HEARING BEFORE THE SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR & PENSIONS

SECURING THE FUTURE OF HEALTH CARE: ENHANCING CYBERSECURITY AND PROTECTING AMERICANS' PRIVACY

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Introduction

Chair Cassidy, Ranking Member Sanders and Members of the Committee, thank you for the opportunity to testify on the future of health care and considerations to ensure the security and privacy of health data.

My name is René Quashie, and I serve as Vice President of Digital Health at the Consumer Technology Association (CTA), the largest tech trade association in North America. CTA represents more than 1200 companies from iconic global brands to early-stage startups – powering innovation across the U.S. economy and supporting more than 18 million American jobs. Eighty percent of CTA companies are small businesses and startups. We produce CES, the world's most powerful tech event, and lead national efforts on policy, market research, and standards development across emerging technologies.

CTA's Health Division includes a diverse array of companies advancing consumer-based, technology-enabled health solutions to improve health outcomes and reduce overall health care costs. The Division includes telehealth providers, personal health wearable companies, digital health technology companies, healthcare payers, and health systems. Our members use technology to improve nutrition, fitness, mental health, lifestyle management, care access, care coordination, and more – and they are poised to lead the next wave of American innovation with cutting-edge health technology.

Promise of Digital Health

I want to begin by highlighting the innovation happening in health care right now and why it is important. Advancements in wearables, AI, and other advanced technology are transforming not only how patients access care but are also putting them in control by delivering personalized insights and screening for signs of chronic disease before a costly adverse event. This is more important than ever as patients across the country face incredible barriers to accessing care, driven by provider shortages. More than 77 million Americans live in a primary care health care professional shortage area and more than 122 million Americans live in a mental health professional shortage area.[1]

CTA member companies are leading innovation to bridge these barriers – including the first FDA-cleared obstructive sleep apnea (OSA) risk detection feature for consumer wearables. OSA remains an incredibly underdiagnosed condition – according to the American Academy of Sleep Medicine, an estimated 80 percent of cases remain undiagnosed – and it can lead to serious consequences such as heart disease, stroke, diabetes and depression.[2] More, undiagnosed cases of sleep apnea cost the system approximately $149.6 billion annually.[3] But technology is not just transforming how OSA is detected – now, instead of time- and resource-intense sleep labs, patients can often complete sleep tests to screen for OSA in the comfort of their homes using at-home monitors. Paired with CTA members who have pioneered the first connected Continuous Positive Airway Pressure (CPAP) and accompanying patient engagement applications which greatly improve patient adherence to treatment, we are

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[1] *Designated Health Professional Shortage Areas Statistics*. Bureau of Health Workforce, Health Resources and Services Administration (HRSA), U.S. Department of Health & Human Services. March 2025.
[2] *New national indicator report details importance of prompt sleep apnea diagnosis and treatment*. American Academy of Sleep Medicine. April 2023.
[3] Ibid

transforming a condition that has been called a “silent killer.” Through data and advancements in detection, we hope it will soon be neither.

This is just one example of how technology holds the promise to greatly improve health outcomes and lower costs. CTA research has found that a majority of health care providers (58%) feel digital health solutions help alleviate the burden on the U.S. health care system.[4] CTA research has also found that consumers are overall very satisfied with these solutions – of those who have used telehealth services, 80% were fairly or extremely satisfied.[5] Similarly, 76% of those who have used online counseling or therapy platforms were fairly or extremely satisfied.[6] Consumers surveyed noted less time spent in a doctor’s office, improved health, help remembering medication, and saved time while making health a priority as reasons for using digital health tools.[7]

CTA member companies are pioneering advances across the spectrum – from artificial intelligence (AI)-powered continuous glucose monitors to remote patient monitoring paired with AI-driven outreach to improve adherence – we are just beginning to see the promise of advanced technology in health care.

Importance of Patient Data Privacy

As we embrace the promise of digital health, we must also confront a core truth: none of this innovation matters if Americans don’t trust that their health data is protected. Health data is among the most personal and sensitive information we generate. It includes not only medical diagnoses and treatment data, but behavioral data, biometric signals, and emotional wellness patterns – often collected outside traditional clinical settings. Patients will not adopt tools they do not trust. Providers will not recommend platforms that they believe put patients at risk. And companies cannot innovate at scale if they are navigating conflicting, outdated or unclear data laws.

