

FDA Issues Final Guidance on Mobile Medical Apps

On September 23, 2013, the U.S. Food & Drug Administration (FDA or the Agency) issued its final Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications (Guidance).¹ The Guidance is the result of a two-year process, which started when FDA issued its Draft Guidance for Industry and Food and Drug Administration Staff - Mobile Medical Applications in July 2011 (Draft Guidance). The final Guidance is one component of a multi-tiered, multi-agency legislative mandate² to develop a comprehensive regulatory framework for health information technology (Health IT). The Guidance clarifies that FDA does not intend to regulate most general health and wellness apps, but instead intends to focus on a subset of mobile apps that have the same functions and characteristics as regulated medical devices. It also provides an overview of medical device requirements that apply to Mobile Medical Applications (MMAs) and the Agency's recommendations for manufacturers and developers. By declining to regulate a variety of apps that support general health and wellness, patient education, and general disease management, FDA has paved the way for greater innovation of mobile technology designed to meet broader healthcare goals, such as improving coordination of care, increasing patient engagement, and improving the overall quality of care. While the Guidance is one of the more significant examples of FDA deregulation in recent years, it is only an initial step in a broader regulatory strategy that hopefully will provide greater clarity regarding the regulatory status of other Health IT products, such as stand-alone clinical decision support (CDS) devices.

Background

Manufacturers and developers are creating mobile apps that leverage the portability of mobile platforms, such as smart phones and tablet computers to provide more efficient medical care. Many of these apps relate to health and medicine, but not all of them are medical devices. The Federal Food, Drug, and Cosmetic Act (FFDCA) defines a medical device, in part, as an instrument, apparatus, or implement that: (1) is intended for use in the diagnosis,

1 The official notice was published in the Federal Register on September 25, 2013. See 78 Fed. Reg. 59038 (Sept. 25, 2013). The Guidance is available from FDA's website at: <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf>.

2 In response to questions and concerns from manufacturers and developers, Congress added Section 618 to the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), which required FDA to finalize the Draft Guidance and publish a report describing a regulatory framework for Health IT, including mobile apps. Consistent with this mandate, FDA, the Office of the National Coordinator for Health IT (ONC), and the Federal Communications Commission (FCC) established a FDASIA Working Group under ONC's Health IT policy Committee. The Working Group includes industry and other stakeholders. Under FDASIA, the Working Group must publish the report by January 2014.

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cure, mitigation, treatment, or prevention of disease or other conditions; or (2) affects the structure or function of the body.³ FDA's 2011 Draft Guidance put industry on notice that the Agency intended to regulate mobile apps that perform medical device functions, but it did not provide concrete information regarding the regulatory status of health and wellness apps that merely support patient care. The risk-based regulatory strategy described in the final Guidance provides greater clarity and also provides a window into the future of Health IT regulation.

Definitions and Terms of Art

The Guidance describes the following terms and concepts:

- **Mobile Platform** - a commercial off-the-shelf handheld computing platform, whether or not it has wireless connectivity capabilities. Examples include PDAs, tablets, and smart phones.
- **Mobile Application** - a software application that can be used on a mobile platform or a web-based software application that is tailored for use on a mobile platform but is executed on a server.
- **Mobile Medical Application** - 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.
- **Mobile Medical Application Manufacturer** - an entity or person who initiates specifications, designs, labels, or creates a software system or application, whether in whole or from multiple software components.

For example, the Guidance states that “when a developer (i.e., an entity that provides engineering, design, and development services) creates a mobile medical app from the specifications that were initiated by the ‘author,’ the ‘author’ who initiated and developed specifications for the mobile medical app is considered the ‘manufacturer.’”⁴ It also notes that persons who create an MMA or software system that allows users to access a medical device function through a website subscription (i.e., software

as a service) are considered manufacturers.⁵ In addition, a licensed healthcare professional who develops an MMA solely for use in his/her professional practice is not considered a manufacturer for purposes of the medical device requirements, but a healthcare professional who markets, labels, or promotes the MMA for use by other practitioners or patients is considered a manufacturer.⁶

Entities or persons who exclusively or solely distribute an MMA are not considered manufacturers. Examples include distributors of mobile platforms and online retailers of apps who do not engage in manufacturing activities. The Guidance also clarifies that manufacturers of smartphones, tablets, and other mobile platforms are not considered MMA manufacturers when they market platforms for general use. When an MMA runs on a commercially available general use mobile platform, FDA treats the platform as a component of the MMA's intended use. This means that FDA will not regulate the smartphone or its manufacturer simply because an MMA runs on the manufacturer's smartphone, unless the smartphone itself is marketed as a regulated medical device. Practically speaking, this means that MMA developers need to consider the specifications and limitations of the platforms on which their apps will run. These considerations are relevant for important processes, such as design and development, contracting, pre-market risk-management, and post-market compliance.

