# The U.S. FDA's Regulation and Oversight of Mobile Medical Applications

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As smart phones and portable tablet computers become the preferred computing platform for millions of people, developers are creating a growing number of mobile applications (commonly referred to as "apps") addressing health, wellness and medical issues. According to one report, there are more than 13,000 health and fitness mobile apps already available for consumers and another 5,000 apps intended for use by medical professionals.[1] Available mobile medical apps range from software that tracks weight and body-fat percentages through a WiFi enabled scale, to sophisticated blood pressure and glucose level monitoring applications.

However, confusion remains among medical device manufacturers and software developers regarding the regulatory oversight applicable to mobile medical apps. Although more than 100 mobile medical apps have already been approved by the U.S. Food and Drug Administration (FDA), many software developers are simply unaware that their apps are potentially subject to regulatory approval. Still others are unclear about the approval process itself and the steps necessary to obtain approval. This confusion can result in the marketing of mobile medical apps that can unknowingly expose consumers to health and safety risks, and potentially subject software developers to product recalls and other federal enforcement actions.

This UL white paper discusses the FDA's current regulation and oversight of medical software applications used with mobile devices. The paper first discusses the defining characteristics of mobile medical apps, and reviews potential safety issues associated with their use. The paper then describes the regulatory requirements and approval process generally applicable to mobile medical apps in the U.S. The white paper concludes with recommendations for developers of mobile medical apps seeking to achieve regulatory compliance for their products.

## What Are Mobile Medical Applications?

Smart phones, tablet computers and other mobile platforms have transformed the professional and personal lives of millions of people around the world. But this transformation would not have been possible without the software applications that convert mobile platforms into powerful tools that can support the delivery of healthcare services. Global revenue from the sale of mobile apps was projected to reach $25 billion in 2013, and major online mobile app retail outlets operated by Apple and Google reportedly offer more than 700,000 different mobile apps apiece.[2]

The healthcare industry has embraced the use of mobile platforms and mobile apps as key elements in efforts to increase access to healthcare services, improve both personal wellness and patient outcomes and control growth in the cost of healthcare delivery. As a result, a growing number of mobile apps are expressly designed for use by healthcare professionals in connection with the diagnosis, treatment or monitoring of specific medical conditions in patients. These mobile medical apps can effectively transform a smart phone or tablet computer into a remote control mechanism for a medical device, a medical device accessory, or even into a medical device itself.

According to the U.S. FDA, a "mobile app" is a software application that can run on a mobile platform or a web-based software application for a mobile platform that is run on a computer server. A "mobile medical app" is either "intended to be used as an accessory to a regulated medical device," or "intended to transform a mobile platform into a regulated medical device." Mobile medical apps can be considered "medical devices" and subject to FDA oversight if they are "intended for use in the diagnosis or the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body." [3]

Today, mobile medical apps generally fall into one of the following three categories:

- **Apps that connect to a medical device to control its operation** — Often, mobile medical apps are used to control or adjust, either through wired or wireless connection, the operation of implantable medical devices or devices attached to or worn on a human body. Examples include apps used to control infusion pumps, blood pressure cuffs, implantable neuromuscular stimulators and cochlear implants.
- **Apps that receive, display or transfer patient-specific information from a connected medical device** — Mobile medical apps support remote monitoring of patients by displaying or monitoring information collected by a medical device attached to a patient through a wired or wireless connection. Examples include apps connected to bedside monitors that transfer patient data to a nearby nursing station in real-time.
- **Apps that transform a mobile device or platform into a medical device** — Mobile medical apps are sometimes used in conjunction with sensors or electrodes that are directly attached to a host mobile device or platform to measure or display specific body functions and characteristics. Examples include app/device combinations used as an electronic stethoscope, an electrocardiograph, an audiometer, or a skin resurfacing laser.

There are also certain types of mobile apps used in healthcare settings that are not generally categorized as medical devices and that are not generally subject to medical device regulations and requirements. This could include mobile apps that:

- Facilitate access by medical professionals to relevant reference information, such as electronic versions of standard medical reference books, dictionaries of medical terminology, scientific literature and articles.
- Support education and training initiatives, such as training videos, interactive diagrams, and computer-based simulations, as well as evaluations and quizzes used to assess the effectiveness of training.
- Facilitate patient access to general and patient-specific information, such as patient record portals, healthcare guides and other general educational material, and hospital and physician locators and contact information.

