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June 30, 2013

Farzad Mostashari, MD, ScM, National Coordinator
Office of the National Coordinator for Health IT
U.S. Department of Health and Human Services
Attention: FDASIA Report
Hubert H. Humphrey Building, Suite 729D
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Mostashari,

On behalf of the Electronic Health Record Association (the Association), we are pleased to offer our comments in response to the May 30, 2013 Request for Comments (RFC) on the Development of a Risk-Based Regulatory Framework and Strategy for Health Information Technology. This request was issued by the Food and Drug Administration (FDA), the Office of the National Coordinator for Health Information Technology (ONC), and Federal Communication Commission (FCC) to support work pursuant to the implementation of the Food and Drug Administration Safety and Innovation Act (FDASIA).

The Association is fully committed to patient safety in general and, in particular, enhanced patient safety associated with electronic health records (EHRs) and other health information technology (health IT). We therefore applaud efforts to provide a framework to enhance patient safety, and urge recognition of the many safety advantages that arise through the proper use of EHRs and health IT. We are committed to assuring that development and implementation of EHRs that do not introduce unacceptable patient safety risk, and to fulfilling our role with others in the shared stakeholder responsibility toward patient safety.

We have previously submitted comments, relevant to this RFC, on the ONC's *Health Information Technology Patient Safety Action & Surveillance Plan for Public Comment* (the Plan), published in December 2012. That comment letter is attached. Specifically, we emphasize that the framework for health IT oversight must be designed to:

- evolve as the needs and capabilities of the industry change;
- emphasize joint stakeholder responsibility;

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- build toward a non-punitive nationwide learning system; and
- not limit innovation.

We organize our comments according to the structure and questions in the RFC.

1. Taxonomy

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

For the purposes of the FDASIA study, and consistent with the statutory intent, the EHR Association believes that the full range of health IT (e.g., revenue cycle management systems, EHRs, picture archiving and communications systems, lab systems, and mobile devices), including that currently regulated by the FDA, should be in scope for consideration, but not necessarily for regulation or oversight.

Like many others, the EHR Association sees health information technology as a component in the continuum of the assessment of patient safety risk, which must consider the many factors that affect risk, including the overall system in which the health IT is used. At the high risk end of the continuum is health IT that is integrated with devices that interact directly with the patient with limited or no human intervention (e. g., software in implantable devices). At the low end is administrative software that does not have material clinical implications. In the middle are EHRs and most clinical decision support systems intended to assist but not direct clinicians.

In assessing the dimensions of risk and the associated approach to oversight and regulation, we recommend that the agencies and the FDASIA Workgroup of the HIT Policy Committee consider the approach taken by the Bipartisan Policy Center (BPC) in its February 2013 Framework report¹. Specifically, see Figures 1 and 2 in the Framework report. Consistent with the BPC report, at the highest end of the continuum, we suggest the current status quo of FDA regulation. At the low end, where administrative health IT has little or no implication for patient safety, there should be no additional oversight or regulation.

In the middle of this range, where health IT primarily supports and informs independent clinician action, we support a general oversight approach that:

- Leverages a framework that is more flexible, given the iterative nature of health IT. The Association suggests that this approach avoid the prescriptive and expensive characteristics of current Class 1, 2 and 3 medical device regulation, which is better suited for traditional devices than EHRs and most health IT.
- Focuses on ensuring safe processes in the design, development, implementation, use, customization and maintenance of health IT. We believe that an approach that is prescriptive with respect to product functionalities or capabilities (as can be the case with meaningful use certification regulations, for example) will fail to remain relevant as health IT rapidly evolves.
- Recognizes that the health IT industry is rapidly evolving and highly innovative, and thus is not a candidate for traditional regulation by highly prescriptive requirements.

¹ An Oversight Framework for Assuring Patient Safety in Health Information Technology, Bipartisan Policy Center Health Innovation Initiative, February, 2013 - <http://bipartisanpolicy.org/library/report/oversight-framework-assuring-patient-safety-health-information-technology>

- Recognizes, leverages, and coordinates with the many regulations, requirements, and guidelines already in place in the health care delivery system, including agency regulations (e.g., CMS, ONC, FDA and state regulations), Medicare and Medicaid conditions of participation, state and professional licensing, and private sector requirements associated with regulations (e. g., the Joint Commission);
- Understands that health IT is used as part of a system of systems, with shared responsibility of multiple stakeholders, and that regulation of individual components is ineffective and inappropriate for those risks that are the result of integration or information exchange issues²; and
- Recognizes that health IT provides cognitive and work flow support to human practitioners and does not seek to supersede human clinical decision-making.

