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Mobile Medical Applications

Guidance for Industry and Food and Drug Administration Staff

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U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health

Center for Biologics Evaluation and Research

Preface

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Mobile Medical Applications

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. 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. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

The Food and Drug Administration (FDA) recognizes the extensive variety of actual and potential functions of mobile apps, the rapid pace of innovation in mobile apps, and the potential benefits and risks to public health represented by these apps. The FDA is issuing this guidance document to inform manufacturers, distributors, and other entities about how the FDA intends to apply its regulatory authorities to select software applications intended for use on mobile platforms (mobile applications or "mobile apps"). Given the rapid expansion and broad applicability of mobile apps, the FDA is issuing this guidance document to clarify the subset of mobile apps to which the FDA intends to apply its authority.

Many mobile apps are not medical devices (meaning such mobile apps do not meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), and FDA does not regulate them. Some mobile apps may meet the definition of a medical device but because they pose a lower risk to the public, FDA intends to exercise enforcement discretion over these devices (meaning it will not enforce requirements under the FD&C Act). The majority of mobile apps on the market at this time fit into these two categories.

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.

FDA is issuing this guidance to provide clarity and predictability for manufacturers of mobile medical apps. Should FDA determine at a later date that the policy in this guidance should be changed in light of new information, the agency would follow a public process, including the

opportunity for public input, consistent with FDA's good guidance practices (GGP) regulation in 21 CFR 10.115.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

As mobile platforms become more user friendly, computationally powerful, and readily available, innovators have begun to develop mobile apps of increasing complexity to leverage the portability mobile platforms can offer. Some of these new mobile apps are specifically targeted to assisting individuals in their own health and wellness management. Other mobile apps are targeted to healthcare providers as tools to improve and facilitate the delivery of patient care.

In 1989, FDA prepared a general policy statement on how it planned to determine whether a computer-based product and/or software-based product is a device, and, if so, how the FDA intended to regulate it. The document, "FDA Policy for the Regulation of Computer Products," became known as the "Draft Software Policy." After 1989, however, the use of computer and software products as medical devices grew exponentially and the types of products diversified and grew more complex (and that trend has continued). As a result, the FDA determined that the draft policy did not adequately address all of the issues related to the regulation of all medical devices containing software. Therefore, in 2005, the Draft Software Policy was withdrawn.[1]

Although the FDA has not issued an overarching software policy, the Agency has formally classified certain types of software applications that meet the definition of a device and, through classification, identified specific regulatory requirements that apply to these devices and their manufacturers. These software devices include products that feature one or more software components, parts, or accessories (such as electrocardiographic (ECG) systems used to monitor cardiac rhythms), as well as devices that are composed solely of software (such as laboratory information management systems). On February 15, 2011, the FDA issued a regulation down-classifying certain computer- or software-based devices intended to be used for the electronic transfer, storage, display, and/or format conversion of medical device data – called Medical Device Data Systems (MDDSs) – from Class III (high-risk) to Class I (low-risk).[2]

The 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[3] or as medical device software.

As is the case with traditional medical devices, certain mobile medical apps can pose potential risks to public health. Moreover, certain mobile medical apps may pose risks that are unique to the characteristics of the platform on which the mobile medical app is run. For example, the

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[1] Annual Comprehensive List of Guidance Documents at the Food and Drug Administration (70 FR 824 at 890) (January 5, 2005).

[2] Medical Devices; Medical Device Data Systems Final Rule (76 FR 8637) (Feb. 15, 2011).

[3] See, for example, Content of a 510(k) -- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm ("Accessories to classified devices take on the same classification as the "parent" device. An accessory such as software that accepts input from multiple devices usually takes on the classification of the "parent" device with the highest risk, i.e., class."); See also final Rule, Medical Devices, Medical Device Data Systems, 76 FR 8637 at 8643-8644 – comment 16 and FDA's response (Feb. 15, 2011).

interpretation of radiological images on a mobile device could be adversely affected by the smaller screen size, lower contrast ratio, and uncontrolled ambient light of the mobile platform. FDA intends to take these risks into account in assessing the appropriate regulatory oversight for these products.

This guidance clarifies and outlines the FDA's current thinking. The Agency will continue to evaluate the potential impact these technologies might have on improving health care, reducing potential medical mistakes, and protecting patients.

III. Definitions

A. Mobile Platform

For purposes of this guidance, "mobile platforms" are defined as commercial off-the-shelf (COTS) computing platforms, with or without wireless connectivity, that are handheld in nature. Examples of these mobile platforms include mobile computers such as smart phones, tablet computers, or other portable computers.

B. Mobile Application (Mobile App)

For purposes of this guidance, 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), or a web-based software application that is tailored to a mobile platform but is executed on a server.

C. Mobile Medical Application (Mobile Medical App)

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)[4]; 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.

[4] Products that are built with or consist of computer and/or software components or applications are subject to regulation as devices when they meet the definition of a device in section 201(h) of the FD&C Act. That provision defines a device as "…an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory", that is "… intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man …" or "… intended to affect the structure or any function of the body of man or other animals …." Thus, software applications that run on a desktop computer, laptop computer, remotely on a website or "cloud," or on a handheld computer may be subject to device regulation if they are intended for use in the diagnosis or the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man. The level of regulatory control necessary to assure safety and effectiveness varies based upon the risk the device presents to public health. (See Appendix D for examples).

The intended use of a mobile app determines whether it meets the definition of a "device." As stated in 21 CFR 801.4,[5] intended use may be shown by labeling[6] 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 man, the mobile app is a device.

One example is a mobile app that makes a light emitting diode (LED) operate. If the manufacturer intends the system to illuminate objects generally (i.e., without a specific medical device intended use), the mobile app would not be considered a medical device. If, however, through marketing, labeling, and the circumstances surrounding the distribution, the mobile app is promoted by the manufacturer for use as a light source for doctors to examine patients, then the intended use of the light source would be similar to a conventional device such as an ophthalmoscope.

In general, if a mobile app is intended for use in performing a medical device function (i.e. for diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease) it is a medical device, regardless of the platform on which it is run. For example, mobile apps intended to run on smart phones to analyze and interpret EKG waveforms to detect heart function irregularities would be considered similar to software running on a desktop computer that serves the same function, which is regulated under 21 CFR 870.2340 ("Electrocardiograph"). FDA's oversight approach to mobile apps is focused on their functionality, just as we focus on the functionality of conventional devices. Our oversight is not determined by the platform. Under this guidance, FDA would **not** regulate the sale or general/conventional consumer use of smartphones or tablets. FDA's oversight applies to mobile apps performing medical device functions, such as when a mobile medical app transforms a mobile platform into a medical device. However, as previously noted, we intend to apply this oversight authority only 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.

[5] "The words 'intended uses' or words of similar import … refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the devices, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put." 21 CFR 801.4.

[6] "The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." Section 201(m) of the FD&C Act, 21 U.S.C. 321(m).

D. Regulated Medical Device

For purposes of this guidance, a "regulated medical device" is defined as a product that meets the definition of device in section 201(h) of the FD&C Act and that has been cleared or approved by the FDA review of a premarket submission or otherwise classified by the FDA.

This definition can include novel devices, whether or not on a mobile platform, that the FDA will clear or approve by the review of a premarket submission or otherwise classify. Examples of regulated medical devices are identified in Appendix D.

