American Hospital Association

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Farzad Mostashari, M.D., Sc.M.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, S.W., Suite 729-D
Washington, DC 20201

Re: Health Information Technology Patient Safety Action and Surveillance Plan, FY 2013 - 2015

Dear Dr. Mostashari:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Health Information Technology (IT) Patient Safety Action and Surveillance Plan that the Office of the National Coordinator for Health IT (ONC) released on Dec. 21, 2012.

The AHA congratulates ONC on a patient safety action plan that recognizes the shared responsibility of health IT vendors, clinicians, health care organizations and federal agencies in ensuring that health IT systems are designed, implemented and used to mitigate harm and promote safety. We concur with the plan's approach to build on "existing patient safety efforts across government programs and the private sector." America's hospitals are committed to providing the safest possible care. They embrace the "culture of safety" called for in the ONC plan as the best approach to prioritizing patient safety and identifying and correcting safety concerns. We also note that in complex health care environments, patient safety issues must be considered in a holistic manner. That is, health IT is most appropriately considered as one of many factors affecting safety, rather than as a topic on its own.

ONC rightly calls for additional work to understand the role of health IT in improving patient safety, as well as mitigating risks that may arise from the deployment of health IT systems. As noted in the plan, we must use health IT to make care safer and to continuously improve the safety of health IT. **We encourage ONC to assume a coordinating role in this endeavor and caution against an approach that leads to duplicative efforts.** In particular, the Agency for

Healthcare Research and Quality (AHRQ) has been a good partner on safety issues, and we are encouraged that the safety plan recognizes AHRQ's unique role. With regard to the Centers for Medicare & Medicaid Services, we note that changes under the Conditions of Participation (CoPs) must be supported by clear evidence of what is essential safe practice and go through the rule-making process. If and when the CoPs for hospitals are updated, we encourage ONC to consider how corresponding safety standards could be built into certification requirements for electronic health records (EHRs) vendors.

The AHA commends ONC for establishing specific steps to encourage EHR vendors to take responsibility for the safe design, implementation and use of their products, including good quality management principles, user-centered design and human factors assessment. Health care providers, especially hospitals, have well-established commitments and mechanisms to promote a culture of safety. It would be reassuring to know that our EHR vendor partners share that commitment and will support end-users in ensuring safe practices.

The AHA supports the development of a voluntary code of conduct for EHR vendors with specific commitments to ensuring and promoting safety. The code of conduct should make clear that vendors are responsible for safe design and product development and will support safe use of their products. In addition, the code of conduct should discourage vendors from including in their contracts indemnity clauses or nondisclosure language that limit the ability of users to identify and raise safety concerns. The code of conduct also should address other areas, such as transparency in pricing and adherence to existing coding conventions for systems that support billing (see the AHA's Nov. 12, 2012 letter to Secretary Sebelius and Attorney General Holder).

The AHA supports the elements of ONC's 2014 edition certification criteria that support safety-enhanced design, including adherence to quality management principles and processes and user-centered design. As indicated in the safety plan, these elements of certification should be considered a starting place, and continue to evolve as we learn more about safe design and the interaction between usability of EHRs and patient safety. America's hospitals take very seriously their responsibility to ensure that care is safe, and bear ultimate responsibility when a patient is harmed. Therefore, it is very important to know that the tools deployed in hospitals also are safe, as developed, sold and used.

We are encouraged that the safety plan includes development and dissemination of best practices in the safe deployment and use of EHRs, particularly now, when the adoption of EHRs is in a critical upswing. It is essential that the uptake in use of EHRs be accompanied by freely available guidance on how to achieve safe implementation. To that end, we commend the research and development activities undertaken by AHRQ and ONC outlined in the report. Consistent with the culture of safety, we believe positive guidance on safe practices will be more effective than punitive measures.

Further, the AHA urges ONC to focus its efforts on a patient safety issue that received limited mention in the safety plan – a single, national approach to matching patients to their records that all parties can use to improve the accuracy and cost-effectiveness of patient matching. The issue of how to match patients with their medical records needs to be solved as

we accelerate information exchange on regional and national levels. The inability to match patients across silos raises safety concerns about mismatches – incorrectly matching patients, or missing a match that should have been made. In addition, without a single, national approach to patient matching, hospitals and health systems are forced to expend significant resources on expensive, proprietary solutions to develop master patient indexes that apply only to that particular hospital or health system's patients.

Finally, we note that the safety plan did not mention the key role of health information exchange to support the safety benefits of EHRs. To that end, we encourage ONC to focus considerable resources on advancing the more robust data exchange infrastructure necessary to support the sharing of health information. The full potential of health IT will not be realized until all relevant health information is easily accessible when and where it is needed to support clinical decisions and healthy behaviors. Key pieces of the exchange infrastructure are still missing, such as technical support for the adoption and use of standards, affordable exchange networks and widely accessible provider directories.

Thank you for the opportunity to comment on ONC's Health Information Technology Patient Safety Action and Surveillance Plan. If you have questions about our comments or would like more information, please contact me or Chantal Worzala, director of policy, at cworzala@aha.org or 202-626-2313.

Sincerely,

/s/

Linda E. Fishman
Senior Vice President
Public Policy Analysis and Development