Analysis

New FDA Rule May Affect Healthcare Facilities Using Customized Health IT Systems

By Michele L. Buenafe, Morgan Lewis & Bockius, LLP, Washington, DC

Hospitals and other healthcare facilities that utilize customized health information technologies (health IT) may soon find themselves subject to regulation by the Food and Drug Administration (FDA) pursuant to a recently issued rule classifying certain health IT systems as Class I medical devices. Specifically, FDA issued on February 15, 2010 its final rule for the regulation of health IT systems that transmit, store, or display data originating from medical devices, which FDA is calling "Medical Device Data Systems" or "MDDS."[1] The new MDDS rule has implications not only for developers of health IT products, but also for healthcare facilities and other purchasers of health IT products that add to or modify such systems. This article discusses the recent and continuing rise of health IT, the scope of the new FDA rule, the applicable regulatory requirements for healthcare facilities affected by the rule, and open issues remaining with respect to FDA's regulation of health IT.

Proliferation of Health IT

The use of health IT solutions by hospitals and other healthcare providers has increased rapidly in recent years. With mounting pressures to increase quality of care while also reducing costs, many healthcare providers have turned to these technologies as a tool to help increase efficiencies, reduce potential errors, and better connect with patients and collaborating physicians. Such technologies include, for example, electronic health records (EHRs), hospital information systems, remote monitoring and other telehealth solutions, and medical image and data management systems. The rise of health IT has been further boosted by the initiatives of the Office of the National Coordinator for Health Information Technology (ONC) within the Department of Health and Human Services (HHS), an agency whose primary mission is to promote the adoption of EHRs and the development of a nationwide health IT infrastructure. The recently implemented federal EHR incentives program, established under the American Recovery and Reinvestment Act of 2009[2] (ARRA), also has served to promote the use of health IT.

The increased use of health IT has not, however, gone unnoticed by federal watchdogs, and some have questioned whether sufficient controls exist to ensure the safe use of such technologies in the healthcare system. For example, questions concerning potential health IT safety issues and implementation problems were raised by Senator Charles Grassley (R- IA) in late 2009 and early 2010. Senator Grassley sent letters to ten sellers of health IT systems and 31 hospitals that used such systems concerning these issues. He sent another letter to HHS Secretary Kathleen Sebelius on February 24, 2010 inquiring about the safe use of health IT and the role of FDA in regulating such technology, including EHRs.[3]

Since that time, FDA has made clear its intentions to regulate at least certain types of health information technologies. The day after Senator Grassley sent his inquiry to Secretary Sebelius, the Director of FDA's Center for Devices and Radiological Health, Dr. Jeffrey Shuren, spoke before ONC's Health IT Policy Committee and stated: "HIT [health IT] software is a medical device."[4] He went on to acknowledge that, in the past, "FDA has largely refrained from enforcing [its] regulatory requirements with respect to HIT devices." If, however, industry hoped or expected FDA to remain dormant with respect to the regulation of health IT, such thoughts were laid to rest in mid-February when FDA issued its final rule for Medical Device Data Systems.

Summary of the New FDA Regulation

FDA's final rule defines Medical Device Data Systems to include systems that electronically transfer, store, or display medical device data (e.g., data originating from glucose meters or blood pressure monitors), and systems that electronically convert medical device data from one form to another in accordance with preset specifications.[5] Any device that falls within the definition of an MDDS is now classified as a Class I medical device and must comply with FDA's regulatory requirements for Class I devices.[6] Prior to its issuance of the final MDDS regulation, FDA had exercised enforcement discretion with respect to MDDS products, and did not require that such products comply with FDA's device regulations.[7] While MDDS products are now subject to active FDA regulation, Class I is the lowest level of FDA regulation for medical devices and does not require FDA premarket review.

