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Peeling Back the Apple Watch: Do HIPAA and the Apple Watch Go Together?

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One of our more tech-savvy partners recently showed us his new Apple Watch and, instinctively, it raised questions as to how would HIPAA impact its use. Two possible answers exist to explain the rationale for the asking of such a question. The first possible answer is that one's healthcare law practice

has so embedded one's way of thinking that HIPAA concerns arise as one views most issues, or the second possible answer is that the features of this new Apple Watch may be the linchpin to a whole new culture in a mobile health industry.

Time will determine which answer is correct, but the new Apple Watch does possess some interesting features that will, at a minimum, impact the mobile healthcare industry. Along with the Apple Watch, the HealthKit app, which is an application that can be utilized by the Apple Watch and is designed to log one's activity and health data, and the ResearchKit software¹ which launched in April 2015, Apple has introduced some interesting "tools" for the healthcare marketplace for the consumer, for the provider, and possibly for other vendors. In addition to changing the healthcare marketplace, the Apple Watch and these other applications have opened the door to multiple legal issues that will need to be addressed.

Apple Watch (and Related Apps) Promise Opportunities for Consumers

The Apple Watch, launched in April 2015 along with Apple Watch Apps, have garnered much public attention.² The Apple Watch has the technology to track and store information about the activity of the wearer. It can show a person's daily activities, such as the amount of time spent sitting, standing, or moving, and it can provide and display goals, suggestions, and incentives for increased activity. The Apple Watch can also collect workout data, such as a person's heart rate, calories burned, and other exercise-related statistics. The Apple Watch is designed to track activity of the wearer through its own accelerometer and heart-rate monitor, but needs to be paired with an iPhone to track the actual distance one travels.³ In the

future, the Apple Watch may also have additional sensing and tracking capabilities.⁴ Reportedly, some of the initial sensors on the Apple Watch did not work well on people with hairy arms or with dry skin or if the Watch was fastened too loosely.⁵

Like other iPhones or mobile devices, Apple's own HealthKit app, or other apps developed by third party developers, can also be utilized on the Apple Watch. Third party developers have designed many new healthcare apps to work with the Apple Watch or have re-designed old healthcare apps to be compatible with it. The new apps tout the benefits to be offered by having the data available right on the user's wrist, whether the end-user be the healthcare consumer or the healthcare provider.⁶ Several Apple Watch apps are designed to allow the healthcare consumer to track his/her own health and to enhance communication between the consumer and his/her healthcare provider. For instance, Cerner has an app that allows patients to track their own health on their watch and to send the data to their electronic health record.⁷ Similarly, there is an app that is designed to help keep track of one's medication usage.⁸ Yet another app is designed to measure the user's blood glucose levels.⁹

Healthcare Providers May also See Opportunities

Some of the new Apple Watch healthcare apps are designed for use by healthcare professionals and other providers. These devices are designed for rapid provider-to-provider communication and to aid in patient care. Some examples include a secure text messaging system by athenahealth, which has now been made available for the Apple Watch so that providers can communicate and sync data among their devices even more quickly.¹⁰ A Vocera clinical communication app will enable faster provider notification of important information,¹¹ and a Mayo Clinic Synthesis app will be offered that allows providers to view their schedule and basic patient information on their watch.¹² The accuracy and reliability of the measurements and healthcare information obtained from the apps over time will determine if healthcare providers can truly utilize these apps in their practice.

Privacy and Security Issues May Make the Data Vulnerable

The excitement brought to the mobile healthcare industry for consumers and providers through the Apple Watch and the many available or soon-to-be-available apps for it needs to also be met with some concern over the mechanisms in place to protect consumer privacy and especially to protect the consumer's healthcare information. The concerns include the privacy and security of the healthcare information tracked by the Apple Watch and related apps as well as the security and privacy of the storage of that healthcare information. Additional privacy and security issues arise in the transfer of the healthcare information measured by the Apple Watch from the consumer to healthcare providers and other third parties. Finally, concerns exist as to the privacy policies of the multiple third-party app vendors as each vendor has its own privacy policy, and these privacy policies vary from vendor to vendor.

There have been many recent stories in the news concerning breaches of people's private personal information, including healthcare records and health-related information. Many people assume that their healthcare information is protected through federal laws like the Health Information

Portability and Accountability Act of 1996 (HIPAA) or related laws or through the Federal Trade Commission Act (the FTC Act). HIPAA as well as subsequent laws, such as the Health Information Technology for Economic and Clinical Health Act (HITECH), are designed to provide privacy and security protections to an individual's protected health information. The FTC Act, Section 5, prohibits unfair or deceptive acts or practices which affect or impact commerce.¹³ The Federal Trade Commission (FTC) has also actively attempted to regulate patient information or healthcare data and the security practices or safeguards of the companies participating in commerce.¹⁴ In addition, the FTC will take action if an app claims benefits or promises to consumers if such healthcare claims are not based on sound science.¹⁵

