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After publishing the article *FDA Regulation of mHealth and Wellness Devices: What You Need to Know* in the December 2017 issue of *The Health Lawyer* ("December article"), the Food and Drug Administration ("FDA") issued "Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act" on December 8, 2017 ("Draft Guidance"). Although the document is draft guidance for purposes of comment only, the author believes it is important to alert readers of possible changes to the information provided in the December article.

The December article differentiates between "mobile medical apps" (which are medical devices regulated by the FDA), "mobile apps" (which are medical devices that fall within the FDA's "enforcement discretion") and "low risk wellness devices" (which are not medical devices at all and therefore not subject to FDA regulation, discretionary or otherwise).

To fall within the category of "low risk wellness device," the device had to meet several requirements:

- Its intended use relates to maintaining or encouraging a general state of health or a healthy activity; or
- Its intended use associates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions; and
- The device presents a very low risk to the user's safety.

Draft Guidance Provides Needed Clarification

The Draft Guidance appears to address an inconsistency within the definition of "low risk wellness device." This inconsistency is that a low risk wellness device should not be related to the diagnosis, cure, mitigation, prevention or treatment of a disease or condition. However, the second category of low risk wellness device identified in the FDA's original 2016 guidance references "chronic diseases or conditions." According to the FDA, wellness devices that relate to the mitigation or prevention of a disease or condition should not be excluded from the definition of "medical device." As a result, the FDA plans to recognize wellness devices in that second category as medical devices, but subject to enforcement discretion as long as the device also presents a low risk to the user's safety.

Likewise, the Draft Guidance moves some mobile apps from the "enforcement discretion" category to the "not a medical device" category. The mobile apps that the FDA is moving to the "not a medical device category" (and therefore not subject to FDA regulation) include mobile apps that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness, such as those that:

- Provide tools to promote or encourage healthy eating, exercise, weight loss or other activities generally related to a healthy lifestyle or wellness;
- Provide dietary logs, calorie counters or make dietary suggestions;
- Provide meal planners and recipes;
- Track general daily activities or make exercise or posture suggestions;
- Track a normal baby's sleeping and feeding habits;
- Actively monitor and trend exercise activity;
- Help healthy people track the quantity or quality of their normal sleep patterns;
- Provide and track scores from mind-challenging games or generic "brain age" tests;
- Provide daily motivational tips (e.g., via text or other types of messaging) to reduce stress and promote a positive mental outlook;
- Use social gaming to encourage healthy lifestyle habits;
- Calculate calories burned in a workout.

The deadline to submit comments about these and other proposed changes found in the Draft Guidance was February 6, 2018.

The use of mHealth in health and wellness programs continues to evolve. Employers, providers and others need to keep abreast of applicable changes and comply with them accordingly.

Barbara J. Zabawa owns the Center for Health and Wellness Law, LLC, a law firm dedicated to improving legal access and compliance for the health and wellness industries. She is also a Clinical Assistant Professor for the University of Wisconsin Milwaukee College of Health Sciences, Department of Health Services Administration.

Ms. Zabawa is lead author of the book *Rule the Rules on Workplace Wellness Programs*, published by the American Bar Association. She is a frequent writer and speaker on health and wellness law topics, having presented for national organizations such as WELCOA, the National Wellness Institute, HPLive, Healthstat University and HERO.

Before graduating with honors from the University of Wisconsin Law School, she obtained an MPH degree from the University of Michigan. Immediately prior to starting her own firm, she was Associate General Counsel and HIPAA Privacy Officer for a large health insurer where she advised on Patient Protection and Affordable Care Act matters. She was also a shareholder and Health Law Team Leader at a large Wisconsin law firm.

Ms. Zabawa serves health and wellness professionals and organizations across the country as an advocate, a transactional lawyer and a compliance resource. Her commitment to improving health and wellness also shows through her community service. She sits on the Board of Directors for Health Promotion Advocates, a national nonprofit organization created to integrate health promotion into the national agenda. She also is a Board Member for the Rogers Memorial Hospital Foundation, a healthcare organization that specializes in treating mental illness, and she chairs the State Bar of Wisconsin Health Law Section.

Ms. Zabawa is licensed to practice law in both Wisconsin and New York. She may be reached at *bzabawa@wellnesslaw.com*.

Endnotes

1 FDA Draft Guidance for Industry and Food and Drug Administration Staff, Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act, Dec. 8, 2017 ("Draft Guidance"), available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587820.pdf. The Draft Guidance is intended to update prior FDA guidance issued December 1, 2016 pursuant to the Cures Act, which clarified that the definition of "device" excluded certain software functions. The December article can be found in *The Health Lawyer*, Volume 30, Number 2, December 2017, at p38, https://www.americanbar.org/groups/health_law/publications/health_lawyer_home.html (membership required).

2 December article at 43.

3 Draft Guidance at 8.

4 Draft Guidance at 9.

5 The FDA also released clarifications to the clinical decision support guidance. For patient decision support software, which is most relevant to this update, the FDA states it does not intend to enforce compliance with applicable regulatory requirements for such software that meets all of the following factors:

- Do not acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system;
- Display, analyze, or print medical information about a patient or other medical information (such as information derived from peer-reviewed clinical studies and clinical practice guidelines);
- Support or provide recommendations to patients or non-healthcare professional caregivers about prevention, diagnosis, or treatment of a disease or condition; and
- Enable the patient or non-healthcare professional caregiver to independently review the basis for the recommendation so that it is not the intent that such patient or non-healthcare professional rely primarily on any of such recommendations to make a decision regarding the patient. *See* https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587819.pdf.