Contains Nonbinding Recommendations
Draft – Not for Implementation

Draft Guidance for Industry and Food and Drug Administration Staff

Mobile Medical Applications

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
Document issued on: July 21, 2011

You should submit comments and suggestions regarding this draft document within **90** days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Bakul Patel at 301-796-5528 or by electronic mail at Bakul.Patel@fda.hhs.gov . For questions regarding this document concerning devices regulated by CBER, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 301-827-1800.

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

Additional Copies

CDRH
Additional copies are available from the Internet. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-827-8149 to receive a hard copy. Please use the document number (1741) to identify the guidance you are requesting.

CBER
Additional copies of this draft guidance are available from the Office of Communication, Outreach and Development (OCOD) (HFM-40), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, or by calling 1-800-835-4709 or 301-827-1800, or from the Internet at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/ default.htm

Table of Contents

I. INTRODUCTION **4**

II. BACKGROUND **5**

III. DEFINITIONS **7**

A. MOBILE PLATFORM 7
B. MOBILE APPLICATION (MOBILE APP) 7
C. MOBILE MEDICAL APPLICATION (MOBILE MEDICAL APP) 7
D. REGULATED MEDICAL DEVICE 8
E. MOBILE MEDICAL APP MANUFACTURER 8

IV. SCOPE **10**

V. REGULATORY APPROACH FOR MOBILE MEDICAL APPS **12**

A. MOBILE MEDICAL APPS FOR WHICH FDA WILL APPLY REGULATORY OVERSIGHT 13

VI. REGULATORY REQUIREMENTS **16**

A. REQUIREMENTS FOR MOBILE MEDICAL DEVICE MANUFACTURERS SUBJECT TO REGULATORY OVERSIGHT 16
B. EXPECTATIONS FOR MOBILE MEDICAL APP DISTRIBUTORS 16

APPENDIX A – EXAMPLES OF MOBILE MEDICAL APPS **18**

APPENDIX B - EXAMPLES OF CURRENT REGULATIONS **21**

APPENDIX C -- BRIEF DESCRIPTION OF REGULATORY REQUIREMENTS **24**

APPENDIX D -- ADDITIONAL RESOURCES **28**

Draft Guidance for Industry and Food and Drug Administration Staff

Mobile Medical Applications

This draft guidance when finalized will represent 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) is issuing this draft 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 draft guidance document to clarify the types of mobile apps to which the FDA intends to apply its authority. At this time, the FDA intends to apply its regulatory requirements solely to a subset of mobile apps that it is calling mobile medical applications or "mobile medical apps."

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

A growing number of software applications are being developed for use on mobile platforms, which include smart phones, tablet computers, and personal digital assistants. As these 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 it would be impractical to prepare an overarching software policy to address all of the issues related to the regulation of all medical devices containing software. Therefore, 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 patient activity), 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]

Moreover, the FDA has previously clarified that when standalone 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, mobile medical apps can pose potential risks to public health. Moreover, mobile medical apps may pose additional or different risks due to the

---

[1] 70 FR 824 at 890 (January 5, 2005) Federal Register Notice [Docket No 1998N-0046], http://edocket.access.gpo.gov/2005/pdf/05-155.pdf.
[2] 76 FR 8637 (Feb. 15, 2011), Final Rule.
[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."); Final Rule, Medical Devices, Medical Device Data Systems, 76 Fed. Reg. 8637, 8643-8644 (Feb. 15, 2011).

unique characteristics of the platform. For example, the 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 limitations 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 the iPhone®, BlackBerry® phones, Android® phones, tablet computers, or other computers that are typically used as smart phones or personal digital assistants (PDAs).

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

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,

---

[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…..", 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 B for examples).

[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,

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 light emitting diode (LED) included on a mobile platform with a mobile app to make that LED operate. If the manufacturer intends the system to illuminate objects generally (i.e., without a specific device intended use), neither the mobile app nor the mobile platform would be considered medical devices. If, however, through marketing and distribution, the mobile app is promoted by the manufacturer for use as a light source to examine patients, then the mobile app would meet the definition of a device. (In this case, 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 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 glucose meter readings would be considered similar to software running on a desktop computer, which is regulated under 21 CFR 862.1345 ("glucose test system").

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 classified by the FDA, or otherwise approved or cleared by the FDA review of a premarket application or other submission for the device. Examples of such devices are identified in Appendix B.

E. Mobile Medical App Manufacturer

For purposes of this guidance, a "mobile medical app manufacturer" is defined as any person or entity that manufactures mobile medical apps in accordance with 21 CFR Parts 803, 806, and 807.[7] This term does not include entities that exclusively distribute mobile medical apps,

---

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).

