Bloomberg BNA

Medical Devices Law & Industry Report™

Final FDA Guidance on Mobile Medical Apps in 2013: Wishful Thinking or a Reasonable Possibility?

BY SONALI P. GUNAWARDHANA

Over the past two years, many who have anxiously awaited the Food and Drug Administration's (FDA) issuance of its final guidance on mobile medical apps continue to be placed in a holding pattern. Earlier this spring during a congressional hearing, Christy L. Foreman, the FDA representative when questioned about the availability of the document, delicately committed to Rep. Michael C. Burgess (R-Texas) that FDA will issue the final guidance by the end of the fiscal year. This timing commitment may be considered wishful thinking given there appears to be another hurdle to overcome due to a provision of the FDA Safety and Innovation Act (FDASIA).

Sonali P. Gunawardhana is Of Counsel in the FDA Practice Group at Wiley Rein LLP in Washington, DC. She worked for nearly 10 years as an attorney at the FDA including serving in the Center for Devices and Radiological Health. She is a member of the advisory board for Bloomberg BNA's Medical Devices Law & Industry Report. She can be reached at (202) 719-7454 or at sgunawardhana@wileyrein.com. *The author acknowledges Summer Associate Claire Frezza for her valuable help in developing this article.*

Background

A coalition of 129 companies and associations[1] jointly sent a letter on June 18, 2013, to leaders at the Department of Health and Human Services (HHS) urging them to delay publication of FDA's final guidance on mobile medical apps. This coalition requested that FDA's final guidance document not be published until the National Coordinator for Health Information Technology (ONC) workgroup completes its report. The report is to focus on ''an appropriate, risk-based regulatory framework pertaining to health information technology (HIT) including mobile medical applications,'' as required by Section 618 of FDASIA.

HHS, through the FDA, the ONC, and the Federal Communications Commission (FCC) formed the FDASIA Workgroup to develop this report. The Workgroup members include agency officials and representatives from a wide range of stakeholders, including patients, consumers, health care providers, startup companies, health plans and other third-party payers, venture capital investors, information technology vendors, health information technology vendors, small businesses, purchasers, and employers. The Workgroup began meeting on April 30, 2013, and held its first public meeting on

[1] http://mobihealthnews.com/23305/final-days-of-waiting-for-fda-mobile-medical-app-guidance/. In addition, please see related article in the Regulatory News section of this issue for coverage of the debate over delaying the FDA guidance.

 ISSN 1935-7230

May 30, 2013. At the public meeting, the Workgroup's Subgroups—Taxonomy, Risk Assessment, and Regulations—presented their findings and continued to deliberate on the appropriate scope of technology, product characteristics that may pose greater risks to patient safety, as well as the appropriate division of regulatory authority.

FDASIA Workgroup

The work that needs to be completed by the FDASIA Workgroup appears vast and complicated based on the presentations at the public meeting. The Taxonomy Subgroup expressed a preference to determine the scope of HIT based on the functions and intended uses of potentially related products or technologies such as software, while the Risk Assessment Subgroup focused on identifying risks to patient safety and innovation as key factors to consider in whether and how to regulate particular products or technologies. Similarly, the Regulations Subgroup also identified several challenges, including distinguishing between products intended to promote wellness with those for medical purposes, identifying regulatory authority over accessories to a medical device, and clarifying regulatory authority over types of clinical decision support software. In addition to input received at the public meeting, HHS will accept comments on the report until August 31, 2013, which may only complicate or expand the issues already identified by each of the Subgroups of the FDASIA Workgroup.

It should be noted that language in FDASIA that originally required the FDA to wait until this report was completed was excluded so that the final guidance could be published at the FDA's discretion.[2] The law also allowed Kathleen Sebelius, the Secretary, of HHS to decide whether a committee should be formed hence the formation of the FDASIA Workgroup. The mHealth Regulatory Coalition, which represents many innovators of mobile health sent a letter on June 21, 2013, to HHS requesting that HHS not delay the publication of the final guidance given that FDA is focused on providing specific details of whether different mobile medical apps will be regulated or not which is unrelated to the broad HIT mandates of the FDASIA Workgroup.

Clarity on the issue may be just a couple days away as the FDASIA Workgroup plans to present its recommendations including policies for regulating mobile medical apps on August 7 to the HIT Policy Committee. David Bates, chairman of the FDASIA Workgroup, recently stated that FDA should subject only certain forms of high-risk clinical decision support software to premarket regulations. The workgroup's recommendations as presented on August 7 could very well sidetrack if not derail FDA's final guidance on mobile medical apps.

[2] http://mobihealthnews.com/17707/how-congress-almost-delayed-the-fdas-mobile-medical-app-guidance/.

Current State of FDA Oversight over Mobile Medical Apps

The FDA has reviewed approximately 100 mobile medical apps through its regulatory process to date; all have been considered either Class I or Class II medical devices. Based on the testimony[3] presented on March 21, 2013, the FDA estimates that the time it takes for a mobile medical app to proceed through its 510(k) process is significantly less than the average time for most medical devices, an impressively brief review time of approximately 67 days for mobile medical apps. The testimony further states that mobile medical apps make up just 0.5 percent of the total medical devices FDA reviews each year, which may seem low in comparison to the number of mobile medical apps that are currently being marketed. FDA has been cautious about taking enforcement actions against mobile medical app developers that have not sought FDA approval in light of the absence of the final guidance.

The testimony of the FDA clearly states its mandate in developing the final guidance: ''FDA recognizes the importance of implementing a balanced, transparent approach that fosters the development of health IT solutions and innovative products like mobile medical apps, while ensuring appropriate patient protections. Like traditional medical devices, mobile medical apps may in some cases present significant health risks to patients. FDA seeks to strike the right balance by providing a risk-based, focused approach to the oversight of a small subset of mobile medical apps that present a potential risk to patients if they do not work as intended.''[4]

Conclusion

It appears that all interested parties, regardless of which side they currently find themselves, share the same end goal which is to establish more clarity and parameters around HIT including mobile medical apps. The question remains whether the suggestions made by the FDASIA Workgroup will be incorporated into the final FDA mobile medical apps guidance document, delaying its publication even further, or whether the FDA will publish its current thinking on the matter without additional input from the FDASIA Workgroup and meet its proposed publication date by the end of this fiscal year. Of course, the million-dollar question remains unanswered as without the final FDA guidance document on mobile medical apps, the mystery remains as to where the FDA will draw the regulatory lines in terms of which mobile medical apps are to be regulated.

[3] http://energycommerce.house.gov/hearing/health-information-technologies-administration-perspectives-innovation-and-regulation#video (Testimony of Witness Christy L. Foreman) (7 MELR 199, 4/3/13).

[4] *Id.*

  MELR ISSN 1935-7230