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FDA Regulation of mHealth and Wellness Devices: What You Need to Know

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Introduction

With the rising costs of healthcare, many employers offer wellness programs to keep employees healthier. As part of workplace wellness programming, employers may offer employees wearable technology or other wellness applications or technology. For example, one recent survey found 35 percent of employers use wearable devices in their wellness programs.[1]

Companies that have made their mark in the wellness industry, such as through wearable technology, are beginning to move into developing clinical technology. In 2016 Fitbit publicized a push to transform itself into a "digital health company" that relies less on consumers and more on the healthcare industry.[2] According to Fitbit's chief executive officer ("CEO"), the goal is for Fitbit gadgets to monitor blood pressure, blood sugar and even diagnose disease.[3] Other companies, such as Apple and Smartlife, seem to be jumping on that bandwagon, as well.[4]

Stepping into the world of diagnosing and treating disease, however, comes with a steep regulatory price. The rules that govern workplace wellness pale in comparison to the rules that govern medical care. Because insurance, including government insurance like Medicare and Medicaid often pays for medical care, healthcare providers must navigate copious amounts of reimbursement rules both at the federal and state level. There are also malpractice and professional licensing issues that weigh heavily in everyday practice. There are rules that govern with whom providers may collaborate or employ, with whom they can share information (and how they can share that information), with whom they can share or waive fees for services, the meeting of quality standards, information submission requirements, information retention requirements, and more. A full discussion of the rules that govern health services delivery, such as the Health Insurance Portability and Accountability Act (HIPAA), fraud and abuse rules, or federal and state billing and licensing rules is beyond the scope of this article. However, it is important to recognize that these rules apply to healthcare delivery, and wellness companies that venture into healthcare will most likely need to contend with those rules.

The company Theranos provides a recent example of a high-tech start-up falling prey to the staggering amount of regulation in healthcare. Theranos developed a laboratory test promising to detect hundreds of diseases requiring only one drop of blood and at a fraction of the costs of a conventional laboratory.[5] Theranos began offering tests to the public in late 2013 and opened 42 blood-drawing wellness centers in Arizona, two in California and one in Pennsylvania.[6] Most other blood-drawing centers are in Walgreens drugstores.[7] The Centers for Medicare & Medicaid Services ("CMS") sent a letter to Theranos on March 18, 2016 proposing sanctions against its leaders and taking away federal licensing for its laboratory facilities for continued failure to correct major problems with testing accuracy and competence.[8] For example, Theranos failed to properly hire and train qualified people to run the testing machines, allowed unlicensed workers to review patient test results, failed to follow manufacturers' instructions on equipment and did not have a proper, written protocol in place to calibrate the machines to maintain accuracy.[9] Indeed, in July 2016, CMS banned Theranos' CEO from owning or operating a medical laboratory for at least two years.[10] The company also faces a fine of $10,000 for every day it is out of compliance.[11]

For wellness companies interested in developing technological devices or tools to market to the healthcare industry, there is also the specter of regulation by the Food and Drug Administration ("FDA"). It is the prospect of FDA regulation that is the focus of this article. Part of this technological revolution in medical care is known as "mobile health" or "mHealth," which is the use of mobile communications devices like smartphones and tablet computers for health or medical purposes, usually for diagnosis, treatment, or simply well-being and maintenance.[12] Most mobile health technologies interface with users through applications ("apps") downloaded onto iPhones, iPads, or Android or Windows devices, for example.[13] One aspiration of mHealth and other healthcare technology is to decentralize, demystify, and democratize medicine, shifting the locus of care away from expensive institutions like hospitals and towards individual patients.[14] The push for medical clinicians to incorporate mHealth into their practices is increasing.[15]

As noted earlier, along with this increased interest by healthcare providers in mHealth or other wellness technology comes an increased likelihood of FDA regulation. The goal behind FDA regulation is consumer safety. In 2015, the FDA issued guidance for the mHealth industry[16] and issued draft guidance for the wellness industry regarding low risk devices, which was finalized in 2016.[17] These

guidance documents do not have the force of law,[18] but they provide wellness professionals and organizations a window into how the FDA views certain health technologies in relation to the Food, Drug, and Cosmetic Act ("FDCA"). After briefly describing the FDCA as applied to medical devices, this article will summarize the current FDA guidance for mHealth and low risk wellness devices.

