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MOBILE MEDICAL APPS: THE NEW “MEDICAL DEVICES”?

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Overview And Intro

Imagine on your right is a medical device, “A”, used in hospitals to track a patient’s blood oxygenation levels. On your left is a mobile health-based application, “B”, that also tracks a patient’s blood oxygenation levels. Medical device “A” is extremely sophisticated and, unsurprisingly, expensive. Mobile health-based application “B” is portable, convenient, and a fraction of the cost of “A”. Assume that “B”, while lacking some marginal features, still collects and transmits data that is as accurate, complex and as reliable “A”. As a patient, if you required frequent checks of your blood oxygen levels and you were aware that the information required could be obtained either through “A” or “B”, which would you choose? If traveling to a hospital to get a check done frequently were a cumbersome task, you would likely choose the convenience of having that information at your fingertips with “B”. Would your choice be deterred in any way by the fact that the manufacturer of

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“B” had stated that its “intended use” was for sport purposes? Or would that be irrelevant in light of the data provided and its utility?

If most users in the above example would choose to continue relying on mobile health-based application “B” rather than go to the hospital to use medical device “A”, it is imperative that mobile health-based applications such as “B” are properly regulated to minimize public risk. This need is increasingly important as the level of data output from these applications become more refined and more comparable to that of a highly regulated medical device.²

Mobile health-based applications, such as “B” in the above example, are applications that are used by consumers on mobile technologies, such as smartphones, to manage their health.³ These applications are also valuable as they can allow “doctors to diagnose patients with potentially life-threatening conditions outside of traditional health care settings.”⁴ As technology rapidly evolves, more and more high-level applications enter the market, and as a result the potential risk to consumers increases.⁵ In order to address these concerns, the Food and Drug Administration (“FDA”) issued a final guidance addressing this growing area, titled “Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff” (“FDA Guidelines”) in 2013.⁶ Through this guidance, the FDA seeks to target a subset of these mobile health-based applications, known as Mobile Medical Applications (“MMA”), to be subjected to stringent FDA oversight.⁷

² Jeffrey Shuren, M.D., J.D., *Examining Federal Regulation of Mobile Medical Apps and Other Health Software*, U.S. FOOD AND DRUG ADMINISTRATION, (Nov.19, 2013), <http://www.fda.gov/NewsEvents/Testimony/ucm375462.htm> (stating that “[a]n inaccurate or malfunctioning mobile medical app that uses a sensor to diagnose skin cancer or to measure critically low blood oxygen levels in chronic lung disease patients, could delay lifesaving diagnosis and treatment”)

³*Id.*

⁴*FDA Issues Final Guidance on Mobile Medical Apps* (FDA News Release), U.S. FOOD AND DRUG ADMINISTRATION (Sept. 23, 2013), <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm369431.htm> [Hereafter FDA News Release]

⁵ Shuren, *supra* note 1.

⁶ *Id.*

⁷ Food & Drug Admin., Dep't of Health & Human Servs., *Guidance for Industry and Food and Drug Administration Staff on Mobile Medical Applications* (2013) at 8, *available at* <http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf> [hereinafter FDA Guidance]

MMA's are of interest to the FDA as they meet the definition of medical device under Section 201 of the Federal Food, Drug, and Cosmetic Act,⁸ and they are applicaitons “whose functionality could pose a risk to a patient’s safety if the mobile app were to not function as intended.”⁹

The FDA’s recently issued guidelines for mobile health-based applications makes a commendable effort in balancing the risk of misuse of such applications with the desire not to stifle innovation in this rapidly growing field.¹⁰ The FDA will focus its oversight on applications that both meet the definition of medical device *and* are intended: (1) “to be used as an accessory to a regulated medical device; or (2) to transform a mobile platform into a regulated medical device.”¹¹ However, failing to classify certain complex mobile health-based applications as MMA's under the current framework, and thereby falling outside the scope of regulation, could increase the risk to public health from potential misuse. By focusing on the stated “intended use” of an application in determining which mobile health-based applications would meet the definition of a medical device,¹² it is possible that the FDA guidance leaves holes for some applications to slip past the regulatory requirements.

As the technology offered on a mobile platforms becomes more advanced, the differences in the function of a regulated medical device and mobile application (whether regulated or not) could become negligible. However, since one of the requirements for an MMA classification requires meeting the definition of a medical device, much of whether the application gets classified turns on the “intended use” of the application.¹³ Broadly speaking, if the application does not explicitly state that its intended use is “in performing a *medical device* function,” it is unlikely to fall into the

⁸ Shuren, *supra* note 1.

