# FDA, ONC, and FCC Issue Report on the Regulation and Oversight of Health IT Technologies

On April 3, 2014, the Food and Drug Administration ("FDA") released its long-awaited report on a proposed framework for the regulation and oversight of health information technology ("health IT"). The report, developed in consultation with the Office of the National Coordinator for Health Information Technology ("ONC") and the Federal Communications Commission ("FCC"), fulfills a mandate in the Food and Drug Administration Safety and Innovation Act ("FDASIA") that required the agencies to produce a report on a "proposed strategy and recommendations" for the regulation of health IT. Public comments on the report are due July 7, 2014.

The report proposes a relatively "light touch" to the oversight of health IT, preferring ONC-coordinated activities and private sector capabilities to increased FDA regulation. Specifically, the report divides health IT into three categories based on the level of risk and functionality, in which only the highest risk category ("medical device health IT functions") will be the focus of FDA's regulatory oversight. This risk-based framework resembles the approach FDA took in its final guidance on mobile medical applications ("mobile apps"), as described in Ropes & Gray's recent alert.

One of the key areas addressed for the first time in the report is FDA's proposed approach to regulating clinical decision-making support ("CDS") tools. FDA proposes to exercise enforcement discretion not to regulate "most" CDS tools, even if they meet the definition of a medical device under the Food Drug & Cosmetic Act ("FDCA"). FDA also states, however, that it will regulate a "subset" of CDS tools as medical devices. The report does not define what will be included in that subset, instead stating that "FDA will work with federal and private stakeholders to clarify the types of medical device clinical decision support that should be the focus of FDA oversight."

## Categories of Health IT Functionalities

The report describes health IT as "a wide range of products, technologies, and services designed for use by health care entities, health care providers, and consumers, to electronically maintain, access, and exchange health information." Taking a risk-based, functional approach, the agencies propose classifying health IT products into the following three categories:

1. Administrative Health IT Functionality. The report provides for "no additional oversight" with respect to this lowest-risk category. Examples of software functions that fall under this category include scheduling, billing and claims processing, and the determination of eligibility for health benefits.

2. Health Management Health IT Functionality. For functions that fall under this second category, the report states that risk to patient safety is "generally low compared to the potential benefits." Examples of such functions include health information and medication management, electronic communication and access to clinical results, provider order entry, and "most" types of CDS. The agencies decided against proposing a formal regulatory approach to this category and chose instead to rely primarily on "ONC-coordinated activities and private sector capabilities" to ensure patient safety. This approach would apply even if the corresponding software meets the definition of a "device" under Section 201(h) of the FDCA. The report goes on to identify four key "priority areas" in its proposed collaborative approach to this second category:



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- promoting the use of **quality management principles**, including a quality systems approach for the safe design, development, implementation, customization, and use of health IT;
- identifying, developing, and adopting **standards and best practices** to deliver high quality health IT products and services;
- leveraging **conformity assessment tools** such as product testing, certification, and accreditation; and
- creating an **environment of learning and continual improvement**, including transparent reporting, aggregation, and analysis of safety issues with health IT products.

The report seeks public comments on specific questions regarding each of these four areas.

3. Medical Device Health IT Functionality. FDA proposes to focus its oversight on this third, highest-risk category. Functions that fall under this category would include computer-aided detection or diagnosis, radiation treatment planning, and robotic surgical planning and control. As FDA already exercises its regulatory authority over software with these functionalities, the agencies propose no additional areas of oversight in the creation of this category.

## Applying the Classification to CDS and Other Specific Functions

The report provides only limited guidance as to how FDA is likely to view the proposed categories of health IT technology. Although the report provides a few specific examples of technologies that would fall within the proposed categories, developers and manufacturers of health IT technologies with functionalities that do not clearly fall under one of these examples will continue to have questions about the status of their products. This is particularly true in the case of CDS, a broad category of health IT that provides "knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care."

While the report states that "most" CDS functionalities would fall under the "health management health IT" category, others would be classified under the high-risk category and remain subject to FDA's continued focus and oversight. CDS functionalities that fall under this latter category include alerts for drug-drug interactions and drug-allergy contraindications, most drug dosing calculations, and software that suggests possible diagnoses based on patient-specific information retrieved from a patient's electronic health record. Examples of CDS software that will be regulated in the medical device category include computer-aided detection/diagnostic software, robotic surgical planning and control software, and electrocardiography analytical software. Further clarity with regard to such CDS software will be needed, and the report specifically seeks comments on the question of which types of CDS functionality should fall within the health management health IT category as opposed to the medical device category.

The report also cautions that categorizations may need to be adapted over time, that many systems (such as EHRs) have functionalities falling under multiple categories, and that many functionalities themselves, such as privacy and security, "cannot be placed in a single category."

## Health IT Safety Center

Finally, the report provides that ONC is in the process of creating a public-private entity known as the Health IT Safety Center, an institution that will be charged with serving as a "trusted convener of



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stakeholders and as a forum for the exchange of ideas and information focused on promoting health IT as an integral part of patient safety." The Center is expected to launch later in 2014.

## Implications and Next Steps

The FDASIA health IT report provides important insight into the proposed regulatory approach that will affect software developers, other manufacturers and vendors of health IT systems, and health care providers that purchase, customize, and implement such systems. The report's focus on limited, risk-based regulation, and public-private cooperation, appears to be intended to address concerns about potential over-regulation by FDA. Some members of Congress who previously introduced legislation to curtail FDA's authority over health IT have already stated that the report, while it comports with FDASIA's mandate to adopt a risk-based approach, is insufficient because it relies on FDA "enforcement discretion" not to regulate lower-risk technologies, rather than setting clear limits in the law. These legislators can be expected to continue to push legislative solutions, which stakeholders should follow closely.

FDA has opened a docket and will be accepting comments on the proposed regulatory approach through July 7, and also is planning to hold a public meeting on the proposed strategy within 90 days of the report's release. After receiving public input and finalizing the proposed strategy and recommendations, the agencies plan to begin implementing the framework. Stakeholders should consider providing input on questions such as the regulation of CDS, the manner in which quality management principles will be applied to health IT products, how standards and conformity assessment tools will be identified and used, how reporting and aggregation of safety information relating to health IT will operate, and the roles and governance of the new Health IT Safety Center.

For questions on FDA regulation of health IT, please contact any member of Ropes & Gray's FDA Regulatory team or your usual Ropes & Gray advisor. For any further questions related to health IT, please contact any member of Ropes & Gray's health IT team or your usual Ropes & Gray advisor.



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