The FDCA and Regulation of Medical Devices

Congress created the FDA in 1906 to govern therapeutic drugs.[19] At that time, medical devices were not thought to be appropriate candidates for federal regulation because very few products existed for prolonged application for the human body.[20] The 1938 FDCA expanded the FDA's authority to include the regulation of medical devices.[21] However, the FDA did not have authority to require the manufacturer of any device to prove the safety, much less the effectiveness, of its product.[22] With the introduction of highly sophisticated medical technologies in the 1960s, the FDA began to push for stronger regulatory authority over medical devices.[23]After almost a decade of debate on the proper regulatory systems, in 1976 Congress amended the FDCA with the Medical Device Amendments ("MDA"). These amendments broadly defined a medical device as follows:

> An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease. . . or intended to affect the structure or function of the body.[24]

Thus, an important consideration of whether a device is subject to FDA medical device regulation is to determine the device's "intended use." To determine the intended use, the FDA looks at a product's labeling claims, advertising matter, or oral or written statements by manufacturers or their representatives.[25] Generally, products, including software, are considered medical devices if they are intended for a medical purpose.[26] Thus, wellness companies that develop devices intended for medical purposes may fall within the ambit of FDA medical device regulation.

If a product is considered a medical device, the manufacturer must comply with certain FDA regulatory requirements. These requirements include:

- **Establishment Registration** – Manufacturers (both domestic and foreign) and initial distributors (importers) of medical devices must register their establishments with the FDA. All establishment registrations must be submitted electronically unless a waiver has been granted by the FDA. All registration information must be verified annually between October 1st and December 31st of each year. In addition to registration, foreign manufacturers must also designate a U.S. Agent.[27] Most establishments are required to pay an establishment registration fee.[28]
- **Medical Device Listing** – Manufacturers must list their devices with the FDA. Establishments required to list their devices include:
  1. manufacturers,
  2. contract manufacturers that commercially distribute the device,
  3. contract sterilizers that commercially distribute the device,
  4. repackagers and relabelers,
  5. specification developers,
  6. reprocessors of single-use devices,
  7. remanufacturers,
  8. manufacturers of accessories and components sold directly to the end user, and
  9. U.S. manufacturers of "export only" devices.[29]
- **Premarket Notification 510(k), unless exempt, or Premarket Approval ("PMA")** – Compared to the 510(k) process, PMA is a much more rigorous process because the manufacturer of PMA devices must prove efficacy and safety by providing data showing the device's performance in humans. The 510(k) process does not require human testing to prove efficacy and safety because these devices are considered to be at least as safe and effective as similar devices already on the market.[30]

  Devices that require the submission of a Premarket Notification 510(k) may not be commercially distributed until the FDA authorizes distribution through a letter of substantial equivalence. A 510(k) device must demonstrate that it is substantially equivalent to one legally in commercial distribution in the United States: (1) before May 28, 1976; or (2) to a device that has been determined by FDA to be substantially equivalent. There are three different classes of devices under FDA regulation, as discussed below. Most Class I devices and some Class II devices are exempt from the Premarket Notification 510(k) submission.[31]

  Products requiring PMAs are Class III devices, high risk devices that pose a significant risk of illness or injury, or devices found not substantially equivalent to Class I and II predicates through the 510(k) process. The PMA process is more involved and includes the submission of clinical data to support claims made for the device.[32]
- **Investigational Device Exemption (IDE) for clinical studies** – An investigational device exemption ("IDE") allows the investigational device to be used in a clinical study

continued on page 40

continued from page 39

in order to collect safety and effectiveness data required to support a PMA application or a Premarket Notification 510(k) submission to the FDA. Clinical studies with devices of significant risk must be approved by the FDA and by an Institutional Review Board ("IRB") before the study can begin. Studies with devices of nonsignificant risk must be approved by an IRB only before the study can begin.[33]

