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Software Regulation in mHealth

The mHealth Regulatory Coalition (MRC) is moving along in its development of a proposed guidance document that clarifies what types of mHealth technologies the Agency should regulate. The guidance document will specifically address three areas—intended use claims, accessory products, and software applications. Having developed a framework for intended use claims and accessory products, we now focus on the third and final topic. In many ways, software regulation is treated the same as any other medical device. mHealth software is subject to the same intended use and accessory analysis as described in the previous parts of this guidance document. In other ways, however, software regulation is distinct, particularly due to the dynamic nature of software in an mHealth system.

This part of the guidance document addresses these software-specific issues in an mHealth system. We hope that you will challenge our thinking and offer ways to improve this framework. Comments should be directed to Bradley Merrill Thompson at BThompson@EBGLaw.com.

Part 4—Software

1. Introduction

1.1. Software is of particular importance to mHealth because the data collected by sensors, wireless medical devices, and other physical products—most of which have their own internal software—is being stored and analyzed by software apps. It is common in mHealth systems that these functions are conducted remotely across interconnected networks via the Internet.

1.2. Software in the mHealth world can come in all shapes and sizes and can perform a variety of functions. Although software is purely non-physical, association with a tangible piece of hardware is required at some point throughout the web of interconnected hardware technology comprising the mHealth system.

1.2.1. Software can be found in any of the following mHealth components:

1.2.1.1. Medical devices;

1.2.1.2. Patient-centered communications technologies;

1.2.1.3. Provider-centered communications technologies;

1.2.1.4. Intermediary-centered communications technologies; and

1.2.1.5. Network infrastructure technologies.

1.3. Software in a medical device can come in two forms: the first is called *firmware*, while the second uses the generic *software* term.

1.4. Software also can be found outside of the medical device and at any point along the information pathway from the patient to the *healthcare professional*. Patient-centered communications technologies (e.g., a personal computer, smartphone, tablet, or proprietary communications device, etc.) can utilize software to perform analytical tasks or to control the transmission of patient data.

1.5. Provider- and intermediary-centered communications technologies may be any of the same types of communications technologies used by the patient but instead are used by a *healthcare professional* or a third-party intermediary. These technologies can employ any of the types of software that are designed for patient use. The software also could be used for the same or different purposes as the patient-centered devices.

1.6. The network infrastructure of an mHealth system can include any number of servers, mainframe computers, data storage devices, wireless routers, and telephone service switches, among other things. These products are distinct from the patient-, provider-, and intermediary-centered communications technologies in that the network infrastructure technologies function independently of the other technologies and require no involvement from the patient, clinician, or intermediary. Software that resides on these components may or may not be specific to the mHealth system. The software, however, need not "reside" on a network infrastructure component in the way that software is traditionally downloaded onto a computer. Cloud computing, which is becoming more common in the consumer marketplace as well as the mHealth sphere, distributes software algorithms and functionality over a number of different networked hardware components. The fluidity of this type of software system is technically powerful, promoting advanced algorithmic capabilities but makes identifying where the

software "resides" increasingly difficult. Similarly, aspects of software that once were bundled in a specific software program are now being "outsourced" across the Internet to various developers who provide "software services". These software services perform standard functions (e.g., a search or payment function) across the network infrastructure and separate from any specific mHealth component.

2. Scope

2.1. This document describes the regulation of software products used in mHealth systems. This regulatory framework is not intended to apply to all software used as part of a medical device. Instead, this document focuses on the types of software that an mHealth system might incorporate.

3. Definitions

3.1. ***[This section will be updated as necessary and incorporated with the definitions of the other parts of the guidance document.]***

3.2. *Cloud computing* – cloud computing is the use of distributed computing platforms to perform specific analytical or administrative functions. The term "software as a service" is often used to describe software programs that are performed in the "cloud" (i.e., the network of distributed computing platforms).

3.3. *Electronic Health Record (EHR)* – an EHR is an electronic record of health-related information for a patient that contains information captured from a variety of sources (e.g., during clinical visits from various healthcare professionals), including vital statistics, lab and imaging studies, and other information important to the patient's medical history.

3.4. *Electronic Medical Record (EMR)* – an EMR is an electronic record of health-related information used exclusively by a single healthcare provider (e.g., hospital or ambulatory care facility) as the legal record of a patient's health information.

3.5. *Firmware* – firmware is programming code (e.g., instructions or machine commands) that is embedded in a device and that controls the proper functioning of the device.

3.6. *General purpose article* – a general purpose article is a product that is not labeled or promoted for medical uses but which, by virtue of its application in healthcare, meets the definition of a medical device. These products either pose little or no risk, or are appropriately the sole responsibility of the healthcare professionals who have used them in medical applications. Examples of a general purpose article include a personal computer that has been programmed by a clinical chemist to display values from tests on human specimens; and a database management system, with no medical claims, that is used by a healthcare professional to identify patients at risk for a given medical procedure.[1]

3.7. *Level of Concern* – level of concern refers to an estimate of the severity of injury that a device could permit or inflict, either directly or indirectly, on a patient or operator as a result of device failures, design flaws, or simply by virtue of employing the device for its intended use. Level of Concern is not related to device classification (Class I, II or III) or to hazard or risk analysis

[1] CTR. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., DRAFT POLICY FOR THE REGULATION OF COMPUTER PRODUCTS (1989).

per se.[2]

3.8. *Personal Health Record (PHR)* – a PHR is an electronic record of health information that is maintained, controlled, and shared by a *consumer*. A PHR consists of health-related data that are generated and entered by the consumer and can incorporate data from both EMRs and EHRs.

3.9. *Software* – software is programming code (e.g., instructions or machine commands) that employs a machine or multiple machines, any of which can be real or virtual, to perform certain analytical tasks not specifically traceable to the operation of any particular physical product. Software is inherently non-physical in nature. Common terms include "software", "software application", "software app", "software program", "app", or "program". Examples include stand-alone programs for use on a computer or mobile phone; web-based applications; programs that perform functions on multiple machines (e.g., "cloud computing"); and modularized, third-party software that performs discrete functions (e.g., "software-as-a-service").

