Mobile Medical Apps: FDA's Final Guidance Brings Much Needed Clarity, but Some Questions Remain

By Michele L. Buenafe, Morgan Lewis & Bockius LLP, Washington, DC

On September 23, the Food and Drug Administration (FDA or the Agency) issued its long-awaited final guidance document, *Mobile Medical Applications* (the Final Guidance), describing how FDA intends to apply its regulatory authority to these software products. The Final Guidance comes just over two years after the draft version issued in June 2011. Since that time, industry has waited with bated breath for the Agency to provide certainty on its regulatory policy for mobile medical applications or "apps." Although stakeholders generally agreed that FDA should confirm its position on mobile medical apps, there was some disagreement on what that position should be. Many stakeholders supported FDA's efforts to provide a risk-based approach to mobile medical app regulation, and urged the Agency to finalize the 2011 draft guidance. However, others questioned whether FDA should or could regulate mobile medical apps, asserting that FDA's regulatory scheme could not accommodate these types of products and any regulation by FDA would stifle innovation.

By issuing the Final Guidance, FDA confirmed that it views mobile medical apps to be within its regulatory authority, notwithstanding any objections to the contrary. This should come as no surprise, given the expansive definition of a "device" under the Federal Food, Drug, and Cosmetic Act (FFDCA),[1] and FDA's historical approach in interpreting this term broadly. Moreover, FDA has long held the position that both hardware and software products may be regulated as medical devices if such products fell within the FFDCA's definition of a "device." In fact, FDA's first guidance on the regulation of software as a device dates back to 1989.[2]

FDA also would have been hard-pressed to justify stepping away from mobile apps completely, when at least a few of the currently marketed mobile medical apps perform the same or similar functions as traditional, non-app devices.[3] To regulate a device in a more traditional form, but not when the device is comprised of software on a mobile platform, would raise issues of fairness and could have put FDA at odds with its obligation under the Administrative Procedure Act to treat similarly situated cases in a similar manner.[4] In addition, FDA would need to justify departing from its prior precedent—namely, the 100 or so mobile medical apps that have already gone through FDA's premarket review process.[5]

This article provides an overview of the Final Guidance, a discussion of which apps and entities are subject to regulation, changes in policies and ambiguities from the Final Guidance, and examples of how the Final Guidance applies to different types of apps.

Overview of the Final Guidance

The Final Guidance is similar to the 2011 draft guidance, having the same basic organization, theme, and content. Thus, both the draft and final versions address three different categories of apps:

- Apps that FDA intends to regulate as medical devices;
- Apps that may meet the definition of a "device" under the FFDCA, but that FDA will *not* actively regulate through its exercise of enforcement discretion; and
- Apps that are not "devices" under the FFDCA, and are not subject to FDA regulation.

Notwithstanding these similarities, one noticeable difference between the two versions is that the Final Guidance is significantly longer. The added length is due, at least in part, to the additional discussion and examples of the types of apps for which FDA will exercise enforcement discretion. Although the draft guidance had some discussion on apps subject to enforcement discretion, the Final Guidance includes a much longer section on this topic. It also includes many more examples of apps in the enforcement discretion category. In addition, the Final Guidance includes a more expanded discussion on the types of entities that are not subject to FDA regulation, such as mobile platform manufacturers. Thus, one clear theme from the Final Guidance is that FDA intends for its enforcement in this space to be limited, and there are many apps and entities that will not be subject to active FDA regulation.

This guidance also represents a different approach to defining FDA policy. Usually, FDA provides specific rules or factors to consider in determining the threshold of FDA regulation. With this type of approach, a manufacturer can apply the rules or factors to its specific product to determine whether the product is or is not regulated. The Final Guidance takes a different approach by instead listing various types and examples of apps that FDA will or will not regulate. In other words, FDA is providing guidance by example, rather than providing a specific rule to define what is or is not regulated. This suggests that FDA may have had difficulties in deciding exactly where the line should be between regulated and unregulated apps, or in how to define this line. Although the "guidance by example" approach provides certainty for apps that clearly fall within the examples described in the Final Guidance, it is more problematic for apps that do not fit neatly into one of these examples. For those apps, FDA provides very little guidance on how to determine whether the app is regulated. Instead, the Final Guidance advises that the app developer contact the Agency.