- **Quality System ("QS") regulation** – The QS regulation includes requirements related to the methods used in and the facilities and controls used for the designing, purchasing, manufacturing, packaging, labeling, storing, installing and servicing of medical devices. Manufacturing facilities undergo FDA inspections to assure compliance with the QS requirements.[34]
- **Labeling requirements** – Labeling includes labels on the device as well as descriptive and informational literature that accompanies the device.[35]
- **Medical Device Reporting ("MDR")** – Incidents in which a device may have caused or contributed to a death or serious injury must be reported to the FDA under the Medical Device Reporting program. Certain malfunctions must also be reported. The MDR regulation is a mechanism for the FDA and manufacturers to identify and monitor significant adverse events involving medical devices. The goals of the regulation are to detect and correct problems in a timely manner.[36]

As described earlier, the FDA regulates three different classes of medical devices.[37] Under this classification system, the FDA determines the amount of pre-market and post-market regulation required by the FDCA.[38] The higher the classification, the more scrutiny the device receives.[39] The three classes of medical devices are as follows:

- Class I devices are regulated the least and generally do not require any pre-market review by the FDA. Examples of Class I devices include elastic bandages and examination gloves.[40]
- Class II devices have "moderate risk" and are subject to a relatively cursory premarket notification, known as a 510(k) notice, which the FDA generally accepts.[41] In addition, Class II devices undergo special controls such as performance standards, post-market surveillance, patient registries, special labeling requirements, pre-market data requirements and guidelines.[42] Examples of Class II devices include x-ray machines, powered wheelchairs and acupuncture needles.[43]
- Class III devices are high risk devices and generally require PMA.[44] PMA is a complex and expensive process that obligates the manufacturer to submit clinical data proving the device's safety and effectiveness.[45] The approval process can take over five months, on average, even if a device is simply a newer version of an already approved device (i.e., a 510(k) clearance).[46] Therapeutic drugs must go through a similar approval process.[47] Examples of Class III devices include implantable pacemaker pulse generators and endosseous implants.[48]

The FDCA also gives the FDA the authority to set good manufacturing practice requirements for medical devices, to ban worthless and dangerous products from the market, and to require notification, replacement or refund by makers of defective products.[49]

With regard to software, the FDA has long considered software products to meet the definition of a device when the software is intended for use in diagnosing and treating diseases and other conditions.[50] Although the FDA views software products as within FDCA purview, the FDA announced that it would exercise "enforcement discretion" over many types of low-risk software, such as software that merely provides information.[51] "Enforcement discretion" means that the FDCA applies to the device and the FDA has legal authority to enforce regulations, but it chooses not to enforce those regulations.[52] The take-away regarding FDA regulation of devices is that if the device is intended to diagnose or treat a disease or condition, it is likely that it will be subject to FDA regulation.

Guidance for Mobile Medical Apps and Low Risk Wellness Devices

The FDCA grants the FDA authority to issue regulations and allows interested parties to request a public hearing as part of the rulemaking process.[53] The FDCA also includes residual rulemaking authority to address matters not specifically covered by the formal rulemaking provision.[54] This enables the FDA to conduct notice-and-comment procedures for the promulgation of rules.[55] This "informal" rulemaking procedure avoids the burdensome hearing procedure required with formal rulemaking.[56] Yet even informal rulemaking has become lengthy and difficult for the FDA.[57] As a result, the FDA has resorted to issuing "guidance," offering the FDA a convenient short cut for communicating its expectations to regulated entities.[58] The guidance process is not without critics, however. A primary criticism is that these informal announcements operate as de facto rules without the normal procedural safeguards that allow for public comment and review.[59] Despite this criticism, the FDA has issued guidance documents for both mobile medical apps and low risk wellness devices.