3.10. *Software device* – a software device is *software* that meets the definition of a medical device. *Software* that would otherwise be a *general purpose article*, but which is modified by the user outside of the original manufacturer's specifications, would constitute a *software device*.

3.11. *Software manufacturer* – a software manufacturer is any person or entity who designs and develops *software*, including someone who might commonly be called a "software developer".

3.12. *Software module* – a software module is a discrete element of a software app that performs a specific function upon request by the core software code or by another software module. Software modules are used as part of a software architecture as a means of partitioning specific sub-functions that, when combined in a larger package or "wrapper", create the software app. The specific functions performed by a software module can be analytical (e.g., calculating daily averages of medical device data) as well as procedural (e.g., using standard or proprietary protocols for transmitting and/or converting data streams).

4. General Approach to Software Regulation

4.1. *Software* are treated in the same way that other products are treated for purposes of determining whether and how FDA will regulate these products.

4.2. Any *software* that does not meet the definition of a medical device is not regulated by FDA. Therefore, to be considered for regulation, the software product must be intended by the manufacturer for use in the diagnosis, prevention, or treatment of disease.

4.2.1. Refer to Part 2 of this guidance document for further discussion of the intended use analysis for mHealth products.

4.3. Any *software device* that falls into an existing classification regulation should be subject to the

[2] CTR. FOR DEVICES & RADIOLOGICAL HEALTH & CTR. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR THE CONTENT OF PREMARKET SUBMISSIONS FOR SOFTWARE CONTAINED IN MEDICAL DEVICES 4–8 (2005), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf; *see also* CTR. FOR DEVICES & RADIOLOGICAL HEALTH, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY, FDA REVIEWERS AND COMPLIANCE ON OFF-THE-SHELF SOFTWARE USE IN MEDICAL DEVICES (1999), *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073779.pdf.

regulatory requirements established in that classification regulation.

4.3.1. If no classification regulation exists, the *software device* may be evaluated under the de novo review process for classification purposes.

4.3.2. Appendix A lists the current classification regulations and associated product codes that may apply to software in an mHealth system. Appendix B presents a number of proposed classification regulations that should be implemented to adequately address regulation of mHealth software. For completeness, Appendix B also includes product types that should remain unregulated.

4.4. Any *software device* that meets the definition of an *accessory* should be regulated based on the accessory framework described in Part 3 of this guidance document.

4.4.1. Software apps that are intended to be purchased by a manufacturer of the finished device in which the product will be incorporated should be treated as components. The *software manufacturer* of these types of software apps should not be regulated by FDA. The manufacturer of the finished device, however, should be subject to regulation appropriate for the finished device.

4.5. Any *software device* that is not an *accessory* or a *component* and that is not adequately described by an existing classification regulation or has not been evaluated under the de novo review process should be a Class III device subject to premarket approval requirements.

4.6. A *software manufacturer* must comply with all applicable regulations, including the Quality System Regulations (21 C.F.R. Part 820), premarket notification/approval submissions, registration and listing, as are appropriate for the designated device classification.

5. Risk Model

5.1. The risk model established in Part 1 of this guidance applies to hardware and software alike in an mHealth system.

5.1.1. One factor that influences the risk associated with an mHealth system is the level of involvement of the *consumer*, a *caregiver*, and/or a *health care professional* in the proper use of the product. As with other medical devices, hardware and software components in an mHealth system may or may not involve human interaction or intervention, which may include or consist of:

5.1.1.1. Manual entry of data that is stored, transmitted, analyzed, or manipulated in some other way by the software;

5.1.1.2. Assessment of data stored in, received from, analyzed by, or manipulated in some other way by an mHealth system;

5.1.1.3. Manual manipulation of electronically generated data prior to or to facilitate assessment of the data.

5.1.2. FDA generally believes that human intervention reduces the risk associated with medical devices, including those in an mHealth system. In line with this thinking, a hardware or software device that requires, for example, manual data entry of personal health information or medical device data (e.g., a blood glucose measurement) should be viewed as having less risk than a similar device that automates these activities.

5.1.3. On the other hand, an mHealth system that involves human intervention as an intermediate step (e.g., by the product's manufacturer) between data generation

(manual or automatic) and assessment (e.g., by a healthcare provider) should be viewed as having additional risk when compared to a system that directly transmits the data to the end user. An intermediate step that has no effect on the assessment (e.g., for billing purposes) should have no impact on the associated risk.

5.2. Software may involve additional risk as a result of the associated hardware. For example, a software app built for use on a proprietary, wireless hardware device may involve less risk than the same software app that is built for a general purpose smartphone because the general purpose smartphone involves features and functions that are not specific to the software app, but that may cause the software app to malfunction. A proprietary hardware device, on the other hand, should involve less risk because the design features are limited to the specific intended use and functionality of the software app.

5.3. A software app that uses a cloud computing platform should not be viewed as involving additional risk when compared to a software app that relies on a dedicated hardware device. More specifically, FDA believes that, if you compare two devices of a specific type (e.g., a proprietary wireless device), one device that executes a software app locally involves no more significant risk than another device that executes the same software app on a cloud server.

6. Unregulated mHealth Software

6.1. *Software* that fall into the ADLR Product exclusion do not meet the definition of a medical device and are not subject to FDA regulation.

6.1.1. See Part 2 for a description of the ADLR Product exclusion.

6.1.2. Examples of ADLR Products include:

6.1.2.1. *Software* that alerts a *caregiver* of a low-risk health event because the product does not diagnose, treat, or prevent a specifically identifiable disease or medical condition and is intended for use by a *caregiver*.

