



June 27, 2013

Jodi Daniel, JD, MPH
Director, Office of Policy and Planning
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave. SW
Washington, DC 20201

FDASIA: Request for Comments on the development of a risk-based regulatory framework and strategy for health information technology

Dear Ms. Daniel:

On behalf of AMIA (American Medical Informatics Association), I am pleased to submit these comments in response to the above-referenced request for comments. 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 request for comments. In providing input, we will address the topics specifically listed in the request for comment, as well as provide some general comments regarding the ongoing need for the development of a risk-based regulatory framework and strategy for health information technology (health IT), based on AMIA's previous and ongoing work in this area.^{1 2}

¹ Bloomrosen M, Starren J, Lorenzi NM, Ash JS, Patel VL, Shortliffe EH. Anticipating and addressing the unintended consequences of health IT and policy: a report from the AMIA 2009 Health Policy Meeting. *J Am Med Inform Assoc.* 2011 Jan-Feb;18(1):82-90.

Introduction

AMIA believes that among the basic objectives of a regulatory framework for health IT should be ensuring the security of health data included, contained, stored, or processed on any device or platform. Further, AMIA suggests that there is a strong need to develop best practices for health IT design and implementation, and for comprehensive and systematic exploration of technological considerations and public policy issues over time.

AMIA suggests that FDA, ONC and FCC consider establishing a standing working group that includes personnel from each of these and other agencies, as well as subject matter experts from the private sector in technology, informatics, computer sciences, consumer protection, and other disciplines, to provide continuing input to a regulatory framework that will, of necessity, evolve.

In 2011, recognizing the critical importance of patient safety and health information technology, AMIA convened an interdisciplinary team of researchers, practitioners and scholars from diverse stakeholders including academia, industry, and providers in a Usability Task Force to address key issues regarding EHR usability, and patient safety. AMIA's recently published recommendations focused attention on critical usability issues that can adversely affect patient safety and the quality of care.³ AMIA and its Task Force recommended the development of a safety reporting system that includes EHR users, vendors and payers.

AMIA noted that a voluntary reporting process could leverage the AHRQ patient safety organizations (PSO), and would investigate and report on adverse events and medical errors related to usability. PSOs could assume responsibility and accountability for establishing an IT-related voluntary error measurement and public reporting system. We suggested that PSOs could follow the NIST Common Industry Format. Reports could be captured locally and reviewed by end-users (facilitated by application functionalities designed for this purpose), and summary reports should be sent to the application vendor and PSO. PSO governance bodies can convene relevant stakeholders to determine best practices for end-user and vendor product anonymity, appropriate levels of data aggregation, report details and frequency, and what summary data are made public. Use of the AHRQ Health IT Hazard Manager is a potential application for this purpose.

² McGowan JJ, Cusack CM, Bloomrosen M. The future of health IT innovation and informatics: a report from AMIA's 2010 policy meeting. *J Am Med Inform Assoc.* 2012 May-Jun;19(3):460-7. d. Epub 2011 Oct 28.

³ Middleton B, Bloomrosen M, Dente MA, Hashmat B, Koppel R, Overhage JM, Payne TH, Rosenbloom ST, Weaver C, Zhang J. *Am Med Inform Assoc.* 2013 Jun;20(e1):e2-8. doi: 10.1136/amiajnl-2012-001458. Epub 2013 Jan 25. Enhancing patient safety and quality of care by improving the usability of electronic health record systems: recommendations from AMIA.. <http://jamia.bmj.com/content/20/e1/e2.long>

Taxonomy

What types of health IT should be addressed by the report developed by FDA, ONC, and FCC?

AMIA views health IT as a complex system of interconnected software applications from different developers and vendors that a healthcare organization, often with help from a systems integrator, implements over time to address the myriad clinical work processes required to care for a complex population of acutely and chronically ill patients. Networked and interconnected health IT components and applications both send and receive data from a wide array of sources, including clinicians and other healthcare staff, patients and medical devices. Therefore appropriate regulatory oversight is critical to ensure the accuracy, safety and security of health IT. At the same time, health IT software and hardware are evolving at an astonishing pace, with new applications and methods for integration arising and being marketed every day, and AMIA believes that HHS must ensure that regulation and/ or oversight by the FDA, ONC and the FCC will not unnecessarily stifle innovation in the health IT marketplace.

