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Strategic Health Care News

FDA Considering Regulation for mHealth Mobile Health Applications

The U.S. Food and Drug Administration (FDA) has been considering how and when to regulate mobile health applications that are used on wireless phones without altering the phone's primary function as a mobile telecommunication device. These mobile devices—such as cell phones, PDAs, and other wireless technologies—used to collect health data and transmit that information between medical personnel are considered to be forms of mobile health, or mHealth. The director of the FDA Center for Device and Radiological Health has testified to Congress that the agency has the authority to regulate mHealth and other information technologies.

The FDA, in coordination with the Federal Communications Commission (FCC), held a public conference July 26-27, 2010 to gain a better understanding of the "convergence of communications technologies and medical devices, the future of wireless health technologies, and challenges." In part, the goal was to explore jurisdictional issues between the FCC and the FDA and to assess stakeholders' concerns. The FDA and FCC focused on trends, risk management related to delivery settings, "medical-grade" wireless technology and communications, and the relationship between FDA approval/clearance and FCC certification of applications, post market, and compliance requirements.

The conference was attended by a broad range of companies operating in the mHealth space. It was also attended by representatives of the newly formed mHealth Regulatory Coalition (MRC), a broad base of mHealth industry stakeholders. MRC was formed to develop a consensus among companies operating within the mHealth space regarding proposed FDA regulation of mHealth technologies. MRC was launched in May 2010; its members include cell phone manufacturing, telecommunications, semiconductor, component, and medical device industries; membership eligibility was extended to pharmaceutical manufacturers contemplating remote monitoring technologies for patient medication adherence.

The FDA also accepted comments on the conference topics through August 16, 2010. In its comments MRC identified three key areas needing clarity regarding which aspects of mHealth technology the FDA will regulate: 1) The regulatory boundary between medical and health and wellness use must be defined to differentiate between a medical use and general consumer use of the same application or device;2) Applications of the FDA's medical device accessory rule must be defined to include the reality that network connectivity will be built in to most medical devices; and 3) Regulation of supporting software not directly involved with the operation of a medical device used by health care professionals to diagnose, treat, or monitor a remote patient should be nuanced to permit a risk-based approach. The group is led by Dane Stout, executive director of the Anson Group; Brad Thompson an attorney with EpsteinBeckerGreen experienced in policy development and FDA interactions; and Robin Strongin with Amplify Public Affairs, LLC.

A link to the full text of "Conference Transcript for FDA Converged Communications and Health Care

Devices Impact on Regulation; Public Meeting: Day 1" may be found in *The OPEN MINDS Circle Library* at www.openminds.com/circlehome/eprint/indres/072410shcnfdaconfmobilehealthtrans1.htm.

A link to the full text of "Conference Transcript for FDA Converged Communications and Health Care Devices Impact on Regulation; Public Meeting: Day 2" may be found in *The OPEN MINDS Circle Library* at www.openminds.com/circlehome/eprint/indres/072410shcnfdaconfmobilehealthtrans2.htm.

A link to the full text of comments submitted to the FDA by the mHealth Regulatory Coalition may be found in *The OPEN MINDS Circle Library* at www.openminds.com/circlehome/eprint/indres/081610shcnfdamhealthcomments.htm.

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