



June 6, 2011

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

Secretary Sebelius,  
Secretary

Department of Health and Human Services  
Attention: CMS -1345-P  
P.O. Box 8013,  
Baltimore, MD, 21244-8013

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

**Re: Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations:** CMS-1345-P; RIN 0938-AQ22; 42 Fed. Reg. Part 425, March 31, 2011.

Dear Administrator Berwick, Secretary Sebelius:

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 applauds the efforts by the Centers for Medicare and Medicaid (CMS) to create a plan for Accountable Care Organizations by which consumers and providers of health care can share in real cost savings resulting from delivery of well-coordinated high quality care. We likewise support the perspective that the Shared Savings Program should provide an entry point for all willing organizations that wish to move in the direction of providing value-driven health care. However, we oppose the construction of this Shared Savings Program in such a way that only Medicare participants assigned to physicians are eligible for either evaluation of the ACOs' performance levels or the calculation of cost savings associated with their care.

**NAQC Board**

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## **Section II.A. Operational Definitions - No Comment**

## **Section II. B. Eligibility Requirements –**

### **II. B. 1. Eligible Entities**

The Nursing Alliance for Quality Care is pleased to see defined in this section that an “ACO professional” initially is defined so as to include “practitioners” such as nurse practitioners, clinical nurse specialists and physician assistants. We would add certified nurse-midwives to that list as well, since they provide much primary care to a substantial segment of the population. However, we object to the subsequent interpretation that the only beneficiaries who count in qualifying an ACO are those whose primary care providers are physicians. This interpretation continues to perpetuate and support a system of health care that limits the expansion of access to high quality services, the opportunities for cost savings, and the ability of providers other than physicians to demonstrate their real value. Providers such as nurse practitioners and nurse midwives play a much needed and often critical role in the delivery of the nation’s health in rural and underserved areas. Their impact needs to be captured in the same manner and with the same opportunities as their colleagues.

This section also addresses the rationale for excluding from participation those providers of services such as Federally Qualified Health Centers, rural health centers, critical access hospitals, and others. We support option three that would allow the inclusion of these entities, for much the same reason that we believe ACO professionals other than physicians should be allowed to participate. All of these alternatives provide additional access to high quality care and it is time the system recognizes and supports their inclusion in the building of new models, such as ACOs. If the current absence of the same level of data needed for evaluation presents challenges regarding measurement of their performance, then it would make more sense to solve that problem, or create a proxy for that data until it can be gathered, rather than eliminate FQHCs, RHCs, NPs and others from consideration and thereby removing new potential solutions to old problems.

### **II. B.2. Legal Structure and Governance**

NAQC would support the proposed rules in this area, including the expectation that the creation of a separate entity would need to be established in order to provide all ACO participants a mechanism for shared governance and decision making. We believe that transparency and shared governance for all participants of an ACO is essential. We support CMS’ proposal that ACO participants (service providers and suppliers) must have at least 75% control of the ACO governing body, and that each ACO participant must choose an appropriate representative from within its organization to represent them on the governing body. NAQC likewise supports the requirement that there be partnerships with community stakeholders and the inclusion of community stakeholder organizations as well as beneficiaries on governing boards of each ACO.

### **II. B. 3. Leadership and Management Structure**

While NAQC appreciates the concern that physicians need to be highly engaged in the quality assurance programs and performance improvement efforts of the ACO, and that physician champions are essential to support of this engagement, we object to the requirement “that each ACO has a physician-directed quality assurance and improvement committee.” This shows a lack of regard for the importance of the interdisciplinary nature of an ACO model, and again perpetuates a philosophy about health care systems where only physicians can direct such activities successfully. NAQC would recommend language that is consistent with the definition of an “ACO professional” that allows health professionals of various disciplines to serve in this capacity, dependent upon the make-up of the team, the skills and strengths of the various members and the needs of the ACO.

#### **II. B. 6. Distribution of Savings**

While NAQC supports that there be sufficient volume of beneficiaries assigned to an ACO and do not argue with the minimum number of 5,000, NAQC contends that these should not be limited to those beneficiaries who have received the plurality of their care from physicians, due to the exclusionary nature of this rule and due to the opportunities for cost savings and improved outcomes that are likely to be lost for both beneficiaries and ACOs. As stated above, the current proposed language ignores the needs of many Medicare beneficiaries who regularly use the services of nurse practitioners (NPs), clinical nurse specialists (CNSs), and certified nurse-midwives (CNMs) for their primary care needs.

