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Mobile Medical Applications: FDA's Final Guidance

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October 9, 2013

Background

- FDA has a long-standing policy to regulate any computer hardware or software product that falls within the definition of a “device”
- Under the Federal Food, Drug and Cosmetic Act (FFDCA), a “device” is defined to include:
  - Any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar related article
  - Intended for use in the diagnosis of disease or other conditions, or in the cure, treatment or prevention of disease, or intended to affect the structure or function of the body
  - Which does not achieve its principal purposes by chemical action in or on the body of man or by being metabolized (i.e., is not a drug)

Background (cont'd)

- 1989
  - FDA issues Guidance Document, "FDA Policy for the Regulation of Computer Products"
- 2005
  - FDA withdraws the 1989 Guidance
- February 8, 2008
  - FDA issues proposed rule to down-classify "Medical Device Data Systems" or "MDDS" to Class I (previously Class III by default)
- February 15, 2011
  - FDA issues its final rule reclassifying MDDS
- June 19, 2011
  - FDA issues a new Draft Guidance, "Mobile Medical Applications"
- July 9, 2012
  - The Food and Drug Administration Safety and Innovation Act (FDASIA) is enacted, requiring FDA to work with the Office of the National Coordinator for Health Information Technology (ONC) and the Federal Communications Commission (FCC) to draft a report on proposed strategies and recommendations for the regulation of health IT, including mobile medical apps

Final Guidance

- On September 23, FDA issued its Final Guidance on Mobile Medical Applications
  - FDA confirmed that it considers mobile medical apps to be within its regulatory authority
  - FDA also confirmed its intent to focus only on a small subset of mobile apps that may present a risk to patients

Final Guidance (cont'd)

- Comparison with 2011 Draft Guidance
  - Very similar to Draft Guidance in overall organization and content
  - Expanded discussion and examples of apps that are subject to enforcement discretion (i.e., not actively regulated by FDA)
  - Expanded discussion on the types of entities that are not subject to FDA regulation
- Different approach to defining FDA policy
  - Generally, FDA provides specific rules or factors to consider in determining the threshold for FDA regulation
  - The Final Guidance takes an unusual approach by listing generic types and specific examples of apps that FDA will or will not regulate, rather than providing guiding principles or factors to determine what is or is not regulated
    - Provides clarity and certainty for those apps that fall clearly within a generic type or specific example listed
    - For those apps that are not clearly within these types/examples, FDA provides little guidance on how to determine whether the apps are regulated

Final Guidance (cont'd)

- What Is Regulated?
- Who Is Regulated?
- What Is Not Regulated?
- Changes in FDA Policy
- Ambiguities
- Examples

What Is Regulated?

- In the Final Guidance, FDA describes its policy for mobile medical app regulation in three ways

- First approach (described in Sections I & IV)
  - FDA will regulate only those apps that fall within the definition of "mobile medical application"

What Is Regulated? (cont'd)

- "Mobile Medical Application" or "Mobile Medical App"
  - A mobile app that:
    - meets the definition of a "device" under the FFDCA, and
    - either (a) is used as an accessory to a regulated medical device or (b) transforms a mobile platform (such as a smart phone) into a regulated medical device
- "Mobile App"
  - A software application that can be executed on a mobile platform (e.g., a smart phone, tablet computer, or other portable computer) or a web-based software application that is tailored to a mobile platform but is executed on a server
- "Regulated Medical Device"
  - A product that:
    - meets the definition of a "device" under the FFDCA, and
    - has been classified by FDA or otherwise cleared or approved by FDA – e.g., via a 510(k) premarket notification or premarket approval application (PMA)
  - Includes novel devices, even if not already cleared, approved, or classified by FDA

What Is Regulated? (cont'd)

- Second Approach (described in Section V):
  - FDA intends to apply its regulatory oversight to only those mobile apps that:
    - Meet the definition of a "device" under the FFDCA, and
    - Have functionality that could pose a risk to patient safety if the mobile apps did not function as intended
- Third Approach (described in Section V.A):
  - FDA intends to apply its regulatory oversight to only the subset of mobile apps identified in Section V.A and Appendix C

Who Is Regulated?

