

AN UPDATE ON MHEALTH REGULATION IN THE UNITED STATES

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In a previous issue of the Journal of Mobile Technology and Medicine, we provided an overview of the regulation in the United States of mobile health (“mHealth”) and mobile medical applications (“mobile medical apps”).¹ On September 25, 2013, the United States Food and Drug Administration (“FDA”) released a Final Guidance for Industry and FDA Staff on Mobile Medical Applications (“Final Mobile Medical Apps Guidance” or “Final Guidance”).² While the basic framework for regulating mobile medical apps in the United States has remained unchanged from our previous article, the new guidance provides further clarity that should be carefully considered by those developing mobile medical apps.

FDA released its previous Draft Guidance regarding mobile medical apps on July 21, 2011.³ This draft guidance established FDA’s basic thinking for how it intended to regulate mobile medical apps. In response to this Draft Guidance, the FDA received, reviewed, and considered numerous comments from the public and industry. The resulting Final Guidance is a forty-three page document containing in-depth discussion of how the FDA intends to regulate the still-emerging area of mobile medical apps. Although similar to the Draft Guidance, the Final Mobile Medical Apps Guidance provides additional clarity and extensive examples of both regulated and non-regulated apps.

In the Final Mobile Medical Apps Guidance, the Agency clarified its position that there are three distinct categories of mobile medical apps:

- (1) apps that are medical devices subject to FDA oversight;
- (2) apps that do not qualify as medical devices and therefore are not regulated by FDA

- (3) apps that are medical devices subject to FDA oversight, but for which the Agency will refrain from regulating for the current time.

The FDA has the ability to refrain from regulating a category of medical devices under its ability to exercise enforcement discretion. FDA acknowledged in the Final Mobile Medical Apps Guidance that the majority of mobile medical apps on the market would fall into the last two categories and would not be subject to FDA regulation at this time.⁴

To determine whether the FDA will regulate a mobile app or manufacturer of a mobile app, the FDA makes several important points in the Final Guidance document.

First, the FDA’s regulatory oversight only extends to those “mobile apps” that are also “mobile medical apps.” A mobile medical app meets the statutory definition of a “device” in the Federal Food, Drug, and Cosmetic Act (“FFDCA”)⁵, and is intended to either be used as an accessory to a regulated medical device or to transform a mobile platform into a regulated medical device.

Second, only “mobile medical app manufacturers” are subject to FDA’s oversight. These manufacturers are entities that initiate specifications, designs, or labels, or who create software systems or applications from multiple software components for a regulated medical device. The FDA notes that a number of parties would not be classified as mobile medical app manufacturers, including owners and operators of online app stores, licensed practitioners who manufacture or alter a mobile medical app solely for their own professional practice, and

persons who manufacture a mobile medical app only for research, teaching, or analytical purposes.

Third, the FDA addresses its risk-based approach to Agency oversight of mobile medical apps. The FDA intends to focus its enforcement efforts on apps that pose the greatest safety risks to patients if they do not function as designed.

As discussed above, the FDA has established three levels of regulation of mobile apps as follows:

- **Apps that do not meet the FDCA definition of a medical device and are therefore not regulated by FDA.**⁶ These are mobile apps, but not mobile *medical* apps. For example:
 - Apps that provide electronic access to reference materials (*e.g.*, a medical dictionary);
 - Apps that are intended to educate medical practitioners (*e.g.*, medical flash cards);
 - Apps that are intended for patient education (*e.g.*, drug cost comparisons);
 - Apps used to automate general office operations in a health clinic (*e.g.*, determining billing codes); and
 - Apps that are generic tools not intended for medical purposes (*e.g.*, an app that acts as a magnifying glass).
- **Apps that are medical devices under the FDCA and will be subject to FDA oversight.**⁷ These mobile apps are mobile medical apps. For example:
 - Apps that are an extension of one or more medical devices by connecting to the device to control the device or display, store, analyze, or transmit patient-specific medical device data (*e.g.*, the remote display of a patient's data from a bedside monitor);
 - Apps that transform a platform into a regulated medical device by using attachments, displays, or sensors, or including functionalities similar to regulated medical devices (*e.g.*, the attachment of a blood glucose strip reader to a mobile platform that allows a glucose reading); and
 - Apps that become a regulated medical device by performing patient-specific analysis and providing diagnosis or treatment recommendations for that particular patient (*e.g.*, an app that calculates a radiation dosage based on the patient's own data).

- **Apps that may be medical devices under the FDCA and otherwise subject to FDA oversight, but for which the Agency will refrain from regulating at this time.**⁸ These are mobile apps that may or may not be mobile medical apps. For those that are mobile *medical* apps, FDA will not take enforcement action against them. For example:
 - Apps that provide or supplement clinical care by coaching or prompting patients to manage their health (*e.g.*, promoting exercise);
 - Apps that provide patients with tools to organize and track their own health information (*e.g.*, tracking blood pressure measurements);
 - Apps that provide access to information about a patient's medical condition or treatment (*e.g.*, a drug-drug interaction information tool);
 - Apps that are marketed to help patients communicate with their providers about possible medical conditions (*e.g.*, apps that are intended to allow videoconferencing between a patient and their caregiver);
 - Apps that perform simple medical calculations (*e.g.*, calculating body mass index); and
 - Apps that enable patients to interact with patient health records or electronic health records that are meant to facilitate the management of patient health information.

The Final Mobile Medical Apps Guidance provides a level of clarity and detail not often seen in either draft or final FDA guidance documents. This clarity and detail, however, extends only to step one of mobile medical app regulation – whether the FDA will regulate the particular manufacturer or app in the first place. Step two – determining what product code and device category apply to a specific mobile medical app (which will dictate the FDA's level of regulation) – is not addressed in detail. Although the Agency provides an overview of medical device requirements⁹ and current device codes and regulations¹⁰ that might be applicable to mobile medical apps, further information in the form of a decision tree or step-by-step decision-making support tool would have been very helpful to this segment of FDA-regulated industry, particularly because many mobile medical app manufacturers may not have been subject to FDA oversight in the past.

The Final Mobile Medical App Guidance illustrates that the FDA is acting in a relatively open-minded manner and has taken a logical, risk-based approach to the regulation of mobile medical apps. However, we expect the FDA's position to evolve over time, particularly if an app that is currently subject to enforcement discretion causes patient harm in the future. Such an event may cause the FDA to rethink its regulatory approach. Therefore, industry should not rely on the FDA's decision to exercise enforcement discretion, but should stay informed of developments in this emerging area of FDA oversight.

References

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3. FDA. Draft Guidance, Mobile Medical Applications (July 21, 2011).
4. Final Mobile Medical Apps Guidance, p. 4.
5. FDCA § 321(h), codified at 21 U.S.C. § 201(h).
6. Final Mobile Medical Apps Guidance, Appendix A.
7. Final Mobile Medical Apps Guidance, pp. 13–6 and Appendix C.
8. Final Mobile Medical Apps Guidance, pp. 16–8 and Appendix B.
9. Final Mobile Medical Apps Guidance, Appendix E.
10. Final Mobile Medical Apps Guidance, Appendices C and D.