With regard to the consequences for an ACO falling below the 5,000 minimum numbers of beneficiaries, we support the compromise language proposed in the rule, allowing for this to be noted, the ACO warned, but also allowing the ACO to remain eligible for shared savings in that year while they rebuild their volume.

#### **II. B. 9. Processes to Promote Evidence-Based Medicine, Patient Engagement, Reporting and Coordination of Care**

NAQC supports the proposed rule with regard to documentation in each ACO application describing its plans to: promote evidence-based medicine, although we believe this more appropriately should be “evidence-based health care”. We believe that health care is the goal of this model, not just better “medicine”. NAQC also supports the inclusion in this proposed rule of the language requiring plans to promote beneficiary engagement, to report internally on quality and cost metrics, and to plan for coordination of care. However, we believe this proposed language needs to go much further than including the use of telemedicine, remote monitoring, and enabling technologies. Such enabling technologies are merely tools to be used in care coordination; they do not provide care coordination in and of themselves. More important, it is the manpower and the skill set of those human beings, (e.g. RNs) who provide the care coordination for patients and families that is individualized, timely, sensitive to patient preferences, and jointly agreed upon by patients and professionals. The proposed language ignores the integrated health care principles that we believed ACOs were to address. (See *Integrative Medicine and Patient-Centered Care* by Maizes, V., Raket, D., and C. Niemiec, Commissioned Paper for the IOM Summit on Integrative Medicine and the Health of the Public, February, 2009.)

As the state of the science continues to improve in the development of measures for patient engagement and coordination of care, we would support a more prescriptive approach to this plan and its implementation. We applaud efforts to ensure that patient engagement is clearly evident in the plans of each ACO. With regard to “define processes to report on quality and cost measures” NAQC believes that ACOs should not be required to focus just on physician data, but instead should also use data that are reflective of the interdisciplinary team, including all ACO professionals and Registered Nurses (RNs).

NAQC supports the emphasis on coordination of care. However, the section describing this planning is very limiting, seemingly focused on a disease-centric medical model, rather than incorporating the greater challenges to coordination, such as transitions from acute care to rehab or long term care or home, or those services requiring the care of other members of the interdisciplinary team in order to return to optimal health. Many of the transition issues impacting positive patient outcomes require input and support from an interdisciplinary team, and include everything from medication reconciliation to financial considerations in obtaining adequate resources, supplies and equipment, patient education, and even assistance in obtaining necessary follow up appointments. NAQC believes that stronger and more inclusive language to describe this set of expectations is needed in order to ensure that such coordination will in fact occur for the beneficiaries. We believe that more specific guidance should be stipulated in this section so there can be no mistake about the level of care coordination required, including implementation of safe, timely, efficient, effective, equitable patient-centered transitions. The proposed language also needs to acknowledge the interdisciplinary nature of this coordination and the recognition that physicians are neither the logical or likely coordinators of this care.

#### **II. B. 10. Patient-Centeredness Criteria**

NAQC applauds the language in the proposed rule that supports the individualization of care in accord with the patient’s own preferences and the encouragement that patients and families be partners in their care. We would request that it go further to strongly state that patients and their families have the right to fully-shared decision making and that ACO professionals strongly encourage and accept this as the patient’s right. Language about being a partner may imply that this is the case, but we think it often is interpreted as far less.

NAQC applauds the language in this section that beneficiaries have access to their own medical records and to relevant clinical knowledge. We do request that this stipulate that such access to medical records be at no or very minimal cost to the patient, recognizing that \$50-100 fees are not considered minimal for most Medicare beneficiaries.

NAQC applauds the proposed rule’s provision that would prohibit any ACO from developing or restraining a beneficiary’s freedom to seek care from providers and suppliers outside the ACO. This will continue to allow for greater access to care from providers of their choosing, particularly under the current proposed language where only physician services determine the beneficiary assignment to an ACO. It also allows for beneficiaries dissatisfied with their service to seek other services or suppliers more accountable or accessible, driving the system to meet the needs of its consumers.

NAQC supports the proposed patient centered requirement that an ACO has a process for evaluating the health needs of the population, including consideration of diversity in its patient population base, and a plan to meet the needs it finds. We do not wish this to become prescriptive, because we believe that there are many good opportunities for such community assessments, and that the skills of various professionals and community agencies should be encouraged to support this effort. We also think that while this is a crucial element in delivery of patient-centered care, it should not become an enormous financial burden to smaller ACOs.

