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Health IT Alert

Regulation of Health IT: A Risk-Based Approach

05.08.2014

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The FDA will hold a public workshop on May 13-15, 2014 to discuss the long-awaited report (the "Report") issued on April 3, 2014 by the three federal agencies charged with regulating health information technology ("health IT"), the Food and Drug Administration ("FDA"),[1] The Office of the Nation Coordinator for Health Information Technology ("ONC")[2] and the Federal Communications Commission ("FCC")[3] (collectively, the "Agencies").

Overview of the Report

Congress mandated the development of the Report as part of the 2012 Food and Drug Administration Safety and Innovation Act ("FDASIA"), which requires the Agencies to coordinate their efforts to regulate health IT and to develop and post a report on their websites to further the foregoing.

The Report, *Proposed Strategy and Recommendations for a Risk-Based Framework*, proposes a strategy and recommendations for regulation of health IT that focus on the potential risks while promoting innovation, protecting patient safety, and avoiding regulatory duplication. The Agencies recognize that the continued development, implementation and use of health IT products have tremendous benefits to the public. Accordingly, the Agencies have set forth in the Report a strategy and recommendations that the Agencies believe are flexible enough to accommodate the rapidly developing health IT field. The Report recommends an approach to foster the development of a culture of safety and quality, leverage standards and best practices, employ industry-led testing and certification and selectively use tools such as voluntary listing, reporting and training to enable the development of a health care environment that is transparent and promotes learning and continual health IT improvement.

Importantly, the Agencies do not call for additional regulation, stating that "we do not believe that regulation should be or needs to be the first approach used to reach this outcome." Rather, the Report suggests the adoption of a limited, narrowly tailored approach that primarily relies on ONC-coordinated activities and private sector capabilities, and that a non-governmental, independent program may be effective in monitoring compliance. The recommendations in the Report include continued interagency cooperation and collaboration, the creation of a public-private safety entity — the Health IT Safety Center — and a risk-based approach to the regulation of health IT.

To guide the analysis of the appropriate amount of oversight, the Report identifies and distinguishes between three types of health IT: (i) administrative health IT (products for billing and claims processing, scheduling and inventory management); (ii) health management health IT (e.g., products for health information and data exchange, some clinical decision support products, provider order entry products and electronic access to clinical results) and (iii) medical device health IT (e.g., products for detection/diagnostics and remote monitoring). The distinction between these three categories represents the Agencies' intent to focus on the functionality of a particular product – rather than the platform (e.g., on-premise, web-based, mobile application, etc.) – as a means for determining the relative risks associated with these products and determining the appropriate recommendations.

The Report sets forth a framework for regulation of health IT that applies mainly to health management health IT. The Agencies conclude that administrative health IT functionalities pose limited or no risk to patient safety and therefore do not require additional oversight. With respect to medical device health IT, the Agencies note that


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medical device health IT is subject to greater oversight through FDA regulations that already focus on the functional risks of these products, and as such, “no new or additional areas of FDA oversight are needed.”

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Proposed Strategy and Recommendations: Four Priority Areas

The majority of the Report describes a framework based on the following four key areas, with recommendations for each. The Agencies also seek public comment on certain specific aspects of each area.

1. *Promote the use of quality management principles:*

- The Agencies recognize that many providers and users of health IT already apply quality management principles. The Agencies will work with multiple health IT stakeholders (developers, users, regulators, etc.) to develop a comprehensive health IT quality management framework that will ensure safe design, development, implementation, customization and use of health IT. This approach will leverage existing quality management principles and identify areas where new quality management principles can or should be applied.
- The Agencies view this strategy, rather than a formal regulatory approach, as the appropriate method for advancing a health IT quality framework.
- The Agencies seek input from the community on certain questions to assist in developing these quality management principles, including the following: What essential quality management principles should apply to health IT? How should they apply to different stakeholders and at different stages of the health IT product life cycle? How do we assure stakeholder accountability for adoption of quality management principles?

2. *Identify, develop and adopt standards and best practices:*

- The Report emphasizes that the identification, development and adoption of applicable health IT standards and best practices can help to deliver consistently high quality health IT products and services to consumers. The Report identifies several priority areas of the health IT life cycle to be the focus areas for standards and best practices, including design, development, implementation, customization, maintenance and interoperability.
- The Agencies seek input on certain questions to assist in identifying, developing and adopting standards and best practices, including: Are the identified priority areas for standards and practices the proper areas of focus? If not, what areas should be prioritized? How can the private sector help facilitate the development and adoption of applicable health IT standards and best practices?

