

March 10, 2010

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Medicare and Medicaid Programs; Electronic Health Record Incentive Program

42 CFR Parts 412, 413, 422, and 495
CMS-0033-P
RIN 0938-AP78

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 Centers for Medicare and Medicaid Services (CMS) for issuing this proposed rule, which implements the initial stage of incentive funding for meaningful use (MU) of certified EHR technology as called for by the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111-5). In providing input, we will respond to the requests for specific comment included in the Federal Register and discuss as well other selected provisions of the proposed rule.

General Comments

AMIA strongly believes that three principles 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 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 (in part because of the financial incentives outlined in the proposed rule), 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 the Office of the National Coordinator for Health Information Technology (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.

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

A recent study of eight highly-regarded health care systems with substantial EHR systems concluded: ¹

....Today, clinicians spend a great deal of time and energy searching and sifting through raw data about patients and trying to integrate these data with their general medical knowledge to form mental abstractions relevant to the patient's situation. Such sifting efforts force clinicians to devote precious cognitive resources to details of data and make it more likely that they will overlook some important higher order consideration.

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 21st 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.

We agree with Stead and Lin, and are 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.

As written, many of the MU criteria and measures appear to be somewhat arbitrary “add-on” functionalities that may or may not support valid use of the EHR by clinicians under practice conditions. Instead, MU criteria and quality measures should be carefully designed and tested to minimize the burden required to process and connect new pieces of information cognitively with the existing clinical

¹ *National Research Council 2009. Editors: Stead WW. & H. Lin; Computational technology for effective health care: Immediate steps and strategic directions*
AMIA Response to Meaningful Use

record. Showing that a user can record, modify, and retrieve a single piece of information or measure it effectively is very different from demonstrating that the EHR fully supports the user to use that information in a way that meaningfully impacts the delivery and the quality of care.

AMIA believes that the CMS proposed rule discussed here and the associated interim final rule outlining an initial set of standards, implementation specifications, and certification criteria for EHR technology issued by ONC should include directions for testing that will ensure 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. We are concerned about the leap of faith required to demonstrate ‘meaningful use’ of discrete objectives (such as, “implement drug-drug, drug-allergy, and drug-formulary checks”). We are also concerned that this same leap of faith says that we will arrive 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. .

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

Explaining its rulemaking approach, CMS states: “In defining meaningful use through the creation of criteria, we have balanced competing considerations of proposing a definition that best ensures reform of health care and improved health care quality, encourages widespread EHR adoption, promotes innovation, and avoids excessive or unnecessary burdens on healthcare providers, while at the same time recognizing the short time-frame available under the HITECH Act for providers to begin using certified EHR technology.” AMIA supports the Department’s goal of developing MU criteria and payment policies that will in fact improve health care quality and promote innovation in care delivery and patient involvement, but we are concerned about the mixture of care (e.g., “maintain an up-to-date problem list”) and health objectives (“report ambulatory quality measures to CMS or the States”) with objectives that seem to be administrative (“submit claims electronically to public and private payers”) and aspirational (“provide patients with timely electronic access to their health information...within 96 hours”) in nature. Recognizing that making broad improvements to health and health care is essential, we are nonetheless concerned about the use of EHR incentives to advance policy objectives (e.g., increasing the use of generic medications, or increasing the use of patient-specific education resources) 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.

In order to balance more effectively the benefits of EHR use with new requirements, AMIA supports several of the recommendations made by the HIT Policy Committee in a letter of February 17, 2010. Specifically, we agree that the four “core” clinical quality measures enumerated in the proposed rule

should be removed from the Stage 1 criteria and that a method for allowing providers a degree of flexibility in meeting meaningful use criteria should be adopted by CMS.

Provisions of the Proposed Rule on Which Comments are Specifically Requested

- CMS states “For the first payment year only, we propose to define the term EHR reporting period...to mean any continuous 90-day period within a payment year in which an EP or eligible hospital successfully demonstrates meaningful use of certified EHR technology.” AMIA agrees that these time periods are reasonable. The shorter timeframe for the first year takes into account the initial implementation process or a process upgrade that occurs late in the year. However, once an eligible provider or hospital can make meaningful use of a certified EHR for 90 consecutive days, continuous operation and reporting should not be a problem. We agree that the reporting period for year 2 and thereafter should be the full year.
- For Medicaid incentives, CMS “would allow States to add additional objectives to the definition of meaningful use or modify how the existing objectives are measured.” Further, “we solicit comments as to whether there exist compelling reasons to give the states additional flexibility in creating disparate definitions beyond what is proposed.” Finally, “hospitals deemed as meaningful users by Medicare would not have to meet the State-specific additional meaningful use requirements in order to qualify for the Medicaid incentive payment.”

While AMIA recognizes that Medicaid is a combined federal-state program, we strongly disagree that individual states be allowed to add additional objectives to the definition of meaningful use or to modify how such objectives are measured. AMIA believes it is essential that the Meaningful Use objectives and measures articulated in the present rule constitute standards that can be built to by EHR technology vendors and used by EPs and hospitals on a nationwide basis – to reproduce another patchwork quilt of varying objectives, measures, and standards is exceedingly ill-advised. Whatever the gain in healthcare quality that could be obtained by any individual state, the negative impact of such variability cannot be overstated. AMIA supports the decision that hospitals deemed as meaningful users by Medicare would not have to meet any state-specific additional requirements in order to qualify for the Medicaid incentive payment – as this decision illustrates our previous point: that Meaningful Use should be a national, not state-by-state, objective.

