Basics of FDA Medical Device Regulation
And How They Interface with FDA’s Final Guidance on
Mobile Medical Applications

Definition of a Device

Under the Federal Food Drug and Cosmetic Act (the Act), as amended by the Medical Device Amendments of 1976 (the ’76 Amendments) and subsequent legislation, FDA has extensive authority to regulate medical devices. Under Section 201(h) of the Act, a medical device is defined as follows:

(b) The term “device” (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

1. recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
3. intended to affect the structure or any function of the body of man or other animals, and
which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

In reviewing the “device” definition, it is important to keep in mind, especially in today’s digital health world, that a device is not just a physical product, but also can include not only software components, but, in some cases, a product that is solely software-based, itself can be a medical device.

Device Classifications

Once it is determined that a particular product meets the definition of a medical device, the next question we must examine is whether FDA has already classified the device as required under the ’76 Amendments. Under those amendments, FDA was ordered by Congress to review every medical device then on the market and classify the device from a risk perspective into one of three classes, designated by the roman numerals I, II or III.

Class I Devices

Class I devices are those that pose the least amount of risk and typically can be introduced into commerce without any prior FDA clearance as long as the company otherwise complies with all of what are known as the “General Controls” applicable to medical devices under the Act and applicable regulations. The General Controls include such requirements as:

♦ registering the establishment at which the device is made and listing the device (a notice process not requiring FDA approval) with FDA;

1 FDA will base a person’s intent relative to the purpose for which a product is sold from many circumstances. Among the key sources of the “intended use” of a product its labeling and advertising. Labeling includes not only printed materials that accompany a device, but also, under FDA’s view (which has been successfully challenged on at least one very recent occasion) websites and social media sites sponsored by the person marketing the product.
abiding by applicable provisions of FDA’s Quality Systems Regulation (QSR) regulations that implement the Good Manufacturing Practice (GMP) requirements for medical devices;

♦ implementing a Medical Device Reporting (MDR) system to keep FDA informed of potential defects and other problems associated with the use of the device;

♦ compliance with device labeling requirements; and

♦ other general provisions that apply to all medical devices regardless of their class.

Examples of Class I devices include such basic things as band aids, tongue depressors, and most stethoscopes. Clipped below is an example of what a Class I device classification regulation looks like:

**Sec. 880.6230 Tongue depressor.**

(a) **Identification.** A tongue depressor is a device intended to displace the tongue to facilitate examination of the surrounding organs and tissues.

(b) **Classification.** 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 880.9. If the device is not labeled or otherwise represented as sterile, it is also 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. [45 FR 69682-69737, Oct. 21, 1980, as amended at 66 FR 38806, July 25, 2001]

As one can see -- and this approach applies to all levels of classification, whether it Class I, II, or III -- in the regulation formally classifying a particular type of device, FDA first identifies the device and its intended use(s) and then states how it is classified. In some cases, particularly Class I devices, the Agency may exempt the device from certain requirements under the QSR regulations that are not viewed as needed to properly regulate the device in question and/or exempt the device from the need for a Premarket Notification Submission, which is commonly known as a “510(k)” after the statutory provision from which the notification duty is derived.

**Class II Devices**

Class II devices are subject to more comprehensive regulation by FDA and include devices for which general controls are not adequate to regulate their risk, but for which affirmative safety and effectiveness data are not required typically as would be expected for a Class III device, which requires free market approval. The vast majority of Class II devices, however, must be subject to a cleared2 510(k) prior to the product being marketed.

If a device is classified as a Class II device, in order to secure clearance of a 510(k), the person seeking to market the device must show that its device is “substantially equivalent” to a device that is already legally marketed under a 510(k). To be substantially equivalent, a device must have the same intended use as its “predicate” device (that is, the device to which it is trying to show substantial equivalence) and usually must have the same technological characteristics as the predicate device. Some deviations from technological characteristics are allowed if the 510(k) applicant can demonstrate that those differences do not affect the safety or effectiveness of the device. In many cases, where technological differences

---

2 A 510(k) is technically not “approved” by FDA. Rather, they are said to be “cleared” at such time as FDA formally, by letter, informs the 510(k) submitter that the device subject to the 510(k) can be legally marketed in the United States.
are present between the 510(k) device and its predicate, FDA will expect the applicant to conduct clinical studies to demonstrate that the device still performs in the same manner as would be expected of the predicate device.

