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November 6, 2013

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
U.S. Department of Health and Human Services
Washington, DC 20201

Dear Secretary Sebelius,

On behalf of the Electronic Health Record (EHR) Association, we would like to offer the following comments on the draft recommendations presented by the FDA Safety and Innovation Act (FDASIA) Workgroup and approved by the Health IT Policy Committee at its meeting on September 4, 2013.

Our Association represents more than 40 EHR developer companies, serving the vast majority of hospitals and physicians' practices actively using EHRs to improve the quality and efficiency of patient care in the US. We hope that our comments on this work, informed by our collective experiences in designing, developing, deploying, and supporting EHRs, will be useful as you develop recommendations for a risk-based regulatory framework for health IT as mandated by FDASIA. We stand ready to engage with you to provide the perspectives of the companies that develop the vast majority of electronic health records in use today.

We agree with the Workgroup's recommendation on slide 52 that regulation of health information technology (HIT) beyond what is currently in place is not appropriate until further analysis of data and the establishment of a risk-based framework have been completed. We interpret this recommendation to mean that most HIT that is not currently regulated as a medical device should remain unregulated, but that current Federal Drug Administration (FDA), Office of the National Coordinator for Health IT (ONC), and Federal Communications Commission (FCC) regulations may review and recommend improvements to resolve agency and cross-agency issues, and to address recent and emerging technology developments.

We do, however, believe that additional definition and clarification is needed in some areas addressed by the FDASIA Workgroup or that are otherwise pertinent to your work on this issue. Our specific concerns and views are outlined below:

November 6, 2013

- **“Class 0”** – We are not convinced that most HIT not regulated as a medical device should receive a new “Class 0” device classification by the FDA. Such a classification and application for a formal regulatory approach to HIT is not warranted in our view, and is not needed to apply a risk-based oversight approach as referenced in the body of our comments.
- **MDDS** – We believe that the language and construct of the 2011 MDDS rule could use refinement and clarification. In one sense, the MDDS rule helps reduce problems because it states that the software that simply stores, transfers, or displays medical device data does not assume the FDA classification of the device that generated the data in the first instance. That approach keeps certain software from being described as a more regulated Class II or Class III device. Unfortunately, the MDDS rule and its constructs also appear to pull an extremely broad swath of software in as Class I medical devices. Moreover, failure to meet the MDDS definition through small modifications to basic functionality could then make that type of software an accessory to a Class II or Class III device.

Unlike EHRs and clinical decision support, MDDS are not under a current category of enforcement discretion. Class I devices have to follow a number of basic requirements including registration and listing. We understand that the agency is considering revisions to the MDDS rule with the possibility of some of the software captured by that rule being subject to enforcement discretion. We support such a revision of the FDA’s approach to MDDS and strongly endorse the principle that simply transmitting, storing, or displaying medical device data should not be enough to make software a medical device at all.

- **Medical device accessories** – We believe that there should be a clear statement that not all medical device accessories are subject to pre-market review. The subset of accessories subject to pre-market review should be specifically identified.
- **Clinical decision support (CDS)** – It is important to clearly differentiate between most CDS, which poses relatively low risk to patient safety, and other applications with higher associated risk, such as Computer Aided Diagnostics. EHR Association members have extensive experience implementing CDS in a variety of clinical environments, and understand the variations that exist in those implementations even among similar healthcare organizations.
- **Determining risk** – We do not believe that the risk grid detailed in the FDASIA Workgroup report provides a valid and reliable basis to assign risk levels to HIT applications as it lacks any formal model and associated weights to combine and process specific risk elements and, as presented in the report, seemed to generate results without face validity (e.g., infusion pump at lower risk level than EHRs). We therefore recommend that a weighted model for HIT risk assessment, framed around the intended use of the subject HIT applications, be developed with input from key stakeholders, including HIT developers and providers who use those technologies.
- **“High” risk vs. “higher” risk** – Building on the point above, we also do not believe that the Workgroup report, as approved, provides a firm basis to determine “higher risk” and “high risk”. To begin with, the nomenclature is misleading. “Higher risk” is actually lower in risk than “high risk” as FDASIA discusses risk, so it will be important to clearly differentiate and understand what falls into each category. “High risk” applications would likely be regulated by FDA anyway; whereas many “higher risk” applications should fall into the Bipartisan Policy

Committee's (BPC) mid-level risk definition¹, and be therefore subject to a new oversight process distinct from traditional FDA device regulation.

FDA listing of all products – With regard to the recommendation that vendors be required to list all products that are considered to represent “at least some risk”, the Workgroup did not adequately describe anticipated benefits of this kind of listing, nor justify the burden of complying with such a requirement – a justification threshold that even the Workgroup itself acknowledged. The level of risk that would require listing is vague and, given newer methods of software development like Agile, it would be very difficult to assess risk and comply with listing requirements in a fast-moving market. To the extent that this kind of listing may be useful, ONC has already established a certification process that should be sufficient for EHR technology.

Post-market surveillance – The EHR Association agrees that any post-market surveillance of HIT must be based on a collaborative process with multi-stakeholder participation. We support a national learning system that is non-punitive and that leverages the strengths of existing programs (e.g., the Agency for Healthcare Research and Quality (AHRQ) Patient Safety Organization (PSO) system). Such an approach can meet the national learning system objective while holding stakeholders accountable for patient safety. In any such program, benefits must exceed costs for all stakeholders. The most useful information will come from users, but vendors play a critical role in helping users to collect and report data that is essential to root cause analyses.

