"The Gray Sheet"

U.S. mHealth Stakeholders Seek To Eliminate Barriers To Growth

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By Monica Hogan

The Federal Communications Commission hosted various health care-related federal agencies, medical device executives and other wireless health stakeholders at a June 6 mHealth Summit in Washington, D.C., to brainstorm ways to speed adoption of the technologies.

"Innovation at the intersection of communications technology and health care is essential to the quality of care for all Americans," said FCC Chairman Julius Genachowski in introducing the mHealth Summit. He explained that FCC has helped to promote wireless innovation across a number of vertical industries, including education and energy. Health care was specifically addressed in FCC's National Broadband Plan released in 2010. (See "National Broadband Plan Asks HHS To Work With FCC On Wireless Devices" — *"The Gray Sheet,"* Mar. 22, 2010.)

This mobile app from WellDoc helps patients manage their diabetes.
Image: WellDoc

Genachowski warned, however, against the dangers of "pseudo-innovations," and suggested that the overarching goals of mHealth innovation should be geared to improving care quality while lowering health care costs.

In a lightning round held at the end of the meeting, Genachowski called upon each attendee to identify one mHealth challenge the group could work on, and he appointed a smaller committee to present a white paper with suggested solutions at a follow-up meeting sometime during the next few months.

Last week, "The Gray Sheet" caught up with several attendees who outlined barriers to developing a wireless health ecosystem. Key requirements, sources said, include greater regulatory clarity; interoperability standards for sharing data among medical devices and health information technologies; reimbursement for mHealth services; and demonstrable clinical outcomes.

FDA, FCC Partnership

Stakeholders were encouraged to see the various government agencies – including FCC, FDA, CMS, NIH and the Department of Veterans Affairs – sitting at the same table to address wireless health.

"mHealth in particular benefits from the FDA and the FCC working together," said Joseph Smith, chief medical and science officer for West Wireless Health Institute. "You're looking at a space that is really the collision of consumer-scale technologies running into a heavily regulated marketplace."

Smith said there is a "sense of urgency" to the way the agencies are working on mHealth issues, but added that FDA and FCC work on "quite different timelines. The FCC has shorter regulatory approvals, for the most part, and a light regulatory touch." Bringing the agencies together offers an opportunity for shared learning, he added.

Two years ago, FCC and FDA signed a memo of understanding to work together to spur the development of wireless medical technology. (See "FDA Partners With FCC To Spur Wireless Health Technology Development" — *"The Gray Sheet,"* Aug. 2, 2010.) Since then, officials from the two agencies meet fairly regularly, and communicate far more often by phone and email exchange, said Julius Knapp, chief of FCC's office of engineering and technology.

Wireless medical device makers can seek regulatory approval from each agency in sequence or in parallel.

FCC looks to make sure that the devices are operating on the proper part of the radiofrequency spectrum and with the right power levels and that they don't emit on frequencies used by other services, Knapp said.

Part of FDA's authority is to review a wireless medical device for reliability to see whether it is robust enough to withstand signal interference if it were to occur, he added.

Clarity Sought On FDA Mobile Medical Guidance

Last July, FDA released its draft guidance on mobile medical software applications, which drew reactions from a wide array of stakeholders from within and outside the medical device industry. (See "FDA Mobile Health Policy Proposal Draws Fire From Far And Wide" — *"The Gray Sheet,"* Oct. 31, 2011.) Some in Congress want FDA to delay finalizing its guidance until after it submits a formal report on the topic. (See "Latest Senate FDA Reform Bill Would Delay Guidance On Mobile Health Apps" — *"The Gray Sheet,"* May 21, 2012.)

But many industry stakeholders who have closely followed the FDA process see no reason for such a slowdown.

"It would be a disservice not to finalize [the guidance] at this point," said Smith, who called the draft a deregulatory effort that attempts to draw clear lines between products that impact only health and wellness (and thus should not be regulated) and traditional medical device applications.

"We all need to have faith in the process as it's been described and as it has worked, and I don't think it's particularly helpful to throw a wrench into that machine at this point," Smith said.

Dale Wiggins, VP and chief technology officer for patient care and clinical informatics at Philips Healthcare, agreed. "Uncertainty is always the worst thing to have, so getting that to the next step would be useful," he said.

By publishing the guidance, said WellDoc CEO Anand Iyer, FDA "can actually take some of the noise and confusion away."

New Payment Model Explored

Iyer predicted that WellDoc may be about six months away from gaining new payment codes that would allow Medicare and other payers to reimburse doctors that prescribe the company's software app to help patients manage their diabetes.

Under such a coding structure, Iyer explained, there might be separate codes to pay for the software application itself and for a social worker to train the patient on using the technology. Another code would allow physicians to prescribe a renewable monthly subscription to the service that would reimburse the doctor for remotely reviewing the electronic log book of blood glucose levels.

Anand Iyer is CEO of diabetes management app developer WellDoc. *Photo: WellDoc*

"This would be paid for by the health plans because the amounts they pay for this is such a small number when compared to the amount of money we're saving" through reduced hospital admissions and visits to the emergency room that come with better diabetes control, Iyer said.

Speeding Up R&D

At the June 6 meeting, FCC highlighted draft rulemaking that looks to advance its experimental radiofrequency spectrum licensing program by allowing certain health care facilities and researchers more freedom to conduct experiments without having to go back and re-file for a new license for each variation on their experiments. (See "FDA, FCC Prepare Regulatory Ground For Wireless Health Care Innovation" — *"The Gray Sheet,"* May 2, 2011.)

Knapp explained that especially in medical environments densely packed with wireless devices, it can be hard to predict how the devices might interact, "so having environments where you can try out these new wireless technologies to make sure that they don't interact in unexpected or adverse ways is very helpful."

According to Philips Healthcare's Wiggins, new licensing rules are a great example of a specific step FCC can take to speed innovation.

"We do a lot of research work, and any time we have a mechanism in place to allow for research and advanced development to really prove out the clinical outcomes and clinical benefits of a solution early, that's really going to help innovation," he said. "If you can't get to that benefit study early on, it creates a lot of uncertainty in terms of your end payback on that investment."

Interoperability Seen As Key Challenge

One of the big barriers facing mHealth developers is the issue of interoperability among technologies that send and receive medical data so that it can be used by any of them, Wiggins said.

At the meeting, he explained, FCC asked whether there are models that have already worked well. Industry replied that the Office of the National Coordinator for Health Information Technology (ONC), which also sent a representative to the summit, "has done a really good job of creating mechanisms for both policy and standards around interoperability," especially when it comes to electronic health records and health information exchanges.

"We haven't really gotten into the device interoperability level yet," Wiggins added. "That's clearly an area that needs to have some focus to speed adoption and get these devices fully utilized in improving the outcomes."

Possible aids include having ONC cite device interoperability among its criteria for health IT meaningful use stage 2 or stage 3, or expanding the ONC charter to specifically include the medical device space, Wiggins suggested.

Smith said West Wireless has been a “big champion of wireless medical device interoperability,” arguing that when data is free to flow from one device to another, patient outcomes are maximized at the lowest possible cost.

He called for FDA to set a date by which medical devices could be labeled for interoperability if manufacturers choose to include it as a feature. “That’s work yet to be done, but at least we’re engaged in a conversation,” Smith said, noting that FDA plays a role in a medical device interoperability working group. “There’s reason to be hopeful here around an issue which is terribly important.”