The rule limits the MDDS definition to the most basic data systems and specifically excludes systems that control or alter the function of any connected medical devices or that are intended for use in connection with active patient monitoring (e.g., EKG monitoring systems).[8] Systems with 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, depending on the intended use of the device.[9]

The final rule requires all "manufacturers" of MDDS systems and products to ensure such products comply with FDA's Class I device requirements, as described further below. In the preamble to the final rule, FDA clarified that the term "manufacturer" includes not only traditional hardware and software developers, but also users (such as hospitals and other providers) that modify MDDS hardware or software products beyond the original manufacturer's specifications, or create their own in-house MDDS products, and use such products for their "clinical practice or otherwise for commercial distribution."[10]

The FDA's express intention to regulate hospitals and other healthcare facilities pursuant to the MDDS final rule is unusual and may be met with resistance from healthcare providers. Generally, FDA does not step in to regulate a healthcare provider's use of medical device products, as the practice of medicine is an area traditionally left to the states. In fact, the Federal Food, Drug, and Cosmetic Act explicitly limits FDA's authority with respect to the use of devices by providers, stating: "Nothing in this Act shall be construed to limit or interfere with the authority of a healthcare practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate healthcare practitioner-patient relationship."[11] Thus, FDA does not regulate or restrict a healthcare provider's use of a legally marketed medical device in a manner that was not intended by the device manufacturer and not included in the FDA-approved or -cleared device labeling (i.e., an "off-label" use). FDA has, however, exercised regulation over providers and practitioners that *modify* legally marketed devices. For example, FDA previously has taken regulatory action against physicians using modified lasers for Lasik procedures and physicians who assemble unapproved lasers using component parts.[12]

The regulation of healthcare providers, as described by FDA in the preamble to the MDDS final rule, follows these same principles. FDA stated in the preamble that healthcare institutions will not be considered "manufacturers" if they buy off-the-shelf hardware or software that was not "labeled or otherwise denoted as an MDDS," and use such hardware or software as an MDDS.[13] Such a use would be equivalent to an off-label use by a provider, an area FDA generally does not regulate. FDA stated that it will, however, regulate a healthcare institution as a medical device manufacturer if the institution: (1) makes modifications to a purchased MDDS device that are outside the parameters of the original manufacturer's specifications; (2) adds to, reconfigures, or modifies a general purpose hardware or software product such that it becomes an MDDS device; or (3) develops its own software protocols for MDDS uses.[14]

Therefore, healthcare institutions that currently customize or modify health IT products or create their own software protocols will need to consider whether any such products are subject to the new MDDS rule and, if so, whether the institution's customization or modification would qualify it as a device manufacturer in FDA's eyes. Institutions that fall within FDA's regulatory scope as MDDS manufacturers will need to take steps to ensure compliance with the applicable Class I device requirements.

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Class I Device Requirements Applicable to MDDS

Healthcare institutions that find they fall within the scope of the MDDS rule will need to comply with the FDA regulatory requirements applicable to Class I devices. Class I devices are considered low risk, and are subject to FDA's "general controls," which include establishment registration, device listing, quality system regulation, device labeling, medical device reporting, and corrections and removals reporting requirements. However, unlike higher risk Class II and Class III devices that require FDA clearance or approval prior to marketing, Class I MDDS devices are not subject to FDA premarket review. The relevant general controls requirements for MDDS devices are summarized below:

Establishment registration and device listing—FDA requires registration for all foreign and domestic establishments that engage in device manufacturing activities (including device design, preparation, assembly, processing, repackaging, and relabeling activities), or that serve as the initial importer of devices into the United States, or export to the United States.[15] In addition, all such establishments must submit a listing of the medical devices manufactured, imported, or exported at or from their facility.[16] As noted above, FDA has stated that healthcare facilities would be considered "manufacturers" if they modify or customize MDDS products beyond the scope of the original manufacturer's specifications. Thus, such facilities are now required to submit to FDA an establishment registra-

tion and device listing. However, FDA has provided a grace period for registration and listing, stating in the preamble to the final rule that MDDS manufacturers have 90 days to do so.[17] Establishment registrations and devices listings are fairly simple submissions that must be done electronically using FDA's Unified Registration and Listing Systems (FURLS). A registration must be renewed annually and requires the payment of a user fee ($2,179 for fiscal year 2011). Once a facility is registered, it is subject to periodic inspection by FDA for compliance with other FDA requirements. FDA seeks to inspect device facilities once every two years, but inspections often are less frequent due to resource constraints.

