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FDA Issues Final Rule for Medical Device Data Systems, Classifying Certain Health IT Products

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On February 15, 2011, three years after issuing its proposed rule for the classification of Medical Device Data Systems (MDDS), the Food and Drug Administration (FDA) issued the long-awaited final rule for MDDS devices.[1] The final rule classifies certain computer/software systems that electronically transfer, store or display data originating from medical devices (e.g., glucose meters or nurse call systems) as Class I. This new classification affects the regulatory status of many health information technology (health IT) systems, and imposes new requirements on certain hospitals and other health care providers that employ such systems in their facilities.

Scope of Final Rule

Consistent with its 2008 proposed rule, FDA's final rule defines MDDS as including systems that electronically transfer, store or display medical device data, and systems that electronically convert medical device data from one form to another in accordance with preset specifications. Any device that falls within the definition of an MDDS is now classified as a Class I device, exempt from 510(k) premarket notification requirements. This includes devices that fall within the MDDS definition, but were previously cleared through the premarket notification process as accessories to other device types. The MDDS definition is limited, however, to the most basic data systems. For example, the rule specifically excludes systems that control or alter the function of any connected medical devices, or systems intended for use in connection with active patient monitoring. Systems that include additional functionality—such as processing, characterizing, categorizing or analyzing medical device data or providing clinical diagnostic functions—also are outside the scope of the MDDS rule, and would be regulated by FDA as Class II or III devices, depend-

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ing on the intended use of the device.

MDDS manufacturers will be required to comply with Class I device requirements, including registration, listing, labeling, quality systems regulation (QSR), medical device reporting (MDR) and correction and removal reporting requirements. However, acknowledging that device regulation is new to many MDDS manufacturers, FDA has provided a staged implementation schedule, giving manufacturers 90 days to register and list with FDA, and 12 months to establish systems and procedures for compliance with QSR and MDR requirements. FDA also stated that it does not intend to enforce the QSR design control requirements retroactively to currently marketed MDDS devices, but will enforce these requirements prospectively for any design changes to a currently marketed device.

The most significant change from the MDDS proposed rule issued in 2008 is the elimination of 510(k) premarket clearance requirements for MDDS devices that perform irreversible data compression or that are intended for lay use. In the final rule, FDA determined that 510(k) clearance was not necessary for MDDS devices that feature irreversible data compression. Similarly, FDA found that MDDS devices continue to be low risk whether used by lay persons or health care professionals. Thus, FDA is not requiring 510(k) clearance for lay use MDDS devices, but noted that it is reserving the right to change its decision if reports suggest that this broader use presents an unreasonable safety risks.

Evolving Regulatory Climate for Health IT

Publication of the rule marks an important step in FDA's approach to regulation of health IT devices, and likely signals further regulation of this broad product category. The Agency has been cautious to date with computer/software products, while, in the meantime, the uses of such technology have continued to grow and evolve at an unprecedented pace. Although FDA has long regulated systems for the storage, communication and management of medical images[2] and laboratory information systems,[3] it has been slow to tackle other types of electronic data systems and software utilized by the health care community. The agency first attempted to define a broad regulatory policy for these products in 1989 through the issuance of its draft guidance, "FDA Policy for the Regulation of Computer Products." This was followed six years later by a "software workshop" held by FDA in 1996. Almost a decade later, in 2005, realizing that technology had bypassed its 1989 draft software policy, FDA formally withdrew this document.[4]

In 2008, FDA took a more focused approach with the proposed MDDS rule.[5] Rather than attempting to regulate the entire computer/software product category, the Agency sought to define, classify and regulate only a subset of such products—those that transfer, store or display data originating from medical devices. FDA's approach for MDDS devices was modeled after its regulation of medical image management devices. Like medical image management devices that simply store or transmit medical images, under the proposed MDDS rule, software products intended only to display data from medical devices would be regulated as Class I devices.

However, the timing of the final MDDS rule, as well as the progress of FDA efforts to develop guidance on health IT, appear to have been impacted by other federal priorities. Since its enactment in 2009, a significant priority of the Administration has been implementation of the provisions of the American Recovery and Reinvestment Act of 2009 (ARRA) for the promotion of health information technologies.[6] This law provides for federal incentive payments to physicians and hospitals when they adopt certified electronic health records (EHRs) and demonstrate their use to improve quality, safety and effectiveness of care.[7] The provisions under ARRA also formalized the Office of the National Coordinator for Health Information Technology (ONC) within the Department of Health and Human Services (HHS), and charged ONC with promoting the adoption of EHRs and the development of a nationwide health IT infrastructure that allows for electronic use and exchange of information.[8] Thus, efforts by FDA (also within HHS) to increase its regulatory oversight of health IT, at a time when ONC was promoting the adoption of electronic health records and health IT generally, may have been viewed as sending a mixed signal.

