Special Audio Report Transcript

Headline: Health IT Policy Committee Debates Role of FDA in Overseeing Safety of E-Health Record Systems

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I'm Kelly Wilkinson with a look at what the Food and Drug Administration's role could be in overseeing the safety of electronic health record systems. This is a special report for *iHealthBeat*, a daily news service from the California HealthCare Foundation.

As the federal government ramps up its plan to help doctors and hospitals invest in EHR systems, a committee has been debating what role FDA may have in overseeing the safety of those systems.

FDA has regulatory authority over medical devices and is responsible for monitoring products for patient safety. Some say that oversight could extend to the safety of EHR systems.

The federal Health IT Policy Committee recently debated what FDA's role could be. Paul Tang is vice chair of that committee, and chief innovation and technology officer for the Palo Alto Medical Foundation.

(Tang):"There were people that thought, well we need the FDA to act because they do have the authority to mandate reporting. And then on the other hand, there were folks that were concerned that if the FDA got involved -- particularly in the pre-marketing approvals like with drugs and devices -- that that might get in the way of innovation in software."

In its report to the Office of the National Coordinator for Health IT, the Policy Committee called for the development of a national program that would monitor patient safety problems in health IT systems … but the committee stopped short of saying what agency should run it. Again, Paul Tang.

(Tang):"We didn't go so far as to say, well, what kind of entity. But we wanted to list some of the attributes of an entity that would be able to collect information and to act on it and to better protect the public."

One way FDA could be involved is setting up a system for reporting vendors that don't meet certification and safety criteria.

(McGraw):"In many respects, there's at least an argument to be made that there's some crossover of authority here."

Deven McGraw is director of the Health Privacy Project at the Center for Democracy and Technology.

(McGraw):"To the extent that there's two agencies both with authority to look at the safety of EHRs potentially, it would totally make sense that those initiatives move forward in a consistent way."

McGraw says the worse case scenario would be for two agencies to be working at dual purposes.

But some vendors and health IT experts worry that FDA's involvement could stifle innovation.

Dave deBronkart, also known as "e-patient Dave," is an advocate for involving patients in health IT. He says certifying electronic health record systems is very different to the kind of work FDA does certifying medications and medical devices.

(deBronkart):"If you're certifying a medication, you can measure whether it's effective and you can measure whether it's safe. But there's nothing remotely that clear or straightforward about a medical record system."

deBronkart says the range of data presented in an EHR -- and the circumstances in which doctors will use those systems -- is enormously complex. So whatever agency certifies the systems needs to operate using methods that move at the pace of modern innovation.

(deBronkart):"I don't want us to be hamstrung to the point where nothing good gets introduced to the market by an approach to certification that essentially makes it an insurmountable hill to get something approved and released to the market."

The Center for Technology and Democracy's Deven McGraw says that depends on how the criteria are set by ONC. If they are set too narrowly and are dependent on today's technology, they could quickly become outdated. McGraw says in the first round of the criteria for "meaningful use," ONC did not specify particular standards very often, and instead looked to functionality.

McGraw says regardless of how vendors perceive FDA, they have a job to do.

(McGraw):"A lot of the vendors of EHRs are nervous about the prospect of regulation by the Food and Drug Administration because I think, rightly or wrongly, that agency has the reputation of stifling innovation. I'm not sure whether that's an accurate characterization or not. But whether it is or it isn't is not an issue. They have the obligation to make sure that medical devices are safe, and so to the extent that some of the functionalities of an EHR arguably perform the same types of functionalities that medical devices do, it's their obligation to do something about it."

This has been a special report for *iHealthBeat*, a daily news service from the California HealthCare Foundation. If you have feedback or other issues you'd like to have addressed, please email us at ihb@chcf.org. I'm Kelly Wilkinson. Thanks for listening.