[7] Regulatory definitions of the term "manufacturer" or "manufacture" appear in 21 CFR Parts 803, 806, and 807. The Medical Device Reporting regulation defines manufacturer to mean: "any person who manufactures, prepares, propagates compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. The term includes any person who either: (1) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture; (2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications; (3) Manufactures components or accessories that are devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed

without engaging in manufacturing functions; examples of such distributors may include owners and operators of "android market", "iTunes store", and "BlackBerry App World." A mobile medical device manufacturer may include anyone who initiates specifications, designs, labels, or creates a software system or application in whole or from multiple software components. Examples of mobile medical device manufacturers include any person or entity that:

- Creates, designs, develops, labels, re-labels, remanufactures, modifies, or creates a 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;
- Provides mobile medical app functionality through a "web service" or "web support" for use on a mobile platform. For example, a manufacturer of a mobile medical app that allows users to access the application's medical device functionality over the web is considered a mobile medical app manufacturer;
- 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 app, unless another entity assumes all responsibility for manufacturing and distributing the mobile medical app, in which case that other entity would be the

---

practitioner or other qualified person to meet the needs of a particular patient; or (4) Is the U.S. agent of a foreign manufacturer." 21 CFR 803.3.

FDA's regulation requiring reports of corrections and removals defines manufacturer to mean: "any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedures. The term includes any person who: (1) Repackages or otherwise changes the container, wrapper, or labeling of a device 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 user or consumer; (2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications; or (3) Manufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and are intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient." 21 CFR 806.2 (g).

Under FDA's establishment and registration regulation, registration and listing requirements apply to anyone engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device, activities that are defined to include: "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. . . . includ[ing] 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) Initiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution by the person initiating specifications." 21 CFR 807.3(d).

"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; or

- Creates a mobile medical app intended to be used on a mobile platform, or that manufactures a mobile app to be supported by hardware attachments to the mobile platform with a device intended use.

For purposes of this guidance, a mobile platform manufacturer that commercially markets a mobile platform with an intended use (as defined in 21 CFR 801.4) of, or to be used with, a device is considered a device manufacturer under 21 CFR 803, 806 and 807. In contrast, a mobile platform manufacturer that solely distributes or markets its platform with no device intended use is considered a component[9] manufacturer and is exempt from quality systems, registration and listing requirements as described in those regulations.[10] In other words, the fact that a mobile platform could be used to run a mobile medical app identified by this guidance does not mean that the mobile platform manufacturer is considered a medical device manufacturer. For example, if it is possible to run mobile medical apps on BrandNamePhone but BrandNamePhone is not marketed by BrandNameCompany with a medical device intended use, then BrandNameCompany would not be a medical device manufacturer.

IV. Scope

This guidance explains FDA intentions to apply its regulatory requirements to a subset of mobile apps. This subset, which we are calling mobile medical apps as defined in section III, includes only those that meet the statutory definition of a device; and either:

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

This guidance does not specifically address wireless safety considerations, classification and submission requirements related to clinical decision support software, or the application of quality systems to software. The FDA intends to address these topics through separate guidance(s).

This guidance is limited only to mobile medical apps. The following examples represent mobile apps that FDA does **not** consider to be mobile medical apps for purposes of this guidance:

- Mobile apps that are electronic "copies" of medical textbooks, teaching aids or reference materials, or are solely used to provide clinicians with training or reinforce training previously received. These types of apps do not contain any patient-specific information, but could show examples for a specific medical specialty. Examples of such medical text books include the electronic Physician's Desk Reference and similar reference materials

[8] See 21 CFR 803.3 (definition of manufacturer) & 807.20(a)(2).
[9] See 21 CFR 820.3(c).
[10] See 21 CFR 807.65(a) & 820.1(a).

that are typically used as part of course instruction and are implemented as electronic books. Exemplary teaching aids and reference materials include: flash cards or quizzes that are used for training purposes or as reference material (e.g., with preloaded medical images, conditions, pictures, graphs, etc.); slideshows of common conditions; lists of medical terminology; and review materials that are to be used by medical students during training. (In contrast, mobile apps that allow the user to input patient-specific information along with reference material to automatically diagnose a disease or condition are considered mobile medical apps).

