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HIMMS, Chronic Care Management, and the Top 5 Overlooked Items

March 20, 2018 – Dorsey Health Law
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Harnessing existing digital health solutions to improve chronic care management was a prominent topic at HIMMS this year (amongst many others, including AI and cybersecurity, both of which we will cover in upcoming blog posts). While this is not a new topic, it was particularly "buzzy" this year due to the ever-increasing number of large technology and wearables vendors entering the healthcare space, and as medical device manufacturers look to pair services with their existing devices. Chronic care management, as its name denotes, involves higher-touch and *ongoing* communication between the patient and the provider. Since digital health solutions are a cost-effective means to connect patients and providers, and because providers can use them to reach patients at home to help correct behaviors that contribute to or ameliorate chronic conditions, digital health solutions hold great promise as an effective chronic care management tool – and, indeed, as HIMMS this year made apparent, digital health solutions are poised for exponential growth. As with any relatively new field, however, we have noticed that certain key issues tend to be overlooked, often at great cost. Here are the top 5 overlooked issues we have noted:

- **Value proposition in a crowded market:** Make no mistake about it: this is a crowded market with many different *types* of vendors hoping to launch the next big thing in digital chronic care management solutions. So many of the pitch decks and conversations we have been privileged to be a part of tend to focus on the market size in terms of clinical need: that there are X number of patients with Y chronic condition who would welcome Z solution. The mistake, however, is presuming that this suffices to capture attention. The barrier to market entry is relatively low (FDA

considerations, if applicable, notwithstanding!), and the customers – providers and patients – are relatively wary of yet another device, application, or website to manage. Investors and customers alike will ask, what, specifically, is your digital health chronic care solution's real value proposition; what truly differentiates you? Effectively managing a chronic condition is the baseline minimum expectation. You must offer something more.

- **EHR integration – the *how* and where:** Many sellers of digital health chronic care solutions tout the ability of the device or software program to integrate with a provider's EHR and/or with a patient-facing application so that providers and patients can monitor the relevant condition. This is all to the good, as transparent, real-time results are a key facet of chronic care management. The item that is missed, however, is *how* that information will be displayed in the EHR; *where*, exactly, will it appear? Is that in readable and, importantly, *reportable* format for the providers? It does a provider little good if a blood viscosity result appears in the EHR as a pdf attachment that is not searchable as a discrete data element. It is important to ask vendors and potential partners this at the outset, and to obtain the answer in writing.

- **Process flow:** Providers and medical device manufacturers alike are doing a good job of convening clinical experts to discuss particular care needs and associated care management regimen. This is then translated into the digital health offering. What is missed, however, is thinking through the end-to-end process between provider, patient, and both their interactions with the software, to ensure that it's as seamless and hassle-free as possible. Patients who would be, well, *patient* with a clinician who is taking a few extra moments to answer a question would not necessarily be as patient with extra clicks or wait time from a digital health program. Providers, in turn, are looking for the least amount of clicks to enable them to do what they do best: offer the patients helpful advice. Mapping out the *exact* flow of when and how the software – and any integrated devices – will behave, and who is required to do what, is critical.

- **Data ownership and access:** While vendors – medical device and software and analytics alike – race to develop in-house chronic-care solutions, many are looking to partner with providers to provide clinical input and data and to serve as a beta testing and initial customer site. Partnerships are proliferating, and while good attention is paid in the negotiating process to the typical business terms, we have noted that data flow, ownership, and access tends to be a secondary thought. To be clear, HIPAA, privacy, and cybersecurity are still at the front of everyone's minds; however, the operational brass tacks of exactly what data will display where, which party will provide that data, and exactly who will access the data and its derivatives is still oft-overlooked. Just as we recommend process flows from the user-end perspective (see above point), we also have found that data maps are instrumental to a successful partnership. If you have created one for your organization for cybersecurity and breach incident response, you will find that to be a useful starting point; you will then want to discuss and create a new, macro-level flow that reflects the flow across the parties. Then, check with counsel, and ensure that the relevant contracts (e.g., partnership, services, and/or BAA agreement(s)) align with that data map.

- **Licensure – you probably need it:** “Chronic care management” encompasses so many conditions that it can, at times, be used as a marketing lure to sell wellness-related devices and services. Any company that considers itself in the “wellness” sphere and employing people to provide ongoing advice – whether by phone, video, e-mail, or other means – should make a point to check with counsel as to whether professional licensure is required. It does not matter what label you give to those employees (e.g., “coach” vs. “counselor,” or “care guide” vs. “RN”), rather, it matters what type of care is being offered through the digital health solution and what condition(s) it is addressing. A digital health solution that addresses a specific clinical condition is likely one that is regulated, which means that the employees interacting with the patient are also likely to need some form of relevant licensure. This one is a mission-critical ask, so be sure to check with counsel early on (and title your employees correctly on your website and sales materials).

We welcome your suggestions for additional focus topics within this series on digital health-related issues. Please contact Shira Hauschen at Hauschen.Shira@Dorsey.com with any comments, suggestions, or questions.