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FDA RELEASES FINAL MOBILE MEDICAL APPS GUIDANCE

On Monday, FDA released a final version of its guidance document, Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff. The guidance document describes FDA's approach for regulating certain mobile applications ("apps") as medical devices under the Federal Food, Drug, and Cosmetic Act ("FDCA").

Although the final guidance retains the basic framework of the draft guidance released in July of 2011, it features several significant changes.[1] In particular, the final guidance appears to narrow the scope of mobile apps that FDA intends to regulate as medical devices, and it expands the categories of apps that will be subject to enforcement discretion. At the same time, however, the final guidance leaves open several questions regarding how FDA intends to regulate apps that serve as accessories to other devices, as well as apps that do not clearly fall into the enforcement discretion categories. In addition, while the final guidance also expressly states that it does not address "the approach for software that performs patient-specific analysis to aid or support clinical decision-making," it does describe categories of apps that are used in supporting clinical decisions.[2]

BACKGROUND

Before 2011, few sources were available regarding FDA's views on the application of the FDCA to software and mobile apps. In 1989, FDA issued a draft policy regarding the regulation of computer- or software-based medical devices. In that document, FDA stated that if computer programs met the definition of device in the FDCA, they were potentially subject to regulation as a device.[3] The agency stated that it would exercise enforcement discretion in several key respects, however. For example, it indicated that it would not regulate software that merely provided "traditional 'library' functions such as storage, retrieval, and dissemination of medical information—functions traditionally carried out through textbooks and journals." Moreover, the policy exempted software programs that allowed for "competent human intervention"—where clinical judgment and experience can be used to check and interpret a system's output.[4]

In 2005, FDA withdrew the draft policy. FDA later explained that, due to the "history, complexity, and diversity of computer systems and controlling software, it would be impractical to adopt one 'software' or 'computer' policy to address all computer and software medical devices."[5]

In July 2011, FDA released a draft guidance document setting forth a proposal for regulating certain mobile apps. According to the draft guidance, FDA planned to regulate only a subset of apps that

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[1] See our client alert of August 4, 2011, for review of the draft guidance.
[2] Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff, at 12 (2013) ("Final Guidance").
[3] Draft FDA Policy for the Regulation of Computer Products 1 (Nov. 13, 1989) (withdrawn Feb. 15, 2011).
[4] *Id.* at 3.
[5] 76 Fed. Reg. 8637, 8638 (Feb. 15, 2011).

both meet the definition of a medical device[6] and (1) are used as an accessory to a "regulated medical device" or (2) transform a mobile platform into a "regulated medical device." FDA termed these apps "mobile medical apps." According to FDA, this category included apps that connect to and act as an extension of a medical device (e.g., remotely displaying data from a bedside monitor), apps that transform a mobile platform into a traditionally regulated medical device (e.g., an iPhone as a stethoscope), and apps that allow the user to enter patient-specific information and, using formulae or processing algorithms, output a patient-specific result.[7] The draft guidance stated that apps subject to regulation include those that perform calculations resulting in an index or score, calculate dosage for a specific medication or radiation treatment, or provide recommendations that aid a clinician in making a diagnosis or selecting a specific treatment for a patient.[8] Examples included apps that automate a Glasgow Coma Scale, pain index, Apgar score, or NIH stroke scale.[9]

The two years following the release of the draft guidance were eventful. A number of stakeholders filed comments on the document. Among other issues, some comments criticized the agency's proposal to regulate relatively simple apps to support clinical tasks like an Apgar score app, and other stakeholders urged FDA to clarify how it would regulate apps that serve as accessories to other devices.

Congress also began to show interest in FDA's regulation of mobile apps and other health technology. Section 618 of the Food and Drug Administration Safety and Innovation Act ("FDASIA") of 2012 directed FDA to hold a public meeting with a diverse set of stakeholders and issue a report to Congress by January 2014 setting forth a "risk-based regulatory framework pertaining to health information technology, including mobile medical applications." Some stakeholders urged FDA to allow the FDASIA workgroup to complete its work before issuing a final guidance document. The House of Representatives also held three days of hearings on mobile medical apps and health technology in March of 2013.[10]

THE FINAL GUIDANCE

The final guidance preserves the basic framework of the draft guidance while making a number of key changes, including narrowing the scope of apps that FDA intends to regulate and expanding the categories of apps subject to enforcement discretion. FDA stated that the final guidance's risk-based approach will allow the Agency to focus its regulatory oversight on mobile medical apps that present a greater risk to patients if they do not work as intended.[11]

Like the draft guidance, the final guidance states that FDA intends to regulate "mobile medical apps"—an app that meets the statutory definition of a "device" and is intended to be "used as an

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[6] Section 201(h) of the FDCA defines a device, in relevant part, as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or . . . . intended to affect the structure or any function of the body of man or other animals . . . ."

