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VIA ELECTRONIC SUBMISSION

Division of Dockets Management (HFA– 305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA–2011–N–0090: Food and Drug Administration Unique Device Identification System; Proposed Rule

Dear Sir or Madam:

The mHealth Regulatory Coalition ("MRC" or "Coalition") appreciates the opportunity to comment on the proposed rule that the Food and Drug Administration ("FDA" or "Agency") has published for the Unique Device Identification ("UDI") System.[1] While we recognize the significant value that the UDI System may have for public health, we encourage that the Agency consider the impact of the proposed rule on the mobile health ("mHealth") industry. We offer our comments in hopes that the final rule will address the concerns of this unique and nascent industry, which is set to revolutionize the delivery of healthcare in America.

The mHealth Regulatory Coalition

The MRC represents the heterogeneity of the stakeholders in the mHealth ecosystem, consisting of non-governmental, industry representatives; nonprofit associations; healthcare payors; and individual as well as integrated healthcare providers. Industry members include traditional medical device manufacturers, mobile app developers, online marketplaces for mobile apps, mobile platform manufacturers, telecommunications service providers, and information and communications technology companies, such as:[2]

[1] Unique Device Identification System, 77 Fed. Reg. 40,736 (July 10, 2012), *available at* http://www.gpo.gov/fdsys/pkg/FR-2012-07-10/pdf/2012-16621.pdf [hereinafter UDI Proposed Rule].

[2] This list does not include the names of individual members who are not associated with a specific organization.

- AgaMatrix
- AT&T
- Continua Health Alliance
- Ideal Life Online
- Great Call
- MedApps
- Medical Graphics Corp.
- Medical Imaging & Technology Alliance (MITA)
- OmniScience Mobile
- Partners/Ctr. for Connected Health
- Philips
- Qualcomm Inc.
- Roche
- Verizon Wireless
- View720.com
- Voxiva, Inc.
- WellDoc, Inc.

The purpose of the Coalition is to propose a means by which FDA can tailor and apply its existing regulatory framework to mHealth technologies. To achieve this goal, the MRC spent nearly two years identifying the challenges with the existing regulatory scheme and developing a proposed guidance document—which we submitted to FDA in October 2011—that describes the approach FDA should take in defining what types of mHealth products should be regulated and at what classification.[3]

Specific Comments on the UDI Proposed Rule

The Coalition recognizes the value that the proposed rule would have on the medical device industry. Indeed, we believe that a properly implemented UDI System has the potential to reduce medical errors, provide for rapid identification of device-related adverse events and solutions to reported problems, promote rapid and efficient resolution of device recalls, enable targeted and effective FDA safety communications, and improve access to device identification information.[4] Furthermore, we agree with the Agency that the burdens of the proposed rule must be minimized, with the regulatory requirements becoming effective over time based on risk.[5]

Despite the merits of the proposed rule, there are a number of aspects that impact the mHealth industry and warrant further consideration. For example, the proposed rule creates a retail exception to the general rule that "[t]he label of every medical device shall bear a unique device identifier . . . ."[6] More specifically, the retail exception applies to "[a] device, other than a prescription device, that is made available for purchase at a retail establishment."[7] As the proposed rule states: "This exception shall also apply to such a device when delivered directly to a hospital, ambulatory surgical facility, nursing home, outpatient treatment facility, or other health care facility."[8]

The Coalition supports the retail exception, yet requests that the Agency provide clarity as it relates to mHealth technologies. For example, it is unclear whether mobile medical apps sold via an online marketplace constitute devices sold at retail. FDA should clarify that the exception in the proposed § 801.30(a) includes apps that are purchased by the end user via online marketplaces. Online marketplaces have the unique ability to remove an app from distribution and replace it with an updated version by deleting or updating a single instance of the app. This model arguably provides a more efficient and effective system to remove defective products from the market and rapidly resolve product recalls. Similarly, mobile medical apps that are targeted for use by physicians, nurses, and other

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[3] *See* Letter from Bradley Merrill Thompson on behalf of the mHealth Regulatory Coalition to Bakul Patel, Policy Advisor, U.S. Food & Drug Admin. (Oct. 19, 2011), *available at* http://www.regulations.gov/#!document Detail;D=FDA-2011-D-0530-0082.

[4] UDI Proposed Rule, *supra* note 1, at 40,737.

[5] *Id.* at 40,744.

[6] *Id.* at 40,769.

[7] *Id.* at 40,770.

[8] *Id.*

healthcare providers should fall within the "delivered directly to a hospital" exception despite the fact that delivery might occur outside of the physical healthcare facility.