**Class III Devices**

The final classification level is the Class III device, which requires prior FDA approval of a Premarket Approval Application (PMA) before the device may be introduced into commerce in the United States. In order to secure approval of PMA, the PMA applicant must submit substantial evidence of safety and effectiveness in the form of clinical investigations to substantiate the PMA approval. Thus, the standard for marketing of a PMA device under Class III focuses on safety and effectiveness as opposed to most Class II devices, where the standard for market clearance is substantial equivalence to a predicate device.

**How to Analyze the Legal/Regulatory Status of Medical Device**

FDA has classified literally hundreds of different types of devices since the enactment of the 76 Amendments. These classification regulations appear in 21 CFR parts 862 through part 894. To determine the legal/regulatory status of a particular medical, we must see if its intended uses and technological characteristics match any type of device that FDA has previously classified by regulation. If a match can be found, we then would be able to determine how FDA regulates that device; for example, whether a 510(k) would be required or whether the device was exempt from 510(k) and could be marketed subject to the general controls of the Act and applicable regulations.

When a match is found, the key next step to assess what data and other information will be needed by the person proposing to market the device in order to support its marketing consistent with FDA requirements, especially what may be needed to be submitted to FDA if the applicable device classification requires that a 510(k) or PMA be filed and cleared/approved by FDA.

Sometimes, the information needed to support marketing can be fairly clear, especially if FDA has issued a guidance document that applies to the specific device in question. If that has occurred, the applicable guidance document often is cited in the specific device classification regulation that governs that device.

On other occasions, and often more frequently than we would like, the data and other information needed to support marketing of a device under a 510(k) or PMA will not be clear. In that circumstance, most companies will elect to seek a “pre-submission” meeting with FDA to clarify what data will be needed to be able to go forward with a marketing submission.

**What if There is No Device Classification that Matches The Device Sought to be Marketed?**

Occasionally, a person will seek to market a medical device that does not match any medical device that has been previously classified either due to the nature of the technology or the intended uses to which the person seeks to market the device. If that occurs, by operation of law under the ’76 Amendments, as amended, specifically Section 513(f) of the Act, the device is automatically classified into Class III and would require approval of a PMA before the product can be marketed. This applies even if the device in question is very safe or treats a fairly innocuous condition.
While a mechanism does exist to request that FDA change the classification of such a device so that it no longer requires premarket approval and might be marketed under a 510(k), that mechanism – which is known as the “de novo” process -- has not commonly been used by FDA. In addition, in recent years, FDA has required that a person seeking a de novo reclassification include data in such detail as to the risk of the device that some critics have regarded the de novo process as a “mini-PMA.” On the other hand, because many modern technologies did not exist in 1976, the use of the de novo process will likely expand as medical device makers increasingly create products using technology that did not exist at the time the '76 Amendments were enacted. In particular, Mobile Medical Applications, to be discussed in more detail below, may often fall into the realm of automatic Class III status, leading to greater use of the de novo process.

**Review of Impact of FDA’s Final Guidance on Assessing Regulatory Status of a Mobile Medical Application**

Because of the accelerated proliferation of apps used on smart phones and other handheld devices related to either maintaining health or, in many cases, actually treating or diagnosing disease, FDA has been under tremendous pressure to develop a regulatory regime that, while consistent with the requirements of the Act, acknowledges that, in many cases, over-regulation of applications that might be or are medical devices under the law is not warranted by the risk presented by those applications. The agency’s response to this was a draft guidance on what it calls “mobile medical application” (“MMA”) in July 2011, followed by a final guidance that was issued in late September 2013.

Essentially, what FDA has done in the final guidance is identify three categories of mobile medical applications: (1) those that FDA does not regard as medical devices at all and thus are outside its legal control; (2) those that are or may be medical devices, but that present a low risk to patients and will be the subject of “enforcement discretion;” and (3) those that are medical devices and present enough of a risk that FDA will exercise regulatory control over them. I will refer to these hereafter as Categories 1, 2 and 3, respectively, although FDA has not, to my knowledge, adopted that terminology.

The final guidance provides both written descriptions of the types of apps that fall into the three categories as well as specific examples of many of those types of devices. However, for those devices that FDA regards as medical devices subject to its immediate regulation, the guidance does not provide any information on how to satisfy FDA requirements for bringing such a regulated app to the market. To determine what data will be needed, a person seeking to market a MMA will still need to take the measures discussed earlier in this document, which may include meeting with FDA to nail down the expected data requirements depending on the appropriate device classification that applies to the MMA.

