



March 15, 2010

Department of Health and Human Services  
Office of the National Coordinator for Health Information Technology  
Attention: HITECH Initial Set Interim Final Rule  
Hubert H. Humphrey Building  
Suite 729 D  
200 Independence Avenue, SW  
Washington, DC 20201

**Health Information Technology: Initial Set of Standards, Implementation Specifications,  
and Certification Criteria for Electronic Health Record Technology  
45 CFR Part 170  
RIN 0991-AB58**

Dear Secretary Sebelius:

On behalf of the American Medical Informatics Association (AMIA), I am pleased to submit these comments in response to the above-referenced interim final 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 interim final rule, which adopts an "initial set of standards, implementation specifications, and certification

criteria” as called for by the HITECH Act contained within the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5). The goal of this rule is “...to enhance the interoperability, functionality, utility, and security of health information technology and to support its meaningful use.” In tandem with the proposed rule published by the Centers for Medicare and Medicaid Services (CMS) that aims to define “meaningful use” (MU) of electronic health records (EHR), the Department has set forth standards – ranging from vocabulary standards to certification criteria that will support the demonstration of MU – with the aim of ensuring the use of Certified EHR technology with a range of capabilities that will improve the delivery of health care and healthcare quality.

### **Comments regarding certification criteria**

In this interim final rule, ONC requests comment as to whether the adopted certification criteria are “insufficiently specific” to be used to test and certify Complete EHRs or EHR modules with “reasonable assurance that the technology will effectively support the delivery of health care as well as the achievement of meaningful use Stage 1, once finalized.” We believe that one of the challenges is that a number of the certification criteria merely restate the MU objective; e.g., “generate lists of patients by specific conditions...” becomes “enable a user to electronically select, sort, retrieve, and output a list of patients...” It is unclear as to how users or vendors will actually test and certify such criteria. We believe that the absence of detail about testing and certifying these criteria is a significant weakness of the criteria and such ambiguity could lead to unintended consequences. In contrast, we do note that a few criteria, such as the one used to meet the MU Stage 1 objective of “protect electronic health information” are considerably clearer and more detailed, enumerating a long and useful list of necessary capabilities, including, in this instance, encryption, decryption, audit logs, and the like.

Beyond the question of testing and certifying EHRs to meet MU criteria is the much larger question of ensuring that those MU criteria are evidence-based and that the EHR will significantly extend the user’s cognitive skills. As we pointed out in a similar comment to CMS, AMIA strongly believes that **users need EHR systems that provide cognitive and decision support and evidence-based functionalities** if those EHRs are to improve patient care and safety, minimize potential harm, and achieve genuine “meaningful use”.

AMIA suggests that the interim final rule outlining an initial set of standards, implementation specifications, and certification criteria for EHR technology issued by ONC **be revised to include directions for testing that will ensure that vendor systems integrate standards, specifications, and criteria in ways that provide validated cognitive and decision support to clinicians.** Given the current state of EHRs, it is critical that this rule, and the associated CMS MU proposed rule, 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. We are concerned about the leap of faith required to believe that

demonstrating ‘meaningful use’ of discrete objectives (such as, “implement drug-drug, drug-allergy, and drug-formulary checks”) will facilitate arrival at interoperable EHR systems that will allow real-time availability of comprehensive patient data and embedded clinical decision support, while also improving patient and family engagement, care coordination, public health reporting, etc. Planned and systematic testing and evaluation are needed to demonstrate achievement of meaningful use, interoperable health systems, and attainment of the desired impacts on improved quality of care.

Our recommendation is based on a recent National Research Council study of eight highly-regarded health care systems with substantial EHR systems that concluded:

The health IT systems of today tend to squeeze all cognitive support for the clinician through the lens of health care transactions and related raw data without an underlying representation of a conceptual model for the patient showing how data fit together and which are important or unimportant. As a result, an understanding of the patient can get lost amidst all the data, all the tests, and all the monitoring equipment.

...current efforts aimed at the nationwide deployment of healthcare IT will not be sufficient to achieve the vision of the 21<sup>st</sup> century and may even set back the cause if efforts continue wholly without change from their present course. Specifically success in this regard will require greater emphasis on providing (validated) cognitive support for health care providers, patients and families... Vendors, health care institutions, and government will also have to pay attention to cognitive support, which refers to computer based tools that offer clinicians and patients (validated) assistance for thinking about and solving problems.

Simply, while the proposed EHR certification criteria include requirements for enabling or demonstrating functionalities of systems, they do not require evidence that those functionalities work as intended once implemented in a specific environment under real-time conditions of use. Absent requirements for planned and systematic testing and evaluation of individual implementations, AMIA is concerned that too many EHR systems – even those that may be ‘certified’ under this rule – 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.

