American Medical Informatics Association
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Statement of the
American Medical Informatics Association (AMIA)

HIT Policy Committee Certification/Adoption Workgroup Hearings on
EHR Certification July 14-15, 2009 and
HIT Policy Committee Hearing on July 16, 2009 on Meaningful Use

On behalf of the American Medical Informatics Association (AMIA) we are pleased to submit these comments regarding electronic health record (EHR) certification and the related issues about meaningful use.

Increasingly, the adoption and meaningful use of electronic health records (EHRs) is pivotal to strategies aimed at strengthening the U.S. health system. We urge the Secretary of DHHS to recognize the growing and compelling potential of informatics tools and techniques to contribute to a more robust evidence base about what "works" as we assess the functionality of EHRs and seek to assure quality and efficient patient care and population/public health. The potentially transformative power of EHRs rests with the increased availability of data that we can use in order to enhance clinical and preventive care, knowledge building, and evidence creation. The motivation lies with what the technology can and must do for the nation's health and healthcare—not with the technology itself.

We believe that the volume of health data collected and stored in EHRs will dramatically increase and, as a result, we will also see an increase in the potential for EHRs to improve clinical care and decision-making and at the same time to advance public health activities such as surveillance, measurement of outcomes and performance, research, and public policy.[1] However, certifying an EHR does not necessarily equate with effectively using the system's available functions nor does implementation of a certified product necessarily achieve or ensure actual changes in either clinical practice or patient outcomes. The challenge facing us is to implement EHRs to drive predictable improvement in health outcomes within and across multiple settings.

Increasingly researchers are studying EHR implementations in an effort to identify those factors that contribute most to a successful implementation. Achieving the benefits of EHR implementations raises many technical, clinical, and organizational issues that must be confronted as part of user acceptance and adoption. AMIA strongly believes that EHR implementation success requires a mix of organizational, behavioral, cognitive, and social factors in addition to the technology itself. Thus, we ask the Committee to consider the following:

- **EHRs are an evolving technology, with good applications currently available, but substantial improvements and enhanced functionality are anticipated.** Though we recognize the statutory mandate to develop definitions for "meaningful use," the notions of "meaningful use" and "certification" are themselves best viewed as evolving concepts, with today's reasonable expectations more limited than what we are likely to achieve or to mandate in five or ten years. Quality and performance measurement, reporting, and ongoing clinical care and process improvements require the foundation of an interoperable health information system including the use of electronic health records with evidence-based clinical decision support (CDS) systems.

- **A dynamic and comprehensive certification approach makes sense, although the current certification approach and processes are not sufficient.** Although we support the concept of a dynamic EHR product certification program, such as the approach undertaken by the Certification Commission for Healthcare Information Technology (CCHIT), we believe that the current certification processes are not sufficient. For example, an evolving issue relates to current certification standards that are increasingly more prescriptive and detailed – even possibly moving into what some might consider the domain of clinicians: practice workflow (such as what data appear on which screen and which queries should be real time versus daily batch). Healthcare organizations and clinical practice settings vary in several ways including size, location, number and type of technical and support staff, technology skills of the users, and state regulatory environments. We believe that highly prescriptive and detailed, one-size-fits-all requirements will ultimately be counter productive. Further, we urge the Secretary to consider maintaining a flexible but ultimately more robust process for identifying specific functions and attributes as required components of a certified EHR product. In addition, we believe that any certification process should minimize real or perceived conflicts of interest, such as those that could arise from commercial vendors' participation in making recommendations for EHR functionality.

- **EHRs should be certified through a suitable process that includes attention to how they are implemented and used for patient care and health promotion.** For example, decision-support capabilities should not simply be "present" in an implemented EHR but should be tested against an external standard, such as the Leapfrog test, which verifies that specific elements of decision support are in place and in use. Consistent with the National Academies' Report on Computational Technology for Effective Health Care, the criteria should focus on clinical endpoints achieved. Future efforts should examine the relationship between, and effectiveness of, key EHR functions and performance on quality measures over time.[2]

- **EHR certification should focus on process and care improvements.** AMIA subscribes to the principles of the Institute of Medicine (IOM) Quality Chasm Report regarding the aims for quality care, e.g., care that is safe, timely, equitable, efficient, effective, and patient-centered. Value-driven care must focus upon both evidence-based practices and policies that support the needs and wishes of individuals and populations. This requires the development of learning healthcare systems. Such systems can ensure the continuous capacity for improvement through teamwork, practicing to the best standards of the day, keeping the patient at the center of care, reinventing care processes capable of assuring superior outcomes for individuals, and accomplishing these ends through the use of informatics supported EHRs.

