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February 4, 2013

Farzad Mostashari, MD
National Coordinator for Health Information Technology
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

Re: ONC's Request for Comments (RFC) about the Proposed Health IT Patient Safety Action and Surveillance Plan

Dear Dr. Mostashari:

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 comment. In providing input, we will provide general comments about the Proposed Health IT Patient Safety Action and Surveillance Plan (the Plan) as well as respond to selected components of the proposed plan.

General Comments

AMIA applauds ONC's efforts to address this critical and complex topic. While we believe that this initial draft provides a starting point for this important discussion, we are concerned that the lack of specificity makes it difficult to assess whether the proposed implementation steps are realistic. For example, the report continues to portray EHRs as self-contained, software

applications developed and installed by a single vendor that users simply install and run within a healthcare organization. This is far from the actual practice. More commonly, the EHR is but a small part of a complex network of interconnected software applications from different 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 complex, acutely ill patients[1]. Simply testing and certifying the individual components does not address how they will function when combined and integrated within a complex healthcare delivery system. While HIT offers opportunities to improve reliability and to enhance safety, it also may contribute to complexity in terms of workflow and work processes that need to be considered in the development of the Plan. Thus, AMIA believes that the surveillance plan would be significantly improved by acknowledging these types of challenges and committing new resources to developing solutions for ways to oversee these complex systems.

Need for Ongoing Research and Evaluation. We believe that the Plan should leverage relevant current and ongoing research that contributes to the growing body of science and evidence about what works to improve patient safety. AMIA strongly suggests more scientific grounding and evidence for the recommendations set forth in this Plan.

AMIA strongly recommends that HHS continue to fund and widely disseminate findings from HIT-related safety research and evaluation efforts including methods to:

- Automatically identify and track potential HIT-related safety issues
- Address the potential inherent limitations of self-reporting of adverse events
- Investigate, evaluate and report on HIT-related safety issues
- Test and certify highly networked and inter-connected HIT components and applications
- Test and certify highly networked and inter-connected data sources including medical devices

Usability. As EHR adoption increases, HIT and EHR usability issues must be addressed along with a growing body of evidence and concerns about patient safety. We recommend that usability be considered in the context of each health care delivery setting in addition to the proposed focus on vendor/supplier organizations. Human factors and implementation science precepts are central to understanding and improving usability and patient safety. We believe that that both domains should receive greater focus in future iterations of the draft plan.

[1] Clayton PD, Narus SP, Huff SM, Pryor TA, Haug PJ, Larkin T, Matney S, Evans RS, Rocha BH, Bowes WA 3rd, Holston FT, Gundersen ML. Building a comprehensive clinical information system from components. The approach at Intermountain HealthCare. Methods Inf Med. 2003;42(1):1-7.

AMIA directs ONC to a new health information technology (IT) policy report that has been published in the Journal of AMIA (JAMIA) entitled, Enhancing Patient Safety and the Quality of Care by Improving the Usability of Electronic Health Records: Recommendations from AMIA. The report reflects the results of a year-long project undertaken by AMIA to help address usability issues as EHR adoption increases against a growing body of evidence and concerns about patient safety issues. The AMIA report recognizes that numerous stakeholders, organizations, and individuals play a critical role in addressing challenges with EHR usability, and AMIA makes recommendations for various stakeholders. The report is available online at http://jamia.bmj.com/content/early/recent.

Infrastructure Costs. AMIA believes that appropriate aggregation, investigation, and dissemination activities are likely to be resource intensive and potentially costly and we are concerned that they will not be performed. It is essential to investigate and publicly report on the findings from recent simultaneous major, widespread, multi-site, multi-state, multi-organization EHR failures affecting thousands of patients, such as those reported in the press on May 9, 2006 at Kaiser Permanente;[2] on Aug 31, 2007 within the VA healthcare system;[3] on April 21, 2010 at the Rhode Island Hospitals;[4] and on July 23, 2012 by the Cerner Corporation.[5] We are concerned that future publicity about these types of events may contribute to perceptions that such potentially catastrophic patient safety events could re-occur unabated. It is vital that the nation's increasingly HIT-enabled healthcare system study and learn from these events so they are not repeated.

We are also concerned that the proposed strategy for integrating Health IT patient safety into existing federal programs (p. 20) may not be sufficient, and we question if there is sufficient capacity within existing Federal agencies and programs to do so. Further, we are concerned that the activity will not be adequately resourced. We believe that monitoring activities should be conducted at multiple levels. For example, relatively isolated and non-life-threatening patient safety issues could be investigated and reported to the organization's leadership on a periodic basis, while more widespread and potentially harmful events could be reported to the organization's PSO and investigated with their help. Finally, larger scale or widespread events could be reported to the local PSO but also to an independent national body who could help conduct the investigation and disseminate the findings.

