United States Government Accountability Office

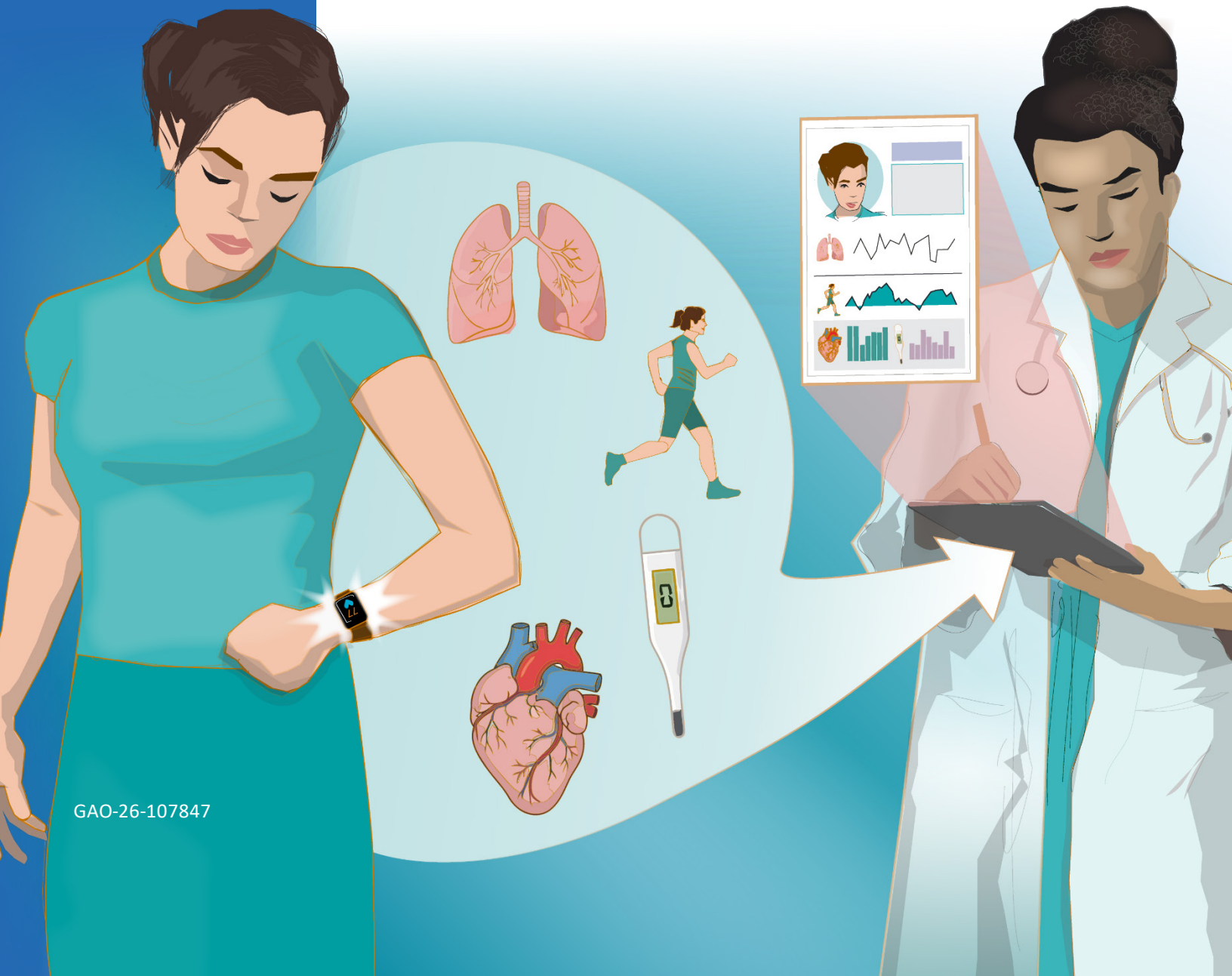
Report to Congressional Committees

August 2026

TECHNOLOGY ASSESSMENT

Wearable Technologies

Potential Benefits and Challenges in Clinical Decision-Making



GAO-26-107847

The cover image depicts a patient wearing a smartwatch that transfers data to a medical professional to aid in the patient's overall medical assessment.

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Highlights of GAO-26-107847, a report to congressional committees

August 2026

Why GAO did this study

Because wearables may facilitate more timely and personalized patient care, manufacturers and medical association representatives have suggested increasing their integration into clinical decision-making. In addition, in 2025 leaders at the Department of Health and Human Services announced support for increasing the use of wearables in health care.

GAO was asked to review the potential role of wearables in clinical decision-making. This report examines (1) the potential benefits and challenges of using wearables in clinical decision-making, (2) the potential benefits and challenges of using AI to augment the decision-making capabilities of such wearables, and (3) what policy options might help address challenges and enhance benefits associated with the use of wearables in clinical decision-making.

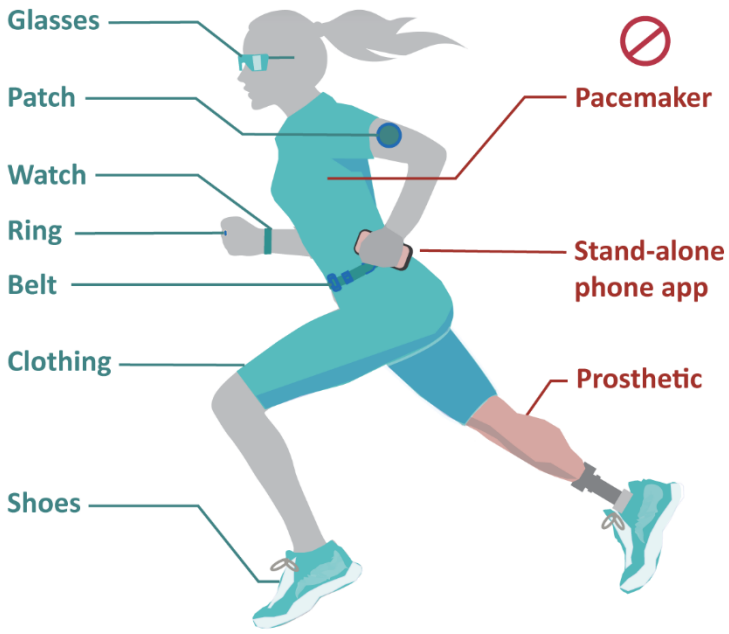
To conduct this engagement, GAO reviewed scientific literature, federal agency guidance, and other documents; interviewed a wide range of stakeholders and agency representatives; and conducted site visits to laboratories, medical and research centers, and manufacturers to better understand these technologies.

View GAO-26-107847. For more information, contact Sarah Harvey at HarveyS@gao.gov.

What GAO found

Wearable devices (wearables) with health-related features have the potential to be used in clinical decision-making (see figure). Wearables can be either medical or wellness devices, and their features can be augmented by artificial intelligence (AI). Wearables use sensors to track vital signs and establish patient health baselines; alert users, caregivers, or clinicians of medical events or suggested lifestyle changes; and provide additional assessments of user data that can be sent to a clinician for interpretation. Clinicians could use such data as a source of information when diagnosing and treating patients.

Examples of wearables that could be used in clinical decision-making



Source: Maxim Filitov/stock.adobe.com (illustration); GAO analysis of information. | GAO-26-107847

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. Wearables may also benefit underserved populations by expanding remote patient monitoring. However, wearables vary in accuracy and reliability.

AI has the potential to increase the capabilities of wearables by, for example, improving autonomous decision-making. However, the extent to which wearables will be able to make clinical decisions autonomously is unclear at this time.

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.

GAO developed three policy options that could help address the challenges and enhance the benefits of using wearables in clinical decision-making. The first is the status quo, whereby policymakers would continue with current efforts and activities in the field. The other two policy options identify possible new actions by policymakers, which may include legislative bodies, government agencies, standards-setting organizations, industry, and other groups. See below for details of the policy options and relevant opportunities and considerations.

Policy Options to Help Address Challenges with Use of Wearables in Clinical Decision-Making

	Opportunities	Considerations
Continue the status quo (report page 24) Policymakers could continue ongoing digital health technology activities, and policymakers outside of government could continue voluntarily testing the use of wearables for clinical purposes.	• Monitoring and assessing recent and ongoing activities related to digital health technologies, including wearables, may help address some of the challenges GAO identified. Such challenges include ensuring patient health benefits, integrating wearables into clinical workflows, and navigating the health technology market.	• Some of the challenges GAO identified may remain unaddressed by recent or ongoing activities, and some activities may worsen some challenges.
Integration of wearables into clinical workflows (report page 26) Policymakers could refine the clinical workflows and technology infrastructure of medical facilities to support the integration of wearables into clinical decision-making.	• Improving clinical workflow integration could help establish common practices for receiving, responding to, and protecting patient health data, which could protect privacy and improve patient outcomes. • It could also help clarify clinician responsibilities surrounding the use of wearables data in clinical decision-making, which could ease liability concerns.	• Resource requirements for wearables integration could shift resources away from other priorities. • Patients and clinicians may experience variable results according to the local implementation strategy. • If administrators improve the integration of selected wearables, the use of wearables not selected may decline.
Improvements to wearables performance (report page 27) 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. Clinicians and patients could then use the database to help find certified devices.	• Testing and disclosure of wearables performance could help medical facility administrators, clinicians, and patients make more informed decisions about the benefits and risks of selecting specific wearables. • Encouraging companies to maintain a certification may increase manufacturer testing of wearables' effect on patient health and safety.	• 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. • Research and development costs may rise significantly, hindering the market for new wearables and potentially advantaging larger, established manufacturers.

