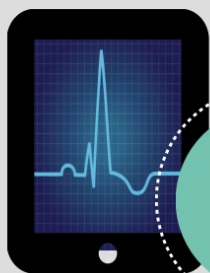


# The Basics: mHealth



## AND THE FDA



**Medical Device?**

### What is a regulated medical device?

Healthcare products intended for diagnosis, cure mitigation, treatment, or prevention of a medical condition intended to affect the structure or any function of the body.

### Not all devices are created equal!

#### Class I

Low risk and subject to less regulatory control

#### Class II

Requires greater regulatory controls to provide reasonable assurance of safety and effectiveness

#### Class III

Highest risk and subject to highest regulatory control

### Are there exceptions?

Certain persons are exempt from needing to register medical devices with the FDA, including licensed practitioners who manufacture or alter devices solely for use in their own practice.





## What about mobile apps?

Apps are subject to FDA regulatory oversight if they:

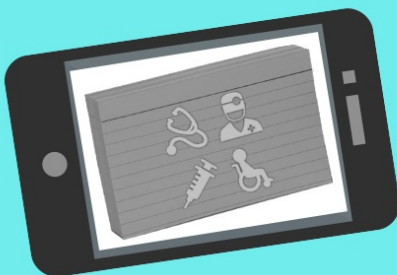
- \* Are extensions of a medical device for the purposes of controlling the device or displaying, storing, analyzing or transmitting patient specific medical device data.
- \* Transforms mobile platform into a regulated device by using attachments, display screens or sensors or by including functionalities similar to those of current medical devices.
- \* Uses patient specific information to analyze, diagnose and/or treat a patient.
- \* Involved in active patient monitoring.

The FDA will exercise "enforcement discretion" on mobile medical apps that pose a low risk to patients. This means that the FDA retains the right to enforce requirements on these apps, but are not doing so at this time.

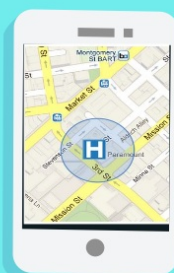
### Examples of Apps Subject to Enforcement Discretion

- \* Used for self-management.
- \* Used to track medication usage or drug-drug interactions.
- \* Used to perform calculations used in clinical practice.
- \* Used as medical device data systems.

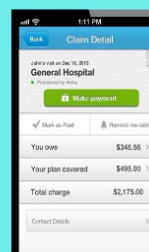
### Examples of Apps Not Considered Medical Devices



Medical Flash Cards



Find Closest Medical Facility



Track and Review Medical Bills



Medical Textbooks and Education Materials

#### Sources:

- 1 Sec 201(h) of the Federal Food, Drug and Cosmetic Act.
- 2 CFR Section 807.65
- 3 CFR Section 808

Have questions? Contact a Telehealth Resource Center!  
[TelehealthResourceCenter.org](http://TelehealthResourceCenter.org)