

## FDA and Health IT—As Role of Health IT Gains New Significance, Regulators Will Be Keeping Watch

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The American Recovery and Reinvestment Act of 2009<sup>1</sup> brings new focus and billions in funding for the development and use of health information technology (HIT), including electronic health records (EHRs) and a nationwide HIT infrastructure. While there has been much discussion around new statutory provisions formalizing the Office of the National Coordinator for Health Information Technology (ONCHIT) and expanding the Health Insurance Portability and Accountability Act's security and privacy requirements, little attention has been given to a lesser-known area of existing health IT regulation—namely, the regulation of this technology by the Food and Drug Administration (FDA or Agency). While FDA's regulatory efforts for health IT products have, in the past, been somewhat limited, the expanded use of HIT and EHR systems under the stimulus legislation is likely to increase the Agency's interest in the safety and effectiveness of such systems and, thus, hasten its efforts to establish regulatory policy in this area. Consequently, companies hoping to profit from the new funding for

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This article provides (1) a comparison of the regulatory authority and purposes of ONCHIT and FDA, as each relates to HIT; (2) an overview of FDA's existing and developing regulatory requirements affecting HIT/EHR products; and (3) a discussion of how FDA regulation of HIT and EHR systems fits in with the goals of the new stimulus legislation.

*New Legislation Gives ONCHIT Responsibility for HIT Standards, but Existing FDA Regulatory Authority for HIT Will Continue*

The new legislation formalizes the existing ONCHIT within the Department of Health and Human Services (HHS).<sup>2</sup> ONCHIT, however, is not the only HHS agency interested in health information technologies. In particular, FDA has already claimed jurisdiction over many HIT and EHR systems using its medical device authority. While this may seem to be the makings of a turf war, the scope and mission of these two agencies differ, and thus, their regulatory efforts for HIT and EHR are intended to be complementary, rather than redundant.

The new stimulus legislation provides ONCHIT with a mission to promote the development of a nationwide HIT infrastructure, with the goal of improving both the quality and efficiency of the nation's healthcare system.<sup>3</sup> ONCHIT also is tasked with developing and adopting standards, specifications, and certification criteria for HIT, and establishing

a certification program for HIT systems.<sup>4</sup> Under the new legislation, an initial set of standards must be adopted by December 31, 2009.<sup>5</sup> Although certification by ONCHIT is voluntary,<sup>6</sup> the new legislation ties certain financial incentives for the healthcare sector to the use of HIT and EHR systems that are certified by ONCHIT. For example, Medicare incentive payments are available only to providers who use certified EHR technology.<sup>7</sup>

In contrast, FDA's focus for HIT/EHR products (which FDA considers to be medical devices) is driven by its mission to promote and protect the public health,<sup>8</sup> and ensure that "there is reasonable assurance of the safety and effectiveness of devices intended for human use."<sup>9</sup> To accomplish these goals, FDA has established general controls that apply to all devices, including registration and listing, good manufacturing practices, and reporting requirements for serious injuries and deaths related to medical devices. The Agency also uses a risk-based approach to determine whether additional requirements are necessary, such as premarket approval, premarket clearance, or special controls. Unlike ONCHIT standards and certification, FDA's requirements are mandatory for those HIT/EHR products that fall within its medical device jurisdiction.

### **Current FDA Regulation for Health IT and EHR Systems**

In the last few years, a number of technology companies not previously regulated by the FDA have begun manufacturing and marketing HIT and EHR products. These companies, and others contemplating entrance into this market to take advantage of the stimulus funding, should be aware of existing and developing FDA requirements for such technologies. FDA considers HIT/EHR

systems to be within its jurisdiction if, for example, such systems are intended for use with medical devices (such as heart rate monitors, blood glucose meters, or nurse call systems) or provide clinical decision-making support. Thus, many of the technologies covered by the new stimulus legislation will be subject to FDA regulation, including "certified EHR technologies," which are required under the new legislation to include "clinical decision support" capabilities.

Although FDA considers computer- and software-based devices, such as HIT and EHR products, to be within its regulatory purview, the Agency has not

enable hospital nurses to monitor and manage patients on multiple floors.

- Clinical decision support software that utilizes existing treatment guidelines, complex algorithms, and a patient's own clinical data to provide physicians with patient-specific clinical treatment recommendations.

FDA, however, has failed to keep its regulatory policies current with the changes and advances in these technologies. Because FDA's regulation in this area has been uneven and sometimes outdated, companies often find it difficult to assess the FDA regulatory status and

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been diligent in establishing a clear and comprehensive regulatory framework for such devices. In the nearly 20 years since FDA began regulating computer/software-based devices, these technologies have advanced at breakneck speeds and their use in healthcare and medical applications has exploded. Examples include:

- Telemedicine systems that allow physicians to transmit and receive medical data on their home or office PC, or on wireless PDAs, which can be used to remotely monitor patients at home, or to facilitate the communication of patient information (e.g., EKG readings or X-ray images) between specialists.
- Wireless devices (e.g., PDAs, pagers, cell phones) that

pathway for their computer- and software-based products. However, in early 2008, after several years of inaction, FDA began to revitalize its regulatory efforts for computer/software-based devices with the issuance of its proposed rule for Medical Device Data Systems (discussed further below). The expansion of HIT/EHR systems is likely to further promote these renewed efforts. In fact, recognizing an increased need for regulatory clarity in this area as a result of the stimulus funding, FDA has recently established a new working group to assess which EHR systems may be subject to medical device regulation.<sup>10</sup>

While FDA's regulation of HIT and EHRs likely will develop and expand, provided below is an overview of the existing FDA

device classifications that are most relevant for these types of products.

