May 7, 2012

Farzad Mostashari, MD
Office of the National Coordinator
Hubert H. Humphrey Building,
Suite 729D, 200 Independence Ave. SW.
Washington, DC 20201

Re: Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology

Dear Dr. Mostashari:

On behalf of AMIA (American Medical Informatics Association), I am pleased to submit these comments in response to the above-referenced proposed rule. AMIA is the professional home for biomedical and health informatics and is dedicated to the development and application of informatics in support of patient care, public health, teaching, research, administration, and related policy. AMIA seeks to enhance health and healthcare delivery through the transformative use of information and communications technology.

AMIA’s 4,000 members advance the use of health information and communications technology in clinical care and clinical research, personal health management, public and population health, and translational science with the ultimate objective of improving health. Our members work throughout the health system in various clinical care, research, academic, government, and commercial organizations.

AMIA thanks the Department of Health and Human Services (the Department) and the Office of the National Coordinator for Health Information Technology (ONC) for issuing this proposed rule, which implements Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology. In providing input, we will provide general comments about the proposed approach, respond to the requests for specific comments included in the Federal Register, and discuss other selected provisions of the proposed rule.

**General Comments**

AMIA strongly believes that there are several underlying principles that are essential to achieving meaningful use of certified electronic health record (EHR) technology: 1) we must invest in people, as well as technology; 2) users need EHR systems that provide cognitive support and evidence-based functionalities; and 3) adoption of EHR systems requires a balancing of benefits and burdens that users will accept.
1. The need to invest in people, as well as technology.

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 the substantial investment in technology and resources, 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—to build an informatics-aware healthcare workforce. That is, we must ensure that healthcare providers not only invest in 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.

With the health sector experiencing wide-scale implementation of robust health information technology (in part because of the financial incentives available), AMIA strongly believes there is a pressing need to increase and broaden the pool of workers who can help healthcare organizations and clinicians to maximize the effectiveness of their investments in such technology. Strengthening the breadth and depth of the biomedical and health informatics workforce is a critical component of the transformation of the American healthcare system through the deployment and use of health information technology (health IT), and AMIA commends the ONC for its efforts to enhance the health IT workforce through a variety of innovative stimulus programs. Funding for these programs is time-limited, and the success of those training programs has not yet been evaluated in terms of employability of the trainees and/or their demonstrable skills and competencies. Thus, we do not believe that adequate attention has yet been paid to assuring a long-term and robust pipeline of a trained and skilled informatics workforce.

In brief, achieving “meaningful use” is a matter not only of providing financial assistance to eligible providers and hospitals to purchase qualified systems and 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 use EHR systems fully. It will mean developing an organizational infrastructure with the technical, administrative, and clerical staff necessary to support a healthcare enterprise built on electronic platforms. It will also require supporting the basic and applied information science needed to address issues of design safety, change implementation, error monitoring and reduction, and the like.

2. The need for cognitive and decision support as well as evidence-based functionalities to improve patient safety and minimize potential harm.

AMIA continues to be concerned that under the proposed rule (and the underlying legislation) achieving meaningful use goals and objectives is, ultimately, the responsibility of eligible professionals (EPs) and hospitals. But, unfortunately, while EHR certification criteria include requirements for enabling or demonstrating functionalities, they do not include requirements for evidence that those functionalities work as intended under real-time conditions of use. While we are enormously supportive of the financial incentives afforded to eligible providers and hospitals under the proposed rule, we are concerned that EHRs will continue to serve as large, costly receptacles of data and decision support that do not enable clinicians to provide the desired levels of continuity, quality, and safety of care.
AMIA continues to believe that the CMS proposed rule for MU Stage 2 and the associated ONC proposed rule outlining the revised set of standards, implementation specifications, and certification criteria for EHR technology should include explicit directions for testing to ensure that vendor systems integrate standards, specifications, and criteria in ways that genuinely provide cognitive support to clinicians. Given the current state of EHRs, it is critical that these rules support “meaningful use” that is genuinely achieved, and are not just one more set of documentation standards that bring no value at the point of care.

3. The need to find a balance of benefits and burdens.

AMIA supports the Department’s goal of developing Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology that will in fact improve health care quality and promote innovation in care delivery and patient involvement. However, we remain concerned about the wide range of goals that the 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology seem to be aimed at, from changing physician and other stakeholder behavior to shaping and in some instances dictating health IT functions and performance. Simply, we are concerned about the use of standards, specifications and criteria to advance policy objectives that may be useful to our society as a whole, but may create significant burdens for providers and are only indirectly related to advancing processes of care or improvements in quality, safety, or efficiency.

As we have recommended in our comments to earlier versions of Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, AMIA suggests that only mature technology applications should be included. There seems to be an underlying assumption by ONC that if a technology exists and is in use that it should be made a requirement for everyone. We think there should be an emphasis on technologies that are mature and have been demonstrated to be efficacious. Process change takes time and resources, and incremental progress is preferable to wholesale process change. Further we again encourage the Department to continue to consider requirements that reflect the inter-disciplinary nature of care delivery and care coordination beyond the walls of the hospital and beyond the current spectrum of EPs.

Clinical Data Capture and Documentation

AMIA’s 2011 Health Policy meeting (http://www.amia.org/meetings-and-events/2011-annual-health-policy-invitational-meeting) focused on clinical data capture and documentation and noted the following principle: The main purpose of data capture and documentation is to support and enhance patient care by facilitating clinical reasoning and decision-making of individual clinicians, as well as by supporting communication and coordination in clinical teams. However, as MU objectives and associated electronic health record certification requirements are implemented, they become yet another form of “mandate” that dictates required clinical data and documentation. AMIA urges that ONC work with other agencies to assure that Federal clinical data capture and documentation and reporting requirements are aligned and harmonized to reduce recording burdens on hospitals and eligible providers. The final report from AMIA’s 2011 Health Policy meeting is in process and we would be happy to summarize our discussions and share the findings and recommendations with ONC and others.

