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Farzad Mostashari, MD
National Coordinator
Health Information Technology
Office of the National Coordinator
for Health Information Technology
Attention: HITECH Initial Set Interim Final Rule
Hubert H. Humphrey Building, Suite 729D
200 Independence Avenue, SW
Washington, DC 20201

Carolyn M. Clancy, MD
Director
Agency for Healthcare Research and Quality
Department of Health and Human Services
540 Gaither Road, Suite 2000
Rockville, MD 20850

Re: Health IT and Patient Safety

Dear Dr. Mostashari and Dr. Clancy:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to express our commitment to working with you and other key stakeholders to study and monitor the impact of health IT on patient safety. The November 2011 Institute of Medicine (IOM) report, "Health IT and Patient Safety: Building Safer Systems for Better Care," helps to highlight the potential benefits and risks that health IT use has on patient safety. We agree with the IOM's recommendation that stakeholders should coordinate efforts to increase our understanding of risks associated with health IT and come up with solutions to improve the safe design, implementation, and use of health IT systems.

It is widely accepted that health IT, particularly electronic health record (EHRs), can support better clinical decisions, facilitate information exchange, and reduce duplicative efforts and costs. But some studies find that these same tools can also result in unintended patient safety issues. In some cases, EHR design and software flaws have been found to contribute directly

to errors, including some that have caused patient harm. Many examples were discussed in the recent IOM report. Some recent anecdotal examples of clinical usability issues that have been brought to our attention as potentially contributing to unsafe conditions include use of certain colors on screens (e.g., persons with red-green color blindness might not see important distinctions), information overload due to packing too much information onto a single screen, poor organization of information (such as medications listed alphabetically rather than by disease or drug type) creating cognitive strain, difficult or non-intuitive navigation steps to obtain and synthesize key data, use of small fonts, facilitation of "cut-and-paste" issues, use of forcing functions that prevent tailored care, alert overload leading to alert fatigue, and selecting the wrong patient when multiple patient records are open. Importantly, each of these issues can be addressed and ameliorated or eliminated when health IT systems undergo proper usability testing during development and implementation. The Healthcare Information and Management Systems Society (HIMSS) EHR Usability Task Force has acknowledged these problems and has found, "Clinical systems are complex as well as information dense–it is essential for efficiency as well as patient safety that displays are easy to read, that important information stands out, and that function options are straightforward."[1] The AMA agrees with the IOM committee that **there is an urgent need for standardized quality and risk management processes in the development and testing of health IT; we further emphasize the importance of careful usability testing in clinical settings.**

The Agency for Healthcare Research and Quality (AHRQ) similarly concluded that health IT can negatively impact patient safety if there is "a lack of integration of health IT into clinical workflow in a way that supports the cognitive work of the clinician and the workflows among organizations (e.g., between a clinic and community pharmacy), within a clinic and within a visit."[2] While research has been done on health IT systems and patient safety in the hospital setting, there has been limited research on the impact of EHR use on patient safety in the ambulatory setting.[3] **The AMA believes more research is needed in the ambulatory setting to determine and monitor the effects of EHR use on patient safety**. While EHR vendors today have both formal and informal processes for identifying patient safety concerns, we agree with AHRQ that more research and the development of more effective and reliable methods to detect and track patient safety issues arising from EHR use are warranted. EHR vendors need to be engaged in the assessment and solution processes in order to increase our understanding of and minimize the safety risks associated with EHRs.

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[1] HIMSS EHR Usability Task Force, "Defining and Testing EMR Usability: Principles and Proposed Methods of EMR usability Evaluation and Rating," June 2009.
[2] AHRQ Incorporating Health Information Technology Into Workflow Redesign, AHRQ Publication No. 10-0098-EF, October 2010.
[3] Lorincz CY, Drazen E, Sokol PE, Neerukonda KV, Metzger J, Toepp MC, Maul L, Classen DC, Wynia MK. Research in Ambulatory Patient Safety 2000–2010: A 10-Year Review. American Medical Association, Chicago IL 2011. Available at: www.ama-assn.org/go/patientsafety.

The voluntary, confidential reporting of health IT–related patient safety events that result from EHR use in the ambulatory setting should become an important avenue for collecting data necessary to identify safety risks. The Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) (Patient Safety Act) provides for the formation of Patient Safety Organizations (PSOs), which collect and analyze confidential information voluntarily reported by health care providers for the purpose of improving patient safety. A critical aspect of the Patient Safety Act is to ensure the confidentiality and legal protections of patient safety work product to encourage the reporting of patient safety events. The Patient Safety Act also authorizes the collection of this patient safety information in a standardized manner, to facilitate data aggregation and analyses. As requested by the Secretary of the Department of Health and Human Services (HHS), the AHRQ is tasked with coordinating the development of a set of common definitions and reporting formats (common formats), which facilitate the voluntary collection of patient safety data and reporting of this information to PSOs. The common formats are developed and tested by those involved in the delivery of health care services to ensure that they are usable and meaningful. Ongoing refinement of the formats is also expected to occur, to encourage reporting and further advance a culture of patient safety. In addition, these standardized formats are helpful for use in data collection in the aggregate and help to conserve resources because PSOs can use the common formats in lieu of creating their own formats. We believe that **the existing common format report entitled, "Device or Medical/Surgical Supply, including Health Information Technology (HIT)" is a good starting point for developing a common format that would enable health care providers to report health IT–related patient safety events,** including those that occur in the ambulatory setting. By encouraging voluntary, confidential reporting of health IT-related patient safety events through PSOs, PSOs will be able to learn of underlying causes of risks and harms of EHR use in the ambulatory setting and share these findings to advance patient safety and health IT improvement activities on a national scale.

Education and outreach will be necessary to encourage physician and other stakeholders' participation in the reporting of health IT – related patient safety events. We recommend that AHRQ pursue outreach initiatives to educate physicians on how to identify and report this type of patient safety event. This will build physician understanding of the importance of reporting health IT events to advance the development of health IT systems that enhance safer performance. Knowing that they are contributing to health IT safety solutions might serve as a catalyst for physicians to report these events, thus increasing physician participation in PSOs and voluntary reporting. **AHRQ should also coordinate efforts with stakeholders to undertake a detailed and ongoing education program for the public to reinforce the importance and value of a voluntary, confidential reporting system working along side other reporting systems and to build public confidence in the objectives of the Patient Safety Act.** We also welcome the opportunity to work with AHRQ and other key stakeholders on physician outreach and education initiatives and materials that can maximize physician participation in patient safety reporting.

We are also very concerned about certain clauses that vendors use and require in their contracts with physicians, including some hold harmless clauses, which can shift liability for software malfunctions to the user, and nondisclosure clauses, which may include contractual requirements not to reveal information about software problems. Both of these contract clauses prevent learning about safety issues. The IOM report, like the American Medical Informatics Association (AMIA), has called the use of these clauses in agreements as unethical because they are contrary to basic professional responsibilities to share information that might affect patient care and impact outcomes. Likewise, physician ethics require physicians to share information that might impact patient care and outcomes, and specifically to share information related to medical errors and harm. **Contracts that include certain types of hold harmless and nondisclosure clauses pose challenges for physicians and should be examined.**

The AMA looks forward to continuing to work collaboratively with the Office of the National Coordinator (ONC), AHRQ, and respective stakeholders to increase our understanding of safety risks associated with health IT and use this knowledge to improve the safe design, implementation, and use of health IT systems. Should you have any questions on this letter, please contact Mari Savickis, Assistant Director, Division of Federal Affairs, at mari.savickis@ama-assn.org or (202) 789-7414.

Sincerely,

James L. Madara, MD