National Health IT Regulatory Strategy Proposed

The U.S. Department of Health and Human Services (HHS) announced on April 3 the release of a draft report including a proposed strategy and recommendations for a national health information technology (IT) framework to promote "product innovation while maintaining appropriate patient protections and avoiding regulatory duplication." The congressionally mandated report was developed in consultation with health IT experts and consumer representatives and proposes oversight based on a health IT product's function and potential risk to patients who use it. The report was developed by the U.S. Food and Drug Administration (FDA) in consultation with 2 other federal agencies that oversee health IT: the HHS Office of the National Coordinator for Health IT (ONC) and the Federal Communications Commission (FCC).

"The diverse and rapidly developing industry of health IT requires a thoughtful, flexible approach," said HHS Secretary Kathleen Sebelius. "This proposed strategy is designed to promote innovation and provide technology to consumers and health care providers while maintaining patient safety." The draft report outlines 3 health IT categories, based on function and level of risk, that focus on what products do, not on the platform (e.g., mobile device or cloud-based application) on which they operate. These categories include:

(1) Products with administrative health IT functions, which pose little or no risk to patient safety and as such require no additional oversight. These include software for billing and claims processing, scheduling, and practice and inventory management.

(2) Products with health management IT functions, including software for health information and data management, medication management, provider order entry, knowledge management, electronic access to clinical results, and most clinical decision support software. Because these are usually low risk, FDA indicated that it will not focus oversight on products with health management IT functions, even when these meet the statutory definition of medical devices. Instead, the intention is to rely primarily on ONC-coordinated activities and private sector capabilities that highlight quality management principles, industry standards, and best practices. The draft report also proposes relying on tools for testing, certification, and accreditation of this category of products.

(3) The third category, products with medical device health IT functions, is a narrowly defined group that, when not performing as intended, might pose greater risks to patients. The draft report proposes that FDA continue regulating these products, which include computer-aided detection software, software for bedside monitor alarms, and radiation treatment software.

Included in the report's prospective framework is a proposal for ONC to create a public–private Health IT Safety Center in collaboration with the FDA, FCC, Agency for Healthcare Research and Quality, and other stakeholders. The Health IT Safety Center would work on best practices and provide a forum for the exchange of ideas and information focused on patient safety. The 3 agencies held a public workshop from May 13 to 15 on the campus of the National Institute of Standards and Technology (Gaithersburg, MD) to solicit feedback from experts and stakeholders on the outlined strategy and approach.

The full draft report is available at: www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm390588.htm. The FDA has opened a docket for stakeholder comment at www.regulations.gov/#!documentDetail;D=FDA-2014-N-0339-0001. The docket portal provides information on submitting electronic or hardcopy comments before a July 7 deadline.

U.S. Department of Health and Human Services