BNA, INC.

MEDICAL DEVICES LAW & INDUSTRY

BNA Employee-Owned Since 1947

VOL. 0, NO. 0 REPORT MARCH 9, 2011

FDA Final Rule on Medical Device Data Systems And the Potentially Crippling Impact on IT and Telecom Companies

By James N. Czaban

On Feb. 15, 2011, the Food and Drug Administration issued a new final rule expanding the agency's regulatory reach into the area of Medical Device Data Systems (MDDS) (5 MELR 119, 2/23/11). Although FDA claims that the rule ''provides a less-burdensome path to market for certain hardware and software products used with medical devices,'' this claim must be taken with two important caveats. First, while MDDS products will be exempt from pre-market notification requirements, their manufacturers will be subject to other regulatory requirements including establishment registration and device listing[1], adherence to FDA's Quality Systems Regulation (QSR)[2], and reporting adverse events associated with such devices.[3] Second, although FDA has technically ''down-classified'' such products from Class III to the much less burdensome Class I, in reality these products have not been actively regulated and thus the new rule will impose more burdens than previously existed.

Under the agency's definition of an MDDS device, a multitude of hardware and software products, including products that are primarily intended for general, non-medical device uses, may be swept into this new regulatory regime. Companies in the Information Technology, computer hardware and software, and telecommunications industries should carefully evaluate the impact of the new regulation on their products and business and take steps to either avoid classification as an MDDS or

James N. Czaban is a partner and the chair of the FDA Practice Group at Wiley Rein LLP in Washington. He also is on the advisory board for BNA's Pharmaceutical Law & Industry Report. *He can be reached at (202) 719-7411, or jczaban@wileyrein.com.*

[1] *See* 21 C.F.R. Part 807
[2] *See* 21 C.F.R. Part 820.
[3] *See* 21 C.F.R. Part 803.

 ISSN 1935-7230

other type of medical device, or to ensure compliance with the new rules.

What is an MDDS?

The new regulations define an MDDS as a product intended for one of the following uses: ''(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.''[4] As FDA further explained in the preamble to the final rule,

> An MDDS acts *only as the mechanism by which medical device data can be transferred, stored, converted, or displayed*. An *MDDS does not modify the data or modify the display of the data*. An MDDS by *itself does not control the functions or parameters of any other medical device*. An MDDS can only control its own functionality. This device is *not intended to provide or be used in connection with active patient monitoring*. Any product that controls or alters the functions or parameters of a medical device, or is used in active patient monitoring, is not an MDDS.[5]

The final rule limits the MDDS classification to those products that serve merely as a conduit for data and which do not add any value to the data or the device(s) with which it is used. For example, FDA explains that *''. . . .flagging (via email or otherwise), analyzing, prioritizing, plotting, or graphing data [are] uses that add value or knowledge to the existing data and thereby exceed the limited functionality of an MDDS*.''[6] Thus, the rule's inclusion of ''conversion'' of medical data as an allowable use of an MDDS is much more limiting than the words of the regulation might suggest. As FDA explains the concept of ''conversion,''

> Use of an MDDS *for conversion is limited to translation, so that data can be viewed or transmitted in the same form that it was received by the MDDS*. An MDDS can convert data into different languages, so that devices or equipment from different vendors can share information. An *MDDS cannot, however, interpret the data or change the form in which the data was received by the MDDS*. For example, an MDDS could 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. But *numerical data from a medical device connected to an MDDS could not be displayed graphically by the MDDS, nor could the MDDS display graphic data in spreadsheet form or otherwise in a different graphic form*.[7]

Are Standard Hardware and Software Systems Exempt?

As illustrated above, the FDA's definition of MDDS devices is narrow in its scope, but could be very broad in its impact. By classifying as an MDDS device any product that transmits, stores, displays, or converts ''medical device information'' the regulation on its face could potentially apply to a vast array of common IT, computer, and telecom products and systems including mobile devices, laptop and desktop computers, chipsets, wireless network systems, hard drives and other data storage systems, computer monitors, word processing and spreadsheet software, and even items as innocuous as USB cables that can be connected to medical devices.

Importantly, the limitations enumerated in the regulation—excluding from the MDDS classification products that control the functions of another device or otherwise ''add value or knowledge to the existing data''—are not safe harbors from FDA regulation; rather, products that include such features will be regulated under other, typically stricter, device classifications.

The breadth of the rule's definition of MDDS devices begs the question whether FDA really intends to require all such products to be regulated as MDDSs and for their manufacturers to comply with the registration, listing, QSR, and adverse event reporting requirements applicable to Class I devices. While some of FDA's statements in the final rule preamble suggest that the answer to this question may be ''no,'' the crucial question of how companies can avoid regulation of their products as an MDDS or as another type of device is not as easily answered.

The ''Intended Use'' Doctrine

The ''intended use'' of the product is an essential element of the classification calculus. The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines ''device'' in relevant part, as follows:

> (h) The term ''device''. . .means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is— * * *
>
> (2) *intended for use* in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals,. . . .[8]

The relevant ''intended use'' is that of the manufacturer and/or the marketer of the product. FDA's longstanding device regulations provide that:

> The words *intended uses* . . . refer to the *objective intent* of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be *shown by the circumstances surrounding the distribution of the article*. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. . . . if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate com-

[4] 21 C.F.R. § 880.6310(a) (emphasis added), promulgated at 76 Fed. Reg. 8637, 8649 (Feb. 15, 2011).
[5] 76 Fed. Reg. at 8638 (emphasis added).
[6] 76 Fed. Reg. at 8642 (emphasis added).
[7] Id. (emphasis added).
[8] 21 U.S.C. § 321(h) (emphasis added).

