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Life Sciences Health Industry Alert

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Three Years Later, FDA Finalizes Medical Device Data Systems ("MDDS") Rule

Health Information Technology Developers and Users Must Determine Whether Their Products May Be MDDS Subject to Registration and Listing Requirements Within 90 Days

I. Introduction

On February 15, 2011, the Food and Drug Administration ("FDA" or the "Agency") published a final rule ("Final Rule")[1] reclassifying Medical Device Data Systems ("MDDS") as Class I medical devices exempt from 510(k) premarket notification requirements. FDA defined MDDS as medical devices that are intended to transfer, store, convert from one format to another according to preset specifications, or display "medical device data." FDA explicitly excluded electronic health record ("EHR") and computerized physician order entry ("CPOE") systems from the MDDS Final Rule. Because MDDS do not "provide new or unique algorithms or functions," FDA concluded that general controls, such as the Quality System Regulations ("QSRs")[2], are sufficient to mitigate any risks associated with MDDS.

The Final Rule will become effective April 18, 2011. By May 18, 2011, FDA expects all manufacturers of MDDS to register their establishments and list their MDDS products with FDA.[3] No later than April 18, 2012, FDA expects all manufacturers of MDDS to develop and implement procedures to ensure compliance with the QSRs and the Medical Device Reporting ("MDR") requirements.[4] FDA stated that it does not intend to enforce design control requirements retroactively to any currently marketed device that is classified as "MDDS" under the Final Rule. However, FDA stated that it will enforce design control requirements for design changes made after the April 18, 2011 effective date to currently marketed MDDS.

II. Summary of Rulemaking

A. Proposed Rule and Regulatory History

By way of background, FDA published a proposed rule titled "Devices: General Hospital and Personal Use Devices; Reclassification of Medical Device Data System," ("Proposed Rule") in February 2008.[5] Under the Proposed Rule, MDDS would be reclassified to Class I, and would be exempt from premarket notification requirements where (1) only "healthcare professionals" would use the MDDS and (2) the MDDS did not perform "irreversible data compression."[6]

The Proposed Rule defined MDDS as devices intended to be used for any of the following purposes:

- The electronic transfer or exchange of medical device data from a medical device, without altering the function or parameters of any connected devices
- The electronic storage and retrieval of medical device data from a medical device, without altering the function or parameters of connected devices
- The electronic display of medical device data from a medical device, without altering the function or parameters of connected devices, or
- The electronic conversion of medical device data from one format to another format in accordance with a preset specification

The Proposed Rule explained that "medical device data" referred to "numerical or other information available from a medical device in a form suitable for processing by a computer," including "any type of information or knowledge"; for example, "clinical values, alarm conditions, [or] error messages." Further, the Proposed Rule stated that the following would be outside the scope of the definition: any device that "creates diagnostic, decision support, or alarm functions"; any "report-writing functions

of a data system that allows for the manual input of data by practitioners"; and any device with "real time, active or online patient monitoring."[7]

B. The MDDS Final Rule

1. In General

The MDDS Final Rule applies "only to data systems with specific intended uses and functions." Data systems intended for other uses and with different functions beyond those listed in the Final Rule "will remain Class III devices," which would require the submission of a premarket application and significant data to support their safe and effective use. All Class I data systems are exempt from 510(k) premarket notification, but will remain subject to general controls, including the QSRs to provide a reasonable assurance of safety and effectiveness. Specifically, the Final Rule states:

> (a) Identification.
>
> (1) A medical device data system (MDDS) is a device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:
>
> (i) The electronic transfer of medical device data;
>
> (ii) The electronic storage of medical device data;
>
> (iii) The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or
>
> (iv) The electronic display of medical device data.
>
> (2) An MDDS may include software, electronic or electrical hardware, such as a physical communications medium (including wireless hardware), modems, interfaces, and a communications protocol. This identification does not include devices intended to be used in connection with active patient monitoring.
>
> (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

Significantly, FDA removed the criteria that MDDS must be used "only by a health care professional" and may not perform "irreversible data compression" to qualify for the exemption from premarket notification requirements. The Final Rule also provides specific examples of permissible MDDS system components, including software, hardware, modems, interfaces, and communication protocols.

2. Scope of MDDS Final Rule

The following chart illustrates some of the complicated distinctions FDA drew in the Final Rule in an attempt to identify and articulate, in the abstract, what types of data systems qualify as MDDS within the purview of the reclassification and 510(k) exemption.

MDDS UNDER THE FINAL RULE	NOT MDDS
Systems that "transfer, store, convert according to present specifications, or display medical device data without controlling or altering the function or parameters of any connected medical device."	A system that "performs any other function or any additional function." Systems that do not "transfer store, convert, or display medical device data."
A system that "acts only as the mechanism through which medical device data can be transferred, stored, converted, or displayed."	Systems that "modify, interpret, or add value to the data or the display of the data" or "add to or modify the intended uses or clinical functions that are already contained within the medical devices that provide data to (or receive data through) the MDDS."
A system that could "pass" a control signal to an infusion pump.	A system that could "initiate" a control signal to an infusion pump.
A system that can "control its own functionality."	A system that "by itself . . . controls the functioning of any other medical device."
A system that can "generate signals to establish and implement communication of medical device data."	A system that "stores data and contains diagnostic functionality that allows it to perform clinical assessments or clinical monitoring, such as alarm functionality based on preset clinical parameters."

