

CTA™

Consumer Technology Association, producer of CES®

From Fitness Tracker to Health Tool: The Next Generation of Wearables

November 2026

Introduction

In January 2026, a trend reviving memories of 2016 swept social media. If health wearable devices participated, we'd be seeing physical fitness trackers like Apple Watch Series 2 and Fitbit Charge 2 dominate the throwbacks. You might catch a glimpse of the Consumer Technology Association's (CTA) first digital health standard creating definitions and performance criteria for measuring step counting on consumer wearable or app-based Physical Activity Monitoring Devices. Fitness trackers were even a headliner of CES 2016 – including the debut of Under Armour HealthBox, Fitbit Blaze and Withings Go[i] – yet only a quarter of Americans owned a wearable.[ii]



We've come a long way since 2016. At CES 2026, AI-driven wearables offering personalized health insights – from smart glasses to smart rings to EEG earbuds – drove headlines. We now have wearables that can continuously track heart rhythms, sleep, activity, and other health signals and leverage that data with AI to drive personalized insights, coaching, and even disease screening – a dramatic shift from 2016, when the market was just beginning to scale. In 2026, 42 percent of U.S. households report owning a smartwatch, 26 percent report owning an activity/fitness tracker, and 13 percent report owning a smart ring.[iii] The sensor technology in these wearables has also advanced to a place where they are driving clinical-grade information and data collection through FDA-cleared functions.



Despite these advancements, 2016 was also the year the last major law directly related to how tools like wearables are regulated – the *21st Century Cures Act* – was passed and signed into law. In 2016, the line between 'wellness' and 'medical device' was black and white – in 2026, it's much grayer. Against this backdrop, the promise of wearables lies not only in what the technology can do, but in how frameworks can evolve to responsibly support their expanding role in healthcare.

All rights reserved.

The Promise of Wearables

The promise of health wearables is expanding rapidly as new technologies push them far beyond simple step counting into continuous, meaningful health insight. Advances in sensors, artificial intelligence and miniaturization now allow wearables to track complex physiological signals like heart rhythm irregularities, blood oxygen levels, sleep architecture, stress responses and even early markers of illness in real time.

As these devices become more accurate and integrated with clinical systems, they have the potential to shift healthcare from reactive to proactive - enabling earlier intervention, more personalized care and better patient engagement instead of relying solely on snapshots of health information gathered at a doctor's appointment or in a hospital.

Over the past year, CTA has hosted numerous events and panels focused on health wearables – a full-day conference entitled *Evolving Access: Navigating the Future of Consumer Health Products, a Health Wearables Symposium* at CES 2026, an expert panel as part of the CES Digital Health Summit entitled *The Sensor Revolution: Wearables Driving Precision Medicine, a Roundtable on Wearable Technology*, co-hosted with the Congressional Digital Health Caucus and *From Data to Care; Unlocking the Clinical Value of Wearables*, co-hosted with the American Medical Association.

At all events, industry experts agreed on key points shaping the wearables industry today and in the future:

- Current generations of wearables provide consumers with health insights they previously could only access in traditional healthcare settings and this gives consumers more agency in managing their own health;
- FDA review continues to be the gold standard for provider trust and payer reimbursement, but as the technology advances, there is a need to rethink and potentially expand the DA's binary regulatory processes governing wearables;
- Health systems and payers are trying to move as much care as possible into the home – safely; and
- Data from wearables can also be useful for clinicians in managing their patients' care, but we must improve data interoperability and trust.

These technological developments coincide with a very real need in the health sector. While the prevalence of chronic conditions – and subsequent economic impact – continues to rise, so do provider shortages and appointment wait times. While wearables do not replace the need to see a healthcare provider, they can serve as important screening and monitoring tools – alerting patients and providers to abnormalities that could require additional testing – and help consumers take a more active role in their health and ultimately lower healthcare costs. For example, some wearables now include FDA-cleared features to flag for warning signs of sleep apnea or atrial fibrillation.

This whitepaper will dive into more depth on these points, as well as chart a path forward to ensure wearables deliver on their promise.

Regulatory Challenges

In 2016, passage of the *21st Century Cures Act* set statutory restrictions on FDA's jurisdiction over low-risk software applications – specifically carving out low-risk products such as electronic health records (EHRs), administrative software and general wellness apps from the definition of a medical device under the *Food, Drug & Cosmetics Act*. This set an important precedent that the FDA has followed through today – that products intended for general wellness or administrative functions are not medical devices and therefore do not require pre-market approval.