⁹ FDA Guidance at 4

¹⁰ Shuren, *supra* note 1.

¹¹ FDA Guidance at 12.

¹² *Id.* at 8.

¹³ *Id.*

classification of an MMA,¹⁴ so classification depends on how the manufacturer decides “to label, promote or use[]” the application.¹⁵ In effect, there may be a risk of a manufacturer releasing an application that performs high-level medical analysis and therefore avoids the FDA regulatory framework by simply stating that the application is not intended for medical uses, as demonstrated in the opening example. This may be a tempting option as the required premarketing and post-marketing regulatory controls by the FDA can be costly for those that would be required to go through such oversight.¹⁶

Questions as to the implications of the FDA guidelines are further complicated by the Affordable Care Act’s provision instituting a 2.3% excise tax on devices meeting the definition of “medical device” under FDA classifications (“Medical Device Tax”).¹⁷ Therefore, as the scope of the “medical device” definition expands to include MMAs, the possible implications of the Medical Device Tax on these apps come into question.¹⁸

Part I of this note will provide an overview of the FDA regulation of mobile health-based applications as it currently stands, while Part II will address current weaknesses in this regulation as a result of the focus on a manufacturer’s stated “intended use”. Part III will propose a new standard for the FDA’s regulation of mobile health-based applications to provide a solution to the gap that exists in the current regulatory standard as noted in Part II. Finally, Part IV will provide a cursory examination of the implications of the Medical Device Tax as it pertains to the FDA’s recently expanded scope of the medical device definition.

¹⁴ *Id.*

¹⁵ Catherine Barrett, *FDA Applies a Risk-Based Approach to Regulating Mobile Apps*, ABA HEALTH ESOURCE, Volume 10 Number 2 (Oct. 2013), http://www.americanbar.org/content/newsletter/publications/aba_health_esource_home/aba_health_law_esource_13_10_barrett.html.

¹⁶ Anna Edney, *FDA Regulators Eye Medical Apps for Mobile Devices*, BLOOMBERGBUSINESSWEEK, (Sept. 26, 2013), <http://www.businessweek.com/articles/2013-09-26/fda-regulators-eye-medical-apps-for-mobile-devices> (claiming that “[p]ursuing FDA approval can cost tens of thousands of dollars and consume several months or even years.”)

¹⁷ I.R.C. §4191 (2012).

¹⁸ Barrett, *supra* note 12.

Part I: Overview Of The FDA Guidelines

As of recent FDA regulations, section 201(h) of the Federal Food, Drug, and Cosmetic Act's definition of medical devices will soon encompass certain mobile medical applications.¹⁹ In order to better understand the impetus behind the FDA's decision to regulate certain mobile medical applications, it is helpful to gain an understanding of the growth of this booming area. Due to the ease of use of the mobile platform, and the rapidly evolving technology in this area, more and more consumers and medical professionals utilize mobile applications in every day transactions.²⁰ It is estimated that in 2015, almost 500 million smartphone users will utilize a health care application in some manner, and it is estimated that in just three years, "50 percent of the more than 3.4 billion smartphone and tablet users will have downloaded mobile health applications."²¹

With such rapid growth and relative ease of use, the potential for error in the absence of regulation could be high, and could result in an increased risk to the public. While society recognizes and commends innovation and ever-changing technology, innovation must be balanced with oversight to ensure "reasonable assurance of safety and effectiveness."²² As a result of these concerns with mobile health-based applications, the FDA released final guidelines in 2013 to clarify the agency's current thinking regarding mobile medical applications.²³

The purpose of the FDA's current regulation is to create appropriate regulatory oversight for mobile health-based applications that carry high possibilities of risk if misused.²⁴ Since only those mobile health-based applications that pose the highest risks will be targeted, only a few applications will meet the definition of "Mobile Medical Applications" and will be subject to these regulations.²⁵

¹⁹ Shuren, *supra* note 1.

²⁰ FDA News Release, *supra* note 2.

²¹ Raif-Gordon Jahns, *500m People Will be Using Healthcare mobile Applications in 2015*, RESEARCH2GUIDANCE (Nov. 10, 2010), <http://research2guidance.com/500m-people-will-be-using-healthcare-mobile-applications-in-2015/>

²² Shuren, *supra* note 1.

²³ FDA Guidance at 4.

²⁴ *Id.*

²⁵ *Id.* at 8.

