FDA's Final Rule on Medical Device Data Systems Signals Active Regulation of Data Communication Technologies

On February 15, 2011, the U.S. Food and Drug Administration (FDA) issued a final regulation to formally classify Medical Device Data Systems (MDDS) as class I devices, signaling an end to the standing agency policy of exercising enforcement discretion—not enforcing medical device requirements—with respect to software or other technologies that transfer, store, convert, or display data generated by medical devices.[1] With publication of the final rule, FDA has completed a three-year process of reviewing public comments on the proposed MDDS regulation, which was issued for public comment in early 2008.[2] Going forward, FDA will regulate MDDS as class I, general control medical devices. Previously, such devices were ostensibly regulated as class III medical devices, subject to premarket approval, which is the most stringent approval process for medical devices. The regulation will require hospital systems, clinics, and medical software and hardware manufacturers to evaluate whether their actions or products make them MDDS manufacturers, and, if so, how they will establish appropriate regulatory compliance programs to ensure they meet their legal obligations and avoid adverse regulatory actions.

Background on FDA's Regulation of MDDS

FDA has historically regulated software and hardware products as medical devices under the Federal Food, Drug, and Cosmetic Act (FDCA).[3] A product is considered a medical device under the FDCA if, among other things, it: is intended to be used to diagnose a disease or condition; is intended to cure, mitigate, treat, or prevent disease; is intended to affect the structure or function of the body; or is a component of, or accessory to, another medical device.[4] Medical devices are broadly separated

1 76 Fed. Reg. 8637 (Feb. 15, 2011) (to be codified at 21 C.F.R. § 880.6310).

2 73 Fed. Reg. 7498 (Feb. 8, 2008).

3 The "Draft Software Policy" that first set out guidelines for the regulation of computer software products was officially withdrawn in 2005, although FDA's policy that information technology could fall under FDCA authority did not change. *See* 70 Fed. Reg. 824 (Jan. 5, 2005).

4 FDCA § 201(h), 21 U.S.C. § 321(h).

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into three distinct regulatory paradigms, or classes, numbered from lowest (class I) to highest risk (class III).[5] Class III devices require a manufacturer or "sponsor" to file a Premarket Approval Application (PMA) and obtain specific approval from FDA before lawful marketing of the device. Class II devices require a manufacturer to file a premarket notification (referred to as 510(k)), to establish that its proposed device is "substantially equivalent"—has the same characteristics, intended use, and safety profile—to a legally marketed device. Class I devices, with some limited exceptions, do not require premarket approval from FDA.[6] Unless provided for by regulation, all new devices are, by default, class III devices.

Although FDA has historically exercised enforcement discretion with respect to MDDS, the agency apparently determined that such a policy is not sustainable given the proliferation of software-based medical devices systems and technologies. During the two-year period beginning January 2008, over 350 adverse events involving health information technology were reported to FDA, at least some of which were the result of errors in proper MDDS design, testing, or installation.[7] Because such reporting was voluntary during that time, the agency believes that the actual incidence rate is likely markedly higher. Furthermore, as the scope and complexity of medical device technology inevitably increase over time, so do the potential hazards and risks of these same technologies. Inaccurate or incomplete data transfer, storage, display, or conversion may result from inadequate software quality or incorrect device functioning, which may be the direct cause of incorrect patient diagnosis or treatment.

To address these issues, FDA has undertaken a risk-based approach to the regulation of MDDS. Based on FDA's experience with MDDS as well as the limitations on what qualifies as an MDDS, FDA believes that general controls over the design and development are sufficient to manage and mitigate any associated risks. Accordingly, FDA has now formally reclassified MDDS as class I devices.[8]

Under the final rule, which goes into effect on April 18, 2011, MDDS manufacturers will have until May 16, 2011 to meet their registration and listing requirements, and until February 15, 2012 to develop and implement a quality system that will meet the applicable requirements of medical device Current Good Manufacturing Practices (cGMPs) provided in the Quality System Regulation (QSR). These requirements are discussed in further detail below.

