REGULATORY FOCUS

Perspectives on the FDASIA Health IT Report and Public Workshop

By Ben Berg, Meaghan Bailey, RAC, and Deborah Baker-Janis

On 7 April 2014, a *Food and Drug Administration Safety and Innovation Act* (*FDASIA*)-mandated workgroup issued its strategy and regulatory framework document on health IT to Congress.[1] The workgroup is comprised of representatives from the US Food and Drug Administration (FDA), the Federal Communications Commission (FCC) and the Office of the National Coordinator for Health Information Technology (ONC). A public workshop was held 13–15 May 2014 to discuss the proposed risk-based regulatory framework and strategy on health IT, and to seek input from stakeholders and experts. The Health IT Report and subsequent workshop discussion represent, at best, a preliminary regulatory framework. The report somewhat clarifies how clinical decision support (CDS) systems will be regulated, and discusses how industry and regulatory bodies need to work together through a proposed Health IT Safety Center to create an environment of safety and innovation for health IT. However, the "platform agnostic," risk-based framework proposed is not new, but resembles the insight provided by FDA's *Final Guidance on Mobile Medical Applications*, and more concrete clarifications and definitions are needed for this new and rapidly changing technology.

Report Summary

The *FDASIA* workgroup seeks to create a regulatory framework that can ensure the safety of health IT products, while fostering innovation and development in this rapidly changing space. To accomplish this broad objective, the workgroup has proposed a regulatory approach based on the functionality and risk profile of the health IT product.

Health IT Categories (Functionality)

The Health IT Report proposes three categories of health IT functionality—administrative, health management and medical device.

Administrative IT functionalities are products that do not pose a patient safety risk, including billing and claims processing systems, inventory management systems and population health management systems. The workgroup did not recommend additional oversight for these products.

Health management functionalities are products in which patient benefits outweigh risks, and include most clinical decision support systems, data capture and encounter documentation systems, medication management systems and health data management systems.

Medical device health IT products currently are the focus of FDA's oversight and include computer-aided detection/diagnostic software, radiation treatment planning and robotic surgical planning and control software. The report did not propose additional areas of oversight for these products, although it recommended FDA provide additional clarification on claims relating to wellness versus disease states, accessories, clinical decision support software, software modules and mobile medical apps.

Risk-Based Framework Priority Areas

The risk-based framework proposed in the Health IT Report includes four key priority areas:

1. promote the use of quality management principles
2. identify, develop and adopt standards and best practices
3. leverage conformity assessment tools
4. create an environment of learning and continual improvement

Furthermore, the workgroup recommended the use of conformity assessment tools, including product testing and certification, to further demonstrate product safety and effectiveness and ensure quality. Finally, the workgroup encouraged collaboration and transparency among stakeholders as well as the development of a culture of continual process improvement and accountability, including rigorous reporting and analysis of patient adverse events.

In addition to the four key priority areas, the workgroup proposed creating a public-private entity called the Health IT Safety Center. This group would be comprised of members of FDA, FCC, ONC, the Agency for Healthcare Research and Quality (AHRQ) and industry, and would focus on leveraging the four priority areas to create a sustainable health IT learning system, while avoiding regulatory duplication.

Clinical Decision Support (CDS) Systems

CDS systems have been, and continue to be, an area of regulatory uncertainty. In FDA's *Final Guidance on Mobile Medical Applications*,[2] the agency did not address how it plans to regulate these products. According to the report, the majority of clinical decision support systems will be categorized as health management IT and fall under FDA enforcement discretion. Examples of these types of applications may include drug-dosing calculators, reminders for preventative care, drug formulary guidelines and suggestions for possible diagnoses based on patient-specific information from an electronic health record (EHR). Some CDS applications, however, carry higher risks and would warrant FDA's more focused oversight. Examples of these applications may include radiation treatment planning, electrocardiography analytical software and computer-aided detection/diagnostic software.

Public Workshop Discussion and Feedback

During the FDA public workshop, discussion focused on six key areas of the Health IT Report:

1. the risk-based framework
2. health IT categories
3. clinical decision support systems
4. quality management and best practices
5. Health IT interoperability and safety standards
6. the Health IT Safety Center

Panelists included representatives from FDA, FCC, ONC, regulated industry (including healthcare systems, health IT application manufacturers and electronic health record vendors) and industry trade organizations, among others. FDA representatives included Bakul Patel (senior policy advisor to FDA's Center for Devices and Radiological Health (CDRH)), William Maisel, MD (CDRH deputy center director for science and chief scientist), Tom Gross, MD (CDRH director of Office of Surveillance and Biometrics) and Jeffrey Shuren, MD (CDRH center director). Participant feedback most notably requested further guidance and clarification regarding the proposed content of the Health IT Report from the *FDASIA* workgroup, although limited resolution was provided during the three-day workshop.

Risk-Based Framework

Industry representatives agreed the risk-based approach to regulating health IT products, based on product functionality, was appropriate to ensure patient safety and encourage innovation. Although functionality is the primary factor in determining how health IT should be regulated, panel members noted that other factors such as the user experience and context of the product's use need to be considered, despite the report's proposed "platform agnostic" approach. Additionally, industry members expressed concern regarding the care taken to ensure the established best practices and standards are clear and easy to follow, and avoid excessive oversight from multiple regulatory entities.

Health IT Categories

With respect to the three categories proposed in the Health IT Report, industry members commented there needs to be more definitive guidance on how products will be classified, beyond simply providing a list of examples of each category of health IT products. In addition to functionality, panelists suggested considering other factors to further segment health IT within the three proposed categories. These additional factors included the user identity, the context of the product's use and the significance of the decision mediated or performed by health IT software. Further, it was noted patient safety is not the only means of determining risk, and, additionally, data integrity should be prioritized. Despite agreement that the three-category, risk-based approach proposed in the Health IT Report is a good starting point, the panel did not provide any more definitive information on how health IT will be categorized or regulated, which remains a point of continuing uncertainty.