Mobile Medical Apps Guidance

The FDA provided guidance relating to mobile medical applications on February 9, 2015.[60] The guidance defines "mobile medical app" as a software application that can be run on a smart phone, tablet or other portable computer, or a web-based software platform tailored to a mobile platform but executed on a server that meets the definition of device in § 201(h) of the FDCA and either is intended: a) to be used as an accessory to a regulated medical device; or b) to transform a mobile platform into a regulated medical device.[61] Generally, if a mobile app is intended for use in performing a medical device function (i.e., for diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease) it is a medical device, regardless of the platform on which it is run.[62] Recall that the FDA looks at a product's labeling claims, advertising materials or oral or written statements by manufacturers or their representatives to determine a device's intended use.[63]

The key for wellness professionals and organizations is to determine whether a mobile app constitutes a mobile "medical" app or just a mobile app. If the latter, the FDA will exercise enforcement discretion, which as noted earlier means the FDA chooses not to enforce compliance of those apps under the FDCA.[64] If the app is a mobile "medical" app, then the FDA will apply its regulatory oversight over those apps at one of the three classification levels discussed earlier.[65] See Table 1 for examples of apps the FDA considers to be mobile "medical" apps subject to its oversight.[66] Examples of mobile apps over which the FDA intends to exercise enforcement discretion because they are lower risk are listed in Table 2.[67]

Regardless of whether a medical device is subject to FDA enforcement authority or is one for which the FDA applies enforcement discretion, the FDA strongly recommends that manufacturers of all mobile apps that may meet the definition of a medical device follow the QS regulation in the design and development of those apps.[68] This regulation includes good manufacturing practices.[69] A partial list of these practices are:

1. Having a quality policy
2. Conducting quality audits
3. Having sufficient personnel with the necessary education, background, training and experience to ensure a quality device
4. Having design controls to ensure that specified design requirements are met
5. Having production and process controls
6. Having procedures to ensure devices are routinely calibrated, inspected, checked and maintained
7. Having procedures to handle products that do not conform to specified requirements
8. Creating and maintaining a device history record.[70]

In addition to mobile apps, wellness professionals and organizations may develop or encounter other products that the FDA considers to present

Table 1 – Mobile Medical Apps with FDA Regulatory Oversight

TYPE OF MOBILE MEDICAL APP	EXAMPLES	MUST COMPY WITH:
Apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices.	• Blood glucose strip reader attached to a mobile platform to function as glucose meter; • Attachment of electrocardiograph electrodes to mobile platform to measure, store, and display ECG signals; • Apps that use built-in accelerometer on a mobile platform to collect motion information for monitoring sleep apnea; • Apps that use sensors (internal and external) on a mobile platform for creating electronic stethoscope function; • Apps that display radiological images for diagnosis.	The device classification associated with the transformed platform.
Apps that become a regulated medical device (software) by performing patient-specific analysis and providing patient specific diagnosis or treatment recommendations.	• Apps that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy; • Computer Aided Detection ("CAD") software image processing software; • Radiation therapy treatment planning software.	The FDA encourages manufacturers of this type of app to contact the FDA to discuss what, if any, regulatory requirements may apply.

