

FDA Regulation of Mobile Medical Applications: Current Changes and Potential Issues

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I. Introduction

In today's digital era, the advancement of technology has had innumerable effects upon the medical field. The recent development of mobile technology has provided the opportunity to put certain health-related resources quite literally in the hands of the everyday consumer. This democratization of health information not only empowers and emancipates the consumers from the traditional medical structure, but it also facilitates new channels of communication. Hand-held technology, such as Mobile Medical Applications (defined below), can directly link patients to providers while improving the quality of health related data, thus making individualized medical decisions possible. As with any new technology, with great benefits also comes a high potential for harms. Because this technology will prospectively change the dynamics of the health care system, issues regarding human error, hardware and software failure, malicious tampering, and regulation become even more pertinent.

II. From Mobile Applications to Mobile Medical Devices

According to the Food and Drug Administration ("FDA"), a Mobile Application is a software application that can be executed on a mobile platform (i.e., a handheld, commercial, off-the-shelf computing platform, with or without wireless connectivity, e.g., *WordsWithFriends*), or a web-based software application that is tailored to a mobile platform but is executed on a server.¹ The Federal Food, Drug and Cosmetic Act defines "device" as an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory..." that is

¹ U.S. Dep't of Health and Human Serv. Food and Drug Admin., Mobile Medical Applications, Guidance for Industry and Food and Drug Administration Staff 7 (2015), <http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf>.

“intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man... or to affect the structure or any function of the body of man.” (e.g., IUD, Pacemaker).²

The combination of these two items creates a hybrid known as a Mobile Medical Application, which denotes a mobile application that meets the definition of a device, and is intended either: a) to be used as an accessory to a regulated medical device, or b) to transform a mobile platform into a regulated medical device.³

To understand when a mobile application crosses the line from simply being a consumer novelty to being considered a Mobile Medical Application, it is important to analyze the type of data involved, the intended use of the data, and how that data is actually used in regards to making medical decisions by either the patient, a medical professional, or the application itself. A Mobile Application that is intended for the use in the diagnosis or the cure, mitigation, treatment, or prevention of a disease, or to affect the structure or any function of the body, falls within the medical device definition and will most probably be subject to regulation, which ultimately depends on functionality. In other words, a difference must be established between mere informational data and diagnostic or prescriptive data⁴: Applications that provide for the former allow the user to read, input their own data, and gather resources to make medical decisions; applications that provide for the latter allow decision processes normally handled by medical professionals to be entirely dependent on the software, thus giving the user substantial information regarding their condition and their treatment.

III. FDA Regulation

Before the FDA released its Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices: Guidance for

² 21 U.S.C. § 321 (2013).

³ U.S. Dep't of Health and Hum. Serv. Food and Drug Admin., *supra* note 1, at page 7.

⁴ Alex Krouse. *IPads, iPhones, Androids, and Smartphones: FDA Regulation of Mobile Phone Applications as Medical Devices*, 9 Ind. Health Law Rev. 731, 756 (2012), available at <http://mhealthregulatorycoalition.org/wp-content/uploads/2013/05/lawrev.pdf>.

Industry and Food and Drug Administration Staff (“MDDS Guidance”)⁵ on February 9th 2015, all medical devices and applications (intended for use to cure, mediate, prevent, treat, or diagnose a disease) which transferred, stored, converted, and/or displayed medical data, had to be in full compliance with FDA’s regulatory processes and controls. At the time, there were no filters or distinctions, regardless of different intent, risk-levels and potential harms, and the amount of FDA regulation of products was overbearing. In an attempt to alleviate this overregulation and subsequent undue burden, the FDA has undertaken several measures toward a less stringent regulatory regime for medical devices and mobile applications. Beginning in 2011, the agency first reclassified Medical Device Data Systems (“MDDS”) from Class III to Class I and subsequently fully deregulated them.⁶ Ultimately, the FDA decided to limit the scope of its regulation by establishing a risk-based framework for the assertion of safety and effectiveness. Four guidelines were drafted (two already approved) with that purpose:

- a. *General Wellness (draft guidelines)*: for low-risk devices and applications, whose intended use is to promote general wellness and a healthy lifestyle; not intended for invasive uses, risky interventions or technologies; doesn't raise questions of usability nor of biocompatibility.⁷
- b. *Medical Device Accessory (draft guidelines)*: regulatory classification based on its own or according to parent device; uncertainty still remains regarding *de novo* classification only for new low-risk accessory

⁵ U.S. Dep’t of Health and Hum. Serv. Food and Drug Admin., Medical Devices Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices, Guidance for Industry and Food and Drug Administration Staff (2015), <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM401996.pdf>.