Quality System Regulation—Healthcare facilities that "manufacture" MDDS devices will be required to ensure that such products are developed and manufactured in accordance with FDA's good manufacturing practice (GMP) requirements, as set forth in the quality system regulation (QSR).[18] This regulation includes requirements related to quality management and organization, device design, purchasing controls, production and process controls, installation and servicing, complaint handling, investigations, corrective and preventative actions, and record-keeping. In the preamble to the final MDDS rule, FDA acknowledged that device regulation may be new to many MDDS manufacturers and provided a staged implementation schedule for the QSR requirements.[19] Thus, FDA is allowing MDDS manufacturers 12 months to establish systems and procedures for compliance with these requirements.[20] 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 new MDDS devices and for any design changes to currently marketed devices.[21]

Labeling—FDA imposes requirements for medical device labels and labeling, including the requirement to provide certain manufacturer/distributor information and adequate directions for use.[22] Any claims stated on MDDS labeling must be adequately substantiated and consistent with the MDDS definition set forth in the final rule. The labeling also cannot be false or misleading in any respect.

Medical Device Reporting—Healthcare facilities subject to MDDS regulation will need to establish systems to ensure compliance with FDA's medical device reporting (MDR) requirements.[23] Specifically, device manufacturers are required to submit an MDR to FDA within 30 days if they receive information concerning a device-related death or serious injury, or a device malfunction that could lead to a death/serious injury. Manufacturers also must submit within five days reports on events that require remedial action to prevent an unreasonable risk of substantial harm to the public health and other types of events designated by FDA. As with QSR requirements, FDA is giving MDDS manufacturers 12 months to establish MDR-compliant systems and procedures.[24]

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Corrections and Removals Reports—MDDS manufacturers also must comply with FDA regulations for corrections and removals reports.[25] Such reports must be submitted when a device manufacturer initiates a correction (i.e., a repair, modification, adjustment, relabeling, destruction, or inspection) or removal (i.e., a recall) of a device to reduce a risk to health posed by the device, or to remedy a violation of FDA requirements caused by the device that may present a risk to health. Healthcare facilities subject to MDDS regulations should, therefore, establish written correction and removal procedures to facilitate the conduct of such actions and ensure timely reporting to FDA.

Questions Remaining Under the MDDS Rule

While the final MDDS rule has clarified the regulatory requirements applicable to these types of devices, a number of questions remain. FDA has left open, for example, the regulatory status of more complex systems that transmit, store, or display medical device data, including those with clinical decision support or patient monitoring capabilities. As these more complex systems do not qualify for the low-risk Class I designation under the MDDS rule, such systems are, presumably, subject to either Class II or Class III device requirements. Further rulemaking to clarify the regulatory classifications of these other data systems seems likely. The approach used by FDA with respect to MDDS regulation appears to be modeled after FDA's classification of medical image management devices, where FDA classified systems with more limited functions, such as image storage and communication, as Class I devices, but classified systems with more complex functionality, including medical image digitizers, hardcopy devices, and PACS systems, as Class II.[26] Thus, it is expected that FDA, having completed its classification for the simplest types of

medical device data systems, will soon move forward in tackling the regulatory classifications and requirements for systems with additional functionality.

The regulatory status of EHRs also remains an open issue. FDA stated in the preamble to the MDDS final rule that both EHR and personal health record systems are explicitly excluded from the rule.[27] This statement seems inconsistent with the scope of the regulation, as many EHR systems are capable of receiving and storing data originating from medical devices as part of an EHR. FDA's unwillingness to delve into EHR regulation at this time may be due to the competing priorities of other HHS agencies—namely ONC and the Centers for Medicare and Medicaid Services (CMS). Since its enactment in 2009, ONC and CMS have worked hard to implement the EHR incentive program established under ARRA, which provides Medicare and Medicaid financial incentive payments for eligible providers that adopt EHR systems certified in accordance with ONC regulations. While many such systems may include functionalities that fall within the scope of FDA's device authority (e.g., those that store medical device data or include clinical decision support capabilities), FDA may be reluctant to impose its device regulatory requirements on such systems, so soon after the launch of the EHR incentive program.

In addition, it is not clear how the MDDS final rule may affect FDA regulatory initiatives with respect to other types of health IT products. Prior to FDA's issuance of the MDDS rule, certain other technologies were already actively regulated pursuant to existing FDA regulations. Although not stated expressly, the principles described in the preamble to the MDDS rule concerning the regulation of healthcare facilities as manufacturers may also apply to other types of FDA-regulated health IT products. Thus, while the MDDS final rule was limited in scope, covering only the simplest systems that handle medical device data, healthcare facilities should be mindful of device regulations applicable to other types of health IT products, such as medical image management devices[28] and laboratory information systems.[29] To the extent that healthcare facilities customize or modify these other types of device systems, such modifications should be evaluated to assess whether they trigger FDA regulation as a device manufacturer.