AMIA believes that basic to successful regulation of health IT is the need for adoption of consistent terminology for terms such as “electronic health records (EHRs)”, “personal health records (PHRs)”, “mobile apps”, “telehealth”, “telemedicine”, “m-health”, “patient-managed tools” (e.g., PatientsLikeMe) and other forms of health IT. AMIA strongly encourages HHS to ensure that the report articulating a strategy going forward will include actions to address the ongoing need for consistent terminology and use of that terminology. For example, HHS should consider distinctions between mobile apps that stand alone from those that allow access to larger systems, such as EHRs or health information exchanges (HIEs).

Furthermore, AMIA believes that defining clinical decision support (CDS) software is essential as a precursor to efforts to “identify and distinguish what types of software should potentially be regulated as a medical device, and which software should not. In a 2006 “Roadmap” AMIA produced with funding from ONC and AHRQ, we said that CDS “encompasses a variety of approaches to provide clinicians, staff, patients, and other individuals with timely, relevant information that can improve decision making, prevent errors, and enhance health and health care.”⁴ CDS tools and interventions include simple information retrieval, such as access to peer-reviewed articles on the outcomes of clinical studies, as well as computerized alerts and reminders, clinical guidelines, order sets, patient data reports and dashboards, documentation templates, diagnostic support, therapeutic advice, and clinical workflow tools. We consider CDS software to be any application which brings relevant clinical data and knowledge together to improve clinical decision making by either care providers or patients.

⁴ AMIA CDS Roadmap <http://www.amia.org/public-policy/reports-and-fact-sheets/a-roadmap-for-national-action-on-clinical-decision-support>

Given the enormously broad scope of the software in question, AMIA cautions HHS in focusing too narrowly on CDS, or in considering mobile apps in isolation from other CDS delivery methods or contexts. While there has lately been much discussion of *mobile* medical or clinical apps, AMIA believes that in terms of medical apps the distinction between “mobile” and “fixed” is not particularly meaningful. AMIA also notes the growing, number of available tools targeted to patients and consumers to use to manage their health. AMIA believes that HHS should take a comprehensive look at the rapidly emerging and converging technologies and devices along with new and evolving forms of patient care delivery and payment methods (such as medical homes and accountable care organizations).

AMIA is an active member of the Bipartisan Policy Center (BPC) HIT workgroup⁵, and we have been involved in the process as BPC has developed its recommendations about federal oversight of HIT. AMIA suggests that HHS leverage the work of the BPC and others in developing its framework for potential regulation in the area of health IT. AMIA notes that one of the basic ideas underlying the BPC project was the recognition that the degree to which software directly affects patients corresponds to the potential for patient harm when the software fails, so a concomitant level of regulatory oversight for different classes of software is appropriate.

What is the difference in risk presented by the accuracy of a digital scale that feeds data directly into a PHR of a patient with congestive heart failure versus the use of that same scale by a diabetic patient who is managing her insulin dosing at home without a computer? When is a wrist band that provides an EKG tracing a medical device and when is it a consumer product? There are likely to be many challenges in broad application of an overarching approach to health IT regulations; at the outset we would suggest that consumer-oriented health IT devices and applications (such as those which do not provide data directly to the individual’s EHR) should not be directly regulated.

Risk and Innovation

What are the risks to patient safety posed by health IT and what is the likelihood of these risks? What factors or approaches could be included in a risk-based regulatory approach for health IT to promote innovation and protect patient safety?

AMIA notes that we have previously provided comments to HHS on related issues and we ask HHS to revisit our prior feedback.^{6 7} Additionally AMIA encourages HHS to leverage the

⁵ An Oversight Framework for Assuring Patient Safety in Health Information Technology *Feb. 13, 2013*
<http://bipartisanpolicy.org/library/report/oversight-framework-assuring-patient-safety-health-information-technology>

⁶ <http://www.amia.org/sites/amaia.org/files/AMIA-ResponseSubmitted-toONC-HIT-Patient-Safety-Plan.pdf>