Consideration of patient safety issues requires understanding healthcare delivery processes, the human elements of the information systems, the role of implementation and training, and many other factors. Patient safety involves many roles and responsibilities. We believe that the agencies and the FDASIA Workgroup should expand this question to ask how care delivery roles and various human and technical aspects of health IT can improve patient safety.

EHR Association members do not just sell software to our clients. We build and maintain working relationships that involve the use of EHR software as an integral component of healthcare information systems that support healthcare delivery. We rely on our customers and they rely on us to make sure those systems work in concert to serve patients.

2. Risk and Innovation

a) **What are the risks to patient safety posed by health IT and what is the likelihood of these risks?**

We welcome the opportunity to work with the government, providers, and all other stakeholders to create an effective and efficient system to gather information on patient safety. The Institute of Medicine (IOM) report on health IT and patient safety notes that, “[d]espite a growing body of research on patient safety, the IOM found ‘little published evidence’ quantifying the magnitude of risks associated with health IT.” We know that EHRs and other health IT can be very effective in reducing certain types of patient safety events, like medication errors, relative to paper record systems. We also underscore the indications of low incidence and prevalence of HIT-related safety issues as reported by the IOM and the references in the ONC Draft Plan and the BPC Report to data from Pennsylvania state reporting.

Nonetheless, there is much that we have yet to learn about other aspects of EHR safety. **To that point, we suggest building on what is known, while refraining from regulatory solutions to problems that have yet to be fully defined.**

It is helpful to look to the National Quality Strategy, the Partnership for Patients, CMS actions around safety, state efforts, the Joint Commission, and Patient Safety Organizations (PSOs) for information about patient safety risks. The Association supports additional efforts to review patient safety reporting information to evaluate the role of health IT in these reported incidents.

² See HIMSS System Risk Analysis Guide at <http://www.himss.org/library/quality-patient-safety/medical-devices/systems-risk-analysis?navItemNumber=16595>

We believe that it would be useful to explore how health IT can be used to enhance and support provider reporting of safety events and risks in general through Patient Safety Organizations (PSO) established under the Patient Safety and Quality Improvement Act, and other applicable bodies, which should be expanded into a national aggregated, non-punitive learning system. At the same time, we caution that it is essential to consider appropriate EHR and reporting workflows for providers and their organizations. For example, given that most patient safety reporting will not be done by a single EHR user, and will occur within intra-organizational workflows and review processes, it critical to consider carefully whether and how EHRs might be used to help collect the data needed by healthcare organizations as they review safety issues internally and potentially report them externally. In looking to PSOs and other organizations and processes, including the Medicare Patient Safety Monitoring System (MPSMS), the AHRQ Quality and Safety Reporting System (QSRS), and other reporting systems, it will be important to guard against duplicate reports in order for the information to be accurate and not misleading.

In sum, health IT presents clear benefits but also has the potential to introduce some risk relative to patient safety. It is essential to avoid a siloed approach to patient safety reporting, but rather to focus on the full ecosystem of factors that can affect 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.

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 support the concept that patient safety is a “shared responsibility” of providers, developers, regulators, researchers, advocacy communities, patients, and other stakeholders. Although we recognize that Congress has asked for development of a risk-based approach, we suggest a few important additional considerations in developing an effective approach.

Unfortunately, the question itself suggests an assumption that patient safety can be improved by a regulatory approach and one that solely focuses on health IT. First, it is essential to broaden the focus from traditional regulation to a consideration of “oversight” that does not use traditional regulatory approaches. By “oversight”, we suggest an approach that emphasizes and supports appropriate standards, flexibility, evolution, and innovation, and which stops short of regulation. Regulation would be a tool to be used only for well understood, narrowly circumscribed purposes where the potential downstream effects are clearly known. Second, as previously emphasized, it is essential to avoid, to the greatest extent possible, a siloed approach to patient safety that isolates health IT from the broader context in which it is used and from its inclusion in more generalized patient safety tools and programs.