- Mobile apps that are solely used to log, record, track, evaluate, or make decisions or suggestions related to developing or maintaining general health and wellness. Such decisions, suggestions, or recommendations are **not** intended for curing, treating, seeking treatment for mitigating, or diagnosing a specific disease, disorder, patient state, or any specific, identifiable health condition. Examples of these apps include dietary tracking logs, appointment reminders, dietary suggestions based on a calorie counter, posture suggestions, exercise suggestions, or similar decision tools that generally relate to a healthy lifestyle and wellness.
- Mobile apps that only automate general office operations with functionalities that include billing, inventory, appointments, or insurance transactions. Examples include: apps that determine billing codes like ICD-9 (international statistical classification of diseases); medical business accounting functions and aids that track and trend billable hours, procedures, and reminders for scheduled medical appointments or blood donation appointments; apps that automate functions such as collecting patient histories that replace paper-based entry; apps that enable insurance claims data collection and processing; and other apps that are similarly administrative in nature.
- Mobile apps that are generic aids that assist users but are not commercially marketed for a specific medical indication. Examples include apps that use the mobile platform as a magnifying glass (but **not** specifically for medical purposes),[11] recording audio, note-taking, replaying audio with amplification, and other similar functionalities.
- Mobile apps that perform the functionality of an electronic health record system or personal health record system.

[11] Medical purpose magnifiers are classified devices and 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").

V. Regulatory approach for mobile medical apps

The FDA recognizes the extensive variety of actual and potential functions of mobile apps, the rapid pace of innovation in mobile apps, and potential benefits and risks to public health. Some manufacturers of mobile medical apps have sought premarket clearance for their devices; however, many may be unsure about how the FDA regulations apply to their products.

As described in this guidance, the FDA plans to apply its regulatory oversight only to certain types of mobile apps.

This narrowly-tailored approach focuses on a subset of mobile apps that either have traditionally been considered medical devices or affect the performance or functionality of a currently regulated medical device. The FDA believes that this subset of mobile apps poses the same or similar potential risk to the public health as currently regulated devices if they fail to function as intended. Using mobile or other innovative platforms along with a mobile medical app to perform medical device functions does not necessarily change the intended use or the risk to patients if the device fails to operate properly.

Although some mobile apps that do not meet the definition of a mobile medical app may meet the FD&C Act's definition of a device, FDA intends to exercise enforcement discretion[12] towards those mobile apps. The FDA intends to monitor the performance of other[13] mobile apps that are outside this guidance and determine whether additional or different actions are necessary to protect the public health. A manufacturer may, however, at its discretion, elect to register and list, and to seek approval or clearance for these mobile apps with the FDA.

Nevertheless, the FDA strongly recommends that manufacturers of all mobile apps that may meet the definition of a device follow the Quality Systems[14] regulations (which include good manufacturing practices) in the design and development of their mobile medical apps and initiate prompt corrections to their mobile medical apps, when appropriate, to prevent patient and user harm. The FDA has found that the majority of software-related device failures are due to design

[12] This means that the FDA intends to exercise its discretion to decline to pursue enforcement actions for violations of the FD&C Act and applicable regulations by a manufacturer of a mobile medical app, as specified in this guidance. This does not constitute a change in the requirements of the FD&C Act or any applicable regulations.

[13] The FDA's review of these products indicates that the majority of these other mobile apps that may meet the definition of a medical device have functionality either to automate common medical knowledge available in the medical literature or to allow individuals to self-manage their disease or condition. Many of these mobile medical apps also automate common clinician's diagnostic and treatment tasks using simple general purpose tools, including spreadsheets, timers, or other general computer applications, by performing logging and tracking. For example, mobile medical apps that: log, track, and graph manually-entered (keyed in) data that lead to reminders or alarms; act as data viewers for patient education; organize, store, and display personal health data, such as lab results, doctor visits, dosages, calories consumed, etc.; or allow for general dose over the counter (OTC) lookups and use drug labeling to provide information that is typically available on a drug label, e.g., acetaminophen dosage for children and adults.

[14] *See* 21 CFR part 820.

errors. In one study, the most common problem was failure to validate software prior to routine maintenance.[15]

For the subset of mobile medical apps that are subject to regulatory oversight, 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).[16]

The FDA has typically expected that the manufacturer of an accessory would meet the requirements associated with the classification of the connected device. However, this approach may not be well-suited for mobile medical apps that serve as an accessory to another medical device because of the wide variety of functions mobile medical apps can potentially perform. Therefore, FDA is seeking comment on how it should approach mobile medical apps that are accessories to other medical devices so safety and effectiveness can be reasonably assured. Mobile medical devices that are intended to be used as accessories to a regulated medical device may do so for purposes of (a) displaying, analyzing, storing, or transmitting patient-specific medical device data, or (b) controlling the operation, function, or energy source of the medical device (see Appendix A for examples).

Finally, if the mobile medical app adds medical device functionality to a mobile platform, the mobile medical app manufacturer must meet the classification requirements applicable to that functionality.

