FDA Releases Final Guidance On Mobile Medical Apps

On September 23, 2013, the U.S. Food and Drug Administration ("FDA") issued long-awaited final guidance ("Final Guidance") on its approach to regulating mobile medical applications ("mobile medical apps") for smart phones, tablets, and other mobile computing devices. Recognizing the "coming revolution" in the rapidly growing mobile health industry, the FDA's guidance attempts to provide manufactures of mobile medical apps with a "clear and predictable roadmap" to determine whether their apps are subject to active FDA oversight.

What Are Mobile Medical Apps?

The Final Guidance defines a mobile medical app as an app that (i) meets the definition of "device" under Section 201(h) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), *and* (ii) is either used as an accessory to a regulated medical device, or transforms a mobile platform (such as a mobile phone) into a regulated medical device.

The "intended use" of a mobile app is a dispositive factor in determining whether it constitutes a "device" subject to regulation. Under the FD&C Act, intent may be shown by a manufacturer or its representative's labeling claims, advertising materials and other marketing claims. If the intended use of a mobile app is for the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body of man, the mobile app is a device.

Categories of Mobile Apps Subject to FDA Oversight

Because the FDA intends only to regulate those mobile apps "that are medical devices and whose functionality could pose a risk to a patient's safety if the mobile app were not to function as intended," the FDA adopted a risk-based approach to govern its regulatory oversight.

Under this risk-based framework, the following specific categories of mobile apps have been identified as the focus of the FDA's oversight:

1. Mobile apps that are an extension of one or more medical devices by connecting to such device(s) for the purposes of controlling the device(s) or displaying, storing, analyzing, or transmitting patient-specific medical device data, such as apps that provide the remote display of data from bedside monitors or that control the delivery of insulin on an insulin pump by transmitting

control signals to the pump from a mobile platform.

2. 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, such as apps that attach a blood glucose strip reader to a mobile platform to function as a glucose meter, use a built-in accelerometer on a mobile platform to collect motion information for monitoring sleep apnea, use the attachment of a transducer to a mobile platform to function as a stethoscope, or use an attached light source or laser to treat acne, reduce wrinkles, or remove hair.

3. Mobile apps that become a regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendation, such as apps that use patient-specific information to calculate dosage for a specific medication or radiation treatment.

Manufacturers of mobile medical apps must meet the requirements associated with the applicable device classification. If the mobile medical app, on its own, falls within a medical device classification, its manufacturer is subject to the requirements associated with that classification: Class I (General Controls), Class II (Special Controls in addition to General Controls), or Class III (Premarket Approval).

Categories of Mobile Apps Not Subject to FDA Oversight

The following categories of mobile apps — the majority of the mobile apps on the market today — *are not* currently the target of FDA's regulatory oversight, either because they are considered not to be "devices" or because they pose only a low risk to patient health and safety:

Mobile apps that are not considered medical devices (not subject to FDA oversight)

1. Mobile apps that are intended to provide access to electronic copies of medical textbooks or other reference materials, such as electronic medical dictionaries, translators, and other reference materials

2. Mobile apps that are intended for health care providers to use as educational tools for medical training, such as apps that function as medical flash cards, medical quizzes, or surgical training videos

3. Mobile apps that are intended for general patient education and facilitate patient access to commonly used reference information, such as apps that

provide lists of medical emergency hotlines, compare costs of drugs and medical products at pharmacies in the user's location, or help patients find nearby medical facilities.

4. Mobile apps that automate general office operations in a health care setting and are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, such as apps that enable insurance claims data collection and processing, perform medical business accounting functions, generate reminders for scheduled medical appointments, or help patients track, review and pay medical claims and bills online.

5. Mobile apps that are generic aids or general purpose products, such as apps that allow mobile platforms to function as a magnifying glasses or audio recorders, or which allow providers and patients to communicate via email.

Low-risk mobile medical apps (not subject to FDA oversight, at least at this time)

The FDA intends to exercise "enforcement discretion" for certain mobile apps that, while potentially meeting the definition of a "device" under the FD&C Act, pose only a low risk to patients' safety if the apps fail to function as intended.

The categories of apps subject to enforcement discretion — meaning that the FDA will not require manufacturers to submit premarket review applications, register and list their apps with the FDA, or otherwise observe similar FD&C Act provisions — include apps that:

1. Help patients self-manage their disease or conditions without providing specific treatment or treatment suggestions, such as apps that help asthmatics track inhaler usage and asthma attacks, use video games to motivate patients to do their physical therapy exercises at home, or offer medication reminders intended to improve adherence.

2. Provide patients with simple tools to organize and track their health information, such as apps that log, track, or trend their events or measurements (*e.g.*, blood pressure measurements, drug intake times, diet, daily routine or emotional state) and share this information with their health care provider as part of a disease-management plan.

3. Provide easy access to information related to patients' health conditions or treatments, such as drug-drug

interaction or drug-allergy search tools, or apps that use patient characteristics such as age, sex, and behavioral risk factors to provide patient-specific screening, counseling, and preventive recommendations from well-known and established authorities.

4. Are specifically marketed to help patients document, show, or communicate potential medical condition to healthcare providers, such as apps that allow users to collect blood pressure data and share this data through email or upload it to an electronic health record, or videoconferencing portals specifically for medical use.

5. Automate simple calculations routinely used in clinical practice, such as medical calculators for body mass index or mean arterial pressure.

6. Enable patients or providers interact with Personal Health Record (PHR) systems or Electronic Health Record (EHR) systems.

Conclusion

The FDA intends to exercise its regulatory oversight over manufacturers of mobile medical apps, which it broadly defines to include entities that initiate specifications for a mobile medical app or create, design, label, remanufacture, or modify a mobile medical app.

Being deemed a "manufacturer" carries significant regulatory compliance obligations, including those relating to: medical device (adverse event) reporting when malfunctions, injuries or deaths occur (21 C.F.R. Part 803); reporting of device corrections or removals (21 C.F.R. Part 806); establishment registration and listing (21 CFR Part 807); premarket notification (510(k)) (21 C.F.R. Part 807); and Quality System (QS) Regulation/Good Manufacturing Practice (21 CFR Part 820) requirements. It is therefore imperative that manufacturers proactively assess whether their mobile offerings constitute devices subject to these regulatory requirements and ensure strict compliance.

Regardless of whether your app falls within a category currently identified by the FDA as a mobile medical app (device) subject to FDA oversight, manufacturers of all mobile apps that may meet the definition of a device are well advised to adopt the FDA's recommendation to follow the Quality System Regulation in the design and development of their mobile medical apps and initiate prompt corrections when appropriate to prevent patient harm. After all, good design practices and quality control systems are the right prescriptions for patient safety, customer satisfaction, and keeping the FDA away.

The Final Guidance is available here.

If you have any questions about this article, please contact:

Robert McHale, Esq.
R | McHale Law
9 West Broadway, Suite 422
Boston, MA 02127
Tel. 617.306.2183
Email: robert.mchale@rmchale.com