continued on page 42

continued from page 41

Table 2 – Mobile Apps with FDA Enforcement Discretion

TYPE OF MOBILE APP	EXAMPLES
Apps that provide or facilitate supplemental clinical care, by coaching or prompting, to help patients manage their health in their daily environment.	• Apps that coach patients with conditions such as cardiovascular disease, hypertension, diabetes or obesity, and promote strategies for maintaining a healthy weight, getting optimal nutrition, exercising, managing salt intake, or adhering to pre-determined medication dosing schedules by simple prompting. • Apps that use video and video games to motivate patients to do their physical therapy exercises at home. • Apps that provide periodic educational information, reminders, or motivational guidance to smokers trying to quit, patients recovering from addiction, or pregnant women. • Apps that prompt a user to enter which herb and drug they would like to take concurrently and provide information about whether interactions have been seen in the literature and a summary of what type of interaction was reported; • Apps that use patient characteristics such as age, sex, and behavioral risk factors to provide patient-specific screening, counseling and preventive recommendations from well-known and established authorities.
Apps that provide patients with simple tools to organize and track their health information.	Apps that provide simple tools for patients with specific conditions or chronic disease such as obesity, Anorexia, arthritis, diabetes, or heart disease to log, track or trend their events or measurements (e.g., blood pressure measurements, drug intake times, diet, daily routine or emotional state) and share this information with their healthcare provider as part of a disease management plan.
Apps that are specifically marketed to help patients document, show or communicate to providers potential medical conditions.	• Apps that serve as videoconferencing portals specifically intended for medical use and to enhance communications among patients, healthcare providers, and caregivers; • Apps specifically intended for medical uses that utilize a mobile device's built-in camera or a connected camera for purposes of documenting or transmitting pictures (e.g., photos of a patient's skin lesions or wounds) to supplement or augment what would otherwise be a verbal description in a consultation between or with a healthcare provider.
Apps that perform simple calculations routinely used in clinical practice.	Medical calculators for: • Body Mass Index ("BMI") • Total Body Water/Urea Volume of Distribution • Mean arterial pressure • Glascow Coma Scale score • APGAR score • National Institutes of Health Stroke Scale • Delivery date estimator
Apps that meet the definition of Medical Device Data Systems.	• Apps intended to transfer, store, convert format, and display medical device data, without controlling or altering the functions or parameters of any connected medical device. These apps include those that are used as a secondary display to a regulated medical device when these apps are not intended to provide primary diagnosis, treatment decisions, or to be used in connection with active patient monitoring.

"low risk" to consumer safety. Unlike mobile apps that the FDA still considers are medical devices (and either applies its enforcement authority or does not), the FDA concludes that this third category of mobile apps are not medical devices at all and therefore have no regulatory requirements under the FDCA.[71] These include apps intended to provide access to e-copies of reference materials not meant for use in the diagnosis, treatment or prevention of disease, apps intended as medical training tools, apps for general patient education, apps that automate general healthcare office operations, and apps that are generic aids not specifically intended for medical purposes, such as an app that uses the mobile platform for note taking or as a magnifying glass.

Guidance for Low Risk Wellness Devices

The FDA released its final guidance regarding low risk wellness devices on July 29, 2016.[73] According to the FDA, low risk products generally promote a healthy lifestyle and meet the following two factors: (1) are intended for only general wellness use; and (2) present a very low risk to users' safety.[74]

Intended for General Wellness Only

The FDA defines a general wellness product as one that meets one of the following: (1) has an intended use that relates to maintaining or encouraging a general state of health or a healthy activity; or (2) an intended use claim that associates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.[75]

Importantly, the first category of general wellness product does not make any reference to diseases or conditions. To fall within this category, the general wellness product may relate to:

- Weight management
- Physical fitness, including products intended for recreational use
- Relaxation or stress management
- Mental acuity
- Self-esteem (e.g., devices with a cosmetic function that make claims related only to self-esteem)
- Sleep management
- Sexual function.[76]

In contrast, products that relate to the following would not qualify as general wellness products (and therefore could be subject to FDA regulation under one of the three class levels discussed earlier):

- The treatment or diagnosis of obesity
- The treatment of an eating disorder
- The treatment of anxiety
- A computer game that will diagnose or treat autism
- The treatment of muscle atrophy or erectile dysfunction
- The restoration of a structure or function impaired due to a disease (e.g., a claim that a prosthetic device enables amputees to play basketball).[77]

The second category of general wellness products is comprised of two subcategories: (1) intended uses to promote, track, and/or encourage choices, which, as part of a healthy lifestyle, may help to reduce the risk of certain chronic diseases or conditions; and (2) intended uses to promote, track and/or encourage choices which, as a part of a healthy lifestyle, may help living well with certain chronic diseases or conditions.[78] Both subcategories of disease-related wellness products should only make claims about healthy lifestyle choices reducing the risk of chronic disease or a medical condition if those claims are generally accepted and described in peer-reviewed scientific publications.[79] For example, it is generally accepted that a healthy lifestyle reduces the risk of or helps better manage heart disease, high blood pressure and type 2 diabetes.[80]

