January 14, 2013

Farzad Mostashari, MD  
National Coordinator for Health Information Technology  
Office of the National Coordinator for Health Information Technology  
Department of Health and Human Services  
Hubert H. Humphrey Building  
Suite 729D, 200 Independence Ave. SW.  
Washington, DC 20201

Re: Health Information Technology; HIT Policy Committee: Request for Comment Regarding the Stage 3 Definition of Meaningful Use of Electronic Health Records (EHRs)

Dear Dr. Mostashari:

On behalf of AMIA (American Medical Informatics Association), I am pleased to submit these comments in response to the above-referenced request for comment. 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’s (ONC’s) Health Information Technology Policy Committee (HITPC) for issuing this request for comment. In providing input, we will provide general comments about the proposed approach to Meaningful Use (MU) Stage 3 as well as respond to selected components of the request for specific comments and responses to questions.
General Comments

AMIA continues to strongly believe that there are several underlying principles that are essential to achieving meaningful use (MU) of certified electronic health record (EHR) technology: we must invest in people, as well as technology; users need EHR systems that provide cognitive support and evidence-based functionalities; and 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 continues to believe that 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). However, 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, and it will mean developing the clerical, administrative and technical staff necessary to support a healthcare enterprise built on electronic platforms. It also requires 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 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 EPs 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 strongly believes that the MU Stage 3 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 that will ensure vendor systems integrate standards, specifications, and criteria in ways that genuinely provide cognitive support to clinicians and facilitate shared decision-making with patients, caregivers, and family members. 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 data capture and documentation requirements 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 (Health IT): 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, but we remain concerned about the wide range of goals that the MU criteria 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 without sufficient evidence that it provides “value” or that it “works.” We think there should be an emphasis on technologies that 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 that extends beyond the walls of the acute care hospital (for
example to include home monitoring and other care settings) and beyond the current spectrum of EPs (other medical specialties as well as other professions and disciplines). Additionally, we strongly urge the HITC to further recognize and integrate mechanisms for patient-generated data collection and capture and patient-mediated data reconciliation.

**AMIA’s Usability Efforts**

A new health information technology (IT) policy report will be published early in 2013 in the Journal of AMIA (JAMIA) entitled, Enhancing Patient Safety and the Quality of Care by Improving the Usability of Electronic Health Records: Recommendations from AMIA. The report reflects the results of a year-long project undertaken by AMIA to help address usability issues as EHR adoption increases against a growing body of evidence of and concerns about patient safety issues.

An interdisciplinary team of researchers, practitioners and scholars from diverse stakeholders including academia, industry, and providers were convened by the AMIA Board of Directors and produced a report addressing key issues regarding electronic health records (EHRs), usability, and patient safety. Preliminary findings from the Task Force were discussed during a panel presentation at AMIA’s Annual Symposium held in Chicago in November 2012. The report recognizes that numerous stakeholders, organizations, and individuals play a critical role in addressing challenges with EHR usability, and AMIA makes recommendations for various components of the industry.

AMIA believes that it is important to raise questions on various nationally significant public policy issues. We are especially proud of our ongoing work and that of our members relating to electronic health records/health information technology, patient safety, and quality of care. We believe that this report will help inform and propel national discussions about EHRs; the challenges faced in order to safely and effectively develop, implement, maintain and update systems; and potential solutions to address these challenges. We look forward to sharing the report with DHHS as soon as it is published.

**AMIA’s Activities Regarding Data Capture, Collection and Use**

AMIA has focused on policy issues that are very relevant to ONC’s deployment of Meaningful Use Stage 3. For example, at AMIA’s 2012 Health Policy Conference, discussions focused on furthering a national understanding of data use, re-use, stewardship and governance opportunities and challenges that are being created by current initiatives to increase the deployment of EHRs and PHRs and the increasing availability of data from biologic sources. AMIA looks forward to sharing the conference findings and recommendations with DHHS once the final report from the meeting is finalized.
Another AMIA report entitled, “The future state of clinical data capture and documentation: a report from AMIA’s 2011 Policy Meeting”¹ is also pertinent to ONC’s ongoing MU efforts. The report identified numerous limitations with existing data capture, recording and documentation approaches, systems and processes. The report notes that users often experience significant frustrations such as data overload, documentation redundancies, and data entry inefficiencies. Furthermore, technological capabilities such as the emergence and convergence of devices are outpacing current public policies. At the same time, potentially outdated legacy documentation requirements are hampering source data capture and documentation and hindering innovations in health information technology design. The report is available at:
http://jamia.bmjjournals.com/content/early/2012/09/07/amiajnl-2012-001093.abstract

The Federal Role

ONC plays a key role in coordinating the work of the Federal government, including Department of Health and Human Services Agencies (DHHS) 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 (VA) and the National Science Foundation (NSF), in order to assure that Health IT is seen as a strategic driver of health system strengthening. Increasingly, other agencies including the Federal Communications Commission (FCC) and the Federal Trade Commission (FTC) are involved in aspects of health information technology and applications, especially as technological developments regarding the use of cloud computing and mobile applications and devices have gained prominence.

Health IT is certainly not the entire solution for health system transformation. Payment incentives should avoid fostering “technology for technology’s sake,” but rather encourage EHR system designers and implementers to focus on the use of Health IT to contribute to the ultimate goal of improvement in clinical process and patient outcomes. AMIA continues to strongly believe that resources should be allocated to develop and implement critical evaluative efforts of Health IT systems. Enhanced communication among stakeholders in different sectors and disciplines about common challenges and best practices 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, disseminate, and increase acceptance of 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 capture innovative approaches and successes by individual organizations and facilitate sharing of these findings to other Health IT system implementers so that they have broader impact.

We continue to be concerned that MU Stage 3 may still fall short of ensuring Heath IT systems that provide not just information but effective cognitive support to multidisciplinary care teams in increasing diverse settings. Put another way, given the current state of EHRs it is critical that payment and certification rules support “meaningful use” that is genuinely achieved, that facilitate information-sharing among clinicians and with patients, and are not just an additional set of data collection requirements 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 and the patient experience.

Enhanced communication among stakeholders in and across 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. We urge the Federal government to fund the ongoing development and dissemination of lessons learned and best practices from Federally-funded projects (such as those funded by AHRQ, CMS, NIH, NSF, and ONC) including the Beacon Community sites as well as research undertaken by other national leaders. Furthermore, AMIA recommends that organizations such as AHRQ and the National Library of Medicine (NLM) be provided resources to fund additional evaluation efforts to assess continuously whether the benefits promised by efforts to implement health information technology (including MU and EHR certification) and health information exchange are attained and to widely disseminate the results of such studies. AMIA strongly supports accelerating ongoing efforts that focus on interoperability.

**Proposed Items on Which Comments are Specifically Requested**

We refer you to the annotated Table (attached), which includes AMIA’s comments (highlighted in red) to many of the proposed criteria. To help facilitate responses to future requests for comments, we urge HITPC to consider alternative (document) formats and submission technologies.
Concluding Comments

AMIA appreciates the opportunity to submit these comments. Again, we thank the Department for issuing this request for comments. 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
AMIA President and CEO