

Mobile Health in the Regulatory Crosshairs

The FDA has its sights set on the m-health space, and some fret that regulation will stop innovation in its tracks.

By Tracy Granzyk Wetzel

In July of 2011, the U.S. Food & Drug Administration issued draft guidance around the regulation of mobile medical applications, and gathered comments through October.

While the intent of the guidance was to target a small group of mobile medical apps that turn mobile devices into diagnostic medical devices, it also raised questions—and concerns—about subjecting a rapidly evolving health information technology market to the arduous process that drug and medical device manufacturers have dedicated entire departments to managing since the 1938 Food, Drug and Cosmetics Act was enacted.

Today the iTunes store alone has approximately 9,000 consumer-focused mobile health applications and 4,000 targeted to health care professionals.

Those numbers are projected to grow to 13,000 and 6,000, respectively, this year provided the regulatory environment does not change drastically, according to Brian Dolan at *mobihealthnews.com*.

The mobile medical apps for providers range from study aids for medical students, such as the USMLE Wiz 2 Flashcards by Current Clinical Strategies Publishing, to applications such as the ThinkLabs Stetho-



scope app, which is designed to enable a mobile device to capture and display heart and lung sounds, among other types of body sounds.

Classifying risk

In FDA-speak, medical devices, and now most likely their related mobile medical applications, are classified according to the risk they pose to the patient, and with greater risk comes greater regulatory potential.

Class I devices, such as an elastic bandage or exam gown, pose little risk to a patient. Class II devices, such as a glucose monitor or radiologic imaging device pose

moderate risk and Class III devices, such as a drug eluting stent or intravascular catheter, pose the greatest risk to a patient if not manufactured according to best practice manufacturing standards.

Many of the Class I, and some of the Class II devices, are exempt from the FDA's Premarket Notification 510(k) process, but those that are not can submit a 510(k) if they are substantially equivalent (SE) to a legally marketed, or predicate device, not subject to a Premarket Application (PMA).

The cost of a 510(k) submission for FY2012, according to www.fda.gov, is \$4,049, or \$2,024 for a small business with less than \$100 million in gross receipts or sales. Class III devices are most often subject to the PMA process, a more extensive and costly process when evaluating from the perspectives of time, money and manpower. The standard fee for a PMA in FY2012 is listed at \$220,050, and \$55,013 for a small business.

While many mobile medical apps don't pose any obvious risks to patients, it isn't always easy to separate the wheat from the chaff of what is now the growing crop of app developers and products entering the marketplace.

A medical student who is erroneously taught incorrect anatomy or medical Spanish via an app would most likely fail a test

long before touching a patient. But developers entering the market with mobile medical apps that interpret X-ray findings, or calculate test results in order to diagnose or monitor patient information for treatment planning purposes, could have direct impact on patient care.

The FDA has stepped up to regulate this subset of medical apps. What remains unclear is which apps will fall under regulatory auspices and which will remain free of this additional cost burden to their business.

According to a 2011 study by Manhattan Research on the use of mobile devices and technology by U.S. physicians, 81 percent of the more than 2,000 survey respondents owned a smartphone in 2011, compared with 30 percent in 2010, and more than half used a mobile medical app for professional purposes in 2011, compared with one-third in 2010.

No smooth ride

Mark Cain, chief technology officer at MIM Software Inc., has been through the FDA regulatory process with the company's MobileMIM application, and the process went anything but smoothly.

A journey that began in August of 2008 with its first 510(k) submission finally ended with FDA clearance on Feb. 4, 2011. The app provides mobile access to display SPECT, PET, CT or MRI scans for diagnostic purposes when a workstation is unavailable, and was presented in 2008 at Apple's World Wide Developers Conference where it was awarded the 2008 Apple Design Award for Best iPhone Healthcare & Fitness Application.

According to Cain, who has been developing software for medical imaging devices since 2002, MIM Software was already familiar with the regulatory process for medical devices, and was pretty certain the app would fall under the same regulations.

When radiologists who viewed the app confirmed their assumptions, MIM Software made plans to submit a 510(k).