Source: GAO. | GAO-26-107847

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Abbreviations

ACCESS	Advancing Chronic Care with Effective, Scalable Solutions
AFib	atrial fibrillation
AI	artificial intelligence
CMS	Centers for Medicare & Medicaid Services
DHT	digital health technology
ECG	electrocardiogram
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
HIPAA	Health Insurance Portability and Accountability Act of 1996
HHS	Department of Health and Human Services
PCCPs	Predetermined Change Control Plans
PHI	protected health information
PPG	photoplethysmograph
RAPID	Regulatory Alignment for Predictable and Immediate Device
TCET	Transitional Coverage for Emerging Technologies
TEMPO	Technology-Enabled Meaningful Patient Outcomes
VA	Department of Veterans Affairs
VHA	Veterans Health Administration

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Wearable devices (wearables) with health-related features, which can be medical or wellness devices, have the potential to be used in clinical decision-making. Medical devices, such as continuous glucose monitors and prescription-based watches, can be used to monitor aspects of a user's health, including tracking their vital signs, to detect signs of low blood sugar, heart problems, or other medical issues.[1] Wellness devices, such as fitness trackers and some smart rings, may also track a user's vital signs, but are intended by manufacturers to support users in living a generally healthy life, and are not intended for use in medical diagnosis, treatment, or prevention of disease.

Wearables of all kinds are growing in popularity, partly due to advances in artificial intelligence (AI). According to one market research report, the global market for all wearable devices was almost $87 billion in 2025 and may approach $240 billion by 2032, with most devices falling into the wrist-worn category.[2] Recently, manufacturers have suggested that AI-augmented wearables could facilitate more timely and personalized patient care. Therefore, device manufacturers and medical association representatives have suggested increasing the integration of wearables into clinical decision-making. Other stakeholders, such as leaders from the Department of Health and Human Services (HHS), have also announced support for increasing the use of wearables in health care.[3]

You asked us to review the use of wearables, including both medical and wellness devices, and their potential role in clinical decision-making. This report examines (1) the potential benefits and challenges of using wearables in clinical decision-making; (2) the potential benefits and challenges of using AI to augment the decision-making capabilities of such wearables; and (3)

[1]Vital signs are measurements of the body's basic functions and are used by clinicians to evaluate physical health, detect medical problems, and monitor treatment. Body temperature, pulse rate (heart rate), blood pressure, and respiratory rate (breathing) are examples of vital signs that are measured by some wearables.

[2]The referenced market research report was commissioned by a private firm, and includes wearables used for enterprise and industrial uses, in addition to health tracking: MarketsandMarkets, *Wearable Technology Market Size, Share, Growth, & Trends* (Jun. 2026).

[3]For example, during a House Committee on Energy and Commerce Subcommittee on Health hearing, "The Fiscal Year 2026 Department of Health and Human Services Budget" (June 24, 2025), the HHS Secretary stated, "…my vision is that every American is wearing a wearable within 4 years."

what policy options might help enhance benefits and address challenges associated with the use of wearables in clinical decision-making.

For the purposes of this report, we define wearables as devices worn externally on the human body or clothing, typically for prolonged periods; contain sensors; perform at least one specific health-related function that could be used in clinical decision-making; and are currently available or expected to be on the market in the next 5 years. We did not include wearables only used in clinical trials to support the testing of other devices or products, or those used in one-off testing. We also excluded, among other types of devices, display-only devices, such as pedometers; treatment-only devices, such as hearing aids; ambient AI devices (also called "nearables"), which are placed in the user's environment instead of being worn on the body or clothing; and prosthetics. See appendix I for a full list of what is included and excluded from our scope, and for more information on our methodology—which included reviews of scientific literature, federal agency guidance, and other documents; interviews with a wide range of stakeholders and agency representatives; and site visits to laboratories, medical and research centers, and manufacturers.

We conducted our work from September 2024 to August 2026 in accordance with all sections of GAO's Quality Assurance Framework that are relevant to our objectives. The framework requires that we plan and perform the engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations in our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for any findings and conclusions in this product.

1 Background

1.1 The role of wearables in clinical decision-making

To better understand the potential use of wearables in clinical decision-making, it is important to clarify (1) what wearables are, including medical and wellness device types; (2) the clinical decision-making process; and (3) the role of AI in augmenting wearables, including functions related to clinical decision-making.

1.1.1 Wearables are medical or wellness devices

Generally, any wearable has the potential to be used in clinical decision-making, regardless of the manufacturer's intent. However, whether the wearable is defined as a medical or wellness device depends on its intended use. Specifically:

- **Medical devices**. Manufacturers of medical devices intend these wearables to be used for clinical purposes, such as diagnosing or treating a disease or medical condition. Such wearables are subject to review and oversight by the Food and Drug Administration (FDA) to ensure they are safe and effective when used as intended.
- **Wellness devices**. Manufacturers of wellness devices intend these wearables to be used only to promote general wellness and not for clinical uses, such as diagnosis or treatment. Such wearables may have features that track health-related metrics to help with issues like weight management or sleep quality, as long as the intended purpose of such tracking is limited to supporting healthy lifestyle choices. Wellness devices are not reviewed by FDA.[4]

Wearables, whether medical or wellness devices, are worn externally on the human body or clothing, contain sensors, and are intended for frequent, long-term monitoring of health-related metrics, such as a user's vital signs. Categories of wearables that could be used in clinical decision-making include wristbands, rings, headwear, patches and stickers (including minimally invasive continuous glucose monitors worn on the body), and clothing (see fig. 1)

[4]In our report, "devices" does not refer only to those devices that are specifically defined by the Federal Food, Drug, and Cosmetic (FD&C) Act. We use the term more broadly to include devices that meet the definition provided under section 201(h) of the FD&C Act and to include certain products used for general wellness. While this report refers to the latter category as "wellness devices", they may also be referred to as consumer wearables, consumer devices, and personal fitness, activity, or wellness trackers, among other terms. FDA's regulatory framework is described in more detail in appendix II.

Figure 1. **Examples of wearables that could be used in clinical decision-making**

Source: Maxim Filitov/stock.adobe.com (illustration); GAO analysis of information. | GAO-26-107847

Note: In this report, we define wearables as medical or wellness devices that are worn externally on the human body or clothing, typically for prolonged periods, contain sensors, and perform at least one specific health-related function, such as monitoring a user's vital signs.

1.1.2 The Clinical decision-making process

Clinical decision-making is a complex process involving the evaluation of evidence and knowledge to diagnose conditions and recommend treatment. A clinician may draw upon many sources of information to guide this process, including a patient's medical history, stated symptoms, and diagnostic test results. In the last decade, data collected by digital health technologies, such as wearables, have become additional sources of information that a clinician can consider. For example, a clinician may prescribe the use of a wearable for patients to collect additional data that may inform the patient's diagnosis or treatment. Alternatively, a patient may self-initiate use of a wearable and share the data it collects with their clinician. Clinical decisions can directly affect the quality of care patients receive and their health outcomes.

1.1.3 Role of AI in augmenting wearables for clinical decision-making

Wearable functions can be augmented by AI, which can help users or clinicians interpret wearable data, and could affect the clinical decision-making process. In general, AI refers to computer systems that can solve problems and perform tasks that have traditionally required human intelligence. There are several subcategories of AI, such as machine learning and generative AI.[5] Manufacturers have said that machine learning, which can augment diagnostic capabilities by processing complex data, has enhanced analyses of wearables data for at least a decade. Generative AI refers to tools that can create text, images, audio, and other content using patterns learned from datasets. Generative AI may be incorporated into wearables to provide a human-like interactive interface, helping users better understand device outputs.

1.2 Federal role for the use of wearables in clinical decision-making

The federal government plays a role in the regulation and use of wearables that have the potential for use in clinical decision-making.

How wearables could be used in clinical decision-making is shaped by (1) the agencies involved, (2) marketing pathways, and (3) recent federal activities affecting how wearables are regulated.

1.2.1 Federal agencies involved in wearables regulation and use

Federal agencies, such as FDA and the Centers for Medicare & Medicaid Services (CMS), have a role in regulating medical devices in the U.S. Additionally, clinicians in the Department of Veterans Affairs (VA) medical facilities use medical and wellness devices as tools for patient care, including for use in clinical decision-making.[6] Specifically:

- **Food and Drug Administration (FDA).** FDA regulates the safety and effectiveness of medical devices. To do so, FDA reviews manufacturers' safety data before and sometimes after manufacturers are allowed to sell their

[5]For more information on AI, see GAO, *Artificial Intelligence in Health Care: Benefits and Challenges of Technologies to Augment Patient Care*, GAO-21-7sp (Washington, D.C.: Nov. 2020); GAO, *Artificial Intelligence in Health Care: Benefits and Challenges of Machine Learning Technologies for Medical Diagnostics*, GAO-22-104629 (Washington, D.C.: Sep. 2022); GAO, *Science & Tech Spotlight: Generative AI in Health Care,* GAO-24-107634 (Washington, D.C.: Sep. 2024).

[6]FDA and CMS are divisions within HHS. Additional federal entities that have a role in regulating or using wearables but are not the focus of this report include: HHS's National Institutes of Health (provides grants to support medical research, including wearables development); HHS's Office of the National Coordinator for Health Information Technology (formally dually titled with the Assistant Secretary for Technology Policy—develops standards for electronic health information exchange); HHS's Office for Civil Rights (enforces privacy and security of protected health information including those under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its related rules) (Pub. L. No. 104-191, 110 Stat. 1936, 42 U.S.C. § 1320d et seq., with privacy and security regulations found in the Code of Federal Regulations at 45 C.F.R. Parts 160 and 164); the Federal Trade Commission (enforces consumer protection laws); the Consumer Product Safety Commission (has joint jurisdiction with FDA over certain medical devices); and entities within the Department of Defense (conduct technology research and development and patient care under its responsibilities for ensuring military medical readiness).

wearables to consumers as a medical device.[7]

- **Centers for Medicare & Medicaid Services (CMS).** CMS regulates medical device coverage under Medicare. Other health insurers typically follow Medicare's lead when issuing coverage decisions for new medical devices.

- **Veterans Health Administration (VHA).** VHA, an entity within VA, uses medical and wellness devices as tools for patient care. VHA is the largest integrated health care system in the U.S., providing care at 1,380 medical facilities to more than 9.1 million veterans. As a system that mainly provides health care services to veterans, VHA primarily uses federal tax dollars to maintain its operations.

