July 7, 2014

Margaret A. Hamburg
Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
5630 Fishers Lane, Rm. 1061, Rockville, MD 20852

Attention: Docket No. FDA-2014-N-0339
Submitted electronically at: http://www.regulations.gov

Re: FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework.

Dear Commissioner Hamburg:

The College of Healthcare Information Management Executives (CHIME) and the Association of Medical Directors of Information Systems (AMDIS) are writing in response to the, "FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework," published via announcement in the April 7, 2014 edition of the *Federal Register*.

CHIME has more than 1,400 members, composed of chief information officers (CIOs) and other top information technology executives at hospitals and clinics across the nation. CHIME members have frontline experience in implementing the kinds of clinical and business IT systems needed to realize healthcare transformation. AMDIS is the premier professional organization for physicians interested in and responsible for healthcare information technology. With more than 2,800 physician members worldwide, 250 associate members and 40 provider organization members, AMDIS members are the thought leaders, decision makers and opinion influencers dedicated to advancing the field of Applied Medical Informatics and thereby improving the practice of medicine.

Both organizations share the vision of an e-enabled healthcare system as described by the many efforts under way at the Department of Health and Human Services and other federal agencies.

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CHIME and AMDIS appreciate the opportunity to comment on the multi-agency report, and below we offer recommendations to inform the Administration's final strategy for a risk-based regulatory approach to health IT. We support the general approach and conceptual frameworks outlined in the FDASIA Health IT Report, including the agencies' focus on software functionality. Our recommendations in the attached document focus primarily on the proposed strategies outlined in section five of the report, including proposals meant to identify standards and best practices, improve interoperability and address conformance to standards. However, we first have a set of over-arching recommendations we believe merit attention.

We believe several converging factors present federal regulators with a unique opportunity to address some key challenges in the coming months. Specifically, we believe ONC should reconsider the role and composition of its certification program to address patient safety risks and interoperability. Five years following passage of HITECH, there exists an opportunity to make policy decisions apart from the arbitrary deadlines of the EHR Incentives Program and pivot towards the long-term goal of building and supporting a national health IT ecosystem.

ONC's certification program was built out of regulatory necessity to accommodate misguided timelines driven by Meaningful Use, not in acknowledgement of how technology is developed, tested, implemented and optimized. This has led to a market dynamic that incentivizes data silos, vendor lock-in and rewards developers who are "first-to-certify" rather than a market characterized by usable, safe and mature health IT products.

In so far as certification appears to be one of the government's best tools to assure adherence to technical standards and specifications, we believe the form and function of certification needs to adapt.

CHIME and AMDIS recommend that ONC re-tool its certification program to have a specific focus on beta-testing, post-certified performance and live-setting standards adherence. Designing a certification program that more closely resembles the software development lifecycle would have a tremendously positive impact on both interoperability and patient safety. Further, we believe the results from these more robust tests should be made publicly available, to ensure providers know which products are performing well and adhering to standards in the real-world. By reorienting and leveraging its certification program, ONC could help the private/non-profit sector establish a learning health system, characterized by continuous improvement and consistent accountability.

Additional recommendations, covered in more detail below, suggest federal officials:

- Engage with private-sector testing bodies who are developing tools to more consistently test and continuously monitor adherence to standards;

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- Identify and incorporate key interoperability tests that have implications for patient safety, especially those related to transitions of care and the management of chronic care;
- Develop, as part of certification, a mechanism to monitor post-market use of health IT in live settings;
- Form a public-private partnership to develop an adaptable process for identifying standards and best practices, especially related to local implementation, customization and maintenance of health IT;
- Understand that different stakeholders have varying degrees of influence on the safety of health IT and should be expected to conform to different levels of rigorous assessments;
- Ensure that providers have an open pathway to report technology failures with implications for patient safety ***before*** such failures inflict patient harm; and
- Work to bolster a national network of patient safety organizations to help achieve a continuous learning environment.

More detailed recommendations and rationale are offered in the attached document to address questions posed by the FDASIA report authors. We note that several questions transcend defined sections of the report and urge officials to contact Jeffery Smith at jsmith@cio-chime.org or (703) 562-8876, with any questions, comments or concerns.

We look forward to a continuing dialogue with your offices on this and related matters.