During this time of competing government interests related to health IT, at least one member of Congress weighed in to support FDA regulation of health IT, citing safety concerns. In late 2009 and early 2010, Senator Grassley (R-Iowa) raised questions about health IT safety issues and implementation problems in letters sent to 10 sellers of health IT systems and 31 hospitals that used such systems. Subsequently, on February 24, 2010, Senator Grassley sent a letter to HHS Secretary Kathleen Sebelius inquiring about the safe use of health IT and FDA's role in regulating such technology, including EHRs.[9] The next day, in testimony before ONC's Health IT Policy Committee, Jeffrey

Shuren, Director of FDA's Center for Devices and Radiological Health, stated: "HIT [health IT] software is a medical device."[10] He went on to acknowledge that "FDA has largely refrained from enforcing [its] regulatory requirements with respect to HIT devices," but addressed ways in which FDA could address health IT-related safety issues.[11]

Notwithstanding Dr. Shuren's testimony, FDA's efforts to regulate software appear to have been given lower priority over the past year. The ONC, on the other hand, moved forward with its rulemaking activities and published proposed and final rules for the implementation of the standards and certification criteria for the EHR incentive program under ARRA.[12] The recent issuance of the final MDDS rule, however, could signal a shift in FDA's priorities and mark a turning point in the tension between promotion of health IT by the ONC and regulation of health IT by FDA.

FDA Signals Increased Focus on Health IT

As ONC's goals for the widespread adoption of EHRs and other health information technologies are realized over the next months and years, FDA may take a more active role in regulation of health IT. FDA has already announced its willingness to extend its regulatory reach to healthcare providers that use health IT, the very entities ONC is trying to encourage to adopt such technologies. Specifically, FDA stated in the preamble to the MDDS final rule that the MDDS requirements would apply not only to traditional computer/software manufacturers, but also to users (such as hospitals and other providers) that modify computer/software products beyond the original manufacturer's specifications, and use the modified products for their "clinical practice or otherwise for commercial distribution."[13] The express inclusion of health care providers signals a shift for FDA, which generally limits its focus to manufacturers/sellers of device products.

While FDA has clearly staked out certain health IT products for regulation—including medical image management devices and MDDS—it is not yet clear how or whether FDA will regulate EHRs. In the preamble to the final MDDS rule, FDA stated that EHR and PHR systems are explicitly excluded from the rulemaking. Further clarification on this issue may come in the form of guidance documents. For example, FDA Commissioner Margaret Hamburg announced in July of last year, at a joint FDA-FCC meeting, that the Agency is drafting a guidance document on mobile health devices.[14] There are also informal reports that FDA is drafting a guidance to define what aspects of health IT are considered regulated medical devices (e.g., clinical decision support systems, EHRs).

Increased FDA attention may not be the only regulatory worry for health IT manufacturers. Companies that are new to the medical device space may find themselves subject to additional device requirements imposed by other governmental authorities. For example, a new excise tax, enacted under the Health Care and Education Reconciliation Act of 2010,[15] imposes a 2.3 percent tax on medical device sales starting in 2013. A number of states also impose regulatory requirements for manufacturers and distributors of medical devices, including requirements related to interactions with healthcare professionals, reporting of gifts and payments to physicians and prescription device distributor/manufacturer licensure.

The use of health IT is expected to continue to grow and become even more essential to the efficient delivery of health care. While the focus to date has been promoting the development and adoption of health IT, FDA has signaled its intent to ensure that such technologies, when implemented, are safe and effective. The final MDDS rule may be only the first step in FDA's renewed efforts to police these critical technologies.

1 76 Fed. Reg. 8637 (Feb. 15, 2011) (to be codified at 21 C.F.R. § 880.6310).
2 21 C.F.R. §§ 892.2010, 892.2020, 892.2030, 892.2040, 892.2050.
3 21 C.F.R. § 862.2100.
4 70 Fed. Reg. 824, 890 (Jan. 5, 2005).
5 73 Fed. Reg. 7498 (Feb. 8, 2008).
6 Pub. L. No. 111-5.
7 42 U.S.C. § 1395w-4(o).
8 42 U.S.C. §300jj-11. ONC was created by Executive Order in 2004. Exec. Order No. 13,335, 69 Fed. Reg. 24059 (Apr. 30, 2004).
9 Letter from Senator Chuck Grassley, Ranking Member, Committee on Finance, U.S. Senate, to the Honorable Kathleen Sebelius, Secretary, U.S. Department of Health and Human Services (Feb. 24, 2010).
10 Testimony of Jeffrey Shuren, M.D., J.D., Director, Center for Devices and Radiological Health, FDA, before the Health Information Technology Policy Committee, Adoption/Certification Workgroup (Feb. 25, 2010).
11 Id.
12 See, e.g., 75 Fed. Reg. 44589 (July 28, 2010) (final rule for the initial set of standards, implementation specifications, and certification criteria for electronic health record technology); 76 Fed. Reg. 1262 (Jan. 7, 2011) (final rule for the establishment of the permanent certification criteria for health information technology); 75 Fed. Reg. 44313 (July 28, 2010) (final rule on EHR incentive programs).
13 76 Fed. Reg. 8637, 8645 (Feb. 15, 2011)
14 Remarks delivered by Margaret A. Hamburg, M.D., Commissioner of Food and Drugs, at the FDA/FCC Public Workshop: Enabling the Convergence of Communications and Medical Systems (July 26, 2010).
15 Pub. L. No. 111-152.