E. Mobile Medical App Manufacturer

For purposes of this guidance, a "mobile medical app manufacturer" is any person or entity that manufactures mobile medical apps in accordance with the definitions of manufacturer in 21 CFR Parts 803, 806, 807, and 820.[7] A mobile medical app manufacturer may include anyone who initiates specifications, designs, labels, or creates a software system or application for a regulated medical device in whole or from multiple software components. This term does not include persons who exclusively distribute mobile medical apps without engaging in manufacturing functions; examples of such distributors may include owners and operators of "Google play," "iTunes App store," and "BlackBerry App World." Examples of mobile medical app manufacturers include any person or entity that:

- Creates, designs, develops, labels, re-labels, remanufactures, modifies, or creates a mobile medical app software system from multiple components. This could include a person or entity that 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;
- Initiates specifications or requirements for mobile medical apps or procures product development/manufacturing services from other individuals or entities (second party) for subsequent commercial distribution. For example, when a "developer" (i.e., an entity that provides engineering, design, and development services) creates a mobile medical app from the specifications that were initiated by the "author," the "author" who initiated and developed specifications for the mobile medical app is considered a "manufacturer" of the mobile medical app under 21 CFR 803.3. For purposes of this guidance, manufacturers of a mobile medical app would include persons or entities who are the creators of the original idea (initial specifications) for a mobile medical

[7] Regulatory definitions of the term "manufacturer" or "manufacture" appear in 21 CFR Parts 803, 806, 807, and 820. For example -- under FDA's 21 CFR 807.3(d)-- establishment registration and device listing for manufacturers and initial importers of devices-- ,"*Manufacture, preparation, propagation, compounding, assembly, or processing of a device means the making by chemical, physical, biological, or other procedures of any article that meets the definition of device in section 201(h) of the act." These terms include the following activities: (1) Repackaging or otherwise changing the container, wrapper, or labeling of any device package in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer; (2) Initial importation of devices manufactured in foreign establishments; or (3) Iinitiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution by the person initiating specifications*."

app, unless another entity assumes all responsibility for manufacturing and distributing the mobile medical app, in which case that other entity would be the "manufacturer."[8] Software "developers" of a mobile medical app that are only responsible for performing design and development activities to transform the author's specifications into a mobile medical app would not constitute manufacturers, and instead the author would be considered the manufacturer;

- 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, hardware attachments, and the mobile platform;
- 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,[9] or other similar means.

In contrast, the following are examples of persons or entities that are NOT considered to be mobile medical app manufacturers (i.e., persons *not* within the definition of manufacturer in 21 CFR Parts 803, 806, 807, and 820). Because they are not manufacturers, none of the persons or entities in these examples would have to register their establishments, list their products with the FDA[10] or submit a premarket application:

- Manufacturers or distributors of mobile platforms who solely distribute or market their platform and do not intend (by marketing claims -- e.g., labeling claims or advertising material) the platform to be used for medical device functions. When mobile medical apps are run on a mobile platform, the mobile platform is treated as a component of the mobile medical app's intended use. [11] Therefore the mobile platform manufacturer is exempt from the Quality System regulation and registration and listing requirements. [12] For example, if it is possible to run mobile medical apps on BrandNamePhone but BrandNamePhone is not marketed by BrandNameCompany as intended for use as a medical device, then BrandNameCompany would not be considered a mobile medical app manufacturer or a medical device manufacturer. Also, in this example, the BrandName Phone sold to consumers would not be regulated by FDA as a medical device. FDA does **not** consider entities that exclusively distribute mobile medical apps, such as the owners and operators of the "iTunes App store" or the "Android market," to be medical device manufacturers. FDA also does not consider mobile platform manufacturers to be medical device manufacturer just because their mobile platform could be used to run a mobile medical app regulated by FDA.
- Third parties who solely provide market access to mobile medical apps (i.e. solely distribute mobile apps), but do not engage in any manufacturing functions as defined in

[8] See 21 CFR 803.3 (definition of manufacturer) and 21 CFR 807.20(a)(2).
[9] By this we mean to include any "server software application" that provides a service to a client software application on a mobile platform.
[10] 21 CFR 807.65 and 21 CFR 807.85
[11] See 21 CFR 820.3(c) which defines a component as "any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.".
[12] 21 CFR 807.65(a) and 21 CFR 820.1(a).

21 CFR Parts 803, 806, 807, and 820. Examples of such third parties may include owners and operators that are only engaged in providing an online market place that allow mobile medical app manufacturers to commercially distribute their mobile medical apps. Specific examples of such online market places include "Google play," "iTunes store," and "BlackBerry App World";

- Providers of tools, services or infrastructure used in the development, distribution, or use of a mobile medical app. Examples include providers of internet connectivity (i.e., internet service), providers of general purpose computer or information technology, providers that host the web service for content or software application. Other examples of providers of tools, services, or infrastructure include customer support services, data center hosting services, cloud hosting services, application hosting services, wireless carriers, or providers of software development kits. However, a creator of 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,[13] or other similar means *is* considered a mobile medical app manufacturer;

- 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.[14,15] For example, if Dr. XYZ, a licensed practitioner, creates a mobile medical app called the "XYZ-recorder" which enables attaching an ECG electrode to a smartphone, and provides the "XYZ-recorder" to his/her patient to use it to record the patient's electrocardiographic readings for 24 hours, Dr. XYZ is not considered a mobile medical app manufacturer. If Dr. XYZ is in a group practice (including a telehealth network) and permits other physicians in the practice to provide the XYZ-recorder to their patients, Dr. XYZ is not considered a mobile medical apps manufacturer. However, 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;

- Persons who manufacture mobile medical apps solely for use in research, teaching, or analysis and do not introduce such devices into commercial distribution. We note that while persons conducting research using mobile medical apps involving human subjects are exempt from registration and listing, they may instead be subject to investigational device exemption regulations.[16,17]

[13] See footnote 9.
[14] Section 510(g)(2) of the FD&C Act: - *Registration of producers of drugs or devices – Exclusions from application of section*: "practitioners licensed by law to prescribe or administer drugs or devices and who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in the course of their professional practice."
[15] See 21 CFR 807.65(d).
[16] See 21 CFR 807.65(f).
[17] See 21 CFR 812.1.

IV. Scope

This guidance explains the FDA's intentions to focus its oversight on a subset of mobile apps. Mobile medical apps as defined in section III include only those mobile apps that meet the statutory definition of a device and either are intended:

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

Appendix A provides examples of mobile apps that FDA does **NOT** consider to meet the definition of medical device and, therefore, are NOT mobile medical apps for the purposes of this guidance.

Section V-B and Appendix B provide examples of mobile apps that MAY meet the definition of a medical device but for which the FDA intends to exercise enforcement discretion because they pose a low risk to patients.[18]

This guidance does not address the approach for software that performs patient-specific analysis to aid or support clinical decision-making.

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.

If you are developing a mobile medical app with an entirely new intended use, we encourage you to contact FDA to discuss what regulatory requirements may apply.

[18] This indicates that for certain mobile medical app devices, such as those in Appendix B, the FDA intends not to pursue enforcement action for violations of the FD&C Act and applicable regulations by a manufacturer of a mobile app that meets the definition of a device in section 201(h) of the FD&C Act as specified in this guidance. This does not constitute a change in the requirements of the FD&C Act or any applicable regulation.

V. Regulatory approach for mobile medical apps

As described in this guidance, 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 approach to overseeing mobile medical apps is consistent with our existing approach to overseeing medical device functionality of a product and the risks it poses to patients regardless of the shape, size or the platform. The FDA believes that this subset of mobile medical apps poses the same or similar potential risks to the public health as currently regulated devices if they fail to function as intended.

The FDA strongly recommends that manufacturers of all mobile apps that may meet the definition of a device follow the Quality System[19] regulation (which includes good manufacturing practices) in the design and development[20] of their mobile medical apps and initiate prompt corrections to their mobile medical apps, when appropriate, to prevent patient and user harm.

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).[21]

A. Mobile medical apps: Subset of mobile apps that are the focus of FDA's regulatory oversight

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 identified below and in Appendix C. These mobile apps can transform a mobile platform into a regulated medical device by using attachments, display screens, sensors, or other such methods. Regardless of the mechanism behind the transformation, FDA considers such mobile apps to be mobile medical apps.