6.1.2.2. *Software* that facilitates the monitoring of behavioral activities or basic health information (e.g., food consumption, weight trends, etc.) to evaluate general wellness of an individual because the product does not diagnose, treat, or prevent a specifically identifiable disease or medical condition and is intended to target behavioral activities not generally associated with a specific disease or medical condition.

6.1.2.3. *Software* that helps a *consumer* manage personal health information because the product does not diagnose, treat, or prevent a specifically identifiable disease or medical condition.

6.2. FDA believes that there are a number of *software devices* for which the associated risk is sufficiently low such that regulation is not warranted at this time. FDA is choosing to exercise its enforcement discretion for these *software devices* that are part of an mHealth system. FDA reserves the right to reevaluate any enforcement discretion decision.

6.2.1. *Software devices* that meet the SBLR Device exemption (see Part 2 for a description) or that have any of the following functions fall into this unregulated category:

6.2.1.1. Automates a function for ease-of-use;

6.2.1.2. Performs library functions;

6.2.1.3. Stores or transmits personal health information in electronic medical records

(EMR), electronic health records (EHR), or personal health records (PHR) systems;[3]

6.2.1.4. Analyzes for non-diagnostic purposes personal health information stored in an EMR (or other similar EHR or PHR system);

6.2.1.5. Performs general IT functions;[4] or

6.2.1.6. Performs general business functions.

6.2.2. The intended use and design functions of these *software devices* must not exceed the functional limits described here.

6.2.3. Examples of *software devices* that should remain unregulated at this time include:

6.2.3.1. *Software* that sends notifications to a patient to take a pill or to remind them to visit their healthcare provider because such *software* automates a function of the *healthcare professional* or *caregiver* for ease-of-use.

6.2.3.2. *Software* that prompts the *consumer* to answer pre-determined, health-related questions because such *software* performs library functions typically associated with the activities of a *healthcare professional* or *caregiver*. Similarly, *software* that transmits this information to a *healthcare professional* or *caregiver* in a report is unregulated because such *software* automates the report-writing and record-keeping function of a *healthcare professional* or *caregiver* for ease-of-use and because the information, which FDA does not consider to be medical device data, is manually entered.

6.2.3.2.1. The location where the *software* executes or is used (i.e., on a device in the *consumer's* home or a *healthcare professional's* office, on a third-party cloud server, etc.) does not affect this analysis.

6.2.3.3. *Software* that stores or transmits personal health information (e.g., EMR, EHR, or PHR software) even if automatically obtained from a Class I

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[3] FDA is currently exercising its enforcement discretion, but is considering several possible approaches to regulation of EMRs, including:

> 1) Focusing on post-market safety by requiring HIT device establishments to electronically register and list their HIT devices, and to submit Medical Device Reports (MDRs) to the FDA;
> 2) Focusing on manufacturing quality and post-market safety by requiring HIT device manufacturers to comply with the above requirements and also to adhere to FDA's Quality Systems Regulation (QSR); and
> 3) Applying the traditional regulatory framework, in which HIT device manufacturers would be required to meet all the same regulatory requirements as other, more traditional devices, including risk-based premarket review.

Testimony of Jeff Shuren, Director of Ctr. for Devices & Radiological Health, U.S. Food & Drug Admin., before the Adoption/Certification Workgroup of the HIT Policy Committee (Feb. 25, 2010), *available at* http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_910717_0_0_18/3Shuren_Testimony022510.pdf.

[4] This exemption applies to a general purpose IT product that is used in an mHealth system and that is not altered or reconfigured outside of its manufactured specifications. Modifications within the off-the-shelf parameters of operation are still considered exempt.

medical device (e.g., data obtained from an electronic blood pressure cuff). More specifically, EMR software that stores or transmits (e.g., to another EMR software system) personal health information (including data from a Class I device, e.g., blood pressure measurements) is unregulated such that once the information enters the EMR software, it can be stored and transmitted freely throughout the EMR system and to other EMR systems without triggering FDA regulation. Similarly, *software* that allows an individual to manually enter personal health information (including medical device data) is unregulated.

6.2.3.4. *Software* that calculates and graphically displays trends in personal health incidents (e.g., hospitalization rates or alert notification rates). Similarly, *software* that generates a report based on data stored in a EMR, EHR, or PHR system is unregulated.

6.2.3.5. *Software* that controls the equipment used to communicate health-related information from one location to another because such *software* performs general IT functions.

6.2.3.6. *Software* that allows a "face-to-face" HD video conversations with a *healthcare provider* if marketed as a general purpose IT product.

6.2.3.7. *Software* that monitors a *consumer's* use of the mHealth system for billing purposes because such *software* performs a general business function.

6.3. As with any product, *software* that do not meet the definition of a medical device are not regulated as *software devices*. Examples of products that could be confused with regulated *software devices* but are not regulated include:

6.3.1. *Software* that stores, analyzes, and transmits calorie consumption and/or exercise activity for personal use.

6.3.2. *Software* that provides educational information related to medical diseases or conditions.

6.3.3. *Software* that provides educational information, advice, or motivational guidance related to behavioral activities that may be associated with a medical disease or condition (e.g., to help quit smoking or to improve medication compliance).

6.3.4. *Software* that allows "face-to-face" HD video conversations (or other means of communication, e.g., instant messenger, email, SMS text, etc.) between a *consumer* and a *caregiver*.

6.3.5. *Software* that allows a *patient* or *healthcare provider* to manage administrative activities associated with the delivery of healthcare (e.g., electronic appointment scheduling, prescription writing/filling, billing, etc.).

6.3.6. *Software* that allows a *consumer* to play "mind challenging" games.

6.3.7. General communication software that are used for telecommunications purposes to transmit data in an mHealth system and that comply with applicable standards for such products. These include wireless routers, modems, switches, Bluetooth transmitters/receivers, cables, connectors, adaptors, and any other similar product used for basic connectivity purposes. This also includes software drivers and accessories associated with the basic functionality of these devices.