We continue to be concerned that due to the dynamic policy, political, cultural, and technology landscape providers and clinicians face increasing challenges about what needs to be included in
the record to meet various regulatory, payment, accreditation, legal and now MU requirements. We urge ONC to review the growing array of studies that explore the use of specific EHR functionality as well as their effects on clinicians’ time, efficiency and workflow. Several are noted here. 1 2 3 4 5 6 7 8

AMIA’s Usability Efforts

Enhanced communication among stakeholders in different sectors and disciplines will strengthen our collective ability to identify and address critical issues in the development, implementation and safe and effective use of health information technologies. The Federal government should lead efforts to develop, vet, and disseminate widely-accepted methods to identify system design features and organizational attributes that can lead to failure or success of health IT implementations, as well as ways to avoid or minimize unintended consequences. Federal leadership is required to deploy financial and other incentives so that organizations will be more willing and able to share information about technical and organizational safeguards that address potential system failures or unintended consequences. Further, mechanisms are needed to facilitate sharing of the findings of health IT system implementers so that data and lessons learned captured by individual organizations can have broader impact.

We continue to be concerned that the proposed rule issued by ONC for certification of EHR technology may still fall short of ensuring health IT systems that provide not just information but effective cognitive support to users in the clinical setting. Put another way, given the current state of EHRs, it is critical that payment and certification rules support “meaningful use” that is genuinely achieved, and are not just an additional set of documentation standards that bring little value at the point of care. Planned and systematic testing and ongoing evaluation are needed to demonstrate achievement of meaningful use, interoperable health systems, and attainment of the desired effects on improved quality of care.


2 Murray MD, Harris LE, Overhage JM, Zhou XH, Eckert GJ, Smith FE, Buchanan NN, Wolinsky FD, McDonald CJ, Tierney WM. Failure of computerized treatment suggestions to improve the health outcomes of outpatients with uncomplicated hypertension: Results of a randomized controlled trial. Pharmacotherapy 2004; 24:324-337.
explore the complexities and challenges inherent in electronic health record usability practice – design, evaluation, and testing.

The topic is not without controversy. Issues of regulation, certification, and meaningful use criteria have become entwined with the topic of EHR usability. The timely and critical importance of usability of EHRs is underscored by the number of projects underway by several public and private sector organizations in addition to those undertaken by NIST. We expect that the recommendations from the AMIA Usability Task Force will be extremely important for the field and for health care more broadly. The AMIA Usability Task Force is exploring a number of topics including: the role that current and future research can and should play in usability science and the practical implications of incorporating usability testing into the product life cycle. We look forward to sharing the results of our Task Force’s deliberations when it has completed its work.

The Federal Role

Not only ONC, but the broader Federal government (including HHS agencies such as the Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), National Institutes of Health (NIH)), and other Federal agencies such as the Veterans’ Administration and the National Science Foundation (NSF)) should take a leadership role in assuring that health IT is seen as a strategic driver of health system strengthening. However, health IT is certainly not the entire solution. Payment incentives should avoid fostering “technology for technology’s sake,” and rather should encourage EHR system designers and implementers to focus on the use of health IT to contribute to the ultimate goal of improvement in outcomes.

AMIA strongly believes that resources should be allocated to develop and implement critical evaluative efforts of health IT systems. For example, the Federal government could fund the development and dissemination of a validated toolkit that could be used to measure implementation impact and help identify needed changes. The Federal government also could fund the ongoing development and dissemination of lessons learned and best practices. Further, AMIA recommends that organizations such as the National Library of Medicine (NLM) and/or AHRQ be provided resources to fund evaluation efforts to assess continuously whether the benefits promised by this effort are attained and to disseminate the results of such studies.

Enhanced communication among stakeholders in different sectors and disciplines will strengthen our collective ability to identify and address critical issues in the development, implementation and use of health information technologies. The Federal government should lead efforts to develop, vet and disseminate widely-accepted methods to identify system design features and organizational attributes that can lead to failure or success of health IT implementations, as well as ways to avoid or minimize unintended consequences. Federal leadership is required to deploy financial and other incentives so that organizations will be more willing and able to share information about technical and organizational safeguards that address potential system failures or unintended consequences. Further, mechanisms are needed to facilitate sharing of the findings of health IT system implementers so that data captured by individual organizations can have broader impact.
Provisions of the Proposed Rule on Which Comments are Specifically Requested

The proposed rule contains several specific requests for comments. We refer you to AMIA’s annotated Table (attached), which includes sophisticated user reactions to many of the proposed criteria.

Concluding Comments

As a source of informed, unbiased opinions on policy issues relating to the national health information infrastructure, uses and protection of clinical and personal health information, and public health considerations, AMIA and its members are active in developing policy proposals and commentaries to inform the federal government, regional/state governments, and provider organizations in a wide variety of matters related to health IT and its effective and safe use.

AMIA appreciates the opportunity to submit these comments. Again, we thank the Department for issuing this proposed rule which we anticipate will be revised in timely fashion so that eligible providers and hospitals and technology vendors can prepare their systems to demonstrate meaningful use of EHR and qualify for payment incentives under the Medicare and Medicaid programs. Please feel free to contact me or Meryl Bloomrosen, AMIA’s Vice President for Public Policy at any time for further discussion of the issues raised here.

Sincerely,

Kevin Fickenscher, MD, President / CEO