The following are mobile apps that FDA considers to be mobile medical apps subject to regulatory oversight:

[19] See 21 CFR part 820.

[20] The FDA has found that the majority of software-related device failures are due to design errors. In one study, the most common problem was failure to validate software prior to routine production. See Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule); Quality System Regulation (61 FR 52602) (October 7, 1996).

[21] See footnotes 3 and 4.

1. **Mobile apps that are an extension of one or more medical devices by connecting[22] to such device(s) for purposes of controlling[23] the device(s) or displaying, storing, analyzing, or transmitting patient-specific medical device data.**

    - *Examples of displays of patient-specific medical device data include:* remote display of data from bedside monitors, display of previously stored EEG waveforms, and display of medical images directly from a Picture Archiving and Communication System (PACS) server, or similar display functions that meet the definition of an MDDS. Mobile medical apps that display medical device data to perform active patient monitoring are subject to regulations associated with such devices.

    - *Examples of mobile apps that control medical devices include:* apps that provide the ability to control inflation and deflation of a blood pressure cuff through a mobile platform and mobile apps that control the delivery of insulin on an insulin pump by transmitting control signals to the pumps from the mobile platform.

      Mobile medical apps of this type are considered an accessory to the connected device and are required to comply with the controls applicable to that connected device. The FDA considers such mobile medical apps to extend the intended use and functionality of the connected medical device. As a result, the mobile medical app would be required to comply with the regulations applicable to the connected medical device in order to address any associated risks.

    - *Examples of mobile apps that display, store, or transfer medical device data in its original format include:* apps that are intended to display or store medical device data, without controlling or altering the functions or parameters of any connected medical device constitute a Medical Device Data System (MDDS) (21 CFR 880.6310) and are subject to class I requirements (general controls). Class I are the lowest risk devices with the fewest requirements and generally no premarket submission. Class I general controls include these basics: adequate design controls, registration, device listing, adverse event reporting, and corrections and removals. The FDA believes that requiring general controls sufficiently manages the risks for mobile medical apps that are used as a secondary display to a regulated medical device and are not intended to provide primary diagnosis or treatment decisions (i.e., mobile medical apps that meet the MDDS definition).

2. **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 use attachments, display screens, sensors or other such similar components to**

[22] To meet this criterion, the mobile medical apps need not be physically connected to the regulated medical device (i.e. the connection can be wired or wireless).
[23] Controlling the intended use, function, modes, or energy source of the connected medical device.

transform a mobile platform into a regulated medical device are required to comply with the device classification associated with the transformed platform.

- *Examples of these types of mobile apps include:* a mobile app that uses a mobile platform for medical device functions, such as attachment of a blood glucose strip reader to a mobile platform to function as a glucose meter; or attachment of electrocardiograph (ECG) electrodes to a mobile platform to measure, store, and display ECG signals; a mobile app that uses the built-in accelerometer on a mobile platform to collect motion information for monitoring sleep apnea; a mobile app that uses sensors (internal or external) on a mobile platform for creating electronic stethoscope function is considered to transform the mobile platform into an electronic stethoscope; manufacturers of such a mobile app are required to follow the requirements of 21 CFR 870.1875(b) (Electronic Stethoscope); and similarly a mobile app that displays radiological images for diagnosis transforms the mobile platform into a class II Picture Archiving and Communications System (PACS) under 21 CFR 892.2050.

  The FDA has cleared several mobile medical apps with attachments to a mobile platform. Specifically, patient monitoring mobile apps that monitors a patient for heart rate variability from a signal produced by an electrocardiograph, vectorcardiograph, or blood pressure monitor are classified as cardiac monitoring software under 21 CFR 870.2300 (Cardiac monitor). Other mobile medical apps that use a hardware attachment or interface to a monitoring system that have been cleared include an automatic electronic blood pressure monitor under 21 CFR 870.1130 and a perinatal monitoring system under 21 CFR 884.2740.

3. **Mobile apps that become a regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations. These types of mobile medical apps are similar to or perform the same function as those types of software devices that have been previously cleared or approved.**

   - *Examples of mobile apps that perform sophisticated analysis or interpret data (electronically collected or manually entered) from another medical device include:* apps that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy; Computer Aided Detection software (CAD); image processing software[24]; and radiation therapy treatment planning software [25]. We believe that these types of software present the same level of risk to patients regardless of the platform on which they run.

[24] 21 CFR 892.2050.
[25] 21 CFR 892.5050.

The FDA encourages manufacturers of such mobile medical apps that perform patient-specific analysis to contact FDA to discuss what, if any, regulatory requirements may apply to their mobile app. For additional examples see Appendix C.

B. Mobile Apps for which FDA intends to exercise enforcement discretion (meaning that FDA does not intend to enforce requirements under the FD&C Act)

FDA intends to exercise enforcement discretion for 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.

Some mobile apps in the above categories and listed below may be considered mobile medical apps, and others might not. For those mobile apps listed below that are devices, FDA intends to exercise enforcement discretion because they pose a low risk to patients.

The following examples represent mobile apps for which the FDA intends to exercise enforcement discretion:

1. **Mobile apps that provide or facilitate supplemental clinical care, by coaching or prompting, to help patients manage their health in their daily environment.** – These are apps that supplement[26] professional clinical care by facilitating behavioral change or coaching patients with specific diseases or identifiable health conditions in their daily environment. Examples include:
    - 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[27] by simple prompting.

[26] By this we mean that the app can be safely used by a patient without active oversight by a medical professional and, when used for serious conditions necessitating professional medical care, use of the app is not intended to replace or discourage seeking treatment from a health care provider.

[27] We consider these mobile medical apps as "medication reminders – Product code NXQ" currently defined as "*A medication reminder is a device intended for medical purposes to provide alerts to patients or healthcare providers for pre-determined medication dosing schedules. The device may incorporate wireless communication.*" The FDA

2. **Mobile apps that provide patients with simple tools to organize and track their health information** – These are apps that provide patients with tools[28] to organize and track health information without providing recommendations to alter or change a previously prescribed treatment or therapy. Examples include:
    - 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.

3. **Mobile apps that provide easy access to information related to patients' health conditions or treatments (beyond providing an electronic "copy" of a medical reference)** – These are apps that provide contextually-relevant information to users by matching patient-specific information (e.g., diagnosis, treatments, allergies, signs or symptoms) to reference information routinely used in clinical practice[29] (e.g., practice guidelines) to facilitate a user's assessment of a specific patient. Examples include:
    - 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.

4. **Mobile apps that are specifically marketed to help patients document, show, or communicate to providers potential medical conditions** – These are apps that in their labeling or promotional materials are not promoted for medical uses but which, by virtue of other circumstances surrounding their distribution, may meet the definition of a medical device. These products either pose little or no risk, or are the sole responsibility of the health care providers who have used them in medical applications. Examples include:
    - 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.

5. **Mobile apps that perform simple calculations routinely used in clinical practice** – These are apps that are intended to provide a convenient way for clinicians to perform various

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intends to exercise enforcement discretion for this specific product code (NXQ) identified under 21 CFR 890.5050 – Daily activity assist device.

[28] We consider these mobile apps to be tools which are not intended to provide specific treatment recommendations and/or are not part of diabetes management referred to in 21 CFR 862.9(c)(5).

[29] The type of information provided in these apps is from authoritative medical sources, as recognized by the field or discipline that is the subject of the app.

simple medical calculations taught in medical schools[30] and are routinely used in clinical practice. These apps are generally tailored for clinical use, but retain functionality that is similar to simple general purpose tools such as paper charts, spread sheets, timers or generic mathematical calculators. Examples of such general purpose tools include medical calculators for:

- Body Mass Index (BMI)
- Total Body Water / Urea Volume of Distribution
- Mean arterial pressure
- Glascow Coma Scale score
- APGAR score
- NIH Stroke Scale
- Delivery date estimator

6. **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.

See Appendix B for additional examples for the six categories discussed.