1.2.2 Marketing pathways for wearables

When a manufacturer seeks to market a new wearable, its pathway to market primarily depends on whether the wearable meets the statutory definition of a medical device. Under Section 201(h)(1) of the Federal Food, Drug, and Cosmetic (FD&C) Act, medical devices are determined in part by the device's intended use. If the new wearable meets the statutory definition of a medical device—including that it is "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease"—then the manufacturer must submit information about the device to FDA for review prior to marketing, unless the device is exempt from premarket review.[8] If FDA determines the device is safe and effective according to statutory requirements, the manufacturer can then market the wearable as a medical device.

Once medical device manufacturers successfully complete FDA review, they may also choose to pursue CMS review or to sell the device directly without seeking insurance coverage, counting on the users to pay for the device. If a manufacturer chooses to seek CMS review and CMS determines that the device may be medically "reasonable and necessary" for the diagnosis or treatment of illness or injury of beneficiaries, the device may be approved for Medicare coverage. Other insurers may opt to cover the wearable as well. Coverage determinations by private

[7]FDA may review a medical device through multiple pathways. These include FDA clearance through the 510(k) premarket notification pathway, which FDA may primarily grant to low-risk (Class I) and medium-risk (Class II) medical devices, as well as approval (FDA approval through the Premarket Approval pathway), which the FDA may grant to high-risk (Class III) medical devices. FDA review also includes the pathway for devices with a De Novo classification. FDA's classification of the medical device is based on risk and determines the controls needed for the device and the review pathway and required submissions for marketing authorization. See 21 U.S.C. § 360c(a)(1) (risk-based classification), 21 U.S.C. § 360e (Premarket Approval), 21 U.S.C. § 360(k) (510(k) notification), and 21 U.S.C. § 360c(f)(2) (De Novo). Some Class I and Class II devices are exempt from premarket notification (510(k)) and can be commercially distributed without undergoing FDA review and clearance. See 21 U.S.C. § 360(l) and (m).

[8]Some medical devices are exempt from the 510(k) premarket notification pathway and can be commercially distributed without undergoing FDA review and clearance. See 21 U.S.C. § 360(l) and (m).

insurance generally follow Medicare but are not required to.

If a new wearable does not meet the definition of a medical device, then the manufacturer may market the new wearable to consumers as a wellness device, without the need for FDA review.[9] For example, a wearable that is intended to help users make healthy lifestyle choices may be marketed as a wellness device. Wellness devices are generally not covered by CMS, but other insurers can choose to cover such devices.

Finally, a manufacturer may choose to remove the wearable from the market at any time and for any reason. In addition to potentially influencing how a device is marketed or covered by insurance, the designation of a wearable as either a medical or wellness device may have other implications. For example, a device's intended use may affect the extent to which Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations are likely to be involved.[10]

1.2.3 Recent federal activities that may affect the use of wearables in clinical decision-making

Federal regulations and activities related to digital health technologies—a class of technology that is broader than wearables—may affect the way wearables are regulated or used in health care, including in clinical decision-making. Table 1 summarizes how these broad federal activities relate to wearables.[11]

[9]If a new wearable is a medical device but is only intended for general wellness and presents a low-risk to the safety of users, FDA officials stated that the agency does not intend to review such devices for compliance with the FD&C Act. See appendix II for more information about low-risk devices.

[10]For example, HIPAA Rules protect individually identifiable health information that is maintained or transmitted by a HIPAA-covered entity or business associate. Pub. L. No. 104-191, 110 Stat. 1936, 2021 (1996) (codified at 42 U.S.C. §§ 1320d–1320d-9) and the HIPAA Privacy, Security, and Breach Notification Rules, 45 C.F.R. pts. 160, 164. HIPAA Rules requirements apply to covered entities (health plans, most health care providers, and health care clearinghouses) and business associates (an entity that creates, receives, maintains, or transmits protected health information on behalf of a covered entity or another business associate). Only health care providers that conduct standard transactions adopted by HHS under HIPAA are covered entities. When a HIPAA-regulated entity employs a wearable in clinical decision-making, any protected health information (PHI) created, received, maintained, or transmitted by the device is subject to the protections under the HIPAA Rules.

[11]For more information on regulations that affect wearables and other digital health technologies, including information about HHS's evolving approach, see appendix II.

Figure 2. Examples of federal activities that may affect the use of wearables in clinical decision-making

Agency component	Initiative	Relationship to wearables
Department of Health and Human Services (HHS) Health Technology Ecosystem and related initiatives		
Centers for Medicare & Medicaid Services (CMS)	Health Technology Ecosystem (2025)	Encourages industry to collaborate with HHS to implement technological integration and clinical workflow solutions.
CMS	Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) Model (2026)	In coordination with the Health Technology Ecosystem and Technology-Enabled Meaningful Patient Outcomes (TEMPO) Pilot, could allow medical facilities to expand access for patients with Medicare to wearables.[a]
Food and Drug Administration (FDA)	TEMPO for Digital Health Devices Pilot (2026)	Could promote access to some wearables and protect patient safety in CMS's ACCESS Model.
HHS Breakthrough Devices and related initiatives		
FDA	Breakthrough Devices Program (2015)	Could provide patients and clinicians with timely access to some wearables by speeding up development, assessment, and FDA review.
CMS	Transitional Coverage for Emerging Technologies (TCET) Pathway (2024)[b]	Could facilitate access for patients with Medicare to wearables, reduce uncertainty about coverage, and encourage evidence development. But manufacturers must obtain FDA Breakthrough Device designation.
Department of Veterans Affairs (VA) wearables initiatives		
Veterans Health Administration (VHA)	VA Share My Health Data app study (2020)	Allows patients to view data from many types of wearables in one place and share it with VHA care teams.
VA	Use of wearables by VA clinicians	Could be used by VA clinicians to monitor patient activity, in some cases.

Source: GAO analysis of agency information. | GAO-26-107847

[a]CMS's ACCESS Model specifically applies to patients covered under Medicare fee-for-service, also called Traditional or Original Medicare.

[b]In April 2026, FDA and CMS announced a pause for new candidates for TCET, as CMS focuses on implementing a new coverage pathway, Regulatory Alignment for Predictable and Immediate Device (RAPID). RAPID is a new CMS pathway designed to expedite access to certain FDA-designated Breakthrough Devices for people with Medicare. See CMS, *CMS and FDA Announce RAPID Coverage Pathway to Accelerate Patient Access to Life-Changing Medical Devices*. Press Release (Apr. 23, 2026), available at https://www.cms.gov/newsroom/press-releases/cms-fda-announce-rapid-coverage-pathway-accelerate-patient-access-life-changing-medical-devices.

2 Current Capabilities of Wearables for Use in Clinical Decision-Making

Wearables make measurements using sensors, and their capabilities in clinical decision-making depend on their accuracy and reliability. In the future, AI augmentation could increase autonomy in wearables and may expand their potential in clinical decision-making.

2.1 Current wearables rely on sensors

The current capabilities of wearables include:

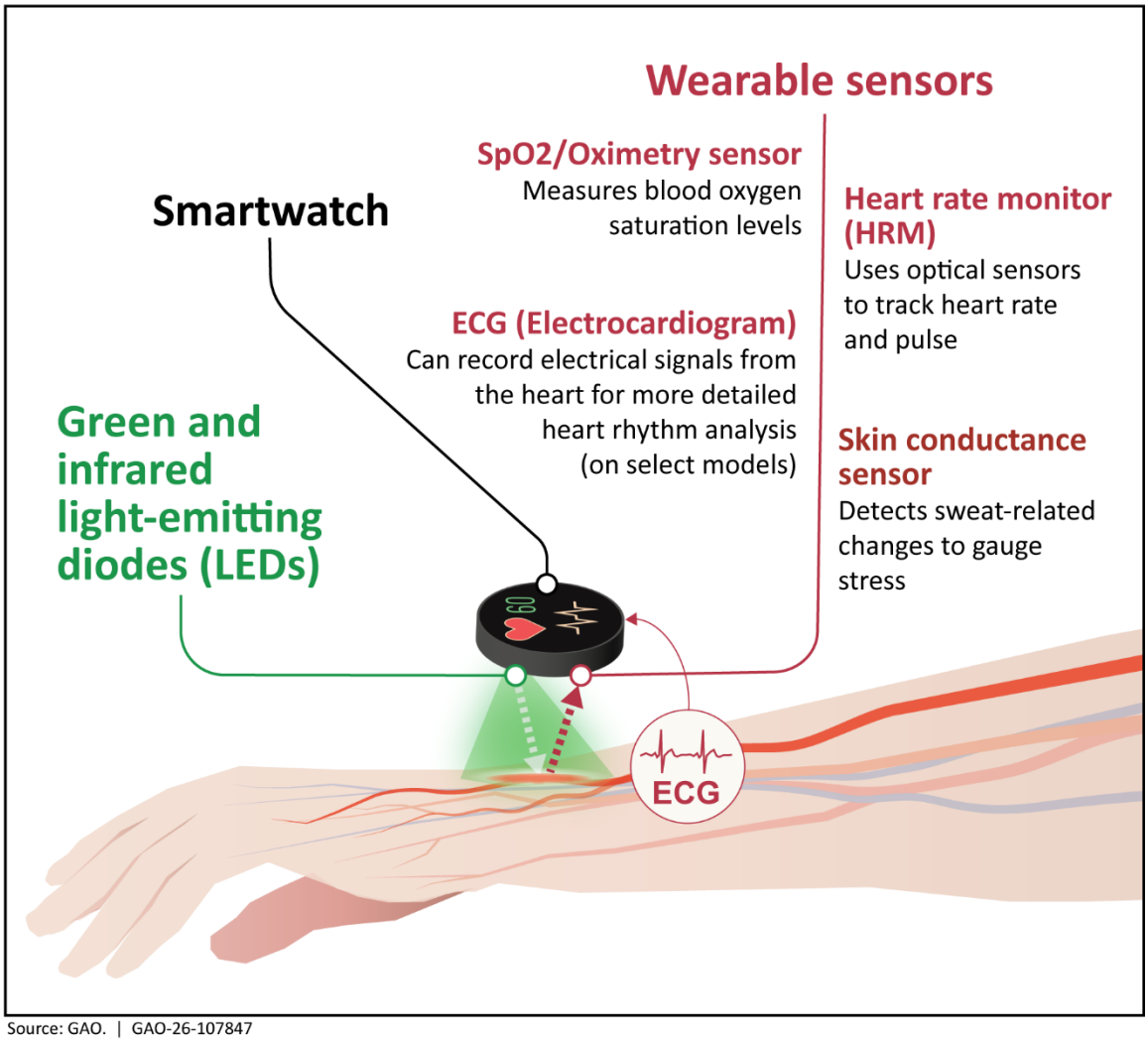
- monitoring selected vital signs of users over the long term to establish a baseline;
- analyzing trends in comparison to established baselines to alert users, caregivers, or clinicians of medical events or suggested lifestyle changes; and
- providing additional assessments of user data that can be sent to a clinician for interpretation or used in the clinical decision-making process.

