Bloomberg BNA

Medical Devices Law & Industry Report™

New Draft Guidance Would Clear Regulatory Hurdles for Software Developers

BY ALLISON FULTON AND LAUREN SILVIS

On June 20, 2014, the Food and Drug Administration issued a draft guidance titled ''Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices'' (''MDDS draft guidance'') (8 MELR 423, 6/25/14). The draft announces that FDA does not intend to enforce compliance with the regulatory controls that apply to Medical Device Data Systems (MDDS), medical image storage devices, or medical image communications devices, because of the low risk they pose to patients and the importance they play in advancing digital health.

The draft guidance would reduce regulatory hurdles for developers and manufacturers of MDDS and image communication software, which play a vital role in advancing health information technology (''health IT''). Manufacturers should note, however, that FDA continues to ''regulate'' cutting edge software through nonbinding guidance, which creates uncertainty regarding the status of certain novel software products.

Allison Fulton (afulton@sidley.com) and Lauren Silvis (lsilvis@sidley.com) are with Sidley Austin LLP in Washington, D.C. Allison is a senior associate and advises medical device and pharmaceutical companies on regulatory and enforcement matters, including QSR/cGMP requirements. Lauren, a partner, provides strategic regulatory counseling for leading medical device and pharmaceutical industry clients.

Regulatory Scheme for MDDS, Image Storage and Image Communication Devices. According to the device classification regulations, MDDS are hardware or software products that transfer, store, convert from one format to another, or display medical device data. 21 CFR 880.6310. Medical image storage devices and medical image communication devices, according to FDA regulations, store and transfer medical image data, respectively. 21 CFR 892.2010 and 21 CFR 892.2020. Each of these devices is regulated as a Class 1 device, which is the classification for low-risk devices.

Given the apparent ''hands-off'' regulatory approach, developers of these software products would be able to create software and hardware solutions that connect medical devices without having to satisfy the regulatory requirements associated with the medical device classification regulations. The regulatory requirements include registration and listing, postmarket reporting, and good manufacturing practice under the quality system regulation (QSR).

The devices were already exempt from premarket notification, subject to the limitations on these exemptions in FDA regulations. According to the draft guidance, even when a limitation on the exemption applies to an MDDS, image storage, or image communication device, FDA does not intend to enforce the premarket notification requirements.

The draft guidance also would eliminate a manufacturer's obligation to comply with the QSR. The QSR requires manufacturers to implement and document controls used during the product lifecycle, including during software design, production, distribution, and post-distribution. While software manufacturers may follow industry standards during product development, the QSR presents some unique requirements. Manufacturers of MDDS, image storage, and image communication devices also would not be subject to QSR inspections of their processes or facilities.

MDDS Software Is Key to Advancing Health IT and Presents Low Risk to Patients. MDDS software systems, along with image storage and communication software, play an integral role in health IT. They allow health information to be stored, transferred wirelessly, and read anytime, anywhere by a physician, patient, or caretaker. Health information includes patient information

 ISSN 1935-7230

such as blood pressure readings, electrocardiograms, or X-rays. MDDS also can transfer health information to a central repository, such as a hospital database that stores electronic health information (also called electronic health records, or EHRs) for all of its patients.

Device interoperability—*i.e.*, the ability to exchange information across multiple systems—is key to advancing digital health IT because it enables the exchange of information between various medical devices and systems that electronically store health IT. It allows physicians and patients to access health records when they need it and where they want it.

Despite their key role in health IT, MDDS are low risk products with limited functionality beyond information exchange. The MDDS classification regulation and draft guidance make clear that MDDS do not modify the data exchanged, are not intended to be used in active patient monitoring, and do not control or alter the function of any connected medical device. For example, software that allows a physician to view a patient's blood pressure reading on a smart phone may be considered an MDDS. But software that allows a physician to view a patient's blood pressure reading *and* to send instructions to the blood pressure cuff to inflate would not be considered an MDDS.

