AMA
AMERICAN MEDICAL ASSOCIATION

James L. Madara, MD
Executive Vice President, CEO

American Medical Association
515 N. State Street
Chicago, Illinois 60654

ama-assn.org

(p) 312.464.5000
(f) 312.464.4184

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Farzad Mostashari, MD, ScM
National Coordinator
Health Information Technology
Office of the National Coordinator for Health
Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: The Office of the National Coordinator for Health Information Technology (ONC) Health Information Technology Patient Safety Action and Surveillance Plan

Dear Dr. Mostashari:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on ONC's Health Information Technology Patient Safety Action and Surveillance Plan (Health IT Patient Safety Plan). We want to reiterate our commitment to working with you and other stakeholders 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. Your Health IT Patient Safety Plan is a comprehensive first step that not only reflects your commitment to patient safety but also builds upon the issues raised in the 2011 Institute of Medicine Report, "Health IT and Patient Safety: Building Safer Systems for Better Care." We support several aspects of your plan and agree that all stakeholders need to be engaged as patient safety is a shared responsibility.

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 the IOM report, as well as other studies, finds 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.

We believe that ONC should coordinate efforts with the public and private sectors, EHR vendors, physician and consumer advocates, and other stakeholders to discuss the recommended voluntary code of conduct for health IT developers in order to improve the safety of health IT products that physicians and other health care providers use. Disseminating and piloting interventions and tools aimed at improving health IT safety and evaluating the effectiveness of these tools in hospital and physician practice settings are also critically important. Your ongoing commitment to issue guidance

to help physicians and others to anticipate, avoid, and troubleshoot problems and challenges that can emerge when implementing and using EHRs will be very helpful.

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. Physicians are concerned about potential liabilities from EHR system design and software flaws as well as lack of interoperability among EHR systems that could result in incomplete or missing information, which may lead to errors in patient diagnosis and treatment (e.g., patient matching). In addition, the impact that EHRs have on physician practice workflows can lead to unintended consequences. Those impacts are the result of how the software is developed, and we believe more needs to be done to address these concerns during the ONC EHR certification process. ONC indicates that the Health IT Policy Committee is recommending a meaningful use measure for Stage 3 of the Medicare/Medicaid meaningful use EHR program requiring health care providers to conduct a health IT safety risk assessment. We are concerned that physicians do not have the necessary tools or resources to make a meaningful safety risk assessment. We seek clarification on this proposal. Without clear standards and guidance, this measure could be burdensome for health care providers, especially smaller practices, to meet.

The AMA believes more research is needed in the ambulatory setting to determine and monitor the effects of EHR use on patient safety. We support ONC's recommendation to encourage health care providers to report health IT related patient safety events through the use of Patient Safety Organization (PSOs) and the Agency for Healthcare Research and Quality's (AHRQ) common formats. The use of PSOs and the common formats enables the voluntary, confidential reporting of health IT–related patient safety.

In addition, we support ONC's recommendation to work towards incorporating the AHRQ common format into certified EHRs in order to make it easier for physicians and other health care providers to confidentially report patient safety events to PSOs via certified EHR technology. Careful attention needs to be paid to ensure that the reporting of patient safety events to PSOs via certified EHRs occurs in a manner that maintains the confidentiality and legal protections of the information reported. It is also important to distinguish ONC's recommendation to support the use of PSOs with another recommendation to align the Centers for Medicare & Medicaid Services' (CMS) health and safety standards with the safety of health IT, and training surveyors to identify safe and unsafe practices associated with health IT. Although the end goal for both recommendations is the same—to enhance patient safety in the delivery of quality health care—it should be clear to all parties that the information that would be collected and investigated by surveyors is reported separately from the patient safety work product submitted to PSOs. PSOs are the mechanism under federal law to ensure that information about errors that are submitted for purposes of evaluating and improving patient safety are legally protected and confidential, along with the identity of the reporter. We are concerned with the use of safety event and error reporting systems that do not have these federal protections, which would leave both patients and the subjects of their reports in extremely vulnerable positions.

Educating physicians on how to identify and report this type of patient safety event is also necessary. 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 also serve as a catalyst for physicians to report these events, thus increasing physician participation in PSOs and voluntary reporting. In addition to physician education outreach efforts, we stand ready to work with ONC, AHRQ, and others to coordinate efforts to undertake a detailed and ongoing education program for the public to reinforce the importance and value of a voluntary, confidential reporting system working alongside other reporting systems.

The AMA looks forward to continuing to work collaboratively with 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 questions or require additional clarification about these comments, they may be directed to Mari Savickis, Assistant Director, Division of Federal Affairs at (202) 789-7414 or mari.savickis@ama-assn.org.

Sincerely,

James L. Madara, MD