Recent Developments in Medical Device Software – Overview of Mobile Medical Apps and Medical Device Data Systems

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February 14, 2016
Goals for Today

This talk is meant to help you if ...

- You want to develop a great new app
- You are not sure if your app is regulated by FDA
- You want to know what your responsibilities are

What we are going to do:

I. Develop a common vocabulary for medical devices

II. Discuss how the Mobile Medical Apps (MMAs) Guidance may affect your great new app

III. Discuss how the Medical Device Data Systems (MDDSs) Guidance makes dealing with medical device data easier
I. Medical Devices
II. MMAs
III. MDDSs
What is a Medical Device?

According to Section 201(h) of the Food, Drug, and Cosmetics Act, a device 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:

1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."
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Devices can be pretty much anything, including hardware and software.
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This part doesn’t really apply to software devices.
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Devices affect are things that affect structure or function and aren’t drugs.
Example of How Intended Use Affects Designation
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Medical devices:
• diagnose
• cure
• mitigate
• treat
• prevent
disease*

*: see Section 201(h) of the FD&C Act
Mobile Medical Applications (MMA) Guidance Document

History:
• MMA Guidance issued on September 25, 2013
• MMA Guidance updated on February 9, 2015, to reflect Medical Device Data Systems (MDDSs)

Provides:
• Definitions
• Regulatory Approach for MMAs
• Summary of Regulatory Requirements for Medical Devices
• Many Examples
• FAQs

Please see: “Mobile Medical Applications - Guidance for Industry and Food and Drug Administration Staff.”
Using Venn Diagrams to get a sense of the Landscape

Medical Devices

Software

Mobile Apps

MMAs
Using Venn Diagrams to get a sense of the Landscape

Medical Devices

Software

Mobile Apps

MMAs
Formal Definition of a Mobile Medical App (MMA)

For purposes of this guidance, a “mobile medical app” is a mobile app that meets the definition of device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act); and 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.
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Intended to:
- diagnose,
- cure,
- mitigate,
- treat, or
- prevent
disease AND...
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... transforms the mobile platform INTO a regulated medical device.
FDA’s Regulatory Approach

• Regulatory approach is based on risk to patient safety if the mobile app did not function as intended.

• May help to think of placing a mobile application into one of three “buckets”:

- Not a medical device
- May be a medical device, but FDA intends to exercise enforcement discretion
- The focus of FDA’s Regulatory Oversight

Not a device
Lower Risk
Higher Risk
FDA’s Regulatory Approach

- Regulatory approach is based on risk to patient safety if the mobile app did not function as intended.
- May help to think of placing a mobile application into one of three “buckets”:
Examples of Mobile Apps that are NOT Medical Devices

Examples
- First-aid or emergency care information encyclopedias
Examples of Mobile Apps that are NOT Medical Devices

Examples

- Apps that simulate cardiac arrest scenarios to train health professionals in advanced CPR
Examples of Mobile Apps that are NOT Medical Devices

Examples
- Allow users to input pill shape, color or imprint and display pictures and names of pills that match this description;
Examples of Mobile Apps that are NOT Medical Devices

Examples

- Determine billing codes
- Analyze insurance claims for fraud or abuse
- Generate reminders for scheduled medical or blood donation appointments
Examples of Mobile Apps that are NOT Medical Devices

Examples
- Allow health care providers to communicate in a secure and protected method
Examples of Mobile Apps for which FDA Intends to Exercise Enforcement Discretion

- Patient Coaching or Prompting
- Easy Access to Information Related to Patients' Conditions
- Health Tracking
- Apps that Meet Definition of an MDDS
- Enable Interaction with PHR or EHR Systems
- Simple Calculations Routinely Used in Clinical Practice
- Help Patients Document, Show, or Communicate to Providers
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Not a device Lower Risk Higher Risk
Examples of Mobile Apps for which FDA Intends to Exercise Enforcement Discretion

“… for certain MMA devices... FDA intends not to pursue enforcement action for violations of the FD&C Act and applicable regulations...

This does not constitute a change in the requirements of the FD&C Act or any applicable regulation.”
Subset of Mobile Apps that are the Focus of FDA’s Regulatory Oversight (MMAs)

Mobile Medical Apps
Mobile AND Medical AND
(Accessory OR Transforms)

- Control, Active Monitoring, & Analyze Medical Data
- Patient-Specific Diagnosis or Treatment Recommendations
- Transform Mobile Platform into a Regulated Medical Device

Not a device → Lower Risk → Higher Risk
**MMA Review**

- **MMAs are Mobile AND Medical AND (Accessory OR Transforms)**
- **Medical Device: Intended use is a critical factor**
- **Regulatory Approach: Based on risk to patient safety**

- MMA Guidance provides starting point for responsibilities of MMA manufacturers.
- More information about responsibilities for medical device manufacturers can be found at “CDRH Learn” and “Device Advice”.

\[\text{**: see MMAs Guidance Document}\]
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II. MMAs

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- Medical AND
- (Accessory OR Transforms)**

III. MDDoS

*: see Section 201(h) of the FD&C Act
**: see MMAs Guidance Document
So now you might be thinking...

- How does FDA regulate the transfer, storage, conversion, and display of data generated and/or collected by my app?

- Medical Device Data Systems perform this set of features.
How MDDSSs are Regulated

Good News!

- MDDSSs were down-classified to Class I (low-risk) on February 15, 2011.
- MDDS Guidance issued on February 9, 2015, and again placed under enforcement discretion.

Please see: “Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices.”
The Four Things MDDSs do with Medical Device Data

Transfer

°F lbs. {json}

Convert Formats

°C kg </xml>

Store

Display
Definition of a Medical Device Data System (MDDDS)

21 CFR 880.6310 Medical device data system

(a) Identification.

(1) A medical device data system (MDDS) is a device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:

(i) The electronic transfer of medical device data;

(ii) The electronic storage of medical device data;

(iii) The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or

(iv) The electronic display of medical device data.

(2) An MDDS may include software, electronic or electrical hardware such as a physical communications medium (including wireless hardware), modems, interfaces, and a communications protocol. This identification does not include devices intended to be used in connection with active patient monitoring.
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MDDSs include both hardware and software.
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MDDSs do NOT include devices for active patient monitoring.
MDDS Review

- MDDSs are medical devices that:
  - Transfer medical device data,
  - Store medical device data,
  - Display medical device data, or
  - Convert medical device data from one data format to another format using a preset specification.

But do NOT:
- Control functions of connected medical devices,
- Alter parameters of connected medical devices,
- Actively monitor patients.

- MDDSs are Class I (low-risk) devices, and FDA does not intend to enforce compliance with the regulatory controls.
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Medical devices:
- diagnose
- cure
- mitigate
- treat
- prevent disease*

II. MMAs

MMAs are:
- Mobile AND
- Medical AND
- (Accessory OR Transforms)**

III. MDDSSs

MDDSSs:
- transfer data
- store data
- convert data
- display data
- control
- alter
- monitor***

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* see Section 201(h) of the FD&C Act
** see MMAs Guidance Document
*** see MDDS Guidance Document
How to Get Help

CDRH Learn - Multimedia Industry Education:
- http://www.fda.gov/Training/CDRHLearn/

Device Advice - Text-based Education:
- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/

Digital Health Website:
- http://www.fda.gov/MedicalDevices/DigitalHealth/default.htm

FDA Contact Information:
- MobileMedicalApps@fda.hhs.gov
- DICE@fda.hhs.gov

The Pre-Submission Program
Questions?