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May 7, 2012

The Honorable Kathleen Sebelius, Secretary of Health and Human Services
U.S. Department of Health and Human Services 200 Independence Ave, SW Washington, DC

Marilyn Tavenner, Acting Administrator and Chief Operating Officer
Centers for Medicare and Medicaid Services 7500 Security Boulevard Baltimore, MD

RE: 42 CFR Parts 412, 413, and 495 [CMS–0044–P] RIN 0938–AQ84
Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2
Comments submitted electronically

Dear Secretary Sebelius and Administrator Tavenner:

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 health information technology (health IT).

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 stage 2 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 provide general comments about the approach to MU Stage 2, respond to the requests for specific comment included in the Federal Register, and discuss other selected provisions of the proposed rule.

General Comments

AMIA strongly believes that the following underlying 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 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 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 IT and AMIA commends the Office of the National Coordinator for Health Information Technology (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 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 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 assisting providers in obtaining the competencies necessary to use EHR systems fully. This will require developing an infrastructure of 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.

We are also concerned that not all proposed Clinical Quality Measures (CQMs) have eMeasures specifications defined and tested in the field in an EHR. We urge CMS to assure that not only should CQMs be tested and validated by the measure developer, but also the measure must be endorsed by the National Quality Forum (NQF) and should only be included in MU if published in advance, in order to give vendors and hospitals and eligible providers sufficient time to test and implement.

AMIA continues to believe that the CMS proposed rule discussed here and the associated proposed rule outlining the revised set of standards, implementation specifications, and certification criteria for EHR technology issued by ONC 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 or requirements for data collection that brings 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 MU criteria and payment policies that will improve health care quality and promote innovation in care delivery and patient involvement. However, we are concerned about the seemingly increased complexity and diversity of the proposed objectives. AMIA is concerned that some of the proposed objectives appear to be aimed at public policy changes beyond the scope of Meaningful Use per se. Thus, while some proposed objectives focused on care delivery, others appear to be designed to drive broader policy goals. 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 hospitals and eligible providers and are only indirectly related to advancing processes of care or improvements in quality, safety, or efficiency. For example,

- Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medical administration record (eMAR).

AMIA believes that most hospitals use some form of eMAR in medication administration today. However, we note that it is impossible to meet this criterion unless the hospital uses an eMAR or the EHR includes that as part of a non-standard feature set. While the use of an eMAR is a valuable safety feature, it appears that MU is being used a vehicle to force the adaptation of another tool. Further, it is not clear to what extent this potential "requirement" is consistent with the accompanying EHR certification standards.

AMIA is also concerned about the CMS decision to remove the requirement that hospitals report laboratory results in structured format to ordering professionals that seemed to be implied in the ONC MU2 NPRM. On page 13732 of the CMS NPRM, CMS asserts that they will not require hospitals to report laboratory results as structured data (in the message structures and with the codes specified by ONC) to EPs (practitioners) who order laboratory tests from outside the hospital. AMIA believes that getting the results of the laboratory tests that office practitioners

ordered from a hospital laboratory in the structured format specified by ONC would allow the results to flow into the record, without manual intervention. Furthermore, with hospitals using same ONC-specified standard, the costs of interfaces would likely be reduced.

Hospital systems are already required to support structured and coded laboratory data for inclusion in the care summary and to support structured data in their EMR. Furthermore they will need to support the HL7 messaging standard for reportable diseases and for biosurveillance. Office practices are obliged to enter laboratory orders. It seems counterproductive not to be able to obtain results in a structured format too.

Definitions and Levels of Specificity The proposed MU stage 2 objectives and measures are inconsistent and sometimes confusing with respect to clearly articulated terms, terminology and definitions. For example:

- Proposed Objective: Use CPOE for medication, laboratory, and radiology orders entered by any licensed healthcare professionals who can enter orders into the medical record per State, local, and professional guidelines to create the first record of the order.

AMIA notes that CPOE is defined as Physician Order Entry but the criterion refers to Provider Order Entry. The definition should change. Further, the definition of the phrase "first record of the order" is unclear.

- Proposed Objective: Use clinical decision support to improve performance on high priority health conditions.

AMIA believes that the term "high priority health conditions" is confusing. Many of the CQM measures relate to process quality improvement and not outcomes and may not be considered a high priority health condition outside payment requirements. Renaming this criterion would be advisable to make it clear that it refers to the use in CQM measures.