- Mobile Medical App Manufacturer
  - Any person or entity that manufactures mobile medical apps in accordance with the definitions of a "manufacturer" in 21 C.F.R. Parts 803, 806, 807, 820
  - Includes any entity that:
    - Creates, designs, develops, labels, re-labels, remanufactures, modifies, or creates a mobile medical app software system from multiple components;
    - Initiates specifications or requirements for mobile medical apps or procures product development/manufacturing services from other individuals or entities (second parties) for subsequent commercial distribution;
    - Creates a mobile medical app and hardware attachments for a mobile platform that are intended to be used as a medical device by any combination of the mobile medical app, the hardware attachments, and the mobile platform; and
    - Creates a mobile medical app or a software system that provides users access to the medical device function through a website subscription, software as a service, or other similar means.

Who Is Regulated? (cont'd)

- Mobile Medical App Manufacturer
  - Does not include
    - Entities that only sell or distribute mobile medical apps (e.g., in app stores)
    - Manufacturers or distributors of general purpose mobile platforms, such as smart phones and tablet computers, that are not marketed for medical device functions
    - Providers of tools, services, or infrastructure used in the development, distribution, or use of a mobile medical app
    - Licensed practitioners that create mobile medical apps solely for use in their professional practices
    - Manufacturers that use mobile medical apps solely in research, teaching, or analysis and do not introduce such apps in commercial distribution

What Is Not Regulated?

- FDA intends to exercise enforcement discretion for mobile apps that:
  - May meet the definition of a "device" under the FFDCA, but
  - Present only a low risk to patients
- FDA lists generic types and specific examples of mobile apps subject to enforcement discretion in Section V.B and Appendix B of the Final Guidance

What Is Not Regulated? (cont'd)

- FDA will not regulate mobile apps that do not meet the definition of a "device" under the FFDCA
- FDA lists generic types and specific examples of mobile apps that are not "devices" in Appendix A of the Final Guidance

Changes in FDA Policy: Licensed Practitioners

FDA Final Guidance

- Not regulated as manufacturers:
  - Licensed practitioners who manufacture a mobile medical app or alter a mobile medical app solely for use in their professional practice and do not label or promote their mobile medical apps to be generally used by other licensed practitioners or other individuals
  - Exemption applies even if a doctor in a group practice (including a telehealth network) permits other physicians in the practice to provide the mobile app to their patients

Prior FDA Policy/Regulation

- Preamble to MDDS Final Rule:
  - The term "manufacturer" includes not only traditional hardware and software developers, but also users, such as hospitals and other providers, that create their own in-house MDDS products or modify another manufacturer's MDDS product, and use such products "for purposes of the user's clinical practice or otherwise for commercial distribution"

Changes in FDA Policy: Emergency Alerts and Nurse Call

FDA Final Guidance

- Enforcement discretion applies to:
  - Apps that enable a patient or caregiver to create and send an alert or general emergency notification to first responders
  - Apps intended to allow a user to initiate a pre-specified nurse call or emergency call using broadband or cellular phone technology

Prior FDA Policy/Regulation

- Medical alert devices and nurse call systems are regulated as Class II, 510(k)-exempt devices
- Product code ILQ, 21 C.F.R. § 890.3710

Changes in FDA Policy: Medication Reminders

FDA Final Guidance

- Enforcement discretion applies to:
  - Apps that assist patients in adhering to pre-determined medication dosing schedules by simple prompting
  - Apps that keep track of medications and provide user-configured reminders for improved medication adherence

Prior FDA Policy/Regulation

- Medication reminder devices are regulated as Class I, 510(k)-exempt devices
- Product code NXQ, 21 C.F.R. § 890.5050

Changes in FDA Policy: Device Accessories

- No change
  - "FDA's policies regarding accessories to medical devices are not unique to mobile medical apps and go beyond the scope of this guidance. Specifically this guidance does not address FDA's general approach for accessories to medical devices."
  - "FDA has previously clarified that when stand-alone software is used to analyze medical device data, it has traditionally been regulated as an accessory to a medical device or as medical devices software."