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[2] http://www.computerworld.com/s/article/9005004/Problems_abound_for_Kaiser_e_health_records_management_system_

[3] http://www.govexec.com/defense/2007/10/august-va-systems-outage-crippled-western-hospitals-clinics/25469/

[4] http://www.npr.org/templates/story/story.php?storyId=126168997&sc=17&f=1001

[5] Terhune, Chad. Los Angeles Times, August 3 2012. "Patient Data Outage Exposes Risks of Electronic Medical Records" http://articles.latimes.com/2012/aug/03/business/la-fi-hospital-data-outage-20120803

Reporting Burdens. We urge ONC to consider the potential burdens on healthcare providers and organizations to implement, administer, and manage the proposed reporting process. Furthermore, we believe that the reporting burden must be monitored to ensure that it remains as feasible as possible. We believe that any HIT-related incident reporting should work within existing healthcare quality and safety processes, state reporting requirements, and accreditation and licensure regulations.

Finally, the ONC should acknowledge that in any complex, adaptive work system the vast majority of errors or safety events are not detectable by a single individual (and thus not reportable) due to the complex, hidden, inner workings and data transformations of these systems.[6] For example, when clinicians send an order for a specific medication to the pharmacy, they have no way of knowing what the pharmacist receives. Furthermore, the pharmacist has no way of knowing that the medication order received is not what the ordering provider sent. When this order is transmitted to the automated, robotic, medication bar-coding packaging system, filled and sent to the registered nurse (RN) for administration, once again, the RN has no way of determining whether the medication received is what the doctor ordered or the pharmacist filled. Even when the RN scans the barcode on the medication and the patient, and gets a match, the wrong medication can be administered. If there is such a "systematic" error in any one of the interfaces between the order entry system, pharmacy inventory system, barcoded packaging system, or medication administration record system (all potentially made by different vendors and never tested by an external, independent party), these errors can and have continued unabated and undetected for extended periods of time. We suggest that ONC acknowledge these types of complex issues and consider asking licensing and/or accrediting bodies (such as the Joint Commission or local health departments) to include random inspections of computerized provider order entry (CPOE)/pharmacy interfaces in their routine surveillance activities.

Other General Comments

We suggest that ONC implement a flexible approach with feedback loops so that over time ONC can update and refine the Plan and address the likely evolution of technical capabilities and new technologies. These updates should reflect lessons learned and be evidence-based.

We support embedding reporting functionality in certified EHR systems, and we suggest that such reported data should remain separate from the legal patient record so that information is confidential and undiscoverable.

There are a number of existing and applicable standards that could be adopted and used to the fullest extent possible. One example is the National Quality Forum (NQF) Safe Practice for Computerized Provider Order Entry which includes post deployment testing of EHRs for high

[6] Sittig DF, Singh H. Electronic health records and national patient-safety goals. N Engl J Med. 2012 Nov 8;367(19):1854-60. doi: 10.1056/NEJMsb1205420.

impact safety interventions as recommended in recommendation # 1c in the IOM Report (Health IT and Patient Safety: Building Safer Systems for Better Care).

It is unclear if clinical decision support systems (CDSS) are included within the focus on HIT. We suggest that ONC clarify the extent to which CDSS will be considered as a central component of enterprise clinical systems.

Comments on Specific Recommendations

We offer the following feedback regarding specific recommendations contained in the Plan:

- Recommendation 1.a. We support the expansion of AHRQ and NLM funding for research, training, and education of safe practices. We believe such funding should be allocated in addition to the funding of existing health IT programs, rather than as a reallocation of funds currently budgeted for health IT.
- Recommendation 2a. We are concerned that a voluntary code that carries no penalties for failure to report adverse events is unlikely to significantly improve the patient safety environment. While there is merit in avoiding penalties so severe as to discourage innovation, the current unacceptably frequent occurrence of patient safety events may indicate that a voluntary approach is inadequate.
- Recommendation 5. The public listing of health IT products should include a list of the features incorporated by vendors to promote patient safety. Listing such product features in a public place will aid health care organizations in selecting products and promote innovation by allowing vendors to track, in general terms, the state of the art in patient safety initiatives.
- Recommendation 7a. ONC should engage developers and facilitate the development of a mandatory code of conduct that requires vendors to work with safety organizations to aggregate and analyze events and promote adverse event reporting among providers. AMIA believes that consideration of the developer and vendor code of conduct is critical to the successful implementation of any approach to assuring patient safety and health information technology. There is a need to reconcile potential (real and/or perceived) tensions between the organizational (developers/vendors) need to protect intellectual property and the equally compelling need to share safety issues and safety experiences. Thus, it is important to support the developer/vendor code of conduct.