- **No EHRs should be certified that are incapable of evolving into more robust versions over time.** Initial EHR implementations should result in the use of as much data and as many functions as are needed to assure immediate value for enhanced care.[3] The required data and functions to comply with "certification" could be phased in as long as there are mechanisms and processes in place that assure continuing progress and improvement. We believe that if done right, EHR certification can help assure that EHRs address population and public health needs, in addition to the needs of individual patients. It is necessary to look ahead to the potential influence of the future evolution of EHRs, advances in technology and communications capabilities, forthcoming biomedical research, and large scale, population-based genomic studies that will generate vast amounts of data. The emerging patient-centered medical or health home is becoming a concrete implementation model for achieving the IOM healthcare vision, and it uses a scaled approach such as we are advocating here.

- **Certification should work towards evidence-based standards and criteria for EHRs implementations.** There is an increasing amount of experience and growing body of knowledge that indicates that some of the EHR functions and attributes being specified for certification have typically been shown to be successful in only a small number of settings (and many of these are academic and/or research settings with strong informatics groups). However, there are virtually no empirical data that demonstrate that more widespread implementation of these features/functions in other settings can or will improve the quality or efficiency of care. With the Federal government poised to spend significant resources on comparative effectiveness research -- for example, to determine which treatments clinical decision-support systems should recommend -- there is an equally compelling need to devote appropriate resources to use empirical and evidence-based data to certify EHRs (for example, which clinical decision support (CDS) functions and features).

- **Continued research and evaluation are needed to determine those EHR functions and capabilities that will assure value and benefits.**[4] Providers face growing financial pressures and incentives to adopt EHRs. Yet, there is a growing body of knowledge and experience that demonstrates that achieving the potential benefits of EHRs is in part dependent on successful implementation. Thus, the organizational context of any implementation must be considered.[5] One set of measures could address the ways in which EHRs are being demonstrably used to support important aspects of care, e.g., medication safety, patient transitions, quality and process improvement, or public health reporting. Further, ongoing research and evaluation must help to strengthen insights into the effectiveness and efficiency of EHRs, including their specific functions and attributes.

- **EHR certification should closely align with DHHS efforts to define and implement meaningful use as well as with DHHS efforts to conduct and support robust research and comparative effectiveness studies and to assure public and population health improvements. Certification must address the following functions and capabilities:**
    - Support for clinical practice
        - Improved patient care through communications and documentation, both within a practice and with other practitioners caring for the same patient
        - Improved office efficiency through process improvements
    - Data recording and results reporting
        - Improved data use and re-use capability for making multiple uses of the data that have been entered without requiring re-entry or translation
        - Basic interoperability capabilities, using standards to support exchange of EHR information between EHR systems from different vendors
        - Cognitively sensitive features for reviewing and sharing results
        - Movement of EHR data into a repository capable of tracking clinical processes and outcomes.
    - Quality metrics reporting and quality measurement results, helping to assure the effective implementation of best current evidence
        - Measurement of improvements in health outcomes
        - Evaluation of outcomes and revision/improvement of processes
    - Creation and implementation/delivery of evidence-based workflow guidelines for decision-support
    - Implementation of workflows that assure high quality and efficient processes
    - Implementation of uniform care processes where applicable and appropriate
    - Public health reporting

Summary

AMIA applauds the Committee's efforts to oversee this important national and public discourse and we stand ready to work collaboratively with the Department and other organizations to address these complex policy issues. If we can answer any questions for you, or offer testimony on this subject at any future events, please feel free to contact us.

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[1] Bloomrosen M, Detmer D. Advancing the Framework: Use of Health Data—A Report of a Working Conference of the American Medical Informatics Association. J Am Med Inform Assoc. 2008 Nov-Dec;15(6):715-22.

[2] Kilbridge PM, Classen, DC. The informatics opportunities at the intersection of patient safety and clinical informatics. J Am Med Inform Assoc. 2008;15:397–407.

[3] Lorenzi NM, Kouroubali A, Detmer DE, Bloomrosen M. How to successfully select and implement electronic health records (EHR) in small ambulatory practice settings. BMC Med Inform Decis Mak. 2009 Feb 23;9:15.

[4] Shekelle PG, Morton SC, Keeler EB. Evid Rep Technol Assess (Full Rep). 2006 Apr;(132):1-71.

[5] Lorenzi NM, Riley R, Blyth A, Southon G, Dixon B. Antecedents of the people and organizational aspects of medical informatics. Review of the literature. J Am Med Inform Assoc. 1997 Mar–Apr; 4(2): 79–93.