[30] The types of information in these calculators are available in medical sources which includes medical textbooks used in the curriculum of accredited medical schools.

VI. Regulatory requirements

This guidance, including Appendix C and existing medical device regulatory classifications in Appendix D, is intended to assist manufacturers in determining if a product is a mobile medical app and FDA's expectations for that product. Additional information can be found in "Device Advice: Classify Your Medical Device" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm. This section describes in greater detail the regulatory requirements applicable to mobile medical apps under this guidance (as described in Section V).

Manufacturers of mobile medical apps are subject to the requirements described in the applicable device classification regulation below. Depending on the classification and the associated regulation for the mobile medical apps, manufacturers of mobile medical apps are required to follow associated controls established by the regulation.

In general, the associated controls for each class of device is outlined below.

Class I devices: General Controls, including:

- 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);
- Premarket notification (21 CFR Part 807);
- Reporting Corrections and Removals (21 CFR Part 806); and
- Investigational Device Exemption (IDE) requirements for clinical studies of investigational devices (21 CFR Part 812).

Class II devices: General Controls (as described for Class I), Special Controls, and (for most Class II devices) Premarket Notification.

Class III devices: General Controls (as described for Class I), and Premarket Approval (21 CFR Part 814).

Appendix E provides a brief summary of the above requirements. Additional information is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm, under "Overview of Medical Device Regulation" and "How to Market Your Device."
If you need further assistance, you may contact the Division of Small Manufacturers, International and Consumer Assistance: Email: dsmica@fda.hhs.gov; phone: 301-796-7100 or 800-638-2041.

Appendix A Examples of mobile apps that are NOT medical devices

This Appendix provides a representative list of mobile app functionalities to illustrate the types of mobile apps that could be used in a healthcare environment, in clinical care or patient management, but are not considered medical devices. Because these mobile apps are not considered medical devices, FDA does not regulate them. The FDA understands that there may be other unique and innovative mobile apps that may not be covered in this list that may also constitute healthcare related mobile apps. **This list is not exhaustive**; it is only intended to provide clarity and assistance in identifying when a mobile app is not considered to be a medical device.

Specific examples of mobile apps that FDA does not consider to be devices and with no regulatory requirements under the current laws administered by FDA include:

1. 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. These are not devices because these apps are intended to be used as reference materials 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 facilitating a health professional's assessment of a specific patient, replacing the judgment of clinical personnel, or performing any clinical assessment. Examples include mobile apps that are:
    - Medical dictionaries;
    - Electronic copies of medical textbooks or literature articles such as the Physician's Desk Reference or Diagnostic and Statistical Manual of Mental Disorders (DSM);
    - Library of clinical descriptions for diseases and conditions;
    - Encyclopedia of first-aid or emergency care information;
    - Medical abbreviations and definitions;
    - Translations of medical terms across multiple languages.

2. Mobile apps that are intended for health care providers to use as educational tools for medical training or to reinforce training previously received. These may have more functionality than providing an electronic copy of text (e.g., videos, interactive diagrams), but are not devices because they are intended generally for user 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 facilitating a health professional's assessment of a specific patient, replacing the judgment of clinical personnel, or performing any clinical assessment. Examples include mobile apps that are:
    - Medical flash cards with medical images, pictures, graphs, etc.;
    - Question/Answer quiz apps;
    - Interactive anatomy diagrams or videos;
    - Surgical training videos;
    - Medical board certification or recertification preparation apps;
    - Games that simulate various cardiac arrest scenarios to train health professionals in advanced CPR skills.

3. 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. These are not devices because they 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). Examples include mobile apps that:
    - Provide a portal for healthcare providers to distribute educational information (e.g., interactive diagrams, useful links and resources) to their patients regarding their disease, condition, treatment or up-coming procedure;
    - Help guide patients to ask appropriate questions to their physician relevant to their particular disease, condition, or concern;
    - Provide information about gluten-free food products or restaurants;
    - Help match patients with potentially appropriate clinical trials and facilitate communication between the patient and clinical trial investigators;
    - Provide tutorials or training videos on how to administer first-aid or CPR;
    - Allow users to input pill shape, color or imprint and displays pictures and names of pills that match this description;
    - Find the closest medical facilities and doctors to the user's location;
    - Provide lists of emergency hotlines and physician/nurse advice lines;
    - Provide and compare costs of drugs and medical products at pharmacies in the user's location.

4. 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. Examples include mobile apps that:
    - Determine billing codes like ICD-9 (international statistical classification of diseases);
    - Enable insurance claims data collection and processing and other apps that are similarly administrative in nature;
    - Analyze insurance claims for fraud or abuse;
    - Perform medical business accounting functions or track and trend billable hours and procedures;
    - Generate reminders for scheduled medical appointments or blood donation appointments;
    - Help patients track, review and pay medical claims and bills online;
    - Manage shifts for doctors;
    - Manage or schedule hospital rooms or bed spaces;
    - Provide wait times and electronic check-in for hospital emergency rooms and urgent care facilities.

5. 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. Examples include mobile apps that:

- Use the mobile platform as a magnifying glass (but are not specifically intended for medical purposes[31]);
- Use the mobile platform for recording audio, note-taking, replaying audio with amplification, or other similar functionalities;
- Allow patients or healthcare providers to interact through email, web-based platforms, video or other communication mechanisms (but are not specifically intended for medical purposes);
- Provide maps and turn-by-turn directions to medical facilities.

[31] Medical purpose magnifiers are regulated either under 21 CFR 886.5840 - Magnifying spectacles ("devices that consist of spectacle frames with convex lenses intended to be worn by a patient who has impaired vision to enlarge images"), or under 21 CFR 886.5540 - Low-vision magnifiers ("a device that consists of a magnifying lens intended for use by a patient who has impaired vision. The device may be held in the hand or attached to spectacles").

Appendix B Examples of mobile apps for which FDA intends to exercise enforcement discretion

This Appendix provides examples of 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 medical device, FDA intends to exercise enforcement discretion for these mobile apps because they pose lower risk to the public.

The FDA understands that there may be other unique and innovative mobile apps that may not be covered in this list that may also constitute healthcare related mobile apps. This list is not exhaustive; it is only intended to provide clarity and assistance in identifying the mobile apps that will not be subject to regulatory requirements at this time

- Mobile apps that help patients with diagnosed psychiatric conditions (e.g., post-traumatic stress disorder (PTSD), depression, anxiety, obsessive compulsive disorder) maintain their behavioral coping skills by providing a "Skill of the Day" behavioral technique or audio messages that the user can access when experiencing increased anxiety;

- Mobile apps that provide periodic educational information, reminders, or motivational guidance to smokers trying to quit, patients recovering from addiction, or pregnant women;

- Mobile apps that use GPS location information to alert asthmatics of environmental conditions that may cause asthma symptoms or alert an addiction patient (substance abusers) when near a pre-identified, high-risk location;

- Mobile apps that use video and video games to motivate patients to do their physical therapy exercises at home;

- Mobile apps that prompt a user to enter which herb and drug they would like to take concurrently and provide information about whether interactions have been seen in the literature and a summary of what type of interaction was reported;

- Mobile apps that help asthmatics track inhaler usage, asthma episodes experienced, location of user at the time of an attack, or environmental triggers of asthma attacks;

- Mobile apps that prompt the user to manually enter symptomatic, behavioral or environmental information, the specifics of which are pre-defined by a health care provider, and store the information for later review;

- Mobile apps that use patient characteristics such as age, sex, and behavioral risk factors to provide patient-specific screening, counseling and preventive recommendations from well-known and established authorities;

- Mobile apps that use a checklist of common signs and symptoms to provide a list of possible medical conditions and advice on when to consult a health care provider;

- Mobile apps that guide a user through a questionnaire of signs and symptoms to provide a recommendation for the type of health care facility most appropriate to their needs;