Given the "first category" and "second category" descriptions above of general wellness products, it appears that wearable technology (e.g. Fitbit, Jawbone) devices that track data such as exercise and dietary behavior would be considered low risk wellness devices and therefore not subject to any FDA regulatory requirements. They also present a very low risk to the user's safety, as described below. However, if this technology changes in the future (e.g., it becomes a medical device that is intended to diagnose and treat a disease), it would be subject to FDA regulations. Therefore, workplace wellness programs that provide wearable technology for their employees may not need to be concerned with these FDA regulations at the moment, but may need to comply with FDA requirements as technology changes and moves more into clinical applications. And of course, wellness programs that use information collecting devices must still address compliance with privacy, confidentiality, and security regulations.

Presents a Very Low Risk to User's Safety

In addition to being intended for general wellness, in order for a product to qualify as a low risk wellness device the product must also not present inherent risks to a user's safety.[81] The FDA considers a product to present an inherent risk to a user's safety if the product:

- Is invasive,
- Involves an intervention or technology that may pose a risk to a user's safety if device controls are not applied, such as risks from lasers, radiation exposure, or implants,
- Raises novel questions of usability, or
- Raises questions of biocompatibility.[82]

continued on page 44

continued from page 43

Examples of such products include:

- Sunlamp products promoted for tanning purposes (exposure to ultraviolet radiation creates an increased risk of skin cancer),
- Implants promoted for improved self-image or enhanced sexual function (creates an increased risk of rupture or adverse reaction to implant materials, as well as from the implantation procedure),
- A laser product that claims to improve confidence in a user's appearance by rejuvenating the skin (laser technology presents risk of skin and eye burns and presents usability considerations that may be addressed with labeling and other device controls).[83]

Another way to determine whether a wellness device qualifies as low risk is to investigate whether the FDA already regulates products of the same type as the product in question.[84] Wellness professionals and organizations may visit the FDA website[85] to search for similar products that the FDA might already regulate. For example, a wellness organization may develop a glucose monitor for diabetic employees. Upon searching the FDA website, one discovers that the FDA regulates as a Class I device a "continuous glucose monitor retrospective data analysis software."[86] Thus, to the extent that the wellness organization's device is similar to the device already regulated by the FDA, the new device would not qualify as a low risk wellness device exempt from FDA regulation.

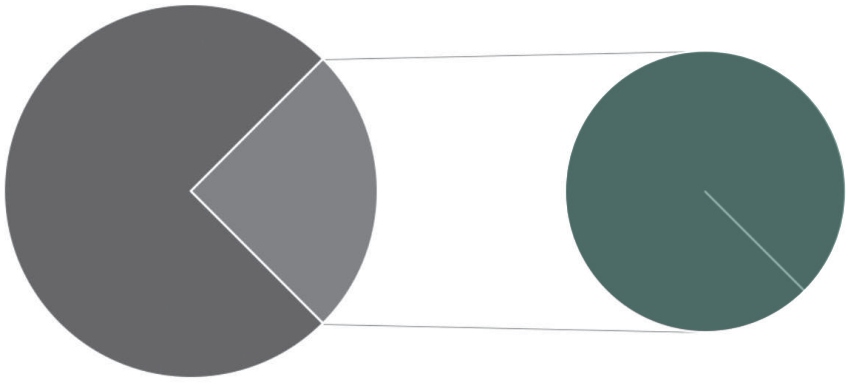
Thus, a product that qualifies as a low risk wellness device is not subject to FDA regulation. The FDA does not intend to examine these low risk products to determine whether they are "medical devices" subject to the FDCA or, if they are devices, whether they are in compliance with the FDCA.[87] As of the date of this article, the author is not aware of any cases or other enforcement action raising the issue of FDA regulation of low-risk wellness devices. Moreover, the Cures Act clarifies that exempt from FDA regulation are any software functions intended "for maintaining or encouraging a healthy lifestyle" and is unrelated to the "diagnosis, cure, mitigation, prevention, or treatment of a disease or condition."[88]

Putting it Together

Wellness professionals and organizations may wonder how the FDA Guidance for Mobile Apps and Guidance for Low Risk Wellness Devices relate. Mobile apps can be a type of low risk wellness device, as shown in the diagram in Figure 1.