⁶ *Id.* at 5. (Hardware or software products that transfer, store, convert formats, and display medical device data; an MDDS does not modify the data, and it does not by itself control the functions or parameters of any other medical device; they are not intended to be used for active patient monitoring; U.S. Dep’t of Health and Hum. Serv. Food and Drug Admin., *supra* note 1. (Classification provides the type of regulatory controls, according to characteristics that may affect safety and effectiveness.)

⁷ U.S. Dep’t of Health and Hum. Serv. Food and Drug Admin., General Wellness: Policy for Low Risk Devices, Draft Guidance for Industry and Food and Drug Administration Staff (2015), <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429674.pdf>.

devices.⁸

- c. *Medical Devices Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices (final guidelines)*: FDA exercises enforcement discretion to not require compliance with quality system regulations or medical device requirements.⁹
- d. *Mobile Medical Applications (final guidelines)*: FDA exercises enforcement discretion, if application is consistent with the MDDS guidelines; establishment of distinction between applications that are not medical devices, applications that are medical devices but FDA will exercise enforcement discretion not to regulate them, and applications that are medical devices and require regulatory oversight; provide for risk-management plan guidelines manufacturers must create for their applications (emphasizing usability, vulnerability, assessment, and design security).

The current MDDS Guidance establishes that the FDA will regulate Mobile Applications that are considered medical devices and whose functionality could pose a high-risk to the safety of consumers and public health (because they do not function as intended, or because they significantly impact and control the ordinary performance of traditional medical devices). Mobile Applications that would be regulated include those that engage in: conspicuously monitoring patients; analyzing, transforming and transmitting complex health data; or offering patient-specific diagnosis or treatment. However, the FDA will exercise its discretion by not requiring compliance when the Mobile Application (even if defined as a medical device) poses low or no risk to the consumers health (applications that record vital variables for personal tracking; applications for self-managing conditions that are not serious diseases and do not require medical treatment; applications that provide general suggestions on healthy diets; applications for

⁸ U.S. Dep't of Health and Hum. Serv. Food and Drug Admin., Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types, Draft Guidance for Industry and Food and Drug Administration Staff (2015), <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429672.pdf>.

⁹ U.S. Dep't of Health and Hum. Serv. Food and Drug Admin., *supra* note 5, at 8.

medical image storage; applications for general health education). With these regulations, the FDA encourages the development and innovation of health care related technology, while ensuring consumers safety and maintaining the quality of the system.

IV. Current and Future Potential Issues

Despite the available guidelines, the FDA's regulatory process in this field still lacks certainty in some areas. Among other things, it is difficult to assess under what exact classification a Mobile Medical Application falls; there might be an application of low-risk that implicates a high-risk if used as an accessory to an existing medical device; also, an application might have a certain intended use but there is no complete control on the actual use it will be given. Therefore, there is the issue that the interoperability between a Mobile Application and a medical device can't automatically deem the former to be a medical device accessory (this would require validation from the product manufacturer). Another related issue is the lack of a clear regulatory path for innovative products. Innovators may not want to connote their applications as medical diagnosing devices in order to avoid long and costly FDA regulations, which would not necessarily guarantee success (clearance and approval). Additionally, there are terms among the guidelines, such as "*risk to safety*" and "*treatment,*" that have not yet been clarified and provide no guidance in development. The FDA's risk based approach must be further tailored to create a more eclectic and comprehensive framework, which would be able to balance innovation and regulation with security and privacy, issues currently outside of its scope.

V. Conclusion

Mobile technology is indisputably transforming the health care system from physician-centered to a much more patient-focused one. The development of Mobile Applications will increase in usage and complexity, which implies that FDA guidelines must be constantly revised and restructured to satisfy existing trends. Some critics may argue that the guidelines are not enough and that statutory

measures should be analyzed and implemented; they might rely on the idea that as long as the FDA maintains the power of exercising enforcement discretion, there will always be uncertainty regarding the processes and regulations that guide the developments in these areas.

Although a firm limit on FDA regulatory control would help establish clearer and more predictable standards, the truth is that an absolute regulation approach would be impractical, due to the rapid and dynamic changes in technology. In contrast, guidance regulations and periodical updates provide for the recognition that the system constantly changes and evolves, for which there will always be a need for adaptation. The biggest challenge will continue to be balancing FDA regulation for safety and effectiveness, with permitting more liberal innovation and marketing strategies. After all, only one thing is certain: the investment of time and money in the development of Mobile Medical Applications is definitely worth it; it is the price to pay to enhance the health care system, to improve health care access, and uphold quality and safety standards.

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