BNA

# Medical Devices Law & Industry Report™

VOL. 5, NO. 16 AUGUST 10, 2011

## New FDA Draft Guidance Sheds Light On Regulation of 'Mobile Medical Apps' and Other Software

By Keith A. Barritt

FDA regulatory attorneys have appreciated for decades that software alone can be considered a ''medical device.'' As early as 1989 the FDA issued a draft policy on the regulation of software. However, in 2005, recognizing that medical software had advanced by leaps and bounds since 1989 and would likely continue to evolve rapidly, the FDA took the rather unusual step of rescinding its 1989 draft policy, erasing it completely from the website, leaving industry somewhat in the dark as to when software would be considered a regulated device.

With the growing phenomenon of medical device applications for smartphones and other mobile platforms, in late July the FDA released a new draft guidance on the regulation of ''mobile medical applications'' (see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm263280.htm) (5 MELR 476, 7/27/11). This document is a very welcome effort to bring clarity to the issue of when a mobile phone app is subject to FDA regulation as a ''medical device.'' Public comments are due by October 19, 2011.

The FDA defines a ''mobile'' platform as being ''handheld in nature,'' such as iPhones, Blackberrys, iPads, or other personal digital assistants. A ''mobile application'' is defined as software that can be run on a mobile platform or a web-based software application that is tailored to a mobile platform but executed on a server.

The question immediately arises as to why the FDA's draft guidance should be confined only to ''mobile'' apps and not software in general. Does it really matter if software is run on a platform that is ''handheld in nature''? If the computing platform consists of hardware resting on a nurse's cart, or is a separate box on wheels, or is chained to a desk in a hospital, there is no obvious reason why software that runs on it should not be subject to the same scrutiny in determining whether it is a medical device.

Of course, there are some instances where the mobile platform makes operation of the device more challenging. For example, software that allows viewing medical imagery on a smartphone must contend with the small screen size, resolution, and lighting issues. But that should not determine whether the app is a regulated ''medical device'' to begin with. For many if not most devices, the size of the device the software resides on is largely irrelevant to the function of the software.

In any event, reading the FDA's draft guidance as applicable to all software is probably prudent, since the test for determining whether a mobile application is a regulated mobile ''medical'' application is the same test one would use to determine if any software is regulated. Indeed, as stated in the FDA's draft guidance, ''if a mobile app is intended for use in performing a medical device function it is a medical device ***regardless of the platform on which it is run***.'' The FDA even notes that a mobile medical app (read ''software'') that provides functionality through a ''web service'' or ''web support'' system can be a regulated device. If the platform is irrelevant for determining if the software is a medical device, there is no obvious reason to limit the FDA's draft guidance to ''mobile'' apps at all.

### What is the Software's 'Intended Use'?

The issue of whether software—mobile or not—is subject to regulation depends on whether it is a ''medical device,'' which depends on whether it is intended to (1) diagnosis disease or other conditions (e.g. pregnancy), (2) cure, mitigate, treat, or prevent disease, or (3) affect the structure or function of the body of man. Intended use may be shown by labeling claims, advertising, website promotions, and even oral statements by the manufacturer or its representatives. The formal labeling of a product is not necessarily the end of the story when determining intended use, but rather how the product is actually marketed is key.

Thus, FDA jurisdiction does not necessarily extend to all self-stylized mobile ''health'' or ''telemedicine'' apps.

*Keith A. Barritt is a principal in the Washington office of Fish & Richardson P.C. He also is a member of the advisory board for BNA's Medical Devices Law & Industry Report. He can be reached at barritt@fr.com.*

 ISSN 1935-7230

Rather, only mobile apps that are ''medical devices'' as defined by law are covered. The FDA's draft guidance lists four broad categories of intended uses of a mobile medical app (and gives dozens of specific examples) that would make software a medical device and thus subject to regulation, as follows:

1) display, storage, or transmission of patient-specific medical device data in its original format

   The FDA considers such software to be a ''medical device data system,'' for which the agency recently issued a final rule (see http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/MedicalDeviceDataSystems/default.htm) (5 MELR 119, 2/23/11). An example is custom software written by someone other than the original medical device manufacturer that directly connects to the device to obtain medical information.

2) control the intended use, function, modes, or energy source of another connected medical device

   The FDA considers such software to be an ''accessory'' to the connected device and subject to the same regulatory treatment as the connected device. An example is software that controls the delivery of insulin by transmitting control signals to a pump.

3) transform the mobile platform into a regulated device

   The FDA considers the software and associated platform to be regulated the same as the device it has been transformed into. Such products may include attachments to an existing device. An example is software that allows for the attachment of a transducer to convert a smartphone into a stethoscope.