Sincerely,

/ s /

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/ s /

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CC: Dr. Karen DeSalvo, National Coordinator, Office of the National Coordinator for Health IT
Dr. Jeffrey Shuren, Director, Center for Devices and Radiological Health, FDA
Thomas Wheeler, Chairman, Federal Communications Commission

Attachment

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Below, CHIME and AMDIS respond to questions and ideas posed in Section 5 of the FDASIA Health IT Report, including Section 5.1 – Promote the Use of Quality Management Principles; Section 5.2 – Identify, Develop, & Adopt Standards / Best Practices; Section 5.2.1 – Interoperability; Section 5.3 Conformance Testing; and 5.4 – Create an Environment of Learning and Continual Improvement.

Section 5.1 – Promote the Use of Quality Management Principles

CHIME and AMDIS generally agree with the agencies' view that "the application of quality management principles, including a quality systems approach by health IT stakeholders, is necessary for the safe design, development, implementation, customization, and use of health IT." We also believe the proposed strategy to avoid formal regulation is the correct approach.

In discussing the questions related to Section 5.1, we identified the need to develop a quality framework steeped in traditional IT quality management, as well as consider more novel approaches that recognize the unique workflows of healthcare across settings and facility types. For a traditional IT framework, we point federal officials to ITIL – an internationally recognized approach for planning, delivering and supporting IT services.[1] We believe ITIL is an extensible framework that could be used by both large and small institutions. We also note that various ISO standards already exist that can and should be referenced during software development and deployment.

Given the availability of existing frameworks and standards related to quality management, CHIME and AMDIS urge policymakers to be cognizant that quality management requirements cannot be the same for all provider types and sizes. Rather, the determinant for conformance to quality management requirements should be focused on the degree of development or customization required to produce the functionality. We believe industry best-practices are preferred to government oversight. As a model, the Payment Card Industry's Data Security Standard (PCI DSS) is maintained and monitored by a private-sector entity and we believe this approach should be examined for similar application to healthcare quality management principles.

[1] Information Technology Infrastructure Library (ITIL) http://www.itil-officialsite.com/

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Section 5.2 – Identify, Develop, & Adopt Standards / Best Practices

The FDAISA Health IT Report identifies five areas for which standards and best practices should be identified and / or developed. These include:

- Health IT design and development, including usability;
- Local implementation, customization and maintenance of health IT;
- Interoperability;
- Quality management, including quality systems; and
- Risk management.

CHIME and AMDIS agree with the focus areas identified by the agencies; however, we do not believe that those focus areas should garner equal prioritization, nor are they equally supported by mature standards / best practices. To be impactful, we believe that areas related to interoperability; local implementation, customization and maintenance; and health IT design and development should take priority.

Further, we believe public input on standards and best practices will create buy-in that can be leveraged to support their adoption and promote their wide use. We recommend that ONC use its federal advisory committees to identify potential standards and best practices with input from health IT stakeholders and IT stakeholders from other sectors. This effort would also include a mechanism to periodically review and evaluate standards and best practices.

We note that National Institute for Standards & Technology (NIST) has developed resources for health IT usability and would encourage the agencies to reference that body of work when identifying standards and best practices for usability. We believe the agencies should conduct a thorough environmental scan to determine what other defined paths exist through government and academia to build on existing standards and best practices in these areas.

We understand the Agency for Healthcare Research and Quality (AHRQ), the National Library of Medicine (NLM) and NIST have a portfolio of tools and reports for addressing potential safety issues that arise when implementing and using EHRs. However, it is unknown which of these tools are impactful. HHS should seek feedback from users of the SAFER Guides, the Workflow Assessment for Health IT toolkit and other government-developed tools, to determine their efficacy. If no known users exist, HHS could seek volunteers – or establish funding opportunities – to use the SAFER Guides and obtain feedback. Regardless, HHS should dedicate substantial funding to evaluate the efficacy of such best practices and tools before making them part of any conformity assessment.

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Section 5.2.1 – Interoperability

The agencies recommend that entities be identified to develop tests to validate interoperability, test product conformance with standards, and transparently share results of product performance to promote broader adoption of interoperable solutions. CHIME and AMDIS concur with this view and would encourage the agencies to look toward a public-private model to achieve interoperability.

We urge federal officials to leverage interoperability testing platforms used in the private market – or enable the private sector to lead conformance testing for interoperability. For example, Healtheway currently uses AEGIS to onboard public and private participants to the eHealth Exchange. Through AEGIS' Developers Integration Lab, vendors, providers and other health information organizations are able to validate adherence to standards and best practices. Likewise, the Electronic Healthcare Network Accreditation Commission (EHNAC) has services and solutions that could serve as a basis for interoperability testing and conformance.

