mHealth Community Summary and Analysis FDA Mobile Medical Applications Final Guidance

On September 24, 2013, the Food and Drug Administration (FDA) released final guidance on mobile medical applications (apps). The guidance provides industry with an in-depth explanation of the agency’s “current thinking” on the appropriate regulation of mobile apps, limiting its scope to apps that transform a mobile device or platform into a medical device. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance.

In response to industry feedback during the public comment period following the release of the draft guidance, FDA took care to expand definitions and provide concrete, detailed examples of what the agency will regulate, what is clearly out of scope and what it will choose not to regulate through enforcement discretion.

The following analysis is provided by the mHealth Legal/Policy Task Force. Questions to FDA can be sent to mobilemedicalapps@fda.hhs.gov

GUIDANCE – KEY TAKEAWAYS

Purpose of the guidance:
This guidance explains the FDA’s intentions to exercise its authority over a subset of mobile apps, to promote innovation and to protect patient safety.

Consistent with the FDA’s existing oversight approach that considers functionality rather than platform, the FDA intends to apply its regulatory oversight to only those mobile apps that are medical devices and whose functionality could pose a risk to a patient’s safety if the mobile app were to not function as intended. This subset of mobile apps the FDA refers to as mobile medical apps.

Keep in mind that the FDA regime is largely self-policing, and that Guidance is non-binding (i.e., it is not a “safe harbor”). You should continue to consult the regulations, contact the FDA in areas of uncertainty or seek appropriate legal counsel.

What changed since the Draft Guidance?
The FDA has also added two new appendices: Examples of mobile apps that are not considered medical devices, and examples of apps on which the FDA would exercise enforcement discretion.

The FDA will not regulate general purpose tools including some medical calculators such as Body Mass Index (BMI), total body water / urea volume of distribution, mean arterial pressure, Glasgow Coma Scale score, APGAR score, NIH Stroke Scale and delivery date estimators. In the draft guidance, the FDA had indicated it would regulate those apps.
The FDA also indicated that it would not regulate NXQ product code devices, which are Medication Reminder Class I, 510(k) and GMP-exempt medical devices. Copyright 2013 mHIMSS Page 2 9/27/2013

**It's not about the platform, it's about the functionality**

In general, if a mobile app is intended for use in performing a medical device function, FDA will continue to regulate that function, regardless of the platform on which it is run. The regulatory requirements manufacturers must meet are determined by the intended use of the mobile medical app. FDA only intends to apply oversight authority to those mobile apps whose functionality could pose a risk to a patient’s safety if the mobile app were to not function as intended.

**“Intended Use” [Language extracted from the FDA Final Guidance]**

The intended use of a mobile app determines whether it meets the definition of a “device” and is subject to regulation. Intended use may be shown by labeling claims, advertising materials, or oral or written statements by manufacturers or their representatives. When the intended use of a mobile app is for the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body of humans, the mobile app is a device.

A mobile app is deemed a “mobile medical application” if it is a device and its intent is:

- To be used as an accessory to a regulated medical device; or
- To transform a mobile platform into a regulated medical device

A mobile application or “mobile app” is defined as a software application that can be executed (run) on a mobile platform (i.e., a handheld commercial off-the-shelf computing platform, with or without wireless connectivity such as mobile computers including smart phones, tablet computers, or other portable computers), or a web-based software application (like HTML5) that is tailored to a mobile platform but is executed on a server.

**What the guidance does not address:**

This guidance does not address the approach for software that performs patient-specific analysis to aid or support clinical decision-making. Clinical Decision Support (CDS) provides clinicians, staff, patients or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care. CDS encompasses a variety of tools to enhance decision-making in the clinical workflow. These tools include computerized alerts and reminders to care providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support, and contextually relevant reference information, among other tools.

This guidance does not address FDA’s general approach for accessories to medical devices

**“Three Key Concepts”**

1. “Not regulated” means mobile apps that are not considered medical devices under the FDA regulations
2. “Enforcement discretion” means FDA’s decision not to enforce requirements under the Food, Drug, and Cosmetics Act (FD&C Act) on mobile apps that are medical devices, but pose a low risk to patients
3. “Regulated” means mobile apps that are considered medical devices under the FDA regulations (i.e., “mobile medical apps”)
What is regulated? [Language extracted from the FDA Final Guidance]

Mobile apps may take a number of forms, but it is important to note that the FDA intends to apply its regulatory oversight to only the subset of mobile apps that can transform a 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. Regardless of the mechanism behind the transformation, FDA considers such mobile apps to be medical devices, i.e., mobile medical apps.