"Unlike the average mobile medical app developer who may not know this world," says Cain, "we are medical device developers. We knew this would be used in the treatment and diagnosis of disease so we knew we could, and should, go to the FDA with a 510(k)."

In summary, the FDA draft guidance issued July 21, 2011, states that a "mobile medical app" is one that meets the definition of "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act and is either used as an accessory to a regulated medical device, or transforms a mobile platform (iPhone, Blackberry, iPad, etc.) into a regulated medical device.

The FDA defines a device as "an instrument, apparatus, implement ... intended for the use in the diagnosis, cure, mitigation, treatment or prevention of disease in man, or intended to affect the structure or any function of the body of man or animal." And moving forward, disclaimers such as "not for diagnostic use" may not be enough to protect a developer from skirting regulatory responsibilities.

Cain puts it simply, "is it used in the treatment of, or diagnosis of disease? Period. End of story."

As Cain found, knowledge can be power but can also present obstacles others less aware avoid, at least in the short term.

As MIM Software traversed the approximately 29-month-long learning curve alongside the FDA, neither side found they were prepared for what the clearance of a mobile medical application would be like from a regulatory point of view.

When its first 510(k) submission was made in August of 2008, MobileMIM was deemed NSE, or not substantially equivalent, meaning the app was not deemed to be as safe or effective as the "predicate," i.e., an "equivalent" product already on the market.

A second 510(k) was filed in the summer of 2009 along with the additional data requested. And that is where the process broke down. For 221 days, the company heard nothing back from the FDA, and

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—Mark Cain

when it finally did, it was another rejection and a request for a PMA.

"At some point management changed, and an FDA ombudsman suggested we appeal the second 510(k), and forgo the request for the PMA—that this was not a Class III product," says Cain. "We added the calibration piece and performed additional testing and viewing with radiologists and resubmitted a third 510(k) in December of 2010." Approval came shortly thereafter, on Feb. 4, 2011, and Cain says the last 510(k) process was like night and day compared with the previous ones once the new reviewer stepped in.

Fine line

"I wish it [the process] were less painful, but I also realize you don't want devices used that aren't approved," says Cain. "The FDA has a fine line to walk to provide the best impact for the industry given guidelines in relationship to timelines so that industry can plan. We had other products earning revenue so we could wait it out."

While they were inadvertently helping the FDA craft the clearance process for their industry, the industry went on doing its thing in the background. A number of imaging apps remained available for sale, labeled "not for diagnostic use" but similar to the ones commercially sold. "The rest of the industry has been moving ahead while we were going through the process," says Cain. "Not much has changed for other developers—it has been business as usual for them." However once the guidance is complete, this may change, Cain predicts, and the FDA may go back and clean up.

Bakul Patel, who currently holds the position of Policy Advisor in the Center

for Devices and Radiological Health at the FDA, understands very well the need to provide clarity and direction around how developers should proceed, especially those unfamiliar with medical device regulatory language.

In addition to holding an MBA, he is an electrical engineer by training, a Lean Six Sigma Black Belt and brings with him experience in fast paced, technology driven environments as a software engineer and manager.

“MIM Software already had a desktop viewer and was aware of the process, and we had been reviewing similar technology for a while,” says Patel. “We now understand this area is growing quickly and need to rationalize where we need to be without compromising patient safety—thus the guidance. This example [MIM Software] led us to better understand what was needed.”

FDA assurances

Patel says the FDA is committed to providing the appropriate level of oversight only to the narrow definition of the mobile medical apps as defined in the guidance.

For apps that meet the definition of medical devices per the guidance, the agency expects only a small number to submit for premarket clearance prior to marketing the app, and that the majority of apps would be considered Class I (low risk) devices and simply be required to register and list their products with the FDA.

“We are eager to support the continued development of mobile medical apps, without burdensome regulations that would stifle innovation,” says Patel.

Patel is now busy sorting through 400, multiple-page comments in response to last year’s proposed guidance, in order to finalize a guidance that makes sense for everyone—patients, users, manufacturers and developers—as soon as possible. Because of the volume of comments, Patel says that additional steps may be necessary before the final guidance is complete,

sometime in 2012.

