Medical Mobile Applications

Regulatory Overview of FDA Requirements

Mobile Medical App Guidance

- What you intend your app to do will determine the level FDA enforcement of your app.
  - FDA Regulatory Focus Vs. Enforcement Discretion
- Terms:
  - Mobile Medical Platform: Handheld COTS
  - Mobile App: software app that can run on mobile platform or a web-based software application that is tailored to a mobile platform but is executed on a server. Note: App becomes Mobile Medical App if…
    - used as an accessory to a regulated medical device; or
    - Transforms mobile platform into a regulated medical device.
  - Mobile Medical Manufacturer

Regulatory Focus: Group A

- Apps that are extensions of med devices by and connect to those devices to control device, or are used for active patient monitoring or analyzing medical device data.
- 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
- Mobile apps that become a regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations.

Enforcement Discretion: Group B

- 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;
- Enable patients or providers to interact with 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 regulation 880.6310 OUG).
- **Note: For Group B always check Appendix in Guidance and FDA website for updated examples.** http://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368744.htm

Software Verification and Validation

- V&V should be based on the safety risks associated with the device as well as the complexity of the code
- More testing does not mean better quality software.
- Always describe why your testing based on risk/complexity
- Agree on terminology and align with FDA

Software Documentation

- **Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices**
- This guidance gives an overview of the software documentation expected to be created for 510k submission based upon the safety "level of concern" of the software.
- Main take away should be defining your level of concern, and ensuring you have all the deliverables needed regardless if premarket submission is needed.

Next Steps

- Intended Use
- Indications For Use
- Software Risk Management (IEC 62304)
- Development Verification
- Verification and Validation
- Human Factors/Usability
- Clinical Evaluation
- PMA, 510k, Enforcement Discretion

Other Guidances

- OTS Guidance
- Cybersecurity
- Radiofrequency