MDDS UNDER THE FINAL RULE	NOT MDDS
A system that is "intended to be a conduit for medical device data."	A system that can "create or generate . . . its own data, including signals, to be sent to a medical device."
A system that may "transmit medical device data that originates from a source that is external to the MDDS either to, or away from, another medical device."	A system that controls or alters the functions or parameters of those devices between which the system transmits data.
Systems that "feature the functions identified in this rule but that do not fall under another device type regulation."	A system that "meets the definition" of another "already classified device . . . even if one or more of its intended uses might overlap with the MDDS classification."
A system with a "display function . . . intended only to display data in the same form in which the data was received from a connected medical device."	A system that includes "flagging (via email or otherwise), analyzing, prioritizing, plotting, or graphing data."
A system that "can convert data into different languages, so that devices or equipment from different vendors can share information."	A system that can "interpret the data or change the form in which the data was received by the MDDS."
A system that can "convert data to or from the HL7 format, so that data provided from a connected medical device in spreadsheet form could be displayed in spreadsheet form by the MDDS or another connected device."	A system that displays "graphically" numerical data from a connected medical device or displays "graphic data in spreadsheet form or otherwise in a different graphic form."
A system that only transfers "a signal or other data from an initiating device" (a "non-MDDS initiating device," separately classified) that alters the parameters of a connected device."	A system that "generates a signal or other data that controls or alters the functioning of the connected device" or "any software, or corresponding informational technology (IT) system, that issues or creates data or system changes, including clock time, or modifies any control parameters of any connected device such as software updates or database information."
A system that converts "medical data from one format to another format in accordance with a preset specification," including conversion of data to "HTML, PDF, HL7, or similar format."	A system that otherwise converts, alters, modifies, or interprets the data that is received from a medical device or changes "the form in which the data is stored, transferred, or displayed (e.g., from a graph to a spreadsheet)."

3. Treatment of EHR and CPOE Software Systems

In response to comments, FDA indicated that it expects EHR systems to fall outside the MDDS classification. Similarly, FDA stated that CPOE systems that "order tests, medications, or procedures, would not meet the MDDS definition because [their] intended uses fall outside that definition's scope." However, FDA did not state in the Final Rule that EHR and CPOE systems are not medical devices. Nor did FDA state whether the Agency will continue to exercise enforcement discretion with respect to Class III requirements for such systems. FDA's silence creates a great deal of uncertainty about the regulatory status of EHR and CPOE systems.

4. Treatment of APACHE or Apgar Scoring Tools

In response to comments, FDA has excluded APACHE decision support systems and software-based Apgar scoring systems from the MDDS Final Rule because they perform additional functions beyond those intended for MDDS. FDA stated in the Final Rule that any "functionality such as processing, characterizing, categorizing, or analyzing the data would be outside the scope of an MDDS." FDA further stated that any system performing "any clinical or medical diagnostic function" is not considered MDDS. Again, FDA did not affirmatively state that such tools are not medical devices or that the Agency would continue to exercise enforcement discretion with respect to Class III premarket submission requirements.

5. Treatment of "General IT Equipment"

FDA stated in the Final Rule that, "any system, or component of a system, that is solely intended for use as general IT equipment" and not intended for a device use under section 201(h) of the Food, Drug, and Cosmetic Act "would not be considered a medical device." However, the Final Rule provides examples of components that could alone, or in conjunction with other components,

constitute MDDS, depending on their intended use. Specifically, MDDS "may include software, electronic or electrical hardware such as a physical communications medium (including wireless hardware), modems, interfaces, and a communications protocol."

6. Treatment of Health Care Facilities and Other Purchasers of MDDS

FDA stated that, where purchasers of MDDS use, configure, or modify the MDDS "in accordance with the original manufacturer's labeling, instructions for use, intended use, original design, and validation," they will not be considered a "manufacturer" of MDDS. However, it is possible for an MDDS purchaser to "become a manufacturer" (for purposes of registration and listing requirements and the QSRs) if the purchaser "makes any modifications to the MDDS that are outside the parameters of the original manufacturer's specifications for the device." Further, if "a third-party company or hospital develops its own software protocols or interfaces that have an intended use consistent with an MDDS," or "creates a system from multiple components of devices and uses it clinically for functions covered by the MDDS classification," it could also be a "manufacturer."

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1 76 Fed. Reg. 8637 (Feb. 15, 2011).

2 21 C.F.R. part 820 (the QSRs, which set forth the current good manufacturing practice requirements for medical devices).

3 The fee associated with registration and listing is $2,179 for fiscal year 2011 and $2,364 for fiscal year 2012. Registration and listing can be done electronically at the following website: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm.

4 21 C.F.R. part 803.

5 73 Fed. Reg. 7498 (Feb. 8, 2008).

6 73 Fed. Reg. at 7500.

7 73 Fed. Reg. at 7503.

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