6.3.8. General purpose health applications that are used in an mHealth system to electronically collect, store, transmit, display, or analyze (e.g., trend, aggregate, or generate reports) health-related data for educational purposes or as a tool to affect normal behavioral activity (e.g., food consumption or exercise activity). An example of a general purpose health application is a software device stored on a smartphone that electronically collects daily exercise and weight information from a variety of sensors and displays the data for personal monitoring purposes.

7. Class I exempt mHealth Software

7.1. FDA believes that certain *software devices* have sufficient risk associated with their intended use that enforcement discretion is inappropriate; however, there also exist a number of *software devices* for which general controls will adequately address the associate risk. FDA should regulate these *software devices* as Class I devices exempt from premarket notification requirements.

7.2. *Software devices* that meet any of the following should be Class I exempt from premarket notification:

7.2.1. *General purpose articles*;

7.2.2. *Firmware* associated with a Class I exempt medical device;

7.2.3. *Software* that fall into an existing Class I exempt regulation (e.g., medical device data systems (MDDS) under 21 CFR § 880.6310, laboratory information systems (LIS) under § 862.2100, or medical image management systems (MIMS) under §§ 892.2010 and 892.2020) and that do not fall within the 8xx.9 limitations on exemption; or

7.2.4. Low-risk *software* that do not meet the SBLR Device exemption or ADLR Product exclusion criteria.

8. Class II or III mHealth Software

8.1. FDA believes that, for a number of *software devices*, the associated risk requires additional regulatory controls to ensure safety and effectiveness of the devices. These *software devices* are regulated as Class II or III devices.

8.2. FDA applies its long-standing Level of Concern and inherent risk analysis to determine the appropriate regulatory controls for the following:

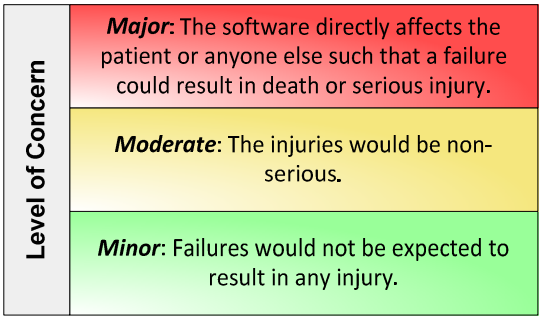
8.2.1. *Firmware* associated with a Class II or III medical device; and

8.2.2. *Software* that fall into an existing Class II or III regulation as a stand-alone product, a *component*, or an *accessory*; and

8.2.3. *Software* that does not fall into an existing classification but involves moderate to high risk.

8.3. The Level of Concern analysis focuses on the severity of an injury.

8.3.1. The categories in which a given software device can fall is as follows:



8.3.2. The Level of Concern analysis is independent of the device classification determination and is used to establish:

8.3.2.1. The depth and degree of hazard analysis and mitigation that is expected;

8.3.2.2. The depth and degree of documentation;

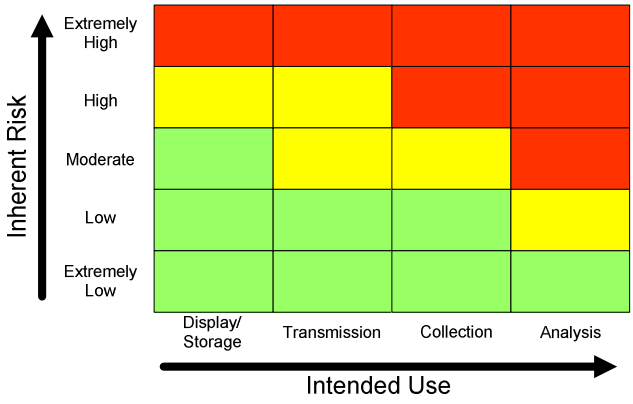
8.3.2.3. What needs to be submitted as opposed to simply documented;

8.3.2.4. The rigor applied to the verification and validation of the software; and

8.3.2.5. The degree to which the device manufacturer's software development process is scrutinized.[5]

8.4. The inherent risk analysis involves the likelihood and severity of an injury occurring. The association between inherent risk and the intended use forms the basis of the total risk.

8.4.1. An example of the association between inherent risk and intended use for a software device that collects patient data is demonstrated below.



8.4.2. The total risk (shown in green as low, yellow as moderate, and red as high) associated with the various functions in this example may depend on:

8.4.2.1. The data associated with the function performed by the *software device*;

[5] CTR. FOR DEVICES & RADIOLOGICAL HEALTH & CTR. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., *supra* note 2.

8.4.2.2. The means through which the *software device* receives and/or transmits the data; and

8.4.2.3. The purpose for which the *software device* performs its function.

9. Categories of mHealth Software

9.1. At a high-level, mHealth *software* can be broken into the following three product types:

9.1.1. Hardware drivers and software accessories;

9.1.2. Communication device apps; and

9.1.3. Stand-alone and web apps.

9.2. For each of the product types, a software product can fall into any of the following classification categories:

9.2.1. Class II or III;

9.2.2. Class I (exempt from premarket notification); or

9.2.3. Unregulated software.

9.3. The following describes each of the product types in more detail with examples of software and their associated classification category.

9.3.1. **Hardware Drivers and Software Accessories**

9.3.1.1. Generally, software that fall into this product type include *firmware* or other device controllers (e.g., operating systems).

9.3.1.2. Class II or III devices that fall into this product type include:

9.3.1.2.1. Firmware for a Class II or III device (e.g., blood glucose meter or pacemaker);

9.3.1.2.2. Software that sends signals to a Class II or III device to control device operation (e.g., establishing a set-point for a control parameter or "waking up" the device).

9.3.1.3. Devices that are Class I exempt from premarket notification and that fall into this product type include:

9.3.1.3.1. Firmware for a Class I device (e.g., MDDS or weight scale);

9.3.1.3.2. Software that sends signals to a Class I device to control device operation (e.g., establishing a set-point for a control parameter or "waking up" the device).