FDA's Regulatory Approach for MMAs

The Guidance clarifies that FDA will only regulate a small subset of mobile apps that function as medical devices and pose greater risks to patients. This means that the core functions and intended use of the app itself, rather than the platform, are most relevant to determining whether an app is a medical device. If a mobile app transforms a platform into a medical device or acts as an accessory and is the kind of functionality FDA already regulates, FDA will regulate that app according to the classification regulations and requirements that apply to other devices in that category.

³ FFDCFA § 201(h), 21 U.S.C. § 321(h).

⁴ Guidance at 9.

⁵ *Id.* at 10.

⁶ *Id.* at 11.

To determine whether an app is intended for use as a medical device, FDA reviews the app's specifications and functions, as well as labeling claims, advertising materials, and oral or written statements by manufacturers or their representatives as to the app's intended use.⁷ For example, the Guidance explains that a mobile app that creates a light emitting diode (LED) would not be an MMA if the manufacturer markets the app to illuminate objects generally. If, however, the manufacturer markets the app as a light source for use in medical or clinical examinations, the app would be an MMA because it performs the same function as currently regulated medical devices, such as ophthalmoscopes.⁸ This approach necessarily assumes that mobile apps which provide the same or similar functions as regulated medical devices pose the same or similar risks as those devices if they fail to function as intended. Accordingly, FDA will require manufacturers and developers of MMAs to adhere to the regulatory requirements that apply to traditional medical devices. These include, among other things: (1) Registration and listing;⁹ (2) Implementation of a Quality System;¹⁰ (3) Product labeling requirements;¹¹ (4) Adverse event reporting;¹² and (5) Reporting of corrections and market removals.¹³ Certain types of MMAs may be subject to other device-specific technological or performance standards.¹⁴

The Guidance lists the following three categories of MMAs that FDA intends to regulate and provides examples in Appendix C:

1. *Apps that Connect to a Medical Device to Control the Device or Display, Store, Analyze, or Transmit Patient-Specific Medical Device Data.* FDA treats many of these apps as accessories or extensions of the medical devices to which they are connected

⁷ *Id.* at 8 (citing 21 CFR § 801.4 (FDA's regulations on Intended Use)).

⁸ *See id.*

⁹ 21 CFR Part 807.

¹⁰ 21 CFR Part 820.

¹¹ 21 CFR Part 801.

¹² 21 CFR Part 803.

¹³ 21 CFR Part 806.

¹⁴ Special controls may include certain technological specifications set by national or international standard-setting organizations, such as the International Standards Organization (ISO), International Electrotechnical Commission (IEC), and American National Standards Institute (ANSI).

(including wireless connections). Therefore, in most cases, the apps will be subject to the regulatory requirements that apply to the underlying or connected devices. Examples include: (1) *Medical Device Data Display Apps* that display patient-specific data from bedside monitors, display previously stored EEG waveforms, connect to and/or display data from a Picture Archiving and Communication System (PACS) service, and display medical device data for active patient monitoring; (2) *Medical Device Control Apps* that control device functions, such as inflation and deflation of a blood pressure cuff through a smartphone, or control delivery of insulin or other drugs; and (3) *Medical Device Data System (MDDS)¹⁵ Apps* that display, store, or transmit medical device data in their original form without controlling or altering the functions of any connected device. MDDS apps appear to differ from medical device data display apps in that the former do not alter the data or their presentation.

2. *Apps that Transform a Mobile Platform into a Regulated Medical Device.* These apps use attachments, display screens, sensors or similar components to perform the functions of regulated medical devices. Examples include: (1) apps that allow a smartphone to function as a blood glucose meter by attaching a blood glucose strip reader through a USB or other port; (2) apps that measure and store ECG signals through the use of electrodes or sensors; (3) apps that use a built-in accelerometer to collect motion information for monitoring sleep apnea; and (4) apps that use either internal or external sensors to function as electronic stethoscopes.
3. *Apps that Perform Patient-Specific Analysis and Provide Patient-Specific Diagnosis, or Treatment Recommendations.* These apps use patient-specific parameters to perform "sophisticated" analysis or interpret data from another medical

¹⁵ MDDS products are Class I devices that facilitate the passive transfer, storage and display of data derived from medical devices. *See* 21 CFR § 880.6310.

device. Examples include: (1) apps that use patient-specific information to calculate dosage or create a dosage plan for radiation therapy; (2) Computer Aided Detection (CAD) software; (3) image processing software; and (4) radiation therapy treatment planning software. Presumably, FDA used the word “sophisticated” to differentiate these apps from other unregulated apps that use patient-specific data to provide general education or symptom tracking without providing specific treatment recommendations or diagnoses.