Mary Ellen Harrison, vice president of the HealthID division at PositiveID Corp., recently experienced the 510(k) process with iglucose, a mobile health system that aids diabetic patients in the management of their disease by transmitting data from compatible glucometers to a Web portal, allowing health care professionals access to their patients’ information in real-time. She agrees that the 510(k) process is time consuming and requires dedicated effort and energy, but found the FDA to be very responsive to questions.

“It’s a process that adds time and cost, but the end result is most important so that the consumer and health care provider can trust it [the iglucose system] works properly,” says Harrison.

PositiveID filed its 510(k) in July of 2011 and was cleared by the FDA in November. All in all, it was a positive experience for the company, but Harrison says that its documentation was in order from the beginning and it dedicated both internal and external resources to the process, including engineers and other personnel who had worked with larger organizations on similar projects.

“You can’t develop something like this in your garage,” says Harrison. “If we didn’t have a quality system and development process in place that we followed, there wouldn’t be the same accountability.”

While it’s true that FDA regulations provide a check and balance system for medical-related products, it’s the uncertainty around what the final guidance will look like that is leaving others less experienced with regulatory processes—but no less creative—on the sidelines, slowing the very innovation that could help solve today’s health care woes, experts say.

Rebecca Kennis, a Systems Analyst from United Health Services health system in Johnson City, N.Y., has spent the last three years working on a hand-held version of its physician access application, called iCare.

Through iCare, physicians can securely access via iPhones both inpatient and

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outpatient data and view their census lists, patient labs, medications, ED reports, radiology transcription and sign-out notes. Kennis and her team, led by Afzal ur Rehman, M.D., a cardiologist with a love for computer programming, have also built in a billing component so that providers can not only input clinical information in real-time, but CPT codes and billing information as well.

“Even though iCare is view-only right now, we have received really good feedback from the physicians,” Kennis says. “Providers like the fact that they can access this information from anywhere via their iPhone while they’re on call. They can return a call from dinner, or right from their bed, and instantaneously receive information regarding their patient.”

The next step for iCare would be to add decision support, such as alerts when labs or vitals indicate a potentially acute health issue.

But according to Kennis, adding those capabilities may be a regulatory game changer in the eyes of the FDA. “This is where things get gray.”

After reading the guidance, Kennis says the company in a holding pattern on adding the decision support as it waits to find out what the FDA will require.

“We’re running a medical system off a medical device and we’re not sure when the FDA needs to regulate. Right now its guidance appears contradictory—one section says clinical decision support is falls under its regulatory guidance, and another section says it’s not.”

As a not-for-profit organization with limited manpower, Kennis hesitates to expand the iCare project in ways that

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may require FDA scrutiny because of the increased investment necessary to address the regulations.

The entire iCare project was developed by a three-person team, all of whom are also involved in a number of additional health system information technology and clinical projects, such as fulfilling meaningful use requirements, and in the case of Rehman, treating patients.

Because of its limited resources, UHS did not have time to send comments to the FDA about the regulatory guidance, and is relying in large part on industry associations like the Healthcare Information and Management Systems Society (HIMSS) to do so in its best interest, Kennis says.

Let's be clear

Edna Boone, senior director of mHIMSS, the new mobile initiative the organization kicked off last year, says the pace at which mobile technologies are being adopted is outpacing organizational, national and international policies in place to regulate them.

HIMSS is focused on providing education around the new FDA guidance to its members, but would like the agency to provide more clarity about its intentions.

"We believe the FDA does understand its role in making sure outreach and education is out there," says Boone. "We would like to see them narrow their focus on the intended use, so we can better understand what needs to be regulated.

"This would help clarify things for those using the devices in hospitals and other health care settings."

In September of 2011, HIMSS polled its membership around the topic of mobile medical applications, and 243 members responded.

One-third of those responding felt the proposed FDA regulation was excessive, 41 percent believed the regulation to be appropriate and 6 percent felt additional regulation was necessary. ■

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