Regulated Mobile Medical Apps

The Final Guidance describes FDA's policy for determining which mobile apps will be actively regulated in three different ways: (1) through the use of definitions; (2) by evaluating the risk to patient safety; and (3) by listing examples. Each of these methods is described further below.

Definitions

The first method offered by FDA to determine whether an app is actively regulated is through the definitions set forth in the Final Guidance. The Final Guidance states that FDA will regulate only a subset of mobile apps that meet the definition of a "mobile medical app."[6] The Final Guidance defines this term to include mobile apps that:

- Meet the definition of a "device" under the FFDCA.
- Are intended either (1) to be used as an accessory to a "regulated medical device," or (2) to be used to transform a mobile platform into a "regulated medical device."

This definition, standing alone, is rather complicated, but it becomes even more complicated because it incorporates two other definitions from the Final Guidance. The first is the definition for a "mobile app," which is defined as a software application that is either executed on a mobile platform, or is web-based and tailored to a mobile platform, but executed on a server. The second definition is for a "regulated medical device," which basically includes any device that has been classified by FDA or cleared or approved by FDA through the 510(k) premarket notification or premarket approval process. The Final Guidance includes a slight tweak to this definition by noting that a "regulated medical device" can include a novel device, even if it has not yet been cleared, approved, or classified.

Even with the understanding of these additional definitions, the intended scope of the term "mobile medical app" seems unclear. Moreover, the definition is somewhat duplicative because the definition of a "device" under the Act includes both device accessories and regulated medical devices. Thus, this first test is not very useful in determining which apps will be actively regulated by FDA.

Risk to Patient Safety

For the second approach, the Final Guidance states that FDA will apply its regulatory oversight only to those mobile apps that are "devices" under the FFDCA and have functionality that could *pose a risk to patient safety* if the mobile app does not function as intended.[7] Conversely, the Final Guidance states that FDA will exercise enforcement discretion for apps that may fall within the definition of a "device," but only *pose a low risk to patients*.[8] Unfortunately, the Final Guidance does not further describe what level of risk to patient safety would trigger active FDA oversight, or what FDA considers to be only a low risk justifying enforcement discretion. Therefore, the second approach also fails to provide a useful test in determining which apps will be actively regulated.

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Examples

The third approach described in the Final Guidance sets forth the true test for determining which apps are subject to FDA regulation. FDA states in Section V.A that it will regulate only the subset of mobile apps identified in Section V.A and Appendix C of the Final Guidance.[9] This third approach is really the key to understanding what FDA considers to be regulated mobile medical apps. As noted earlier, this is really a "guidance by example" approach, because Section V.A and Appendix C each list generic types and specific examples of different apps that FDA considers to be regulated. Thus, if an app falls within the scope of one of these examples, it will be considered a regulated mobile medical app and must comply with the applicable regulatory requirements for medical devices.

Unregulated Apps

As noted above, the Final Guidance describes two categories of apps that are not subject to active FDA regulation. The first includes apps for which FDA will apply enforcement discretion. These are apps that may meet the definition of a "device" under the FFDCA, but present only a low risk to patients.[10] The Final Guidance does not define what is considered to be "low risk," so using this as a baseline would be difficult. However, keeping with the "guidance by example" approach, Section V.B and Appendix B of the Final Guidance list generic types and specific examples of apps subject to enforcement discretion.[11] Any app that falls within the scope of one of these examples qualifies for enforcement discretion.

The other category of apps that are not subject to FDA regulation are those that do not meet the definition of a "device" under the FFDCA.[12] This is obvious, of course, for apps that are not used in the medical space, such as gaming apps or weather apps. However, there are many apps that are intended for use in the medical space, but still do not meet the definition of a device for one reason or another. These include, for example, apps that provide electronic access to medical reference texts and apps that automate general office functions

in a health care setting (e.g., to determine billing codes or schedule medical appointments). FDA lists different types and examples of mobile apps that are not "devices" in Appendix A of the Final Guidance.