FDA’s Approach for Unregulated Mobile Apps

The Guidance describes two categories of unregulated apps: (1) apps that are not medical devices, and therefore are not subject to FDA’s jurisdiction; and (2) mobile apps that provide health or medical functions that FDA does not intend to regulate. Appendix A of the Guidance lists examples of apps that are not medical devices. These include electronic textbooks, apps that provide archived copies of healthcare provider training videos, and apps that support clerical and administrative functions, such as billing, claims processing, and appointment reminders. The second category of unregulated apps includes those that may meet the legal definition of a medical device or an MMA, but are subject to FDA’s “enforcement discretion” because the Agency believes that they are low risk. This means that FDA will not enforce the FFDCRA requirements for these apps, but the Agency could decide to impose these requirements in the future based on new information or new safety data. Although manufacturers are not required to follow the Quality System regulation for these apps, the Agency “strongly recommends” that manufacturers incorporate Quality System principles in the design and life-cycle management plan for these products.

The Guidance lists the following five categories of unregulated mobile apps and provides examples in Appendix B:

1. *Disease Management Apps.* These apps support adherence to treatment regimens, medications, and disease management plans by providing behavioral coaching and information to patients with specific diseases. Examples include: (1) apps that coach

patients with conditions such as cardiovascular disease, hypertension, diabetes or obesity, and promote strategies for maintaining health; and (2) medication reminder apps that provide alerts to patients and healthcare providers based on pre-determined medication dosing schedules.¹⁶ FDA believes that these apps can be used safely by a patient without active oversight of a medical professional. Even when these apps are used for serious conditions that require professional medical care, FDA believes they are low risk because they are not intended to replace the advice and care of a medical professional.

2. *Patient-Specific Health Information Tracking Apps.* These apps allow patients to organize and track their information related to specific diseases, including chronic diseases, such as obesity, anorexia, arthritis, diabetes, and heart disease. They allow patients to input data, such as blood pressure measurements, drug intake, diet, weight, daily routine, or emotional state. These apps do not provide any recommendations and are not intended to alter a previously prescribed treatment or therapy, and thus FDA considers them to be different from regulated MMAs that provide disease and patient-specific treatment recommendations.
3. *Health Education and Care Coordination Apps.* These apps provide what FDA describes as “contextually-relevant information” by matching patient-specific inputs regarding diagnosis, treatment, allergies, and symptoms to clinical reference information, such as recognized and established medical sources and texts or specialists in a particular geographic area. Examples include apps that provide standard treatment guidelines for common illnesses such as the flu or apps that allow users to look up drug-drug interaction and drug-allergy information.

¹⁶ FDA currently regulates this type of medication reminder app under the product code NXQ, which applies to “daily assist devices” under 21 CFR § 890.5050.

4. *Apps that Facilitate Patient and Healthcare Provider Communication.* These apps include videoconferencing portals or use a built-in camera on a mobile platform to help the user document or transmit photos (e.g., pictures or video of skin lesions or wounds) to supplement verbal descriptions.
5. *Apps that Perform Basic Clinical Calculations.* These apps automate simple medical calculations that clinicians would otherwise perform manually. The information supporting the underlying algorithms is derived from and available in medical sources and texts, and the Guidance describes these as calculations that are taught in medical schools. Examples include calculators for: (1) Body Mass Index (BMI); (2) Mean arterial pressure; (3) APGAR score; and (4) NIH Stroke Scale.
6. *Apps that Facilitate Interaction with Electronic Health Records (EHRs).* These apps allow patients to download and view information in their EHR. They are intended solely for information and record-keeping purposes.

Key Take-Aways

The Guidance provides a level of transparency that is sometimes lacking in Agency Guidance, but gives rise to other questions. For instance, the Guidance does not clarify how FDA intends to deal with mobile apps that have received a premarket clearance (510(k)) that is no longer relevant or necessary in light of the clarification provided in the Guidance. In addition, while the Guidance addresses FDA's role in regulating mobile apps, it does not address how FDA plans to coordinate with other regulators, such as FCC, ONC, and FTC, that also have jurisdiction over certain aspects of mobile apps. The Guidance also does not resolve questions regarding the regulatory status of certain stand-alone CDS tools. Further, although the Guidance provides high-level recommendations

regarding the implementation of medical device requirements for MMAs, the Agency may need to provide more targeted guidance to address the potential regulatory challenges and nuances associated with implementation of Quality System, adverse event, and recall procedures for mobile apps. Finally, the Guidance does not specify whether FDA will stay or delay enforcement of such requirements for a specific period of time to allow manufacturers and developers to comply with applicable requirements, although past practice suggests that FDA will take a measured approach to enforcement for the immediate future. Despite these and other unresolved issues, the Guidance is a step in the right direction that reflects a significant effort to strike an appropriate balance between promoting innovation and protecting the public health.

We hope that you have found this advisory useful. If you have any questions about how the Guidance applies to you, please contact your Arnold & Porter attorney or:

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