



June 6, 2011

Dr. Donald M. Berwick
Administrator
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013
[Submitted electronically via <http://www.regulations.gov>]

RE: AMIA Comments on Medicare Shared Savings Program: Accountable Care Organizations – CMS-1345-P

Dear Dr. Berwick:

On behalf of AMIA (the American Medical Informatics Association), I am pleased to submit the following comments on the proposed rule for the Medicare Shared Savings Program: Accountable Care Organizations (ACOs). AMIA thanks the Centers for Medicare and Medicaid Services (CMS) for providing this opportunity to inform the development of the next generation of healthcare delivery models in the United States.

AMIA supports CMS's efforts toward developing better models of care. We believe that ACOs, especially as enabled by the science of biomedical and health informatics and tools such as health information technology (health IT), have the potential for achieving needed healthcare delivery and system reforms. Indeed, in any successful, modern model of care the adoption of clinical, administrative, and financially oriented health IT will be critical to the management of patient populations, including scheduling, referrals management, predictive modeling, and cost measurement and management. AMIA also supports such key accountable care concepts as care coordination, patient-centered care, use of evidence based medicine, and quality measurement. However, AMIA also has a number of concerns about the proposed rule as currently written, and we provide more detailed comments and suggestions on these areas below.

Definitions

AMIA suggests that CMS provide clearer definitions for several terms such as "ACO participant," "ACO provider/supplier," "ACO professional," and "Primary care provider." We suggest that CMS clarify that an OB/GYN provider is included in the definition of "primary care provider". In section 425.5(d)(3)(iv)(A)(3), we request that CMS provide a definition for "quality data" and clarify what is meant by "other information".

High Initial Investment

AMIA urges CMS to consider the high initial and ongoing investments in health IT and related infrastructure that will be needed by some participants (especially those in rural or underserved areas of the country) in order to participate in the ACO program. AMIA suggests that CMS further align ACO program IT requirements and timelines with existing and contemplated meaningful use (MU) incentives. To that end, we are encouraged to see the proposed requirement that primary care professionals in an ACO achieve meaningful use by the second year of the ACO agreement. However, we are not certain that the stated 50% requirement is easily attainable. Further, we suggest that CMS expand the requirement to receive MU incentives to additional providers and provider types based on actual experience with the meaningful use program.

IT Governance/Integration

The proposed rule provides specificity in several aspects of the governance of an ACO. Given the importance of health IT to the successful attainment of goals specified in the program, AMIA recommends that CMS require applicants to include detailed plans for managing the health IT needs of the ACO, including but not limited to identifying personnel responsible for health IT. AMIA has previously submitted comments to DHHS and others that describe our position about how the use of health information technologies and information science principles, tools and practices will, ultimately, enable clinicians to make healthcare safer, more effective, efficient, patient-centered, timely, and equitable. This goal can be achieved only if such concepts and technologies are fully integrated into clinical practice and education. In addition to a substantial investment in technology, the successful implementation of a safe electronic platform to improve healthcare delivery and quality will require an investment in people across a broad range of expertise levels. That is, we must ensure that healthcare providers not only invest in electronic health record (EHR) systems, but obtain the competencies required to work with electronic records, including basic computer skills, information literacy, and an understanding of informatics and information management capabilities. In brief, achieving “meaningful use” will be a matter not only of providing financial assistance to eligible providers and hospitals to purchase qualified systems and then expecting technology vendors to provide adequate training and support for the use of those systems, but also to assist providers in obtaining the competencies necessary to select and use EHR systems effectively, and it will mean developing the clerical, administrative, and technical staff necessary to support a healthcare enterprise built on electronic platforms.

Importantly, developing a real “meaningful use” pathway for EHRs will also require supporting the basic and applied informatics science needed to address issues of design safety, change implementation, error monitoring and reduction, and the like. ACO’s IT governance, operational,

and management teams should have access to personnel with appropriate levels of expertise and training in biomedical and health informatics.

Care coordination and patient centeredness require comprehensive care management and sharing of patient information. It is not clear how the proposed ACO rule structure will accommodate Medicare beneficiaries who agree to be assigned to an ACO yet seek some care and provider services out of the ACO structure, particularly among beneficiaries who travel and/or have seasonal residence in other cities, states, or countries. Lastly, if beneficiaries agree to ACO participation, it does not seem reasonable to allow data sharing to be optional as sharing of patient information is essential to communication among the care team in a true patient-centered care coordinated model.

We support CMS's generally non-prescriptive approach to the specific requirements ACOs should take for care coordination, patient centeredness, patient engagement, and use of evidence-based medicine, including which types of health IT to use. Clearly, for each of these areas, health IT will not be the sole solution, but we think that it would be impossible to meet CMS's objectives without active use of health IT, EHRs, robust health information exchange (HIE), and technologies such as patient portals and secure messaging to communicate with patients and to link patients with their EHR data. Thus we suggest that CMS's final rule and application review process ensure that the ACO is making effective use of health IT where applicable technologies are available to help meet a given objective. In addition, we believe that CMS should monitor ACOs for ongoing conformance with key elements of the ACO's approved application, such as health IT use.

Care coordination requires access to patient data that are beyond what would be generated just at transitions of care and that, to this end, robust, bidirectional, query-based approaches to access to patient data, including images, will be important for overall ACO program success. Although there is variation in specific approaches to health information exchange (HIE) the ability to facilitate information exchange among affiliated and unaffiliated providers through the use of interoperability standards is an important ingredient in the success of ACOs. With respect to HIE, it will also be important to provide real-time and clinically rich data for care provided outside of the ACO to supplement the monthly Medicare claims data that CMS proposes to provide.