In addition, while some applications could potentially meet the definition of medical device, the application may not face FDA oversight if it poses a low level of risk.²⁶

The FDA's focus in this guidance is on "mobile apps that are medical devices and whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended."²⁷ Such an application, the MMA, is "a mobile app that meets the definition of device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and either is intended to be used as an accessory to a regulated medical device; or to transform a mobile platform into a regulated medical device."²⁸ This transformation can be made through the use of sensors, display screens and similar attachments.²⁹ Section 201(h) defines a device as "[A]n instrument, apparatus, implement, . . . 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, in man. . . or intended to affect the structure or any function of the body of man."³⁰ In addition, this section also provides that if the product meets the definition of a medical device, it will be subject to pre- and post-marketing regulatory controls by the FDA.³¹

As the range of mobile health-based applications vary significantly, the FDA utilizes a risk-based approach in order to classify the increasing numbers of mobile health-based applications, from "Class III (high-risk) to Class I (low-risk)".³² The first group of mobile health-based applications, known as Class I, are largely informational, and or administrative,³³ and offer little to no interaction with the user. This would include applications that "display, store, or transfer medical

²⁶ *Id.* at 4 (stating that "some mobile apps may meet the definition of a medical device but because they pose a lower risk to the public, FDA intends to exercise enforcement discretion over these devices (meaning it will not enforce requirements under the FD&C Act).

²⁷ *Id.* at 4.

²⁸ *Id.* at 7.

²⁹ *Id.* at 13.

³⁰ 21 U.S.C. §321(h)

³¹ Barrett, *supra* note 12.

³² FDA Guidance at 6.

³³ *Id.* at 21.

device data in its original format,” since they merely act as a secondary display to a regulated medical device.³⁴ These low-risk applications would only be subject to general controls, such as “adequate design controls, registration, device listing, adverse event reporting, and corrections and removals.”³⁵ The second classification of applications, Class II, do not pose great enough risk to require stringent regulations even though they may possibly meet the definition of a medical device.³⁶ These applications range from utilizing video features to encouraging physical therapy at home, to applications that allow asthmatics to track inhaler usage.³⁷ Those classified in this second group are mobile health-based applications for which the FDA will exercise enforcement discretion.³⁸ Within this group, mobile health-based applications that allow users to track and make behavioral decisions regarding their wellness would be subject to FDA enforcement discretion only if they are intended for use in the diagnosis, mitigation, and prevention of disease.³⁹ The final subset, Class III, is for those determined to be MMAs that pose the highest-risk and are the focus of the FDA guidance document.⁴⁰

MMAs in this target group are further divided into three groups:

[1] Mobile apps that are an extension of one or more medical devices by connecting to such device(s) for purpose of controlling the device(s) or displaying, storing, analyzing, or transmitting patient-specific medical device data . . . [2] Mobile 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 . . . [3] mobile apps that become a regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations.⁴¹

Examples of MMAs included in the first grouping include those that use tools within the platform to conduct diagnostic hearing evaluations, MMAs that use an attachment to test for blood

³⁴ *Id.* at 14.

³⁵ *Id.*

³⁶ *Id.* at 23.

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.* at 24 n.32.

⁴⁰ *Id.* at 26.

⁴¹ *Id.* at 15.

oxygen saturation for the purpose of diagnosis, and MMAs that use attachments to measure blood glucose levels. The second grouping are MMAs “that control the operation or function (e.g., change settings) of an implantable or body worn medical device.”⁴² This group includes MMAs that control settings of infusion pumps, MMAs that act as remote controls for X-Ray machines, and those that control settings of cochlear implants.⁴³ Examples of MMAs falling within the final category include those apps that connect to bedside monitors and transfer data for patient monitoring, and those that allow for monitoring of the labor process via a connection.⁴⁴

In order to classify the sea of mobile health-based applications, the FDA looks to the “intended use” of the application to determine whether or not it meets the definition of medical device under 201(h).⁴⁵ The FDA seeks out the objective intent of those labeling devices through the examination of various factors, such as labels, advertisements, or statements made by those responsible for the application.⁴⁶ It must also be clarified that the FDA does not regulate the sale of the mobile platform (such as smartphones) or the mobile platform itself, but rather the mobile applications that turn these mobile platforms into medical devices.⁴⁷

Although the guidelines focus significantly on the scope of the FDA’s regulation, the guidelines do not provide an in-depth analysis of how the regulations will actually apply to mobile health-based applications.⁴⁸ Depending on how a mobile health-based application is classified, manufacturers will be subject to the “associated controls established by regulation.”⁴⁹ Class I devices

⁴² *Id.* at 27.

⁴³ *Id.* at 27-28.