The draft guidance comes on the heels of the FDASIA Health IT Report (Apr. 3, 2014)(8 MELR 241, 4/16/14), which recommends a narrowly-tailored approach to FDA regulation of health IT.[1] The report acknowledges that fostering the development of interoperable devices facilitates new models of health care delivery by increasing access to information.

The FDASIA report identifies three categories of health IT products according to their risk to patients:

(1) Products with administrative health IT functions (*e.g.*, software for billing and claims processing or scheduling);

(2) Products with health management heath IT functions (*e.g.*, software for health information or medication management, order entry software, and most clinical decision support software); and

(3) Products with medical device health IT functions (*e.g.*, software for bedside monitor alarms and radiation treatment software).

According to the report's recommendations, FDA would regulate only the last of those categories; the others would not be subject to active FDA regulation.

Notably, the FDASIA report recommends no new or additional areas of FDA oversight of health IT. The report instead recommends an approach that relies primarily on private sector capabilities and leveraging industry standards and best practices to accommodate the rapid evolution of health IT. The approach reflects an attempt to balance FDA's intent to regulate health IT under the medical device provisions of the Federal Food, Drug, and Cosmetic Act (FDCA), the need to foster continued advances in digital health IT, and the practical limitations on FDA's ability to handle the volume of regulatory submissions it would receive under the broadest possible application of its authority to health IT software. The June draft guidance is consistent with this approach.

FDA Continues to 'Regulate' Software Through Non-Binding Guidance. While the draft guidance should be commended for attempting to support the development of digital health products, it also signals FDA's continued intent to regulate software through informal guidance, as opposed to formal notice-and-comment rulemaking.

The guidance process may allow FDA to react more quickly to evolving technology, but guidance documents do not have the force of law and provide less certainty to software developers than binding regulations. By their own terms, guidance documents merely describe the Agency's ''current thinking'' on a particular topic and can be ''viewed only as recommendations.'' In fact, less than one year ago, FDA issued the Mobile Medical Applications (MMA) guidance, which identifies MDDS software as an actively regulated device. The June draft guidance proposes edits to the MMA guidance.

The MMA guidance, published in September 2013, introduced a regulatory regime for a specific category of software—mobile apps (7 MELR 607, 10/2/13). In the MMA guidance, FDA declared its regulatory authority over a broad range of mobile apps but then clarified that it intends to regulate only a small subset of those apps. The approach is similar to the one taken in the draft MDDS guidance.

The MMA guidance largely defines the parameters of devices FDA intends to regulate by providing examples of specific devices, including MDDS apps. Those examples, however, may become obsolete or irrelevant, as seen with issuance of the June draft guidance, which announces that FDA does not intend to actively regulate MDDS. App developers may continue to question the regulatory status of their devices that do not squarely fit into the definition of MDDS.

Manufacturers Still Left With Some Uncertainty on the Regulatory Status of Cutting-Edge Software. The draft guidance would carve out from active regulation three specific categories of Class 1 products with limited functionality beyond information storage and exchange. It is only a draft, however, and is subject to change. It is important to note that FDA does not intend to abandon its overall authority over these devices. Instead, the Agency adopts an ''enforcement discretion'' approach that still allows some flexibility.

The draft guidance does not address products with more complex functionality. FDA appears to be willing to give some ground to developers on the ''easy'' devices, but the draft guidance does not address many important categories of software. Manufacturers of cutting edge software products may want to engage the Center for Devices and Radiological Health (CDRH) on issues that affect the development of new products. Given the rapid development of new and improved software products, engaging CDRH provides both an opportunity to educate regulators about the advances industry is making and to gain alignment about a regulatory approach that would allow continued improvement in the delivery of health IT.

[1] Section 618 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), Public Law 112-144, mandated that FDA, in consultation with the Office of the National Coordinator for Health IT (ONC) within the Department of Health and Human Services and the Federal Communications Commission (FCC), issue a report with a proposed strategy and recommendations on an appropriate, risk-based regulatory framework for health IT.

  MELR ISSN 1935-7230