3. *Leverage conformity assessment tools:*

- The Agencies identify conformity assessment tools, such as product testing, certification and accreditation, as a means for providing assurance that certain health IT products and services, as well as their providers, meet specified standards or fulfill certain requirements. The Report recommends that these conformity assessment tools should be used and applied with reference to the relative risk, and in a manner that will distinguish high quality products from low quality products.
- With respect to conformity assessment tools, the Agencies recommend development of non-governmental, independent programs to perform conformity assessments. The Agencies view this strategy rather than a formal regulatory approach as the appropriate method for advancing conformity assessments.
- The Agencies seek input on many questions related to clarifying the value and role of conformity assessment tools in health IT, including: What conformity assessment tools, if any, should be incorporated into a risk-based health IT framework? How should they apply to different

stakeholders and at different stages of the health IT product life cycle? How can adoption of and adherence to conformity assessment programs be promoted? Should interoperability standard(s) be adopted? How should conformance assessment results be communicated to stakeholders? Is there a role for a non-governmental, independent health IT conformity assessment program? Should the ONC Health IT Certification Program be leveraged to protect patient safety through the use of conformity assessment tools?

4. ***Create an environment of learning and continual improvement:***

- The Report encourages the collaboration of the public and private sectors to develop a culture of safety, transparency, learning, continual improvement and shared responsibility with better-defined accountability. The Report recommends that the various stakeholders report serious health IT-related safety events to a trusted source that can aggregate and analyze information and disseminate findings.
- The Report recommends the creation of a public-private entity — the Health IT Safety Center — that would identify the governance structures and functions needed for the creation of a sustainable, integrated health IT learning system.

- The Agencies seek public input on certain questions related to creating an environment of learning and continual improvement, including: What should be the governance structure and functions of the Health IT Safety Center? How can comparative user experiences with health IT be captured and made available to the health IT community and other members of the public to promote learning? What type of safety-related surveillance is appropriate for health IT products categorized as health management functionality? What continued or expanded role(s), if any, should the ONC Health IT Certification Program play in the safety-related surveillance of health IT products?

Focus on Clinical Decision Support

In addition to the recommendations above, the Report sets forth much needed guidance on clinical decision support ("CDS") products. CDS products provide health care providers and patients with information to improve health and health care, such as computerized reminders and alerts for providers and patients. The Report concludes that *most* CDS functionalities can be categorized as health management health IT and therefore would not be subject to FDA regulation. However, certain types of CDS tools that present higher risks to patients, such as computer-aided detection/diagnostic software, warrant FDA's continued oversight as medical device health IT. The FDA will work with federal and private stakeholders to clarify the types of medical device CDS that should be the focus of FDA's oversight.

With respect to the CDS products that fall within the health management health IT category, the Agencies recommend that health IT stakeholders work together to develop policies for the transparent disclosure of the rules and information sources underlying CDS products. The Agencies seek input from the community in developing such rules, with reference to certain questions, such as: What types of CDS functionality should be subject to the health management health IT framework? Which types should be the focus of FDA oversight? Are there additional safeguards for CDS, such as greater transparency with respect to CDS rules and information sources, that are needed to appropriately balance patient safety and the promotion of innovation? How can the private sector help assure the facilitation of the development, application and adoption of high quality CDS with health management health IT functionality in lieu of a regulatory approach? What role, if any, should government play?

The Agencies are seeking public comments by July 7, 2014 on whether the focus areas identified in the Report are the appropriate ones, and whether the proposed next steps will accomplish the purposes of protecting patient safety, promoting innovation and avoiding regulatory duplication.

[1] The FDA is involved in the oversight of health IT because a subset of health IT products meets the statutory definition of "medical device," and as such are subject to regulation of the Federal Food, Drug, and Cosmetic

Act. In September 2013, the FDA issued final guidance on the agency's oversight of mobile medical applications.

[2] The ONC is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health IT and the electronic exchange of health information.

[3] The FCC is the regulatory body charged with overseeing spectrum used by individuals, private organizations, and public safety and health officials.

3961-0514-NAT-HIT