4) create alarms, recommendations, or new information by analyzing or interpreting medical device data from another device

   The FDA considers such software to be an ''accessory'' to the connected device (if any) and subject to the same regulatory treatment (unless it already has its own separate classification such as burst suppression detection software for electroencephalographs under 21 C.F.R. 882.1400). In a footnote, the FDA indicates that it would generally not regulate software that creates alarms or reminders by merely automating spreadsheets or timers, such as software that logs, tracks, and graphs manually-entered data.

   With respect to software that creates ''recommendations or new information,'' included in this category is software that uses formulae or processing algorithms on patient-specific information to produce a patient-specific result, diagnosis, or treatment recommendation to be used in clinical practice or to assist in making clinical decisions. Examples include an automated questionnaire that allows the user to input patient-specific lab results and compute the prognosis of a particular condition or disease, performance of calculations that result in an index or score, calculation of dosage for a specific medication or radiation treatment, or providing recommendations that aid a clinician in making a diagnosis or selecting a specific treatment for a patient. The FDA specifically stated that its draft guidance does not address classification or pre-market submission requirements for clinical decision support software, which the FDA says it will address in a separate guidance.

   For apps that analyze, process, or interpret medical device data (electronically or manually entered) from ***more than one device***, the FDA intends to issue separate guidance and in the interim encourages manufacturers to contact the agency regarding the regulatory status of their software.

## Scope of Applicable FDA Regulation

Not all medical devices are regulated the same. Under the agency's three-tiered risk classification system, most Class I devices (including medical device data systems) do not require prior FDA authorization to market, though they are still subject to the Quality System Regulation, medical device establishment registration, device listing, labeling, and reporting requirements for adverse events.

Class II devices generally require prior FDA authorization via the 510(k) program, requiring the manufacturer to identify a lawfully marketed ''predicate device'' to which its device can be deemed ''substantially equivalent.'' This is not always an easy task, and as technology develops it can become a greater and greater challenge to identify an appropriate predicate device. Unfortunately, the FDA's draft guidance document does not clarify when a novel software application might still be able to claim substantial equivalence to an existing device, leaving some uncertainty as to the classification of certain apps.

Class III devices, i.e. those that are truly novel or have already been placed in Class III, generally require FDA ''approval,'' a much higher regulatory burden than mere ''authorization'' under the 510(k) program. A cumbersome process exists for potential reclassification, which may be subject to revision in the future. Most manufacturers prefer to stay out of Class III if possible, though there are some advantages, such as avoiding being considered a potential predicate device for a competitor's own subsequent 510(k) application.

Whatever the regulatory classification, software manufacturers should comply with the FDA's Quality System Regulation and related design controls. For software that requires 510(k) authorization, the FDA has a guidance document on information that should be included in the application, which largely depends on the ''level of concern'' based on the risk of the software. The FDA also has separate guidances on use of off-the-shelf software in medical devices and on general principles of software validation (see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm, http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM073779.pdf, and http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085281.htm).

Apart from the software, the FDA is also very concerned about the wireless transmission of medical data.

  MELR ISSN 1935-7230

Not every mobile medical app includes transmission of wireless signals, but device manufacturers should be aware that this is also of great concern to the FDA. A draft guidance on the use of ''radio frequency wireless technology'' in medical devices was issued by the FDA in 2007 (see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077210.htm). A final guidance is anticipated in the near future.

## What is Not Regulated?

Under the FDA's draft guidance document, several types of mobile apps (and presumably software in general) are considered ***outside the scope of regulation***, as follows:

- electronic copies of medical textbooks, teaching aids, or reference materials;
- software used solely to provide clinicians with training or to reinforce previous training that does not contain any patient-specific information;
- software solely used to log, record, or track information and evaluate or make decisions or suggestions related to developing or maintaining ''general health and wellness'' such as dietary tracking logs, posture suggestions, or exercise suggestions (i.e. not related to a specific disease or condition);
- software that provides ''generic aids'' to assist users but are not marketed for a specific medical indication, such as magnifying glasses, recording audio, or note-taking functions;
- software that automates ''general office operations'' such as billing, inventory, appointments, or insurance transactions;
- software that performs the functionality of an electronic health record system or personal health record system.

Also outside the scope of regulation are manufacturers of mobile phones and similar devices who do not specifically promote their devices as having an intended use for medical applications. Similarly, entities that only distribute medical apps, without themselves writing any software or engaging in any other FDA-regulated ''manufacturing'' activities, are outside the FDA's jurisdiction. However, someone who creates the original idea (the ''initial specifications'') for medical software would be considered the ''manufacturer'' and subject to regulation, unless another entity agrees to assume all responsibility for manufacturing and distribution.

Developers of software with a medical purpose should welcome the FDA efforts to bring some clarity to what is inherently a very murky area. While no guidance document, or even final regulation, is free from gray areas, the FDA has at least advanced the ball on helping developers determine whether their software would be considered a regulated ''medical device.'' If software falls within the FDA's jurisdiction, developers would be wise to fully comply with the applicable regulations.