

# ConnectedHealthInitiative

July 17, 2025

The Honorable Dr. Mehmet Oz  
Administrator  
U.S. Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, Maryland 21244

Abe Sutton  
Director  
Center for Medicare and Medicaid Innovation  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

**RE: Center for Medicare and Medicaid Services Action Needed to Provide Every American with Access to Wearables within Four Years**

Dear Administrator Oz and Director Sutton:

The Connected Health Initiative (CHI)<sup>1</sup> shares your commitment to innovating, collaborating, and adopting cutting edge wearable health and fitness technology to measure and promote better health for all Americans. We are encouraged by Secretary Kennedy's announcement of the Department's priority for providing every American with access to a wearable within four years. Our community writes to you to encourage rapid modernization of the ways in which the Centers for Medicare & Medicaid Services (CMS) handles these technologies to fulfill the promise of the demonstrated ability of wearables to improve patient outcomes, augment population health management, and reduce costs.

The Connected Health Initiative (CHI) is the leading multistakeholder policy and legal advocacy effort dedicated to improving health outcomes while reducing costs. Our work is driven by the consensus of stakeholders from across the connected health ecosystem. CHI aims to realize an environment in which Americans can see improvements in their health through policies that allow for connected technologies to advance outcomes and reduce costs. We advocate before Congress, numerous U.S. federal agencies, and state legislatures and agencies, to accomplish responsible pro-digital health policy and law changes in areas including reimbursement/payment, privacy/security, effectiveness/quality assurance, U.S. Food and Drug Administration (FDA) regulation of digital health, health data interoperability, and the rising role of artificial intelligence (AI) in care delivery. For more information, see [www.connectedhi.com](http://www.connectedhi.com).

Wearable health devices have become widely available as tools to empower patients to proactively engage in their own efforts to combat disease. Wearables that provide timely and actionable patient-generated health data (PGHD) enhance situational awareness for both the patient and their care team, better informing decisions related to preventative measures and treatment plans. Recent advancements in edge computing (processing and storing data closer to the device), cloud computing, and AI/machine learning have enabled the development of numerous personal and population health innovations. Notably, wearables provide health insights through measuring various physiological and therapeutic metrics, including activity levels, sleep patterns, heart rate

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<sup>1</sup> [www.connectedhi.com](http://www.connectedhi.com).

variability, and oxygen saturation. While such readings are indispensable in disease treatment, they also enable the detection of early warning signs that often signal the onset or further development of disease, providing a critical window to prevent disease. These functionalities that support disease prevention and improve engagement in care provide CMS with an immense opportunity to reduce costs. Wearables and the data they provide should be the foundation for any modernized healthcare system.

Unfortunately, CMS coverage of wearables writ large is currently overly restrictive and prevents beneficiaries from realizing these benefits. With the Administration's renewed focus on tackling chronic disease, and especially with Secretary Kennedy's recent statements before Congress in favor of supporting the use of wearables, now is the time to modernize CMS's approach to this paradigm-shifting technology. A Center for Medicare and Medicaid Innovation (CMMI) model could potentially assist CMS in achieving these goals.

**First, we urge CMMI to launch a new pilot to explore the impacts wearables and timely leveraging of PGHD, focusing on impacts on individual patient outcomes, population health management, and cost savings.** This pilot should explore both the prevention and treatment of disease, and explore how patient data will be protected, how the effectiveness of wearable devices in improving patient care will be evaluated, how data from wearables will be meaningfully integrated into treatment plans, and how the clinical validity and reliability of such data will be demonstrated. Wearables' role in realizing Medicare reform is long overdue, and Section 1115A of the Social Security Act provides CMMI broad authority to design, test, and evaluate innovative payment and service delivery models, including pilot programs, aimed at reducing costs and improving quality within Medicare and Medicaid. Further, CMMI's focus on wearables is critical to realizing Secretary Kennedy's goal of providing every American with access to a wearable within four years.

**Second, we call on CMS to appropriately pursue programmatic updates across its existing payment rules to support the responsible uptake of PGHD/wearables.** While CMS has made notable updates to key payment rules, such as the Physician Fee Schedule and Medicare Advantage, in recent years to shift the system to better leverage PGHD, this incremental progress has not kept pace with new innovations, leaving far too many beneficiaries behind. CMS' efforts to achieve Secretary Kennedy's goal could be informed by a standalone request for information on existing barriers to the widespread use of wearables by Medicare beneficiaries and how to overcome those barriers. CHI welcomes the opportunity to provide its detailed recommendations on changes that can be made across key Medicare payment rules under CMS' existing authority.

We appreciate your consideration of our input at this critical time for the American healthcare system and the countless Americans who depend on it. We stand ready to assist you in any way that we can.

Sincerely,

A handwritten signature in black ink, appearing to read 'B. Scarpelli', with a stylized flourish at the end.

Brian Scarpelli  
Executive Director

**Connected Health Initiative**  
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