Regardless of regulatory oversight, manufacturers are encouraged to follow the Quality Systems regulations to prevent harm in the development of all mobile apps.

FDA believes all manufacturers of medical device software should have in place an adequate quality management system that helps ensure that their products consistently meet applicable requirements and specifications and can support the software throughout its total life cycle. Having and maintaining an adequate quality management system is also important since the FDA has found that the majority of software-related failures in medical devices are due to design errors. In one study, the most common problem was failure to validate software prior to routine maintenance.

What is not regulated? [Language extracted from the FDA Final Guidance]

Mobile apps that are not considered devices, and therefore are not subject to regulation are those that are intended generally for patient education, and are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease by aiding clinical decision-making (i.e., to facilitate a health professional’s assessment of a specific patient, replace the judgment of a health professional, or perform any clinical assessment). See Appendix A of the Final Guidance for additional description and examples.

What is subject to FDA’s enforcement discretion? [Language extracted from the FDA Final Guidance]

Mobile apps that MAY meet the definition of medical device but for which FDA intends to exercise enforcement discretion. These mobile apps may be intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease. Even though these mobile apps MAY meet the definition of a medical device, FDA intends to exercise enforcement discretion for these mobile apps because they pose lower risk to the public. Mobile apps that:

- 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; or
- Enable patients or providers to interact with Personal Health Record (PHR) or Electronic Health Record (EHR) systems.

Responsible Parties: Mobile Medical App Manufacturers [Language extracted from the FDA Final Guidance]
“Mobile Medical App Manufacturer” encompasses any person or entity that manufactures mobile medical apps in accordance with 21 CFR Parts 803, 806, 807, and 820. Includes: Anyone who initiates specifications, designs, labels, or creates a software system or application in whole or from multiple software components.

Examples of mobile medical app manufacturers include any person or entity that:
1. Creates a mobile medical app by using commercial off the shelf (COTS) software components and markets the product to perform as a mobile medical app;
2. Creators of the original idea for a mobile medical app. Software developers (design and development) would not constitute manufacturers, and instead the author is considered the manufacturer;
3. Creates a mobile medical app or software system that provides users access to the medical device function through a website subscription, software as a service, or similar means.

Examples of persons or entities NOT considered to be mobile medical app manufacturers:
1. Manufacturers or distributors of mobile platforms who solely distribute or market their platform and do not intend (by marketing claims) the platform to be used for medical device functions;
2. FDA does not consider entities that exclusively distribute mobile medical apps (such as the owners/operators of the (Apple App Store, Microsoft App Store, Google Play) to be medical device manufacturers;
3. Providers of tools, services, or infrastructure used in the development, distribution, or use of a mobile medical app (e.g., internet service including 3rd party tool kits, development environments and Software Development Kits (SDK))
   a. Exception: A creator of a medical app or a software system that provides user access to the medical device function through a website subscription, software as a service, or other similar means IS considered a mobile medical app manufacturer;
4. Licensed practitioners, including physicians, dentists, and optometrists, 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.
   a. Exception: If Dr. XYZ, the licensed practitioner, distributes the “XYZ-recorder” and, through labeling or promotion intends to make it generally available to or to be generally used by other physicians (or other specially qualified persons), Dr. XYZ would be considered a mobile medical app manufacturer;
5. Persons who manufacture mobile medical apps solely for use in research, teaching, or analysis and do not introduce such devices into commercial distribution.

Mobile apps that transform a mobile platform into a regulated medical device and therefore are mobile medical apps: These mobile apps 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). Possible product codes: Varies depending on the intended use and function of the mobile medical app; see additional examples below.