Accordingly, most clinicians and wearable manufacturers we interviewed said they view current wearable technologies as tools that may help identify potential issues or refer users to a clinician for further tests. [12] They do not view current wearables as a complete replacement for a diagnosis made by a clinician.

To collect data on user vital signs, wearables use several different sensors such as accelerometers and photoplethysmographs (PPGs) (fig. 2). Accelerometers are sensors that detect the motion of a device and are often placed on a user's body to monitor movement. PPG technology uses optical sensors to measure blood flow under the skin, enabling heart rate measurements. Many wearables use these measurements, combined with their own proprietary algorithms, to infer more complicated information about a user's health. For example, some devices on the market claim to be able to track sleep stages, blood oxygen levels, and estimate how exercise affects a user's heart and circulatory function.

[12]We conducted 27 semi-structured interviews with stakeholders; including six academics; seven associations representing patients, medical groups, or industry; seven manufacturers, clinicians from five health care facilities; and two agencies to obtain a variety of perspectives of wearable development and use. For more information on our stakeholder selection, see appendix I.

Figure 3. **Types of sensors used in wearables for clinical decision-making**



Source: GAO. | GAO-26-107847

A key reason that most clinicians we spoke with view current wearables as helpful tools in clinical decision-making (and not independent diagnostic devices) is due to the ways they collect data. The size and placement of wearables and their respective sensors influence how clinicians currently use data from wellness devices in clinical decision-making, because these factors sometimes limit the diagnostic capabilities of wearables when compared to more traditional medical devices. For example, a clinician told us that they may rely on the results of a watch-based electrocardiogram (ECG) with a single measurement lead attached to the body as a preliminary sign of a condition like atrial fibrillation. This may prompt the clinician to request that the user come into the clinic for more targeted tests. However, for a formal diagnosis of a heart condition, they would instead use a standard 12-lead ECG, which attaches to the body in 10 places, to confirm the symptoms and diagnosis.

Regarding treatment capabilities, stakeholders said they were not aware of any wearables that currently prescribe medication or other treatment based on data processed by the wearable alone.[13] However, some current wearable medical devices can dispense medication, such as insulin, within ranges predetermined by the clinician, or prompt consultation with a clinician for treatment. Similarly, they noted that wellness devices can only suggest lifestyle changes, such as physical activity or relaxation exercises.

2.2 Wearables' capabilities depend on their accuracy and reliability

The capability of wearables to provide usable information in clinical decision-making depends on their accuracy and reliability. Stakeholders we interviewed, including clinicians, academics, medical associations, and manufacturers, had varied opinions of and experiences with wearables, and told us that medical devices that complete FDA review may be more accurate and precise than wellness devices that are not reviewed by FDA. These stakeholders described two main reasons for the differences between wellness and medical devices:

- Certain medical devices can take truly continuous readings because they are single-purpose devices that can concentrate all their resources on measurements. Most wellness devices, however, only take periodic sample readings, to conserve resources for other device functions. (For example, a consumer watch may monitor heart rate and blood oxygen levels, in addition to keeping time.)

- Some traditional medical devices that monitor health conditions are often only meant to be worn for comparatively short periods, and therefore patient comfort may not be a high concern. These devices are often worn at locations on the body that are more conducive to accurate measurement, such as the chest or fingertips. Conversely, wellness devices are designed for long-term comfort and may have sensors in areas that are more convenient for a user but less conducive to accurate measurement, such as the wrist.

Stakeholders provided a range of opinions on whether differences in performance between medical and wellness devices would ever be eliminated. Some stakeholders mentioned several obstacles to narrowing this difference, including development costs and cultural barriers (e.g., reluctance by both patients and clinicians to use wearables in clinical decision-making). Additionally, manufacturers may not have an incentive to make wellness devices as accurate and reliable as FDA-reviewed medical devices, because doing so requires a significant investment of time, money, and

[13]Some wearable devices, such as hearing aids or physical rehabilitation devices, can deliver predetermined treatment options, set by a clinician, but cannot independently prescribe treatment. Such devices fall outside of our scope, as they are designed to treat a known or existing issue and are not used to inform the clinical decision-making process.

development resources.[14] Further, manufacturers that do not intend to seek the medical device designation may not develop wearables that rise to this level. Finally, manufacturers may conclude that if they do go through the FDA review process, the investment is not worth the marginal advantage they would gain by being marketed as an FDA-reviewed medical device. However, that said, most stakeholders we spoke to about this topic agree that any change to better-performing wellness devices would likely be driven by demand from both patients and clinicians.

2.3 AI augmentation of wearables could increase autonomous decision-making

Currently, there are no fully autonomous wearables marketed for use in clinical decision-making, such as for diagnosing conditions or prescribing treatment. Fully autonomous medical devices would make independent diagnosis or treatment decisions for a patient based on data from the wearable with no clinician intervention.

Stakeholders told us that AI augmentation of certain wearables could increase their autonomy; however, the extent to which wearables could be fully autonomous is unclear. Some currently marketed wearables can operate with a degree of independence, but they cannot make decisions autonomously. For example, continuous glucose monitors can be coupled with insulin pumps to form a closed-loop insulin delivery system. These devices are able to independently and automatically measure and adjust insulin dosage, but they only operate within a range pre-established by the patient's clinician. Therefore, clinicians and medical associations we spoke to do not consider them to be fully autonomous.

Stakeholders told us that current wearables use a simple type of AI but could be augmented further by advances in AI technology. As is, they are not capable of advanced decision-making, like diagnosis, but can interpret sensor readings to notify a user about an abnormality, such as an abnormal heart rate. For example, some clinicians and manufacturers we spoke with mentioned that there are cardiac monitors currently on the market which can accurately detect atrial fibrillation, notify users about the potential diagnosis, and suggest they seek confirmation from a clinician.

Due to technological limitations, some current wearables use external processing, separate from the wearable itself, to conduct

[14]In January 2026, FDA modified its General Wellness: Policy for Low Risk Devices guidance. FDA officials told us they do not intend to examine low-risk general wellness products to determine whether they are medical devices within the meaning of the FD&C Act, or if they are medical devices under the act, whether they comply with the premarket review and post-market regulatory requirements for devices under the FD&C Act and implementing regulations. See also FDA Guidance: *General Wellness: Policy for Low Risk Devices* (Rockville, MD: Jan. 2026), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices.

any advanced analysis—such as recommending a personalized workout based on analysis of heart rate data—or any potential decision-making capabilities.

Most stakeholders agree that—even with AI—wearables will not be capable of fully autonomous decision-making for users all the time. Others noted that it may be possible for AI-augmented wearables to play a role in diagnosis and treatment for certain patients with low-risk conditions.

However, stakeholders noted challenges, including reliability and accuracy of the technology, limitations of current regulations on what wearables are allowed to claim they do, and lack of patient or physician interest or acceptance of AI, among others. Stakeholders who viewed full autonomy as a possibility told us it will be at least 5 years, but potentially several decades, before AI-augmented autonomous wearables will be used in clinical decision-making.

3 Potential Benefits of Wearables in Clinical Decision-Making

Wearables may be able to provide a range of benefits to both individuals and the general public, including the health of underserved populations who do not have adequate access to health care. Wearables have the potential to provide clinicians with direct access to readily available and continuously updated streams of information. This may enable quicker diagnoses, more personalized care plans, and improved patient compliance. Underserved populations may particularly benefit from expanded remote patient monitoring and improved disease treatment.

3.1 Wearables may provide benefits to individual health

More information. According to the stakeholders we interviewed, wearables could increase information for users and clinicians, leading to improved clinical decision-making. For example, users could proactively monitor how their actions affect their measurement of certain vital signs, such as resting heart rate, instead of waiting for an appointment to have a measurement taken. Additionally, stakeholders noted that availability of real-time information can motivate compliance with medication or healthy behaviors by providing users with feedback on how their actions affect their health. Users can also use data from wearables to show a clinician that they are having a specific health issue, or to show symptoms they may have trouble describing.

Clinicians told us they can also benefit from wearables information. Wearables can provide clinicians with data showing the day-to-day fluctuations of a patient's vital signs. Such data can provide a better indication of the patient's condition than measurements from sporadic in-person visits, which may not always be representative of a patient's true condition. For example, patients may become nervous when having their blood pressure checked during an office visit, which could lead to higher readings. Clinicians told us data provided by wearables between patient visits may also allow them to triage patients more quickly. Finally, larger datasets collected from wearables could help give clinicians more information about conditions that are challenging to diagnose.

Example of an emerging benefit

We spoke to a clinician who described instances where wearables could provide improved information about heart rate and glucose levels to clinicians, which may allow them to offer treatment options to patients sooner.

Additionally, we reviewed one study showing that diabetic patients who use continuous glucose monitors—a medical device—were able to manage their glucose levels better than those who use only traditional finger-prick methods. Clinicians and patients can use information from wearables to improve their treatments.