Indeed, CTA published research that found thirty percent of providers surveyed said evidence of increased security of patient data would help drive better adoption.[8] At the same time, the collection and sharing of health information is critical to improving care quality, ensuring patient safety, and driving innovation that benefits consumer health. In fact, studies have found patients are generally willing to share their personal health data for health research, contributing to advancements in healthcare and motivated by altruism to help future patients.[9]

Yet our current framework – rooted in the *Health Insurance Portability and Accountability Act* (HIPAA) – is outdated and incomplete. Many consumer-facing digital health manufacturers and deployers are not considered covered entities under HIPAA and often are not subject to

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[4] *Driving Consumer Adoption of Digital Health Solutions* (February 2023). Consumer Technology Association.
[5] Ibid
[6] Ibid
[7] Ibid
[8] Ibid
[9] Kalkman S, van Delden J, Banerjee A, Tyl B, Mostert M, van Thiel G. Patients' and public views and attitudes towards the sharing of health data for research: a narrative review of the empirical evidence. J Med Ethics. 2022 Jan;48(1):3-13. doi: 10.1136/medethics-2019-105651. Epub 2019 Nov 12. PMID: 31719155; PMCID: PMC8717474.

business associate agreements with a HIPAA covered entity.

That's why CTA has taken a leadership role in advancing both privacy and security in health innovation. In 2015, CTA released *Guiding Principles for the Privacy of Personal Health Data*, a voluntary framework designed to help companies, especially those outside HIPAA's scope, implement responsible data practices.[10] The Guiding Principles were developed, and subsequently updated, by a working group that included technology companies, telehealth and remote patient monitoring companies, health care providers, commercial payers and other innovators. These principles emphasize:

1. Be open and transparent about the personal health data you collect and why.
2. Be careful about how you use personal health data.
3. Make it easy for consumers to access and control the sharing of their personal health data and empower them to do so.
4. Build strong security into your technology.
5. Be accountable for your practices and promises.

CTA is also an American National Standards Institute (ANSI) accredited Standards Development Organization (SDO). With more than 30 published digital health standards[i], CTA is advancing cutting-edge technology in health AI, stress monitoring, physical activity monitoring, and sleep tracking. By emphasizing best practices in data security and privacy throughout a product lifecycle, CTA's digital health standards promote secure, interoperable and privacy-conscious technology solutions.

The Need for a Federal Solution

While CTA believes voluntary guidelines and industry standards play an important role, we recognize the importance of a comprehensive and preemptive federal data privacy bill that protects consumers and promotes innovation without incentivizing frivolous lawsuits and creating a patchwork of state privacy laws.

Currently, there is a patchwork of 20 state privacy laws.[11] For businesses, especially small businesses and startups, this stifles innovation and creates unnecessary barriers to entry. Navigating conflicting or inconsistent requirements increases legal risk, drives up operational costs and makes it harder to build uniform products and services that meet consumer expectations nationwide. For consumers, it makes little sense why one person located in one state might have differing rights than another in a different state even if they are using the same product.

As Congress considers a federal privacy law, it is important to strike the right balance between promoting individual privacy rights and allowing for innovation. Congress should carefully consider the lessons learned from the European Union's (EU) approach to privacy regulation. Mario Draghi, former Prime Minister of Italy and European Central Bank President, authored a report in 2024 that points to excessive regulation as a major factor inhibiting innovation in the EU, specifically in the digital economy.[12] At the same time, the U.S. should not follow the example of countries like China, where individuals have virtually no privacy rights and the government exercises broad control over personal data. As a country with a long history of

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[10] *Guiding Principles for the Privacy of Personal Health Data*. Consumer Technology Association. 2021.
[11] *U.S. State Privacy Laws*. LewisRice. July 2024.
[12] *The future of European competitiveness*. European Union. September 2024.

valuing both innovation and individual rights, the U.S. can and should strike an appropriate balance when crafting a federal privacy law.

Conclusion

Health data privacy and security are continually evolving concepts. They require a dialogue among technology stakeholders, healthcare providers, patients and regulators. As patient preferences and comfort with technology evolve, so too will products and services. Innovative technologies like AI and machine learning continue to transform health care and the ways in which clinicians and patients use data to improve care coordination, diagnostic accuracy, and quality of care. Consumers increasingly want to be active participants in their own care and able to monitor their health and wellness, and share their data with health care providers, applications, caregivers, and family members.