Since 2016, health technology has changed drastically. The FDA has attempted to keep pace through several new and updated guidance documents on issues like clinical decision support (CDS) tools and general wellness devices. Most recently, at CES 2026, then-FDA Commissioner Makary announced two new updated

final guidance documents – *Clinical Decision Support Software and General Wellness: Policy for Low Risk Devices*. Most relevant to wearables, the updated General Wellness guidance document expands the scope of what the FDA will consider "general wellness" devices, and therefore not subject to FDA pre-market approval, by allowing non-invasive wearable products that measure physiological parameters such as blood pressure, oxygen saturation and blood glucose to be considered general wellness products as long as they are marketed for general wellness purposes and do not make medical claims.

While generally supported by industry, the FDA can update guidance documents at any point with no warning – they are sub-regulatory documents intended to "communicate the current thinking of the FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public."[iv] In order to ensure clarity, the definitions and principles in the guidance document would need to be put in statute by Congress.

FDA has taken an important first step in establishing the TEMPO for Digital Health Devices Pilot. Through TEMPO, device manufacturers can request FDA exercise enforcement discretion for certain requirements; however, the device must be offered through the Center for Medicare and Medicaid Innovation (CMMI) ACCESS model. While its scope is limited, it demonstrates FDA's acknowledgement that there is a need for flexible approval pathways for devices and device functions that fall somewhere between low-risk and high-risk.

In the meantime, the updated General Wellness guidance document carves out more wearables and wearable features from FDA's purview, leaving the question: who decides what are "good" products versus "bad" products? What products have gone through testing and validation, delivering accurate information to consumers versus those who haven't undergone as rigorous of a development process and might provide inaccurate information. Even in unregulated products, consumers want products that work as they are intended. This is where industry-developed consensus standards play an important role. As an American National Standards Institute accredited standards development organization, CTA has developed and published more than 35 digital health standards.[v] The newest working group, "Wearable Performance and Trust," will define recommendations and best practices for demonstrating outcome-driven verification and validation methods across a variety of wearable technologies. In the absence of regulatory review, voluntary industry-driven consensus-based standards can and should help align the industry around best practices and strengthen consumer confidence, support clinical adoption.

Privacy and Trust

As we embrace the promise of wearables, 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. Data generated from wearables can include behavioral data, biometric signals, and emotional wellness patterns. 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.[vi] 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.[vii]

Yet our current framework – rooted in the *Health Insurance Portability and Accountability Act* (HIPAA) – is outdated and incomplete. Many consumer-facing wearable manufacturers are not considered covered entities under HIPAA and often are not subject to business associate agreements with a HIPAA covered entity. Today it makes little sense that the same data are protected differently by who holds the data.

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.[viii] The Guiding Principles were developed, and subsequently updated, by a working group that included technology companies, telehealth and remote patient monitoring companies, healthcare 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.

While voluntary guidelines and industry standards play an important role, Congress must pass 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.

In addition to trusting their data is protected, consumers want their devices to perform as advertised and clinicians and consumers alike want to trust in the data and insights provided. CTA research shows that a top factor consumers stop using digital health tools is because of a lack of effectiveness.[x] Research conducted by the American Medical Association found that among US-based physicians, accuracy concerns are a top barrier to using wearable data in patient care.[ix] As wearables continue to integrate AI and advanced physiological monitoring technology, consumer trust and transparency are crucial to adoption.

CTA supports a risk-based approach to regulating AI and recognizes that many use cases of AI in wearables would fall into a lower risk or unregulated category. To that end, CTA, as an American National Standards Institute (ANSI) accredited standards development organization, has published six health AI standards, including:

- AI in Healthcare Trustworthiness (ANSI/CTA-2090)
- AI in Healthcare: Managing, Characterizing, and Safeguarding Data (ANSI/CTA-2107-A)
- AI in Healthcare: Practices for Identifying and Managing Bias (ANSI/CTA-2116)
- Performance Verification and Validation for Predictive Health AI Solutions (ANSI/CTA-2135)
- Operations and Monitoring of Predictive Health AI Solutions (CTA-2136)

Data interoperability

Wearables are generating vast amounts of valuable health information, but that information has limited value if it is not reaching clinicians. These data often remain trapped in individual apps and platforms, disconnected from electronic health records and clinical workflows. While progress is being made in interoperability of clinical data between healthcare settings, there is less focus on integrating non-traditional data like data from wearables into a patient's clinical record.[xi]