- Assist in the automation of general healthcare operations not related to the diagnosis or treatment of medical conditions, such as insurance claim data collection and processing, staff and patient scheduling, and business financial accounting.
- Enhance general productivity, such as email, voice mail and video communications, and audio recording and note-taking.

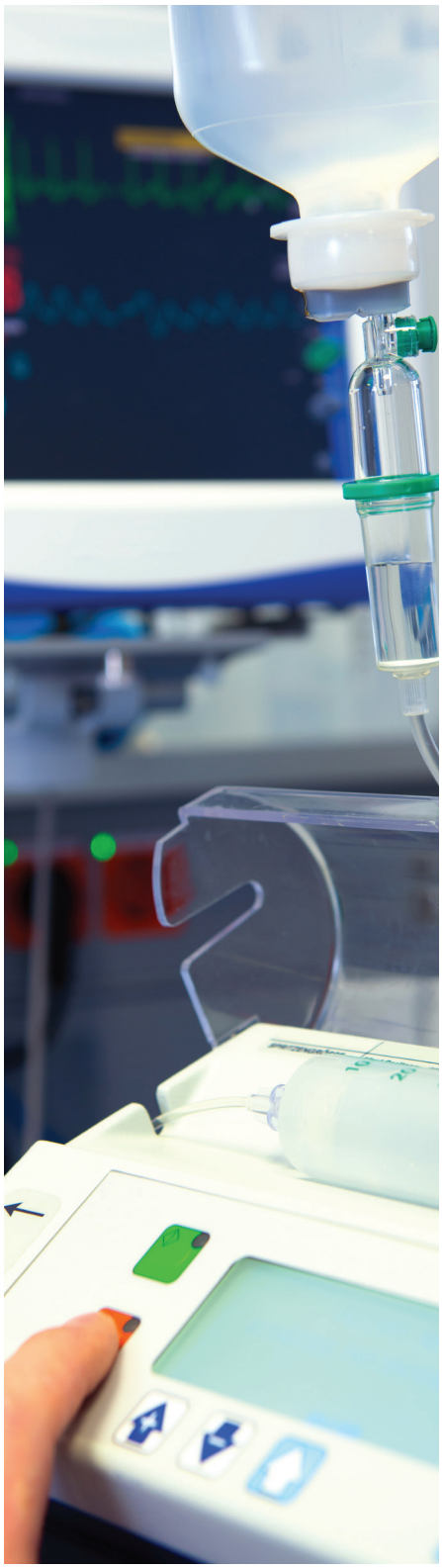
These and similar mobile apps that provide these functions are generally exempt from regulatory oversight. However, whether a mobile app or any device is a regulated medical device is ultimately determined by whether its intended use is for the diagnosis, treatment or prevention of a medical condition. For example, the intended use of a mobile app expressly designed to work on a tablet computer equipped to measure patient blood pressure is likely to be considered a mobile medical app and subject to regulatory oversight. On the other hand, a general use mobile app that provides illumination or magnification for general purposes might be used in some instances by a healthcare professional to examine a patient, but would probably not be considered a mobile medical app due to its broad application.

Under most medical device regulations and standards, it is the device manufacturer or developer that determines the intended use of a given device. IEC 60601-1, the international standard on the safety of medical electrical equipment, defines intended use as the "use for which a product, process, or service is intended according to the specifications, instructions and information provided by the manufacturer." [4] Similarly, under medical device regulations in the U.S., "intended use may be shown by labeling, claims, advertising materials, or oral or written statements by manufacturers or their representatives." [5]

## Safety Issues Specific to Mobile Medical Applications

Despite their potential benefits in healthcare, mobile medical apps can present a unique set of safety and effectiveness considerations relative to both patients and healthcare professionals using them. Some of these considerations include:

- **Connectivity** — The safety and effectiveness of many mobile medical apps depends on their connection with other medical devices or other software services. However, connectivity via wired and wireless technologies can be subject to unintentional interference or service interruptions, which can impact the performance of the system or devices monitored or controlled by a mobile medical app.
- **Data integrity** — Electromagnetic interference or single-event upsets can also result in the corruption of data being received or transmitted by a mobile medical app. When the integrity of data is compromised, it can potentially lead to the display of inaccurate information to the user, incorrect



operation of an attached system or device, an unintended initiation or termination of an intended operation, or the failure to initiate system operation altogether.