⁴⁴ *Id.* at 28.

⁴⁵ *Id.* at 8.

⁴⁶ 21 C.F.R. §801.4.

⁴⁷ FDA Guidance at 8.

⁴⁸ Kyle Pomerleau, *The ACA Medical Device Tax: Bad Policy in Need of Repeal*, TAX FOUNDATION (Apr. 9, 2013) <http://taxfoundation.org/article/aca-medical-device-tax-bad-policy-need-repeal>.

⁴⁹ FDA Guidance at 19.

are subject to General Controls⁵⁰ as stated before, while Class II devices are subject to General Controls, Special Controls, as well as for some, Premarket Notification.⁵¹ Class III devices are also subject to General Controls, but in addition require Premarket Approval.⁵² By looking at examples of current regulations, manufacturers are able to see how their applications will be classified and what submission type is required.⁵³

**Part II: Potential Problem Area Of The FDA Guidelines And The Loophole That
May Result**

As highlighted in the beginning of the note, the FDA's reliance on the "intended use" of a mobile health-based application could result in some high-tech applications avoiding stringent FDA regulations by altering their stated "intended use." Therefore a mobile health-based application, which produces data at a level comparable to a regulated medical device and carries a similar risk from misuse, could avoid the regulations by altering its intended use. As a result, a mobile health-based application that provides the same data as a medical device and has not been regulated could result in an increased risk for the public health. And as more users switch to cheaper, more convenient mobile alternatives, the risks could be aggravated especially if that alternative has not gone through stringent FDA oversight.

The FDA's current regulations look to intended uses, or rather the "objective intent of the persons legally responsible for labeling of devices."⁵⁴ To determine the intended use, the FDA looks to advertisements, labeling, and statements as to whether the application's intended use is for diagnosis, mitigation, and or prevention of the disease.⁵⁵ This is a sound standard for most of the

⁵⁰ General Controls include Quality system regulation, Labeling requirements, Premarket notifications, etc. *See* FDA Guidance at 19.

⁵¹ FDA Guidance at 19.

⁵² *Id.*

⁵³ *Id.* at 29.

⁵⁴ 21 C.F.R. §801.4.

⁵⁵ *Id.*

mobile health-based applications on the market, and an efficient way to curb the risk to the public health. However, a standard that looks mainly to the “intended use,” as provided by the manufacturer, makes it easy for a mobile health-based application to avoid FDA oversight simply by disclaiming the intended use. With the current regulation as is, an application that functions at the same level as a regulated medical device and/or provides the same level of accuracy as a regulated medical device could simply avoid regulation by including a simple disclaimer stating that the application is not intended to be used for diagnosis, but rather for recreational use.

The FDA does provide that if a manufacturer knows that their device is being used for other purposes outside the “intended uses,” the manufacturer must adapt the labeling to reflect this change.⁵⁶ Unfortunately, these safeguards would only prompt action from manufacturers long after the application has entered the stream of commerce and after a significant number of users have begun to use the application in a manner non-compliant with the intended use. This would open the doors to public harm during that period of time.

Part III: Proposed Changes To FDA Regulatory Method- Analysis

The “intended uses” standard, while correctly diverting a majority of mobile health-based applications through the regulatory process, might fail to capture some risky mobile health-related applications in a timely manner. A big problem arises with those high-level mobile health-related applications that potentially evade or postpone a costly regulatory process simply by issuing a disclaimer that the application is not intended for diagnostic purposes. By not taking into consideration the potential risk inherent in the mobile health-based application itself in the initial stages, the FDA is potentially opening the doors to increased risk to the public health. In the

⁵⁶ FDA Guidance at 8 n.5. (quoting that “it may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised” and “if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device...”)

current regime, a manufacturer could disclaim the intended uses of an application even if the data is such that it is clear to a user that the application could be used for diagnostic purposes.⁵⁷ Further, if a physician user knows from experience that the data provided by the mobile health-based application is just as accurate as using a regulated medical device, a medical professional might rely on the application more often due to the ease of use and possibility for remote monitoring.⁵⁸

In lieu of, or in addition to, the “intended use” standard, FDA should introduce a “reasonable end-user standard.” This standard will target those mobile health-based applications that *functionally* fall within the list of FDA regulated MMAs and instead of looking only to the “intended use,” would instead ask whether a *reasonable end-user* would *believe* that the mobile health-based application *could accurately* be used for the same purpose as a regulated medical device.⁵⁹ If the answer is in the affirmative, those mobile health-based applications should also be considered MMAs. Once included within the medical device categorization, the applications would be subject to more stringent regulations⁶⁰ more fitting with the potential risk they pose. This would allow the FDA to capture these mobile health-based applications much earlier and more effectively than the current safeguard that requires the manufacturer to have knowledge of the user’s change in use.⁶¹