A more lengthy description of how the final guidance operates is included in a *Summary of the Final Guidance* that we prepared for our clients that is attached as *Appendix A* to this document and should be reviewed as if fully set forth herein. A copy of the final guidance itself is available on FDA’s website and is not included here due to its length.

---

3 The mechanism is called a de novo petition, but is far from a simple process and has been successfully used less than 100 times in the 16 years since being enacted in 1997.

To shed greater insights on some of the ambiguities raised by the final guidance, our firm issued a client alert discussed FDA’s Final MMA Guidance on October 4, 2013. A copy of that Client Alert is attached as Appendix B to this document.

What emerges clearly from the final guidance is that, if a person seeks to market a mobile medical application, they will need to carefully analyze how the guidance applies to their proposed app. This will involve a careful comparison of both the technological characteristics and the intended uses of the app to the three key categories of app described in the final guidance. The result of the exercise ideally will be to find that the proposed app matches a type of app already described in the final guidance. If the proposed app does match an app described in the final guidance, the person proposing to market the app then will have a clearer view of how or to what extent FDA will regulate their app. At that point, if their app is one that FDA will regulate as a medical device, as discussed above, they then will need to turn to the task of determining what data will be needed – and what type of marketing submission (if any) – to allow them to market their MMA.

To help you visualize the basics of FDA regulation of Mobile Medical Apps, we also have prepared a schematic flow chart that walks the reader through the basics of how FDA approaches mobile medical apps. A copy of that flow chart is attached as Appendix C to this document.

###

**Attachments**:

**Appendix A** – Duane Morris Summary of FDA Final Guidance on Mobile Medical Applications (MMA)  
**Appendix B** – Duane Morris Client Alert on FDA Final MMA Guidance  
**Appendix C** – Flow Chart of Basics of FDA Regulation of Mobile Medical Applications

**Disclaimer**: This document has been prepared and published for informational purposes only and is not offered, nor should be construed, as legal advice.
APPENDIX A

Duane Morris Summary of FDA Final Guidance on Mobile Medical Applications

(issued September 25, 2013)

(actual document follows on next page)
A SUMMARY OF FDA’S SEPTEMBER 2013 FINAL MOBILE MEDICAL APPLICATIONS GUIDANCE

On September 23, 2013, the U.S. Food and Drug Administration (FDA) released its long-awaited final guidance on how the agency plans to regulate mobile medical applications. While certain aspects of the guidance remain very similar to the 2011 draft, particularly the definitions of what is a “mobile application” and when it rises to the level of being a “mobile medical application” subject to overt FDA regulation, the guidance was a major improvement over the 2011 draft in many respects. Most significantly, the agency laid out fairly clear distinctions among mobile apps that FDA asserted:

- Are not medical devices at all and, thus, fall outside FDA’s regime;
- Are - or may be medical devices, but will be subject to FDA "enforcement discretion;"3
and
- Are medical devices that FDA will regulate.

For each of these three mobile app categories, FDA not only described specific types of functions that would place an app into one of the three categories, but also provided industry with numerous examples of specific devices that fit into each category, both in the narrative of the guidance and in several appendices. While guidance documents are not legally binding on FDA, they do represent the agency’s best advice on how to comply with the law relative to the subject covered by the guidance. Thus, for industry, the guidance provides much greater certainty on whether products are subject to FDA’s regulatory regime or can come to the market without overt interaction with the agency.

Key Definitions

Mobile platform: "commercial off-the-shelf computing platforms, with or without wireless connectivity, that are handheld in nature." This includes smartphones and tablets, such as the iPhone and iPad.5

Mobile application: “a software application that can be executed on a mobile platform ... or a web-based software application that is tailored to a mobile platform but is executed on a server.” The latter part of the mobile app definition clarifies that the application does not have to be resident on the mobile platform to be subject to the guidance. The guidance thus covers apps solely in a web-browser running on a mobile platform.

Mobile medical application: a mobile application that meets the definition of a “device" under Section 201(h) of the Federal Food, Drug, and Cosmetic Act ("the Act") and is intended to either (a) be used as
an accessory to a regulated medical device or (b) transform a mobile platform into a regulated medical device.

**Key Principles on How FDA Will Regulate Mobile Apps**

Two fundamental principles are underlying how FDA will regulate mobile apps emerge from the guidance.