9.3.1.4. Unregulated software products that fall into this category include:

9.3.1.4.1. General purpose device operating systems.

9.3.2. **Communication Device Apps**

9.3.2.1. Generally, software that fall into this product type receive and/or transmit data (e.g., a smartphone app).

9.3.2.2. Class II or III devices that fall into this product type include:

9.3.2.2.1. A smartphone app that is intended:

9.3.2.2.1.1. To alert a *healthcare professional* or emergency service of a moderate- or high-risk medical event;

9.3.2.2.1.2. To facilitate real-time diagnosis or treatment;

9.3.2.2.1.3. To facilitate monitoring patient activity associated with a moderate- or high-risk disease.

9.3.2.3. Devices that are Class I exempt from premarket notification and that fall into this product type include:

9.3.2.3.1. MDDS software (21 CFR § 880.6310);

9.3.2.3.2. MIMS communication software (21 CFR. § 892.2020);

9.3.2.3.3. A smartphone app intended:

9.3.2.3.3.1. To alert a *healthcare professional* of a low-risk medical event;

9.3.2.3.3.2. To facilitate monitoring patient activity associated with a lower-risk disease.

9.3.2.4. Unregulated software products that fall into this category include:

9.3.2.4.1. A smartphone app intended:

9.3.2.4.1.1. To alert a caregiver of a low-risk health event;

9.3.2.4.1.2. To facilitate monitoring activity to evaluate general wellness.

9.3.2.4.2. Apps that perform general IT functions (e.g., e-mail or SMS text messaging).

9.3.3. **Stand-Alone and Web Apps**

9.3.3.1. Generally, software that fall into this product type perform data analysis (e.g., for professional decision support or personal health management).

9.3.3.2. Class II or III devices that fall into this product type include:

9.3.3.2.1. PC-, smartphone-, or web-based apps intended:

9.3.3.2.1.1. To analyze patient data for medical diagnosis or treatment;

9.3.3.2.1.2. To allow a *healthcare professional* to monitor Class II or III device data or patient activity for diagnosis or treatment of a moderate- or high risk-disease;

9.3.3.2.1.3. To track and report activity for treatment of a moderate- or high-risk disease.

9.3.3.3. Devices that are Class I exempt from premarket notification and that fall

into this product type include:

9.3.3.3.1. PC-, smartphone-, or web-based apps intended:

9.3.3.3.1.1. To allow a *healthcare professional* to monitor Class I device data or patient activity for diagnosis or treatment of a low-risk disease;

9.3.3.3.1.2. To track and report activity for treatment of a low-risk disease.

9.3.3.4. Unregulated software products that fall into this category include:

9.3.3.4.1. PC-, smartphone-, or web-based app intended:

9.3.3.4.1.1. To manage personal health information;

9.3.3.4.1.2. To track, display, or report basic health information (e.g., daily/monthly exercise activity, food consumption, weight trends, etc.) to evaluate general wellness;

9.3.3.4.1.3. To automate manual office and/or record-keeping functions (e.g., EHRs).

10. Other Considerations

10.1. Software Modularization

10.1.1. It is possible—in fact, quite probable—that a single software product may involve functionality that places it in more than one of these product types. In the event that a software product involves different product types and classification categories, the highest classification should apply.

10.1.1.1. Alternatively, the *software manufacturer* may choose to separate these functions so that a single product type is applicable. To achieve this modularization, each *software device* should be marketed as separate products with the specific intended use described in one of the product types and associated classification categories.

10.1.1.2. As yet another alternative, the *software manufacturer* may choose to separate the software app such that specific functions that fall into a lower classification or that are unregulated are unaffected by functions that fall into a higher classification. This may be achieved through various software architecture standards.

10.1.1.3. FDA encourages the use of standard software design principles in the development of mHealth software and system architectures. Use of standard design principles reduces inherent risk and enables modularization of discrete functions within a software app (i.e., software modules) as well as within an mHealth system that involves more than one hardware or software element.

10.1.1.3.1. Example of App-level Modularization: An MDDS device is an example of how data can be transmitted from one software app to another without affecting the regulatory status of either software app. Assume for this example that App A collects

medical device data within a blood pressure cuff. App A transmits the blood pressure data to a separate software app (App B). App A is regulated based on its intended use (i.e., Class II under 21 C.F.R § 870.1120), while App B is regulated as a Class I exempt MDDS device (assuming for the sake of this example that App B fits squarely within the MDDS rule). Even though Apps A & B communicate and share information with each other, each is regulated independently.

10.1.1.3.1.1. Use of standard design principles should ensure the inherent risk associated with each app and with the communication between each app is minimized.

10.1.1.3.1.2. Apps A & B in this example need not be separate products. At a minimum, there should be separation in the software architecture such that the functions are independent (see example below).

10.1.1.3.1.3. The principle presented in this example is not limited to MDDS devices. App B in this example could be replaced with other Class I devices or unregulated devices. The software modularization principle remains the same.

10.1.1.3.1.4. It is important to note the distinction between *firmware* and *software* in relation to this principle. Firmware is the code the controls the basic functionality of a traditional medical device (e.g., controlling the timing of a pacemaker). The software modularization principle is not intended to apply to firmware. Instead, this principle applies to software used, for example, in mobile apps or a store-and-forward system that involves back-end software for use by a *healthcare professional* or some third-party intermediary.

10.1.1.3.2. Example of Module-level Modularization: Now consider a single software app that is designed using multiple software modules to perform discrete functions within the app. Module A receives and stores medical device data transmitted from a Class II blood pressure cuff. For the sake of this example, assume that Module A fits squarely within the Class I MDDS regulation. Module B compiles the blood pressure data into a trend graph and displays the trend upon request.

10.1.1.3.2.1. If appropriate software design principles are employed in the development of the software app (including Modules A & B), the risk that Module B will influence Module A is low, such that Module A should be regulated under the MDDS classification regardless of the fact that Module A is packaged in a software app that also includes

non-MDDS functions in Module B.

