Introduction

The past decade has witnessed rapid advancement in telecommunication and computer technologies. The smartphone is one result of that technological development and has been adopted by hundreds of millions of people worldwide. Innovators in the medical device industry quickly recognized the potential to use smartphones to expand the capabilities of healthcare professionals via mobile medical applications (“apps”) resident on these devices. These apps raise unique challenges for regulation by the Food and Drug Administration (FDA).


The guidance defines mobile apps that constitute medical devices. Next, FDA indicates the kinds of medical mobile apps for which the Agency will exercise “enforcement discretion,” meaning it will not enforce the applicable requirements of the Food, Drug, and Cosmetics Act. It then outlines regulatory requirements and closes with appendices focusing on examples to illustrate the principles of the guidance.

Review of FDA’s Draft Guidance on Mobile Medical Apps

Definition of a Medical Device

Section III of the draft guidance is devoted to definitions.

Mobile applications (mobile apps) are defined as software run on a mobile platform such as a smartphone (with or without wireless functionality) or web-based software run on a server, but designed to communicate with a mobile platform.

A mobile app is a medical device if it meets the following definition:

...an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- 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, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.”
Appendix A of the guidance gives examples of mobile apps that are not medical devices. Appendix B provides examples of mobile medical apps for which FDA intended to exercise enforcement discretion. Appendix C gives examples of medical mobile apps on which FDA will focus its regulatory oversight.

Companies that sell apps need to keep in mind that the intended use is not determined solely by the indications for use statement (or intended use statement) that the company provides. As stated in 21 Code of Federal Regulations (CFR) 801.4, intended use may be shown by labeling claims, advertising materials, or oral or written statements by manufacturers or their representatives.

To illustrate the issue, consider an app that measures heart rate (sensed by a chest strap) and can both display the data on the smartphone and transmit the data to a remote computer server. Let us assume the app shows the following statement on the smartphone display whenever the app is used:

This app is intended to monitor heart rate for use as a health and fitness tool.

On the basis of this information, the app is not a medical device. Heart rate monitoring is a common tool for fitness training and the intended use statement clearly makes no medical claims.

But if the company provides sales and marketing literature that suggests the heart rate information can be sent to a physician or other healthcare professional, FDA can determine that the app is now a medical device.

Now consider a similar app, one which can display and transmit electrocardiographic (ECG) tracings and provide alarms when arrhythmia is detected. Let us assume the app displays the following statement when turned on:

This app is for monitoring heart activity for use as a health and fitness tool and is not for medical use.

FDA will consider the app to be a medical device in spite of the above statement, since arrhythmia detection has well-known medical utility, is not commonly used for health and fitness, and requires the skills of a medical professional for correct interpretation.

A company can sometimes avoid regulation as a medical device by disavowing medical use, but when it is clear that the app serves as a medical device, such disavowals are ineffective.
Section III, E. defines a “mobile medical app manufacturer,” which is very helpful as responsibilities are often less clear for apps than for physical medical devices. FDA states that:

...mobile medical app manufacturers include a person or entity that:

- Creates, designs, develops, labels, re-labels, remanufactures, modifies, or creates a mobile medical app software system from multiple components.
- Initiates specifications or requirements for mobile medical apps or procures product development/ manufacturing services from other individuals or entities (second party) for subsequent commercial distribution.
- Creates a mobile medical app and hardware attachments for a mobile platform that are intended to be used as a medical device by any combination of the mobile medical app, hardware attachments, and the mobile platform;
- Creates a mobile medical app or a software system that provides users access to the medical device function through a website subscription, software as a service, or other similar means.

**Devices Subject to FDA Regulation**

Section V-A and Appendix C of the guidance detail which apps FDA will regulate. FDA discusses its plans to regulate three categories of mobile medical apps as summarized below.

- Mobile apps that are an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s) or displaying, storing, analyzing, or transmitting patient-specific medical device data. One example would be an app used for display of data from bedside monitors.
- Mobile apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices. An example would be an attachment of a blood glucose strip reader to a mobile platform to function as a glucose meter.
- Mobile apps that become a regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations. These types of mobile medical apps are similar to or perform the same function as those types of software devices that have been previously cleared or approved. One example would be a mobile app that uses patient-specific parameters to create a dosage plan for radiation therapy.

“A company can sometimes avoid regulation as a medical device by disavowing medical use, but when it is clear that the app serves as a medical device, such disavowals are ineffective.”
“FDA cannot anticipate the nature of every future mobile medical app and small details in a product’s design and/or intended use can have a dramatic effect on how the Agency decides to regulate that particular device.”

**Devices Subject to FDA Enforcement Discretion**

As per Section V-B and Appendix B of the guidance, FDA intends to exercise enforcement discretion for medical mobile apps that:

- Help patients (ie, users) self-manage their disease or conditions without providing specific treatment or treatment suggestions;
- Provide patients with simple tools to organize and track their health information;
- Provide easy access to information related to patients’ health conditions or treatments;
- Help patients document, show, or communicate potential medical conditions to health care providers;
- Automate simple tasks for health care providers; or
- Enable patients or providers to interact with Personal Health Record (PHR) or Electronic Health Record (EHR) systems.

On June 11, 2014, FDA posted “Examples of Mobile Apps for Which the FDA Will Exercise Enforcement Discretion” on its website. This expands the list of devices subject to enforcement discretion:

[http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/ucm368744.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/ucm368744.htm)
Discussion

FDA’s guidance provides valuable information for companies developing mobile apps, including mobile medical apps. Having said this, the industry needs to keep in mind the caveat included in the black box under the title of the guidance:

“This guidance represents the Food and Drug Administration’s (FDA’s) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

An FDA guidance document can only point you in the right direction. FDA cannot anticipate the nature of every future mobile medical app and small details in a product’s design and/or intended use can have a dramatic effect on how the Agency decides to regulate that particular device.

In addition, FDA’s own understanding of how best to regulate mobile medical apps will grow and evolve over time, as has the Agency’s approach to the regulation of countless older technologies. The pre-submission (formerly “pre-IDE”) process is one means of obtaining a better understanding of FDA’s expectations for your specific mobile medical app.”
Resources

Sept 25, 2013 FDA guidance on mobile medical apps:

FDA “It Has Come to Our Attention” letter to app developer Biosense Technologies (uChek Urine Analyzer) requesting FDA clearance of the analyzer app:
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm353513.htm (5/21/13)

Some industry responses:

http://www.mddionline.com/blog/devicetalk/wanted-fda-app-enforcement (3/13/13)


http://www.fdanews.com/qmn/newsletter/article?issueId=16857&articleId=155944 (5/31/13)

http://www.mondaq.com/unitedstates/x/244126/food+drugs+law/FDA+Letter+To+Mobile+App+Developer+Signals+Regulatory+Scheme (6/10/13)
“Everything we do must be in our clients’ best interests.”

Ted Gorski, NAMSA Founder

Throughout our 46-year history NAMSA has assisted thousands of companies around the world in translating their great ideas into medical products for the patients who need them most.

Our regulatory strategy, testing services, quality system consulting, clinical research, and sterilization products support the medical product development process. With NAMSA’s MRO™ approach to testing and consulting, you maintain project control while gaining the benefit of on-demand external support: extending your in-house capabilities, accessing specialized expertise at exactly the right time, or having a completely outsourced development process.