Quality Measures

We are concerned with the large number of proposed quality measures and suggest that CMS reduce and carefully prioritize these measures for inclusion in the final rule. We believe that the domains for quality measures are generally appropriate and call out the importance of aligning ACO quality measures with other public and private sector initiatives already underway, such as

the National Priority Partnership Goals and NQF's Measures Application Partnership (MAP). For example, we agree with the importance of measures addressing healthcare acquired conditions (HACs). Although the reporting for the HAC composite is proposed to be from claims data, health IT can play an important role in using clinical data, evidence-based medicine, and other tools to measure and reduce HAC incidence. The work of the NQF MAP and Safety workgroups should define measures to achieve stated goals to reduce HACs.

Finally, we emphasize in the strongest possible terms that it is essential that the final ACO quality measures and specifications be released as early as possible so that providers and vendors can make needed changes in their systems and workflow. This need is especially acute for existing measures that may have been specified at the level of the individual provider and not at the group or ACO level.

Lastly, we believe that harmonization of the various quality measures and pay for performance measures across different quality and reporting entities is required. There is undue burden placed on providers today reporting on same/similar quality and related pay for performance measures that are similar but sometimes required in different formats or time sequencing.

Methods of Data Submission

AMIA is concerned about the lack of specificity in the rule's requirements for data submission (Section 425.17) and we suggest that CMS provide additional clarification. We also urge CMS to consider the potential administrative burden that might arise for ACO participants if the rule does not allow participants to take full advantage of their health IT infrastructures. AMIA encourages CMS to move as rapidly as possible toward taking advantage of EHR-based quality reporting capabilities that are included in the health IT incentives program and the NQF eMeasure re-tooling process.

Although we recognize that the group practice reporting option (GPRO) tool may be appropriate for clinically based quality measures that cannot be generated from claims data, we urge CMS to work as quickly as possible with stakeholders, including EHR vendors and HIEs, to assure efficient interfaces between EHRs, HIEs, and the GPRO tool.

Data Sharing

AMIA believes that meaningful, robust, and secure use and sharing of health data will form the basis for many innovations and improvements in healthcare delivery and quality for many years to come. For this reason, we are concerned about the section of the proposed rule (Section 425.19(d)) that would allow beneficiaries to opt out of having their claims data shared between CMS and an ACO.

Use of such data can help: improve the quality of healthcare experiences for individuals; expand knowledge about disease and treatment and prevention; improve understanding about the effectiveness and efficiency of healthcare systems; aid businesses in meeting the needs of their employees and customers; and support public health. AMIA believes that protecting patient privacy is a key element in broadening access to data for activities such as research, and health planning. To protect privacy while allowing access to data, all the personnel, systems, and processes engaging in health information storage and exchange within and across organizations should adhere to principles of data stewardship. Data stewardship encompasses the full range of responsibilities and accountabilities associated with any use of personal health information.¹

In subsection (v), it is noted that the quality assurance program must establish internal performance standards for quality of care and services, cost effectiveness, and process and outcomes improvements, and hold ACO's providers/suppliers accountable for meeting the performance standards. There are 65 proposed Measure Domains. Should this section be clarified to provide that the process and outcomes improvements should at least be targeted with the 65 in mind?

In subsection (vi), it is noted that the guidelines and care delivery process must cover diagnoses with significant potential for the ACO to achieve quality and cost improvement. We suggest that CMS clarify the types and/or numbers of diagnoses that would qualify.

In subsection (viii), it is noted that the ACO must have an infrastructure, such as information technology that enables the ACO to collect and provide feedback to ACO participants and ACO providers/suppliers across the entire ACO, including providing information to influence care at the point of care. We suggest that CMS address what infrastructures will suffice, and what measures might be in place to ensure that the necessary data can be shared across the entire ACO.

Concluding Remarks

AMIA appreciates this opportunity to submit comments and participate in CMS's development of the ACO program, and we thank the CMS for soliciting public input. We serve as a source of informed, unbiased opinions on issues relating to the national health information infrastructure,

¹ Charles Safran, MD, MS, Meryl Bloomrosen, MBA, W. Edward Hammond, PHD, Steven Labkoff, MD; Suzanne Markel-Fox, PHD, Paul C. Tang, MD, Don E. Detmer, MD, MA, Toward a National Framework for the Secondary Use of Health Data: An American Medical Informatics Association White Paper Available from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2329823/pdf/1-S106750270600212X.main.pdf>.

the uses and protection of clinical and personal health information, and a variety of public health considerations, and we are grateful for the opportunity to contribute to your deliberations. Please contact us at any time for further discussion of the issues we have raised.

Sincerely,

A handwritten signature in black ink that reads "Edward H. Shortliffe". The signature is written in a cursive style with a large initial 'E'.

Edward H. Shortliffe, MD, PhD

President and CEO, AMIA

About AMIA

AMIA is an unbiased, authoritative source within the informatics community and the healthcare industry. AMIA and its members are transforming health care through trusted science, education, and practice in biomedical and health informatics. AMIA members – 4,000 informatics professionals from more than 65 countries – belong to a world-class informatics community where they actively share best practices and research for the advancement of the field. Members are subject matter experts dedicated to expanding the role that informaticians play in patient care, public health, teaching, research, administration, and related policy. As the voice of the nation’s top biomedical and health informatics professionals, AMIA plays a leading role in moving basic research findings from bench to bedside, evaluating interventions across communities, assessing the effects of health innovations on public policy, and advancing the field of informatics. See <http://www.amia.org> for more information.