### **Comments regarding adopted standards**

AMIA appreciates that the interim final rule has organized its adopted standards into the four categories recommended by the HIT Standards Committee: Vocabulary, Content Exchange, Transport, and Privacy and Security. Whether the choice is HL7, LOINC, or applicable HIPAA transaction standards, we are supportive of the choices that have been made in regard to vocabulary, content exchange, and transport. In regard to privacy and security, we support the Department’s decision to require Certified EHR Technology to

include encryption capability, as a way of encouraging the use of encryption. At the same time, we note that this interim final rule has not made any changes to existing HIPAA Privacy Rule or Security Rule requirements, and AMIA supports this decision since we would not support making changes to those rules via the adoption of EHR Technology standards.

### **Comments regarding certification criteria and standard regarding accounting of disclosures**

AMIA is concerned about the significant costs and other organizational and logistical impacts of § 13405(c) of the HITECH Act on HIPAA covered entities (CEs). The Act calls for revision of the HIPAA Privacy Rule at 45 CFR 164.528 to require CEs to provide to individuals an accounting of disclosures made through an EHR for purposes of treatment, payment, and health care operations. While we believe that the basic data elements of the functional requirement specified in the rule – date, time, patient ID and user ID – should be within the capacity of a certified EHR, the recording of the final requirement, “a description of the disclosure,” may prove to be a technical and clinical nightmare, unless the Secretary balances very carefully the putative “interests of individuals” with the “administrative burden” on CEs. The interim final rule solicits feedback regarding concerns about the inability of current software to distinguish between “use” and “disclosure” and the amount of electronic storage necessary to record three years of disclosure information, as well as about the technical feasibility of recording other elements of information about a disclosure. “We are specifically interested in comments as to the technical feasibility of recording the purpose or reason for the disclosure, to whom the disclosure was made (i.e., recipient), and any other elements that may be beneficial for a patient to know about with respect to their health information.” Again, AMIA is concerned about the burden on providers, who will have to log all of this information for questionable purposes. Unless patients are getting periodic “disclosure reports,” like credit reports, what is the purpose of keeping these records? Recording the recipient of a disclosure should be straightforward; recording the reason, however, will become burdensome unless there is a standard checklist. We await with great interest a separate rule from the Office for Civil Rights (OCR) that will define in detail the new accounting of disclosures requirements.

### **Comment regarding EHR modules**

The interim final rule gives providers the option to separately procure EHR Modules that preserve the continuity of the providers’ existing systems, but with the added burden of requiring the providers undertake additional due diligence to make sure the resulting Complete EHR is capable of achieving meaningful use. ONC then asks, “Does this trade-off make the procurement of separate EHR Modules attractive?” AMIA believes this tradeoff is reasonable, since the assumption is that providers will be using MU-qualifying systems, and that modules for those systems will also qualify. If the alternative to modules is buying a whole new system, that

approach would slow the development over time of integrated EHR systems that allow and facilitate meaningful use, and replace ‘homegrown’ legacy systems.

### **A Few General Comments**

*First*, we 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 capital, 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 on the brink of wide-scale implementation of robust health information technology, AMIA strongly believes there is a pressing need to increase and broaden the pool of workers who can help healthcare organizations and clinicians not only to meet MU criteria but 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 (HIT), and AMIA commends ONC for its current efforts to enhance the HIT workforce through a variety of novel stimulus programs.

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 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 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.

*Second*, not only ONC and CMS, 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 HIT is seen as a strategic driver of health system strengthening – but HIT is certainly not the entire solution. Payment incentives should avoid fostering “technology for technology’s sake,” but rather encourage EHR

system designers and implementers to focus on the use of HIT 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 and implementation strategies for systems purchased with ARRA-designated funds. For example, the Federal government could fund the development and dissemination of a validated toolkit that could be used to assist with implementation efforts, measure implementation impact and identify needed changes. The Federal government could fund the ongoing development and dissemination of lessons learned and best practices from ARRA-funded implementations and associated activities. 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 HIT 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 HIT system implementers so that data captured by individual organizations can have broader impact.

### **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 appreciates the opportunity to submit these comments. Again, we thank the Department for issuing this interim final rule which we anticipate will be revised as necessary going forward. Please feel free to contact me at any time for further discussion of the issues raised here.

Sincerely,

A handwritten signature in black ink that reads "Edward H. Shortliffe". The signature is written in a cursive, flowing style.

Edward H. Shortliffe, MD, PhD  
President and CEO