GAO: Wearables Regs Could Address Physician Liability Concerns

Aug 12, 2026, 6:42 PM EDT

(Inside Health Policy)

The Government Accountability Office (GAO) is urging policy makers to regulate wearables used in making health care decisions to ease physician liability concerns, and said a separate certification process for wearables outside of FDA might cause confusion among manufacturers. FDA currently allows certain wellness apps and wearables to avoid being regulated as a medical device, but some industry stakeholders say there is still a blurry line between a regulated device and a general wellness product not subject to agency oversight.

In early August, GAO released a technology assessment “Wearable Technologies, Potential Benefits and Challenges in Clinical Decision-Making" offering policymakers suggestions to improve wearables integration into clinical workflows.

The report comes as the Trump administration continues to advocate that wearables be used across the health system to provide data patients and providers could use to make better-informed medical decisions.

"Wearables increase the amount of information considered during clinical decision making, which may allow for quicker diagnoses by clinicians, more personalized care plans, and improved patient compliance,” GAO wrote. “Wearables may also benefit underserved populations by expanding remote patient monitoring. However, wearables vary in accuracy and reliability."

Artificial intelligence has potential to increase wearable capability, according to GAO, but it does not mean that the wearables should wade into clinical decision making just yet.

"GAO identified challenges to using wearables for clinical decision-making, including challenges related to ensuring wearables benefit patients as intended, integrating

wearables into clinical workflows, and navigating the health technology market," the office wrote.

GAO provided policy recommendations that could optimize the benefits of using wearables and address the aforementioned challenges.

Integrate wearables into clinical workflows

GAO said policymakers could refine the clinical workflows and health technology infrastructure to incorporate wearables data into clinical decision-making. There are opportunities to establish common practices for receiving and protecting patient health data from wearables that have the potential to improve outcomes.

GAO is urging policymakers to consider that "resource requirements for wearables integration could shift resources away from other priorities" and patients and providers may experience different results within local implementation strategies.

Policymakers should also consider that if "administrators improve the integration of selected wearables, the use of wearables not selected may decline," GAO wrote.

Integrating wearables into clinical workflows could help standardize the way medical facilities and clinicians handle wearables data and address questions about liability.

"Specifically, it may help standardize the way health care providers receive, respond to, and protect patient health data," GAO wrote in the report. "That standardization could, in turn, protect privacy and improve patient outcomes. For example, it could improve both technological connectedness and clinical workflows through integration with electronic health records, which could ease the cognitive burden on clinicians and enable them to consider pertinent information from more data sources simultaneously."

However, wearables integration may require hiring new staff or shifting responsibilities of current staff, creating new workflows and locating millions of dollars in new funding.

Improve wearables performance through a public database of certified products

GAO wrote that testing and disclosure of wearables performance could help medical administrators, providers and patients make informed decision about the benefits and risks of certain types of wearables.

“Policymakers could incentivize manufacturers to improve the performance of wearables by building and maintaining a comprehensive public database of recommended wearables that have completed a selected, independent certification process,” GAO wrote. “Clinicians and patients could then use the database to help find certified devices.”

But GAO wrote that research and development costs for wearables may rise if more policies are adopted, potentially stymieing the market for new wearables and even larger established manufacturers.

“Incentivizing participation in a certification process that is separate from the Food and Drug Administration’s review process may create confusion for wearables manufacturers, clinicians, and patients, with potential effects on patient safety,” GAO wrote.

Continue the status quo

GAO said policymakers could simply continue to participate in ongoing digital health technology activities, like monitoring and assessing recent and ongoing activities related to digital health technologies.

" Many ongoing activities may help address some of the challenges we identified. One example of a federal activity is CMS’s 2025 Health Technology Ecosystem, which could help address the challenges of technological integration and data privacy and security," GAO wrote. "This voluntary initiative provides information and encourages collaboration between stakeholders to enhance integration of digital health technologies and data security and privacy. Furthermore, CMS’s ACCESS Model could ease health care market concerns of uncertain insurance coverage for wearables.”

State-level activities may also be useful in determining the willingness of stakeholders to automate aspects of clinical decision-making using digital health technologies.

"Policymakers, such as national medical associations, could incentivize manufacturers to improve the performance of wearables by building and maintaining a comprehensive public database of recommended wearables that have completed a selected, independent certification process," GAO wrote. "Clinicians and patients could then use the database to help find certified devices."

National Medical Associations could encourage wearables manufacturers to participate in independent certification processes, according to GAO.

"This policy option could (1) improve the testing and disclosure of the clinical performance of wearables and (2) increase evaluation of how wearables affect patient health and safety once they are on the market," the agency wrote.

But GAO warned that “some of the challenges GAO identified may remain unaddressed by recent or ongoing activities, and some activities may worsen some challenges.” -- *Cara Smith* (csmith@iwpnews.com)