A. Mobile medical apps for which FDA will apply regulatory oversight

Mobile apps may take a number of forms, but it is important to note that the FDA will apply its regulatory oversight to only the subset of mobile medical apps as expressed in this guidance.

Similarly, mobile medical apps that transform a mobile platform into a regulated medical device may do so by using attachments, display screens, sensors, or other such methods (see Appendix A for examples).

The following examples represent mobile apps FDA considers mobile medical apps and that will be subject to its regulatory oversight:

- Mobile apps that are an extension of one or more medical device(s) by connecting[17] to such device(s) for purposes of controlling 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

[15] See Final Rule, Current Good Manufacturing Practice (CGMP); Quality System Regulation, 61 FR 52602 (October 7, 1996).
[16] *See* fns. 3 and 4.
[17] To meet this criterion, the mobile medical apps need not be physically connected to the regulated medical device.

from a Picture Archiving and Communication System (PACS) server, or similar display functions that meet the definition of an MDDS. 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 apps that transform the mobile platform into a medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices. Examples include a mobile app that uses a mobile platform for medical device functions, such as attachment of a transducer to a mobile platform to function as a stethoscope, 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; or, a mobile app that uses the built-in accelerometer on a mobile platform to collect motion information for monitoring sleep apnea.
- Mobile apps that allow the user to input patient-specific information and - using formulae or processing algorithms - output a patient-specific result, diagnosis, or treatment recommendation to be used in clinical practice or to assist in making clinical decisions. Examples include mobile apps that provide a questionnaire for collecting patient-specific lab results and compute the prognosis of a particular condition or disease, perform calculations that result in an index or score, calculate dosage for a specific medication or radiation treatment, or provide recommendations that aid a clinician in making a diagnosis or selecting a specific treatment for a patient.

To further clarify, the following categories identify the types of mobile medical apps and their associated classifications.

- **Displaying, storing or transmitting patient-specific medical device data in its original format –** Mobile medical apps with this functionality constitute an MDDS (21 CFR 880.6310) and are subject to class I requirements (general controls), which include adequate design controls, registration, device listing, adverse event reporting, and corrections and removals. The FDA believes that requiring general controls sufficiently manage the risks for mobile medical apps that are used as a secondary display to a regulated medical device and are not intended for providing primary diagnosis or treatment decisions (i.e. mobile medical apps that meet the MDDS definition).

- **Controlling the intended use, function, modes, or energy source of the connected medical device -** 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 a mobile medical app to extend the 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.

- **Transforming or making the mobile platform into a regulated medical device** – Mobile medical devices that use attachments, display screens, sensors or other such

similar components to transform a mobile platform into a regulated medial device are required to comply with the device classification associated with the transformed platform. For example, a mobile medical app that uses sensors (internal or external) on a mobile platform for electronic stethoscope functions is considered to convert the mobile platform into an electronic stethoscope; manufacturers of such a mobile medical app are required to follow the requirements of 21 CFR 870.1875(b) (Electronic Stethoscope). Similarly, a mobile medical app that displays radiological images for diagnosis transforms the mobile platform into a class II PACS under 21 CFR 892.2050. The FDA has already cleared such mobile medical apps.

- **Creating alarms, recommendations or creating new information (data) by analyzing or interpreting medical device data** – Mobile medical apps of this type that analyze or interpret data (electronically collected or manually entered) from another medical device are considered an accessory to that medical device. These mobile medical apps are generally required to comply with the device classification associated with that other medical device. These types of systems have been previously classified under the same regulations as the connected device; specifically, the decision support tool is treated as an accessory and subject to the same regulatory requirements as the connected device as determined by the connected device's classification. For example, software that analyzes blood glucose readings to help manage diabetes has been classified as part of a "Glucose Test System" under 21 CFR 862.1345. The FDA has cleared several mobile medical apps with attachments to a mobile platform. Examples include patient monitoring mobile apps that 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 (21 CFR 870.1130) and a perinatal monitoring system (21 CFR 884.2740).

  The FDA plans to address in a separate issuance mobile medical apps intended to analyze, process, or interpret medical device data (electronically collected or manually entered) from more than one medical device. The implications of these analyses and interpretations may pose a wide range of risks to public health and patient safety. Requiring such mobile medical apps to comply with the same requirements as their connected devices may not be appropriate in some cases. For example, analysis of class I device information along with other demographic information can result in an interpretation of a highly acute patient condition, which presents a greater risk than the connected class I device. On the other hand, an analysis or interpretation of data from class II or class III devices can lead to a simple informational result, with minimal implications or risks to public health and patient safety—in other words, a level of risk more characteristic of a class I device. The FDA has previously classified software that calculates a drug dose based on a patients height, weight, mass, and other patient-specific information as a "Drug Dose Calculator" under 21 CFR 868.1890. The FDA encourages manufacturers of such mobile medical apps to contact the Agency to determine the classification of their mobile app. In addition, the FDA seeks public comment on whether and how it can provide greater clarity for these types of mobile medical apps.