Source: RW Beck, TD Riddlesworth, et al., Continuous Glucose Monitoring Versus Usual Care in Patients With Type 2 Diabetes Receiving Multiple Daily Insulin Injections: A Randomized Trial., Annals of Internal Medicine, 167(2017): 365–374. https://doi.org/10.7326/M16-2855. | GAO-26-107847

Quicker diagnoses. Many clinicians face increasing patient loads, extensive documentation requirements, and administrative burdens that can contribute to long wait times for services and reduced interactions with patients. Stakeholders suggested that AI-augmented data processing could decrease the time to diagnosis. For example, AI could help reduce the time clinicians spend sorting through data collected by wearables to identify trends or indicators of health concerns by consolidating data into more manageable formats, which

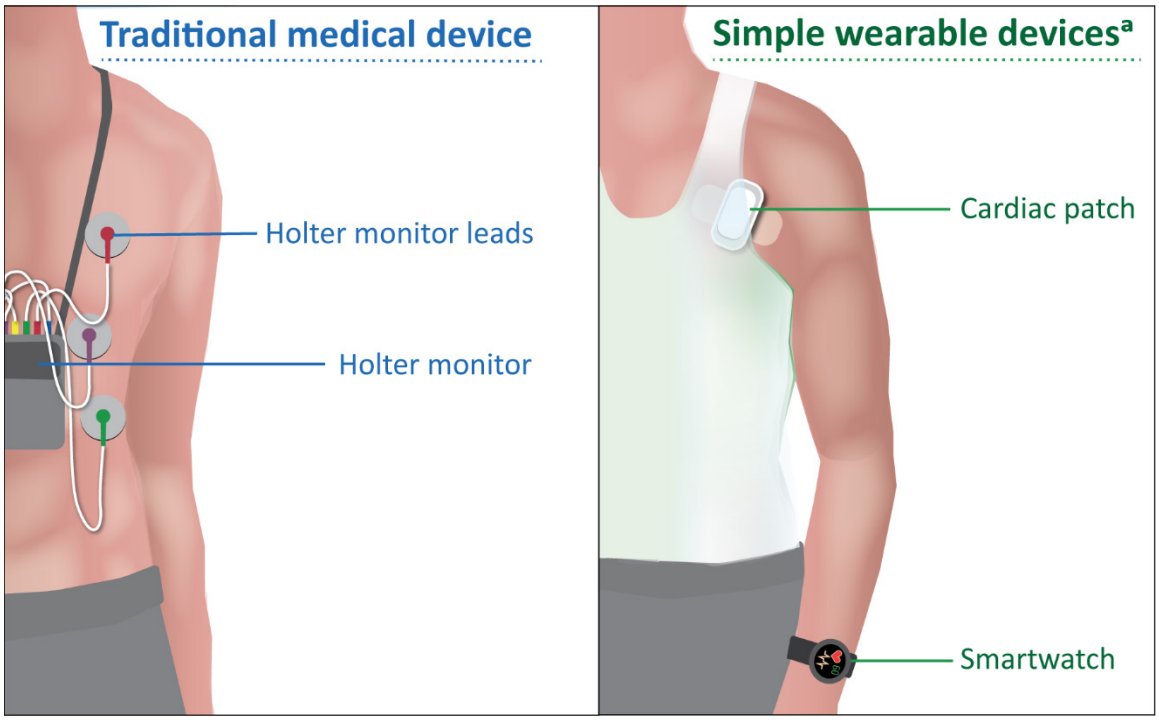
could then reduce wait times and expedite diagnoses. Wearables could also reduce the time it takes a clinician to diagnose and prescribe treatment by lessening the need for laboratory testing if clinicians can pull data from the devices to show a patient's vital signs over an extended period.

Personalization. Wearable medical devices can enable more personalized care than currently available methods. Traditionally, patient measurements are compared to the average measurement for individuals with similar demographics. This can result in false alarms for some patients if their normal range of vital signs is outside of the average. Wearables used in conjunction with AI capabilities could reduce such false alarms by more readily comparing readings to a patient's own personal baseline.

Improved compliance. Clinicians told us that wearables may help remove the common obstacle of patient compliance with their treatment plans and may encourage patient engagement in the clinical decision-making process. According to clinicians, older adults do not like the stigma of frailty associated with traditional medical devices such as fall pendants or larger devices like Holter monitors, which monitor heart rhythms to help detect cardiac problems.[15] According to stakeholders, using wearables that are less obtrusive and more fashionable, such as a smartwatch or a ring, for fall detection or ECG monitoring, may encourage users to comply with treatment plans by reducing the associated stigma (fig. 3). Similarly, other users may find traditional medical devices uncomfortable or inconvenient but may be more willing to use wearables, ultimately improving compliance with wearing them. For example, a Holter monitor requires two to 12 leads attached to the body, and the device is worn around a patient's neck, waist, or shoulder. By comparison, a cardiac patch is unobtrusive, usually has fewer leads, and is much smaller and lighter. Patients may be more willing to wear the more comfortable device.

[15]A fall pendant is a medical alert device, usually a necklace with an alert button, designed for older adults or individuals at risk of falling, which automatically detects when the wearer has fallen and alerts a monitoring center. A Holter monitor is a type of 24-hour continuous ECG worn by heart patients that is electronically recorded and analyzed. This type of monitoring helps clinicians detect cardiac abnormalities such as clogged arteries and arrhythmias.

Figure 4. Differences between a traditional medical device and wearable medical devices



Source: GAO. | GAO-26-107847

[a]In this report, we define wearables as medical or wellness devices that are worn externally on the human body or clothing, typically for prolonged periods, contain sensors, and perform at least one specific health-related function such as monitoring a user's vital signs.

3.2 Wearables could provide benefits to underserved populations

Use of wearables in clinical decision-making could benefit the health of the population at large, including expanded remote patient monitoring and improved disease treatment. This could particularly benefit underserved communities and patients with rare diseases.

Expanded remote patient monitoring. Clinicians told us that wearables could help medical facilities and clinicians expand remote patient monitoring services to reduce the need for in-person clinical visits. Clinicians could then receive information collected by wearables outside of clinical settings or without the need for an in-person connection. Clinicians could access the information either when a user comes in for a visit, or remotely via a live connection. According to one review of the literature, wearables may be particularly useful for expanding remote patient monitoring services by collecting and providing more data than other devices.[16]

[16]Yue Liao, Carrie Thompson, Susan Peterson, John Mandrola, and Muhammad Shaalan Beg. "The Future of Wearable Technologies and Remote Monitoring in Health Care." *American Society of Clinical Oncology Educational Book*, no. 39 (2019): 115-121, https://doi.org/10.1200/EDBK_238919.

Clinicians told us that rural and other underserved patient populations may especially benefit from using wearables to expand remote patient monitoring because these patients have limited access to in-person visits due to schedule, travel, and cost constraints.

Example of an emerging benefit

One manufacturer we spoke with noted that studies on their pulmonary wearable patch showed benefits to clinical decision-making by predicting the likelihood of a medical event a week in advance, allowing patients to seek care to prevent hospitalization. One of the studies we reviewed looked at what happened after patients started a remote patient monitor program. In this program, data collected using the pulmonary wearable patch were used to determine when patients received a risk assessment phone call. In the first year of the program, patients experienced 65 percent fewer hospitalizations than the prior year.

Source: Michael Polsky, Nemma Moraveji, Ashley Hendricks, Robert Teresi, Richard Murray, Diego Maselli. "Use of Remote Cardiorespiratory Monitoring is Associated with a Reduction in Hospitalizations for Subjects with COPD." International Journal of Chronic Obstructive Pulmonary Disease. Vol. 18. (2023): 219 – 229. | GAO-26-107847

Improved disease treatment. Widespread wearables use in clinical decision-making processes could generate large datasets for research or the development of improved AI models for rare or chronic diseases. Due to their low incidence, modeling of rare diseases suffers from statistical limitations. By pooling data from wearables, researchers may be able to identify the onset and spread of diseases. These data could help generate insights on disease progression and new or improved treatments.

4 Challenges Limiting the Use of Wearables in Clinical Decision-Making

Using wearables in clinical decision-making has a range of potential benefits, but current challenges may continue to affect whether such benefits are realized. We identified challenges to the use of wearables in three areas: ensuring patient health benefits, integrating wearables into clinical workflows, and navigating the health technology market.

4.1 Challenges of ensuring patient health benefits

The use of wearables in clinical decision-making may not always benefit individual health as intended and, in some cases, may put patient health and safety at risk, according to clinicians and agency documents. Factors contributing to these risks include limited public disclosure of testing before wellness devices are on the market, limited monitoring after wearables are on the market, and limited manufacturer participation in voluntary certification processes.

4.1.1 Limited disclosure of testing before wellness devices are on the market

There is no requirement for wellness device manufacturers to publicly disclose their performance testing methods or results.[17]

Wellness device manufacturers usually conduct internal testing during product development and may take additional steps to validate measurements of reliability and accuracy. However, manufacturers may safeguard this information for proprietary or other reasons. Stakeholders told us that because this information is not publicly available, neither patients nor clinicians are fully informed. Further, clinicians cannot typically judge the suitability of such devices for clinical decision-making. This lack of information could lead to avoidance of wearables when they may be helpful, or use of wearables in ways that do not improve patient health.

4.1.2 Limited monitoring after wearables are on the market

Medical and wellness devices are subject to limited monitoring after they are on the market. For example, medical device manufacturers must follow certain requirements and regulations once devices are on the market. These include reporting of device-associated deaths, serious injuries, and certain malfunctions, and reporting of device corrections and removals. Furthermore, in 2025 we reported that the capacity of FDA to conduct its own postmarket monitoring of medical devices is limited.[18] Similarly, there

[17]In comparison, unless a medical device is exempt from the requirement of premarket notification, medical device manufacturers are required to obtain premarket authorization prior to marketing their devices. In doing so, the manufacturer must submit information to FDA from which FDA can determine there is reasonable assurance of the device's safety and effectiveness when used as intended, some of which is later publicly disclosed.