First, FDA's oversight of mobile medical applications will focus on how the app functions, not the particular platform upon which it runs.

Second, FDA will aim its regulatory powers at those mobile medical apps that present a potential risk of safety to patients when the app functions incorrectly. In contrast, FDA will exercise enforcement discretion on mobile apps that, despite being legally medical devices, have a lower-risk profile in the event of a malfunction. However, where “lower risk” leaves off and a “risk of safety” begins is not clearly defined in the guidance.

The guidance also clarifies that FDA will not regulate the use or sale of smartphones or tablets simply because they provide a platform on which a mobile medical app could run, squelching a major concern by many in the app world.

**Mobile Apps FDA Will Regulate**

The guidance articulates three categories of mobile medical applications that FDA will be regulating:

1. Apps that function as an extension of an existing medical device by connecting to it - either via wired or wireless links - to control the device, or display, store, analyze or transmit patient-specific data.

   **Example:** a device with the ability to control a blood pressure cuff.

2. Apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to currently regulated medical devices.²

   **Example:** attaching electrocardiograph (ECG) electrodes to a mobile platform to measure, store and display ECG signals.
3. Apps that use patient-specific information for analysis to provide patient specific diagnosis, or treatment recommendations.

**Example:** apps that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy.

In addition to describing the characteristics that distinguish the three types of regulated mobile apps, FDA, in Appendix C to the guidance (pp. 26-29), provided a detailed list—broken down by the three types above—of mobile apps that the agency will regulate.

**Mobile Apps Receiving Enforcement Discretion**

For mobile apps that are—or may be—medical devices, but do not fit within the three types of regulated apps detailed above, FDA will exercise enforcement discretion. As mentioned, while the extent of enforcement discretion is not revealed in the guidance, FDA states that these types of apps include those that are a “lower risk” of harm to patients in the event of a malfunction. Among the apps qualifying for enforcement discretion are those:

1. Apps that help patients self-manage diseases without providing specific treatment suggestions.

   **Example:** apps that coach patients with conditions such as diabetes with simple prompts to promote strategies for actions that will help their health situation such as maintaining healthy weight, getting optimal nutrition, etc.

2. Apps that help organize and track health information, but do not recommend any change in existing treatments.

   **Example:** apps that provide simple tools for patients with specific conditions or chronic disease to log, track, or trend their events or measurements (e.g., blood pressure, drug intake, diet) and share this information with their healthcare provider (HCP) as part of a disease management plan.

3. Apps that provide easy access to information regarding the patient’s health condition or treatment by matching patient-specific information (e.g., diagnosis, treatments, allergies, signs or symptoms) to reference information normally used in clinical practice.
Example: apps that use a patient’s diagnosis to provide an HCP with best practice treatment guidelines for common illnesses.

4. Apps that help patients document and communicate potential medical conditions to providers that are not promoted for medical uses, but, due to other circumstances surrounding their distribution, may meet the medical device definition.

Example: apps that serve as videoconferencing portals specifically intended for medical use and to enhance communications between patients and HCPs.

5. Apps that automate simple tasks for providers such as to perform basic calculations in clinical practice.

Example: a medical calculator for body mass index (BMI).

6. Apps that enable patients/providers to interact with personal health record (PHR) or electronic health records (EHR) and their systems.

Example: an app that allows a patient a portal into their own health information.

Additional examples of mobile apps that are or may be devices, yet will receive enforcement discretion, are listed in Appendix B to the guidance. Of particular note for many of today’s popular apps—and related devices—such as the FitBit® and Nike+®, FDA clarified in Footnote 32, in Appendix B, that those apps used for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions relating to developing or maintaining general fitness, health or wellness—such as apps that log dietary intake, track normal sleep patterns, or calculate calories burned during exercise—are not medical devices unless they are marketed in a manner that meets the definition of a medical device.

**Regulation of Mobile Medical App Manufacturers**

A key feature of the guidance was the agency's description of those entities involved in the app business that would be regarded as a “manufacturer” under FDA's medical device regulatory regime, which is a designation that carries greater regulatory burdens than terms such as distributor or importer. While the guidance provides several examples discussed below—of when a mobile app player may, or may not, be regarded as a manufacturer—those involved in app development should read both the guidance and applicable FDA regulations with care to determine whether they meet the definition of a manufacturer relative to their role in bringing a mobile medical app to the market.
Who Is a Manufacturer?