EHR developers have responsibilities to make sure EHRs do not add to patient safety risks, and to provide the tools that in fact enhance patient safety. EHRs are central to the flow of patient information. That information may come through other software, from diagnostic devices, across health information exchanges, or from providers with different health information systems. Many information issues cannot be evaluated simply by looking at one particular system. We note that EHRs are already subject to certification requirements for certain functionality. EHR developers work to ensure that their systems perform reliably and integrate properly with other health IT. **We do not believe additional regulatory programs are warranted, but recognize that patient safety-focused oversight that places special considerations on health IT could be useful, as outlined in the BPC report.**

In terms of the specific factors that should be considered in developing and applying a risk-based oversight framework, we suggest that such a framework for EHRs in context of their use should take into account the following:

- The various dimensions of risk -- that is, the likelihood of harm resulting from a specific risk and the likelihood of this risk itself occurring;
- The availability of mitigation factors that are embedded in workflows and that are activated should a risk materialize, such as clinician or patient intervention; and
- If a problem occurs and goes unmitigated, the potential severity of the harm.

In addition, a risk-based regulatory framework should also consider the costs and benefits of regulation, as well as the feasibility of an effective regulatory process.

More generally, in developing and applying such a framework, the Association agrees with and supports:

- Instilling awareness that patient safety is everyone's responsibility;
- Ensuring that health IT-related patient safety is approached as a seamless component within the overall patient safety ecosystem, rather than a stand-alone system;
- Developing the concept and then building a nationwide, non-punitive safety data reporting, analysis, and learning system;
- The use by health IT developers of standards-based approaches to quality management systems and usability, with private-sector (e.g., third party) focused approaches to assessing the use of such methods, including accreditation and attestation;
- Supports efforts to improve the accuracy of patient matching;
- Leveraging the Patient Safety Act and the Patient Safety Organizations created under that Act;
- Leveraging enhanced versions of the AHRQ Common Formats that will incorporate health IT-related data sets into existing reporting processes, and aggregation and analysis processes for both inpatient and ambulatory settings;
- Conducting and publishing research; and
- Providing coordination of patient safety monitoring programs across diverse industry programs such as the Center for Medicaid and Medicare Services (CMS) Conditions of Participation, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and others;

In general, we do not support:

- Using meaningful use regulations and certification to embed intrusive requirements into EHR design that are not conducive to or needed for a learning system;
- Expanding the role of the ONC Authorized Certification Bodies (ACBs) into patient safety evaluation and enforcement, which is not within their core competencies; and
- Equating usability with patient safety. Although some usability issues may affect safety, we do not agree that comparing users' experiences can determine safety among EHRs. We suggest that it is more appropriate to implement evaluation processes such as reporting, analyzing, and learning to determine the impacts of health IT and usability on patient safety, before devising a regulatory or oversight approach to usability.

Patient safety knowledge and actions must evolve and grow as part of a learning healthcare system. Approaches to safety must be forward-looking and appropriate for the stage of development of our rapidly evolving industry.

Overall, goals must be clear. Interventions should be made only after thorough understanding of the issues, thorough testing and demonstrated repeatability of the solution, and empirical experience that ensures no unintended adverse consequences of the intervention. Moreover, health IT-focused interventions and solutions must also be evaluated for how they fit or do not fit within the overall patient safety systems, including both health IT and non-health IT aspects.

EHR Association member companies have a deep commitment to patient safety and a learning health care system. Safe design policies and practices should be in place for every vendor. We believe that our new industry EHR Developer Code of Conduct will be an extremely useful tool in implementing this commitment.

As we look to optimal use of health IT patient safety reporting, we believe with many others that such reporting should fit seamlessly into broader approaches to patient safety reporting. As indicated in our Code of Conduct, we believe that it would be useful for health IT developers to work with PSOs and other such organizations on a voluntary basis. The Association recognizes that provider reporting of safety events is essential and should be encouraged. Voluntary provider reporting to PSOs on safety issues should be the primary focus, given that safety events generally happen in a provider context and that health IT is likely to be only one element of any safety event. In implementing reporting that involves providers and developers, it is important to understand, preserve, and in some cases expand or clarify the protections afforded to such reporting under the Patient Safety Act.

The EHR Association supports leveraging the AHRQ Network of Patient Safety Databases for aggregation and high-level analysis of safety reports. Aggregate data on safety reports should not identify specific developers or product brands, but rather focus on patterns and types of health IT functionality involved, since most reports are unlikely to undergo full root cause analysis, especially with reporting expected to extend beyond instances of death and serious injury. To fully realize a non-punitive learning environment and to increase the accuracy of safety signal detection, it is essential to address the potentially negative impact of the collection of incomplete or misleading data. Aggregated reports should be de-identified by provider, developer, and specific product (as opposed to product type), and focus on trends and patterns to encourage robust, widespread, and consistent reporting.