We offer the following other specific comments in the order in which they appear in the Plan:

- Page 9. ONC intends to propose using EHR certification criteria to ensure that, where appropriate, EHR technology can facilitate reporting of safety events in AHRQ's Common Formats. AMIA believes that it is important to differentiate the reporting of EHR related safety events from using the EHR as a "reporting tool" for safety events. However, a mechanism by EHR vendors to report HIT related patient safety events to Patient Safety Organizations (PSOs) seems reasonable. It also seems reasonable for PSOs

to adopt the AHRQ Common Formats. We refer ONC to AMIA's prior comments submitted to AHRQ[7] about the Common Report Formats and we urge ONC to continue to work to enhance and improve those formats as related to HIT. We are not convinced that it will be possible to clearly distinguish instances where EHRs have not been used appropriately, as intended or as designed.

- Page 11. Step 2, the Plan discusses "engage Health IT developers to embrace their shared responsibility." In our view, this step does not sufficiently address concerns expressed in previous AMIA writings.[8] Although ONC has cause to avoid truly Draconian penalties for failure to comply, we believe that current experience indicates that a voluntary approach may fail to ensure complete and comprehensive reporting and adverse event reduction. In addition, ONC-ACBs should be required – not simply encouraged – to review documentation of complaints and provide de-identified reports to ONC. Some of our members question the potential role of ONC-Authorized Certification Bodies (ACBs) given the potential far reach of this process into the health system enterprise, its organization, workflows and clinical practice standards that are best determined locally by health care providers. The role of the ONC-ACB to indicate whether the EHR technology is functioning in a manner consistent with certification may potentially be an overreach for a government.

- Page 11. Ensure health IT developers work with a PSO, 15 or a similar entity, to report, aggregate, and analyze health IT-related safety events. While there is agreement with this statement, we urge ONC to clarify how to assure that there will not be any unintended duplicate reporting when a provider organization may report to one PSO and the IT vendor reports to another PSO.

- Page 17. It appears that ONC intends to continue using its standards and certification criteria and certification program rulemaking in ways that enhance health IT patient safety, focusing on human factors, safety culture, and user -centered design. AMIA agrees and urges ONC to continue to emphasize this focus.

- Page 21. Congress passed the Food and Drug Administration (FDA) Safety and Innovation Safety Act of 2012. This Act tasked the FDA – in collaboration with ONC and the Federal Communications Commission (FCC) – to create a report, within 18

[7] http://www.amia.org/sites/amia.org/files/AMIA-Comments-re-Common-Format-including-HIT-11-23-10.pdf

[8] See, for example, Challenges in ethics, safety, best practices, and oversight regarding HIT vendors, their customers, and patients: a report of an AMIA special task force (http://jamia.bmj.com/site/icons/amiajnl8946.pdf) and Anticipating and addressing the unintended consequences of health IT and policy: a report from the AMIA 2009 Health Policy Meeting (http://jamia.bmj.com/content/18/1/82.long) .

months, that proposes a strategy and recommendations for an appropriate, risk-based regulatory framework for health IT that promotes safety and innovation. This report will be developed with significant public input and will incorporate what HHS learns about risk, safety, and opportunity for innovative technologies to support improved health outcomes. AMIA is concerned that a heavy-handed and tightly regulated approach by the FDA/FCC would have the potential to stifle innovation and the speed of products to market.

- Page 22. AHRQ has encouraged states to use the Common Formats to make it possible to aggregate and compare adverse events across federal and state programs. AMIA urges ONC to align state and federal adverse event reporting requirements to minimize undue burden and fragmentation for reporting entities.

- Page 32. Currently, the Health IT Safety Plan does not include the establishment of an independent federal entity. However, the plan incorporates many of the functions described in IOM's recommendation 8 into existing patient safety efforts across government programs and the private sector — including health care providers, technology companies, and health care safety oversight bodies. While we acknowledge ONC's current decision not to identify a separate federal entity for investigating HIT safety, we recommend that ONC leverage (and harmonize) existing processes across the multiple bodies/organizations that investigate patient safety events including HIT. We also suggest that consideration be given to the intersection of HIT safety in the context of existing state and/or national level regulatory, licensure and accreditation oversight.

Concluding Comments

AMIA appreciates the opportunity to submit these comments. Again, we thank the ONC for issuing this request for comments. 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; AMIA President and CEO