We need a uniform, risk-based, and innovation-friendly federal privacy law to achieve this balance. The absence of a comprehensive federal framework has led to an increasingly complex and fragmented patchwork of state rules, creating consumer confusion and placing undue compliance burdens on small and medium-sized businesses. A well-structured federal framework without a private right of action would enhance consumer protection while fostering regulatory certainty that spurs American innovation. CTA stands ready to work with the Committee to advance the use of digital health tools, including supporting comprehensive federal data privacy legislation.

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[i] CTA Active Digital Health Standards:

- Physical Activity Monitoring for Step Counting (ANSI/CTA-2056-A)
- Definitions and Characteristics for Wearable Sleep Monitors (ANSI/CTA/NSF-2052.1-A)
- Methodology of Measurements for Features in Sleep Tracking Consumer Technology Devices and Applications (ANSI/CTA/NSF-2052.2-A)
- Performance Criteria and Testing Protocols for Features in Sleep Tracking Consumer Technology Devices and Applications (CTA/NSF-2052.3-A)
- Performance Requirements for Sleep Monitoring Solutions detecting snoring (ANSI/CTA/NSF-2092)
- Recommendations and Best Practices of Sleep Quality Determination in Consumer Sleep Monitoring Solutions (ANSI/CTA/NSF-2110)
- Wearable Sound Amplifier Performance Criteria (ANSI/CTA-2051-A)
- Interoperability Standards Series for Consumer EEG Data - File Storage (ANSI/CTA-2060 R-2023)
- Physical Activity Monitoring for Heart Rate - Real World Analysis (ANSI/CTA-2065.1)
- Physical Activity Monitoring for Heart Rate (ANSI/CTA-2065-A)
- Definitions and Characteristics of Consumer Technologies for Monitoring Physical and Psychosocial Stress (ANSI/CTA-2068 R-2025)
- Definitions and Characteristics of Consumer Technologies for Monitoring Physical and Psychosocial Stress - Heart Rate and Related Measures (ANSI/CTA-2068.1)
- Intensity Metrics: Physical Activity Monitoring (ANSI/CTA-2074 R-2025)
- AI Definitions for Health Care (ANSI/CTA-2089.1)
- The Use of Artificial Intelligence in Health Care: Trustworthiness (ANSI/CTA-2090)
- Health Data: Reporting Format Best Practices (ANSI/CTA-2093)
- Definitions & Characteristics of Digital Therapeutics (ANSI/CTA-2098)
- Best Practices for Consumer Cardiovascular Technology Solutions (ANSI/CTA-2105)
- Characteristics and Requirements for Chronic Stress Technology Solutions (ANSI/CTA-2106)

- The Use of Artificial Intelligence in Health Care: Managing, Characterizing, and Safeguarding Data (ANSI/CTA-2107-A)
- Framework for Validation of Digital Health Technology-Derived Metrics under Naturalistic or Unconstrained Test Conditions (ANSI/CTA-2108)
- Evidence Based Performance Criteria for Digital Therapeutics (ANSI/CTA-2109)
- Best Practices for Consumer Cardiovascular Technology Solutions: Screening and Diagnosis (ANSI/CTA-2112)
- Best Practices and Recommendations for Telehealth Solutions (ANSI/CTA-2113)
- Artificial Intelligence in Health Care: Practices for Identifying and Managing Bias (ANSI/CTA-2116)
- Pure Tone Average Testing Methodology and Reporting Metrics for Consumer Facing Hearing Solutions (ANSI/CTA-2118)
- Best Practices and Recommendations for Information Disclosure (ANSI/CTA-2125)
- Physical Activity Monitoring for Human Gait Biomechanics (CTA-2128)
- Guiding Principles of Practice and Transparency for Mobile Health Solutions (CTA-2073)
- Remote Patient Monitoring Resources Kit (CTA-2101)
- Performance Criteria and Testing Protocols for Breathing Parameters (CTA-2102)
- Characteristics and Requirements for Consumer Pulse Oximetry Monitoring Solutions (CTA-2127)