



**American Hospital
Association**

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June 28, 2013

Jodi Daniel, J.D.
Director
Office of Policy and Planning, Office of the 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: Request for Comment: Food and Drug Administration Safety and Innovation Act (FDASIA): Request for Comments on the Development of a Risk-Based Regulatory Framework and Strategy for Health Information Technology

Dear Ms. Daniel:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to respond to the request for comment (RFC) on a risk-based regulatory framework for health information technology (IT) that was published in the May 30 *Federal Register*.

The RFC asks for public input on the issues to be considered by the Food and Drug Administration Safety and Innovation Act Work Group of the Health IT Policy Committee as it provides input on a congressionally mandated report that the Food and Drug Administration (FDA) must produce in coordination with the Office of the National Coordinator for Health IT (ONC) and the Federal Communications Commission (FCC). Specifically, input is requested in three areas:

- The scope and range of health IT (taxonomy)
- The balance between risk and innovation
- Areas of possible regulatory overlap

TAXONOMY

America's hospitals use health IT as one of many tools to continuously ensure and improve the safety of health care. However, despite the safety benefits, health IT can pose unintended risks.



The AHA encourages FDA, ONC and FCC to look across the full range of health IT products and carefully judge the extent to which they pose risk to patients. Key factors to be considered include the potential for harm, the extent of harm, and the extent to which software is automating and or guiding clinical decision-making. The agencies also should consider the extent to which a product is transforming data points (such as laboratory values or drug dosages) used to guide clinical decision-making and treatment. For example, when drug dosage data are sent from an order entry system to a pharmacy information system, it is crucial for safety that both the data points and their units of measure are accurate within each system and across systems.

RISK AND INNOVATION

The RFC asks about the types of risks to patient safety posed by health IT, and the factors to be considered that would protect patient safety while promoting innovation. 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 and sold. Many, if not most, of the traditional medical devices already subject to FDA approval – such as drug infusion pumps or imaging equipment – contain health IT applications that are reviewed as part of the device. At the other end of the spectrum, products such as scheduling systems are highly unlikely to raise safety concerns.

In looking at specific products, attributes such as safe design, use of quality management principles, user-centered design and human factors assessments have been shown to improve safety. Therefore, the agencies should look carefully at the interaction between usability of health IT products and patient safety. The general inability of systems to easily share data using the same set of standards (interoperability) also can pose safety risks. For example, as hospitals connect systems to bring data from a medical device into the electronic health record (EHR), they often must establish multiple interfaces that need to be updated over time. In addition, all information systems must increasingly be assessed against state-of-the-art information security protocols.

Manufacturers also must be committed to supporting safe use of their products after they are sold. In addition to providing adequate training and safety updates, they should not be allowed to include in their contracts indemnity clauses or nondisclosure language that limits the ability of users to identify and publicly raise safety concerns.

The AHA recognizes that factors in the use of health IT also will affect health outcomes. We believe, however, that the panoply of existing patient safety efforts across government programs and the private sector already address what happens as care is provided. For example, all hospitals must be accredited against the Medicare conditions of participation, which take a comprehensive look at the full range of safety practices in a hospital, including information management. That said, we support increased 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. These issues are addressed further in the section on regulation.

The AHA urges the agencies to include in the report consideration of the safety issues that stem from the lack of a single, national approach to matching patients to their records that all parties can use to accurately and efficiently exchange health information. 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.

REGULATORY OVERLAP

The hospital field is highly regulated by federal, state and local governments, and includes many private sector activities aimed to ensure and enhance patient safety. These include, but are not limited to, Medicare’s conditions of participation, accreditation by The Joint Commission or other federally recognized entities (which includes extensive analysis of health information and record management), Centers for Medicare & Medicaid Services requirements for hospital laboratories (including lab information systems), state licensure of hospitals and health care providers, certifications from professional societies and many other ongoing activities. Therefore, we urge the FDA, in coordination with ONC and the FCC, to conduct a broad environmental scan of existing regulatory efforts as context for its report, and seek to minimize duplicative, or worse, conflicting regulations.

When considering the use of health IT by providers, the report should recommend building on existing patient safety efforts that providers engage in across government programs and the private sector, rather than establishing new efforts. America’s hospitals are committed to providing the safest possible care and embrace the “culture of safety” 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. Hospitals already participate in a variety of state, federal and private safety reporting and improvement activities, such as The Joint Commission sentinel event monitoring and voluntary participation with patient safety organizations. In general, ensuring that these existing channels have the knowledge needed to address health IT safety issues would be more productive than establishing efforts specifically targeted to health IT.

That said, the emergence of new health IT tools raises the need for additional research 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. Ongoing development and dissemination of best practices in the safe design, development, deployment and use of EHRs would be helpful. It is essential that the uptake in use of EHRs be accompanied by freely available guidance on how to achieve safe implementation. Consistent with the culture of safety, we believe positive guidance on safe practices would be more effective than punitive measures.

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Page 4 of 4

Thank you for the opportunity to comment on the risk-based regulatory framework for health IT. 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 & Development

cc: Bakul Patel, FDA