This is partly because of advancement in wearables over recent years. Previously, data from wearables was not as clinically relevant nor as sophisticated. Healthcare providers had little clinical use for how many steps a patient was taking in a day or how many times they woke during the night. Now, providers acknowledge the value of wearables as helpful tools to identify potential issues and refer for additional testing.[xii]

As technology and sensor functionality has advanced, so too have the potential benefits of incorporating these data into patient records; however, barriers remain. Currently, only six percent of U.S. physicians report that wearable data is integrated into their clinical workflow.[xiii] While some wearable developers have made it easier to "pull" a patient record into a health app on their platform that also includes wearable data, it is more difficult to "push" wearable data into a clinical record that resides with a



healthcare professional. Integration must extend beyond transferring raw data. Clinicians, who frequently manage monitoring, triage, patient education and care coordination need accurate, reliable and actionable data presented in their existing workflow and in a format that they are familiar with. Systems should filter and summarize data, distinguish meaningful changes from normal variation, route findings to the appropriate team member, document resulting actions and define responsibility for review and escalation. Voluntary consensus-based industry standards are essential to reaching this goal. CTA is participating in HL7's "Caliper," a FHIR accelerator program focused on realizing an ecosystem of interoperable health device technologies.[xiv]

Clearly the challenge is not generating data, it is ensuring data can be used to improve health outcomes and improving interoperability is critical.

Coverage and Reimbursement

America's healthcare system spends enormous sums treating health conditions and much less on prevention. In fact, ninety percent of the nation's $5.3 trillion in annual healthcare expenditures are for people with chronic and mental health conditions.[xiv] While wearables can play a key role in screening and prevention of chronic disease, thus helping lower healthcare expenditures, many payers, including Medicare, still treat wearables as optional tools rather than essential components of care. This is directly impacting adoption as CTA research shows that cost remains one of the most important factors influencing whether consumers adopt health technologies.[xvi]

Medicare is statutorily bound to cover only services and supplies that are "medically necessary," defined as items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury.[xvii] When it comes to coverage of medical devices, the Centers for Medicare and Medicaid Services (CMS) generally draw the medically necessary line at FDA approved or cleared devices. This line is blurring significantly as wearable technology advances. Many consumer wearables contain software functions that are FDA cleared/approved, but the device that houses the software is not. This issue is not unique to consumer wearables – CMS faced a similar dilemma when determining coverage of virtual reality (VR) headsets that deliver FDA cleared/approved treatments via software. CMS determined it will cover VR headsets through the durable medical equipment (DME) program, but the headsets cannot be "off the shelf" headsets and must be programed to only deliver the medical treatment – therefore blocking any other "recreational" use. While this

follows the letter of the law, one could question if it drives up device prices, therefore increasing Medicare costs.

CMS has taken an important first step in establishing the CMMI ACCESS model. While initially limited to three clinical indications and recently expanded to an additional five areas beginning in spring 2027, this model will allow a limited number of devices under FDA enforcement discretion to be reimbursed while generating evidence to help shape permanent coverage policies.

Similarly to CMS, private insurers are also still grappling with coverage and reimbursement of wearables. Many who have private insurance coverage use HSAs or FSAs to purchase wearables with pre-tax dollars. Historically, the IRS has required a Letter of Medical Necessity (LMN) for smartwatches because they are "dual use," meaning they have both health and general consumer functions, while other wearables with solely health tracking functions do not require an LMN. This policy made little sense given the advanced, often FDA-cleared/approved health functions that are now embedded in smartwatches. Recently, the IRS released a new FAQ on wearables HSA or FSA eligibility.[xviii] The new FAQ is device agnostic and instead, the question looks at whether the consumer's primary intent for purchasing a wearable is to address a specific disease, including the individual's symptoms, diagnosis, abnormal test results, or risk factors; the relationship between the information tracked and the disease being evaluated or managed. This updated FAQ is a positive step forward to ensuring access to wearables.[xix] As wearables advance, so too must coverage and reimbursement policies. These tools are increasingly sophisticated and uniquely positioned to expand access to preventive and personalized care. For far too long, the U.S. health system has paid for "sick" care and invested little in prevention. Coverage and reimbursement for health wearables with demonstrated clinical utility and value can help scale prevention where traditional providers cannot reach.