Definition of a Medical Device Data System (MDDS)

The final rule defines an MDDS as a physical communications medium (including wireless hardware), modems, interfaces, software, or a communication protocol that transfers, stores, or displays medical device data, or converts medical device data from one format to another according to preset specifications.[9] Medical device data includes "any electronic data that is available directly from a medical device or that was obtained originally from a medical device." Medical device data also includes data that is manually entered into a device and then subsequently transmitted by or through an MDDS. The characteristics that distinguish an MDDS from other medical devices is that the MDDS does not control the functions or parameters of any other medical device and does not modify medical device data, modify the display of such data, or interpret such data. In essence, an MDDS is a system that acts solely as a conduit for the transmission or storage of medical device data. An MDDS may convert medical device data from one format to another so as to provide greater compatibility between devices and device systems, provided that such a conversion is according to

5 FDCA § 513, 21 U.S.C. § 360c.

6 *Id.*

7 *See* Institute of Medicine Committee on Patient Safety and Health Information Technology Public Meeting, December 14, 2010 (statement of Dr. Jeffrey Shuren, Director, FDA Center for Devices and Radiological Health).

8 FDA is permitted to reclassify class III devices upon its own initiative or upon petition by a manufacturer or importer of such a device. FDCA § 513(f), 21 U.S.C. § 360c(f).

9 It is important to note that devices that utilize broadband or wireless communication may also be regulated by the Federal Communications Commission (FCC) in addition to FDA. This advisory does not attempt to cover specifics of FCC regulation of such devices.

preset specifications. An MDDS may also display medical device data so long as the data is not altered in such a way as to provide interpretation of or add value to the data. As such, an MDDS merely functions as a passive conduit in an integrated system of clinical care.

Although FDA acknowledges that it may be difficult to determine in the abstract whether a particular system is an MDDS, it has provided some guidance as to limitations on the applicability of the final rule.

An MDDS **does not** include:

- Any device intended to be used for, or involved in active patient monitoring (e.g., a device relied upon for information necessary to make an immediate medical decision, or a device used for continuous patient monitoring);
- Any device that modifies, interprets, or adds value (e.g., presenting a list of data points in chart form) to medical device data;
- Any device that initiates a control signal that alters the function of a connected device;
- Any device that performs clinical assessments or clinical monitoring (e.g., provides an alarm based on preset clinical parameters); or
- Any device that falls under any other device type regulation (e.g., laboratory information systems[10] and medical image management systems[11]).

These devices are not covered by the final rule and are either regulated either under their own device type regulation or are considered class III devices. Other systems that may seem to meet the MDDS definition but are not considered MDDS include: systems that capture manually entered data, but do not electronically transfer such data through an MDDS; and systems or system components that are solely intended to be used as general information technology equipment, for example off-the-shelf wireless or backup systems. The final rule does not apply to billing and workflow software, ''report-writing functions of a computer system" (e.g., software that allows for printing data or grouping data sets for reports), or electronic health records and personal health records, although portions of such systems may be subject to regulation as medical devices, depending on their operating parameters and intended use.[12]

Who Qualifies as a Manufacturer of an MDDS

Entities who manufacture MDDS are subject to specific regulatory requirements, discussed below. Any individual, hospital, corporation, or other entity that creates or modifies any hardware, software, or communications protocol in such a way that the resulting system meets the definition of an MDDS is deemed an MDDS manufacturer. FDA does not consider purchasers and users of MDDS manufacturers so long as they do not add to or modify the hardware or software provided in the purchased or used system. These criteria apply to hospitals or other entities that develop their own custom systems, protocols, or interfaces that have intended uses covered by the MDDS definition.

Regulatory Requirements for MDDS Manufacturers and Users

Manufacturers of MDDS are subjected to specific regulatory requirements that apply to all class I devices. These requirements may be more or less burdensome depending on the prior experience that a given manufacturer has with them. Additionally, though to a much lesser degree, users of class I devices, including MDDS, also have responsibilities to FDA.

- **Registration and Listing.** All manufacturers of class I medical devices are required by statute to register and list their devices with FDA.[13] Most manufacturers, upon registration and listing, will be required to pay Medical Device User Fees.[14] For fiscal year 2011, the registration and listing fees are US$2,179; for fiscal year 2012, beginning October 1, 2011, these fees total US$2,364.[15]

10 Regulated under 21 C.F.R. § 862.2100.

11 Regulated under 21 C.F.R. § 892.2020.

12 76 Fed. Reg. 8637, 8647 (Feb. 15, 2011).

