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January 11, 2016

Members of the NQF HIT Safety Committee
National Quality Forum
1030 15th Street NW
Suite 800
Washington, DC 20005

Re: Identification and Prioritization of Health IT Patient Safety Measures Draft Report

Ms. Belmont, Dr. Singh and the NQF HIT Safety Committee:

The American Medical Informatics Association (AMIA) writes to express our strong support for the draft report, "Identification and Prioritization of Health IT Patient Safety Measures," and the development of reportable measures meant to identify the nature, scope and prevalence of health information technology-related safety issues. AMIA has long-advocated for greater focus on the potential patient safety implications of health IT, and we believe this work contributes substantively to a growing corpus of knowledge on the safety and safe use of health IT.

AMIA is the professional home for more than 5,000 informatics professionals, representing researchers, front-line clinicians and public health experts who bring meaning to data, manage information and generate new knowledge across the health and healthcare enterprise. AMIA members play a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across settings and patient populations.

The draft report identifies nine measurement areas for health IT safety and several measure concepts that could reflect performance in health IT safety. **AMIA believes these measures, when fully developed, should serve as a foundation for future policy, and they should catalyze work among developers and providers alike to better prevent and/or mitigate health IT-related concerns**. However, as noted in the *Report of the AMIA EHR 2020 Task Force on the Status and Future Direction of EHRs*,[1] it is paramount that development of these measures be done in a way that minimizes additional collection burden on clinicians. We must ensure that the data collected for safety measures is done in a way similar to how we collect data for quality and value. There must be consistency in how the data is collected and common ways for representing the data in structured way, so that the same fundamental building blocks are used to construct measures using the same data. Our strained healthcare system cannot absorb another regime of performance measurement that is not a byproduct of routine data collection and care delivery.

Health IT safety is a responsibility shared among developers, healthcare organizations, clinicians, patients and government stakeholders. Through the creation of a single body focused on health IT

[1] Payne T., Corely S., et al. Journal of the American Medical Informatics Association. Sep 2015, 22 (5) 1102-1110; DOI: 10.1093/jamia/ocv066

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safety, empowered to collect information on, evaluate, and report on the overall safety of health IT, AMIA believes that event reporting, education, data aggregation, and the creation of best practices can improve patient safety, better engender patient engagement and fulfill the potential of health IT. **To this end, AMIA calls on Congress to fully fund a collaborative, national center for health IT safety, as outlined in the recent Health IT Safety Center Roadmap**.[2] In conjunction with other initiatives, we urge lawmakers to use this work to inform ongoing conversations about how to ensure the safety and effectiveness of health IT functionality not considered a medical device.

Absent a regulatory regime developed by the FDA, we believe some other approach must be in place to ensure the safety and effectiveness of health IT. In April 2014, a risk-based approach was proposed by federal regulators, which helped catalyze conversations among stakeholders inside and outside government.[3] In the nearly two years since its publication, the draft FDASIA Health IT Report joins other important ideas on how to ensure the safety and safe use of health IT. But now is the time to put such ideas into action. **We request that regulators update and finalize their approach to ensure the safety and effectiveness of the software excluded from FDA regulation.**

These measure concepts are an important component to the ongoing feedback loop needed to achieve a learning health system. If we are to improve the safety and safe use of health IT, there must be incentives – positive and negative – to focus efforts of a strained healthcare system.

Below we outline some specific recommendations in more detail. We hope our comments are helpful as you undertake this important work. Should you have questions about these comments or require additional information, please contact Jeffery Smith, Vice President of Public Policy at jsmith@amia.org or (301) 657-1291.

Sincerely,

Douglas B. Fridsma, MD, PhD, FACP, FACMI
President and CEO
AMIA

Thomas H. Payne, MD, FACP
AMIA Board Chair
Medical Director, IT Services, UW Medicine
University of Washington

[2] HHS Office of the National Coordinator for Health IT. 2015. Health IT Safety Center Roadmap *available at* http://www.healthitsafety.org/uploads/4/3/6/4/43647387/roadmap.pdf
[3] Food and Drug Administration, Federal Communications Commission, HHS Office of the National Coordinator for Health IT. 2014. FDASIA Health IT Report: Proposed Risk-Based Regulatory Framework *available at* https://www.healthit.gov/sites/default/files/fdasia_healthitreport_final.pdf

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Attached: Recommendations to Inform the NQF HIT Safety Committee Draft Report Identification and Prioritization of Health IT Patient Safety Measures