- Mobile apps that record the clinical conversation a clinician has with a patient and sends it (or a link) to the patient to access after the visit;

- Mobile apps that are intended to allow a user to initiate a pre-specified nurse call or emergency call using broadband or cellular phone technology;

- Mobile apps that enable a patient or caregiver to create and send an alert or general emergency notification to first responders;

- Mobile apps that keep track of medications and provide user-configured reminders for improved medication adherence;

- Mobile apps that provide patients a portal into their own health information, such as access to information captured during a previous clinical visit or historical trending and comparison of vital signs (e.g., body temperature, heart rate, blood pressure, or respiratory rate);

- Mobile apps that aggregate and display trends in personal health incidents (e.g., hospitalization rates or alert notification rates);

- Mobile 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;

- Mobile apps that provide oral health reminders or tracking tools for users with gum disease;

- Mobile apps that provide prediabetes patients with guidance or tools to help them develop better eating habits or increase physical activity;

- Mobile apps that display, at opportune times, images or other messages for a substance abuser who wants to stop addictive behavior;
- Mobile apps[32] that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness, such as those that:

[32] When these items are not marketed, promoted or intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or do not otherwise meet the definition of medical device, FDA does not regulate them. When they are marketed, promoted or intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or otherwise meet the definition of medical device, FDA intends to exercise enforcement discretion.

- Provide tools to promote or encourage healthy eating, exercise, weight loss or other activities generally related to a healthy lifestyle or wellness;
- Provide dietary logs, calorie counters or make dietary suggestions;
- Provide meal planners and recipes;
- Track general daily activities or make exercise or posture suggestions;
- Track a normal baby's sleeping and feeding habits;
- Actively monitor and trend exercise activity;
- Help healthy people track the quantity or quality of their normal sleep patterns;
- Provide and track scores from mind-challenging games or generic "brain age" tests;
- Provide daily motivational tips (e.g., via text or other types of messaging) to reduce stress and promote a positive mental outlook;
- Use social gaming to encourage healthy lifestyle habits;
- Calculate calories burned in a workout.

Appendix C Examples of mobile apps that are the focus of FDA's regulatory oversight (mobile medical apps)

This Appendix provides examples of mobile apps that are considered medical devices (i.e., mobile medical apps), on which FDA will focus its regulatory oversight. These mobile apps meet the definition of medical device in the FD&C Act and their functionality poses a risk to a patient's safety if the mobile app were to not function as intended. Each example below provides a list of possible relevant product code(s) and/or regulation number.

FDA also encourages mobile medical app manufacturers to search FDA's public databases, such as the "Product Classification" database and the "510(k) Premarket Notification" database, to determine the level of regulation for a given device and for the most up-to-date information about the relevant regulatory requirements. These databases can be accessed through the following links:
(http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm) and
(http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.)

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 (e.g., accelerometer) 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 a sensor attached to the mobile platform or 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): OLV (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, NLF, 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 connect to an existing device type for purposes of controlling its operation, function, or energy source and therefore are mobile medical apps: These mobile apps are those that control the operation or function (e.g., changes settings) of an implantable or body worn medical device. Possible product codes: Varies depending on the intended use and function of the parent medical device; see additional examples below.

- 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 display, transfer, store, or convert patient-specific medical device data from a connected device and therefore are mobile medical apps:

- Mobile apps that connect to a nursing central station and display medical device data to a physician's mobile platform for review. (i.e., a medical device data system or MDDS). Product code: OUG (21 CFR 880.6310).

- Mobile apps that connect to bedside (or cardiac) monitors and transfer the data to a central viewing station for display and active patient monitoring. Possible product code(s): DSI, MHX, MLD (21 CFR 870.1025), DRT, MWI, MSX (21 CFR 870.2300).

- Mobile apps that connect to a perinatal monitoring system and transfer uterine contraction and fetal heart rate data to another display to allow for remote monitoring of labor progress. Possible product code(s): HGM (21 CFR 884.2740).

Appendix D Examples of current regulations

This Appendix provides additional examples of classifications for regulated medical devices, the Class according to which they are regulated, and their regulation numbers as listed in Title 21 of the Code of Federal Regulations (CFR). This list is intended as a starting point for mobile medical app manufacturers to assist them in identifying regulated medical device.

In the table below -- Regulation number 8xx.yyyy refers to regulation 21 CFR 8xx.yyyy; Device class 1, 2, 3 -- indicates the classification that applies to the device; Submission type "510(k) exempt," -- means that the manufacturer is not required to submit a premarket notification (i.e., 510(k)) prior to marketing the device. However, the 510(k) exemption may be subject to certain limitations. Submission type "510(k)," -- means that the manufacturer is typically required to submit a premarket notification.

Regulation number	Regulation Description	Example Device(s) within the Regulation (and current product code)	Device Class	Submission Type
862.1345	Glucose test system	System, Test, Blood Glucose, Over The Counter (NBW)	2	510(k)
862.2100	Calculator/data processing module for clinical use	Digital Image, Storage And Communications, Non-Diagnostic, Laboratory Information System (NVV)	1	510(k) exempt
868.1850	Monitoring spirometer	Spirometer, Monitoring (W/Wo Alarm) (BZK)	2	510(k)
868.1920	Esophageal stethoscope with electrical conductors	Stethoscope, Esophageal, With Electrical Conductors (BZT)	2	510(k)
868.2375	Breathing Frequency Monitor	Ventilatory Effort Recorder (MNR)	2	510(k)
868.2377	Apnea Monitor	Monitor, Apnea, Home Use (NPF)	2	510(k)
870.1025	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	Detector and Alarm, Arrhythmia (DSI)	2	510(k)
870.1110	Blood-Pressure Computer	Computer, Blood-Pressure (DSK)	2	510(k)
870.1130	Noninvasive blood pressure measurement system	System, Measurement, Blood-Pressure, Non-Invasive (DXN)	2	510(k)
870.1875(b)	Stethoscope	Lung Sound Monitor (OCR) Stethoscope, Electronic (DQD)	2 2	510(k) 510(k)
870.2300	Cardiac Monitor (including cardiotachometer and rate alarm)	Monitor, Cardiac (Incl. Cardiotachometer & Rate Alarm) (DRT) Monitor, Physiological, Patient(Without Arrhythmia Detection Or Alarms) (MWI) System, Network And Communication, Physiological Monitors (MSX)	2 2 2	510(k) 510(k) 510(k)
870.2340	Electrocardiograph	Monitor, St Segment (MLC) Single Lead Over-the-Counter Electrocardiograph (OEY)	2 2	510(k) 510(k)
870.2700	Oximeter	Oximeter (DQA)	2	510(k)

