FDA Draft Guidance for Industry on Mobile Medical Applications Released

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On July 21, 2011, the U.S. Food and Drug Administration ("FDA") released draft guidance specifying how the FDA intends to oversee regulation of mobile medical applications for smartphones and other mobile computing devices. The guidance identifies the types of mobile medical applications that the FDA intends to focus on and requests industry comment by October 19, 2011. Although the guidance is not binding, it gives a good indication of the FDA's current position on the regulation of mobile medical applications.

The FDA's guidance is further evidence of the growing influence of mobile technology in the practice of medicine. While FDA oversight will be aimed at the manufacturers of mobile medical applications (which in many cases may not be medical providers) certain circumstances could render a radiology group or an imaging center a "manufacturer" for purposes of FDA oversight. The guidance explains that manufacturers include those parties that initiate specifications for a device to be manufactured by a second party for subsequent commercial distribution. This means that for groups that hire a software consultant to create an application to be used "in-house", the group could potentially be considered a manufacturer if it decides to market the application commercially.

The FDA's proposed oversight will not extend to all mobile medical applications. The FDA is focused on those applications that impact, or may impact, the performance or functionality of currently regulated medical devices. The guidance explains that mobile medical applications can pose risks to public health just as traditional devices do, specifically highlighting risks associated with reviewing radiological images on smartphones and similar devices.

Those applications that essentially turn the provider's phone into a mobile medical device, or allow the phone to link into and function to extend another medical device, are the subject of FDA interest. The proposed guidance gives examples of the types of devices over which the FDA will exercise regulatory authority and clarifies the classifications of different mobile medical application categories. Applications that are electronic versions of teaching aids or reference materials and applications that function as electronic health records will not be considered mobile medical applications.

Although the guidance is non-binding at this time, it provides helpful insight into the FDA's next steps with respect to mobile medical applications. For those medical providers creating mobile applications to be used in the workplace (or those considering the creation of mobile medical applications), this is an area to keep an eye on in the future.

See the FDA New Release and Guidance:
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm263340.htm

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