So, a wellness professional or organization that uses a mobile app as part of a wellness program should first determine if it is a general wellness product not subject to FDA regulation.[89] If it is determined that the mobile app does not qualify as a general wellness product, then the wellness professional or organization should consult the Mobile Medical Applications Guidance to determine whether the FDCA applies to the app.

Figure 1 – Types of Low Risk Wellness Devices



Conclusion

The use of mHealth in health and wellness programs is evolving, as is the technology of mHealth and the law governing it. The increased reliance on mobile devices as a tool to foster health and reduce the cost of care will likely spur more interest in incorporating mHealth into wellness initiatives of all kinds. On the flip side, organizations that have made their mark in the wellness industry are looking to bring their expertise in health promotion and return on investment to the healthcare delivery space. Wellness organizations, employers who offer wellness programs, healthcare systems, and attorneys need to keep an eye on this changing area of the law.

This article is adapted from the ABA Health Law Section's new book, *Rule the Rules of Workplace Wellness Programs*. The book covers health and workplace wellness, with a focus on the legal and logistic aspects and helping guide the professionals developing legally healthy wellness programs in the workplace. For more information, go to:

https://shop.americanbar.org/eBus/Store/ProductDetails.aspx?productId=269881753&term=Rule+the+Rules.

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

Endnotes

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25 *Id.* at 1086 (noting that the regulatory language for medical devices and drugs is identical, but that the level of regulation is much less strict for most devices).

26 *Id.*

27 The U.S. agent must either reside in the United States or maintain a place of business in the United States The U.S. agent cannot use a post office box as an address. The U.S. agent cannot use just an answering service. The agent must be available to answer the phone or have an employee available to answer the phone during normal business hours. The responsibilities of the U.S. agent are limited and include:

- assisting the FDA in communications with the foreign establishment,
- responding to questions concerning the foreign establishment's devices that are imported or offered for import into the United States,
- assisting the FDA in scheduling inspections of the foreign establishment, and
- if the FDA is unable to contact the foreign establishment directly or expeditiously, the FDA may provide information or documents to the U.S. agent, and such an action

continued on page 46

continued from page 45

shall be considered to be equivalent to providing the same information or documents to the foreign establishment.

Please note that the U.S. agent has no responsibility related to reporting of adverse events under the Medical Device Reporting regulation (21 C.F.R. Part 803), or submitting 510(k) Premarket Notifications (21 C.F.R. Part 807, Subpart E). *See* U.S. Food & Drug Fact Sheet, Medical Devices – U.S. Agents (Sept. 5, 2017), available at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053196.htm.

28 U.S. Food and Drug Administration, Overview of Device Regulation, Fact Sheet (August 14, 2015) available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ (last visited November 2, 2017) (citing 21 C.F.R. Part 807).

29 *Id.*

30 Larry Kessler and Philip J. Phillips, Public Health Effectiveness of the FDA 510(k) Clearance Process: Balancing Patient Safety and Innovation: Workshop Report, App. C, Nat'l Academies Press (2010), available at https://www.ncbi.nlm.nih.gov/books/NBK209796/ (last visited Oct. 31, 2017).

31 U.S. Food and Drug Administration, Overview of Device Regulation, Fact Sheet, note 28, *supra* (citing 21 C.F.R. Part 807, Subpart E). The FDA may charge a fee for medical device Premarket Notification 510(k) reviews. A small business may pay a reduced fee. The application fee applies to Traditional, Abbreviated, and Special 510(k)s. The payment of a premarket review fee is not related in any way to the FDA's final decision on a submission. *Id.*

32 *Id.* (citing 21 C.F.R. Part 814). Medical device user fees apply to original PMAs and certain types of PMA supplements. Small businesses are eligible for reduced or waived fees. *Id.*

33 *Id.* (citing 21 C.F.R. Part 812). Under FDA regulations, an IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights, safety and welfare of human research subjects. U.S. Food & Drug Administration Fact Sheet, IDE Institutional Review Boards (IRB) (June 26, 2014), available at https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/investigationaldeviceexemptionide/ucm046745.htm.