Finally, FDA's enforcement of its new MDDS regulation in a real world environment has yet to be tested. Notwithstanding the respective regulatory obligations imposed on health IT developers and healthcare facilities, FDA may find it difficult to determine which entity is responsible for the patchwork of hardware, software, and other IT components that often comprise health IT systems. The customization and integration options offered by many health IT vendors, coupled with broad interoperability, result in a vast number of potential system configurations. Gaps in ensuring end-to-end compliance and validation are likely to exist when healthcare facilities opt to customize and combine systems consistent with manufacturers' specifications. Considering the cost of establishing and implementing systems to ensure compliance with Class I device requirements—in terms of time, resources, and financial expense—many healthcare providers are likely to choose this option to avoid direct FDA regulation as a device manufacturer.

Conclusion

The use of health IT continues to rise as hospitals and other healthcare providers seek to improve efficiency, patient satisfaction, and standard of care. As these technologies become more integrated with and critical to our national healthcare system, regulatory concerns for the safe and effective use of such technologies also will continue to grow. Both health IT developers and health IT users will be affected by increasing FDA regulation of health IT systems, as demonstrated by the new MDDS rule. This new rule, however, is likely not the end of FDA's regulatory initiatives for health IT. In addition to the expected future FDA rulemakings for more complex medical device data systems, FDA also has indicated its intent to issue a guidance document on mobile health devices.[30] Health IT developers and users, therefore, will need to keep abreast of future FDA developments in this area.

About the Author

Michele L. Buenafe (mbuenafe@morganlewis.com) is an Associate with the law firm of Morgan Lewis & Bockius LLP, Washington, DC. Her practice focuses on FDA regulatory, compliance, and enforcement issues pertaining to medical devices and pharmaceuticals.

Endnotes

1 Medical Devices; Medical Device Data Systems, 76 Fed. Reg. 8637 (Feb. 15, 2011) (to be codified at 21 C.F.R. § 880.6310).
2 Pub. L. No. 111-5.
3 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).
4 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).
5 76 Fed. Reg. at 8649.
6 *Id.*
7 Devices: General Hospital and Personal Use Devices; Reclassification of Medical Device Data System, 73 Fed. Reg. 7498, 7501 (proposed Feb. 8, 2008).
8 76 Fed. Reg. at 8649.
9 *Id.* at 8642.
10 *Id.* at 8645.
11 *See, e.g.,* 21 U.S.C. § 396 (Section 906 of the Federal Food, Drug, and Cosmetic Act). *See also* Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration, 37 Fed. Reg. 16503 (proposed Aug. 15, 1972) ("Throughout the debate leading to enactment [of the Federal Food, Drug, and Cosmetic Act], there were repeated statements that Congress did not intend the Food and Drug Administration to interfere with medical practice and

references to the understanding that the bill did not purport to regulate the practice of medicine as between the physician and the patient.").
12 *See, e.g.,* FDA Warning Letter to Dr. Farzad Yaghouti, M.D., Global Laser Vision (July 26, 2001); FDA Warning Letter to J. Trevor Woodhams, M.D., Woodhams Eye Clinic (June 13, 1996).
13 76 Fed. Reg. at 8645.
14 *Id.*
15 21 C.F.R. pt. 807.
16 *Id.*
17 76 Fed. Reg. at 8645.
18 *See* 21 C.F.R. pt. 820.
19 76 Fed. Reg. at 8645.
20 *Id.*
21 *Id.*
22 21 C.F.R. pt. 801.
23 *See* 21 C.F.R. pt. 803.
24 76 Fed. Reg. at 8645.
25 *See* 21 C.F.R. pt. 806.
26 *See* FDA, Guidance for the Submission of Premarket Notifications for Medical Image Management Devices, 6-8 (July 7, 2000). *See also* 21 C.F.R. §§ 892.2010, 892.2020, 892.2030, 892.2040, 892.2050.
27 76 Fed. Reg. at 8647.
28 21 C.F.R. §§ 892.2010, 892.2020, 892.2030, 892.2040, 892.2050.
29 21 C.F.R. § 862.2100.
30 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).