- Mobile apps that use a sensor or lead that is connected to a mobile platform to measure and display the electrical signal produced by the heart (electrocardiograph or ECG). Possible product code(s): DPS, MLC, OEY (21 CFR 870.2340), MLO, MWJ (21 CFR 870.2800).
- Mobile apps that use a sensor or electrode attached to the mobile platform or tools within the mobile platform itself (e.g., microphone and speaker) to electronically amplify and “project sounds associated with the heart, arteries and veins and other internal organs” (i.e., an electronic stethoscope). Possible product code: DQD (21 CFR 870.1875(b)).
- Mobile apps that use a sensor or electrode attached to the mobile platform or tools within the mobile platform itself to measure physiological parameters during cardiopulmonary resuscitation (CPR) and give feedback about the quality of CPR being delivered. Possible product code: LIX (21 CFR 870.5200).
- Mobile apps that use a sensor attached to the mobile platform or tools within the mobile platform itself to record, view, or analyze eye movements for use in the diagnosis of balance disorders (i.e., nystagmograph). Possible product code: GWN (21 CFR 882.1460).
- Mobile apps that use tools within the mobile platform (e.g., speaker) to produce controlled levels of test tones and signals intended for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders (i.e., an audiometer). Possible product code: EWO (21 CFR 874.1050).
- Mobile apps that use a sensor attached to the mobile platform or tools within the mobile platform itself (e.g., accelerometer) to measure the degree of tremor caused by certain diseases (i.e., a tremor transducer). Possible product code: GYD (21 CFR 882.1950).
- Mobile apps that use tools within the mobile platform itself (e.g., accelerometer, microphone) to measure physiological parameters (e.g., limb movement, electrical activity of the brain (EEG)) during sleep and are intended for use in diagnosis of specific diseases or conditions such as sleep apnea. Possible product code(s): OL (21 CFR 882.1400), LEL, MNR (21 CFR 868.2375), FLS, NPF (21 CFR 868.2377).
- Mobile apps that use an attachment to the mobile platform to measure blood oxygen saturation for diagnosis of specific disease or condition. Possible product code(s): DQA, NL, MUD, NMD (21 CFR 870.2700) or DPZ (21 CFR 870.2710).
- Mobile apps that present donor history questions to a potential blood donor and record and/or transmit the responses to those questions for a blood collection facility to use in determining blood donor eligibility prior to collection of blood or blood components. Possible product code: MMH
- Mobile apps that use an attachment to the mobile platform to measure blood glucose levels. Possible product code: NBW (21 CFR 862.1345).
- Mobile apps that use that use an attachment to the mobile platform (e.g., light source, laser) to treat acne, reduce wrinkles, or remove hair. Possible product code: OLP, OHT, OHS (21 CFR 878.4810), OZC (21 CFR 890.5740).
- Mobile apps that use a microphone or speaker within a mobile platform to serve as a audiometer to allow healthcare providers to determine hearing loss at different frequencies. Possible product code: EWO (21 CFR 874.1050) [Added March 12, 2014]
• Mobile apps that analyze an image of a skin lesion using mathematical algorithms, such as fractal analysis, and provide the user with an assessment of the risk of the lesion. [Added March 12, 2014]

In June 2014 FDA provided updates to the appendix of the MMA Guidance. These changes were identified in March of 2014 and noted.

**Mobile apps that connect to an existing device type for purposes of controlling its operation, function, or energy source and therefore are mobile medical apps:**

- Mobile apps that alter the function or settings of an infusion pump. Possible product codes: MEB, FRN, LZH, LZG, OPP, MEA (21 CFR 880.5725), FIH (21 CFR 876.5820), LKK.
- Mobile apps that act as wireless remote controls or synchronization devices for computed tomography (CT) or X-Ray machines. Possible product code: JAK (21 CFR 892.1750), IZL (21 CFR 892.1720), KPR (21 CFR 892.1680).
- Mobile apps that control or change settings of an implantable neuromuscular stimulator. Possible product code(s): GZC (21 CFR 882.5860).
- Mobile apps that calibrate, control, or change settings of a cochlear implant. Possible product code(s): MCM.
- Mobile apps that control the inflation or deflation of a blood-pressure cuff. Possible product code: DSJ (21 CFR 870.1100), DSK (21 CFR 870.1110), DXN (21 CFR 870.1130).
- Mobile apps that are used to calibrate hearing aids and assess the electroacoustic frequency and sound intensity characteristics emanating from a hearing aid, master hearing aid, group hearing aid or group auditory trainer. Possible product code ETW (21 CFR 874.3310) [Added March 12, 2014].

**WHAT IS NOT REGULATED EXAMPLES OF MOBILE APPS THAT ARE NOT MEDICAL DEVICES – SEE “APPENDIX A” FOR ADDITIONAL DESCRIPTION AND EXAMPLES**

[Language extracted from the FDA Final Guidance]

- Mobile apps that are intended to provide access to electronic “copies” (e.g., e-books, audio books) of medical textbooks or other reference materials with generic text search capabilities.
- Mobile apps that are intended for health care providers to use as educational tools for medical training or to reinforce training previously received.
- Mobile apps that are intended for general patient education and facilitate patient access to commonly used reference information. These apps can be patient-specific (i.e., filters information to patient-specific characteristics), but are intended for increased patient awareness, education, and empowerment, and ultimately support patient-centered health care.
- Mobile apps that automate general office operations in a health care setting and are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.
• Mobile apps that are generic aids or general purpose products. These apps are not considered devices because they are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.