Regulation number	Regulation Description	Example Device(s) within the Regulation (and current product code)	Device Class	Submission Type
870.2770	Impedance plethysmograph	Analyzer, Body Composition (MNW)	2	510(k)
870.2800	Medical magnetic tape recorder	Electrocardiograph, Ambulatory, With Analysis Algorithm (MLO)	2	510(k)
		Recorder, Event, Implantable Cardiac, (Without Arrhythmia Detection) (MXC)	2	510(k)
874.1050	Audiometer	Audiometer (EWO)	2	510(k) or 510(k) exempt
874.3400	Tinnitus masker	Masker, Tinnitus (KLW)	2	510(k)
874.4770	Otoscope	Otoscope (ERA)	1	510(k) exempt
876.1500	Endoscope and accessories	Endoscopic Video Imaging System/Component, Gastroenterology-Urology (FET)	2	510(k)
876.1725	Gastrointestinal motility monitoring system	Recorder, External, Pressure, Amplifier & Transducer (FES)	2	510(k)
878.4160	Surgical camera and accessories	Camera, Cine, Microsurgical, With Audio (FWK)	1	510(k) exempt
		Camera, Still, Microsurgical (FTH)	1	510(k) exempt
		Camera, Television, Endoscopic, With Audio (FWG)	1	510(k) exempt
878.4810	Laser surgical instrument for use in general and plastic surgery and in dermatology	Light Based Over The Counter Wrinkle Reduction (OHS)	2	510(k)
		Over-The-Counter Powered Light Based Laser For Acne (OLP)	2	510(k)
880.2400	Bed-patient monitor	Monitor, Bed Patient (KMI)	1	510(k) exempt
880.2700	Stand-on patient scale	Scale, Stand-On, Patient (FRI)	1	510(k) exempt
880.2910	Clinical electronic thermometer	Thermometer, Electronic, Clinical (FLL)	2	510(k)
880.5580	Acupuncture needle	Locator, Acupuncture Point (BWJ)	2	510(k)
880.6310	Medical device data systems	Medical device data system (OUG)	1	510(k) exempt
880.6350	Battery-powered medical examination light	Light, Examination, Medical, Battery Powered (KYT)	1	510(k) exempt
882.1400	Electroencephalograph	Full-montage electroencephalograph (GWQ)	2	510(k)
		Standard polysomnograph with electroencephalograph (OLV)	2	510(k)
882.1550	Nerve conduction velocity measurement device	Device, Nerve conduction velocity measurement (JXE)	2	510(k)
882.1620	Intracranial pressure monitoring device	Device, Monitoring, Intracranial pressure (GWM)	2	510(k)
882.1890	Evoked response photic stimulator	Stimulator, Photic, Evoked response (GWE)	2	510(k)
882.1900	Evoked response auditory stimulator	Stimulator, Auditory, Evoked response (GWJ)	2	510(k)
882.1950	Tremor Transducer	Transducer, Tremor (GYD)	2	510(k)
884.2730	Home uterine activity monitor	Monitor, Heart Rate, Fetal, Non-Stress Test (Home Use) (MOH)	2	510(k)
884.2740	Perinatal monitoring	System, Monitoring, Perinatal (HGM)	2	510(k)

Regulation number	Regulation Description	Example Device(s) within the Regulation (and current product code)	Device Class	Submission Type
	system and accessories			
884.2800	Computerized labor monitoring system	System, Monitoring, For Progress Of Labor (NPB)	2	510(k)
884.2900	Fetal stethoscope	Stethoscope, Fetal (HGN)	1	510(k) exempt
884.6120	Assisted reproductive accessories	Accessories, Assisted Reproduction (MQG)	2	510(k)
884.6190	Assisted reproductive microscopes and microscope accessories	Microscope And Microscope Accessories, Reproduction, Assisted (MTX)	1	510(k) exempt
886.1510	Eye movement monitor	Monitor, Eye Movement, Diagnostic (HMC)	2	510(k)
886.1570	Ophthalmoscope	Ophthalmoscope, Battery-powered (HLJ)	2	510(k)
886.1930	Tonometer and Accessories	Tonometer, Ac-Powered (HPK)	2	510(k)
886.5540	Low-vision magnifier	Magnifier, Hand-Held, Low-Vision (HJF) Spectacle Microscope, Low-Vision (HKC)	1 1	510(k) exempt 510(k) exempt
892.1560	Ultrasonic pulsed echo imaging system	System, Imaging, Optical Coherence Tomography (Oct) (NQQ)	2	510(k)
892.2010	Medical image storage device	Device, Digital Image Storage, Radiological (LMB) Device, Storage, Images, Ophthalmic (NFF)	1 1	510(k) exempt 510(k) exempt
892.2020	Medical image communications device	System, Digital Image Communications, Radiological (LMD) Device, Communications, Images, Ophthalmic (NFG)	1 1	510(k) exempt 510(k) exempt
892.2030	Medical image digitizer	Digitizer, Image, Radiological (LMA) Digitizer, Images, Ophthalmic (NFH)	2 2	Enforcement Discretion for 510(k) submission[33] Enforcement Discretion for 510(k) submission [34]
892.2050	Picture archiving and communications system	System, Image Processing, Radiological (LLZ) System, Image Management, Opthalmic (NFJ)	2 2	510(k) 510(k)

[33] See "Guidance for Industry and Food and Drug Administration Staff - Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices" (December 20, 2011) available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283904.htm

[34] See footnote 31.

Appendix E Brief description of certain device regulatory requirements

This Appendix provides a high level description of certain regulatory requirements for medical devices, including mobile medical apps. The FDA has additional resources and publications online that describe these and other requirements in detail.

1. Establishment Registration and Medical Device Listing

Under 21 CFR Part 807, manufacturers of medical devices are required to annually register their establishments[35] with FDA and provide a list of the devices they market. The registration and listing requirement is a means of keeping FDA advised of who is manufacturing devices, and of the types of devices an establishment is manufacturing. Mobile medical app manufacturers are required to register their establishments with FDA and to list[36] by identifying to FDA the mobile medical apps they are marketing.

Additional information can be found in "Device Advice: Device Registration and Listing" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm. If you need further assistance, you may contact the Division of Risk Management Operations, Regulatory Policy and Systems Branch: Email: reglist@fda.hhs.gov, phone: 301-796-7400. Assistance is also available from, Division of Small Manufacturers, International and Consumer Assistance: Email: dsmica@fda.hhs.gov phone: 301-796-7100 or 800-638-2041.

2. Investigational Device Exemption (IDE) requirements

An IDE allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification 510(k) submission to FDA. Clinical studies with devices of significant risk must be approved by FDA and by an Institutional Review Board (IRB) before the study can begin. Studies with devices of non-significant risk must be approved by the IRB only before the study can begin.

Mobile medical app manufacturers who are creating mobile apps with novel technologies are encouraged to engage in early collaboration meetings with the FDA to receive recommendations for testing and development of those devices requiring clinical investigations to support marketing.

Additional information about these meetings is described in guidance issued on February 28, 2001: "Early Collaboration Meetings Under the FDA Modernization Act (FDAMA); Final Guidance for Industry and for CDRH Staff." This document is available at

[35] Under 21 CFR 807.3(c), "*Establishment*" is defined as "a place of business under one management at one general physical location at which a device is manufactured, assembled, or otherwise processed."
[36] See 21 CFR part 807.

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073604.htm.

Further information regarding the investigational device exemption can be found in "Device Advice: Investigational Device Exemption" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm.

3. Labeling requirements

Medical device manufacturers are required to comply with applicable labeling regulations found in 21 CFR Part 801 for medical devices and Part 809 for in vitro diagnostic products.

4. Premarket submission for approval or clearance

Mobile medical app manufacturers should identify the current classification covering their mobile medical app. Manufacturers are required to prepare and submit to the FDA an appropriate premarket submission, as required for their device classification.

Additional information can be found in "Device Advice: Device Registration and Listing" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm.

5. Quality System Regulation (QS Regulation)

Mobile medical app manufacturers are required to comply with the QS regulation. [37] The QS regulation does not prescribe in detail how a manufacturer must produce a specific device, but provides a framework for all manufacturers to develop and follow to help ensure that their products consistently meet applicable requirements and specifications. As part of this framework, mobile medical app manufacturers are required to develop requirements for their products that will result in devices that are safe and effective, and to establish methods and procedures to design, produce, and distribute their devices.

Furthermore, mobile medical app manufacturers are required, as part of the QS regulation (21 CFR 820.30), to appropriately verify and validate their mobile medical apps along with the mobile platform to ensure safe and effective operation of the mobile medical app.

Mobile medical app manufacturers are required to ensure that adequate controls and processes are in place through purchasing controls to ensure safe distribution, installation, and operation of the mobile medical app.

Additional information regarding the QS regulation and can be found at "Quality System (QS) Regulation/Medical Device Good Manufacturing Practices"

[37] See 21 CFR part 820.

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm.