There are four possible factors that the FDA could consider to determine how a reasonable end-user interprets the utility of the application, in addition to current indicia such as labeling, advertising, statements, etc. The first is the quality of the data transmitted by the mobile health-based application when compared to a similar, regulated medical device. If the quality were clearly poorer and not as reliable as the regulated device, then the application would not be an issue. An

⁵⁷ *Id.* The guidelines are retrospective in nature as they do not specify how the manufacturer must label depending on the functionality of the mobile health-related application. Rather, the class is determined by how the manufacturer has already labeled the application.

⁵⁸ FDA News Release, *supra* note 3.

⁵⁹ Such as for the diagnosing, mitigation or prevention of diseases.

⁶⁰ Depending on the functionality of the mobile app, it would follow the regulations required for the related product code (Class II, Class III)

⁶¹ FDA Guidance at 8 n.5

example of this is iStethoscope Pro, an application that uses a cell phone's microphone to listen to a user's heart.⁶² While the technology provides the user an opportunity to hear a heartbeat, the low quality as a result of ambient sound⁶³ makes the application a recreational choice to a reasonable end-user. A second factor is whether the claims made by the manufacturer that would lead a reasonable user to believe that the level of sophistication in the data is comparable to that of more advanced/regulated medical devices. This could include statements claiming that the mobile health-based application utilizes the same technology as found in hospitals or the same technology as found in existing regulated devices used to prevent disease. Thirdly, the FDA can look to claims made by the manufacturer that would lead a reasonable medical professional to believe that the application could replace a device utilized in a hospital setting. For example, if the application claims that the data produced can be taken directly to a professional to make a diagnosis, then a reasonable doctor could believe that the application could occasionally replace an existing medical device to get the same reading.⁶⁴ Finally, comparisons between the reported "intended uses" for similarly functioning mobile health-based application across various manufacturers could also signal an unreported intended use.⁶⁵

Part IV: Impact Of Medical Device Tax?

The Medical Device Tax is one of the most hotly debated provisions of the Affordable Care Act ("ACA").⁶⁶ The purpose behind this tax provision was for each industry, in this case the medical device industry, to offset the increased patient volume that they would receive as a result of the

⁶² *Why the iPhone Stethoscope is Just a Toy*, QUICKMEDICAL (Nov. 23, 2010), <http://www.quickmedical.com/blog/post/why-the-iphone-stethoscope-is-just-a-toy.html>.

⁶³ *Id.*

⁶⁴ *See generally* AliveCor, <http://www.alivecor.com/what-is-it>.

⁶⁵ For example if only three out of ten manufacturers have disclaimed a mobile health-based application as not being used for diagnosing purposes, while the other seven manufacturers list a similar product and state that the intended use is for diagnosing purposes.

⁶⁶ Sarah Kliff, *How Obamacare's Medical Device Tax Became a Top Repeal Target*, WASH. POST, Sept. 28, 2013, *available at* <http://www.washingtonpost.com/blogs/wonkblog/wp/2013/09/28/how-obamacares-medical-device-tax-became-a-top-repeal-target/>.

ACA.⁶⁷ The result of this two and three tenths percent (2.3%) tax on sales is expected to generate approximately \$29 billion in revenue over ten years.⁶⁸ Since the tax is an excise tax, and is levied on the manufacturer, the costs will trickle down to the consumer in an increased price per-unit.⁶⁹ This tax, effective as of January 1, 2013,⁷⁰ defines a taxable medical device as “any device, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FFDCA), that is intended for humans.”⁷¹

With the recent changes in the FDA definition of a medical device, the obvious question is how the Medical device tax might impact these new MMAs. While the changes in the definition are within the power of FDA, any questions regarding tax and its implications are within the purview of the Internal Revenue Service (“IRS”).⁷² With the IRS medical tax linking the applicability of the tax to the FDA’s definition of medical devices, there are many possible outcomes for mobile medical applications. Most mobile health-based applications correctly fall outside the FDA’s intended scope of regulation as the applications either do not carry any risk or the risk is too little to require a manufacturer to go through the regulatory process. Therefore, these applications will not be considered a medical device,⁷³ nor will they be subject to the IRS medical device tax. However, the question remains whether MMAs, which do fall within the definition, would be subject to this tax? The answer is likely no.