[7] FDA, Draft Guidance for Industry and FDA Staff, Mobile Medical Applications, at 13-14 (2011) ("Draft Guidance").

[8] *Id.* at 14.

[9] *Id.* at 19-20.

[10] On our blog, www.insidemedicaldevices.com, we cover a number of developments related to mobile medical apps, including FDA enforcement against app developers, Congressional interest in mobile app regulation, and the FDASIA health IT workgroup.

[11] Final Guidance, at 4.

accessory to a regulated medical device" or "transform a mobile platform into a regulated medical device."[12]

According to the final guidance, a "mobile medical app manufacturer" is "any person or entity that manufactures mobile medical apps in accordance with the definitions of manufacturer in 21 CFR Parts 803, 806, 807, and 820."[13] FDA states that it does not intend to regulate manufacturers or distributors of mobile platforms (e.g., smart phones and tablets) unless they intend by "marketing claims" for the platform to be used for medical device functions.[14] Nor does FDA intend to regulate entities that "exclusively distribute mobile medical apps" (e.g., the operators of the "iTunes Apps store").[15] These essentially are the same positions FDA took in the draft guidance.

Again, like the draft guidance, the final guidance states that three categories of apps are subject to regulation.[16]

1. Mobile apps that are an extension of one or more medical devices by connecting to the device for purposes of controlling the device or displaying, storing, analyzing, or transmitting patient-specific medical device data.
    - This category includes display of medical images from a PACS, and medical device data systems (MDDS) regulated under 21 C.F.R. § 880.6310.
2. Mobile apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices. These apps must comply with the device classification associated with the transformed platform.
    - Examples include apps that allow a mobile platform to function as a glucose meter, and apps that use sensors so as to turn the mobile platform into an electronic stethoscope or electrocardiograph. In such cases, the app manufacturer has transformed the mobile platform into the medical device and must comply with regulatory requirements applicable to the risk-based device classification.
3. Mobile apps that become a regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations.
    - Examples are "apps that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy," and computer aided detection (CAD) software, which pose the same level of risk to patients regardless of the platform.

The final guidance contains a revised discussion of the last of these categories, which includes apps that are used to assist clinicians and patients make treatment decisions. FDA explains that "[t]hese types of mobile medical apps are similar to or perform the same function as those types of software devices that have been previously cleared or approved." FDA gives as examples mobile apps that "perform sophisticated analysis or interpret data . . . from another device."[17] This appears to be a narrower description of the category of regulated apps than featured in the draft guidance, which suggested that any app that analyzes patient-specific data and outputs "a patient-specific result" would be regulated as a device.[18]

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[12] *Id.* at 7.
[13] *Id.* at 9.
[14] *Id.* at 10.
[15] *Id.*
[16] *Id.* at 14-15.
[17] *Id.* at 15.
[18] Draft Guidance, at 14.

Like the draft guidance, FDA states that it intends to exercise enforcement discretion toward certain types of apps.[19] This means that FDA does not intend to impose medical device regulatory requirements on these apps, even though there is some basis to consider them to be medical devices. These categories subject to enforcement discretion include apps that:

- help patients (i.e., users) self-manage their disease or conditions without providing specific treatment or treatment suggestions;
- provide patients with simple tools to organize and track their health information;
- provide easy access to information related to patients' health conditions or treatments (including apps that provide contextually relevant information to users by matching patient-specific information to reference information);
- help patients document, show, or communicate potential medical conditions to health care providers;
- automate simple tasks for health care providers (including apps "that perform simple calculations routinely used in clinical practice"); and
- enable patients or providers to interact with Personal Health Record or Electronic Health Record systems.

The final guidance discusses these categories in greater depth than the draft guidance, which had relegated much of the enforcement discretion discussion to a footnote that many stakeholders criticized as confusing.[20] In addition, the final guidance meaningfully expands and clarifies several of these categories.

