes the most sense, as only the individual is likely to be able to determine permanency of any relocation.

The inability of enrollees to change benefit levels during periods of special enrollment may be at odds with the intent of this legislation. Even in consideration of adverse selection, individuals who experience significant life changes include those who may be most vulnerable to catastrophic loss or medical bankruptcy. NAQC **recommends** a review of this portion of the proposed rule.

155.430

NAQC supports maintenance of records by the exchanges and periodic audits by HHS to assure appropriate applications of the guidelines. As noted, we

recommend that a provision be available for de-identified records to be accessible to researchers and others evaluating aspects of quality care.

155.700

Special enrollment periods generally mirroring those provided to individuals is appropriate and provides consistency.

As consumer advocates, we support the greatest flexibility possible for plan selection. We therefore oppose an option for employers to allow only a single QHP for employees. We strongly support a model in which qualified employees may purchase plans across levels, with mitigation of adverse selection risk as described. Provision of only plans which provide 60 - 70% coverage places vulnerable individuals with stable chronic health problems at unacceptable risk. NAQC recognizes the value in simplification of logistics, especially for small employers, and we support the proposal to allow only annual adjustments to rates.

155.715

We support use of standardized and streamlined application forms. In the instance when employees are notified that their employers have ceased coverage via the SHOP, NAQC **recommends** that such notification also inform the individual about eligibility for special enrollment periods and for advance payments and cost sharing.

155.720

NAQC supports similar enrollment processes and timelines across QHPs to allow qualified employees the greatest opportunity to select preferred plans. Federal guidelines for enrollment reconciliation will ease administrative burden for multi-State employers.

155.725

NAQC supports consistency of enrollment dates with those in the individual market whenever possible, to minimize public confusion and aide implementation. Standardization of plan years with the individual market may be beneficial for the same reason. If practical, it may be ideal to allow employers to pro-rate their initial year of participation and roll to a calendar year on January 1st of the following year. This would address the complexity of open enrollment for various employers occurring across the entire calendar year.

155.1000

In view of the decision to move debate about inclusion of plans ("any-willing" vs. the active purchasing approach) to the State level, NAQC **recommends** a Federal monitoring and tracking phase to determine which model or combination of models is more successful.

155.1045

This section is concerning, in that it appears to allow a plan to be certified as a QHP without being issued by a (currently) accredited issuer, which was not the intent of the legislation. The Department notes that accreditation may be a lengthy process of eighteen months or longer. Allowing complete State autonomy in this

regard may fail to offer adequate consumer protection during a prolonged "grace period". We **recommend** Federal guidelines to require that only accredited issuers may submit a plan for certification, or to create a significantly shorter timeline for accreditation.

155.1050

Unless this will be sufficiently addressed in Section 156.235 of the final rule, NAQC strongly **recommends** that this very broad standard include at a minimum the clarification that the Exchange must assure that the network of QHPs offer a sufficient choice of primary and specialty providers to assure appropriate health care for enrollees *in all geographic areas* within the State. The referenced standards of "*QHP issuers would be required to maintain the following: (1) sufficient numbers and types of providers to assure that services are accessible without unreasonable delay; (2) arrangements to ensure a reasonable proximity of participating providers to the residence or workplace of enrollees, including a reasonable proximity and accessibility of providers accepting new patients; (3) an ongoing monitoring process to ensure sufficiency of the network for enrollees; and (4) a process to ensure that an enrollee can obtain a covered benefit from an out-of-network provider at no additional cost if no network provider is accessible for that benefit in a timely manner*" are suitable and appropriate. We also support inclusion of the requirement that the QHP provider network provide sufficient access for enrollees in a medically underserved area.

155.1055

NAQC strongly supports these realistic efforts to prevent issuers from selection of choice populations at the expense of vulnerable individuals.

155.1065

NAQC appreciates the recognition of the role of oral health, and the need for inclusion of pediatric dental services.

156.200

As noted in section 155.200, NAQC **strongly recommends** that the Department facilitate the use of nationally standardized quality improvement measures. Meaningful quality improvement requires extensive development and evaluation measures, as well as substantial data collection and analysis. The commendable intent of this legislation should not result in redundancy or duplication of efforts with other agencies.

156.225

NAQC applauds the recognition of the importance of evaluating QHP marketing practices to assure non-discrimination. We support an aggressive prohibition against unfair or deceptive marketing practices, including a uniform Federal minimum standard and additional State-identified standards. Issuers found to be out of compliance with standards or in violation of acceptable marketing practices should be subject to decertification of the relevant plan and potentially of exclusion from the Exchange.

156.230

Provision of a current provider directory to potential enrollees presents challenges of timeliness and accuracy. NAQC supports presentation of this information via a

link to the issuer's website as well as requiring that Exchanges provide a consolidated directory to allow searches across QHPs. These directories will require frequent updates (every 60 to 90 days) to reach a threshold of usefulness. The goal of identifying which providers accept new patients is laudable but may not be feasible, as provider status in this regard may be quite fluid, and the frequency of updates needed is likely to be unrealistic.

156.235

This section as written presents several important concerns. As noted, the requirement for a QHP issuer to include "a sufficient number" of essential community providers begs the question of how to define sufficiency and the definition provided (that the number be adequate to ensure timely access) does not provide a measureable standard. Failure to provide better specifics risks jeopardizing access to care for the citizens most vulnerable to socioeconomic discrimination. NAQC **recommends** defining sufficiency in this population in terms of ratio of providers to enrollees, and further **recommends** that benchmarks for essential community providers mirror the ratio seen in other populations served by the QHP.

Absent a requirement for an *individual* essential community provider to offer specific services or procedures, NAQC **recommends** that QHPs contract a broad enough panel of providers to assure that all essential medical services are available to each population in question.

In regard to questions about empanelling any-willing essential community provider vs. selection of providers based on attributes of quality and value, NAQC **recommends** a default position of accepting all willing providers in these areas and allowing an opportunity for them to meet threshold quality and value standards. Integrated delivery network plans should be held accountable to the same standards as individual providers, and may themselves be tasked with the requirement to assure that staff members meet targets of quality and efficiency.

Definition of essential community providers

b) Inclusion. Essential community providers under paragraph (a) of this section include:

- (1) Health care providers defined in section 340B(a)(4) of the PHS Act; and
- (2) Providers described in section 1927(c)(1)(D)(i)(IV) of the Act as set forth by section 221 of P.L. 111-8.

In regard to the described conflict with payment of Federally Qualified Health Centers, NAQC supports the requirement that they be reimbursed at their individually established Medicaid prospective payment system (PPS) rate. Although this rate may be higher than that paid to other contracted providers, FQHCs have met rigorous criteria to define rates needed to provide sustainable "safety net" services.

156.245

NAQC supports better definition of a reimbursement strategy for the direct primary care medical home. This model is under wide investigation and expansion, and must be taken into clear account.

156.270

We **recommend** that the notice of termination of coverage outline the options for re-enrollment or future coverage.

156.275

NAQC supports utilization of existing structures where possible for accreditation, including those in place for Medicare Advantage plans.

Collection of Information Requirements

As noted, NAQC strongly **recommends** reduction of the time and cost burden through the Federal development of adoptable models, templates, guidelines and forms. This could include model recommended software for compliance with other data collection and reporting as well. At a minimum, a central clearinghouse should be established for State Exchanges to network best practices and share effective tools.

Thank you for the opportunity to comment on this important rule.



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