13 21 C.F.R. § 807.20.

14 FDCA § 738, 21 U.S.C. § 379j.

15 Current schedule of device registration and listing fees, *available at:* http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/registrationandlisting/default.htm.

There are some limited exceptions to the user fee requirements that may apply to certain manufacturers on a case-by-case basis.

- **Current Good Manufacturing Practices / Quality Systems.** Although class I device manufacturers are not required to obtain premarket approval of their devices, they are required to have in place an adequate system in order to conform with cGMPs for medical devices.[16] FDA has promulgated detailed regulations defining medical device cGMP requirements in its "QSR".[17]

The QSR outlines a flexible framework that all manufacturers must follow, requiring that manufacturers develop and follow procedures and fill in the details that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device. Each manufacturer is responsible for establishing requirements for each type or family of devices that will result in devices that are safe and effective. The QSR covers a broad range of topics, including, among others: device design; document controls and recordkeeping; device production, inspection, and validation; establishing finished device acceptance criteria; dealing with non-conforming devices; and issues of product maintenance and servicing.[18]

Of particular interest to FDA in regards to MDDS quality systems are the design control provisions of the QSR.[19] FDA believes that implementation of strong product design, especially the risk analysis aspects of the design controls[20], are fundamental to risk mitigation when dealing with MDDS.

- **Product Labeling and Promotion.** Medical device labels and promotional materials may not be false or misleading in any particular instance.[21] The particulars of medical device labeling[22] are quite specific, and prohibit, among other things, promotion of off-label, unapproved uses. Furthermore, whether a system meets the definition of an MDDS depends, in part, on the intended use of the system, which may be inferred from product labeling and promotional materials associated with the product. For example, general use information technology equipment, such as a wireless router, which would not be regulated as a medical device, may nonetheless become a regulated MDDS if it is marketed in any manner which would suggest the manufacturer intended the equipment to serve such a specific purpose.
- **Device Experience Reporting.** Finally, medical device manufacturers, as well as importers and "user facilities"[23] have obligations to report certain adverse events to FDA.[24] In general, user facilities and importers are required to inform (1) FDA and known device manufacturers of any device-related deaths, and (2) the manufacturer, or FDA if the manufacturer is unknown, of any serious injuries related to use of the device. Manufacturers must notify FDA of all deaths and serious injuries they are made aware of that are device-related.[25] Distributors must maintain records of incidents and device-related complaints, but they are not required to report these incidents to FDA.

As mentioned above, MDDS manufacturers will have until May 16, 2011 to meet their registration and listing requirements, and until February 15, 2012 to develop and implement a quality system that will meet the applicable QSR requirements.

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The regulation of MDDS as class I devices will likely require many entities to fall within the scope of FDA's device manufacturing regulations for the first time. The obligations for such manufacturers are nuanced and unique to each particular entity and each particular device. For some entities who have product manufacturing quality control and

16 FDCA § 520(f), 21 U.S.C. 360j(f).
17 21 C.F.R. Part 820.
18 *Id.*
19 *See* 21 C.F.R. § 820.30.
20 *See id. at* § 820.30(g).
21 FDCA § 502, 21 U.S.C. § 352(a).
22 *See* 21 C.F.R. Part 801.
23 Examples of "user facilities" include ambulatory surgical facilities, outpatient diagnostic or treatment facilities, hospitals, etc. *See* 21 C.F.R. §§ 803.3 (definitions) and 830.30 (user facility requirements).
24 *See* 21 C.F.R. § 803.10.
25 Additional reporting requirements also apply depending on an individual or entity's status as a manufacturer, importer, or user. *See id.*

quality assurance systems in place as a part of their regular product stewardship plans, these requirements may present less structural changes, but will require that additional administrative issues be appropriately addressed. Other entities will be required to make more significant changes in their businesses. All entities who may potentially fall under the MDDS final rule should take steps to evaluate whether their actions or products render them MDDS manufacturers, and, if so, how they will establish appropriate regulatory compliance programs to ensure they meet their legal obligations and avoid regulatory actions against them.

We hope that you have found this advisory useful. If you have any questions about how these new regulations apply to you, please contact your Arnold & Porter attorney or:

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