



May 10, 2010

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

45 CFR Part 170

RIN 0991-AB59

Proposed Establishment of Certification Programs for Health Information Technology

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 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 establishes both temporary and permanent certification programs for purposes of testing and certifying health information technology (HIT). In this comment, we will offer our thoughts in regard to the permanent certification program proposed by ONC. This proposed rule completes the Department's initial rulemakings to define the meaningful use (MU) of Certified EHR Technology and the use – and the reporting of such use – of EHR technology in order to qualify for payment incentives under the Medicare and Medicaid programs. In fact, Certified EHR Technology must be available before the fall of 2010, as eligible hospitals are scheduled to begin accessing incentive payments on October 1, 2010, (and eligible providers on January 1, 2011).

AMIA previously expressed (in our response to the “initial set of standards, implementation specifications and certification criteria”) the concern that:

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.

We are very much heartened by the extensive testing requirements of the proposed rule, and agree with the distinction between “testing” and “certification”. Further, we strongly support the use of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) ISO/IEC Guides to structure how testing, certification, and accreditation are to be conducted. However, AMIA is concerned that, in order to implement the permanent certification program, it will be quite challenging to develop separate testing laboratories or facilities that are accredited by the NVLAP (National Voluntary Laboratory Accreditation Program), certification organizations approved by the National Coordinator, and ONC-approved accreditation bodies by the 4th quarter of 2012. Likely challenges relate to the timeline of this requirement as well as with the inherent complexities of initiating an accreditation program.

Provisions of Permanent Certification Program

In the section concerning “Application for ONC-ACB Status” the proposed rule notes that “we have added the principle that ONC-ACBs would only be permitted to certify Complete EHRs and/or EHR modules that have been tested by a NVLAP-accredited testing laboratory.” AMIA strongly supports this principle, as it ‘answers’ concerns that have arisen when certifying bodies

also develop and implement (and charge fees for) testing of functions (criteria) to be certified. Similarly, we support the requirement that, prior to submitting an application for ONC-ACB status, an organization would need to be accredited by an ONC-AA as a certifying body. Finally, we support the requirement that ONC-ACBs submit annual surveillance plans relating to previously certified EHRs and EHR modules in accordance with their accreditation. Such ongoing surveillance of certified products will provide essential performance information for prospective purchasers. AMIA further believes that the National Coordinator should take action to “de-certify” EHRs or EHR modules if a pattern of unsatisfactory surveillance results emerges – in our view, not to take such action would undermine industry-wide (practitioner and consumer) confidence in the entire testing/certification/accreditation enterprise.

In the section discussing “Validity of Complete EHR and EHR Module Certification”, AMIA supports the notion of “differential certification”, which we understand as providing a ‘rolling’ process that will keep up with evolving certification criteria. However, for the logistical reasons mentioned above, we suggest that differential certification take effect only when the permanent certification program has begun, and not during the temporary certification program period.

In regard to whether ONC-ACBs should be authorized to certify other HIT, such as PHRs and electronic exchange networks, we appreciate the Department’s willingness to ‘take on’ HIT technologies beyond those that may qualify for payment incentives, but would register significant caution about the applicability of EHR testing and certification processes to products whose functionalities and performance metrics may be fundamentally different from products in the EHR space. We would support the development of separate testing and certification processes for other technologies provided such processes were based on technology-appropriate functionality and performance metrics. Further, a separate accreditation by an ONC-AA would be necessary for an ONC-ACB to certify “other” HIT, such as PHRs or HIEs.

Additional Comments

The use of health information technologies and informatics principles, tools and practices will, ultimately, enable clinicians to make healthcare safer, more effective, efficient, patient-centered, timely and equitable. But 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 in order to build an informatics-aware healthcare workforce. That is, ONC 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.

Simply, 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, clinical and technical staff necessary to support a healthcare enterprise built on and supported by electronic platforms. It will also require leveraging the basic and applied informatics principles needed to address issues of design safety, change implementation, error monitoring and reduction, and the like. Certainly, HIT is a tool but not the entire solution. Payment incentives should avoid fostering “technology for technology’s sake,” but rather encourage EHR system designers, implementers, and users to focus on the application 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 evaluation efforts and implementation strategies for systems purchased with ARRA-designated funds. For example, the Federal government could fund the development and dissemination of validated toolkits 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 the Agency for Research and Quality (AHRQ) be provided resources to fund ongoing evaluation efforts to assess continuously whether the benefits promised by ONC efforts 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.

In Conclusion

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