In construing whether a particular player in the app community is a manufacturer, FDA primarily focused on the creators of the original app concept or those players that assumed both manufacturing and distributions responsibilities, articulating that persons who do any of the following may be regarded as a manufacturer:

- Creates, design, develops, labels, re-labels, remanufacturers, modifies, or creates a mobile medical app software system from multiple components.
- Initiates specifications or requirements for mobile medical apps or procures product development/manufacturing services from other individuals or entities for subsequent commercial distribution.
- Creates a mobile medical app and hardware attachments for a mobile platform that are intended to be used as a medical device by any combination of the mobile medical app, hardware attachments, and the mobile platform.
- Creates a mobile medical app or a software system that provides users access to the medical device function through a website subscription, software as a service, or other similar means.

Who Is Not a Manufacturer?

The guidance describes these types of actors in the app world as outside the “manufacturer” definition:

- Pure distributors of mobile medical apps, such as the “Google Play” or “iTunes App store.”
- Software developers of a mobile medical app that are responsible only for “performing design and development activities” based on an author’s specifications.
- Persons who develop the app for use in research, testing or analysis, as long as the app is not introduced into commercial distribution.
- Those who provide only “tools, services, or infrastructure used in the development, distribution, or use” of mobile medical devices, such as an Internet service provider (ISP).
- Licensed practitioners who develop a mobile medical app, or alter one, for use in their professional practice. While the practitioner may not label or promote the app for use by other licensed practitioners or individuals, the professional is allowed to share the app’s use within his group practice, including telehealth network. However, this exception ends if the professional labels or promotes the app generally for use by others, including other licensed professionals.
For Regulated Apps, FDA’s Rules Remain Unchanged

For those mobile medical apps that the FDA intends to regulate, the agency will expect the mobile app maker to satisfy all of the statutory or regulatory requirements applicable to the specific device classification governing the app. A brief description of those basic regulatory requirements appears in Appendix E of the guidance.

FAQ Portal: Future Guidance

FDA included, as Appendix E to the guidance, answers to a number of common questions that the agency anticipated would be raised about its regulation of mobile apps. While not in the guidance itself, FDA separately announced in conjunction with issuing the guidance that future updates to the agency’s positions on mobile app regulation will be posted to the FDA website.

Acknowledgement: Our thanks to Garrett Lambur, Legal Extern, and 3rd Year Law Student at Drexel University’s Earle Mack School of Law for his extensive contribution to the preparation of this summary.

Notes

2. The agency, at various points in the guidance, says that apps in this "enforcement discretion" category either definitely are medical devices or that they "may be" devices. Hence the qualification here.
3. One possible deficiency of the guidance is that FDA did not elaborate the parameters of what constituted enforcement discretion for this category of mobile apps. This ambiguity is discussed in more detail in the Duane Morris Alert to which this summary is incorporated by reference.
5. The guidance does not define “handheld.” Logically, a handheld device is one that is fully operational while held in a person’s hands. Thus, while not overtly excluded from the definition of a mobile platform, laptops or other devices that cannot be effectively used solely while held could be asserted to be outside the ambit of the guidance. However, as the guidance states that it focuses on the functionality, not the platform, of the apps, FDA has established an analytical
regime in the guidance that arguably should be equally applicable to non-handheld platforms.

6. Section 201(h) defines “device” as follows:

(h) The term “device” (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:
   1. recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them;
   2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or
   3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

7. These apps are required to comply with the device classification associated with the transformed platform.

8. See Guidance at 16.


10. The term "manufacturer" is defined in at least four different FDA regulations - 21 CFR Parts 803, 806, 807, and 820 - in virtually identical ways. For example, 21 CFR 820.3(o), which is part of FDA’s Quality System Regulation (QSR), defines the term as follows:

(o) Manufacturer means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

11. One example of the different way that FDA regulations treat manufacturers versus other categories of those involved in the medical device realm is seen under the Medical Device Reporting (MDR) regulations in 21 CFR Part 803. Under the MDR rules, a manufacturer has detailed duties to report to FDA incidents involving both malfunctions and serious adverse events associated with their devices. In contrast, a distributor has no duties under the MDR rules.
APPENDIX B

Duane Morris Client Alert on FDA Final Guidance on Mobile Medical Applications (issued September 25, 2013)

(actual document follows on next page)
Mobile health ("mHealth") application ("app") developers, manufacturers, investors, healthcare providers and others received welcome news late last month when the U.S. Food and Drug Administration ("FDA") published its long-awaited final guidance on mobile medical applications ("MMA") under the Federal Food, Drug, and Cosmetic Act (the "Act"). It is vital for any app developer to understand whether the guidance applies to their product from the initial design stage. Those who are already marketing software and apps that involve healthcare should also review the guidance with care to try to determine how FDA’s new regime impacts both business plans and continuing operations.