[18]In 2025, we reported that from fiscal years 2020 to 2024, FDA oversaw the recall of 3,934 medical devices, all of which were voluntarily recalled by manufacturers rather than mandated for recall by FDA. According to FDA officials, FDA's ability to conduct oversight activities was limited by a lack of

are no FDA-enforced requirements for wellness device manufacturers to conduct postmarket monitoring.

One example of how wearables performance can degrade after the device is on the market, potentially affecting patient health, is a phenomenon called model drift. Model drift is when an AI model becomes less accurate over time as real-world patterns change. For wearables augmented by AI, the relevant real-world patterns may include changing patient populations and disease patterns. If the AI model no longer reflects real-world patterns, the wearable's diagnosis or treatment predictions may become less accurate. According to medical association representatives we spoke to, AI performance issues in wearables could go unnoticed for long periods of time and may negatively affect many patients. FDA has stated the importance of monitoring AI in medical devices in draft guidance to manufacturers.[19] Additionally, other stakeholders have proposed frameworks for governing marketed AI medical devices. However, these monitoring practices are not yet in widespread use, according to stakeholders.[20]

Without intervention by policymakers, postmarket monitoring of wearables for performance issues, such as model drift, may not become a more common practice due to long-term costs. As a result, medical facility leaders, clinicians, and patients may not have the information they need to make the most informed choices about the potential benefits and risks of using particular wearables in clinical decision-making.

4.1.3 Limited manufacturer participation in voluntary certification processes

Several independent organizations offer voluntary certification processes that assess the performance of wearables before or after they are on the market.[21] However, medical and wellness device manufacturers may lack

sufficient staff. FDA's oversight of medical products, including devices, has been on GAO's High-Risk list since 2009. See GAO *Medical Device Recalls: HHS and FDA Should Address Limitations in Oversight of Recall Process* GAO-26-107619 (Washington, D.C.: Dec. 2025). In addition, in July 2025, FDA officials told us that the agency did not have plans to include any digital health technologies in its Active Postmarket Surveillance System, which is an existing system that FDA uses to monitor some FDA-reviewed products that are on the market. For background on that system, see GAO *Medical Devices: FDA Has Begun Building and Active Postmarket Surveillance System* GAO-24-106699 (Washington, D.C.: Jul. 2024). Wearables performance issues can lead to injury or death. For example, in 2026 a medical device manufacturer recalled several models of glucose monitor sensors following a report of 860 serious injuries and seven deaths. According to FDA, the recall was due to incorrect readings showing lower than actual blood glucose levels.

[19]See FDA, Draft Guidance: *AI-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations* (Rockville, MD: Jan. 2025).

[20]For an example of a framework proposed by other stakeholders, see Shayan Bahadori, Peter Buckle, Tayana Soukup Ascensao, Saira Ghafur, and Patrick Kierkegaard, "Evolving Digital Health Technologies: Aligning With and Enhancing National Institute for Health and Care Excellence Evidence Standards Framework," *JMIR Mhealth Uhealth* 13(2025): e67435. https://pmc.ncbi.nlm.nih.gov/articles/PMC12373408/.

[21]Currently, several independent organizations offer certification processes or conduct evaluations related to digital health technologies, which may include wearables. Examples include the Coalition for Health AI's Applied Model Card and the Digital Medicine Society's DiMe Seal. Additionally, academic researchers, medical associations, and industry representatives sometimes initiate independent evaluations of wearables performance, which can provide additional information to clinicians and patients. E.g., Nelson Barrera, Maria Solorzano, Yomary Jimenez, et al. "Accuracy of smartwatches in the detection of atrial fibrillation," *JACC: Advances 4.11_Part_1* (2025): 102133, https://doi.org/10.1016/j.jacadv.2025.102133; Peterson Health Technology Institute, *Digital Diabetes Management Solutions Health Technology Assessment* (March 2024).

incentive to participate. According to a representative of one certifying organization we spoke to, certifications will not be a useful indicator of device quality without high levels of manufacturer participation. But without existing consumer preference for certified devices, manufacturers are unlikely to participate in the voluntary certification processes. Thus, certifying organizations may be challenged to build certifications that manufacturers want to participate in, and that medical facilities, clinicians, and patients trust when considering whether to use a wearable in clinical decision-making. As one medical association we spoke to stated, "[Clinicians] themselves are regulated via certifications and licenses, so it does not make sense for [clinicians] to adopt technology that has not also been [assessed by an independent entity]."

4.2 Challenges of integrating wearables into clinical workflows

Wearables are not currently integrated into most medical facility technology infrastructure and clinical workflows, according to clinicians and industry representatives.[22] The lack of technological integration has reduced the usefulness of data collected by wearables and has led to increased concerns about data privacy, security, and new liabilities. Together, these challenges have slowed the uptake of wearables in clinical decision-making.

4.2.1 Lack of integration with existing medical technology

Medical facilities may lack easy methods to integrate wearables data into their infrastructure and workflows. Clinicians and representatives of medical and industry associations said many wearables are not compatible with the technology infrastructure or workflows of most medical facilities. For example, VA officials told us that VA took steps to improve integration by implementing a phone app for patients to upload patient-generated health data from wearables and similar devices. However, they said that participation requires the patient to take additional action between appointments, which patients do not always choose to do. The result is that such data are not always available to clinicians for use in clinical decision-making.

In addition to the technological challenges of integration, clinicians told us that information collected by wearables may worsen the cognitive overload that clinicians can experience in their typical workday. Specifically, clinicians must often consider multiple factors when making decisions, such as patient history, test results, and preferences expressed by patients in conversation.

Further, data from wearables may help inform the decision, but the utility of this information depends partly on how the data

[22]HHS's Agency for Healthcare Research and Quality defines clinical workflows as the sequence of physical and mental tasks performed by various people within and between work environments. Workflows can occur at several levels (e.g., one person, between people, across organizations) and can occur sequentially or simultaneously. For example, a workflow for ordering a medication includes the communication between the clinician and the patient, the clinician's thought process and actions to enter a prescription into an electronic health record, and the transmission of that order to a pharmacy to have the prescription filled. Accessed April 2, 2026, https://digital.ahrq.gov/health-it-tools-and-resources/evaluation-resources/workflow-assessment-health-it-toolkit/workflow.

are presented to the clinician. For example, a wearable may collect millions of data points for one patient over several months, but the device itself may lack an effective alert feature that draws the clinician's attention to the likely presence of a disease or condition. Without effective alerts or other design features, clinicians may be burdened with interpreting the data before they can consider this information as a factor in clinical decision-making.

4.2.2 Data privacy and security concerns

Researchers, medical associations, clinicians, and a patient advocacy association we spoke to had concerns about data privacy and security. Such concerns can affect the willingness of patients, clinicians, and medical facility leaders to incorporate wearables into clinical workflows. In 2025, researchers wrote that cybersecurity breaches are one risk of using wearables to collect health data.[23] Moreover, wellness devices are not subject to the cybersecurity requirements that FDA is charged with enforcing for medical devices.[24]

Patients who choose to use wearables generally must first agree to share their personal health data. Specifically, users wishing to take full advantage of device features, including those that could be useful in clinical decision-making, typically must consent to allowing their data to be sold to or shared with third parties, such as data brokers, private health insurers, and other entities. Users may provide consent without appreciating the extent of such sharing and the potential risks.

Data privacy challenges are not likely to be solved without intervention from policymakers because of an inherent tension between privacy concerns and the desire to improve device performance. Large volumes of high-quality data collected by wearables are reportedly needed to improve or correct the performance of AI-based algorithms throughout the life cycle of a wearable device. For example, if a manufacturer wished to market a wearable medical device to a broader demographic than intended when it was first marketed, it may need to collect and analyze new health data from that population.[25] Thus, manufacturers are incentivized to increase data collection by opportunities to maintain or improve software performance, but such improvements could come at the cost of user

[23]Two data breaches from the last 6 years illustrate the risks: one involved 61 million fitness tracker records, and a second, not specific to wearables, involved the compromise of health records from 100 million individuals, held by a private health insurer. See Cailbhe Doherty, Maximus Baldwin, Rory Lambe et al., "Privacy in consumer wearable technologies: a living systematic analysis of data policies across leading manufacturers." *npj Digital Medicine* 8 (2025):363. https://doi.org/10.1038/s41746-025-01757-1.

[24]Under 21 U.S.C. § 360n-2, medical devices must meet certain cybersecurity requirements to complete FDA premarketing review, but wellness devices are not subject to the same oversight, as they are not required to undergo FDA review. The FD&C Act was amended to add section 524B by the Consolidated Appropriations Act, 2023, Pub L. No. 117-328, § 3305, 136 Stat. 5832 (2022), codified at 21 U.S.C. 360n-2. This provision ensured that cyber medical devices are subject to cybersecurity requirements in the law. For more information on how nonmedical devices, including wellness devices, interact with HIPAA regulations, see GAO, *Technology Assessment: Brain-Computer Interfaces*, GAO-25-106952 (Washington, D.C.: Dec. 2024), 15-16.

[25]In its guidance, FDA has noted that such an example—modification of a medical device to market the wearable for a new intended use—could trigger the need to submit new data to FDA. See FDA, *Guidance: Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics*, (Rockville, MD: Sept. 2018).

privacy if user data protections are not strengthened.

4.2.3 Liability uncertainties

Clinicians, researchers, industry representatives, and a medical association we spoke with are uncertain about liabilities when wearables are involved in clinical decision-making. These uncertainties may make clinicians and medical facility leaders hesitant to incorporate wearables into clinical workflows. For example, if a wearable detects an irregular heartbeat but the clinician does not confirm a heart condition, it is unclear whether the clinician or medical facility could be held liable for malpractice if that patient later suffers a negative health outcome, such as a heart attack, and chooses to bring a complaint against the relevant parties. Manufacturers expressed similar concerns. One manufacturer gave the example of a wearable that analyzes a user's mobility (e.g., their gait) to estimate the risk of falls and injury. They said this technology is not yet marketed because clinicians are concerned they could be held responsible for acting on safety alerts that patients receive on their wearables.