Regulated Entities

In addition to discussing which apps are subject to FDA regulation, the Final Guidance also discusses which entities are subject to FDA regulation—in other words, which entities bear the responsibility for ensuring that regulated mobile medical apps are fully compliant with FDA's requirements. FDA's general policy for medical devices imposes the responsibility for device compliance on the device manufacturer. This general policy extends to mobile medical apps. For purposes of determining who is regulated, the Final Guidance defines this to be any person or entity that meets the definition of a "manufacturer" under 21 C.F.R. pts. 803, 806, 807 and 820.[13] This includes not only those entities directly engaged in the creation or manufacture of mobile medical apps, but also specification developers that use contract developers or manufacturers to create apps on their behalf.

The Final Guidance also describes who is *not* subject to FDA regulation, including, for example, entities that only sell or distribute mobile medical apps (e.g., through the iTunes, Google play, or Amazon app stores) and manufacturers and distributors of general purpose mobile platforms (e.g., smartphones and tablet computers).[14] The Final Guidance includes a detailed discussion and examples for various types of non-regulated entities, consistent with FDA's theme for a narrowly targeted regulatory approach in this space.

Changes and Ambiguities

There are a number of interesting issues presented by the guidelines and examples described in the Final Guidance, including some ambiguities and apparent changes from prior FDA policy. Although it is not possible to discuss all of these in this article, a few are highlighted below:

- *Licensed practitioners*—The Final Guidance states that licensed practitioners creating mobile medical apps solely for use in their professional practice are not considered mobile medical app manufacturers and, thus, are not subject to FDA oversight.[15] This exemption applies even when a doctor in a group practice (including a telehealth network) develops a mobile medical app and then permits other physicians in the practice to provide the app to their patients. However, this appears inconsistent with prior FDA statements concerning another type of health IT device—medical device data systems or "MDDS." In the preamble to its final rule down-classifying MDDS devices to Class I, FDA stated that a regulated "manufacturer" includes not only traditional hardware and software developers, but also users, such as hospitals and other providers, that create their own in-house MDDS products or modify another manufacturer's MDDS product, and use such products "for purposes of the user's clinical practice or otherwise for commercial distribution."[16] It is not clear whether the guidance from the MDDS preamble still stands, given the apparent contrary position described in the Final Guidance.

Although the draft guidance had some discussion on apps subject to enforcement discretion, the Final Guidance includes a much longer section on this topic.

- *Nurse Call and Medication Reminders*—In the Final Guidance, FDA lists mobile apps with nurse call and medication reminder functions in the enforcement discretion category.[17] However, FDA has long regulated traditional devices with these functions.[18] In the Final Guidance, FDA suggests in a footnote that it will exercise enforcement discretion for all medication reminder devices, not just mobile apps.[19] However, it is unclear how far FDA's exercise of enforcement discretion will extend for nurse call apps.

- *Clinical Decision Support Software*—FDA has previously stated that it intends to address the regulation of clinical decision support software in a separate document.[20] In addition, the Final Guidance states that it "does not address the approach for software that performs patient-specific analysis to aid or support clinical decision-making."[21] However, the scope of this exclusion remains ambiguous. For example, the list of regulated mobile medical apps in the Final Guidance includes apps that "perform[ ] patient-specific analysis and provid[e] patient-specific diagnosis, or treatment recommendations."[22]

Conclusion and Examples from the Final Guidance

In summary, the Final Guidance will provide clarity and certainty for many app developers, as the guidance is unambiguous for those apps that fall within the listed examples. However, this "guidance by example" approach will be more challenging for developers of apps that fall outside the scope of

these examples. Even when an app is within a listed example, the app developer may still need to consult with FDA to determine what level of regulation applies to its app (Class I, II, or III) and whether a premarket submission, such as a 510(k) notification, is required.

The tables below illustrate how the Final Guidance applies to different types of apps.

Apps for Diabetes

Regulated Apps	Enforcement Discretion	Not a Device
» Apps that use an attachment to the mobile platform to *measure blood glucose levels*[23] » Apps for *diabetes management* per 21 C.F.R. § 862.9(c)(5)[24]	» Apps that coach patients with diabetes and promote strategies for maintaining a healthy weight, getting optimal nutrition, exercising and staying fit, or adhering to pre-determined medication dosing schedules by simple prompting[25] » Apps that provide simple tools for patients with diabetes to log, track, or trend their events or measurements and share this information with their health care providers as part of a disease-management plan[26] » Apps that *provide prediabetes patients with guidance or tools* to help them develop better eating habits or increase physical activity[27]	» Apps that provide patients with *educational and reference information* about diabetes[28]

