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REPORT

Telemedicine

Coalition Defines Three Key Considerations For FDA Regulation of 'mHealth' Technology

As members of the mHealth Regulatory Coalition begin rolling up their sleeves in September to draft proposed guidance to the Food and Drug Administration on how to regulate mobile health products, they are focused on three primary issues they believe, if addressed properly by FDA, would provide much-needed clarity for how mobile health products will be regulated, coalition executives told BNA in August.

The coalition's three primary considerations for regulation were laid out in an Aug. 16 letter to FDA and the Federal Communications Commission, following a meeting of the two agencies in July to discuss regulatory impact on medical devices and converged communications (*see previous article*). FDA oversees medical device safety and effectiveness while FCC is responsible for the public communication spectra, including for wireless and broadband use. The coalition's letter focused on issues relevant to FDA's regulatory authority.

The mHealth Regulatory Coalition (MRC) was formed in May, and has been recruiting vendors, industry groups, and other interested parties to join an effort to draft guidance to FDA on how the agency should exercise its authority to regulate the mobile health space (*see previous article*).

First among those considerations is to define the regulatory boundary between the use of mobile technologies for medical purposes and the use for health and wellness purposes. Medical devices intended for medical use are regulated differently from those intended for so-called health and wellness use, MRC Executive Director Dane Stout and General Counsel Bradley Merrill Thompson, with Epstein Becker & Green PC in Washington, explained.

In some cases, mobile health technologies used in conjunction with regulated medical devices can be used for both medical and health and wellness purposes as well, according to the coalition's letter to FDA and FCC. For example, the group wrote, a digital weight scale connected wirelessly to a mobile phone or gateway might be used as part of a treatment protocol for obesity or cardiology care. However, the same technology might be used by individuals to track their weight and body mass index (BMI) as part of a general wellness regimen.

''MRC believes that the intended use of a device for general wellness rather than medical care purposes is an important consideration that should be addressed in FDA's regulatory oversight strategy,'' the coalition wrote. ''We seek to work with FDA to reconcile both medical and wellness intended uses for a given connected device when determining the regulatory requirements applicable to the device and to the mHealth technologies involved in the capture and transmission of health information from the device.''

Accessory Rule. Second among the considerations spelled out by the coalition is the need to address the challenges of the FDA's device accessory rule—which governs add-ons for medical devices—for mHealth. The coalition said in its letter to FDA and FCC that the medical device accessory rule in effect now made sense for accessories to regulated medical devices ''when medical devices were mainly standalone pieces of equipment and the rule applied to products that end users of the device would physically connect to the primary medical device.''

However, Stout explained, applying that same accessory rule to mobile health technologies could be onerous and complicated, in part because mHealth technology going forward will be built into medical devices, not attached as accessories.

''In the mHealth context, however, traditional medical devices are connected to other devices and systems through a network, intended for a variety of general communications purposes,'' according to the letter. ''Many of these systems and software are necessary for the connected use of the device, but are not, of them-

selves, medical devices. Rather, these system components are broadly used for multiple communications applications. In this context, the beginning and end of the regulated medical devices is unclear.''

Furthermore, Stout said, considering certain mobile technologies as medical device accessories subject to FDA regulation would not be appropriate and could stymie technology developments for the health care industry. For example, in the coalition's letter to the federal agencies, the group said regulating a carrier's mobile network as an accessory to a medical device ''would be untenable policy to apply and would unnecessarily limit the advancements in healthcare delivery offered by mHealth technologies.''

The third consideration the coalition defined for FDA in its letter is the need to address software that is not directly involved in the operation of medical devices but used to support health care providers in their use of mobile devices to diagnose, treat, and monitor patients. The coalition wrote that it recognized that FDA already had begun working on the issue, including a 2008 proposed rule to reclassify Medical Device Data Systems that has never been finalized. The proposal was published Feb. 8, 2008 (73 Fed. Reg. 7498). The coalition made no recommendations in its August letter to the agencies, but said the matter was among considerations it would make as it drafts proposed guidance to FDA.

Investment Concerns. The coalition's broad goal of providing clarity for the mobile health technology industry on how it will be regulated by the federal government is as much about addressing ambiguity for technology developers as it is to ease concerns from potential investors about what role the government might play in any given mobile technology that could be applied in the health space, Stout said.

While software developers and other technology developers might be working on products suitable for use in the medical device industry, they rely on investors who often are not willing to put money behind projects without knowing how the regulatory landscape could affect the projects.

Thompson told BNA he expects the coalition to begin in September working on a 90-day plan to fact-find, learn, and share findings about the mobile health space among coalition members and with FDA, and begin developing solutions toward proposed guidance to FDA.

BY KENDRA CASEY PLANK

The mHealth Regulatory Commission letter to FDA is available at http://op.bna.com/hl.nsf/r?Open=kcpk-88mnq8.

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