4.3 Challenges of navigating the health technology market

Manufacturers face uncertainty about insurance coverage and may be deterred from bringing wearables for uncommon diseases to market. These challenges currently limit the extent to which patients, clinicians, and medical facility leaders have chosen to incorporate wearables into health care.

4.3.1 Uncertain insurance coverage

Stakeholders reported that uncertainty in insurance coverage for wearables may deter some manufacturers from developing medical devices. For instance, representatives of an association of more than 600 medical device manufacturers described this uncertainty as "monumental" and said that it hinders the integration of wearables into clinical settings. Medical device manufacturers told us that decisions about coverage by insurance such as Medicare can be slow and costly, with no guarantee of agency approval even though they have completed FDA review. This uncertainty may lead them to choose to develop wellness devices—which are not reviewed by the FDA—to lower their development costs, shorten their time to market, and broaden their potential consumer base, according to association representatives.

4.3.2 Deterrents to bringing wearables for uncommon diseases to market

Manufacturers that design wearables for uncommon conditions face barriers to bringing their devices to market.[26] For medical devices, stakeholders and agency

[26]For more information on challenges to supporting the development of and regulating treatments for rare diseases, see GAO, *Rare Disease Drugs: FDA Has Steps Underway to Strengthen Coordination of Activities Supporting Drug Development*, GAO-25-106774 (Washington, D.C.: Nov. 18, 2024).

documents stated that manufacturers must expend time and money to complete FDA and CMS reviews, which increases their manufacturing costs. For wellness devices, stakeholders told us that often there is not a compelling business case for expending time and money developing a device that will only appeal to a small number of users, even if they do not have to spend on FDA and CMS reviews. Therefore, both medical and wellness manufacturers may choose not to develop wearables for uncommon conditions.

5 Policy Options Related to Wearables in Clinical Decision-Making

We identified three policy options that policymakers—which may include legislative bodies, government agencies, standards-setting organizations, industry, and other groups—could take to help address the challenges and enhance the benefits of using wearables in clinical decision-making. While we present options that respond to the challenges we identified, the list of options is not intended to be exhaustive. Instead, we intend our policy options to provide policymakers with approaches that could help them to pursue a range of goals related to the future of wearables in clinical decision-making.

5.1 Continue the status quo

Policymakers could continue the status quo and monitor the effectiveness of recent or ongoing activities, such as the federal activities described in table 1 (p. 8). Doing so could address some of the challenges we identified, including challenges of ensuring patient health benefits, integrating wearables into clinical workflows, and navigating the health technology market, by giving additional time to complete programmatic activities.

In addition to continuing those activities, policymakers, including clinicians, health care systems, insurance companies, and patient advocacy groups, could continue voluntarily testing or using wearables for clinical purposes, including clinical decision-making. Examples of such testing have been reported in scientific literature, and some organizations have started consolidating and analyzing select information on wearables. For about a decade, clinicians have used wearables in research to monitor the health of patients who are enrolled in clinical trials for drugs and other products requiring FDA review.[27] Information from such trials can continue being used to assess some aspects of the performance of wearables, as well as their potential for monitoring treatment.

5.1.1 Opportunities

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. 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.

[27]Clinicians can currently use both medical and wellness devices in clinical trials. By the definition used in this report, wellness devices are not intended for clinical purposes such as diagnosis or treatment of a disease. However, there is an exemption for clinical trials granted under the Investigational Device Exemption (21 C.F.R. pt. 812). In explaining the exemption, FDA officials told us that FDA allows researchers to collect clinical data on activities that are not high-risk using wellness devices if the devices meet certain conditions. See FDA, Guidance: *Digital Health Technologies for Remote Data Acquisition in Clinical Investigations:* (Silver Spring, MD: Dec. 2023), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations.

According to CMS, the ACCESS Model is intended to test outcome-aligned insurance payments for coordinated care, which may include technology-enabled interventions. The insurance payments will be based on demonstrated improvements in patient health outcomes.

Nonfederal activities may help address some of the other challenges. In particular, studies that examine the effectiveness of wearables in patient care may provide additional performance information once the wearable is on the market, which may help stakeholders address challenges related to improving patient outcomes. Organizations that consolidate information on effectiveness may further facilitate wearables comparison by clinicians and patients. State-level activities may also be useful indicators of the willingness of stakeholders to automate certain aspects of clinical decision-making using digital health technologies.[28] No additional federal actions would be needed at this time, other than to monitor and assess the outcomes of these activities.

5.1.2 Considerations

Though many recent or ongoing activities may address some challenges of wearables adoption, without action, other challenges will remain. For example, research studies that examine the effectiveness of wearables may not yield the information clinicians need to determine whether a wearable is ready for clinical use. Additionally, the ongoing activities do not specifically address the challenges of developing wearables for rare diseases or conditions that stakeholders reported to us.

Some of the ongoing federal activities to enhance the use of wearables may also worsen some challenges. For example, not all health systems may participate in programs such as CMS's Health Technology Ecosystem. Without additional coordination, it is possible that participating and nonparticipating health systems will develop different data security and privacy solutions, which could cause interconnectivity issues that worsen data transfer options and negatively affect patient care.

[28]There is a recent example of a state-level action to pilot increased automation in clinical decision-making that involved a non-wearable digital health technology. In January 2026, Utah became the first state to take steps toward piloting an autonomous AI prescription system for patients seeking prescription renewals for certain authorized medications. The AI prescription system is technologically capable of automating certain aspects of health care, which wearables may be capable of in the future. One potential result of the AI prescription system pilot is that it could blur the line between clinician actions and medical devices. This is because clinician actions are typically overseen by state medical licensing boards, and medical devices are reviewed by FDA. Therefore, it may become less clear under the AI prescription system pilot who is responsible for the technology's performance once it is on the market, if it is unclear that this use of AI meets FDA's definition of a device. The response of health care system stakeholders to the pilot could offer insights into how stakeholders might respond to wearables that similarly automate new aspects of health care. See Utah Department of Commerce, *News release: Utah and Doctronic announce groundbreaking partnership for AI prescription medication renewals* (Jan. 6, 2026). https://commerce.utah.gov/2026/01/06/news-release-utah-and-doctronic-announce-groundbreaking-partnership-for-ai-prescription-medication-renewals/. Utah's Department of Commerce, Office of Artificial Intelligence Policy has the authority to negotiate and grant limited regulatory mitigation agreements with private companies, such as this pilot program with Doctronic, to further the purposes of its AI Learning Laboratory program. Utah Code § 13-72-302. Participants in the program agree to indemnify the state office from claims, liabilities, and damages, and remain subject to all federal, state, and local laws, and the agreements do not waive or modify legal remedies available to any individual harmed by any action of the participant's AI technology, other members of the public, or the state other than the state office.

5.2 Improve integration of wearables into clinical workflows

Policymakers, such as medical facility leaders, could refine the clinical workflows and technology infrastructure of medical facilities to support the integration of wearables into clinical decision-making.

This policy option is intended to help mitigate the challenges of integrating wearables into clinical workflows. Some status quo activities, such as CMS's Health Technology Ecosystem, intend to achieve similar results, such as enhancing secure technological connectivity in health care systems. However, those activities are voluntary, meaning not all facilities participate, and are not comprehensive. Therefore, these activities may leave some gaps. For example, according to a CMS notice, the Health Technology Ecosystem focuses on improving data infrastructure and collects information on how infrastructure changes could affect workflows, but does not propose clinical workflow solutions. Thus, the initiative may not address all challenges of integrating wearables into clinical workflows. [29]

To implement this policy option, policymakers could require medical facility administrators to improve the integration of technologies and data within their facilities, improve the usability of wearables data by clinicians, and provide clarity to clinicians on future plans for further integrating wearables. To improve integration, administrators could modify technology infrastructure to support transferring and storing wearables data. Technology infrastructure modifications could also incorporate security enhancements to better secure patient health data. To improve the usability of data, administrators could establish an operating procedure to scan wearables alerts of adverse health events and coordinate clinician outreach to patients according to medical risk levels. Last, to provide clarity to clinicians on their plans to further integrate wearables, these medical facility leaders could implement a communication strategy to keep staff updated. Any clinical workflow changes that are announced could be accompanied by training opportunities that familiarize clinicians with new technologies and processes.

5.2.1 Opportunities

This policy option 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. 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. That could result in more informed diagnosis and treatment recommendations by clinicians. This policy option could also help clarify clinician responsibilities surrounding the use of

[29] See CMS, Request for Information: Health Technology Ecosystem, 90 Fed. Reg. 21,034 (May 16, 2025).

wearables data in clinical decision-making, which could ease liability concerns.

5.2.2 Considerations

This policy option would face at least three issues. First, integration can require significant resource investments, according to clinicians we spoke to who were involved in piloting the integration of wearables into their medical facility infrastructures and workflows. For example, they said integration can require hiring new staff or shifting the responsibilities of current staff, creating new training for clinicians and other staff, designing new workflows, and locating millions of dollars in new funding. This investment could shift resources away from medical facility leaders' other priorities. Second, if this policy option is implemented differently across medical facilities, patients and clinicians may experience variable results according to the specific facility's implementation strategy. Third, if administrators improve the integration of wearables into medical facility infrastructure and workflows, they may need to select a subset of wearables. As a result, the use of wearables that were not selected by medical facilities for integration may decline, potentially against patient preferences or based on factors that are not aligned with optimizing clinical or patient outcomes. For example, patients might wish to adopt a smartwatch for its fitness tracking features but be unable to share those data with a clinician at a medical facility that had selected technology infrastructure that was incompatible with that wearable.

5.3 Incentivize improvements to wearables performance in clinical decision-making

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. Clinicians and patients could then use the database to help find certified devices.