VI. Regulatory requirements

This guidance, including the Appendix A and existing medical device regulatory classifications in Appendix B, 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 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).

A. Requirements for mobile medical device manufacturers subject to regulatory oversight

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

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 (21CFR Part 803);
- Premarket notification (21CFR 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, Special Controls, and (for most Class II devices) Premarket Notification

Class III devices: General Controls and Premarket Approval (21 CFR Part 814)

Appendix C 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.

B. Expectations for mobile medical app distributors

The FDA expects distributors of mobile medical apps who may or may not be a platform or service provider will cooperate with manufacturers in conducting corrections and removal actions. Mobile medical app manufacturers are required to make timely reports of corrections

and removals made to reduce a health risk or remedy a violation of the FD&C Act that presents a health risk, and to keep records regarding other corrections and removals.[18]

[18] 21 CFR 806.10 and 806.20.

APPENDIX A – Examples of mobile medical apps

This Appendix provides an exemplary list of functionalities to illustrate types of mobile medical apps. 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 mobile medical apps. This list is not exhaustive; it is only intended to provide clarity and assistance in identifying mobile medical apps.

Mobile medical apps that are extensions of regulated medical device for purposes of controlling the medical device or for the purpose of displaying, storing, analyzing, or transmitting patient-specific medical device data:

- Apps that allow the user to view medical images on a mobile platform and perform an analysis or process for diagnosis;
- Apps that connect to DICOM medical image servers and provide processing functions such as pan, zoom, measurement, auto contrasting, automatic detection of features, and other similar functionality;
- Apps that analyze, assess, or interpret electrocardiogram or electroencephalogram data;
- Apps that connect the mobile platform to vital signs monitors, bedside monitors, cardiac monitors, or other similar devices to:
    - Be used as a central viewing station for display;
    - Remotely access vital sign measurements of patients at home;
    - Be used in displaying and viewing digital images, including digital mammography, for review and analysis by trained medical practitioners;
    - Record arterial oxygen saturation and pulse rate of adult and pediatric patients inside hospitals and activate an alarm based on changes in levels;
    - Remotely review other standard or critical real-time numeric data from labor and delivery;
    - Perform remote Holter monitoring;
    - Connect to medical imaging devices for displaying, processing or storing medical images;
    - Wirelessly connect to medical devices and can relay or generate alarms;
    - Perform remote control, setting changes, or readout via wireless links such as programming or controlling a hearing aid system or implantable or body worn medical device.
- Apps that are used as patient screening tools for blood transfusion (extension of Blood Establishment Computer Software (BECS)) or other biologics;
- Apps that connect to a home use diagnostic medical device such as a blood pressure meter, body composition analyzer, or blood glucose meter to collect historical data or to receive, transmit, store, analyze, and display measurements from connected devices;
- Apps that control a blood-pressure cuff connected to a mobile platform to inflate the cuff and measure a person's blood pressure; or
- Apps that act as wireless remote controls or synchronization devices for MRI or X-Ray machines.

Mobile medical apps that transform or make the mobile platform into a regulated medical device by using attachments or sensors or similar medical device functions:

- Apps that attach EKG/ECG leads to a mobile platform to collect/analyze/monitor EKG/ECG signals;
- Apps that connect wirelessly to a blood glucose tester to display, calculate, trend, convert, or download results to a PDA;
- Apps that generate sine signals from 125Hz to 8kHz (8 steps) to check the user's hearing;
- Apps that act as a blood glucose meter by using an attachment to a mobile platform;
- Apps that act as an electronic stethoscope by connecting (either via wire or wirelessly) to an external sensor to record, manipulate, or measure sound waves;
- Apps that use the mobile platform with or without a sound transducer (microphone) to act as an electronic stethoscope to amplify heart, lung, blood vessel, enteral, and other body sounds;
- Apps that use the built-in accelerometer or other similar sensors in a mobile platform to monitor the user's movement to determine conditions such as sleep apnea, sleep phase, fall detection, or detect motion related to other conditions or diseases or to measure heart rate;
- Apps that use the light source from a mobile platform to cure and treat specific conditions, such as acne;
- Apps that attach sensors to a mobile platform to measure blood glucose, electrocardiograph, or other similar functions;
- Apps that use a mobile platform's built in features such as light, vibrations, camera, or other similar sources to perform medical functions;
- Apps that use a mobile platform to upload electroencephalograph (EEG) recordings and automatically detect seizures;
- Apps that use a mobile platform to record response time and accuracy of patients completing a cognitive task and/or automatically score or interpret cognitive testing results;
- Apps that use pictures and sound to diagnose conditions by comparing to previously determined diagnoses of images, symptoms, sounds, or other physiological measurements; or
- Apps that use a mobile platform in determining blood donor eligibility prior to collection of blood or blood components.