6. Medical Device Reporting (MDR) (Adverse event reporting)

The Medical Device Reporting (MDR) regulation requires manufacturers and importers of medical devices to submit reports to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device they market may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that they market would be likely to cause or contribute to a reportable death or serious injury if the malfunction were to recur.[38] MDR requires medical device manufacturers to:

- Submit MDR reportable events involving their medical devices as described in 21 CFR 803.10(c) and 803.50;
- Submit 5-day reports as described in 21 CFR 803.53;
- Submit supplemental reports as described in 21 CFR 803.56;
- Develop, maintain, and implement written procedures for the identification and evaluation of all medical device events to determine whether the event is MDR reportable as described in 21 CFR 803.17;
- Conduct an investigation of each event and evaluate the cause of the event as described in 21 CFR 803.50(b)(3); and
- Establish and maintain complete files for all complaints concerning adverse medical device events as described in 21 CFR 803.18.

The MDR report (FDA Form 3500A) must contain all the information described in 21 CFR 803.52 that is reasonably known to the manufacturer. Information reasonably known includes any information that:

- Can be obtained by contacting a user facility, importer, or other initial reporter;
- Is in the possession of the manufacturer; or
- Can be obtained by analysis, testing, or other evaluation of the device.

For additional instructions on how to complete the 3500A form, refer to the document titled "Instructions for Completing Form FDA 3500A" at http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/ucm149238.htm.

For additional guidance on the MDR regulation and the reporting requirements, refer to the document titled "Medical Device Reporting for Manufacturers" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094529.htm.

For Questions about Medical Device Reporting, including interpretation of MDR policy:

[38] See 21 CFR part 803.

- Call: (301) 796-6670 (voice)
- Email: RSMB@fda.hhs.gov
- Mail: Food and Drug Administration, Center for Devices and Radiological Health, Reporting Systems Monitoring Branch, 10903 New Hampshire Avenue, WO Bldg. 66, Room 3217, Silver Spring, MD 20993-0002

7. Correcting Problems

A mobile medical app manufacturer may voluntarily take action at any time or may be requested to take action by the FDA to correct problems. Voluntary action is usually taken by device manufacturers. Examples of the types of actions that a mobile medical app manufacturer may be requested to take include, but are not limited to:

- Inspecting the device for problems;
- Repairing the device;
- Adjusting settings on the device; and
- Upgrading software to reduce risk from a "bug" or unintended response.

Under certain circumstances, FDA may initiate a request that a manufacturer address a problem with a device through other means, including by removal of the product from the market. When recommending corrective action, the FDA intends to take into account the essential role that certain mobile medical apps take as an integral part of a larger patient care system.

Reporting Corrections to FDA:

In accordance with 21 CFR 806.10, mobile medical app manufacturers are required to promptly report, within 10 working days from the time the correction is initiated, to the FDA certain actions concerning device corrections and removals for the mobile medical app. Specifically, mobile medical app manufacturers are required to report to FDA any corrections made to a mobile medical app to reduce a risk to health posed by the mobile medical app or to remedy a violation of the FD&C Act caused by the mobile medical app which may present a risk to health.

The reporting requirement does not extend to all modifications to mobile medical apps. For example, certain actions that would improve the quality of a mobile medical app but that would not reduce a risk to health posed by the mobile medical app or remedy a violation of the FD&C Act are not required to be reported under 21 CFR 806.1(b)[39]. If there is not a "risk to health" involved, a report to FDA is not required, but the mobile medical app manufacturer must keep a record of the correction. An example of such action taken by the manufacturer could be changes

[39] Under 21 CFR 806.1(b), the following actions are exempt from the reporting requirements of part 806:
(1) Actions taken by device manufacturers or importers to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the act caused by the device.
(2) Market withdrawals as defined in 21 CFR 806.2(h).
(3) Routine servicing as defined in 21 CFR 806.2(k).
(4) Stock recoveries as defined in 21 CFR 806.2(l).

made to correct a defect that creates a nuisance for the user but does not present a risk to the health of the user or patient.

More information about reporting requirements under 21 CFR Part 806 is available in "Device Advice: Recalls, Corrections, and Removals" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/default.htm.

Appendix F Frequently Asked Questions (FAQs)

1) I have a mobile app not identified in this guidance. What is the best way to get additional information from the FDA about my product?

Answer: FDA recognizes that this guidance does not describe all types of mobile apps used in healthcare. Some manufacturers may be unsure whether their mobile app is considered a medical device which is subject to regulatory oversight, or whether their medical device could be under FDA's intent to exercise enforcement discretion. If the device is subject to regulatory oversight, manufacturers may have questions about which regulatory requirements are applicable to their specific mobile app.

After reviewing this guidance, FDA encourages mobile app manufacturers to contact the Agency to obtain more information using one of the following ways:

- Phone or e-mail - For general regulatory information, contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA). Email: dsmica@fda.hhs.gov; phone: 301-796-7100 or 800-638-2041.
  If your question relates to apps used in blood establishments or another area of CBER regulation, contact the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448; e-mail: ocod@fda.hhs.gov; phone: 1-800-835-4709 or 301-827-1800.

- Online – The FDA has several resources and publications online that describe various regulatory requirements in detail. FDA's "Device Advice" website (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm) and online courses at "CDRH Learn" (http://www.fda.gov/Training/CDRHLearn/default.htm) are a good place to start. Other sections in this guidance provide links to more detailed information related to more specific topics.

- Letter - For written feedback about the classification and the regulatory requirements that may be applicable to a mobile medical app that is a device, manufacturers should use the 513(g) process. Specifically, a manufacturer should submit the following for a 513(g) submission:
  - User fee,
  - Cover letter,
  - Description of the mobile app,
  - Description of what the mobile app is to be used for, and
  - Any proposed labeling or promotional material for the mobile app and, as applicable, any labeling or promotional material of a similar, legally marketed device, if available.

  FDA will generally issue a response to the 513(g), in the form of a confidential letter to the manufacturer, within 60 days of receipt of the request for information. For more specific information about what to include in a 513(g) and where to send it, refer to FDA's guidance document titled "FDA and Industry Procedures for Section 513(g) Requests for Information

Under the Federal Food, Drug, and Cosmetic Act" at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm209841.htm. For more information about 513(g) user fees, refer to FDA's guidance document titled "User Fees for 513(g) Requests for Information" at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm209852.htm.

2) Why does FDA recommend that manufacturers follow the Quality System (QS) regulation for those mobile apps that MAY be devices and could be mobile medical apps but for which FDA intends to exercise enforcement discretion?

Answer: 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.[40]

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.

3) Is FDA's QS regulation similar to software development practices I already use?

Answer: Most likely. Though not all of the principles in the QS regulation are applicable to the development and manufacture of quality mobile medical apps[41], the majority of them are applicable and are consistent with commonly used and accepted good software development practices, such as those from the Institute of Electrical and Electronics Engineers' (IEEE), Software Engineering Body of Knowledge (SWEBOK), and Carnegie Mellon Software Engineering Institute's Capability Maturity Model Integration (CMMI) methods.

The FDA's approach to QS regulation is also harmonized with certain international standards such as ISO 9001 and ISO 13485.[42] Similar to these international standards, the QS regulation does not prescribe in detail how a manufacturer must produce a specific device but provides a framework for all manufacturers to develop and follow to help ensure that their products consistently meet applicable requirements and specifications. The QS regulation can apply to and be scaled for any size manufacturer and any type of product. It also allows for a

[40] See footnote 19.
[41] Certain portions of the QS regulation that apply to medical device hardware (such as the production and process controls outlined in 21 CFR 820.70) may not clearly apply to mobile medical apps.
[42] ISO 9001:2008 "Quality management systems--Requirements," and ISO 13485:2003 ``Medical devices-Quality management systems-Requirements for regulatory purposes." See also ANSI/AAMI/ISO 13485:2003.

manufacturer to choose those requirements most appropriate for its given device and manufacturing process.[43]

4) What are some examples of parts of the QS regulation that are of particular importance to mobile medical apps and where can I find more information about them?