Apps for Calculations and Analysis

Regulated Apps	Enforcement Discretion	Not a Device
» Apps that perform *patient-specific analysis* and provide patient-specific diagnosis or treatment recommendations[29] » Apps that perform *sophisticated analysis* or interpret data from another medical device[30]	» Apps that perform simple calculations routinely used in clinical practice, such as BMI, mean arterial pressure, APGAR score, NIH stroke scale, delivery date estimator[31] » Apps that provide a *checklist* of common signs and symptoms to provide a list of possible medical conditions and advice on when to consult a healthcare provider[32]	» Apps that are *general purpose calculators*[33] » Apps that provide clinicians with *medical reference* materials[34]

About the Author

Michele Buenafe (mbuenafe@morganlewis.com) is an associate in Morgan Lewis's FDA and Healthcare Practice, based in Washington, DC. Her practice focuses on federal and state regulatory, compliance, and enforcement issues pertaining to medical devices, health information technology, pharmaceuticals, and combination products. Ms. Buenafe regularly advises clients on issues related to the development, manufacture, and marketing of medical devices, pharmaceuticals, human tissue products, and combination products; labeling and advertising; FDA registration and listing; product recalls; and MDR and other post-market reporting requirements. In addition, she helps clients navigate state regulatory requirements applicable to drug and device manufacturers, wholesale distributors, pharmacies, durable medical equipment suppliers, and health care providers. Ms. Buenafe also advises clients on regulatory requirements and emerging legal issues related to medical device data systems, mobile medical apps, clinical decision support software, and other health information technology.

Endnotes

1 21 U.S.C. § 321(h) (defining a "device" to include any "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.").

2 Food & Drug Admin., FDA Policy for the Regulation of Computer Products (1989) (withdrawn in 2005).

3 *See, e.g.,* Letter from James L. Woods, Deputy Dir., Patient Safety and Product Quality, Office of In Vitro Diagnostics and Radiological Health, FDA to Myshkin Ingawale, Biosense Technologies Private Ltd. (discussing a mobile phone app that functions as an automated reader for urinalysis dipsticks), *available at* www.fda.gov/medicaldevices/resourcesforyou/industry/ucm353513.htm.

4 *See, e.g., Bracco Diagnostics, Inc. v. Shalala,* 963 F. Supp. 20 (D.D.C. 1997).

5 *See* Christy L. Foreman, Dir. of the Office of Device Evaluation, Food & Drug Admin., Health Information Technologies: Administration Perspectives on Innovation and Regulation, Testimony before the Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce, U.S. House of Representatives (Mar. 21, 2013), *available at* www.fda.gov/NewsEvents/Testimony/ucm344395.htm.

6 Final Guidance at 12. *See also* Food & Drug Admin., Mobile Medical Applications, *available at* www.fda.gov/medicaldevices/productsandmedicalprocedures/connectedhealth/mobilemedicalapplications/default.htm (last visited Nov. 8, 2013).

7 Final Guidance at 13.

8 *Id.* at 16.

9 *Id.* at 13.

10 *Id.* at 16.

11 *Id.*

12 *Id.* at 20.

13 *Id.* at 9.

14 *Id.* at 10.

15 *Id.* at 11.

16 Medical Devices; Medical Device Data Systems, 76 Fed. Reg. 8637, 8645 (Feb. 15, 2011) (codified at 21 C.F.R. § 880.6310).

17 Final Guidance at 16, 24.

18 *See* 21 C.F.R. §§ 890.3725, 890.5050.

19 Final Guidance at 16, n. 27.

20 *See, e.g.,* Draft Guidance for Industry and Food and Drug Administration Staff; Mobile Medical Applications, 76 Fed. Reg. 43689, 43690 (June 21, 2011).

21 Final Guidance at 12.

22 *Id.* at 15.

23 *Id.* at 15.

24 *Id.* at 17, n. 28.

25 *Id.* at 16.

26 *Id.* at 17.

27 *Id.* at 24.

28 *Id.* at 21.

29 *Id.* at 15

30 *Id.*

31 *Id.* at 17-18,

32 *Id.* at 24.

33 *Id.* at 22.

34 *Id.* at 20.