The 43-page final guidance is written and organized in a direct and helpful manner. It answers many questions industry had about FDA’s intentions in the mHealth arena, including alleviating a key concern that the agency might regulate the actual mobile platforms upon which apps operate. To assist in understanding the key features of the guidance, we have prepared a summary of the guidance. While the guidance clarifies FDA’s views on many of the issues impacting the mobile medical app world, unanswered questions remain that warrant consideration to ensure the success of an mHealth product. We will address some of those questions in this Alert.

**The Guidance Says the App Is a Device Subject to FDA Regulation, What Can Be Done Now to Legally Get the App on the Market?**

The final mobile medical application guidance clarified many key issues on how FDA will regulate mobile apps that are medical devices and those that develop, make or market them. However, app makers should understand that the guidance does not provide any advice on the specific information and data that an app maker will need to develop and, in many cases, submit to FDA either in a
premarket notification submission ["510(k)""] or premarket approval application ("PMA") to be able to sell their app.

**Defining an App or What Device Regulation Classification Applies?**

What can be done if it is not apparent what regulation an app falls under ... or if there is even a regulation that covers it? As an initial step, the guidance provides, in Appendix C, details on possible regulations and/or product codes that would govern various types of apps that FDA says are subject to regulation that an app maker should review.

However, if Appendix C does not provide an example of an existing device to which an app matches, both as to technological characteristics and intended use, the guidance provides in Question #1 of the Frequently Asked Questions (FAQ) several mechanisms for gaining clarity from FDA in that circumstance, including, in particular, the "513(g) Request" process. Under that approach, which is provided by the Act, a person can request formal written feedback from FDA on the device classification (if any) that might apply to an app and related regulatory requirements. FDA then has 60 days to reply to the 513(g) request, which also is subject to a user fee. ²

For many apps, a potentially likely result of the 513(g) process may be that FDA concludes the app is a medical device, but also finds that the technological characteristics of the device and/or its intended use are such that no existing FDA regulation classifying the device exists. In that scenario, by operation of Section 513(f) of the Act, such a mobile medical app is automatically classified into Class III, and to be lawfully marketed, the app maker will need to file and secure approval by FDA of a PMA.

App makers facing this issue have a mechanism they can pursue to reclassify their app from its automatic Class III status to Class II or even Class I. Known as the "de novo petition" process, and while not without challenges, FDA has used it on numerous occasions over the past 15 years to move lower-risk devices out of Class III into Class II. In a similar situation, FDA initiated the reclassification of the Medical Device Data System ("MDDS") device from Class III all the way to Class I in February 2011. ³ If an app maker needs to pursue the de novo process, a key challenge it will face is demonstrating to FDA that its device is of a nature—especially the risks that it presents—that it can be adequately regulated by special controls (Class II) or general controls (Class I). ⁴

**What Data Would Satisfy FDA?**

Even if an app maker can determine with confidence what device classification regulation covers its app, it still will face a significant challenge in determining what data it will need to submit to support
a marketing filing. While FDA has cleared or approved about 100 apps over the past 10 years, information on what those applicants had to do to secure FDA market clearance/approval is not easily ascertainable. For those apps cleared under the 510(k) process, the publicly available “510(k) summaries” describing possible predicate devices typically provide little information of practical use for developing a comprehensive data package to support clearance of a later 510(k). Device-specific guidances, which often provide the foundation for data development to support submissions for more conventional devices, are virtually nonexistent for apps that are medical devices.

Facing that situation, an app developer will likely need to seek input from FDA. While the agency is open to advising applicants, the formal process for securing feedback on product development plans—the “pre-submission” meeting—can be slow and does not preclude FDA from later changing its mind on data requirements. However, submitting a 510(k) to FDA without vetting one’s data plan via the agency runs the risk of having too little, too much or simply the wrong data to support the submission.

What Is a Minor, Iterative Change to a Regulated App?