Furthermore, although it may be practical to implement functionality that provides access to information on the bibliographic citation(s) and developer of CDS guidance, it is impractical for EHR systems to provide details on the "funding source" of the CDS intervention or the evidence behind the intervention. Many decision support rules are based on guidelines, which typically are developed as a result of evidence stemming from meta-analyses. Meta-analyses incorporate data from multiple primary studies, all of which may have been funded by different sources.

This requirement, therefore, is both ambiguous and impractical. First, it is unclear as to whether the funder that commissioned the development of the clinical guideline should be displayed or the funder of the meta-analysis that generated the evidence on which the guideline is based. Further, if multiple meta-analyses or systematic reviews provided the evidence for the guideline, are all sources of funding displayed? How about the many disparate sources of funding for the primary studies that provided the data for the meta-analyses? While we agree that it is important to remove any inherent conflicts of interest from CDS interventions, tracking down the true funding source(s) for specific interventions is infeasible for CDS vendors as well as health care providers. Therefore we strongly encourage CMS to re-examine this part of the criterion.

- Proposed Objective: Record smoking status for patients 13 years old or older.

AMIA notes that the smoking status values adopted do not align with those used in the quality measures in Stage 1 and are also proposed for Stage 2, such as NQF 0028, Preventive Care and Screening. Given that NQF 0028 goes beyond documenting smoking status to encouraging

cessation counseling, we suggest alleviating reporting burdens by aligning on a single tobacco use value set. We also urge that common definitions be used whenever possible for the measurement of MU and for quality measurement. This will promote the value of all measures and support correlation between quality measures and MU of EHRs.

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 identified a set of principles, one of which is that the main purpose of clinical data capture and documentation is to support and enhance patient care. This happens in two ways: by facilitating clinical reasoning and decision-making of individual clinicians, and by supporting communication and coordination of information across 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. 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. AMIA urges that CMS 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. Furthermore, as part of the CMS process to consider new or revised MU objectives, we urge CMS 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] 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.

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[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.

[3] Tierney WM, Overhage JM, Murray MD, Harris LE, Zhou XH, Eckert GJ, Smith FE, Nienaber N, McDonald CJ, Wolinsky FD. Can computer-generated evidence-based care suggestions enhance evidence-based management of asthma and chronic obstructive pulmonary disease? A randomized, controlled trial. Health Serv Res 2005; 40:449-469.

[4] Poissant L, Pereira J, Tamblyn R, Kawasumi Y. The impact of electronic health records on time efficiency of physicians and nurses: a systematic review. J Am Med Inform Assoc. 2005 Sep-Oct;12(5):505-16.

[5] Ammenwerth E, Spotl HP. The time needed for clinical documentation versus direct patient care. A work-sampling analysis of physicians' activities. Methods Inf Med. 2009;48(1):84-91.

[6] Rosenbloom ST, Denny JC, Xu H, Lorenzi N, Stead WW, Johnson KB. Data from clinical notes: a perspective on the tension between structure and flexible documentation. J Am Med Inform Assoc. 2011 Mar-Apr;18(2):181-6.

[7] Tang PC, Ralston M, Arrigotti MF, Qureshi L, Graham J. Comparison of methodologies for calculating quality measures based on administrative data versus clinical data from an electronic health record system: implications for performance measures. J Am Med Inform Assoc. 2007 Jan-Feb;14(1):10-5.

[8] Hripcsak G, Vawdrey DK, Fred MR, Bostwick SB. Use of electronic clinical documentation: time spent and team interactions. J Am Med Inform Assoc. 2011 Mar-Apr;18(2):112-7.

The Federal Role

Federal leadership is required in assuring that health IT is seen as a strategic driver of health system strengthening. CMS should collaborate with other HHS agencies, particularly the Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and National Institutes of Health (NIH), and with and other Federal agencies, such as the Veterans' Administration and the National Science Foundation (NSF), to provide coordinated leadership and guidance. However, health IT is certainly not the entire solution for health care transformation: payment incentives should avoid fostering "technology for technology's sake," and 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 for 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 could fund the ongoing development and dissemination of lessons learned and best practices from health IT 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 these 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 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 Tables (attached), which include sophisticated user reactions to many of the proposed MU 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 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 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