Applicability of HIPAA

Interestingly, the application of laws like HIPAA to the Apple Watch and its related apps is not clear. One of the major potential privacy concerns is that current healthcare privacy laws, like HIPAA, do not address healthcare data stored on a consumers' own personal device.¹⁶ The coverage of HIPAA and related laws to the data collected by the Apple Watch depends on who is storing and using the data, as well as to the creation, maintenance, reception and transmission of the data. To the extent that the healthcare data stored on the Apple Watch and used in a health app is "protected health information" and is used by or in the control of a "covered entity" or used by its "business associate," then the framework of HIPAA obligations and restrictions would exist to protect the health data. HIPAA defines a "covered entity" as "(1) health plans, (2) healthcare clearinghouses, and (3) healthcare providers who electronically transmit any health information in connection with a transaction covered by this subchapter [at HIPAA]." ¹⁷ HIPAA defines a "business associate" as "a person who on behalf of such covered entity or of an organized healthcare arrangement in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, creates, receives, maintains, or transmits protected health information for a function or activity regulated by this subchapter" ¹⁸ An example of such a case would be when a user (a patient of Mayo) transmits health data from an Apple Watch or health app to the Mayo Clinic App. At the point the health data is received by Mayo, since Mayo qualifies as a covered entity under HIPAA, then the health data qualifies as protected health information and is HIPAA-protected. Similarly, athenahealth's new text app for the Apple Watch is also promoted as a means for providers to have a more uniform and centralized method of communication that is secure and complies with HIPAA requirements, rather than resorting to a variety of traditional and less secure methods. ¹⁹ Given the number of new health apps that are designed for healthcare professionals and have already been created or are likely to be created in the future for the Apple Watch, it will be important for each covered entity and business associate to understand how HIPAA applies to the design and use of the app and how patient health data is used, maintained and stored.

Another question is whether Apple or other vendors with a role in the app or the storage or transmission of the health data come under the purview of HIPAA as a "business associate." ²⁰ These entities would be considered business associates if they create, receive, maintain, or transmit protected

health information on behalf of a covered entity. The determining factor hinges upon how the health data flows, but if a covered entity provides “the protected health information to a vendor, for claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, patient safety, activities [...], billing, benefit management, practice management, and repricing,” then it is a business associate.²¹ Thus, an app that receives protected health information from a covered entity and then analyzes the data is a business associate and subject to HIPAA.

Questions of the adequacy of privacy controls also arise when the data is simply stored on the user’s wearable or hand-held device, or when the user uploads the data to a third-party health or fitness app that is not covered by HIPAA. It should be noted that Apple has taken some proactive steps to safeguard the privacy of its consumers’ health data. Apple’s HealthKit framework that allows apps to obtain health data from the user’s device has specific privacy parameters in place, but it still raises issues as to the apps with which health information is shared.²² Apple claims that it builds privacy protections into its devices and apps.²³

For covered entities and business associates, it will be important to understand how their use of the Apple Watch and related apps to obtain patient information is covered by HIPAA and to ensure that their privacy practices and uses and disclosures of the health information comply with HIPAA requirements. App developers will likely still have to develop and follow a privacy policy, even if they are not regulated under HIPAA. They also need to consider whether individual state privacy laws have any requirements applicable to them. Finally, consumer demand for privacy may also dictate the increase in privacy policy concerning the Apple Watch and similar mobile devices.

Applicability of the FTC

The FTC has actively shown interest in determining and scrutinizing how the increasing amount of consumer-generated health and fitness data will be safeguarded by companies involved in that relevant sector.²⁴ In particular, the FTC has expressed concerns about the “risks of health data that flows outside of a medical context, such as information collected via wearables and mobile health apps,” and such concerns have prompted discussions with Apple.²⁵ As a result, it has been reported that Apple requires that its users must give consent before app developers are given access to the health information and further, that “data logged by its smartwatch is encrypted.”²⁶ Apple has taken steps to ensure that personal health information obtained through its HealthKit app is not used by developers for advertising or other non-consented purposes, but the FTC remains concerned as to whether Apple will be able to ensure that apps follow the same rule and take the same safeguards.²⁷ It is very likely that the FTC will continue to monitor and review future mobile health developments.

Apple Watch Raises Other Concerns

The Apple Watch and similar mobile devices in healthcare also raises patient safety concerns. Recently, the specter of patient safety in using these devices in order to make medical determinations has been raised. For instance, early reports of the Apple Watch indicated that it might be able to detect heart attacks, or measure health metrics, such as glucose levels,

which would raise the concern of Food and Drug Administration (FDA). However, the Apple Watch appears to be more in line to motivate its wearer to take action to stay healthy versus monitoring the healthcare vitals of the user, so the FDA is less likely to get too involved.²⁸ If more healthcare features are added, then the FDA may become more aggressive.²⁹ FDA regulation of mobile medical apps is evolving.³⁰

Another concern to consider is how health-related data used in an app or stored on an Apple Watch could be obtained through legal e-discovery procedures.³¹ Will the information stored on your Apple Watch become evidence in a legal proceeding? Time will provide judges the opportunity to rule on these discovery/evidentiary issues.

Conclusion

The Apple Watch is neither the first mobile device with capabilities and features that are applicable to healthcare delivery and/or care coordination, nor is it the first wearable device. However, given the potential widespread use and visibility of this and similar such watch devices by healthcare professionals and consumers, the Apple Watch could play a major role in the development of the mobile healthcare industry and have an impact on the regulatory framework used to control patient privacy. Before using the Apple Watch or other wearable devices for their healthcare needs and sharing their sensitive health data, consumers will need to be aware that different apps will have different privacy policies and that not all health apps will be compliant with HIPAA or FTC requirements. It will also be important for regulators and industry experts to understand the capabilities of the wearable devices and all of the new health apps and how their use impacts consumer privacy and to continue to monitor as these features change rapidly. The Apple Watch, peeled back, has provided the core to this mobile health evolution.

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