- **Data security** — Like other modern technologies, mobile medical apps are potentially vulnerable to cyber-attack, either through malware, virus-corrupted messages or other malicious activities. Cyber-attacks can not only impact patient safety, but can also result in breaches of data security that compromises patient privacy.
- **Updating protocols and procedures** — Most software products, including mobile medical apps, are subject to periodic updates to address coding errors or to provide security patches.
- **Display size and resolution** — Mobile platforms offer displays in a variety of sizes and resolutions. Mobile medical apps that have been optimized for a specific screen configuration may unintentionally distort information displayed on a device with a different resolution or dimensions. This distortion can result in the misinterpretation of data or other vital information.

In addition to these safety concerns, some mobile medical apps may utilize certain mobile platform features that support, extend or enhance their functionality. In such cases, patients and healthcare providers may be subject to other types of health and safety risks. For these reasons, developers should fully understand the interactions between their mobile medical app and its intended mobile platform, and assess this functional dependence for potential hazards or event sequences that could compromise either the intended use or the safety of the application.

## The FDA's Regulation of Mobile Medical Apps

The U.S. Food and Drug Administration (FDA) is the federal agency responsible for the regulation and oversight of medical devices, including mobile medical apps. Beginning with its "FDA Policy for the Regulation of Computer Products" issued in 1989, the FDA has carefully monitored the use of software products in connection with medical devices. Over the ensuing two decades, the agency has continuously modified its policies and regulatory procedures to keep pace with the widening use of software products in healthcare.

More recently, the FDA has recognized the emerging use of software applications on mobile platforms in the delivery of healthcare services. To provide assistance to software developers and agency administrative staff on the regulatory framework applicable to mobile medical apps, the FDA issued a draft of its guidance document for mobile medical apps in July, 2011. The agency reportedly received more than 130 comments on the draft guidance, and issued a final guidance document in September 2013.[6]

### Types of Mobile Medical Apps Subject to FDA Regulations

As outlined in the guidance document, the FDA intends to apply a risk-based approach to the regulation and oversight of mobile medical apps. Rather than attempting to regulate all mobile medical apps, the FDA will instead focus its attention primarily on a subset of apps that pose a greater risk to patients. Specific types of mobile medical apps subject to the agency's regulatory oversight include those that:

1. Serve as an extension to an existing medical device through a wired or wireless connection, and which control that device or which display, store, analyze or transmit patient-specific information generated by that device
2. Transform a mobile platform, such as a smart phone or tablet computer, into a regulated medical device through the use of attachments, display screens or sensors in order to create functionality similar to other regulated medical devices
3. Perform patient-specific analysis or provide patient-specific diagnosis or treatment recommendations.

According to the guidance document, certain other mobile medical apps that pose minimal safety risks are subject only to "enforcement discretion," meaning that the FDA will generally not enforce applicable requirements. The FDA has indicated that the following types of mobile medical apps are not currently subject to regulatory oversight:

- Apps that coach patients in managing their health in their daily environment
- Apps that provide patients with tools to organize and track health information
- Apps that allow easy access to