#### **II.B.11. ACO Marketing Guidelines**

NAQC is in support of the need for an ACO's marketing and plan materials to potential beneficiaries to represent fully and accurately the services and freedoms of beneficiaries in utilizing and seeking providers, services and suppliers, both within and outside the ACO. Requiring those to be approved by CMS in every instance has the potential to create a serious bottleneck, but we don't have a better alternative to recommend.

### **Section II. C. Requirements for a 3-year participation agreement and data sharing**

#### **II. C. 5 Identification of Historically Assigned Beneficiaries**

NAQC appreciates the interest in sharing of data with the ACO, available through CMS, regarding the beneficiaries assigned to that ACO. We would caution that care be taken not to share privileged or patient-level data that puts an individual beneficiary at risk when moving among providers, and that the ACO be clearly advised as to how widely such data can be shared. For instance, data shared should be aggregated data, and shared among the professionals and others in an ACO only on a need-to-know basis. Given the integrated design of ACOs, we think that violations could potentially occur without appropriate monitoring and safeguards in place, and would request that CMS be more prescriptive in those policies addressing both its sharing of data and the ACO's sharing of data internally.

NAQC supports the adoption of Data Use Agreements that are very clear with regard to what is considered a violation and to the penalties for such.

NAQC is concerned that since at some points in time provider level data is likely to be used as part of the determination of the ACO's effectiveness and quality of care, how will these data interface with data to the National Practitioner Data Bank (NPDB)? We would ask that some consideration be given to the need to address quality and safety issues of individual professionals that are likely to surface in a new way, and what obligations and safeguards would need to be in place to protect both beneficiaries and ACO professionals and nurses.

NAQC believes that it is important for beneficiaries to have the opportunity to opt-out of claims data sharing and do not believe that the more arduous opt-in approach is required. However, we believe that there must be clear and explicit language to reassure beneficiaries about the process and its pros and cons, and that there is no limit, penalty or modification to their services by choosing to opt out.

### **Section II. D. Methodology for assigning Beneficiaries to ACOs**

NAQC has already stated its dissent with the method for assigning beneficiaries to ACOs, based upon the plurality of their care by physicians, regardless of the amount of care they may receive by others such as nurse practitioners. We would challenge the perspective that the Social Security Act, Section 1899 requires this narrow view and urge revision of this section and others to accommodate the other providers of primary care services.

## **Section II. E. Quality Measures and methodology for measuring**

### **II. E. 2. Scoring Methodology**

NAQC supports the 5 key domains within the dimensions of improved care and improved health that have been proposed to be used as the basis for assessing, benchmarking, rewarding, and improving ACO quality performance. However, we are concerned about the number of measures (65) that are proposed to be reported by all ACOs for each of the three years of the commitment. We believe that this represents an overwhelming burden, a heavy investment, and due to the challenges of time, an unrealistic expectation for this to be in place by January 2012 for all ACOs. In particular, those measures focused on the HITECH requirements and the Use of Clinical Decision Support for instance, are likely to be difficult for smaller ACOs who have not yet fully expanded and tested their technology infrastructure.

NAQC supports the reduction of the initial measures set, and would urge a focus on those measures focused on care coordination or patient engagement. We agree that preference should be placed upon outcome and patient experience of care measures, rather than structural or process measures. We urge the consideration of development and/or use of measures where the larger interdisciplinary team's performance is able to be evaluated. We also urge that measures that assess quality across the continuum of care be retained.

Perhaps additional shared savings could be offered as an incentive to those who complete the entire measure set or an expanded version beyond what is reasonable during this first three years of implementation.

With regard to the use of measures as proposed, NAQC would support that measures designated as all or none, for instance Measures 35 and 52 on Table 1, receive full points if all are achieved or no points if at least one of the criteria are not met. We agree that driving to achievement of important measure bundles is needed to move the bar on population health and this method can be supported from such a perspective.

**Section II. F. Shared Savings Payment Methodology – No Comment**

**Section II. G. Proposed Method for Introducing Risk – No Comment**

**Section II. H. Monitoring ACO Performance – No Comment**

**Section II. I. Coordination with Other Federal Agencies – No Comment**

**Section II. J. Overlap in Medicare Programs and its affect on sharing savings program participants – No Comment**

**Section V. Regulatory impact analysis – No Comment**

NAQC appreciates the opportunity to comment on this important set of proposed rules. If we can be of further assistance, or if you have any questions or comments, please feel free to contact me at 202-994-3484 or at [sonmjs@gwumc.edu](mailto:sonmjs@gwumc.edu)

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