MARYLAND Health Care Commission

Andrew N. Pollak, MD, Chairman
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Wearable Technology and HIPAA

WHAT PROVIDERS NEED TO KNOW

DR. GARCIA'S STORY

Dr. Garcia, a primary care provider, stops in to see her last patient of the day, 55-year-old Diane. Like many of Dr. Garcia's patients, Diane owns a smartwatch, which she connects to a nutrition and fitness app to help stay on track with her weight loss goals. Diane's smartwatch recently detected a series of abnormal pulse rates, which prompted her to make an appointment with Dr. Garcia.

OVERVIEW

Wearable technology (or wearables) is widely available and provides a means for consumers to manage their health and wellness outside of a clinical setting.[1] Approximately 39 percent of Americans own a smartwatch or fitness tracker.[2] Use of these and other wearables can assist health care providers (like Dr. Garcia) with patient monitoring, surveillance, diagnosis, treatment plans, and ongoing management by tracking a wide range of biometric data and lifestyle factors (e.g., glucose levels, UVA exposure, medication adherence, heart rate, blood pressure, body temperature, oxygen saturation, posture, and physical activity).[3] Certain services, such as sleep monitoring, weight loss coaching, and fertility insights are available through online apps that can be purchased or downloaded for free.[4] The evolving telehealth landscape includes the integration of

WHAT ARE WEARABLES?

Wearables are electronic devices that people can wear close to their skin (e.g., wrist-worn fitness trackers, smartwatches, blood pressure monitors, sensors) that are designed to collect a user's personal health and exercise data; some devices have features that allow users to send their electronic data to a health care provider.

Business Insider, *Latest Trends in Medical Monitoring Devices and Wearable Health Technology*, January 2021. Available at: businessinsider.com/wearable-technology-healthcare-medical-devices

wearables. Data collected and shared using wearables calls to light important privacy and security considerations for providers and their patients.[5]

WHEN DOES HIPAA APPLY?

The Health Insurance Portability and Accountability Act of 1996 (HIPAA)[6] generally provides limited protection for data collected, analyzed, or shared using a wearable. This includes data that is often consumer-generated for personal, self-health tracking purposes (like in Diane's case). HIPAA would apply when a wearable serves as an extension of services provided by a covered entity (CE)[7] or business associate (BA)[8] and the exchange of data occurs between the CE or BA and the wearable technology company.[9, 10] This exchange includes a data interface with an electronic health record (EHR) system.[11, 12] If Diane's wearable data were sent directly to Dr. Garcia's EHR, then appropriate HIPAA safeguards need to be in place to ensure the privacy and security of Diane's protected health information.[13, 14]

CYBERSECURITY CONSIDERATIONS

Strong cybersecurity safeguards help keep data secure, including data from wearables that interface with a practice's EHR.[15] Recognize and implement cybersecurity best practices to protect data from all types of cyber-attacks, like phishing, which is most common. Check out this MHCC flyer for more cybersecurity tips: People: The Frontline of Cybersecurity.

THE FUTURE OF WEARABLES IN CARE DELIVERY

More research on the validity and utility of wearables is needed; however, some studies show that wearables help increase patient engagement and give providers more insight into their patients' health and wellness outside of their regularly scheduled visits.[16, 17] Use of wearables can be particularly beneficial for patients with chronic conditions (e.g., diabetes, COPD, cardiovascular disease) who need help cultivating healthy diet, exercise, sleep, and lifestyle habits.[18, 19]

Some clinical scenarios for use of wearables include:

- Assessing fine motor skills of people with neurological or musculoskeletal impairments[20]

- Tracking breathing and oxygen levels, along with environmental factors such as pollen count (particularly for those with asthma attacks)[21]
- Detecting and monitoring infectious diseases (e.g., COVID) through cardiovascular metrics, respiratory rate, temperature, and blood oxygen saturation[22, 23]

TALKING TO PATIENTS ABOUT WEARABLES

Data from wearables will likely come up in patient conversations, even if your practice hasn't created a formal process for receiving or using such data. Consider the following when talking to patients about wearables:

- Leverage wearables as a patient engagement tool – ask patients what kind of health-related data they are tracking and what they plan to do with the information[24, 25]
- Explain how wearables can assist with care management by tracking certain health parameters and identifying when a consultation between a patient and health care provider may be needed based on patterns and trends in the parameters[26]
- Encourage patients to read the privacy policy for a wearable or supporting app to understand how their data will be used; this includes whether data can be sold or shared without their consent or if they can delete their data[27]

This MHCC consumer flyer provides helpful tips for patients using wearables:
Data Privacy When Using Wearable Health and Fitness Devices – What Consumers Need to Know

RESOURCES

Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024
Guidance from the Office of the National Coordinator for Health Information Technology offering suggested practices and questions to consider for the capture, use, and sharing of PGHD in clinical and research settings

Patient Generated Health Data: A Closer Look at Privacy and Security Risks, the Current State of Health Care Cybersecurity, and State-Level Protections
A slide deck prepared by MHCC overviewing the privacy and security landscape of PGHD, information on cybersecurity and breach trends, and legislation passed in select states to strengthen protections for PGHD

Questions?