### *Medical Device Data Systems*

FDA's most recent regulatory effort relevant to health IT is the rule-making initiated in early 2008 for the regulation of "Medical Device Data Systems" or "MDDS."<sup>11</sup> FDA had not actively regulated MDDS devices prior to the issuance of this proposed rule.<sup>12</sup>

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The proposed MDDS rule covers systems and networks that electronically transmit, transfer, store, retrieve, or display data from medical devices (e.g., glucose meters, blood pressure devices, pulse oximeters) without altering the function or parameters of any of the connected devices.<sup>13</sup> The rule, however, does not include devices that (a) are intended for real-time, active, or online patient monitoring; (b) display, create, or detect alarm conditions, or sound an alarm; or (c) have diagnostic or clinical decision-making functions.<sup>14</sup>

Importantly, the proposed MDDS rule appears to be a first step by FDA in a broader attempt to define its regulatory policy for systems used in the management of electronic medical device data. With the MDDS proposal, FDA has carved out for regulation the systems that are most simple and present the least risk to patients.

Once this proposed rule is finalized, FDA is expected to turn its attention to more complex systems, including systems that are used for remote monitoring and systems with clinical decision-making functionality. Although FDA has not yet issued specific regulations or guidance for these more complex systems, FDA has cleared many remote monitoring and telemedicine products using the 510(k)

premarket notification process, and has signaled that systems with clinical decision-support capabilities also may require 510(k) premarket notification clearance.

### *Medical Image Management Devices*

FDA has a well established framework for the regulation of systems that are used for the management and communication of medical images, such as X-rays and MRIs. This includes systems that "provide functions related to the management of medical images after acquisition, including communication, storage, processing and display."<sup>15</sup> FDA uses a tiered approach in its regulation of these devices, depending on the system's functionality and level of risk. For example, systems that merely store and retrieve image data (e.g., servers, digital memory, or optical discs) or transfer image data (e.g., modems or commu-

nications software) must comply with FDA's general controls for medical devices, but do not require premarket review.<sup>16</sup> However, more complex systems that compress, manipulate, enhance, or quantify images, such as Picture Archiving and Communications Systems (PACS), require 510(k) premarket clearance by FDA.<sup>17</sup>

### *Device Accessories and Components*

FDA considers computer or software products that are intended for use with, or included as part of, a finished medical device to be within its jurisdiction as device "accessories" or "components." Thus, a HIT product that is intended for use with a specific medical device, such as a nurse call system, would be considered a device accessory by FDA and would be subject to medical device requirements. Device accessories and components will be subject to the same regulatory requirements as their "parent" devices.

### *FDA Policy and Expanding HIT*

It is not yet clear how FDA regulation of HIT and EHR products will affect the development of such systems, or how the new legislation's goals of advancing the development and implementation of HIT technologies will affect FDA policy in this area. While some may view FDA regulation of HIT/EHR systems as a potential hindrance to the widespread adoption of such technologies, the Agency likely will consider the need for ensuring the safety and effectiveness of HIT/EHR products to be more critical as the use of such products becomes more ubiquitous. Technological advances triggered by the stimulus legislation are expected to cause FDA to extend its regulatory authority to new HIT product categories. As noted above, FDA has already taken the first step by

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establishing a working group to assess which types of HIT/EHR systems may fall under its medical device jurisdiction.<sup>18</sup> Given their significant impact on public health, clinical decision support systems, in particular, are likely to come under FDA scrutiny and be the subject of future rulemakings.

FDA will face challenges, however, in dealing with rapid proliferation of new HIT and EHR products that is almost certain to result from the billions in funding aimed at the promotion of HIT/EHR technology. As discussed above, the Agency has previously struggled to keep up with the progress of technology for computer- and software-based devices. It is not yet clear how FDA will adapt its regulatory efforts in this area and allocate its resources in the Center for Devices and Radiological Health to meet these new challenges

### Conclusion

Manufacturers intending to take advantage of new HIT and EHR opportunities will need to keep abreast of developments in FDA policy, in addition to the standards and certification requirements adopted by ONCHIT. To ensure a

smooth and timely product launch, manufacturers also should assess the applicable FDA requirements during product development, as such requirements may include FDA premarket approval or clearance.

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### End Notes

- 1 Pub. L. No. 111-5.
- 2 42 U.S.C. § 3001(a). ONCHIT was created by Executive Order in 2004. Exec. Order No. 13,335, 69 Fed. Reg. 24059 (Apr. 30, 2004).
- 3 See 42 U.S.C. § 3001(b).
- 4 42 U.S.C. § 3001(c).
- 5 42 U.S.C. § 3004(b)(1).
- 6 42 U.S.C. § 3006(a).
- 7 See 42 U.S.C. § 1395w-4(o)(4).
- 8 See 21 U.S.C. § 393 (Section 903 of the Federal Food, Drug, and Cosmetic Act).
- 9 21 U.S.C. § 393(b).
- 10 M-D-D-I Reports (“The Gray Sheet”), Mar. 30, 2009, at 8.
- 11 Devices: General Hospital and Personal Use Devices; Reclassification of Medical Device Data System, 73 Fed. Reg. 7498 (proposed Feb. 8, 2008) (to be codified at 21 C.F.R. pt. 880).
- 12 *Id.* at 7501.
- 13 *Id.* at 7503.
- 14 *Id.*
- 15 FOOD AND DRUG ADMIN., CENTER FOR DEVICE EVALUATION AND RESEARCH, GUIDANCE FOR THE SUBMISSION OF PREMARKET NOTIFICATIONS FOR MEDICAL IMAGE MANAGEMENT DEVICES (July 27, 2000).
- 16 21 C.F.R. §§ 892.2010, 892.2020.
- 17 21 C.F.R. § 892.2050.
- 18 M-D-D-I Reports (“The Gray Sheet”), Mar. 30, 2009, at 8.