Mobile medical apps that allow the user to input patient-specific information and - *using formulae or a processing algorithm* - output a *patient-specific* result, diagnosis, or treatment recommendation that is used in clinical practice or to assist in making clinical decisions:

- Apps that perform calculations intended to be used by clinicians for automating tasks, such as:
    - eGFR with CKD-Epi, Cockcroft-Gault, and MDRD;
    - A-a gradient, etc.

- Apps that act as calculators or utilize algorithms to produce an index, score, scale, or other similar calculations (e.g., Glasgow Coma Scale, pain index, Apgar score, NIH stroke scale, etc.);
- Apps that calculate parameters associated with the use of radioisotopes;
- Apps that calculate the amount of chemotherapy needed based on the patient's Body Surface Area;
- Apps that assist with patient-specific dosing, e.g., radiation planning;
- Apps that calculate Warfarin Loading and Warfarin Maintenance doses for different anti-coagulation therapies based on nomograms;
- Apps that act as calculators to determine the maximum dosage of local anesthesia based on a patient's weight and age; or
- Apps that calculate Osteoporosis Risk Assessment by Composite Linear Estimate (ORACLE score).
- Apps that collect blood glucose readings and caloric intake to help manage diabetes by calculating pre-meal insulin dose (Bolus) or Basal adjustments; or
- Apps that act as a dosing calculators for a treatment regimen intended for a specific patient population (pediatrics);
- Apps that define disease stage or progression, and provide a prognosis of a medical condition or predict a patient's response to treatment based on a analysis of physiological, laboratory, and other data; or
- Apps that provide differential diagnosis tools for a clinician to systematically compare and contrast clinical findings (symptoms/ results, etc.) to arrive at possible diagnosis for a patient.

APPENDIX B - Examples of current regulations

This appendix provides examples of currently regulated devices, the Class according to which they are regulated, and their regulation numbers. This list is not a complete list of products and is intended only to provide clarity and assistance in identification of applicable regulations. FDA encourages mobile medical app manufacturers to search FDA's public databases, such as the medical device database for premarket cleared (510(k)) devices and product classification database, to determine the level of regulation for a given device. The databases can be accessed through the following link:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm.

For more detailed list and a searchable database of medical device classifications, please visit:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm.

Additional information can also be found at:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm.

Regulation number	Medical Device	Device Class	Submission Type ID
876.1500(b)(2)	Accessories, Photographic, For Endoscope (Exclude Light Sources)	1	510(k) exempt
870.2770	Analyzer, Body Composition	2	510(k)
868.1890	Calculator, Drug Dose	2	510(k)
868.1890	Calculator, Predicted Values, Pulmonary Function	2	510(k)
868.1880	Calculator, Pulmonary Function Data	2	510(k)
868.1900	Calculator, Pulmonary Function Interpretation (Diagnostic)	2	510(k)
862.2100	Calculator/Data Processing Module, For Clinical Use	1	510(k) exempt
874.3310	Calibrator, Hearing Aid / Earphone And Analysis Systems	2	510(k)
878.4160	Camera, Cine, Microsurgical, With Audio	1	510(k) exempt
878.4160	Camera, Still, Microsurgical	1	510(k) exempt
878.4160	Camera, Television, Endoscopic, With Audio	1	510(k) exempt
870.1110	Computer, Blood-Pressure	2	510(k)
870.1425	Computer, Diagnostic, Programmable	2	510(k)
892.2020	Device, Communications, Images, Ophthalmic	1	510(k) exempt
892.2010	Device, Digital Image Storage, Radiological	1	510(k) exempt
892.2010	Device, Storage, Images, Ophthalmic	1	510(k) exempt
876.1500	Device, Telemedicine, Robotic	2	510(k)
862.2100	Digital Image, Storage And Communications, Non-Diagnostic, Laboratory Information System	1	510(k) exempt
892.2030	Digitizer, Image, Radiological	2	510(k)
892.2030	Digitizer, Images, Ophthalmic	2	510(k)
870.2800	Electrocardiograph, Ambulatory, With Analysis Algorithm	2	510(k)
882.1400	Electroencephalograph - Automatic Event Detection Software For Full-Montage Electroencephalograph	2	510(k)
882.1400	Electroencephalograph - Burst Suppression Detection Software For Electroencephalograph	2	510(k)