Nestled into FDA’s webpage discussion of the final guidance was this statement that we could not find in the guidance:

FDA’s mobile medical apps policy does not require mobile medical app developers to seek Agency re-evaluation for minor, iterative product changes. [Emphasis in the original]

While the mobile app industry likely welcomes this statement, what does it mean? App makers that are subject to cleared 510(k)s or PMAs for regulated apps should not regard this as a free pass to disregard regulatory requirements governing how they currently handle changes to their devices.

Is “Enforcement Discretion” a “Get-Out-of-Jail-Free Card” for Every Device Regulatory Duty FDA Law Creates?

In the guidance, FDA states that six types of mobile apps are (or “may be”) medical devices that will be subject to “enforcement discretion.” However, the guidance does not define or provide any parameters to this key phrase. It broadly states, in Footnote 18, on page 12 of the guidance that:

This indicates that for certain mobile medical app devices, such as those in Appendix B, the FDA intends not to pursue enforcement action for violations of the FD&C Act and applicable regulations by a manufacturer of a mobile app that meets the definition of a device in section 201(h) of the FD&C Act as specified in this guidance....
Taken literally, Footnote 18 implies that a manufacturer of a mobile medical app that is a device subject to enforcement discretion does not have to comply with any part of the FD&C Act or any regulation promulgated under it. Is that what FDA meant? In other instances involving enforcement discretion (e.g., in the food arena), the agency has been more specific about what duties were subject to enforcement discretion.

What does enforcement discretion augur for those companies that pursued a 510(k) for an app that may now be subject to enforcement discretion? Can they now ignore any duty to update their 510(k) in the event they want to change their device? Or should they withdraw the 510(k) to avoid the need to update? If they keep their 510(k), can they now expect FDA to impose the same 510(k) duties on their competitors as they had to go through? What incentives do the competitors have now to submit a 510(k)?

*What Is the Level of Risk That Will Cause a Mobile Medical App That Is a Medical Device to Fall into the “Regulated” Category If It Does Not Fall into Any of the Three Subtypes of Regulated Apps?*

The guidance clarifies that it does not address every type of app that is or might be a medical device. In that situation, an app maker may find itself with an app that does not neatly fall into any of the subsets of devices that either are regulated under the guidance or are subject to enforcement discretion.

In an ensuing dialogue with FDA over whether an app should be regulated or subject to enforcement discretion, the key issue based on the guidance is the level of risk presented by the app should it fail to function properly. However, the degree of risk that caused FDA to place some devices into the regulated category and others into enforcement discretion is not articulated with clarity in the guidance. The agency says, at page 4 of the guidance, that it intends to regulate only those apps that are medical devices whose functionality “could pose a risk to a patient’s safety” if the app failed. In contrast, when articulating its approach to apps that are medical devices, but will be subject to enforcement discretion, the agency says at page 16 of the guidance that this category covers apps that “pose a low risk to patients.”

Left unaddressed in the guidance is when the risk linked to a mobile medical app’s potential failure moves from low risk (i.e., enforcement discretion) to a risk to the patient’s safety (i.e., regulated). To advance a position on this issue, an app maker will likely need to conduct a robust risk analysis to support a 513(g) request (see discussion above) seeking FDA’s agreement that enforcement discretion is warranted.
A Key Subject Dodged - Clinical Decision Support Software

The agency avoided at least one question in the guidance. Specifically, the agency stated that the guidance did not address so-called “clinical decision support (CDS) software,” an undefined subset of apps. At page 12 of the guidance, the agency stated:

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

Given that several types of apps covered in the guidance contain descriptions resembling the CDS description in the quote above, further clarification awaits on where the line exists between those covered by the guidance and those excised from its ambit under the above statement. As CDS software is key to the growth of mHealth by providing the physician or other caregiver with the tools to make diagnosis and treatment decisions, app makers should continue to follow FDA developments in the CDS arena. FDA previously has said it will issue guidance on how it plans to regulate CDS software.

Do Not Overlook the FTC

Mobile app makers, who understandably have focused on FDA’s role as the gatekeeper to the marketplace, should keep in mind that the Federal Trade Commission (“FTC”) has the power to regulate their apps due to the FTC’s jurisdiction over the advertising of a large segment of medical devices sold in the United States.9

The FTC’s position on the amount and nature of the data needed to support an advertising claim for an app may even exceed the parallel requirements of the FDA to secure marketing. For example, in 2011, the FTC took regulatory action against two apps that claimed to treat acne. In that proceeding, the FTC took the position that the advertising claims needed to be supported by two adequate and well-controlled clinical investigations to meet its substantiation standard.10

The Future - “Kind” Enforcement (at Least for Now)?

