THE COMMITTEE ON ENERGY AND COMMERCE

MEMORANDUM

March 19, 2013

TO: Members, Subcommittee on Oversight and Investigations

FROM: Subcommittee on Oversight and Investigations Staff

RE: Hearing on "Health Information Technologies: Administration Perspectives on Innovation and Regulation"

On Thursday, March 21, 2013, at 9:00 a.m. in room 2322 of the Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing entitled "Health Information Technologies: Administration Perspectives on Innovation and Regulation."

The Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) are actively involved in the growth of health information technologies and the Federal government's response. This hearing will examine the positions of the HHS and FDA on new and emerging technologies, and the regulatory regimes that should exist to address them.

I. WITNESSES

Dr. Farzad Mostashari
National Coordinator
Health Information Technology
U.S. Department of Health and Human Services

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration

II. BACKGROUND

1. FDA

The emergence of the health care applications for the use on portable electronic devices has created a unique situation for the FDA: how to properly encourage innovation while balancing the needs of patient safety. This balancing act is complicated by the fact that the current regime for the regulation of medical devices was established in 1976 in the Federal Food, Drug, and Cosmetic Act.

Today, there are three classes of medical devices, ranging from those devices that present the most minimal potential for harm (Class 1, e.g., bandages) to devices that support or sustain life or are implanted (Class III, e.g., pacemakers). More details on the establishment and monitoring of these classes are available here.[1]

Against this backdrop, in July 2011 the FDA proposed to oversee mobile medical applications (apps) designed for use on smartphones or other mobile computing devices in a way that would "encourage the development of new apps, focuses only on a select group…and will not regulate the sale or general consumer use of smartphones or tablets."[2] The agency identified a subset of apps that would be subject to oversight—those that impact or may impact the performance of currently regulated medical devices. This would include apps that:

- Are used as an accessory to a medical device already regulated by the FDA; or
- Transform a mobile communications device into a regulated medical device by using attachments, sensors, or other devices.

For example, the first standard would cover an app that allowed for a diagnosis by viewing a medical image from a picture archiving system. An example of the second standard would be an application that turns a smartphone into an ultrasound device.

Of particular interest to many is whether the growth of mobile medical apps will result in increased oversight of the smartphones, tablets or other computing devices that operate them or even their classification as medical devices. According to the July 2011 guidance, "the fact that a mobile platform can be used to run a mobile medical app…does not mean that the mobile platform manufacturer is considered a medical device manufacturer." In the example given by the FDA in the guidance, if it is possible to run a mobile medical device on a smartphone, but that smartphone is not marketed with a medical device intended use, then the maker of the smartphone would not be a medical device manufacturer.

The FDA invited comment on this approach. In September 2011 the FDA held a public workshop[3] on this approach and has received nearly 100 comments.[4] Yet, the FDA has still not released final guidance on this issue.

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[1] http://www.fda.gov/MedicalDevices/ResourcesforYou/Consumers/ucm142523.htm.
[2] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm263340.htm.
[3] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm267821.htm.

While both HHS and FDA monitor many areas of emerging health care technologies, this hearing will focus on the recent developments related to the Office of the National Coordinator (ONC) within HHS and the growing market for mobile medical apps in the health care community, and how FDA is addressing that growth.

2. HHS and the Office of the National Coordinator

The ONC is located within the office of the Secretary at HHS. It is the "principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information."[5] The position was created in 2004 and codified in the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009.

The HITECH Act established incentive payments for providers that undertake steps to adopt the "meaningful use" of certified electronic health records (EHRs). Professionals and hospitals can demonstrate meaningful use by complying with a series of steps. Initially, meaningful use requires use of EHRs to improve quality, safety, and efficiency while engaging patients and families. A detailed description of the stages and their requirements is available here.[6]

Recently, the use of EHRs has been criticized for favoring larger companies that have the ability to crowd out smaller competition, while "doctors and hospitals struggle to make the systems work."[7] Reports indicate that critics of the current push for EHRs believe that the systems can be difficult to use, add hours to the time physicians spend documenting care, and do not allow for the sharing of information with other systems.[8] However, hearing witness Dr. Farzad Mostashari, the head of ONC, recently announced that the administration will "push hospitals and software providers to share patient data."[9]

The ONC has also led efforts to use public data and technology to help prevent, detect, diagnose and treat cancer,[10] to improve a patient's ability to manage and access their own health records,[11] and to encourage the development of technology applications.[12]

III. ISSUES

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[4] http://federal.eregulations.us/rulemaking/docket/FDA-2011-D-0530.
[5] www.healthit.gov/newsroom/about.
[6] https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Meaningful_Use.html.
[7] Julie Creswell, *A Digital Shift on Health Data Swells Profits in an Industry*, N.Y. Times Feb. 19, 2013 at A1.
[8] *Id.*
[9] Alex Nussbaum, *Obama to Push Health Data Vendors to Share Records Widely*, Bloomberg Business Week, Mar. 6, 2013 available at http://www.businessweek.com/news/2013-03-06/obama-to-push-health-data-vendors-to-share-records-widely.
[10] http://www.hhs.gov/news/press/2012pres/01/20120104a.html.
[11] http://www.hhs.gov/news/press/2012pres/10/20121012e.html.
[12] http://www.hhs.gov/news/press/2012pres/03/20120326d.html.

The following issues may be examined at the hearing:

- What investments to date has the Federal government made to encourage the implementation of EHRs or similar advancements in health IT?
- How is the health care industry responding to the push for the use of EHRs?
- Do many of the EHR systems in use have issues with the sharing of information and how does the administration intend to respond?
- Is the FDA prepared and able to handle the market for mobile medical apps using the framework previously established for medical devices?
- What steps can future app developers expect in order to comply with the FDA?
- What has the reaction to the July 2011 guidance been, and when can the industry expect final guidance from the FDA?

IV. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Karen Christian or Sean Hayes with the Committee staff at (202) 225-2927.