The Medical Device Tax provides two avenues for exemption from the tax: 1) Specific Exemptions and 2) Retail Exemptions.⁷⁴ Specific Exemptions include certain items used for medical

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ Pomerleau, *supra* note 47.

⁷⁰ I.R.C. § 4191-1(g).

⁷¹ I.R.C. § 4191-2(a).

⁷² Statement by Christy Foreman (FDA) before the House of Representatives.

⁷³ FDA News Release, *supra* note 3.

⁷⁴ I.R.C. § 4191-2(b).

purposes that do not fall under the definition of taxable medical device.⁷⁵ These items include eyeglasses, contact lenses, and hearing aids.⁷⁶

A second avenue is the multi-factor Retail Exemption that exempts “any device that is generally purchased by the general public at retail for individual use.”⁷⁷ In order to fall under this exemption, it must be shown that the device is *both* “regularly available for purchase and use by individual consumers who are not medical professionals, *and* [that] the device’s design demonstrates that it is not primarily intended for use in a medical institution of office, or by a medical professionals.”⁷⁸

The IRS utilizes a facts-and-circumstances test to determine whether the retail exemption applies under the Medical Device Tax.⁷⁹ There are three factors used to determine whether a device meets the first requirement, that it is regularly available for purchase and use by individual consumers and not medical professionals. The first factor looks at the ease with which the consumer can purchase the device, including if it is available for purchase in person, online, or retail outlets.⁸⁰ The second factor looks at how easily the consumer can use the device with little or no medical training or supervision.⁸¹ The final factor is “whether the device is classified by the FDA under Subpart D of Title 21 and Part 890 of the Code of Federal Regulations (Physical Medicine Devices).”⁸² Devices classified as Physical Medicine Devices under this section include canes,⁸³ crutches,⁸⁴ slings,⁸⁵ wheelchairs,⁸⁶ and similar devices.

⁷⁵ *Id.* § 4191-2(b)(1).

⁷⁶ *Id.*

⁷⁷ *Id.* § 4191-2(b)(2).

⁷⁸ *Id.* (emphasis added).

⁷⁹ GRANT THORNTON, TAX INSIGHTS, , 2 (Dec. 11, 2012), *available at* http://www.grantthornton.com/staticfiles/GTCom/Tax/TF_TLU_TPU%20files/Tax_Insights_2012-14_final_MDET_regulations.pdf.

⁸⁰ I.R.C. § 4191-2(b)(2)(i)(A).

⁸¹ *Id.* § 4191-2(b)(2)(i)(B).

⁸² *Id.* § 4191-2(b)(2)(i)(C).

⁸³ 21 C.F.R. § 890.3075.

⁸⁴ 21 C.F.R. § 890.3150.

Five factors must be weighed to meet the second requirement of the Retail Exemption, which requires that the device is not primarily intended for use by either a medical institution or a medical professional.⁸⁷ The first factor looks at whether the device is one that must be administered by a medical professional.⁸⁸ The second factor looks at how costly the initial and on-going investment is for the consumer, and whether it is unaffordable to the average consumer.⁸⁹ The third factor looks at whether the device is a Class III device as per FDA classifications.⁹⁰ The fourth factor asks whether the FDA classifies the device under specific sections of Title 21 of the Code of Federal Regulations, including cardiovascular devices, dental devices, and obstetrical and gynecological devices.⁹¹ Finally, the fifth factor asks whether the device “qualifies as a durable medical equipment . . . and supplies for which payment is available exclusively on a rental basis under the Medicare Part B payment rules, and is an item requiring frequent and substantial servicing.”⁹² In analyzing whether a device should be exempted from the tax, the IRS looks to totality of circumstances and overall balance of the factors.⁹³ Additionally, whether or not a device requires a prescription does not play a part in the balance.⁹⁴

The Safe Harbor provision provides another means to show that a device falls under the Retail Exemption.⁹⁵ The provision lists devices that are automatically exempt without the need to weigh various factors.⁹⁶ This includes:

[D]evices identified in the FDA’s IVD Home Use Lab Tests (Over-the-Counter Tests) database; devices described as “OTC” or “over the counter” devices in the

⁸⁵ 21 C.F.R. § 890.3640.

⁸⁶ 21 C.F.R. § 890.3850.

⁸⁷ I.R.C. § 4191-2(b)(2)(ii).

⁸⁸ *Id.* § 4191-2(b)(2)(ii)(A).

⁸⁹ *Id.* § 4191-2(b)(2)(ii)(B).