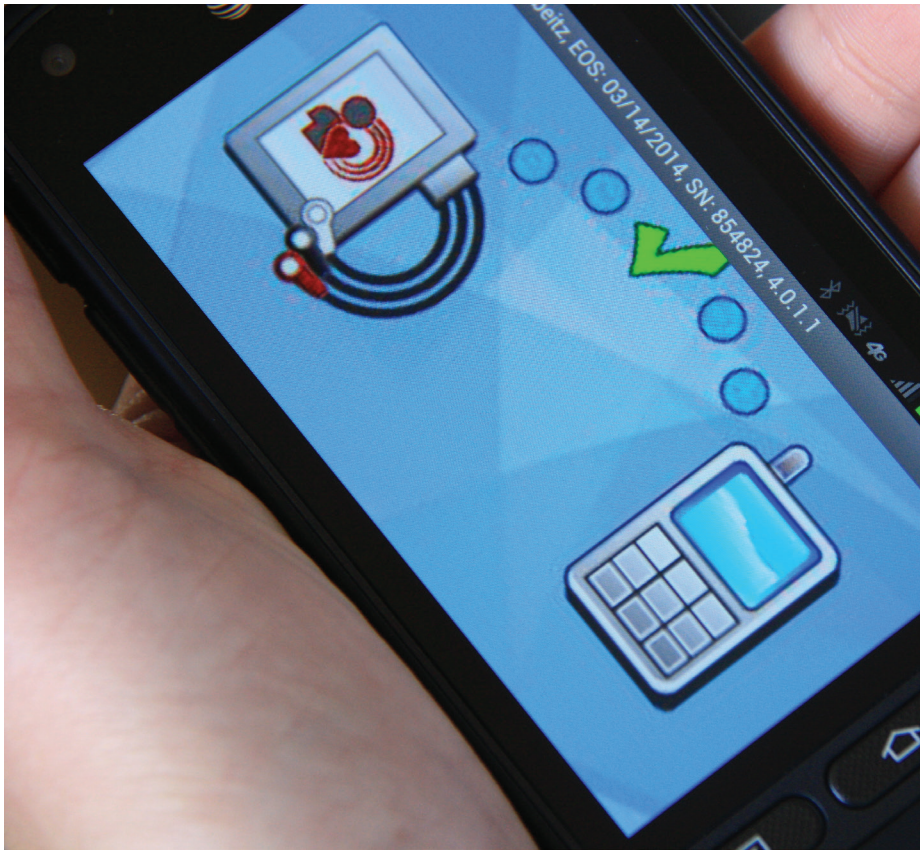
information related to health conditions or treatments

- Apps that help patients document, show or communicate information about their medical conditions to healthcare providers
- Apps that perform simple calculations, such as body mass index (BMI)
- Apps that facilitate patient interaction with patient health record (PHR) or electronic health record (EHR) systems

### FDA Regulations Applicable to Mobile Medical Apps

Appendix E of the FDA's guidance document provides an overview of the regulatory requirements applicable to all medical devices, including mobile medical apps.[7]
Specific requirements include:

- **Establishment registration and medical device listing** — Medical device manufacturers, include companies that develop mobile medical apps, must register with the FDA and provide a complete list of medical devices they market. A manufacturer's registration and device listing must be updated annually.
- **Premarket submission for approval or clearance** — Mobile medical apps developers must prepare and submit to the FDA a premarket submission (510(k)) application consistent with the risk classification appropriate to their app. Appendix D in the guidance document provides examples of specific medical devices and their assigned risk class.
- **Quality system regulation** — Developers of mobile medical apps must comply with the FDA quality system (QS) regulation, requiring them to implement systems and methods to design, produce and distribute devices that are safe and effective. Mobile medical app developers are also required to verify and validate their apps in conjunction with the relevant mobile platform.
- **Product labeling** — All medical devices, including mobile medical apps, must comply with the FDA's device labeling requirements.
- **Adverse event reporting** — Finally, mobile medical apps are subject to the FDA's medical device reporting regulation. App developers must investigate each instance in which a mobile medical app is believed to have caused or contributed to a death or serious injury, as well as each instance in which an app has malfunctioned in such a way as to place a patient at risk of death or injury. App developers must also submit written reports to the FDA in connection with each such instance.



**Other Applicable FDA Regulations**

A mobile medical app may also be subject to other general regulations or device-specific regulations. For example, the FDA has implemented regulations applicable to wireless medical devices [8] which address considerations regarding radio frequency issues. Other FDA regulations cover medical devices intended for home use, [9] which include consumer usability issues. Ultimately, these and other requirements applicable to a given mobile medical app will depend on the app's intended use or specific configuration with other medical devices.

## Recommendations for Mobile Medical Application Developers

The FDA guidance document on mobile medical apps provides a useful starting point for developers seeking to understand their obligations under FDA rules, and how specific FDA requirements apply to their products. However, it is important to note that FDA guidance documents are only intended to provide insight into the agency's planned regulatory approach. As such, statements and positions outlined in guidance documents do not have the force of law and are not a substitute for the FDA's actual requirements.

