In July 2012, the Federal Safety and Innovation Act (FSA) was enacted, creating a framework for regulatory guidance of wireless and mobile health. In 2013, the FDA released a Mobile Apps guidance document. The general guidelines for submitting a medical device in United States are: General controls and 510(k) or PMA depending on risk and intended use of device and compliant to 21 CFR 820 QSR if required.

**FDA Guidance on Mobile Medical Apps**

Most mobile apps are not medical devices under section 201(h) of FD&C act. Although some mobile medical applications meet the definition of a medical device, they will be enforced by “discretion” because they pose low risk. Regardless of the platform, anytime a mobile app meets the definition of a medical device, it is regulated as such.

**Medical Device per 201(h)**

Medical Device per 201(h) are instrument, apparatus, implant, in vitro reagent, or similar or related article that is used to diagnose, prevent, or treat disease or other conditions, and does not achieve its purposes through chemical action within or on the body.

**Devices Regulated by FDA**

The group responsible for owning and controlling the finished good specifications and controlling the marketing claims will be regulated.

**Mobile Apps that will be Regulated**

1. Mobile apps that are extensions of one or more medical devices by connecting, displaying, storing, analyzing or transmitting patient-specific medical device data. Eg: a) Remote display of data from bedside monitors, EEG waveforms, etc.b) Remote activation of blood pressure cuff or data collection.
2. Mobile apps that transform the mobile platform into a regulated medical device by using attachments, display screens or sensors. The app becomes similar to an already regulated medical device. a. This mobile glucose meter performs the same function as a Class II glucose meter. b. This iPad x-ray viewer is equivalent to a Class II Picture Archiving Systems (PACS).
3. Mobile apps that become a regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis or treatment. a. A radiation planning
software that is patient-specific and radiation therapy is planned based on the output. This is a
regulated device.

**Apps Regulated by Discretion**

1. Mobile apps that provide or facilitate supplement clinical care, by prompting, to help patients
   manage their health in their daily environment. eg: a. Devices like Nike Fuel band or calorie
   counters that track health & fitness. b. Medication alert or reminder apps that tell you when to take
   medications.
2. Mobile apps that provide patients with simple tools to organize and track their
   health information. eg: a. Weight tracker that helps you record your weight and your BMI.
3. Mobile apps that provide easy access to information related to patient’s health conditions or treatments.
   a. Apps that help you make decisions specific to your condition like a drug interaction detection app.
   b. Disease specific apps like dLife that help you with daily life like food planning, treatment options,
      etc.
4. Mobile apps that are specifically marketed to help patients document, or communicate to
   providers about potential medical conditions. eg: a. Apps that allow you to take a photo of your
   ailment or condition and send it to a doctor for diagnosis, like Sherpaa.
5. Mobile apps that perform simple calculations routinely used in clinical practice. eg: a. This app helps physicians
   calculate NIH stroke score. b. BMI calculator to determine obesity levels personally or at the clinic.
6. Mobile apps that enable individuals to interact or Personal Health Records or Electronic Health
   Records. Eg: a. Mobile apps like drChronos which allows patient and healthcare provider viewing
   of the EHR/PHR in real time.

**Difference between FDA Regulated Medical Device and non FDA Regulated Devices**

A regulated medical device is not a light emitting diode and flashlight app on an iPhone. It is an
iPhone Gray’s anatomy textbook reference. It is also an MD examination (USMLE) test on an
iPhone. Regulated medical device is an LED illumination of retina for diagnosing eye disease. It is
an iStethoscope that detects heart rate. It is a Pulse Oximeter that reads out into your smart
phone.

**Related Webinars**

- FDA Guidance on Mobile Medical Apps
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