Use of existing standards – From its inception, the Association has supported adoption of existing standards and development of needed new standards, particularly in the area of interoperability. Beyond interoperability, standards relied upon for patient safety should primarily focus on processes and not product functionality, using existing US (and, as appropriate, international) standards, with a non-regulatory and transparent approach to accreditation or self-attestation, without requiring additional specific ISO or other certification. As an example, the EHR Association has been engaged with the AHRQ) to enhance the Common Formats for reporting patient safety events to PSOs. Moreover, standards must be relevant across HIT product lifecycles and engage developers, implementers, and users in their development. Duplicative efforts should be avoided to ensure that we focus on single standards to support specific categories of data exchange. Overall, interoperability standards and implementation requirements should generally be driven by market-derived business cases.

Reporting of safety events – We do agree that approaches are needed to allow aggregation of safety issues at the national level. Specifically, the EHR Association supports leveraging the PSO system for aggregation and high level analysis of safety reports. While other entities might participate in collecting and aggregating patient safety information, it will be critical to coordinate these activities to avoid duplicative reporting and potentially misleading information. Aggregation of patient safety data is useful only if there is a process for sharing lessons learned, while at the same time protecting provider, patient, and HIT developer information.

Post implementation testing – The Association does not believe that mandatory post-implementation testing is necessary to determine that key safety-related decision support is in place as part of HIT deployment. EHR certification testing determines that a baseline set of CDS features are available to

¹ Formal Response to the Food and Drug Administration Safety and Innovation Act: Request for Comments on the Development of a Risk-Based Regulatory Framework and Strategy for Health Information Technology Bipartisan Policy Center Health Innovation Initiative, <http://bipartisanpolicy.org/sites/default/files/BPC%20FDASIA%20Regulatory%20Framework%20and%20Strategy%20for%20Health%20Information%20Technology.pdf>

providers. Provider organizations then make many site-specific choices relative to how CDS will best serve the needs of their clinicians and patients.

Transparency and quality – The EHR Association supports public, transparent processes for customers’ evaluations of HIT and believes that such processes should be multiple and market-driven, as distinct from the Workgroup’s seeming notion of a single such rating process. Examples of such initiatives include KLAS (www.klasresearch.com), Gartner, and services provided by a number of professional societies to their members.

We support standards for quality processes that are measurable and transparent, and point out that EHR certification program currently includes requirements to identify processes used in product development. At the same time, HIT developers use a variety of methods and in recent years many have adopted iterative development approaches that support innovation and more efficient use of resources. Regardless of how any vendor chooses to approach software development, we agree that all such work should reflect the principles and practices of a quality management system.

Shared responsibility – The Association believes strongly that that patient safety is a shared responsibility among HIT developers and their customers, including hospital organizations, large clinics, and physicians’ practices. Although the Association generally supports the spirit behind the FDASIA Workgroup recommendations regarding local control and accountability, we are not sure how important aspects of this approach could be applied in a practical fashion, especially as one moves beyond hospitals and other larger organizations. Specifically the recommendation regarding accreditation of the software implementation process should be carefully considered before any possible implementation. Care should be taken to ensure that any accreditation approaches used do not needlessly increase either the cost or complexity of implementation projects. Additionally, the range of accrediting body(s) must be relevant for all of the various parties to the implementation. As a new framework is developed, and as accreditation is considered among the alternatives to FDA regulation, attention must be focused on the shared responsibility of all parties.

Based on the foregoing concerns, we respectfully offer the following specific recommendations:

- Any definition of HIT used in a new risk-based policy framework should align with existing market definitions. The focus should be on what specific types of HIT are subject to which types of regulation or oversight, if any.
- A patient safety risk framework and examples should be used as building blocks to develop a robust and transparent plan that that would allow application of oversight by level of risk and associated costs and benefits of oversight. Any such framework must include weights for risk elements and a model to combine results.
- To the extent that enforcement discretion is used, it should be used in a manner that creates greater predictability as opposed to regulatory uncertainty, with enforcement discretion identified as the clear outcome of a considered policy process and one that can be expected to remain in place for some time. We believe that the approach taken related to the recent FDA guidance on mobile devices is a good example of providing useful guidance and minimizing uncertainty, while allowing the framework and the market to evolve. As a general proposition, we urge that any deliberations regarding increased oversight of HIT be conducted in ways that increase predictability and certainty for developers and providers.

Finally, we build on the FDASIA Workgroup's recommendations and other policy work over the past months and years to emphasize three points:

1. EHRs, most CDS, and HIT that focuses on transmission and/or storage of data should not be subject to traditional FDA device regulation but rather, should be subject to a new risk-based oversight framework that considers intended use and the cost/benefit of oversight. We believe that the BPC report from earlier this year, as well as identified elements of the FDASIA Workgroup report, provide useful elements of such an oversight framework.
2. As this new risk-based framework is established by Congress on recommendations from the Department of Health and Human Services (HHS), its criteria should be applied to HIT that is currently regulated by FDA as a device in order to identify opportunities for more effective and appropriate oversight, including down classification and shifts out of device regulation to the new framework.
3. Finally, much HIT with lower and low risk should not be subject to any additional HIT-specific oversight or regulation, including software focused on administrative and financial functions, while of course remaining subject to HIPAA and other applicable business regulations.

Thank you for this opportunity to provide feedback on the FDASIA Workgroup report as you consider this and other inputs to your development of the FDASIA-required risk-based oversight framework for health IT.

Sincerely,



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Chair, EHR Association
Siemens



Leigh Burchell
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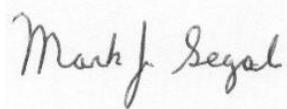
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About HIMSS EHR Association

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 www.ehrassociation.org.

CC:

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