# HHS NEWS RELEASE

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## Proposed health IT strategy aims to promote innovation, protect patients, and avoid regulatory duplication

HHS today released a draft report that includes a proposed strategy and recommendations for a health information technology (health IT) framework, which promotes 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 to clarify oversight of health IT products based on a product's function and the potential risk to patients who use it.

The report was developed by the U.S. Food and Drug Administration (FDA) in consultation with two other federal agencies that oversee health IT: HHS' Office of the National Coordinator for Health IT (ONC) and the Federal Communications Commission (FCC). The FDA seeks public comment on the draft document.

"The diverse and rapidly developing industry of health information technology 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."

Innovative health IT products present tremendous potential benefits, including: greater prevention of medical errors; reductions in unnecessary tests; increased patient engagement; and faster identifications of and response to public health threats and emergencies.

However, if health IT products are not designed, implemented or maintained properly, they can pose varying degrees of risk to the patients who use them. The safety of health IT relies not only on how a product is designed and developed, but on how it is customized, implemented, integrated and used.

As proposed in the draft report, posted on the ONC, FDA and FCC websites, there would be three health IT categories, based on function and level of risk, that focus on what the product does, not on the platform on which it operates (mobile medical device, PC, or cloud-based, for example).

The first category, products with administrative health IT functions, poses little or no risk to patient safety and as such requires no additional oversight. They include software for billing and claims processing, scheduling, and practice and inventory management.

The second category, products with health management heath IT functions, includes 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.

Products with health management health IT functions are of sufficiently low risk and thus, if they meet the statutory definition of a medical device, FDA does not intend to focus its oversight on them. Instead, the draft report proposes relying primarily on ONC-coordinated activities and private sector capabilities that highlight quality management principles, industry standards and best practices. The draft report also proposes to rely on tools for testing, certification and accreditation of this category of products.

"ONC welcomes comment on the draft report and stands ready to collaborate with stakeholders to ensure that health IT is designed and used with both innovation and patient safety in mind," said Karen DeSalvo,

M.D., M.P.H., M.Sc., national coordinator for Health IT.

The third category, products with medical device health IT functions are a narrowly defined group that could potentially pose greater risks to patients if they do not preform as intended. 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.

"This proposed strategy will facilitate innovation, protect patients and support FDA's focused oversight on higher risk technology, similar to medical devices that are currently regulated," said Jeffrey Shuren, M.D., director of the FDA's Center for Devices and Radiological Health. "FDA looks forward to additional stakeholder feedback on the proposed framework in this draft report."

Included in the framework is a proposal for ONC to create a public-private Health IT Safety Center in collaboration with the FDA, the FCC, HHS' Agency for Healthcare Research and Quality (AHRQ) 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 draft report reflects FCC's narrow but important role in encouraging new and innovative wireless medical technologies and ensuring that developers and users of these technologies are minimizing the potential for causing potentially harmful interference to radio services," said Matt Quinn, director of healthcare initiatives at the FCC. "We look forward to future collaboration with all stakeholders to achieve the promise of health IT."

The three agencies also intend to announce a public meeting to solicit comments on the draft report and gather feedback on the outlined strategy and approach. A docket will be available soon for the public to submit any additional comments.

The Food and Drug Administration Safety and Innovation Act of 2012 directed the FDA, in consultation with ONC and FCC, to publish on their respective websites a report on an appropriate, risk-based regulatory framework for health IT that promotes innovation, protects patient safety, and avoids regulatory duplication.

For more information on FDA medical devices, visit: http://www.fda.gov/MedicalDevices/default.htm.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

The ONC, an office within the U.S. Department of Health and Human Services, is at the forefront of the administration's health IT efforts and is a resource to the entire health system to support the adoption of health information technology and the promotion of nationwide health information exchange to improve health care. The ONC is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information. For more information, contact ONC at www.HealthIT.gov and @ONC_HealthIT.

AHRQ's mission is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work with the U.S. Department of Health and Human Services and other partners to make sure that the evidence is understood and used.

The FCC regulates interstate and international communications by radio, television, wire, satellite and cable in all 50 states, the District of Columbia and U.S. territories. An independent U.S. government agency overseen by Congress, the commission is the United States' primary authority for communications law, regulation and technological innovation.

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