10.1.1.4. A variety of approaches can be used to achieve modularization of software such that 1) a single software app, comprised of software modules created by one or more manufacturers, can be separated into distinct device classifications based on the intended use of the discrete functions within the software app and 2) a single software app can be separated from other software apps not associated with the mHealth functionality (e.g., other software apps on a smartphone that perform non-medical functions and that are not intended to influence the mHealth system). These approaches include the use of:

10.1.1.4.1. Library standards (e.g., DLLs or COMs);

10.1.1.4.2. Privileged sections of controlled execution environments (e.g., for memory, task managing, etc.);

10.1.1.4.3. Other object-oriented programming approaches; and

10.1.1.4.4. Harmonized standards for medical devices (e.g., IEC 62304 – for medical device software; IEC 60601 – for medical electrical equipment; IEC61010-1 – for safety requirements for electrical equipment for measurement, control, and laboratory use; ISO 13485 – for medical device quality management systems; and ISO 14971 – for medical device risk management).

10.1.1.5. FDA recognizes that the use of a software app on a platform (e.g., a smartphone) alongside other software apps that are not intended to function with the mHealth system involves some inherent risk that platform-based functions (e.g., communication protocols) may become affected by the non-medical app such that the mHealth app may be exposed to additional risk. FDA believes, however, that using standard software design principles for the mHealth app with standard OTS platforms (e.g., smartphones, tablets, etc.) minimizes this risk. Compliance with ISO 14971 and the Quality System Regulation (21 C.F.R. Part 820) will further reduce this risk.

10.1.2. In some situations, the relationship between software and hardware is inseparable (e.g., device operating systems), while in others the software is not hardware-dependent (e.g., stand-alone software app).

10.1.2.1. Where software cannot be divorced from the hardware on which it executes, the software should take on the classification of the hardware unless the software itself would result in a higher classification.

10.1.2.2. Where the software is not hardware-dependent, the software should be regulated separately from the underlying hardware. More specifically, a smartphone that is used to execute a software app should not by default be regulated at the same classification as the software app (or regulated at all) and vice versa. For example, a software app that allows the user to enter blood glucose readings and weight measurements and that transmits the data to the healthcare provider for monitoring of the patient's diabetes should be regulated as a Class II medical device. The smartphone on which the software app resides should not be regulated as a medical device (unless it

otherwise meets the definition of a medical device).[6]

10.2. 8xx.9 Regulations

10.2.1. As with any medical device, *software devices* that are Class I exempt from premarket notification are also subject to the 8xx.9 regulation restricting the exemption to certain types of devices. See Part 3 for a detailed discussion of the impact of the 8xx.9 regulations.

10.2.2. FDA recognizes the importance of creating a long-lasting regulatory framework for medical device software, particularly software apps used in an mHealth system. The rapid evolution of mHealth technologies and software system architectures poses a significant challenge.

10.2.3. FDA should apply the following general principles to future technology to determine whether the technology is included in the scope of the current classifications and exemptions:

10.2.3.1. A technology fits within the classification and any associated exemption if:

10.2.3.1.1. The new technology fits squarely within the wording of the classification regulation and any associated exemption, which was written with a focus on basic operating principles and intended uses rather than specific technology types; and

10.2.3.1.2. One of the following is true:

10.2.3.1.2.1. The technology is reasonably foreseeable at the time the classification/exemption was created, as demonstrated by literature that existed at that time; or

10.2.3.1.2.2. The technology advances since the creation of the classification/exemption do not create significant new risks that need to be evaluated.

10.2.4. One specific recent technological advancement that challenges the current regulatory framework is the use of cloud computing or "software services" to perform a discrete software function. Cloud computing challenges the current framework because functions that were once embedded in a single software app are now being "outsourced" to external servers and other platforms to take advantage of computing power and a diversity of resources. When functions (or entire apps) are outsourced to a cloud, it becomes difficult to identify where a fault may have occurred.

10.2.4.1. Using standard software design approaches discussed for software modularization should minimize the inherent risk with cloud-based systems. More specifically, architectural frameworks for client-server systems, the simple object access protocol (SOAP) specification, representational state transfer (REST) designs, and extensible markup language (XML)-based methods may be useful to perform certain functions (e.g., to manage/exchange data, resources, access, or security).

10.2.4.2. Risk assessment should focus on software implementation approaches and design controls rather than the platform on which the software performs its functions.

[6] Recall that, although a smartphone might not be regulated, the regulated smartphone app manufacturer would be required to validate claims of compatibility with the smartphone and comply with other guidance regarding security in software devices.

10.2.5. Another technological advancement that challenges the current regulatory framework is the use of over-the-air (OTA) software upgrades. OTA upgrades are used to rapidly disseminate product changes.

10.2.5.1. Use of OTA upgrades should not affect the classification of the software app because the basic functionality of OTA upgrades is not substantially different from downloading an upgrade using traditional approaches (e.g., using a CD or DVD disk in a PC or connecting the device to the Internet via a telephone or cable modem).

10.2.5.2. Some OTA product changes may be superficial (e.g., an app icon update), while others may have a significant impact on the functionality of app (e.g., new features or patches for known software bugs). Even where OTA upgrades implement significant changes to the functionality of the app, not all changes involve the same level of risk. For example, an upgrade that affects a software module that does not perform a medical device function (e.g., a billing module) may involve a substantial change, but may not involve any risk to the medical modules within the app. Modularization approaches described above should be used to mitigate any risk to software modules that perform medical functions.

10.2.5.3. A *software manufacturer* must still comply with all applicable regulations, including design controls under the Quality System Regulations.[7]

11. Conclusion

[7] *See* 21 C.F.R. § 820.30.

