eHEALTH INITIATIVE
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July 1, 2013

Ms. Jodi Daniel
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: **FDASIA Report**
Hubert H. Humphrey Building, Suite 729D
200 Independence Avenue SW
Washington, DC 20201

Submitted via http://www.regulations.gov

Dear Ms. Daniel,

eHealth Initiative (eHI) appreciates the opportunity to respond to the Request for Comments (RFC) on the Development of a Risk-Based Regulatory Framework and Strategy for Health Information Technology (IT) [78FR32390]. An RFC enables flexibility for input and the ability to learn more about how best to leverage current authorities and policy levers to expand efforts. eHI strongly supports government efforts to seek multi stakeholder input on the development of a report that will offer a proposed strategy and recommendations for an appropriate risk-based Health IT regulatory framework that would include, as necessary, the full range of tools and applications and promotes innovation, protects patient safety, and avoids regulatory duplication.

eHI is an independent, non-profit, multi-stakeholder organization. Our mission is to drive improvements in the quality, safety and efficiency of healthcare through information and IT. eHI advocates for the use of health IT that is practical, sustainable and addresses stakeholder needs, particularly those of patients. eHI supports ONC's commitment to fostering a culture of patient safety and as the Food and Drug Administration (FDA), Federal Communication Commission (FCC), and ONC continues developing the final plan, we strongly recommend addressing the critical role health information exchange (HIE) plays in the successful implementation and use of health IT. As the adoption of HIE accelerates, it is critical to ensure a robust exchange infrastructure exists to support accurate patient matching and identification, timely access, and exchange of information for patient care.

eHI offers several comments from our perspective on the questions of patient safety that provide context to the responses to the RFC questions. Additional solicitation of public input, such as town hall meetings and forums, will allow consideration of other public and private processes to support patient safety. Listed below are several high level

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recommendations that support the development of a report for an appropriate risk-based health IT regulatory framework.

1. Taxonomy
a. What types of health IT should be addressed by the report developed by FDA, ONC, and FCC?

We believe the focus of the report should not be placed upon what "types of health IT" should be addressed but rather placing an emphasis on the broader scope of health IT that includes the full range of tools and applications across the risk spectrum and their impact on patient safety, including those currently regulated by the FDA. By conducting this analysis, the framework can further define the level of oversight and regulation, if any, based upon this intersection and the outcome may require no or "light" oversight vs. specific agency regulation, based upon the level of risk and harm to patients.

As the patient safety framework is developed, we strongly urge consideration of the software and use of technology that accomplishes the process of exchanging health information, which may occur as part of or outside of a formal HIE organization. We believe the inclusion of an HIE *organization* falls outside the scope of this effort and suggest the act of exchanging information and mitigating risk factors within HIE organizations should be addressed within the patient safety framework.

2. Risk and Innovation
a. What are the risks to patient safety posed by health IT and what is the likelihood of these risks?

Clearly, health IT as used can present both benefits and risks relative to patient safety. It is essential to avoid a siloed approach to this question but rather to focus on the full ecosystem of factors and mitigating risks that can impact patient safety. We urge the agencies to evaluate the available peer reviewed and other high quality literature on benefits and risks associated with health IT, including incidence and prevalence.

We recognize that the use of health IT, can, in some instances, poses risks to patients; for example, there have been published examples of accidently transposing values and numbers and medication measurement errors. Other factors such as provider workflow, usability, and the way in which health information is leveraged is an important strategy for mitigating patient safety risks and thus requires further analysis. Fundamentally, health IT serves as an enabler in the treatment of patients and thus the usability of systems by which health information is captured at the point of care has tremendous value and potential risk further down the process and should be treated equally as important as the technology itself.

Accurate patient matching and identification is another critical factor that should be examined and steps taken to address mitigating risks within the analysis of the larger health IT ecosystem. eHI has previously submitted comments regarding this topic in response to the ONC Patient Safety Action and Surveillance Plan issued in December 2012, "eHI strongly supports ONC's intent to further improve patient matching with their health information, as this is a critical patient safety issue and is a complex and challenging issue to resolve once a

patient has been mismatched. As the growth of health information exchange continues to accelerate nationwide, accurate patient matching will become more urgent as more providers and health care organizations contribute to a patient's record."

b. What factors or approaches could be included in a risk-based regulatory approach for health IT to promote innovation and protect patient safety?

We encourage a focus on the potential that a technology or product can cause harm, the likelihood that such potentially harmful situations will occur, the extent of harm, and the extent to which the risk can be mitigated or not, for example whether the technology guides clinical decision-making without clinician intervention. A risk based framework should allow for the appropriate level of oversight or regulation, and should also consider the costs and benefits of regulation or oversight and support the continuation and flexibility of innovation of health IT.

We also advocate for and encourage the use of emerging and existing patient safety mechanisms for voluntary reporting that may include but is not limited to Patient Safety Organizations (PSOs), accrediting bodies, state and national level mandatory reporting, and Centers for Disease Control (CDC) required reporting. As the rise of health IT tools and software moves at a rapid pace and changes within regulatory programs such as meaningful use, we believe revisiting reporting programs to ensure they are comprehensive enough to address these changes and other mitigating risk factors is imperative.

The capture, collection, aggregation, and analysis of patient safety information can further inform and support a learning health system whereby vendors, providers, payers, the pharmaceutical industry, consumers, and other stakeholders can better understand areas of vulnerability and potential harm and take steps to improve the overall healthcare system.

3. Regulation

a. Are there current areas of regulatory overlap among FDA, ONC, and/or FCC and if so, what are they? Please be specific if possible.
b. If there are areas of regulatory overlap, what, if any, actions should the agencies take to minimize this overlap? How can further duplication be avoided?

eHI acknowledges the potential for overlap and duplication of regulatory processes. As the emergence of health IT tools and its applications, mobile medical applications, and other technological innovations increase; a pressing need exists to address the prevention of regulatory duplication and burden to the degree possible. As a primary step in the development of the framework we strongly urge the agencies conduct an analysis to determine where gaps exists in the regulatory spectrum. By taking this initial action and creating a gap analysis we believe it will assist in the development of a roadmap to where regulatory actions need to take place and where they should be avoided to prevent redundancy. During the environmental scanning effort, we encourage the inclusion of existing national, state, and local regulations to prevent duplicative and/or conflicting efforts.

In general, we believe that regulatory duplication should be avoided to the extent possible and where overlap is present; it should apply to different aspects of a product or different processes relevant to a company. For example, we recognize that multiple agencies may provide oversight for a given products (e.g., one might deal with specialized telecommunications issues and another with more general safety issues). Where different agencies focus on different products given varying risk levels, but reference the same or similar processes (e.g. a Quality Management System), we believe that the agencies should harmonize methods and requirements to allow companies that have health IT products and tools subject to both agencies' jurisdictions to use the same process to meet both requirements.

Again, we applaud the agencies' efforts to seek multi-stakeholder input, but strongly recommend that you seek additional stakeholder input in further developing recommendations for an appropriate risk-based regulatory framework for health IT. As a multi-stakeholder coalition with significant experience in health IT, eHI is well positioned to help ONC, FDA and FCC by providing additional input as a framework is developed. If you have any questions, please contact me at Jennifer.Covich@ehealthinitiative.org.

Sincerely,

Jennifer Covich Bordenick
Chief Executive Officer
eHealth Initiative