As discussed previously, CHIME and AMDIS believe ONC's best lever to improve interoperability is through its certification program. But the promise of this program has been hampered by stringent timelines and a lack of focus on how to best utilize certification to achieve a more aligned ecosystem of health IT. Our members note that it is commonplace to implement a certified complete EHR alongside a certified patient portal module that do not interoperate. The certification program should allow providers to choose a mix of certified products to meet market demands and stay competitive; yet the certification program incentivizes a single-vendor approach that replaces old data silos with new ones. Millions of dollars are wasted on interfaces that have no value-add and these systems continue to burden and frustrate end users. This dynamic is simply unacceptable and it will continue to diminish the positive impacts made possible through IT.

We believe beta testing at the developer-level, using third-party tools and test data, would advance interoperability. Such testing would improve health IT products before they are deployed in live environments, which would facilitate more robust interoperability and create a safer environment for health IT.

Section 5.3 Conformance Testing

The agencies recommend that conformity assessment tools, such as product testing, certification and accreditation, should be used and applied in a risk-based manner to distinguish high quality products, developers, vendors and organizations from those that fail to meet a specified level of

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quality, safety, or performance. They also recommend that non-governmental, independent programs that perform conformity assessments should be developed to fill current gaps. CHIME and AMDIS agree, generally, with this view and supports the use of testing, certification and accreditation to drive adherence to standards and best practices. However, we believe it is imperative that policymakers understand the roles individual stakeholders play in ensuring safety through the use of health IT and the role they can play to reduce harm caused by health IT.

The concept of shared responsibility underscores the need for a coordinated approach to patient safety – from product development and implementation, to testing, training and use. But we note that patient safety risk is not uniform across the health IT product lifecycle and appropriate measures should be put in place to recognize this disproportionate risk. Physicians who implement a cloud-based electronic health record solution will have very little control over the design and deployment of health IT functionalities; compared to the developer in this situation, the physician has far less control over the safety of the functionality. This is not to say the physician abdicates themselves from having any responsibility, it simply means the onus for ensuring functional safety of the software falls largely on the developer. In cases where the developer and the physician work more closely on the technology's implementation and customization, we believe the risk is more equally distributed.

CHIME and AMDIS believe providers are held to high standards for patient safety and they are expected to use clinical tools appropriately in the treatment of patients. Likewise, developers of health IT should be held to similar standards when developing software. This does not necessitate an overbearing regulatory scheme, but a more periodic review of how software is updated, revised and customized, based on consensus standards and industry best practice.

5.4 – Create an Environment of Learning and Continual Improvement

The agencies recommend the creation of a public-private entity – the Health IT Safety Center - that would serve as a trusted convener of health IT stakeholders and identify the governance structures and functions needed for the creation of a sustainable, integrated health IT learning system that avoids regulatory duplication and leverages and complements existing and ongoing efforts.

CHIME and AMDIS support the creation of a Health IT Safety Center, but would much prefer to see this center established in the private / non-profit sector, with the support of federal agencies.

We believe that ONC is properly suited to help convene and coordinate health IT safety efforts across government, but we question whether ONC has the requisite competencies to make a Health

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IT Safety Center effective. Rather, we believe that implementation of such an endeavor should rely on a stakeholder-driven organization, including participation by – but not owned by – any federal agency. The National Technology Transfer Advancement Act and OMB Circular A-119 provide for the formation of such an organization, known as an independent "voluntary consensus body" to facilitate agreement among healthcare stakeholders on a recognized set of standards and guidelines for patient safety in health IT. We believe such an organization could then be buttressed by an enhanced network of patient safety organizations (PSOs) that could leverage appropriately aggregated reports to encourage continuous learning.

Such an approach would address concerns raised by Congress and industry over ONC's authorizing legislation to establish and lead a Health IT Safety Center; it would distribute the costs of maintaining an open-ended project among public and private-sector stakeholders and it would reinforce ONC's focus on its existing duties – namely, health IT certification.

One area that we believe would be an appropriate focus for federal agencies is on the creation of a legal environment to encourage broad reporting of patient safety events by providers and developers. The current environment does not promote such reporting; developers do not have the same safe harbors that providers have to report patient safety events and providers continue to be hamstrung by contractual language imposed by vendors.

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