[Language extracted from the FDA Final Guidance]

• Mobile apps that provide or facilitate supplemental clinical care, by coaching or prompting, to help patients manage their health in their daily environment.
  o Examples: Apps that coach patients with conditions such as cardiovascular disease, hypertension, diabetes or obesity, and promote strategies for maintaining a healthy weight, getting optimal nutrition, exercising and staying fit, managing salt intake, or adhering to pre-determined medication dosing schedules by simple prompting.

• Mobile apps that provide patients with simple tools to organize and track their health information
  o Examples: Apps that provide simple tools for patients with specific conditions or chronic disease (e.g., obesity, anorexia, arthritis, diabetes, heart disease) to log, track, or trend their events or measurements (e.g., blood pressure measurements, drug intake times, diet, daily routine or emotional state) and share this information with their health care provider as part of a disease management plan.

• Mobile apps that provide easy access to information related to patients’ health conditions or treatments (beyond providing an electronic “copy” of a medical reference)
  o Examples: Apps that use a patient’s diagnosis to provide a clinician with best practice treatment guidelines for common illnesses or conditions such as influenza; Apps that are drug-drug interaction or drug-allergy look-up tools.

• Mobile apps that are specifically marketed to help patients document, show, or communicate to providers potential medical conditions
  o Examples: 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 healthcare providers or between healthcare providers and patients/caregivers.

• Mobile apps that perform simple calculations routinely used in clinical practice
  o Examples of such general purpose tools include medical calculators for: Body Mass Index (BMI); Total Body Water / Urea Volume of Distribution; Mean arterial pressure; Glasgow Coma Scale score; APGAR score; NIH Stroke Scale; Delivery date estimator
• Mobile apps that enable individuals to interact with PHR systems or EHR systems -- These are apps that provide patients and providers with mobile access to health record systems or enables them to gain electronic access to health information stored within a PHR system or EHR system. Applications that only allow individuals to view or download EHR data are also included in this category. These mobile apps are generally meant to facilitate general patient health information management and health record-keeping activities.

**GOOD MANUFACTURING PRINCIPLES AND REGULATORY REQUIREMENTS**

*Language extracted from the FDA Final Guidance*

Additional information can be found in “Device Advice: Classify Your Medical Device”:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm

**Importance of Quality Management Systems for app development**

Regardless of regulatory oversight, manufacturers are *encouraged* to follow the Quality Systems regulations to prevent harm in the development of all mobile apps. FDA believes all manufacturers of medical device software should have in place an adequate quality management system that helps ensure that their products consistently meet applicable requirements and specifications and can support the software throughout its total life cycle. Having and maintaining an adequate quality management system is also important since the FDA has found that the majority of software-related failures in medical devices are due to design errors. In one study, the most common problem was failure to validate software prior to routine maintenance.

Adequate quality management systems incorporate appropriate risk management strategies, good design practices, adequate verification and validation, and appropriate methods to correct and prevent risks to patients and adverse events that may arise from the use of the product. All of these elements are part of FDA’s QS regulation.

For mobile medical apps, manufacturers must meet the requirements associated with the applicable device classification. If the mobile medical app, on its own, falls within a medical device classification, its manufacturer is subject to the requirements associated with that classification. A mobile medical app, like other devices, may be classified as class I (general controls), class II (special controls in addition to general controls), or class III (premarket approval).

If the mobile medical app falls within a specific medical device classification or augments functionality to a specific medical device classification, manufacturers are immediately subject to meet the requirements of that classification (either I, II, or III).

According to the Draft Guidance, these requirements include:

• Class I devices: General Controls
  - Establishment registration, and Medical Device listing (21 CFR Part 807);
  - Quality System (QS) regulation (21 CFR Part 820);
  - Labeling requirements (21 CFR Part 801);
  - Medical Device Reporting (21 CFR Part 803);
To meet the regulatory requirements described above, developers of mobile medical apps should be mindful that preparing, filing, and waiting for FDA clearance or approval will take time and may cost a significant amount of money. The amount and types of resources needed and the duration of the pre-market process is dependent upon the app/device classification per the descriptions in the previous section. In addition, developers should also budget for the ongoing costs or post-market obligations once the device is marketed.

For feedback or questions, please contact David Collins, Sr. Director, mHealth or Thomas Martin, PhD., Director, mHealth. Visit HIMSS mHealth Community [www.himss.org/mobilehealthit](http://www.himss.org/mobilehealthit) for additional resources from mHealth subject matter experts, and [www.mhealthnews.com](http://www.mhealthnews.com) for news updates.