Fda steps up oversight on medical apps

Health & Medicine

When the U. S. Food& Drug Administration sent a warning letter to an Indian app developer in late May, entrepreneurs in this country took notice. The FDA warned Biosense Technologies Private Ltd. that its app—which is designed to work with a urine-testing kit—is actually a medical device, and therefore it must be cleared by the agency.

The large and growing community of doesn't expect this to be the last time the FDA weighs in on mobile apps marketed forhealth-related uses. " There are millions of medical apps out there. The industry is concerned," says Gabriel Vorobiof, a Los Angeles cardiologist and co-founder of PadInMotion, a New York company developing mobile tools for hospital use. " It's just not clear how far [the FDA] will go."

Until now, the FDA has taken a largely hands-off approach to medical apps, but that could change any day. In July 2011, the agency published a draft of proposed rules for medical app developers and posted it online so the public could comment on it. Releasing the final version of those rules " is a priority for the agency and we are working to publish [a guidance document] this year," a spokesperson said in an email.

Most app developers are not shocked that the FDA is cracking down on Biosense. That's because the company markets its app, called uChek, as a tool for analyzing urine-testing strips. The FDA approves the use of those strips—but only if interpreted by a " direct visual reading." Once the mobile phone becomes the chief analyzer of the test results, the entire test system, including the app, must get separate clearance, the agency said in its letter to Biosense.

" That's not surprising," says Brad Weinberg, a partner with New York-based Blueprint Health, an incubator for medicaltechnologystartups. " Any regulateddiagnostictest or medical device needs to get approved," even if it's a variation of an already-approved tool.

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In an email, Biosense founder Abhishek Sen says he won't comment on the content of the FDA's letter, except to say, " We are in touch with the U. S. FDA, and will be working closely with them over the coming months to ensure that we continue to deliver accurate, affordable and convenient diagnostics across the world."

What about apps that don't make diagnoses, but still provide personalized information based on specific patients and their medical conditions? That's where the FDA's oversight could get murky. The draft guidance suggests that when apps are designed to collect information about specific patients and use it to, say, assist physicians in calculating the proper dosage of a drug, they may be subject to FDA oversight.

Nicholas Genes, an assistant professor of emergency medicine at Mount Sinai School of Medicine in New York and a frequent blogger on medical apps, says it's fine if the FDA steps in to ensure that new technology protects patient safety and privacy, but he'll be concerned if the agency oversteps its bounds. " If a couple of programmers have a cool idea, I would hope that the FDA doesn't stifle that, because these are the people that are driving the whole market," Genes says.

Judging from the draft guidance, many makers of health-related apps should be immune from FDA oversight. They will likely include PadInMotion because it provides access to apps via the tablet computers it makes available to hospitals but doesn't actually develop any apps itself. The draft guidance also states that apps providing wellness tools, such as nutrition advice and exercise tips, won't have to be approved.

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For those entrepreneurs who are subject to FDA scrutiny, however, the process can be daunting. Ryan Sysko, co-founder and CEO of Baltimore-based WellDoc, says his company spent more than two years getting FDA clearance for its first product, adiabetesapp designed to help patients interact with their physicians in managing their medications, glucose testing and lifestyle choices.

Sysco says he suspected the technology would need to gain FDA approval from the time the company launched in 2005, because it was designing an app that physicians would prescribe like a drug or device. " The existing regulations were relatively clear," Sysco says. " If you look at the software regs that were written in the 1970s, we felt the types of feedback and support we were going to give patients would make us a device."

Weinberg says he advises entrepreneurs participating in Blueprint Health to start a dialogue with the FDA and their legal advisors early in the startup process so they can clarify regulatory requirements and be prepared for any resulting time and expense. And like many in his industry, he's eagerly

awaiting the final word from the FDA. " It would be helpful if the FDA would be clear about its guidance," he says.

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