CDS Systems

The panel described the differences between health management CDS and medical device CDS systems as specified in the Health IT Report and noted further clarification regarding each type of CDS system is needed. Panelists requested the workgroup to continue to keep the end user in mind when differentiating between the two categories and to consider the importance of the intervention or decision being performed by the CDS system in determining how to regulate the system. Despite extensive discussion, no additional clarity was provided to industry on these topics other than that already detailed in the Health IT Report.

Discussion shifted to the four proposed priority areas of the risk-based framework and how they might be used to improve aspects of health management CDS system implementation. Workshop participants noted training materials should be provided to those using CDS systems. A consensus was reached on the need to collect data and valid scientific evidence prior to establishing which practices, standards and methods of testing would be the best to implement to ensure product quality and patient safety. FDA's Patel commented that improved input from healthcare providers and patients also would be important to determine which aspects of health IT would require more focus.

Quality Management and Best Practices

The panel emphasized the necessity of quality management principles in the design and development of safe products. It was agreed standards and good software engineering practices should be utilized, but the level of detail required might be difficult to define

considering the evolving nature of software development, as well as the sociotechnical system of the health IT industry. Representatives of industry and government agencies in attendance agreed determining best practices will require data collection in order to ensure which issues are most important, and any proposed metrics would need to be flexible to reflect the nature of the constantly changing health IT field.

Health IT Interoperability and Safety Standards

Panelists pointed out even years after implementation of requirements for meaningful use, interoperability is minimal and few electronic health record (EHR) programs are able to transfer data in a useful way. The panel noted standards could play a role in facilitating interoperability and assuring conformity among developers. However, valid scientific data are required to determine how best to do so while also encouraging modular design and collaboration. Members of the panel also noted there is demand, and a reasonable expectation for interoperability between devices and EHR systems, yet the market has not provided a solution. Clear and transparent testing and certification mechanisms need to be developed to ensure health IT product interoperability and conformity to standards for best practices and quality management.

Panelists agreed the quality of safety data is as important as the quantity—it is crucial to know how health IT issues are identified and characterized. One challenge health IT manufacturers and regulators face is health IT adverse events are not always discerned easily from other types of adverse events, such as medication errors. The solution to this problem lies in properly training end users to recognize when a health IT adverse event occurs and how to properly document and report it. The usability of data-capturing technology is also critical and developing work instructions and training procedures for the system's end user is key to collecting accurate safety data. However, more guidance is needed as to how regulatory bodies and industry will develop best practices and safety standards to evaluate health IT.

Health IT Safety Center

The panel agreed the Health IT Center should have a non-punitive structure, and positive incentives should be created to gather honest safety information. Concern arose regarding the use of congressional authority to establish a framework for health IT and whether the proposed Health IT Safety Center would have sufficient enforcement discretion power to ensure compliance with the center's oversight and action. This concern was echoed by the US House of Representatives Committee on Energy and Commerce, which on 3 June 2014 wrote a letter[3] asking ONC to clarify its regulatory authority to create a Health IT Safety Center and impose new user fees to support its creation.

Panel members also speculated the center could play an important role in the oversight of health IT systems and data reporting. To improve efficiency in gathering and analyzing safety data, the center should serve as a single location where FDA, FCC, ONC, industry members and consumers can collaborate as well as access health IT safety information. More clarity is needed as to how the Safety Center would function in order to prevent excessive regulatory oversight while establishing best practices and standards.

Conclusion

The health information technology environment is changing rapidly. The Health IT Report and corresponding workshop provided a starting point to launch the discussion between government bodies and industry on creating the framework for health IT. Representatives of ONC, FCC, FDA and industry stakeholders agree a nationwide health IT infrastructure can offer tremendous benefits to public health, including the prevention of medical errors, improved quality care and reduced costs. Without proper design or implementation, however, health IT can pose a serious risk to patients. To ensure patient safety, federal agencies must provide a more detailed approach to health IT regulation with more extensive guidance than that provided in the Health IT Report or this recent workgroup meeting. Critical to this end could be the accumulation of accurate safety data regarding health IT systems and further development of the Health IT Safety Center as a focal point for

the analysis and dissemination of safety information. Additionally, further clarification of the definitions of each category of health IT products and guidance on interoperability is needed to make progress in establishing the regulatory framework for health IT.

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About the Authors

Ben Berg is a practice manager at NSF Health Sciences Medical Devices. His three years of regulatory affairs experience include developing and managing quality systems programs such as consent decree remediation projects and FDA enforcement action responses, as well as developing and creating regulatory strategies and submissions for medical device products. Berg can be reached at bberg@nsf.org. **Meaghan Bailey, RAC,** is a senior director at NSF Health Sciences Medical Devices, responsible for analyzing complex regulatory challenges, creating regulatory strategies for innovative products, managing FDA interactions and preparing regulatory submissions. She also specializes in FDA Advisory Committee preparations. Her six-plus years of regulatory experience include strategic support for the commercialization of mobile medical applications. She can be reached at mbailey@nsf.org. **Deborah Baker-Janis,** director at NSF Health Sciences Medical Devices, has more than 10 years of experience in the medical device industry, including positions in both regulatory affairs and product development. Her experience includes the development of preclinical testing protocols and reports, FMEA documentation, quality system and regulatory affairs standard operating procedures, sales training materials, MDR and safety reports, and domestic and international regulatory strategies and submissions. She can be reached at dbaker-janis@nsf.org.

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