Appendix A—Current Regulatory Classifications and Product Codes for mHealth Software

Classification Reg. (21 CFR)	Description	Device Class	Product Codes
862.1345	Glucose test system	II	CFR, CFW, CGA, CGD, CGE, LFR, MRV, NBW
862.2050	General purpose laboratory equipment labeled or promoted for a specific medical use	I	JRR, JRS, LCI
862.2100	Calculator/data processing module for clinical use	I	JQP, NVV
864.3600	Microscopes and accessories	I	IBJ, IBK, IBL, IBM, KEG, KEH, KEI, KEJ
868.2377	Apnea monitor	II	NPF
870.1025	Arrhythmia detector and alarm	II	DSI, MHX, MLD, MXD
870.1100	Blood pressure alarm	II	DSJ
870.1110	Blood pressure computer	II	DSK
870.1120	Blood pressure cuff	II	DXQ, NPP, OED
870.1130	Noninvasive blood pressure measurement system	II	DXN
870.1875	Stethoscope	I/II	DQD, LDE, OCR
870.2340	Electrocardiograph	II	DPS, MLC, OEY
870.2390	Phonocardiograph	I	DQC
870.2400	Vectorcardiograph	II	DYC
870.2700	Oximeter	II	DQA, MUD, NLF, NMD, OCH
870.2710	Ear oximeter	II	DPZ
870.2810	Paper chart recorder	I	DSF

Classification Reg. (21 CFR)	Description	Device Class	Product Codes
870.2860	Heart sounds transducer	II	JOO
870.2880	Ultrasonic transducer	II	JOP
870.2910	Radiofrequency physiological signal transmitter and receiver	II	DRG
870.2920	Telephone electrocardiographic transmitter and receiver	II	DXH
876.1300	Ingestible telemetric gastrointestinal capsule imaging system	II	NSI, NEZ, NYZ*
876.1725	Gastrointestinal motility monitoring system	II	FES, FFX, KLA
876.1735	Electrogastrography system	II	MYE
880.2400	Bed-patient monitor	I	KMI
880.2700	Stand-on patient scale	I	FRI
880.2720	Patient scale	I	FRW
880.2910	Clinical electronic thermometer	II	FLL
880.6300	Implantable radiofrequency transponder system for patient identification and health information	II	NRV
880.6310	Medical device data systems	I	OUG
880.6315	Remote medication management system	II	NZH
882.1400	Electroencephalograph	II	GWQ, OLT, OLU, OLV, OLW ,OLX, OLY, OLZ ,OMA, OMB, OMC, ORT
882.1420	Electroencephalograph signal spectrum analyzer	I	GWS
882.1430	Electroencephalograph test signal generator	I	GWR
882.1540	Galvanic skin response measurement device	II	GZO
882.1560	Skin potential measurement device	II	HCJ

Classification Reg. (21 CFR)	Description	Device Class	Product Codes
882.1570	Powered direct-contact temperature measurement device	II	HCS
882.1610	Alpha monitor	II	GXS
882.1835	Physiological signal amplifier	II	GWL
882.1845	Physiological signal conditioner	II	GWK
882.1855	Electroencephalogram telemetry system	II	GYE
882.5050	Biofeedback device	II	HCC
884.2050	Obstetric data analyzer	III	HEO
884.2600	Fetal cardiac monitor	II	KXN
884.2620	Fetal electroencephalographic monitor	III	HGO
884.2640	Fetal phoncardiographic monitor and accessories	II	HFP
884.2660	Fetal ultrasonic monitor and accessories	II	HEI, HEJ, HEK, HEL, HEP, HEQ, KNG, LXE, MAA
884.2730	Home uterine activity monitor	II	LQK, MOH
884.2740	Perinatal monitoring system and accessories	II	HGM
884.2800	Computerized labor monitoring system	II	NPB
890.1375	Diagnostic electromyography	II	IKN, KZM, OAL
890.3075	Cane	I	IPS, KHY
890.3150	Crutch	I	IPR
890.3710	Powered communication system	II	ILQ
890.3725	Powered environmental control system	II	IQA
890.3800	Motorized three-wheeled vehicle	II	INI
890.3825	Mechanical walker	I	ITJ, NXE

Classification Reg. (21 CFR)	Description	Device Class	Product Codes
890.3850	Mechanical wheelchair	I	IOR, LBE
890.3860	Powered wheelchair	II	ITI
890.3880	Special grade wheelchair	II	IQC
890.3890	Stair-climbing wheelchair	III	IMK
890.3900	Standup wheelchair	II	IPL
890.5050	Daily activity assist device	I	IKW, IKX, ILC, ILD, ILS, ILT, ILW, IQG, NXB, NXQ, OAG, OIZ, OJL
890.5350	Exercise component	I	IOD
890.5360	Measuring exercise equipment	II	ISD
890.5380	Powered exercise equipment	I	BXB, IOL, IRR
890.5575	Powered external limb overload warning device	II	IRN
892.1180	Bone sonometer	II	MUA
892.1540	Nonfetal ultrasonic monitor	II	JAF
892.1550	Ultrasonic pulsed Doppler imaging system	II	IYN
892.1560	Ultrasonic pulsed echo imaging system	II	IYO, NQQ, OIJ
892.1720	Mobile x-ray system	II	IZL
892.2010	Medical image storage device	I	LMB, NFF
892.2020	Medical image communications device	I	LMD, NFG
892.2030	Medical image digitizer	II	LMA, NFH
892.2040	Medical image hardcopy device	II	LMC, NFI
892.2050	Picture archiving and communications system	II	LLZ, NFJ, NEW, OEB, OMJ

Appendix B—Proposed Regulatory Classifications for mHealth Software

Description	Definition	Classification
General purpose health applications labeled or promoted for a specific medical use	General purpose health applications labeled or promoted for a specific medical use are software devices used in an mHealth system to electronically collect, store, transmit, display, and analyze (e.g., trending) health-related data and that are labeled or promoted for a specific medical use. An example is a software device stored on a smartphone that electronically trends daily exercise and weight information from a variety of sensors and displays the data for use in the treatment of non-morbid obesity.	Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 8xx.9. The device also is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of 820.180, with respect to general requirements concerning records, and 820.198, with respect to complaint files.
Physical therapy health application	A physical therapy health application is a software device used to electronically collect, store, transmit, display, and analyze (e.g., trending) data for physical therapy purposes. An example is a software device that collects and displays trends of data from an exercise monitoring system to evaluate improvements in muscle or joint function.	Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 8xx.9.
Sleep monitoring health application	A sleep monitoring health application is a software device used to electronically collect, store, transmit, display, and analyze (e.g., trending) data for monitoring a sleep-related medical disease or condition. An example is a software device that collects and displays trends of data from an on-body respiratory sensor, ECG monitor, and limb activity sensor for the detection of insomnia.	Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 8xx.9.