General observations regarding the draft report

This draft report is timely given the broad deployment of EHRs and other health IT, and the growing appreciation for how complex social and technical interactions are in healthcare. The report leverages expertise cultivated over the last decade of health IT implementation, and is aligned with initiatives meant to better understand and better address health IT-related patient safety issues. Building on concepts developed by prominent health IT safety researchers, the measurement approach taken by the report is grounded in well-established sociotechnical models to account for the complex interactions in this space. The report builds on numerous others, including work done by the National Academy of Medicine[4] (formerly the Institute of Medicine), the Joint Commission[5] and the federal government.[6]

Additionally, this report is aligned with important initiatives underway in the private sector, such as the ECRI Institutes Partnership for Health IT Patient Safety[7] and the Association for the Advancement of Medical Instrumentation (AAMI) HIT Standards Development Initiative.[8] The Partnership is actively discovering new ways to identify and categorize patient safety events that may involve health IT, and AAMI is developing new process and risk management standards to improve how health IT is developed, implemented, tested, maintained and retired. In conjunction, these efforts will simultaneously illuminate the depth and breadth of health IT-related patient safety issues experienced in clinical settings across the country, and attempt to better prevent or mitigate harms.

Measurement priorities

We applaud the proposed NQF measurement framework because it addresses the entire spectrum of health IT-related patient safety issues and across the lifecycle of health IT, including safe development of IT, safe use of IT and the use of IT to improve patient safety. Using this framework, the draft report identifies nine measurement areas for health IT safety and several measure concepts that could reflect performance in those area.

In the near-term, we recommend focusing on concepts and measures that can be implemented in a non-disruptive fashion, using data already collected. Specifically, NQF should prioritize measures related to clinical decision support (CDS), patient identification, HIT-focused risk-management

[4] IOM (Institute of Medicine). 2012. Health IT and Patient Safety: Building Safer Systems for Better Care. Washington, DC: The National Academies Press.
[5] The Joint Commission Sentinel Event Alert No. 54: Safe Use of Health Information Technology (March 31, 2015) *available at* http://www.jointcommission.org/assets/1/18/SEA_54.pdf.
[6] Office of the National Coordinator for Health Information Technology. 2013. Health IT Patient Safety Action & Surveillance Plan. *available at* http://www.healthit.gov/sites/default/files/safety_plan_master.pdf
[7] https://www.ecri.org/resource-center/Pages/HITPartnership.aspx
[8] http://www.aami.org/productspublications/articledetail.aspx?ItemNumber=2663

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infrastructure and system downtime. These areas represent categories of high importance, and offer measure developers an opportunity to work within the scope of data that is likely already captured.

Next, we suggest NQF prioritize measures related to user-centered design, use of HIT to facilitate timely and high-quality documentation, patient engagement, and system interoperability. We note that these measure concepts will need further development, and should drive a research agenda that brings together developers, clinicians, researchers, standards developers and measure developers to:

- Identify component data and metadata;
- Assess which data is currently collected through normal workflows, care delivery and through organizational reporting processes;
- Develop standard definitions for the measures; and
- Create mechanisms to export the measures to that they can compare results across organizations.

In conjunction with promotion and wider adoption of ONC's Safety Assurance Factors for EHR Resilience (SAFER) Guides,[9] we believe it is important to make tangible progress towards the finalization of measure concepts, so that organizations can begin testing and reporting. However, experience with quality measurement and health IT "use" measurement tells us it is important to anticipate how the act of compiling and reporting these measures may influence behavior.

Similarly, we urge caution against lowering the evidence thresholds that guide NQF measure development in other domains. While we understand the importance of, and support the need for, advancement in the area of patient safety measurement, we believe it is premature to suggest any circumvention in the endorsement process is warranted, as described on page 33 of the report.

Finally, one area of discussion that may warrant explicit attention is diagnostic errors. As discussed in the recent report from the National Academy of Medicine, "Improving Diagnosis in Health Care," diagnostic errors are so prevalent that "most people will experience at least one diagnostic error in their lifetime, sometimes with devastating consequences."[10] To address this "moral, professional and public health imperative," to improve diagnosis, the report outlined goals to, "ensure that health information technologies support patients and health care professionals in the diagnostic process," and "Develop and deploy approaches to identify, learn from, and reduce diagnostic errors and near misses in clinical practice." We encourage this committee to consider developing specific measures in this realm so we can attempt to capture, categorize and improve the incidence of diagnostic errors, and begin to address this glaring problem.

[9] HHS Office of the National Coordinator for Health IT. 2014. Safety Assurance Factors for EHR Resilience (SAFER) Guides *available at* http://www.healthit.gov/safer/safer-guides.
[10] National Academy of Medicine. 2015. Improving Diagnosis in Health Care. Washington, DC: The National Academies Press.

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