In addition to a careful review of the guidance document and applicable FDA requirements, developers of mobile medical apps should also consider taking the following actions in advance of placing their products on the market:

- **Determine whether a mobile app is subject to regulatory oversight** — As noted earlier, the FDA only intends to apply its regulations to certain types of mobile medical apps, based primarily on the degree of risk they pose to patients and healthcare providers. Therefore, developers of many healthcare-related mobile apps may not be subject to FDA registration and review requirements.
- **Identify and evaluate all probable means for using an app** — Once it has been determined that a specific mobile medical app is subject to FDA oversight, it is important to evaluate the various ways in which a healthcare provider or patient might use an app consistent with its intended use.
- **Conduct a risk management assessment** — With a thorough understanding of how a mobile medical app will be used, a developer should then conduct a thorough risk analysis to evaluate the potential safety hazards associated with the app's design and anticipated user interaction.
- **Determine applicable regulations and standards** — This assessment provides a framework for identifying the specific FDA regulations applicable to a mobile medical app, as well as the third-party standards that may be used to demonstrate compliance with regulatory requirements. With this information, developers of mobile medical apps can create a plan for achieving compliance as required.
- **Coordinate regulatory efforts** — Regulatory oversight in the U.S. may not end with the FDA. Depending on the nature and purpose of their app, developers should also evaluate other possible requirements, such as regulations of the U.S. Federal Communications Commission (FCC) applicable to unintentional radiators, or those of the U.S. Occupational Safety and Health Administration (OSHA) addressing workplace safety.
- **Seek additional technical and regulatory guidance as appropriate** — As previously noted, FDA guidance documents are not a substitute for the agency's actual regulations. Mobile medical app developers subject to FDA oversight should seek counsel from a knowledgeable third-party experienced in both software regulations and the FDA's medical device requirements.

## Summary and Conclusions

The use of mobile medical apps in the provision of healthcare services is growing rapidly, but mobile app developers may be unclear whether their products are subject to the FDA's oversight of medical devices. The FDA's recently published guidance document addressing mobile medical apps provides in-depth information on how the agency plans to regulate these products. However, it is not a substitute for an in-depth understanding of the actual regulations and requirements applicable to mobile medical apps.

Developers should conduct a thorough and systematic review of their mobile apps to determine whether FDA oversight is applicable to their products, and to understand the safety risks inherent in their product's design and anticipated use. An experience third-party can provide expert guidance that can identify potential safety issues early in the product design process and ease the regulatory approval process.

UL offers a complete range of evaluation and consulting services for mobile medical apps and other medical devices, and has a comprehensive knowledge of the regulatory approval process in the U.S. and other key target markets. For additional information, contact Medical.Inquiry@UL.com.

[1] "An Analysis of Consumer Health Apps for Apple's iPhone 2012," Mobile Health News, July 11, 2012. Web. 19 September 2013. http://mobihealthnews.com/research/an-analysis-of-consumer-health-apps-for-apples-iphone-2012/.

[2] "Apps Rocket Toward $25 Billion in Sales," Wall Street Journal, March 4, 2013. Web. 11 November 2013. http://online.wsj.com/news/articles/SB10001424127887323293704578334401534217878.

[3] Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff," U.S. Food and Drug Administration, Center for Device and Radiological Health, September 25, 2013. Web. 14 November 2013. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf

[4] IEC 60601-1 ed 3.1, "Medical electrical equipment – Part 1: General requirements for basic safety and essential performance," August 20, 2008. Web. 11November 2013. https://webstore.iec.ch/webstore/webstore.nsf/standards+ed/IEC%2060601-1%20Ed.%203.1?OpenDocument.

[5] "Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff"

[6] "FDA issues final guidance on mobile medical apps," FDA News Release, September 23, 2013. Web. 14 November 2013. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm369431.htm.

[7] A more detailed review of FDA device regulations is available at the FDA's webpage "Overview of Device Regulation: Introduction," U.S. Food and Drug Administration, updated March 5, 2013. Web. 15 November 2013. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm.

[8] "Radio Frequency Wireless Technology in Medical Devices: Guidance for Industry and Food and Drug Administration Staff," U.S. Food and Drug Administration, Center for Device and Radiological Health, August 13, 2013. Web. 10 December 2013. http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm077210.htm.

[9] "Draft Guidance for Industry and FDA Staff: Design Considerations for Devices Intended for Home Use" U.S. Food and Drug Administration, Center for Device and Radiological Health, December 12, 2012. Web. 10 December 2013. http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm331675.htm.