Description	Definition	Classification
Stress management health application	A stress management health application is a software device used to electronically collect, store, transmit, display, and analyze (e.g., trending) data to diagnose or treat a stress-related medical disease or condition. An example is a software device that collects and trends blood pressure, ECG, and physical activity data to diagnose or treat a stress-related disease or condition (e.g., depression).	Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 8xx.9.
Weight management health application	A weight management health application is a software device used to electronically collect, store, transmit, display, and analyze (e.g., trending) data to diagnose or treat a weight-related medical disease or condition. An example is a software device that analyzes daily weight and physical activity data to monitor pregnancy-related medical diseases or conditions.	Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 8xx.9.
Diabetes health application	A diabetes health application is a software device used to electronically collect, store, transmit, display, and analyze (e.g., trending) data generated from one or more devices used in diabetes management (e.g., a blood glucose meter, weight scale, and blood pressure cuff). This does not include data collected for real-time or active patient monitoring.	Class II (special controls).
Cardiac disease health application	A cardiac disease health application is a software device used to electronically collect, store, transmit, display, and analyze (e.g., trending) data generated from one or more devices used in cardiac disease management (e.g., ECG monitor, weight scale, and blood pressure cuff). This does not include data collected from an implantable cardiac device or for real-time or active patient monitoring.	Class II (special controls).

Description	Definition	Classification
Therapy compliance health application	A therapy compliance health application is a software device used to electronically collect, store, transmit, display, and analyze (e.g., trending) data generated from one or more devices used in therapy compliance (e.g., RF-enabled pill, electronic medication dispensers, electronic pill bottles). This does not include data collected for real-time or active patient monitoring.	Class II (special controls).
Health application for monitoring activity associated with a specific medical disease or condition	A health application for activity monitoring associated with a specific medical disease or condition is a software device used to electronically collect, store, transmit, display, and analyze (e.g., trending) data generated from one or more devices used in the monitoring of an individual's activity associated with a specific medical disease or condition. An example is a software device that analyzes data from home-based sensors that detect falls, physical movement, food consumption, and toileting for physical therapy purposes.	Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 8xx.9.
Device controllers (for Class I exempt devices)	A device controller (for Class I exempt devices) is a hardware or software device used to electronically control the functionality of a Class I device exempt from premarket notification requirements that is part of an mHealth system. An example of a device controller is a software device that electronically triggers a sensor device in an mHealth system to perform a task (e.g., to collect health-related information, or to notify the user to respond to predetermined, health-related questions).	Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 8xx.9.

Description	Definition	Classification
Device controllers (for Class II or III devices)	A device controller (for Class II or III devices) is a hardware or software device used to electronically control the functionality of a Class II or III device that is part of an mHealth system. An example of a device controller is a software device that electronically triggers a sensor device in an mHealth system to perform a task (e.g., to collect health-related information, or to notify the user to respond to predetermined, health-related questions).	a) Class II (special controls) if associated with a Class II device. b) Class III (premarket approval) if associated with a Class III device.
General data aggregator and report generator	A general data aggregator and report generator is a hardware or software device intended to produce an electronic report of health-related and/or medical device data generated from one or more sources connected via an mHealth system. An example of a data aggregator and report generator is a software device that electronically generates a report of data collected from a weight scale, blood pressure cuff, and a proprietary device that manually prompts the user to respond to pre-determined, health-related questions.	a) Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 8xx.9. b) Class II (special controls) if the device analyzes the data for any purpose other than reporting the data in an aggregated form.
Diabetes data aggregator and report generator	A diabetes data aggregator and report generator is a hardware or software device intended to produce an electronic report of data generated from one or more devices used in diabetes management (e.g., a blood glucose meter, weight scale, and blood pressure cuff). This does not include data collected for real-time or active patient monitoring.	a) Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 8xx.9. b) Class II (special controls) if the device analyzes the data for any purpose other than reporting the data in an aggregated form.

Description	Definition	Classification
Cardiac disease data aggregator and report generator	A cardiac disease data aggregator and report generator is a hardware or software device intended to produce an electronic report of data generated from one or more devices used in cardiac disease management (e.g., ECG monitor, weight scale, and blood pressure cuff). This does not include data collected from an implantable cardiac device or for real-time or active patient monitoring.	a) Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 8xx.9. b) Class II (special controls) if the device analyzes the data for any purpose other than reporting the data in an aggregated form.
Therapy compliance data aggregator and report generator	A therapy compliance data aggregator and report generator is a hardware or software device intended to produce an electronic report of data generated from one or more devices used in therapy compliance (e.g., RF-enabled pill, electronic medication dispensers, electronic pill bottles). This does not include data collected for real-time or active patient monitoring.	a) Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 8xx.9. b) Class II (special controls) if the device analyzes the data for any purpose other than reporting the data in an aggregated form.
A data aggregator and report generator for activity monitoring associated with a specific medical disease or condition	A data aggregator and report generator for activity monitoring associated with a specific medical disease or condition is a hardware or software device intended to produce an electronic report of data generated one or more devices used in the monitoring of an individual's activity associated with a specific medical disease or condition. An example is a software device that aggregates data from home-based sensors that detect falls, physical movement, food consumption, and toileting for physical therapy purposes.	Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 8xx.9.