Ambiguities: Clinical Decision Support Software

CDS software not included in the Final Guidance

- Dr. Jeffrey Shuren, Director of CDRH, stated that clinical decision support software will be addressed separately
- The Final Guidance states that it "does not address the approach for software that performs patient-specific analysis to aid or support clinical decision-making"

Or is it?

- The Final Guidance states that regulated mobile medical apps include:
  - Apps that perform patient-specific analysis and provide patient-specific diagnosis or treatment recommendations
  - Apps that perform sophisticated analysis or interpret data from another medical device

Ambiguities: Transmission of Medical Device Data

Enforcement discretion applies to:

- Apps that allow a user to collect (electronically or manually entered) blood pressure data and share this data through e-mail, track and trend it, or upload it to a personal or electronic health record
- Apps that provide simple tools for patients with chronic conditions to log, track, or trend their events or measurements (e.g., blood pressure measurements) and share this information with their health care providers as part of a disease-management plan

Regulated mobile medical apps:

- Mobile apps that display, transfer, store, or convert patient-specific medical device data from a connected device
- Apps that meet the definition of an MDDS

Ambiguities: Applicability to Other Software

- Although the Final Guidance states that it applies to mobile medical applications, it is the only guidance document on how FDA applies its device authority to software products
- FDA confirms in the Final Guidance that software applications performing medical device functions are subject to device regulation, regardless of the platform on which the software is run (e.g., desktop computer or mobile platform)

Example: Apps for Diabetes

Regulated Apps	Enforcement Discretion	Not a Device
• Apps that use an attachment to the mobile platform to measure blood glucose levels • Apps for diabetes management per 21 C.F.R. § 862.9(c)(5)	• Apps that coach patients with diabetes and promote strategies for maintaining a healthy weight, getting optimal nutrition, exercising and staying fit, or adhering to pre-determined medication dosing schedules by simple prompting • Apps that provide simple tools for patients with diabetes to log, track, or trend their events or measurements and share this information with their health care providers as part of a disease-management plan • Apps that provide prediabetes patients with guidance or tools to help them develop better eating habits or increase physical activity	• Apps that provide patients with educational and reference information about diabetes

Example: Apps for Cameras and Videos

Regulated Apps	Enforcement Discretion	Not a Device
• Apps that use a mobile platform's built-in features such as light, vibrations, camera, or other similar sources to perform medical device functions (e.g., mobile medical apps that are used by a licensed practitioner to diagnose or treat a disease) • Apps intended for use as surgical cameras (21 C.F.R. § 878.4160) • Apps for use with endoscopic video imaging systems (21 C.F.R. § 876.1500)	• Apps that serve as videoconferencing portals specifically intended for medical use and to enhance communications between patients, healthcare providers, and caregivers • Apps specifically intended for medical uses that utilize the mobile device's built in camera or a connected camera for purposes of documenting or transmitting pictures (e.g., photos of a patient's skin lesions or wounds) to supplement or augment what would otherwise be a verbal description in a consultation between clinicians or between a clinician and a patient	• Apps that provide surgical training videos for healthcare providers • Apps that allow patients or healthcare providers to interact through video or other communication mechanisms, but are not specifically intended for medical purposes

Example: Apps for Calculations or Analysis

Regulated Apps	Enforcement Discretion	Not a Device
• Apps that perform patient-specific analysis and provide patient-specific diagnosis or treatment recommendations • Apps that perform sophisticated analysis or interpret data from another medical device	• Apps that perform simple calculations routinely used in clinical practice, such as BMI, mean arterial pressure, APGAR score, NIH stroke scale, delivery date estimator • Apps that provide a checklist of common signs and symptoms to provide a list of possible medical conditions and advice on when to consult a healthcare provider	• Apps that are general purpose calculators • Apps that provide clinicians with medical reference materials