882.1400	Electroencephalograph - Index-Generating Electroencephalograph Software	2	510(k)
882.1400	Electroencephalograph - Non-Normalizing Quantitative Electroencephalograph Software	2	510(k)
882.1400	Electroencephalograph - Normalizing Quantitative Electroencephalograph Software	2	510(k)
882.1400	Electroencephalograph - Source Localization Software For Electroencephalograph Or Magnetoencephalograph	2	510(k)
876.1500	Endoscopic Video Imaging System/Component, Gastroenterology-Urology	2	510(k)
884.2225	Imager, Ultrasonic Obstetric-Gynecologic	2	510(k)
876.1500	Led Light Source	2	510(k)
878.4810	Light Based Over The Counter Wrinkle Reduction	2	510(k)
878.4810	Light Based Over-The-Counter Hair Removal	2	510(k)
880.6350	Light, Examination, Medical, Battery Powered	1	510(k) exempt
880.5580	Locator, Acupuncture Point	2	510(k)
870.1875(b)	Lung Sound Monitor	2	510(k)
886.5540	Magnifier, Hand-Held, Low-Vision	1	510(k) exempt
880.6315	Medication Management System, Remote	2	510(k)
884.6190	Microscope And Microscope Accessories, Reproduction, Assisted	1	510(k) exempt
868.2377	Monitor, Apnea, Home Use	2	510(k)
880.2400	Monitor, Bed Patient	1	510(k) exempt
884.2660	Monitor, Blood-Flow, Ultrasonic	2	510(k)
868.2375	Monitor, Breathing Frequency	2	510(k)
870.2300	Monitor, Cardiac (Incl. Cardiotachometer & Rate Alarm)	2	510(k)
886.1510	Monitor, Eye Movement, Diagnostic	2	510(k)
884.2660	Monitor, Fetal Doppler Ultrasound	2	510(k)
884.2730	Monitor, Heart Rate, Fetal, Non-Stress Test (Home Use)	2	510(k)
884.2660	Monitor, Heart Rate, Fetal, Ultrasonic	2	510(k)
884.2660	Monitor, Hemic Sound, Ultrasonic	2	510(k)
884.2640	Monitor, Phonocardiographic, Fetal	2	510(k)
870.2300	Monitor, Physiological, Patient(Without Arrhythmia Detection Or Alarms)	2	510(k)
870.2340	Monitor, St Segment	2	510(k)
884.2660	Monitor, Ultrasonic, Fetal	2	510(k)
884.2720	Monitor, Uterine Contraction, External (For Use In Clinic)	2	510(k)
878.4810	Over-The-Counter Powered Light Based Laser For Acne	2	510(k)
868.2550	Pneumotachometer	2	510(k)
878.4810	Powered Light Based Non-Laser Surgical Instrument	2	510(k)
870.2800	Recorder, Event, Implantable Cardiac,(Without Arrhythmia Detection)	2	510(k)
876.1725	Recorder, External, Pressure, Amplifier & Transducer	2	510(k)
890.5050	Reminder, Medication	1	510(k) exempt
880.2700	Scale, Stand-On, Patient	1	510(k) exempt
864.9175	Software, Blood Bank, Stand Alone Products	2	510(k)
886.5540	Spectacle Microscope, Low-Vision	1	510(k) exempt
868.1850	Spirometer, Monitoring (W/Wo Alarm)	2	510(k)
870.1875(b)	Stethoscope, Electronic	2	510(k)
868.1920	Stethoscope, Esophageal, With Electrical Conductors	2	510(k)
884.2900	Stethoscope, Fetal	1	510(k) exempt
876.4300	System, Alarm, Electrosurgical	2	510(k)

884.2990	System, Documentation, Breast Lesion	2	510(k)
892.2050	System, Image Processing, Radiological	2	510(k)
892.1560	System, Imaging, Optical Coherence Tomography (Oct)	2	510(k)
884.2800	System, Monitoring, For Progress Of Labor	2	510(k)
884.2740	System, Monitoring, Perinatal	2	510(k)
870.2300	System, Network And Communication, Physiological Monitors	2	510(k)
876.1500	System, Surgical, Computer Controlled Instrument	2	510(k)
864.9175	System, Test, Automated Blood Grouping And Antibody	2	510(k)
880.2910	Thermometer, Electronic, Clinical	2	510(k)
886.1930	Tonometer, Ac-Powered	2	510(k)
870.2920	Transmitters And Receivers, Electrocardiograph, Telephone	2	510(k)
870.2910	Transmitters And Receivers, Physiological Signal, Radiofrequency	2	510(k)

APPENDIX C -- Brief description of regulatory requirements

This Appendix provides a high level description of some select regulatory requirements for medical devices, including mobile medical apps. The FDA has additional resources and publications online that describes the 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[19] 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[20] by identifying to FDA the mobile medical apps they are marketing.