Answer: Though not a complete list, some examples of principles within the QS regulation that are relevant to all mobile medical app manufacturers include risk assessment and management, design controls, and corrective and preventive actions. Risk assessment and management is a critical part of good quality management systems. Good design practices are important to the development and manufacture of safe mobile medical apps. It is also important for manufacturers to have procedures in place to identify, analyze, correct, and prevent app-related causes of patient or user harm. References related to these examples are provided in Appendix E of this guidance. Additional references about these principles which mobile medical app manufacturers may find useful include the following:

FDA's "Design Control Guidance for Medical Device Manufacturers" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070627.htm

FDA's "General Principles of Software Validation" guidance at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085281.htm

5) Do all the mobile medical apps have to submit a premarket submission and receive FDA clearance or approval before marketing?

Answer: No, not all mobile medical app manufacturers have to submit a premarket submission (i.e., a 510(k) or PMA) prior to marketing their app. This determination depends on the classification of the device. Manufacturers of devices that are exempt from 510(k) or PMA requirements do not have to file a submission with FDA prior to marketing their device. For example, the majority of class I devices are exempt from the premarket submission requirements and are subject to the least regulatory control.

Regardless of whether medical devices are subject to the premarket submission requirements, most medical devices (including Class I devices) have to comply with other basic regulatory requirements that are called "General Controls." More information about what "General Controls" are and what a medical device manufacturer should do to comply with these requirements, can be found in "Device Advice: General Controls for Medical Devices" at

[43] See 21 CFR 820.1 (stating "if a manufacturer engages in only some operations subject to the requirements in this part, and not in others, that manufacturer need only comply with those requirements applicable to the operations in which it is engaged.")

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm055910.htm and at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm.

6) Some FDA classifications state they are "510(k) exempt." What does 510(k) exempt mean and how do I know if it applies to my product?

Answer: If a classification states the device type is "510(k) exempt," this means that the manufacturer is not required to submit a premarket notification (i.e., a 510(k)) prior to marketing the device. However, the 510(k) exemption may be subject to certain limitations. Manufacturers are encouraged to confirm the device's exempt status and any limitations to that status that may apply in accordance with 21 CFR Parts 862-892. Additional information about 510(k) exempt devices can be found at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm.

7) If a 510(k) is required for my mobile medical app, what type of software documentation does FDA recommend I include in the submission?

Answer: FDA's recommendations for the software-related documentation that you provide in your premarket submission are addressed in detail in the FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." This guidance can be accessed on FDA's website here: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm.

If the mobile medical app uses off-the-shelf software, manufacturers should also refer to FDA's "Guidance for Industry, FDA Reviewers, and Compliance on Off-the-Shelf Software Use in Medical Devices" available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073778.htm.

8) I am a medical device manufacturer and making my product labeling available electronically using a mobile app. Is my app considered a mobile medical app?

Answer: Mobile apps that provide electronic access and are intended for use as a digital version of medical device labeling or instructions for use are not considered medical device on their own and therefore are not considered mobile medical apps. These are apps from a device manufacturer that provide information to support the company's own device. Examples include apps that provide an electronic copy of cleared or approved medical device labeling or apps that provide video instruction for how to use a medical device. These types of apps are not considered devices within themselves, but instead are considered part of the medical device labeling and are subject to the regulatory labeling requirements relevant to that particular product.

9) Does an electronic method of collecting clinical investigations for example through a mobile app considered a mobile medical app, what requirements apply?

Answer: Mobile apps used for data collection in clinical studies (such as electronic Patient Reported Outcomes (ePRO) apps) are not considered on its own a mobile medical app. However, manufacturers and users of this type of mobile app should see FDA's draft guidance related to use of computers in clinical trials, "Electronic Source Data in Clinical Investigations," [44] issued on November 20, 2012. When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of this guidance, check the CDER guidance webpage at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

10) I am a medical device manufacturer. Is an electronic method of collecting and storing quality systems information in my manufacturing process considered a medical device or a mobile medical app?

Answer: Mobile apps used in the production process for medical devices, or for collecting, storing and maintaining quality system data collection for medical devices (including complaint submissions) are not considered medical device on their own and therefore are not considered mobile medical apps. These types of apps do not meet the definition of medical device but are part of the quality system. However these mobile apps are required to comply with the appropriate good manufacturing practices (GMP) regulations (see 21 CFR Part 820).

Appendix G Additional Resources

AAMI = Association for the Advancement of Medical Instrumentation
ANSI = American National Standards Institute
IEC = International Electrotechnical Commission
IEEE = Institute of Electrical and Electronics Engineers
ISO = International Organization for Standardization

1. Guidance for Industry and FDA Staff - Implementation of Medical Device Establishment Registration and Device Listing Requirements Established by the Food and Drug Administration Amendments Act of 2007 (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm185871.htm).

2. ISO/IEC 90003:2004, *Software engineering -- Guidelines for the application of ISO 9001:2000 to computer software*, 2004.

3. ISO 9001:2008, *Quality management systems – Requirements*, 2008.

4. ISO 13485:2003, *Medical devices - Quality management systems - Requirements for regulatory purposes.*, 2003. Note: This has also been adopted in the U.S. as ANSI/AAMI/ISO 13485:2003, *Medical devices - Quality management systems - Requirements for regulatory purposes*, 2003 (identical adoption).

5. ISO 9000:2005 *Quality management systems – Fundamentals and vocabulary*, , 2005.

6. ISO 14971:2007, Medical Devices - Risk Management - Part 1: Application of Risk Analysis, 2007. Note: This has also been adopted in the U.S. as ANSI/AAMI/ISO 14971:2007, *Medical devices - Application of risk management to medical devices*, 2007 (identical adoption).

7. Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077812.htm).

8. Information for Healthcare Organizations about FDA's "Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software" -- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070634.htm

9. IEC 62304:2006, *Medical device software – Software life cycle processes*, 2006. Note: This is also adopted in the U.S as ANSI/AAMI/IEC 62304:2006, *Medical device software - Software life cycle processes*, 2006 (identical adoption).

10. IEEE Std 1012-2004, *IEEE Standard for Software Verification and Validation*, 2004.

11. IEEE 1012-2012, *IEEE Standard for System and Software Verification and Validation*, 2012.

12. *IEEE Standards Collection, Software Engineering*, 1994. ISBN 1-55937-442-X.

13. ISO/IEC 25051:2006, *Software engineering -- Software product Quality Requirements and Evaluation (SQuaRE) -- Requirements for quality of Commercial Off-The-Shelf (COTS) software product and instructions for testing*, 2006.

14. ISO/IEC 12207:2008, *Systems and software engineering – Software life cycle processes, 2008* and IEEE Std 12207-2008, *Systems and software engineering – Software life cycle processes, 2008.*

15. ISO/IEC 14598:1999, *Information technology - Software product evaluation*, 1999.

16. AAMI TIR32:2004, *Medical device software risk management*, 2004.

17. AAMI TIR36:2007, *Validation of software for regulated processes*, 2007.

18. ANSI/AAMI/IEC TIR80002-1:2009, Medical device software - Part 1: *Guidance on the application of ISO 14971 to medical device software*, 2009. (Identical adoption of IEC/TR 80002-1:2009)

19. Guidance for the Submission of Premarket Notifications for Medical Image Management Devices (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073720.htm)

20. *Clause 14* of IEC 60601-1:2005, *Medical electrical equipment, Part 1: General requirements for basic safety and essential performance*, 2005 OR *Clause 14* of ANSI/AAMI ES60601-1:2005, *Medical electrical equipment, Part 1: General requirements for basic safety and essential performance*, 2005 (adoption with national deviations of IEC 60601-1:2005).

21. IEC 61508-2:2010, *Functional safety of electrical/electronic/programmable electronic safety-related systems*, 2010.