Example: Apps for Screening

Regulated Apps	Enforcement Discretion	Not a Device
• Apps that present donor history questions to a potential blood donor and record the responses for use by a blood collection facility in determining donor eligibility	• Apps that use patient characteristics, such as age, sex, and behavioral risk factors, to provide patient-specific screening, counseling and preventative recommendations from well-known and established authorities	• Apps that provide clinicians with medical reference materials on patient or donor screening

Example: Mobile Platform Manufacturers

Not Regulated	Regulated
• Entities that only manufacture, distribute, or market mobile platforms and do not make medical device claims (i.e., labeling or promotional claims that the platform may be used in the diagnosis, cure, mitigation, treatment, or prevention of diseases or other medical conditions or to affect the structure or function of the body)	• Manufacturers or distributors that make medical device claims for their mobile platforms • Manufacturers or distributors that bundle a mobile medical app with their mobile platforms (e.g., selling mobile platform pre-installed with an electronic stethoscope app or medical image viewing software) • Manufacturers or distributors that bundle a mobile platform with another medical device (e.g., a glucose strip reader)

Example: Tools, Services, or Infrastructure

Not Regulated	Regulated
• Providers of Internet connectivity • Providers that host the web service for content or software applications • Cloud hosting services • Application hosting services	• Developer of a mobile app that allows clinicians to access a software application (run on a server) that provides remote storage and display of medical images, EEG waveforms, or other medical device data • Developer of a mobile app that allows clinicians to access a remotely run software service that creates a dosage plan for radiation therapy based on the input of patient-specific parameters by the clinician

FDA's Regulatory Requirements for Mobile Medical Applications

- Degree of FDA regulation depends on the applicable device classification
  - Class I – General Controls
  - Class II – General Controls, Special Controls, and 510(k) Clearance
  - Class III – General Controls and PMA Approval
- Appendix D of the Final Guidance lists examples of current FDA classification regulations that may be applicable to mobile medical apps
- For apps that do not clearly fall within an existing classification regulation, it may be necessary to contact FDA for advice on proper device classification

Other Developments Affecting Mobile Medical Apps

- Medical Device Tax
  - Enacted as part of the healthcare reform law
  - Imposes a 2.3% excise tax on “the sale of any taxable medical device by the manufacturer, producer, or importer”
  - A “taxable medical device” includes any device listed with FDA under 21 C.F.R. Part 807

Other Developments Affecting Mobile Medical Apps (cont'd)

- FDASIA Workgroup Recommendations
  - FDA should actively establish a policy of "Enforcement Discretion" for **lowest**-risk HIT, where enforcement of regulations is inappropriate
  - FDA should assess exemption from GMP for **lower**-risk HIT
  - FDA should in general expedite guidance and provide clarity on issues in this area
  - FDA improve its internal coordination on HIT software, and mobile medical apps policies and regulatory treatment
  - FDA should utilize external facing resources to proactively educate the public about how policies and regulation impact HIT and MMA
  - There may exist a need for additional funding to appropriately staff and build FDA expertise in HIT and mobile medical apps

Other Developments Affecting Mobile Medical Apps (cont'd)

- FDASIA Workgroup Recommendations
  - HIT should not be subject to FDA premarket requirements, except:
    - Medical device accessories (to be defined clearly by FDA)
    - Certain forms of high risk clinical decision support (to be defined clearly by FDA)
    - Higher risk software use cases, including those where the intended use elevates aggregate risk
- Final FDASIA report due to Congress by January 2014

Other Developments Affecting Mobile Medical Apps (cont'd)

- FTC Regulation
  - Privacy Guidelines
  - Enforcement
- Sunshine reporting
  - For apps requiring 510(k) or PMA clearance

Thank You!

Discussion and Questions

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