Conclusion

In 2016, wearables counted steps. Today, they can help identify serious health conditions, support more personalized care and give Americans greater control over their health. Yet the statutes and regulations governing these tools have largely not been updated since 2016. The next decade promises even greater technological advances; realizing their benefits will require policy to keep pace. Policymakers and regulators must advance proportionate regulatory pathways that reflect the risks of wearable features while maintaining expectations for data quality and validation. Industry-developed consensus standards can strengthen confidence in device performance and the reliability of health insights. Congress must establish comprehensive, preemptive federal privacy protections so consumers can trust that their health data is protected. Healthcare organizations and technology companies must make wearable data interoperable and actionable within clinical workflows. Payers must modernize coverage and reimbursement for wearables with demonstrated clinical utility and value, expanding access to preventive care. Coordinated action by policymakers, regulators, healthcare organizations, payers, technology companies, clinicians and standards bodies can turn these priorities into a trusted wearable ecosystem. Success will mean more than collecting more data: it will mean translating reliable insights into earlier intervention, better care and lower costs without adding burden for consumers or clinicians.

All rights reserved.

Sources

[i] CNET, "All the Smartwatches, Fitness Trackers and Wearables at CES 2016," 2016. https://www.cnet.com/pictures/all-the-smartwatches-fitness-trackers-wearables-ces-2016-pictures/

[ii] Rock Health, "Digital Health Consumer Adoption 2016, " 2016. https://rockhealth.com/insights/digital-health-consumer-adoption-2016/

[iii] Consumer Technology Association, "2026 U.S. Consumer Technology Ownership & Market Potential Study," 2026. https://www.cta.tech/research/2026-us-consumer-technology-ownership-market-potential-study/

[iv] Food and Drug Administration, "General Wellness: Policy for Low Risk Devices," 2026. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices

[v] Consumer Technology Association, "Standards." https://www.cta.tech/standards/

[vi] Consumer Technology Association, "Driving Consumer Adoption of Digital Health Solutions," 2023. https://www.cta.tech/research/driving-consumer-adoption-of-digital-health-solutions/

[vii] Kalkman S, et al. "Patients' and public views and attitudes towards the sharing of health data for research: a narrative review of the empirical evidence." Journal of Medical Ethics, 2022. https://pubmed.ncbi.nlm.nih.gov/31719155/

[viii] Consumer Technology Association, "Guiding Principles for the Privacy of Personal Health Data," 2021. https://cdn.cta.tech/cta/media/media/membership/pdfs/final-cta-guiding-principles-for-the-privacy-of-personal-health-and-wellness-information.pdf

[ix] Consumer Technology Association, "Driving Consumer Adoption of Digital Health Solutions," 2023. https://www.cta.tech/research/driving-consumer-adoption-of-digital-health-solutions/

[x] American Medical Association, "AMA Multi-Country Study on Consumer Wearable Data in Clinical Practice," 2026. https://www.ama-assn.org/system/files/ama-wearable-study.pdf

[xi] United States Government Accountability Office, "Wearable Technologies: Potential Benefits and Challenges in Clinical Decision-Making," 2026. https://www.gao.gov/products/gao-26-107847

[xii] Ibid

[xiv] American Medical Association, "AMA Multi-Country Study on Consumer Wearable Data in Clinical Practice," 2026. https://www.ama-assn.org/system/files/ama-wearable-study.pdf

[xv] U.S. Centers for Disease Control and Prevention. "Fast Facts: Health and Economic Costs of Chronic Conditions," 2026.

[xvi] Consumer Technology Association, "Driving Consumer Adoption of Digital Health Solutions," 2023. https://www.cta.tech/research/driving-consumer-adoption-of-digital-health-solutions/

[xvii] Centers for Medicare & Medicaid Services, "Medicare Coverage Determination Process." https://www.cms.gov/medicare/coverage/determination-process

[xviii] Internal Revenue Service, "Frequently Asked Questions About Medical Expenses Related to Nutrition, Wellness and General Health." https://www.irs.gov/individuals/frequently-asked-questions-about-medical-expenses-related-to-nutrition-wellness-and-general-health

About



Consumer Technology Association, producer of CES®

As North America's largest technology trade association, CTA is the tech sector. Our members are the world's leading innovators – from startups to global brands – helping support more than 17 million American jobs. CTA owns and produces CES® – the most powerful tech event in the world.

Find us at CTA.tech. Follow us @CTAtech.



Consumer Technology Association, producer of CES®

© 2026 Consumer Technology Association (CTA)®. | All rights reserved. | **CTA.tech**