The EHR Association also supports efforts to align safety monitoring with CMS via the Medicare Conditions of Participation and other means. We caution, however, that such efforts should address needed educational and harmonization efforts necessary to incorporate the CMS initiative. Furthermore, CMS should qualify (or certify) its surveyors, auditors and other applicable personnel for competency and qualifications to perform such roles.

In sum, we recognize the importance of potential government actions in the face of serious adverse events or unsafe conditions involving EHR technology that are not addressed through other mechanisms, including timely and appropriate provider or developer action. We believe that a national learning system that is non-punitive and leverages the strengths of PSOs is a promising approach. Such a system best fulfills the national learning system objective, yet it does not hinder making stakeholders accountable for patient safety. Finally, any regulation must take the entire health IT ecosystem into consideration, including clinician workflows and interdependencies among systems.

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.

Yes, there are some areas of overlap, and especially potential overlap, depending on future approaches taken by the federal government. Currently, we have both FDA and ONC involved in various aspects of health IT, with some levels of uncertainty regarding FDA plans for EHRs, mobile applications, and clinical decision support. We also have growing FCC interest in aspects of mobile healthcare devices. In some cases, the same product might be subject to multiple regulatory approaches, especially regarding aspects of patient safety. In other cases, the same company might be subject to overlapping regulations by virtue of its product mix. In still others, two different agencies can require or reference use of the same type of safety process, such as quality management systems.

Additionally, there are many programs, both public and private, that create quasi-regulatory obligations on health IT, including patient safety and adverse event reporting, Medicare and Medicaid conditions of participation, provider quality reporting and more.

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?

In general, overlap should be avoided. Where it is unavoidable, it should be minimized and should apply to different aspects of a product rather than the same functionality. For example, we recognize that multiple agencies may provide oversight for a given product (e.g., one might deal with specialized telecommunications issues and another with more general safety issues). In addition, where different agencies focus on different products given varying risk levels or on different aspects of the same product, 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 products subject to both agencies' jurisdictions to use the same process to meet both sets of requirements.

In general, multiple federal regulatory agencies (e.g., FDA, ONC, FCC, CMS, OCR, etc.) have overlapping, complementary, parallel, or similar health IT regulations, for example, the CMS and ONC meaningful use regulations. There also needs to be an effective "single source of truth" across all regulatory agencies to ensure that regulations are clear, unambiguous, and which do not collide or conflict with other regulations or reporting requirements. We therefore recommend that agencies develop a consistent format for the industry to access (via the Web) the current laws, regulations, and guidance, including FAQs. Each of these agencies now has its unique design, navigation, and search capabilities for their websites which hinders industry access and makes the task of locating and understanding the latest information more difficult and subject to error.

We want to emphasize that:

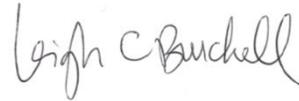
- Heavy regulation in rapidly changing and innovative industries like health IT is undesirable and will stifle necessary innovation.
- The regulatory and oversight structure needs to evolve with the industry, including both health IT software development, implementation, and provider adoption and use of health IT.
- All oversight and regulatory actions should be minimally invasive, unambiguous, non-prescriptive, and conducive to the establishment of a non-punitive national learning system.

Again, we want to thank you for this opportunity to provide input to these important deliberations. We look forward to working with you toward an effective, efficient process for patient safety reporting that works for all stakeholders, particularly for healthcare providers and their patients.

Sincerely,



Michele McGlynn
Chair, EHR Association
Siemens



Leigh Burchell
Vice Chair, EHR Association
Allscripts

HIMSS EHR Association Executive Committee



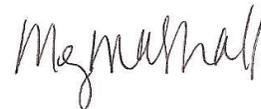
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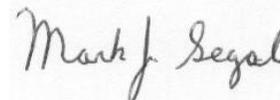
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Two members of the EHR Association Executive Committee serve on the Health IT Policy Committee FDASIA Workgroup in their individual capacities. In submitting this response to the RFC, they are responding as members of the EHR Association Executive Committee, reflecting our collective position separate and distinct from their participation on the Workgroup.

About HIMSS EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of more than 40 companies that supply the vast majority of operational EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of the Healthcare Information and Management Systems Society (HIMSS). For more information, visit <http://www.himssehra.org>.