⁹⁰ *Id.* § 4191-2(b)(2)(ii)(C).

⁹¹ *Id.* § 4191-2(b)(2)(ii)(D).

⁹² *Id.* § 4191-2(b)(2)(ii)(E).

⁹³ *Id.* § 4191-2(b)(2).

⁹⁴ *Id.*

⁹⁵ *Id.* § 4191-2(b)(2)(iii).

⁹⁶ GRANT THORTON, *supra* note 78.

relevant FDA classification regulation heading; devices described as “OTC” or “over the counter” devices in the FDA’s product code name, the FDA’s device classification name or the “classification name” field in the FDA’s device registration and listing database; and certain devices that qualify as durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) for which payment is available on a purchase basis under Medicare Part B payment rules.⁹⁷

The IRS provides various examples to illustrate how the Exemption would work in practice. For example, a blood glucose monitor, that is categorized as a medical device under FDA definitions, would fall under the Retail Exemption since it is included within FDA’s online IVD Home Use Lab Tests database.⁹⁸

Applying the Retail Exemption factors listed above, it is likely that many mobile health-based applications, especially those classified as Class I or Class II applications, will easily fall under the broad Exemption. A simple Internet search or glimpse through an application store will reveal that many, if not all, mobile health-based applications are readily available and easy to purchase.⁹⁹ Secondly, most mobile health-based apps are designed with the user in mind, and are aimed at allowing the user to take control of their health.¹⁰⁰ Therefore, consumers would be able to use the application without any supervision from a medical professional. Finally, mobile health-based applications would not be classified as physical medical devices, as listed above, by the FDA purely as a result of their nature. Therefore, most mobile health-based applications would likely meet the first requirement of the Retail Exemption.

While the second requirement of the Retail Exemption requires more in-depth analysis than the first, the end result will likely be the same: that most if not all mobile health-based applications will meet this requirement as well. First, the ease of purchase for most of these applications indicates

⁹⁷ *Id.*

⁹⁸ *Id.* § 4191-2(b)(2)(iv).

⁹⁹ *See, e.g.*, Medical App Store Downloads, iTunes Preview, <https://itunes.apple.com/us/genre/ios-medical/id6020?mt=8> (last visited Jan. 15, 2015).

¹⁰⁰ *See, e.g.*, Blood Pressure – Smart Blood Pressure (SmartBP) BP Tracker, iTunes Preview, <https://itunes.apple.com/us/app/blood-pressure-smart-blood/id519076558?mt=8> (last visited Jan. 15, 2015) (stating that it is a tool that the user can use to “take a more active role in [his/her] own health”).

they are for use by everyday consumers and do not require administration by medical professionals.¹⁰¹ Even those applications that require attachments to the platform are often designed primarily with the patient user in mind and do not require the application to be administered by a medical professional.¹⁰² Second, many of these applications are one-time purchases at reasonable costs.¹⁰³ Also, given the discussion in the previous section, it is likely that majority of the mobile health-based applications will not be classified as a Class III device, nor as a cardiovascular, dental obstetrical or gynecological device under the third and fourth factors. Under the final factor, a durable medical equipment (“DME”) is purchased or rented equipment that is used in the patient’s home, and includes wheelchairs, hospital beds, catheters, etc.¹⁰⁴ Therefore, most apps would fall outside this definition. However, DMEs also include blood glucose monitors, so mobile health applications that provide such function may fall under this definition.¹⁰⁵ But since the eligibility for the Retail Exemption is determined by looking at the totality of the circumstances,¹⁰⁶ even an application that acts as a blood glucose monitor, if successfully meeting the other factors, would likely still meet the exemption. In addition, even if the Retail Exemption were not met, the Safe Harbor provision would likely provide an additional avenue for exemption for applications that act as blood glucose monitors as blood glucose monitors are included by the FDA in the IVD Home Use Lab Tests (over-the-counter tests) database, and therefore fall within the Safe Harbor.¹⁰⁷

¹⁰¹ *Id.*

¹⁰² *See e.g.*, AliveCor, <http://www.alivecor.com/home> (last visited Jan. 15, 2015) (although data can be sent to a medical professional to give them up-to-the-minute data on a patient’s ECG, the administration is done by the patient user).

¹⁰³ *See generally* Medical App Store Downloads, *supra* note 98; *See e.g.*, AliveCor *supra* note 101. (majority of the medical apps in the iTunes store are either free or at a cost less than twenty dollars. In addition, even apps that have external components, the component cost is typically reasonable at less than one hundred dollars.)