  MELR ISSN 1935-7230

> merce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.[9]

Thus, as a general principle, a product sold for non-medical purposes will not be subject to FDA regulation as a device. For example, a copper bracelet sold merely as fashionable jewelry is not regulated by FDA, whereas if the manufacturer labels or advertises the bracelet as a cure for cancer, that intended medical use provides FDA with the authority to regulate the bracelet as a ''device.'' In the context of IT systems components and the MDDS regulation, FDA has explained that

> ''Products that are built with, or consist of, computer and/or software components are subject to regulation as devices if they meet the definition of a device contained in section 201(h) of the FD&C Act (21 U.S.C. 321(h)).[10]
>
> * * *
>
> ''By themselves, any system, or component of a system, that is *solely* intended for use as general IT equipment (and that is not intended for a device use under section 201(h) of the FD&C Act), would not be considered a medical device.''[11]
>
> * * *
>
> ''Manufacturers of software systems or other products that do not have intended uses covered by the MDDS classification would not be subject to this rule.''[12]

Thus, for example, a company that sells a wireless networking system to myriad commercial users for a wide variety of non-medical industrial applications may feel comfortable that its product is not an MDDS or any other type of medical device and therefore decide not to register with FDA or implement QSR-compliant manufacturing processes. But whether FDA will agree with such an assessment is much more complex and fact-specific, as described below.

Hidden Traps for the Unwary?

The expansive regulatory definition of a product's ''intended use,'' coupled with the potentially broad impact of the MDDS definition, is cause for concern to a range of technology companies which may be engaging in sales and marketing activities that FDA could use to impute an intended use for products as MDDS devices. For example, if the hypothetical company described above is selling a wireless networking system labeled for general use but also specifically conducts sales calls with hospital customers touting the utility of the system for linking certain medical devices to the hospital's computer system, FDA could assert that under its regulatory policy one intended use of the product is as an MDDS device, and thus that the product is subject to FDA regulation. Indeed, FDA's MDDS final rule highlights this possibility by noting that to escape regulation as a device, a product must be ''*solely* intended for use as general IT equipment.'' If FDA can identify any other medical intended use through the company's words or actions, it may regulate the product as a device.

Companies in the IT, computer hardware, and software spaces must therefore be careful and detail-oriented in examining their product lines and the full array of sales and marketing activities supporting those products in order to accurately evaluate which of their products may be subject to FDA regulation. Using the broad ''intended use'' criteria from FDA's regulations, and in light of the extensive marketing to, and use of such equipment by, healthcare customers, the number of products potentially subject to FDA regulation as MDDS devices is enormous. And while such devices are exempt from any premarket notification requirement, the burden of the registration, listing, QSR and adverse event reporting requirements can easily become unmanageable for companies without established experienced FDA-regulatory compliance departments.

Manufacturers must also be prepared for potential changes in their relationships with healthcare industry customers. FDA has put healthcare entities on alert that they may become regulated as device manufacturers based on their purchase and use of IT related products that the original manufacturer does not intend to be used as MDDS devices. Specifically, FDA warns that

> [If] a health care facility or other purchaser that buys software or hardware that has not been labeled or otherwise denoted as an MDDS. . .adds to or modifies any hardware or software such that the software is intended to provide the transfer, storage, conversion according to preset specifications, or display of medical device data (or otherwise modifies the product to render it a medical device) and uses it in clinical practice, the purchaser becomes a device manufacturer in accordance with § 807.3(d).[13]

Hospitals and other healthcare entities are certain to want to avoid being deemed to be device manufacturers based on their use of purchased equipment, so these customers are likely to begin questioning original manufacturers about the regulatory status of IT equipment and systems where the purchaser expects to use the products for MDDS-type uses. Suppliers who support these customers by registering and listing relevant products with the FDA, certifying compliance with QSR, and undertaking the adverse event reporting obligations under the MDDS rule may find competitive advantages for future sales, but whether this advantage outweighs the burdens of declaring their products to be MDDS devices remains to be seen.

Compliance Dates for MDDS Manufacturers

As noted above, manufacturers of products that qualify as MDDS devices must comply with the FDA's registration and device listing requirements, must establish and maintain QSR-compliant manufacturing systems, and submit medical device adverse event reports. The final rule provides that registration and listing must be completed *within 90 days* of publication of the final rule (i.e., by May 16, 2011), and that MDDS manufacturers must *establish compliant quality systems and adverse event reporting systems within 12 months* of the effective date of the rule (by April 18, 2012).

[9] 21 C.F.R. § 801.4 (emphasis added).
[10] 76 Fed. Reg. at 8638.
[11] 76 Fed. Reg. at 8643.
[12] 76 Fed. Reg. at 8645.
[13] 76 Fed. Reg. at 8645.

Conclusion

Given the complexity of determining whether certain products may fall within the scope of the MDDS classification scheme, companies have very little time to evaluate their product lines and marketing efforts and to begin compliance planning for affected products. Unfortunately, as discussed above, the new rule and its preamble leave many questions unanswered and raise the possibility that the agency has not in fact eased the regulatory burdens but rather has created a crippling and ineffectual new regulatory scheme. Industry may want to consider requesting that FDA delay the effective date of the regulations and to issue clarifying guidance to assure that the rule is implemented and followed in a manner that meets appropriate public health goals without creating undue burdens on companies whose products could, but arguably should not, fall within the scope of the MDDS device classification scheme.

  MELR ISSN 1935-7230