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[1] Deloitte, *Why Consumers—and Doctors—Are Wary About Wearable Data,* July 2021. Available at: www2.deloitte.com/us/en/insights/industry/technology/wearable-technology-healthcare-data.html.
[2] *Ibid.*
[3] MedCity News, *How Wearable Devices Empower Healthcare Providers,* July 2021. Available at: medcitynews.com/2021/07/how-wearable-devices-empower-healthcare-providers/.
[4] Business Insider, *Latest Trends in Medical Monitoring Devices and Wearable Health Technology*, January 2021. Available at: www.businessinsider.com/wearable-technology-healthcare-medical-devices.
[5] MDLinx, *Helpful or Hype? Wearable Tech Makes Its Way into Clinical Practice*, January 2022. Available at: www.mdlinx.com/article/helpful-or-hype-wearable-tech-makes-its-way-into-clinical-practice/2Yk3AkLKCHrPcvdbxuKuJ.
[6] The Health Insurance Portability and Accountability Act of 1996 contains standards for the protection of PHI. More information is available at: www.hhs.gov/hipaa/index.html.
[7] CEs include health plans, health care clearinghouses, health care providers, and business associates. More information is available at: www.hhs.gov/hipaa/for-professionals/breach-notification/breach-reporting/index.html.
[8] BAs include entities that create, receive, maintain, or transmit PHI on behalf of a CE or another BA.
[9]Health Tech Magazine, *3 Reasons Why Wearables Bring New Complications for HIPAA Compliance*, September 2020. Available at: healthtechmagazine.net/article/2020/09/3-reasons-why-wearables-bring-new-complications-hipaa-compliance.
[10] OneTrust Data Guidance, *USA: HIPAA and Wearable Technology – Does It Provide a Loophole?* December 2020. Available at: www.dataguidance.com/opinion/usa-hipaa-and-wearable-technology-does-it-provide.
[11] Companies that make wearables and apps still need to comply with laws that safeguard consumer data, though these protections are not equivalent to those mandated by HIPAA. In Maryland, the Personal Information Protection Act (PIPA) mandates that businesses reasonably protect the personal identifying information of Marylanders, and that they are notified when their information has been compromised in a breach. More information is available at: www.marylandattorneygeneral.gov/Pages/IdentityTheft/businessGL.aspx.
[12] If marketed for general health and wellness purposes (and not to specifically diagnose or treat a health condition) wearables and health apps do not need to go through the Food and Drug Administration's premarket approval process, which is stratified by three levels of risk. Products such as syringes and gauze are at the lowest level of risk and receive less scrutiny than devices at the highest level of risk, such as pacemakers. More information is available at: www.ama-assn.org/practice-management/digital/wearables-fda-and-patient-advice-what-physicians-should-know.
[13] Protected health information may include information that is demographic (e.g., name, e-mail, date of birth, social security number, etc.), financial (e.g., service dates, payment method, etc.), or clinical (e.g., diagnoses, prescriptions, treatment, etc.).
[14] Health IT Security, *How Does HIPAA Apply to Wearable Health Technology?* July 2018. Available at: healthitsecurity.com/news/how-does-hipaa-apply-to-wearable-health-technology.
[15] CIO, *Unlocking the Value in Patient-Generated Health Data*, February 2017. Available at: www.cio.com/article/3174732/unlocking-the-value-in-patient-generated-health-data.html.
[16] See n. 3, *Supra*.
[17] See n. 5, *Supra*.
[18] Current Allergy and Asthma Reports, *Wearable Technology and How This Can Be Implemented into Clinical Practice,* June 2020. Available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC7275133/.
[19] HIMSS, *The Endless Possibilities of Wearable Technology in Healthcare*, April 2021. Available at: www.himss.org/resources/endless-possibilities-wearable-technology-healthcare.
[20] BMC Musculoskeletal Disorders, *Wearable Systems for Shoulder Kinematics Assessment: A Systematic Review*, November 2019, Available at: bmcmusculoskeletdisord.biomedcentral.com/articles/10.1186/s12891-019-2930-4.
[21] Unleased Software, *The Wearable Healthcare Trends of 2022 and Beyond*, March 2021. Available at: www.unleashedsoftware.com/blog/the-wearable-healthcare-trends-of-2021-and-beyond.
[22] Homeland Security Affairs, *Wearables: Useful Sentinels of Our Health?* December 2020. Available at: www.hsaj.org/articles/16369.
[23] See n. 21, *Supra*.
[24] Medical Economics, *How Physicians Can Get Useable Data from Wearables*, August 2019. Available at: www.medicaleconomics.com/view/how-physicians-can-get-useable-data-wearables.
[25] American Medical Association, *Wearables, the FDA and Patient Advice: What Physicians Should Know*, July 2019. Available at: www.ama-assn.org/practice-management/digital/wearables-fda-and-patient-advice-what-physicians-should-know.
[26] American Medical Association, *4 Mistakes Your Patients Should Avoid with Wearables*, March 2019. Available at: www.ama-assn.org/practice-management/digital/4-mistakes-your-patients-should-avoid-wearables
[27] Federal Trade Commission, *How to Protect Your Privacy on Apps*. Available at: www.consumer.ftc.gov/articles/how-protect-your-privacy-apps#before.