In addition to the retail exception, the Coalition supports FDA's proposed exception for Class I devices that are exempt from the good manufacturing practice ("GMP") requirements under 21 C.F.R. Part 820,[9] providing a tuning fork, an elastic bandage, an examination gown, a bedpan, and a manual toothbrush as examples of devices that meet this exception.[10] However, these examples are rather limited in scope[11] and do not take into consideration a realistic representation of all Class I devices, some of which are low-risk but not exempt from GMP. These include mHealth products that in those cases warrant manufacturers to establish and follow stringent quality systems to ensure their products meet applicable requirements and specifications. One such device type is the Medical Device Data System ("MDDS")—a Class I medical device that is subject to GMP requirements.[12] FDA should specifically exempt MDDS devices from the UDI rule, particularly hardware and software (e.g., cloud-based applications and their related server systems) that are not accessible by the end user. There are other low risk mHealth device types that should be similarly exempt.[13] The MRC has previously proposed classification regulations for such products and we encourage the Agency to move toward implementation of those classification regulations for low-risk mHealth technologies, specifically identifying those products as exempt from the UDI proposed rule.

Another aspect of the proposed rule that is particularly important to the mHealth industry is the direct marking requirement for stand-alone software. The proposed rule states that "[a] device that must be labeled with a . . . UDI . . . must also bear a permanent marking providing the UDI on the device itself if the device is . . . [s]tand-alone software."[14] The proposed rule requires all stand-alone software to contain "[a]n easily-readable plain-text statement displayed whenever the software is started" or in response to a menu command (e.g., an "about" menu).[15] Each version of the software must contain a unique identifier.[16]

This requirement may prove to be rather burdensome for the mHealth industry, where software updates occur frequently. As such, it is important that FDA describe when such changes would warrant a new version (i.e., a new UDI). FDA provides some examples, including when a change has the potential to affect the safety or effectiveness of the device.[17] The term "potential" is too ambiguous and should be replaced with terminology used for determining when a modification warrants a new 510(k) submission.[18]

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[9] *Id.*
[10] *Id.* at 40,749–50.
[11] FDA confusingly points to references 9 and 10 as the source of a list of product codes that would fall within this exception. *See id.* at 40,750 (referring to "Ref 10"), 40,766 (referring to "Ref 9"). Reference 9 is described as "List of class I devices, by product code, that FDA has by regulation exempted from the GMP requirements of 21 CFR part 820, Quality Systems Regulation, FDA, April 2012." *Id.* at 40,768. This reference is insufficient for the public to access the list of product codes that would be subject to the proposed exception.
[12] 21 C.F.R. § 880.6310.
[13] One example is a light emitting diode (LED) mobile app intended for use as a light source to examine patients.
[14] UDI Proposed Rule, *supra* note 1, at 40,771.
[15] *Id.*
[16] *Id.* at 40,775.
[17] *Id.* at 40,755.
[18] *See* Letter from Director, Office of Device Evaluation to ODE Review Staff, U.S. Food & Drug Admin. (Jan. 10, 1997), *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm

Furthermore, FDA should clarify when software would be subject to the UDI requirement. The proposed rule states that software that is not stand-alone, but is a component of a medical device would not require direct marking.[19] FDA does not define the term *stand-alone software*,[20] instead indicating that "[e]xamples of a software device that is not stand-alone include software incorporated into devices such as infusion pumps and software integrated and used to control systems such as MRI machines."[21] This approach to the distinction between a component and software that is subject to the UDI rule is simply insufficient to inform the public of when the UDI requirement applies.

Consider, for example, a mobile medical app that transmits ECG data and rhythm strip obtained wirelessly from a separate Holter monitor. Such an app could be regulated as either stand-alone software or as a component of the Holter monitor. Put another way, the app may not function independently of the Holter monitor, but the Holter monitor may be able to function without the app. In this way, the mobile app is neither stand-alone nor a component. Depending on its regulatory status, the smartphone app may or may not have a UDI separate and apart from the Holter monitor. FDA should, therefore, clarify the regulatory status of the app in this example (and similar scenarios) and explain when a change in the connected medical device would cause a change in the UDI for the app.

Finally, the FDA proposed to require a UDI for convenience kits and each device within the kit.[22] Convenience kits may become quite common in the mHealth space, as the use of various independent products (both medical devices and non-medical devices) may be co-packaged for the benefit of the consumer. The current convenience kit guidance[23] was published more than 15 years ago before the Internet and smartphones became commonly available. FDA should update the convenience kit guidance and establish its convenience kit regulation in order to provide adequate clarity as to the applicability of the UDI rule to convenience kits.

For these reasons, we encourage the Agency to consider the impact of the UDI rule on mHealth technology. Please do not hesitate to contact me if you have any questions or concerns.

Sincerely,

Bradley Merrill Thompson
On Behalf of the mHealth Regulatory Coalition

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[19] UDI Proposed Rule, *supra* note 1, at 40,771.
[20] *Id.* at 40,766.
[21] *Id.* at 40,753.
[22] *Id.* at 40,769–70.
[23] *See* Convenience Kits Interim Regulatory Guidance, U.S. Food & Drug Admin. (May 20, 1997), *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080216.htm