Journal of Diabetes Science and Technology
Volume 7, Issue 2, March 2013

SYMPOSIUM

Food and Drug Administration Regulation of Diabetes-Related mHealth Technologies

M. Jason Brooke, J.D., M.S.E., B.S.,[1] and Bradley Merrill Thompson, J.D., M.B.A., B.A.[2]

Abstract

mHealth smartphone applications (apps) offer great promise for managing people with diabetes, as well as those with prediabetes. But to realize that potential, industry needs to get clarity from the U.S. Food and Drug Administration (FDA) regarding the scope of its regulatory oversight. Certain smartphone apps, when properly understood, simply help people live healthier lives, assisting with dietary choices, monitoring exercise, and recording other factors important to overall health. The manufacturers of such apps, in an effort to promote their products but also to educate customers, might wish to explain how using the app can help reduce the risk of developing diabetes. Right now, though, the mere mention of the disease "diabetes" would cause the app to be regulated by the FDA. Such regulation, we submit, discourages the kind of education and motivational messages that our country needs to stem the tide of this disease. Further, should the app simply receive data from a blood glucose meter and graph that data for easier comprehension by the patient, the app would become a class II medical device that requires FDA clearance. Again, we submit that such simple software functionality should not be so discouraged. In this article, we identify the issues that we believe need to be clarified by the FDA in order to unleash the potential of mHealth technology in the diabetes space.

J Diabetes Sci Technol 2013;7(2):296–301

Author Affiliations: [1]Vasoptic Medical Inc., Columbia, Maryland; and [2]Epstein Becker Green, P.C., Washington DC

Abbreviations: (app) application, (CDS) clinical decision support, (FDA) Food and Drug Administration, (MDDS) medical device data system

Keywords: accessory, active patient monitoring, app, clinical decision support, class I, class II, class III, device, diabetes, diet, exercise, Food and Drug Administration, glucometer, medical device data system, mHealth, software

Corresponding Author: M. Jason Brooke, M.S.E., J.D., Vasoptic Medical Inc., 9250 Bendix Rd. N., Suite 510, Columbia, MD 21045; email address *Jason.Brooke@VasopticMedical.com*