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Mobile Health
Assessing the Barriers

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Mobile health (mHealth) combines the decentralization of health care with patient centeredness. Mature mHealth applications (apps) and services could provide actionable information, coaching, or alerts at a fraction of the cost of conventional health care. Different categories of apps attract diverse safety and privacy regulation. It is too early to tell whether these apps can overcome questions about their use cases, business models, and regulation.

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ABBREVIATIONS: app = application; EMR = electronic medical record; FDA = US Food and Drug Administration; FTC = Federal Trade Commission; HIPAA = Health Insurance Portability and Accountability Act; mHealth = mobile health; PHR = personal health record

Mobile health (mHealth) promises to be a major force in US health care. Investments in mHealth companies and announcements or rumors of new products from market-leading technology companies continually raise expectations that health care will experience disruption as so many other brick-and-mortar industries have.

In 2013, 95 million Americans used their phones to access health information or use mHealth applications (apps), up 27% from 2012.[1] The US market for mHealth is estimated to reach $6.7 billion in 2014[2] and $49.1 billion in the global market by 2020.[3] As a product category, wearable technologies are expected to grow exponentially from 9.7 million units in 2013 to 135 million in 2018.[4] Not surprisingly, mHealth and wearable technologies businesses are attracting considerable amounts of venture capital

interest,[5,6] with funding in the United States expected to grow from $3.5 billion to $6.5 billion from 2014 to the end of 2017.[7]

The mHealth ideal is very attractive. mHealth promises more personalized, timely interactions with patients. Patients may take more responsibility for their fitness and wellness and become more engaged in their health care. More health care will be delivered away from often inconvenient, centralized locations, and the sophisticated, yet friendly interfaces of mHealth apps should shame traditional health care into improving its processes. There is also some evidence that mHealth may reduce health disparities (or at least not worsen them) due to relative parity in smartphone ownership across black, Latino, and white populations,[8,9] although concerns about the role of socioeconomic status persist.[10,11]

However, any suggestion that mHealth will quickly disrupt traditional health care is naive. Although health care is overdue for a radical rethink, maybe even disruption,[12] mHealth itself faces considerable challenges. This article explains the mHealth landscape and identifies five categories of mHealth apps and discusses their use cases, likely regulation, and some of the financing hurdles they face.

The mHealth Landscape

The concept of digital health has been an increasing trend in health care from traditional health information technologies, such as electronic medical records (EMRs) and telemedicine, to more modern health-care innovations, such as social media interactions. Physicians have long used mobile devices to subscribe to drug interaction applications, and today, they are frequently granted EMR or computerized provider order entry mobile access. Some are even experimenting with innovative wearable technologies such as Google Glass. mHealth is a subset of digital health; its defining characteristic is that it is patient facing. That is, unlike most examples of digital health, patients interact directly with mHealth hardware and software, frequently without the direct involvement of conventional health-care providers.

Typically, mHealth is built on two core components: (1) a platform's hardware and operating system (eg, that found in a modern phone) and (2) the apps that provide fitness, wellness, or any number of other health-related services. In 2014, the number of mHealth apps available for the Apple iOS (Apple Inc) and Android (Google) platforms exceeded 100,000 (having doubled in 2.5 years).[13] Increasingly, the platform-app distinction will blur as platforms are equipped with aggregator apps, such as Apple Health, that pull together data from phone sensor arrays, external biosensors, and other apps.

Two additional technologies feature in the present imagining of mHealth. The first is cloud computing. Mobile apps frequently will store mHealth data in the cloud, and cloud services increasingly will provide the data analytics back end for processing those data. The second is wearables. Currently, fitness bands and exercise monitoring apps dominate this category. They will be joined by more sophisticated biosensors, some of which will be included in watch-like devices.[14] Many phones are equipped with internal sensors, such as microphones, proximity sensors, accelerometers, ambient light sensors, barometers, and gyroscopes. Such phones are not only platforms but also, in a sense, wearables. In 2015, Apple will launch a new category of

wearables called Watch that is equipped with several biosensors.[15] Unlike most wearables, Watch is relatively autonomous and itself a platform that app developers will be able to build out.

Careful attention to legal and, particularly, regulatory issues is recommended because of the complex interaction of state and federal law and the multiplicity of regulatory stakeholders. For example, although US Food and Drug Administration (FDA) regulation covers mHealth manufacturers but not health-care providers, health privacy regulation typically follows an opposite course, applying to health-care insiders but not those who provide mHealth apps and services. Currently, there are five core types of mHealth apps, a taxonomy that is loosely based on the patient-facing categories of mobile apps first published by the FDA in 2013[16]: (1) apps providing access to health records, (2) consumer versions of existing medical devices, (3) condition monitoring and management apps, (4) fitness trackers and wellness coaches, and (5) diagnosis or treatment apps.

Apps Providing Access to Health Records

Providers and health insurers increasingly have been giving patients access to their health records through, for example, web portals such as MyChart (Johns Hopkins Medicine). Many of those initiatives will migrate to apps. For example, health-care providers such as the Mayo Clinic and EMR developers such as Epic Systems Corporation are enabling patients to access their health records through Apple Health.[17]

In 2013, the FDA issued a nonbinding guidance detailing its current regulatory stance on mHealth apps, limiting its scrutiny to "only those 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."[16] The FDA has indicated that apps that enable patient interaction with records will not face device regulation at this time.

In contrast, most records-accessing apps will be subject to health privacy regulation. The records are likely held by Health Insurance Portability and Accountability Act (HIPAA)-covered entities such as hospitals, physicians, and health insurers. App developers will be considered business associates.[18] In such cases, HIPAA's Privacy, Security, and Notification of Breach rules should be applicable. A more nuanced question arises regarding a health data aggregator app such as Apple Health: HIPAA may not apply if data are only stored on the device and the aggregator acts simply as a traffic cop