5 Takeaways From FDA Medical Device Data System Guidance

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On June 20, the U.S. Food and Drug Administration issued a draft guidance titled “Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices.” The draft guidance announces that the FDA does not intend to enforce compliance with the regulatory controls that apply to Medical Device Data Systems ("MDDS"), medical image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, due to the low risk they pose to patients and the importance they play in advancing digital health.

The draft guidance could help foster innovation in medical software. It recognizes that low-risk devices that merely store or transfer patient data should not be subject to a high level of regulatory oversight. The draft guidance acknowledges that less regulation of the products that form the foundation for intercommunication between medical devices and health information technology systems may advance the development of health IT infrastructure.

The draft guidance covers only a small subset of medical devices. It carves out from active regulation three specific categories of Class I products with limited functionality beyond information storage and exchange. It does not cede general authority over these low-risk devices, nor does it address products with more complex functionality and intended uses. Given these limitations, below are five takeaways for developers and manufacturers of cutting edge software products.

Software Developers May Continue to Face Uncertainty Regarding the Regulatory Status of Their Devices

The draft guidance signals the FDA’s intent to “regulate” software through informal guidance documents, as opposed to formal notice-and-comment rulemaking. 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 FDA's “current thinking” on a particular topic and can be “viewed only as recommendations.”

The FDA’s evolving policy on the classification of MDDS illustrates the fluidity of the regulatory environment. In February 2011, the FDA issued a regulation to reduce the classification of MDDS from Class III to Class I, which is reserved for the lowest risk devices. In September 2013, CDRH issued guidance on Mobile Medical Applications ("MMAs") that specifically identifies MDDS apps as actively regulated devices. Then last month, less than one year later, the FDA says in draft guidance that MDDS would not be subject to active regulation.

Although most Class I devices do not require premarket notification, certain limitations apply.

The draft guidance explains that even when an MDDS, image storage or image communication device would require a premarket submission under the limitations on the exemptions set forth in the relevant classification regulations, the FDA does not intend to enforce the premarket notification requirements. For example, the FDA would not enforce premarket notification requirements for MDDS intended to be used in a system for assessing the risk of cardiovascular diseases (21 CFR 880.9(c)(4)) or for use in diabetes management (21 CFR 880.9(c)(5)).

The FDA's use of guidance reflects how quickly the understanding of risks associated with software products can change. Following a more formal approach, for example by issuing regulations, would take more time but could provide more certainty to developers and manufacturers on the regulatory status of their products. This could allow small manufacturers to appropriately allocate resources to meet regulatory requirements and would provide more certainty to companies interested in acquisitions or investments in the software space.

Companies Should Define Product Functionality and Intended Use Early in the Design Phase to Reduce Uncertainty of the Regulatory Status of New Products

Companies should decide where to draw the line on product functionality and intended use early during product development to increase certainty regarding whether products will be regulated by the FDA. Software that allows a physician to view a patient’s insulin level on a smartphone may be considered an MDDS. But, software that allows a physician to view a patient’s insulin levels and send instructions to the device to increase insulin dosage would not be considered an MDDS. (MDDS cannot control the functions of a connected device).

Under the new draft guidance, the first product would not be subject to active FDA regulation, but the second would. Companies should implement a robust review of design changes and product claims during development to prevent design and claims creep — or the broadening of a product’s features and claims — to ensure a product’s regulatory status does not change with product design changes or additional claims.

The regulatory status can have a significant impact on the allocation of resources during the development phase. Most actively regulated devices are subject to the FDA’s general controls, which include, among other things, good manufacturing practice under the quality system regulation. The QSR requires manufacturers to implement and document the controls used during the product lifecycle, including during software design, production, distribution and postmarket release. Although companies may adhere to industry standards with requirements similar to those found in the QSR (e.g., to validate software before it is released) the QSR can present heightened standards for design or production control. MDDS manufacturers would no longer have to comply with QSR, according to the draft guidance.

Strategically Engaging CDRH on Cutting-Edge Mobile Health or Wearable Devices May Reduce Uncertainty of the Regulatory Status of Mobile Health Products

In the last two years, there has been a growing demand for mobile health apps that can track or monitor a person’s activity. There is also a growing demand for wearable devices, such as fitness bands or watches, that can track a person’s movement (e.g., steps taken), calories burned or sleep

patterns.

The FDA stated in its MMA guidance that it does not intend to regulate mobile apps that provide "simple tools" to organize and track health information. These general "health and wellness" apps should face little scrutiny, given the somewhat limited functionality they provide to the end user. The MMA guidance provides specific examples of health and wellness apps, including those that actively monitor and trend exercise activity, calculate calories burned in a workout or make exercise or posture suggestions.

It makes sense for the FDA to decline to actively regulate wearable devices that provide the same general "health and wellness" functionality. The regulatory status of mobile apps and wearable devices becomes less clear, however, with the addition of functionality and claims beyond mere activity tracking and monitoring envisioned in the MMA guidance. The tiny accelerometers and sensors found in cell phones and wearable devices that measure movement and speed (microelectromechanical, or MEMS, devices) are becoming increasingly sophisticated, and innovative companies are developing novel health applications using these tiny devices.

CDRH has encouraged companies to contact them with questions about mobile apps, the level of risk and whether premarket notification is required. Manufactures of cutting-edge health apps or wearable devices may want to consider engaging CDRH on the critical issues that affect their product's regulatory status to ensure that they are aligned with the FDA. Getting alignment early in the process can inform the controls that need to be in place during product design and production, as described above.

The FDA Will Continue to Assert its "Device" Authority Over Low-Risk Technology, Even Where the Agency Acknowledges Regulation is Not Necessary to Ensure Patient Safety

The FDA will continue to claim broad authority over software under its authority to regulate medical devices under the Federal Food, Drug and Cosmetic Act, while at the same time stating that it will not actively regulate those devices. The draft guidance makes clear that the FDA considers MDDS, medical image storage and medical image communication products to be medical devices under the FDCA, just ones that it chooses not to regulate.

The FDA took a similar approach in its MMA guidance. In the MMA guidance, the FDA identified many mobile apps as "devices" that are subject to regulation. It then carved out a small subset of products with limited functionality that the FDA will not actively regulate. While the approach allows the FDA to remain flexible to react to potential product issues in the field, the approach leaves manufacturers uncertain as to the regulatory status of their devices.

Practical Considerations May Hamper the FDA's Assertion of Broad Jurisdiction Over Rapidly Evolving Software

The draft guidance comes on the heels of the FDASIA Health IT Report, which recommends a narrowly tailored approach to FDA regulation of health IT.[1] The report recognizes that pervasive regulation is not the most sensible way to govern health IT, which is rapidly evolving. Instead, the report advocates an approach that leverages industry standards and best practices.

The FDASIA report reflects a balance of the FDA's intention to regulate health IT under the medical device provisions of the FDCA and the practical limitations on the agency's ability to review the volume of premarket submissions it could receive. It also may reflect a consideration of the resources the FDA has available to conduct inspections of software developers if health IT products were to be actively regulated. These resource constraints, as well as the risk calculation, may play into future determinations of which mobile health apps or wearable devices the FDA will choose to actively regulate.

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