34 U.S. Food and Drug Administration, Overview of Device Regulation, Fact Sheet, note 28, *supra* (citing 21 C.F.R. Part 820).

35 *Id.* (citing 21 C.F.R. Part 801).

36 *Id.* (citing 21 C.F.R. Part 803).

37 Stephen McInerney, note 19, *supra*, at 1073, 1086.

38 *Id.*

39 Cortez, The Mobile Health Revolution, 47 U.C.D.L. Rev., at 1201.

40 *Id.*

41 Cortez, The Mobile Health Revolution, 47 U.C.D.L. Rev., at 1201-02.

42 *Id.* at 1087, 1201.

43 McInerney, Can You Diagnose Me Now?, at 1087.

44 *Id.*

45 *Id.*

46 Adam Candeub, Digital Medicine, the FDA, and the First Amendment, 49 Ga. L. Rev. 933, 944 (2014-2015).

47 McInerney, Can You Diagnose Me Now? at 1087.

48 *Id.*

49 *Id.* (citing Medical Device Amendments of 1976, Pub. L. No. 94-295, § 518).

50 *Id.* at 1087-88.

51 *Id.* at 1088.

52 *Id.*

53 Lars Noah, Governance by the Backdoor: Administrative Law(lessness?) at the FDA, 93 Neb. L. Rev. 89, 94 (2014-2015); 21 U.S.C. § 371(e).

54 Noah, Governance by the Backdoor at 94-95; 21 U.S.C. § 371(a).

55 Noah, Governance by the Backdoor at 94-95.

56 *Id.* at 95.

57 *Id.*

58 *Id.* at 97.

59 *Id.*

60 FDA, Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff (Feb. 9, 2015), note 16, *supra*.

61 *Id.* at 7.

62 *Id.* at 8.

63 *Id.*

64 *Id.* at 13.

65 *Id.*

66 *Id.* at 14-15.

67 *Id.* at 16-18; 23.

68 *Id.* at 13.

69 *Id.*

70 21 C.F.R. Part 820.

71 FDA, Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff, at 20.

72 *Id.* at 20-22.

73 FDA, General Wellness: Policy for Low Risk Devices, Guidance for Industry and Food and Drug Administration Staff (July 29, 2016), available at http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429674.pdf. The FDA is assessing how this Guidance may need to be updated in light of the clarifications in the Cures Act which exclude some software functions from the definition of device. *See* note 16, *supra*.

74 *Id.* at 1-2.

75 *Id.* at 3.

76 *Id.* at 3.

77 *Id.* at 4.

78 *Id.*

79 *Id.* at 4.

80 *Id.*

81 *Id.* at 5.

82 *Id.*

83 *Id.*

84 *Id.* at 6.

85 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm.

86 *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?ID=649.

87 FDA, General Wellness: Policy for Low Risk Devices, Guidance for Industry and Food and Drug Administration Staff, note 73, *supra*, at 2.

88 Pub. L. 114-255, § 3060 (Dec. 13, 2016). As noted in note 16, *supra*, the Act also exempts from FDA regulation software functions intended for administrative support of a healthcare facility, such as financial, billing, scheduling, admissions, data analytics, laboratory workflow, population health management or inventory management, as well as certain electronic patient record software. *Id.*

89 The FDA's 2016 general wellness guidance for industry and FDA staff, note 73, *supra*, contains a decision algorithm to determine whether a mobile app is a general wellness product. The FDA may update this algorithm in light of the Cures Act, which clarifies that certain software functions, such as some related to encouraging or maintaining a healthy lifestyle are exempt from such regulation.