Early indications are that at least in the short term, while greater clarity exists due to the guidance, FDA will prefer to educate and work with app makers that now find themselves in the regulated category rather than taking enforcement action. How long any such enforcement grace period will continue is unknown at this time. App developers, manufacturers, investors and others are likely to continue to press for greater clarification from the FDA.
For Further Information

If you have any questions about this Alert, please contact Michael A. Swit, Lisa W. Clark, any member of the mHealth, Telemedicine and Health Information Technology Practice Group, any member of the Pharmaceutical, Medical Device, Pharmacy & Food group or the attorney in the firm with whom you are regularly in contact.

Notes

1. The full text of the guidance is available at:
2. For more information on the 513(g) process, see Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act, (April 6, 2012) at:
4. In October 2011, FDA issued a draft guidance on the de novo process that was designed to replace a 1998 guidance on de novo. In July 2012, Congress revised the de novo portion of the Act to eliminate a requirement that had existed that before a party could pursue the de novo process it had to first file a 510(k) and have it denied as non-substantially equivalent (“NSE”). This statutory change streamlined the process, but also rendered parts of the 2011 draft guidance inapplicable. Thus, any app maker considering the de novo route should consider discussing the strategy with FDA before doing so. The October 2011 draft guidance is available at: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM273903.pdf.
5. For more information on the pre-submission meeting process, see the July 2012 draft guidance FDA issued at:
7. Savvy FDA followers know that the Act is a statute that carries the potential for criminal prosecution of any violation of the law or its implementing regulations. Corporate officials can be criminally prosecuted under the Act even if they did not intend to violate the law or
even know of the actions that constituted a violation if they held a position of responsibility in a corporation where they either could have prevented the violations from occurring or corrected them upon discovery. Known in FDA circles as the “Park Doctrine” after a key 1975 U.S. Supreme Court case, the concept also is referred to as the “Responsible Corporate Official” or “RCO” doctrine. For a more extensive discussion of the RCO Doctrine, see our Duane Morris Alert from August 8, 2012, entitled “D.C. Circuit Affirms HHS Power to Disqualify Corporate Officials Convicted of Misdemeanors Under the ‘Responsible Corporate Official’ (RCO) Doctrine.”

8. While it is a tactic that should be pursued only after careful deliberation, there is at least one collateral reason that app makers that have already secured 510(k)s for apps that are now subject to enforcement discretion might want to consider asking FDA to withdraw the 510(k) clearance for that app. Specifically, under the Sunshine Act and its implementing regulations, medical device companies that do not hold cleared 510(k)s or approved Premarket Approval Applications (PMAs) are not required to report payments to physicians or teaching hospitals [see definition of “Covered Device” in 42 CFR 403.902, as promulgated at 78 Fed. Reg. 9458, 9521 (February 8, 2013)].

9. Under the Federal Food, Drug, and Cosmetic Act, FDA has jurisdiction over the labels and labeling of all medical devices, but only over the advertising of “restricted devices” (primarily devices subject to PMAs). As many apps, even those that are subject to use only under a prescription, are not legally restricted devices, their marketers will need to satisfy FTC requirements over advertising, the most salient of which is for advertising claims to be substantiated by competent and reliable scientific evidence.


Disclaimer: This Alert has been prepared and published for informational purposes only and is not offered, nor should be construed, as legal advice. For more information, please see the firm’s full disclaimer.
APPENDIX C

Flow Chart:

Basics of
FDA Regulation of Mobile Medical Applications

(actual document follows on next page)
Basics of Medical Device Regulation and Mobile Medical Apps

Is it a medical device under Section 201(h) of FFDCA?

- **YES**
  - Subject to FDA Regulatory Oversight
  - Follow that Regulation
    - Exempt
    - 510 (k)
    - PMA

- **NO**
  - Enforcement Discretion
    - Go forth and sell!!
    - But, don’t forget the FTC

How does the FDA MMA Guidance Categorize Your App?

- Has FDA classified, by regulation, a device that matches your app?
  - **YES**
    - Automatically in Class III
  - **NO**
    - Possible solution – "de novo" request

FFDCA = Federal Food, Drug, and Cosmetic Act