¹⁰⁴ 42 U.S.C. § 1395x(n).

¹⁰⁵ *See, e.g.*, iBGStar Blood Glucose Meter, MyStar Sanofi Diabetes, <http://www.mystarsanofi.com/web/products/glucometers/ibgstar> (last visited Jan. 15, 2015).

¹⁰⁶ I.R.C. § 4191-2(b)(2).

¹⁰⁷ *Id.* § 4191-2(b)(2)(iv) (stating in Example seven that blood glucose monitors are included in the IVD Home Use Lab Tests and are considered over-the-counter. In addition, the monitors fall within the safe harbor as found under § 4191-2(b)(2)(iii)(C)).

While most mobile health-based applications would likely not even meet the medical device definition necessary for the tax to apply, in the event an application did, the application would likely qualify for an exemption. However, the handful that of applications that would fall under the medical device definition as of the new FDA regulations may arguably be subject to the tax. For example, MMAs that connect to devices in a hospital setting for the purposes of control, and therefore fall under the medical device definition set by FDA, would possibly fall within the purview of the Medical Device Tax.¹⁰⁸ These would likely not fall under the Retail Exemption, as they are likely to require, at a minimum, some level of oversight, training¹⁰⁹ and administration by medical professionals.¹¹⁰

Part V: Conclusion

The FDA has the authority under the Federal Food, Drug and Cosmetic Act of 1938¹¹¹ to regulate the drugs, medical devices, “most of our nations food supply, all cosmetics, dietary supplements, products that give off radiation” and tobacco in the interest of public health.¹¹² They are the responsible agency that oversees the “safety, effectiveness, quality and security” of these products, and ensures that best efforts are made to protect the public.¹¹³ Comprehensive and effective guidelines and thorough regulatory controls are some ways in which the FDA polices these products and protects the public.¹¹⁴ The recently issued “Mobile Medical Applications” guideline was an attempt to inform those in the mobile health-based application industry of the FDA’s current stance on the matter.¹¹⁵ As discussed in this note, many mobile health-based applications will

¹⁰⁸ FDA Guidance at 6.

¹⁰⁹ I.R.C. § 4191-2(b)(2)(i)(B).

¹¹⁰ *Id.* §4191-2(b)(2)(ii)(A).

¹¹¹ Regulatory Information, U.S. Food and Drug Administration, <http://www.fda.gov/RegulatoryInformation/Legislation/default.htm>.

¹¹² About FDA, U.S. Food and Drug Administration, <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm192695.htm>.

¹¹³ *Id.*

¹¹⁴ FDA Guidance at 6.

¹¹⁵ *Id.* at 5.

successfully move through the regulatory process regardless of the risk level; with the low risk applications requiring only general controls to high-risk Class III applications following a more stringent route of oversight. However, given the subtleties and vagueness in the regulation language and the ease with which a manufacturer could minimize the risk of qualifying as a Class III application by altering the “intended use,” some risk-producing applications may fall through the cracks, at least for period of time.¹¹⁶

The FDA mobile medical application regulation is still in its early stages. The true successes and failures of this will likely not be apparent for months. However, since the FDA has left open the option to amend the language in this directive,¹¹⁷ there is still an opportunity to address any concerns of risk to the public due to applications whose actual use and “intended use” do not match. Using the “reasonable end-user standard,” the FDA would capture more potentially risky applications under its authority than it would have previously. In addition, this proactive approach would allow the controls and changes to occur before a significant amount of product use by the consumer, rather than the current solution that requires amendments after the damage has already been done. The main downside to this proposed standard is that it would require more resources than the current standard since it is more proactive, and would likely capture applications to evaluate through the regulation’s framework. But as mobile health-based applications become more and more sophisticated, perhaps the benefits of this framework would outweigh the costs associated with the additional resources.

While it is likely that mobile health-based applications, including MMAs, will not be impacted by the tax, the increased tax revenues can be utilized, at least in part, for better enforcement of these public safety measures. Mobile applications are unique in their widespread use,

¹¹⁶ *Id.* at 8 n.5. The current guidance as it stands does have safeguards to prevent manufacturers from mislabeling, but would likely only capture these applications long after it has reached the stream of commerce and many users have already used it.

¹¹⁷ *Id.* at 4-5.

rapid development, and ease of accessibility¹¹⁸ and could pose difficulties in articulating standards that adequately control all applications. While the FDA makes commendable efforts in regulating this ever-changing area, these regulations will need to continue to evolve as the mobile health-based applications continue to evolve.

¹¹⁸ Shuren, *supra* note 1.