⁷ <http://www.amia.org/sites/amaia.org/files/AMIA-Response-to-Draft-FDA-Guidance-on-Mobile-Medical-Apps-10-19-11.pdf>

research and evaluation efforts of AMIA and its members to address these complex issues. For example, Walker et al define an EHR-related system flaw as ‘Any characteristic of an EHR or of its interactions with other healthcare systems that has the potential to worsen care quality or patient outcomes.’⁸ Other healthcare systems include individuals, care teams, facilities, policies, care processes, healthcare organizations, and patient-managed health initiatives. Flaws may be introduced during the specification, design, configuration, or continuous-improvement phases of the EHR lifecycle.’ Sittig and Singh define EHR-related errors as occurring ‘anytime health IT is unavailable for use, malfunctions during use, is used incorrectly by someone, or when health IT interacts with another system component incorrectly, resulting in data being lost or incorrectly entered, displayed, or transmitted.’^{9 10}

Additionally, the BPC collaboration identified issues related to the complex relationships between the degree of risk posed by HIT software and the level of regulatory oversight that should apply. However AMIA recognizes the inherent difficulty in understanding and assigning levels of risk to HIT applications that are directed to patients and consumers outside of the medical-legal context of the health care system. AMIA notes that there may be situations in which some data are provided to an individual’s EHR or PHR, upon which the individual may base clinical decisions with or without the involvement of a medical professional (the traditional ‘learned intermediary’).¹¹

AMIA believes that articulation of use cases will facilitate the development and validation of standardized performance measures for assessing the incidence of adverse events and medical errors. These measures should be developed with the participation of experts and representatives drawn from the measure development community, clinical informatics, end-users, patient advocacy organizations, and the vendor community, and they should focus on usability issues that can adversely affect patient safety and the quality of care.

Regulation

Are there current areas of regulatory overlap among FDA, ONC, and/or FCC and if so, what are they? Please be specific if possible. If there are areas of regulatory overlap, what, if any, actions should the agencies take to minimize this overlap? How can further duplication be avoided?

⁸ Walker JM, Carayon P, Leveson N, et al. EHR safety: the way forward to safe and effective systems. *JAMIA* 2008;15:272–7.

⁹ Sittig DF, Singh H. Eight rights of safe electronic health record use. *JAMA* 2009;303:1111–13.

¹⁰ Sittig DF, Singh H. Electronic health records and national patient-safety goals. *N Engl J Med*. 2012 Nov 8;367(19):1854-60.

¹¹ Miller RA, Gardner RM. *J Am Med Inform Assoc*. 1997 Nov-Dec;4(6):442-57. Recommendations for responsible monitoring and regulation of clinical software systems. American Medical Informatics Association, Computer-based Patient Record Institute, Medical Library Association, Association of Academic Health Science Libraries, American Health Information Management Association, American Nurses Association.

AMIA is unclear about the extent to which there are areas of regulatory overlap among FDA, ONC, and/or FCC. However, we strongly urge HHS to clearly articulate and delineate the roles and responsibilities of federal agencies such as FCC, FDA, and ONC, regarding current and/or future potential oversight and regulation of health information technology. There remains an ongoing need to harmonize and coordinate efforts across the federal government and between and within the research and practice communities in the public and private sectors. Furthermore, AMIA is concerned that advances in technology and techniques are surpassing the ability of existing policies, guidances, and regulations to address and “keep up with” emerging the technological functionalities and capabilities.

AMIA suggests that ONC’s current role with respect to certification as of electronic health records in the context of any proposed regulatory framework be clearly articulated; especially in relation to any FDA role and responsibility for in assuring safety. We believe that several key issues need to be considered, such as: If there are safety aspects of certification, should FDA take that over? For example, in the 2014 Certification Criteria, there are usability requirements. Such requirements are likely to grow over time; however it is not clear the extent to which FDA or ONC should be responsible for assessing those requirements. Although AMIA believes that in the near term, it would make sense for ONC to keep responsibility for the safety aspects/components of EHR certification criteria; This may need to be reassessed in the future.

Conclusion

AMIA appreciates the opportunity to submit these comments. Again, we thank ONC for issuing this request for comments. Please feel free to contact me at any time for further discussion of the issues raised here.

Sincerely,

A handwritten signature in black ink, appearing to read "Kevin Fickenscher, MD", is centered on a light pink rectangular background.

Kevin Fickenscher, MD
AMIA President and CEO