FDA Issues Draft Guidance Regarding Mobile Medical "Apps"

On July 19, 2011, the US Food and Drug Administration (FDA) published a Draft Guidance on Mobile Medical Applications (the Draft Guidance).[1] The Draft Guidance is the latest in a growing list of FDA rules and guidelines,[2] which signal FDA's intent to actively regulate and monitor mobile medical and health technology. The Draft Guidance defines a distinct subset of FDA-regulated software, called "mobile medical applications" or "mobile medical apps", and describes FDA's regulatory approach and requirements for such devices. While the Draft Guidance is a significant step in defining the scope of regulatory oversight for mobile medical apps, FDA acknowledges that the line between an FDA-regulated health app and one that is not regulated by FDA can be subtle and unclear. FDA is therefore encouraging developers and manufacturers to evaluate their products on a case-by-case basis and to seek advice from FDA where appropriate. The agency is also requesting public comment on how to provide greater clarity regarding its regulatory approach for mobile apps.

Background

The use of mobile technology has become an integral part of modern life. Software developers, medical device manufacturers, technology companies, and health care providers are developing innovative solutions that leverage the portability provided by mobile platforms such as smart phones, tablet computers, and personal digital assistants to provide greater access and efficiency in the delivery of medical and health-related services. Many of these platforms and solutions perform functions that are similar to traditional medical devices.

1 Food and Drug Administration, Draft Guidance for Industry and Food and Drug Administration Staff—Mobile Medical Applications (2011), *available at*: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263280.htm. The official notice was published in the Federal Register on July 21, 2011. *See* 76 Fed. Reg. 43689 (Jul. 21, 2011).

2 For example, FDA issued a Final Rule on Medical Device Data Systems (MDDS) on February 15, 2011. Our Advisory on the MDDS Rule is *available at*: http://www.arnoldporter.com/public_document.cfm?id=17295&key=8F3.

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The Federal Food, Drug, and Cosmetic Act (FDCA) defines a medical device as an instrument, apparatus, or implement that is intended to: (1) aid in the diagnosis, cure, mitigation, treatment, or prevention of disease or other conditions, or (2) affect the structure or function of the body.[3]

FDA has determined that, in many circumstances, software and mobile applications that meet the statutory definition of a medical device should be regulated as such. The agency has recognized, however, that not every software solution or application that involves a health or medical function is a medical device. It has also acknowledged that certain applications that fall within the medical device definition may require less regulatory oversight, if they do not pose the same degree of risk to public health and safety as other currently regulated medical devices. The Draft Guidance describes the proposed framework for regulating a subset of medical apps that perform or enable critical diagnostic and treatment activities.

Definitions and Terms of Art

The Draft Guidance describes the following terms and concepts that are important to determining which mobile apps FDA intends to regulate, as well as which persons or entities will be considered "manufacturers" of such applications:

- **A Mobile Platform** is defined to be any off-the-shelf commercial handheld platform, whether or not it has wireless connectivity capabilities. Examples include personal digital assistants, tablet computers, and smart phones.
- **A Mobile Application** is a software application that can be used on a mobile platform or a web-based software application that is tailored to a mobile platform but is executed on a server.
- **A Mobile Medical Application (MMA)** is a mobile application that meets the statutory definition of a medical device *and* either is used as an accessory to a regulated medical device or transforms a mobile platform into a regulated medical device.

  The Draft Guidance lists several examples of MMAs, including, but not limited to, apps that: (1) allow healthcare providers to view MRIs or other medical images on a mobile platform; (2) analyze or interpret medical data, such as electrocardiograms, or (3) monitor vital signs and other physiological information through a mobile platform.

  It also lists several examples of apps that *are not* considered MMAs, including: (1) mobile reference materials and textbooks; (2) systems used *solely* to log, record, or make suggestions related to general health and wellness (for example, dietary tracking logs, exercise suggestions, or appointment reminders); (3) automated general office operations and electronic health records; and (4) general personal aids (e.g., applications that use the mobile platform as a magnifying glass or mirror for general use).
- **A Mobile Medical Application Manufacturer** is defined to include anyone who initiates specifications, designs, labels, or creates a software system or application, whether in whole or from multiple software components.[4]

  Manufacturers include entities or persons who create, design, develop, label, or modify a software system to function as an MMA, provide mobile functionality through a website or web service, or initiate specifications or requirements for an MMA. Entities or persons who *exclusively* or *solely* distribute a mobile medical application *are not* considered mobile medical application manufacturers. Examples include distributors of mobile platforms and online retailers of apps who do not engage in manufacturing activities.

3 FDCA § 201(h), 21 U.S.C. § 321(h).

4 Distributors of MMAs are expected to cooperate with manufacturers to facilitate necessary corrections or removals.

FDA's Proposed Regulatory Approach

FDA has defined four broad categories of MMAs that it plans to regulate under the traditional framework for medical devices. Under the traditional framework, FDA classifies devices according to their level or risk and requires devices to meet "general controls" to ensure safety and effectiveness. General controls include, among other things: (1) registration and listing;[5] (2) implementation of a quality system;[6] (3) product labeling requirements;[7] adverse event reporting;[8] and reporting of corrections and market removals.[9] Certain MMAs may be subject to "special controls,"[10] such as device-specific technological or performance standards, that FDA may require for a particular device type.

