Is Your App Considered a Medical Device?

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There are more than two million apps available in the iTunes store. A few clicks on my computer show that there are thousands under the medical category. The top-paid app in this category is a fetal heartbeat monitor that finds the baby's heartbeat from the microphone feature on an iPhone. Another app is a vein finder that uses the flashlight and camera to find veins that would "otherwise be invisible to the naked eye." One of these apps notes that they are not intended for the diagnosis or treatment of disease.

Is your app considered a medical device in the United States? This is a hot topic among anyone with a medical-related app. The answer is not always clear, but it starts with the FDA's definition of a medical device. The applicable portion of the definition for a mobile application is:

> *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.*

The question for apps is: Does the app diagnosis, cure, mitigate, treat, or prevent disease? In February 2015, the FDA posted a 44-page guidance document with extensive information regarding this very topic. Per usual, the FDA starts with definitions regarding the guidance including mobile platforms, apps, and mobile medical apps. A mobile medical application is defined as:

> *a mobile app that is either is intended: to be used as an accessory to a regulated medical device; or to transform a mobile platform into a regulated medical device.*

The document lists dozens of examples of apps and if they would be considered medical devices. An important section in the guidance is called "Subset of mobile apps that are the focus of the FDA's regulatory oversight." This section discusses apps that would be considered medical devices that include the following categories:

1. 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 for use in active patient monitoring or analyzing medical device data. An example is an app that provides the ability to control inflation and deflation of a blood pressure cuff.
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. These apps are required to comply with the device classification associated with the transformed platform. An example is a mobile platform for creating an electronic stethoscope function that is considered to transform the mobile platform into an electronic stethoscope.
3. 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. An example is an app that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy.

Some of the medical apps that the FDA does not intend to enforce requirements include:

- Help patients (i.e., 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;
- Personal Health Record (PHR) or Electronic Health Record (EHR) systems; or
- Intended to transfer, store, convert format, and display medical device data in its original format from a medical device (as defined by MDDS regulations).

In July 2016, the FDA published another guidance document that discusses general wellness devices that promote a healthy lifestyle. Some products that fall in this category are apps to track dietary intake, apps that play music to help reduce stress, apps to track heart rate for exercise, etc.

So, is your app a medical device? A common approach is to ensure that the app is completely clear of diagnosing any specific medical condition or disease. Understanding the guidance documents is also key. If there is uncertainty about your device status, one should check with a professional before marketing their product.