Under the draft guidance, for example, it was unclear whether apps that automated simple tasks for health care providers would be subject to regulation as mobile medical apps because such apps allowed for the input of patient-specific data and produced a patient-specific result. The final guidance, by contrast, clearly places apps that perform "simple calculations routinely used in clinical practice" into the enforcement discretion category.[21] Notably, the final guidance gives several specific examples of apps subject to enforcement discretion (e.g., apps that automate the Glasgow Coma Scale and Apgar score scale) that the draft guidance expressly stated would be regulated.[22]

The final guidance clarifies that FDA will not regulate apps that provide "easy access to information related to patients' health conditions or treatments."[23] FDA states that this category includes apps that provide "contextually-relevant information to users by matching patient-specific information . . . to reference information routinely used in clinical practice . . . to facilitate a user's assessment of a specific patient." Examples are an app that uses a patient's specific diagnosis "to provide a clinician with best practice treatment guidelines for common illnesses or conditions," and drug interaction look-up tools.[24] This category of enforcement discretion should cover apps that conduct search functions targeted to specific patient conditions or characteristics. By contrast, the draft guidance

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[19] Final Guidance, at 16-18.
[20] *See* Draft Guidance, at 12 n.13.
[21] The Final Guidance qualifies that "[t]hese are apps that are intended to provide a convenient way for clinicians to perform various simple medical calculations taught in medical schools and are routinely used in clinical practice." Final Guidance, at 17-18.
[22] Final Guidance, at 17-18.
[23] *Id.* at 17.
[24] *Id.*

document was narrower, stating that FDA would not regulate electronic copies of reference materials, but "these types of apps do not contain any patient-specific information."[25]

The final guidance also clarifies that FDA will not regulate apps "that provide or facilitate supplemental clinical care, by coaching or prompting, to help patients manage their health in their daily environment." Examples include "[a]pps that coach patients with conditions such as cardiovascular disease, hypertension, diabetes or obesity."[26] In addition, the final guidance states that an app that acts as a "medication reminder" that uses "simple prompting" to remind the patient about "adhering to pre-determined medication dosing schedules" would be subject to enforcement discretion.[27] The draft guidance indicated that FDA might exercise enforcement discretion over apps that "allow individuals to self-manage their disease or condition," but it did not clearly articulate what types of apps fell within this category.[28]

OPEN QUESTIONS

While providing greater clarity with respect to several key issues, the final guidance does leave open some critical questions. For example, the final guidance does not address whether apps considered accessories to a device should be regulated differently from the parent device if the app poses a lower risk than the parent device. FDA indicated in the draft guidance document that the traditional accessory approach "may not be well-suited for mobile medical apps that serve as an accessory to another medical device because of the wide variety of functions mobile medical apps can potentially perform."[29] The final guidance does not address this question, however.

The final guidance also leaves open many questions regarding FDA's regulation of apps that are used by patients and clinicians to support medical decisions, often referred to as clinical decision support (CDS) apps. Apps and other CDS software products that support clinical decisions through novel algorithms or calculations are becoming increasingly incorporated into clinical care. As discussed above, the final guidance states that "software that performs patient-specific analysis to aid or support clinical decision-making" is outside the scope of the guidance. The final guidance nevertheless discusses apps that perform such functions and identifies categories of apps that FDA would regulate as devices or would be subject to enforcement discretion. However, the guidance does not clarify how FDA will classify and regulate apps that do not fall within the express categories of enforcement discretion. Particularly in cases where such CDS products do not interact with currently regulated devices (such as radiological imaging equipment), it is unclear how they should be classified, as FDA has issued very few classification regulations addressing standalone software products. It also is unclear whether the concept of "competent human intervention," articulated in the 1989 draft software policy, continues to play a role in regulation of CDS software. FDA has stated that it intends to develop a separate guidance on the regulation of standalone CDS software,[30] which may provide greater clarity on these issues.

The final guidance also leaves open other questions relating to how FDA intends to regulate mobile apps, such as when a new 510(k) submission would be required for updates made to a cleared app. Although the guidance provides a "brief description of certain device regulatory requirements" that

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[25] Draft Guidance, at 10.
[26] Final Guidance, at 16.
[27] *Id.* at 16. Interestingly, medication reminders are classified as devices in 21 C.F.R. § 890.5050 (Daily activity assist device), but FDA stated it will exercise enforcement discretion for their specific product code of NXQ. *Id.* at 16-17 n.27.
[28] Draft Guidance, at 12 n.13.
[29] *Id.* at 13.
[30] 76 Fed. Reg. 50231, 50233 (Aug. 12, 2011).

might apply to apps,[31] it does not address specific regulatory challenges associated with medical device software.

Covington & Burling LLP will continue to closely monitor regulatory developments regarding health technology, including FDA's regulation of mobile apps. If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug Practice Group:

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[31] Final Guidance, at 32-35.