Additional information can be found 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 clear direction 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073604.htm.

---

[19] 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."
[20] *See* 21 CFR part 807.

Further information regarding the investigational device exemption can be found 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, and Part 809 for radiological health 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 at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm.

5. Quality System Regulation (QSR)

Mobile medical app manufacturers are required to comply with the QSR. The QSR 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 QSR (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: 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.[21] MDR requires medical device manufacturers to:

- Submit MDR reportable events involving their medical devices as described in 21 CFR Parts 803.10(c) and 803.50;
- Submit 5-day reports as described in 21 CFR Part 803.53;
- Submit supplemental reports as described in 21 CFR Part 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 Part 803.17;
- Conduct an investigation of each event and evaluate the cause of the event as described in 21 CFR Part 803.50(b)(3); and
- Establish and maintain complete files for all complaints concerning adverse medical device events as described in 21 CFR Part 803.18.

The MDR report (FDA Form 3500A) must contain all the information described in 21 CFR Part 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:

- Call: (301) 796-6670 (voice)
- Email: RSMB@fda.hhs.gov
- Or write to:
    - 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

[21] See 21 CFR part 803.

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, mobile medical app manufacturers are exempt from reporting requirements under 21 CFR 806.1(b)[22] for 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. 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.

More information about reporting requirements under 21 CFR Part 806 is available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals.

For additional general information about medical device recalls, visit: http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/default.htm.

[22] 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 § 806.2(h).
(3) Routine servicing as defined in § 806.2(k).
(4) Stock recoveries as defined in § 806.2(l).

APPENDIX D -- Additional Resources

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. Medical Device Reporting for Manufacturers -- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094529.htm
3. Guidance for the Submission of Premarket Notifications for Medical Image Management Devices -- (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073721.pdf)
4. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices -- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm
5. Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation" (61 FR 52602--52662). The Quality System regulation (Title 21 Code of Federal Regulations Part 820)
6. Design Control Guidance For Medical Device Manufacturers -- http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM070642.pdf
7. General Principles of Software Validation; Final Guidance for Industry and FDA Staff -- http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM085371.pdf
8. Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software -- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077812.htm
9. 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
10. IEC 60601-1-4:1996, *Medical electrical equipment, Part 1: General requirements for safety, 4. Collateral Standard: Programmable electrical medical systems*. International Electrotechnical Commission, 1996.
11. IEC 62304:2006, *Medical device Software – Software life cycle processes*. International Electrotechnical Commission, 2006.
12. IEC 61508:1998, *Functional safety of electrical/electronic/programmable electronic safety-related systems*. International Electrotechnical Commission, 1998.
13. IEEE Std 1012-1986, *Software Verification and Validation Plans*, Institute for Electrical and Electronics Engineers, 1986.
14. *IEEE Standards Collection, Software Engineering*, Institute of Electrical and Electronics Engineers, Inc., 1994. ISBN 1-55937-442-X.

15. ISO 8402:1994, *Quality management and quality assurance - Vocabulary.* International Organization for Standardization, 1994.
16. ISO 9000-3:1997, *Quality management and quality assurance standards - Part 3: Guidelines for the application of ISO 9001:1994 to the development, supply, installation and maintenance of computer software*. International Organization for Standardization, 1997.
17. ISO 9001:1994, *Quality systems - Model for quality assurance in design, development, production, installation, and servicing.* International Organization for Standardization, 1994.
18. ISO 13485:1996, *Quality systems - Medical devices - Particular requirements for the application of ISO 9001.* International Organization for Standardization, 1996.
19. ISO/IEC 12119:1994, *Information technology - Software packages - Quality requirements and testing,* Joint Technical Committee ISO/IEC JTC 1, International Organization for Standardization and International Electrotechnical Commission, 1994.
20. ISO/IEC 12207:1995, *Information technology - Software life cycle processes,* Joint Technical Committee ISO/IEC JTC 1, Subcommittee SC 7, International Organization for Standardization and International Electrotechnical Commission, 1995.
21. ISO/IEC 14598:1999, *Information technology - Software product evaluation,* Joint Technical Committee ISO/IEC JTC 1, Subcommittee SC 7, International Organization for Standardization and International Electrotechnical Commission, 1999.
22. ISO 14971-1:1998, Medical Devices - Risk Management - Part 1: Application of Risk Analysis. International Organization for Standardization, 1998.
23. The draft guidance "Radio-Frequency Wireless Technology in Medical Devices". http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077210.htm