- “While we believe that requiring satisfaction of all (MU) objectives is appropriate for the majority of providers, we are concerned that certain providers may have difficulty meeting one or more of the proposed objectives. We solicit comments on whether this may be the case, and invite commenters to identify the objectives and associated measures that may prove out of reach for certain provider types or specialties, and to suggest specific objective criteria we could use to determine whether an objective and associated measure is appropriate for different provider types or specialists.”

Please see our comment **above** that supports the HIT Policy Committee recommendation that CMS allow some flexibility in the “all-or-nothing” approach to earning meaningful use incentives, “while preserving a floor of important mandatory functional use requirements.”

[In addition, please see AMIA’s annotated CMS Table 2 (attached), which includes sophisticated user reactions to many of the MU criteria.]

- In the proposed rule CPOE entails “the provider’s use of computer assistance to directly enter medical orders”; the order is documented or captured in a digital, structured, and computable format; CPOE does not include electronic transmittal of the order at this time.

While AMIA believes that CPOE should, ultimately, include electronic transmittal of the order, we agree with the rule’s decision to defer this requirement during Stage 1.

- “Record advance directives” has not been included as an MU criterion for either EPs or hospitals.

AMIA suggests that recording of advanced directives be included as an MU criterion for hospitals only in Stage 1.

- This rule establishes HIT functionality measures for 2011 only – CMS requests public comment on potential functionality measures for EPs and hospitals for 2013 and beyond.

AMIA notes that Stage 1 MU criteria and functionality measures are focused entirely on the delivery and measurement of clinical care. We believe that MU criteria specific to research should be included during Stage 2 and Stage 3 – for instance: “create and aggregate de-identified data and limited data sets for quality and research, by diagnosis, treatment, medication, etc.; utilize CDISC (Clinical Data Interchange Standards Consortium) or other agreed-upon standards to allow ‘automatic’ adverse drug event reporting.

- Within the rule 90 proposed quality measures that could be used by EPs and hospitals are listed in Table 3. Table 4 provides a core group of measures for all EPs, Tables 5-19 list quality measures to be used by specific specialty groups, and Tables 20 and 21 cover hospitals. Clinical quality measures are defined as consisting of “measures of processes, experience, and/or outcomes of patient care, observations or treatment that relate to one or more quality aims for health care such as effective, safe, efficient, patient-centered, equitable, and timely care.” Full-scale quality reporting is not required in 2011, but capturing relevant data elements, e.g., numerators and denominators, is. “We welcome comments on the inclusion or exclusion of any given clinical quality measure proposed herein in the EHR incentive programs’ clinical quality measure set for EPs or eligible hospitals for the 2011 or 2012 payment years, and to our approach in selecting clinical quality measures.”

Even assuming that only a handful of the 90+ proposed quality measures that could be used by EPs and hospitals will be required in 2011, AMIA is very much concerned that the capture of relevant data elements, e.g., numerators and denominators, is likely to be a significant burden for participating EPs and hospitals.

- CMS states that its intention is to bring all EPs and hospitals to the same level of MU by 2015 – we agree and appreciate that there should not be a higher standard in 2015 for an early adopter in comparison to requirements imposed on late adopters.
- In regard to providing record access to individuals, CMS states, “electronic copies may be provided through a number of secure electronic methods (for example, personal health record (PHR), patient portal, CD, USB drive).” AMIA is indeed supportive of improved patient access to electronic health records. However, we would disagree with the characterization of many of the methods cited as “secure” – representing EPs and hospitals we may be able to ‘vouch for’ the security of a patient portal, for instance, but certainly would not consider unencrypted CDs or USB drives or PHRs that are not subject to the HIPAA Security Rule as secure, and we do have concerns about providing access via such methods.
- The Stage 1 measure for ensuring adequate privacy and security protections is to conduct or review a security risk analysis per 45 CFR 164.308(a)(1) and implement security updates as necessary. AMIA is concerned that requiring a HIPAA Security Rule review by all EPs and hospitals will constitute a very large compliance task
- The present rule for ensuring adequate privacy and security protections suggests that PHI should be downloaded into PHRs at the request of the patient; we believe that a similar Security Rule analysis should be required of freestanding PHRs as well.
- AMIA is pleased that the proposed rule recognizes the importance and value of health information exchanges (HIEs)/health information organizations (HIOs) as a mechanism for the submission of clinical quality data and, in regard to the Medicaid program specifically allows the directing of incentive payments directly to HIEs/HIOs in their role as entities promoting the adoption of Certified EHR Technology. We believe that allowing Medicaid EPs to voluntarily assign payments to such entities, providing that the entity does not retain more than 5% of assigned Medicaid incentive payments, will accelerate the adoption of Certified EHR Technology.
- The rule states, “Certified EHR Technology has the potential to help reduce medical costs through efficiency improvements such as prompter treatments, avoidance of duplicate or otherwise unnecessary services, and reduced administrative costs (once systems are in place), with most of the savings being realized by the providers rather than by Medicare or Medicaid.” As supportive as we are of the use of Certified EHR Technology to improve care and even reduce costs, AMIA is doubtful that savings “realized” will accrue primarily to providers rather

than to payers. Certainly, we hope to be proven wrong about this. We recommend that CMS be required to evaluate and document cost savings realized by providers and disseminate their findings widely.

The Federal Role

Not only 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 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 measure implementation impact and help 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 proposed rule which we anticipate will be revised in timely fashion so that

eligible providers and hospitals and technology vendors can prepare to demonstrate meaningful use of EHR and qualify for payment incentives under the Medicare and Medicaid programs. 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 style with a large initial 'E' and 'S'.

Edward H. Shortliffe, MD, PhD
President and CEO