The Draft Guidance suggests that most MMAs will be regulated as either Class I devices, which generally are exempt from premarket review, or as Class II devices, which generally require a 510(k) clearance before they can be commercially distributed in the US. FDA has not ruled out the possibility that some MMAs may be Class III devices, which are subject to the more stringent premarket approval (PMA) process.

The four categories of mobile apps that FDA plans to regulate are:

- **Applications that Display, Store, or Transmit Patient-Specific Medical Device Data in its Original Format—**These applications meet the regulatory definition of an MDDS, and are regulated as such under FDA's device-classification regulation, 21 CFR § 880.6310. MDDS products are classified as Class I, general controls medical devices, which requires manufacturers to register and list their products and to conform to quality systems as well as provide FDA with adverse event reporting.
- **Applications that Control the Intended Use, Function, Modes, or Energy Sources of a Connected Medical Device—**These applications are considered an accessory to the connected device and will be required to meet the controls applicable to that device. For example, if the connected device is a Class II medical device, the manufacturer of the application would also need to meet the Class II requirements, most notably, the premarket notification (510(k)) requirement, in addition to the general controls.
- **Applications that Transform or Make a Mobile Platform a Regulated Medical Device—**These applications are required to meet the controls that would apply to the resulting medical device if it were manufactured independent of the mobile platform. For example, an MMA that uses a mobile platform to act as an electronic stethoscope would be required to meet the requirements for electronic stethoscopes, which are regulated as Class II devices under 21 CFR § 860.1875(b).
- **Applications that Create Alarms, Recommendations, or New Information by Analyzing or Interpreting Medical Device Data—**These applications are considered an accessory to the medical device and are regulated according to that device's classification. Importantly, FDA states that this does not necessarily apply to applications that analyze, process, or interpret medical data from more than one medical device. FDA intends to issue separate guidance to address such applications.

The Draft Guidance does not address issues such as wireless safety considerations for MMAs, classification or premarket submission requirements, software used to implement quality systems, or the implementation of

5 21 CFR Part 807.
6 21 CFR Part 820.
7 21 CFR Part 801.
8 21 CFR Part 803.
9 21 CFR Part 806.
10 Special controls may include certain technological specifications set by national or international standard-setting organizations such as the American National Standards Institute (ANSI) or Underwriters Laboratories (UL).

quality system requirements for MMAs. FDA intends to address these issues in future guidance.

Enforcement Discretion for Certain Office Automation and Health Management Apps

For the foreseeable future, FDA intends to exercise enforcement discretion with respect to certain mobile applications that meet the definition of a medical device, but do not qualify as an MMA. These include certain mobile applications that "automate common medical knowledge available in medical literature"[11] to allow individuals to self-manage their disease or condition. Other examples include mobile apps that automate certain tasks that aid a healthcare provider's diagnosis or treatment by logging, tracking, or storing personal data, but are not necessarily critical to patient diagnosis, treatment, or safety.

Although FDA does not plan to enforce the device requirements for such applications, the Draft Guidance states that MMAs can "transform" a mobile platform into a regulated medical device through the use of auxiliary software, attachments, or devices that perform or enable medical device functions. Because certain office automation or health awareness apps may be used with regulated medical devices, or marketed as part of an integrated system that includes a medical device, FDA is encouraging manufacturers to evaluate both stand-alone non-MMA products and the resulting integrated solution to determine whether the entire system or solution transforms an otherwise unregulated app into an MMA.

The agency also expressed concern that design defects and validation failures for unregulated mobile apps can lead to treatment and diagnostic errors. FDA therefore strongly recommends that manufacturers of such applications follow the medical device quality systems regulations. FDA will continue to monitor these types of applications to determine whether additional regulation is necessary in the future.

Issues About Which FDA Seeks Public Comment

FDA is actively seeking public comment on the following issues:

- **Accessories—**FDA has historically required medical device accessories to meet the requirements associated with the device with which the accessory is used. In the Draft Guidance, however, FDA acknowledges that this approach may not be well-suited for MMAs because some MMAs can potentially perform a range of functions for a variety of devices that are subject to different classifications and requirements. FDA is therefore specifically seeking comments on how to regulate MMAs that are accessories to other regulated medical devices to assure safety and effectiveness. The outcome of this process may have important implications for mobile platforms, such as smart phones which could function as an accessory, a mobile platform, or an MMA, depending on the regulatory status and intended use of apps or accessories that work with or through the phone.
- **MMAs for Multiple Devices—**FDA is also interested in public input into how it should classify applications that integrate and analyze data from multiple medical devices. For example, the agency notes that in some cases, integration of data from several Class I devices may result in providing information regarding an acute medical condition, for which FDA believes additional (more than Class I) controls should apply. In other cases, an application may integrate information from several Class II or Class III devices and provide simple informational results that present very low public health risks, making the higher classification of the application inappropriate.

11 *See* Draft Guidance, fn. 13.

The 90-day comment period for the Draft Guidance, which ends October 21, 2011, provides an opportune time for manufactures or marketers of mobile applications to assist FDA in refining and developing its regulatory approach to these products.

We hope that you have found this advisory useful. If you have any questions about how the Draft Guidance applies to you, or if you would like assistance in providing comments to FDA regarding the Draft Guidance, please contact your Arnold & Porter attorney or:

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