This policy option is intended to help mitigate the challenge of ensuring that wearables used in clinical decision-making benefit patients and improve health outcomes. Several catalogs of digital health technologies that include wearables are currently available, as are several independent digital health technology certifications and evaluations.[30] However, gaps exist despite current efforts because (1) some catalogs do not always transparently report device performance metrics and (2) manufacturers currently lack incentive to participate in voluntary certification processes.

To implement this policy option, national medical associations could encourage wearables manufacturers to participate in an independent certification process by making

[30]Examples of current databases that include digital health technologies are FDA's list of AI-enabled medical devices, CMS's Medicare App Library, the American Medical Association's Validated Device Listing, and the Digital Health Measurement Collaborative Community by Digital Medicine Society's Library of Digital Measurement Products. Examples of existing certifications and evaluations include the Coalition for Health AI's Applied Model Card and the Digital Medicine Society's DiMe Seal. Finally, other independent entities have published research and evaluations on specific types of wearables in journal articles and reports.

certification a condition of those associations' determinations that a wearable is suitable for use in clinical decision-making. Medical associations could select a certifying entity that uses standards (or has the capacity to develop standards) that measure the aspects of device performance that clinicians and patients deem most important for enhancing patient health outcomes. These could include measures of the accuracy and reliability of data produced by the wearable when used daily by an average patient. [31]

5.3.1 Opportunities

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.

First, improving testing and public disclosure of wearables performance in a way that aligns with clinical needs could help medical facility administrators, clinicians, and patients make more informed decisions about the benefits and risks of selecting specific wearables. It could also help potential users understand any variation in health outcomes between users, the effects of including clinicians in the loop to a greater or lesser extent, or other factors related to the performance of the wearable. Specifically, if wearables manufacturers are encouraged to participate in independent certification processes in order for the wearable to be determined suitable for clinical decision-making, manufacturers could be incentivized to continue developing their devices consistent with clinically relevant standards, such as "gold standards." [32]

Second, encouraging manufacturers to maintain an active certification may increase manufacturer testing of wearables' effects on patient health and safety once the devices are on the market. Specifically, if manufacturers must demonstrate to an independent certifying entity that their wearable meets performance standards, then manufacturers may be incentivized to increase their studies of the effects of wearables on patient outcomes for purposes beyond marketing.

5.3.2 Considerations

This policy option could (1) create parallel or fragmented review processes that lead to

[31]This policy option could apply to both wellness and medical devices. The certification standards for the accuracy and reliability of the wearable when used regularly by an average patient may differ from FDA's evaluation of medical device safety and effectiveness. This is because FDA reviews the safety and effectiveness of medical devices based on specific intended use cases, which do not necessarily reflect real-world use by wearers. For example, one manufacturer told us they intended their sensor to be worn on the wrist but learned that users sometimes choose to wear the sensor on their upper arm, which they said could affect the accuracy of the data collected by the sensor. FDA may have evaluated the device worn on the wrist, while the certifying entity chosen to help implement our policy option may include data from upper arm wearers in its analysis.

[32]The term "gold standard" refers to a diagnostic tool or method that is considered a reliable and accurate benchmark for diagnosing a particular condition or disease. It is the best available diagnostic test under reasonable conditions and consistently provides correct diagnoses. See David Paul Lovell, "Commentary: statistical analysis of 2 x 2 tables in biomarker studies 1) the four 'indices of test validity'" *Biomarkers* 27(2022): 503–511. https://doi.org/10.1080/1354750X.2022.2093399.

confusion around FDA review requirements and (2) hinder the market for new wearables.

First, incentivizing participation in a certification process that is separate from FDA's review process may create confusion for wearables manufacturers, clinicians, and patients, with potential effects on patient safety. For example, a wellness device manufacturer may choose to obtain certification that its wearable performs to clinical standards but market the device with a statement that the device is not intended for use in diagnosing or treating a medical condition. Doing so could create regulatory confusion because the wearable still may not fall under FDA's regulation authority over medical devices. Clinicians and patients may be uncertain whether to trust the certification without FDA review, such as its review of safety.

Additionally, research and development costs may rise significantly, hindering the market for new wearables and potentially advantaging larger, established manufacturers. Specifically, manufacturers told us they may rely on the wellness market, which has historically not required manufacturers to invest in clinical testing, to recover device research and development costs quickly, even when they intended to move into the medical device market long-term. The increased startup costs needed to participate in certification processes could therefore hinder marketing wearables overall. It could also advantage larger, established manufacturers who can afford increased costs.

6 Agency Comments

We provided a draft of this report to the Department of Health and Human Services and Department of Veterans Affairs with a request for technical comments. We incorporated agency comments into this report as appropriate.

We are sending copies of this report to the appropriate congressional committees, the relevant federal agencies, and other interested parties. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff members have any questions about this report, please contact Sarah Harvey at HarveyS@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix III.

//SIGNED//

Sarah Harvey
Director
Science, Technology Assessment, and Analytics

List of Congressional Committees

The Honorable Bill Cassidy, M.D.
Chair
The Honorable Bernard Sanders
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Shelley Moore Capito
Chair
The Honorable Tammy Baldwin
Ranking Member
Subcommittee on Labor, Health and Human Services, Education, and Related Agencies
Committee on Appropriations
United States Senate

The Honorable Brett Guthrie
Chairman
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Robert Aderholt
Chairman
The Honorable Rosa DeLauro
Ranking Member
Subcommittee on Labor, Health and Human Services, Education, and Related Agencies
Committee on Appropriations
House of Representatives

Appendix I: Objectives, Scope, and Methodology

Objectives

This report examines (1) the potential benefits and challenges of using wearables in clinical decision-making, (2) the potential benefits and challenges of using artificial intelligence (AI) to augment the decision-making capabilities of such wearables, and (3) what policy options, if any, might help address challenges and enhance benefits associated with the use of wearables in clinical decision-making.

Scope

We focused the scope of this technology assessment on available and developing wearable technologies under both medical and wellness device types.[33] For the purposes of this report, such wearables were defined as devices that: (1) are worn externally on the human body or clothing, such as smartwatches or adhesive patches containing sensors; (2) perform at least one specific health-related function such as monitoring a user's vital signs; (3) are typically worn daily, for prolonged periods; and (4) are either currently available on the market, in use or being piloted at a medical facility or expected to be available within the next 5 years.

Devices that were not included as part of the report include: (1) wearables used expressly to gather information during clinical trials for other devices or products, or used in one-off testing such as a sleep apnea testing device that measures the patient's vitals for one night for the purpose of diagnosis; (2) display-only devices, such as pedometers; (3) treatment-only devices such as hearing aids; (4) surgically implanted devices (note that minimally invasive devices, such as blood glucose monitors, are in scope); (5) devices with only point-in-time testing, such as certain blood pressure monitors intended for a single reading; and (6) mental health devices, such as chatbots. Wearables in this report fall under one of five categories: bands worn around the body (including watches), rings, headwear, patches and stickers, and clothing.

Wearables are distinct from other devices that interface with the body or environment, such as "nearables," prosthetics, and implants. "Nearables," also known as ambient devices, are placed in a user's environment instead of being worn on the body or clothing. Examples include motion sensors and pillow sleep sensors. Prosthetics are worn on the body but are primarily designed to restore lost bodily functions or replace lost or missing body parts. In some cases, rehabilitation devices and devices that are worn for the purpose of diagnosis are worn on the body but are only intended for short-term or temporary use. Implants are surgically placed devices that operate inside the body, such as pacemakers. They typically

[33] In our report, "devices" does not refer only to those devices that are specifically defined by the Federal Food, Drug, and Cosmetic (FD&C) Act; we use the term more broadly. Not all wearables are "medical devices" that meet the definition of a device under section 201(h) of the FD&C Act. 21 U.S.C. § 321(h)(1). FDA's regulatory framework is described in more detail in appendix II. We consider other wearables to be "wellness devices;" these wearables have health-related features intended to promote general wellness and lifestyle, but have not been reviewed or authorized for marketing by FDA to diagnose or treat medical conditions.

have sensing or therapeutic capabilities but operate within the body instead of on its surface.

Methodology

For all of our objectives, we reviewed peer-reviewed scientific literature and other documents describing current and developing technologies; interviewed federal agency officials and other stakeholders from academia, industry (wearable manufacturers), associations (patient, medical, industry), and health care facilities (clinicians). We also reviewed federal agency guidance on the development and deployment of relevant technologies, such as the Department of Health and Human Services' Food and Drug Administration (FDA) guidance on device approval and regulation or its Center for Medicare & Medicaid Services (CMS) guidance on device coverage.

Literature search

We conducted a literature search to determine what was already known about the field of wearables and their relationship to clinical decision-making. The purpose of this search was to identify types and performance metrics of wearables for clinical use, to help design questions for interviews, and inform our research for objectives 1 and 2. The literature search was conducted by a GAO research librarian using a variety of databases such as ProQuest and Scopus. We narrowed our search criteria to articles written in the previous 5 years to capture recent developments and uses of wearables.

Searches were conducted using all permutations of "wearable medical/electronic device," "wearable sensor," and "healthcare wearable device." We also combined these searches with supplemental terms including "artificial intelligence," "internet of (medical) things," "telehealth," "telemedicine," "digital health care/technology," "eHealth" or "electronic health," "mHealth" or "mobile health," "pilot," "clinical trials," and "research & development."

We also supplemented these searches with search terms involving companies known to have wearables on the market to identify competing or comparative articles. To ensure that smaller spheres of research and development were not missed, we also searched the following medical terminology: atrial fibrillation, arrythmia, hypertension, cardiac and respiratory health, stroke, epilepsy, Parkinson's disease, diabetes, and "rare diseases." Searches were halted after we reached what we determined to be a saturation point. Out of 287 potentially applicable articles identified, we selected 95 articles fitting our criteria for review.

We also conducted a second literature review to inform and refine the potential policy options. We based this literature review on policy option development during brainstorming sessions and via policy ideas based on the challenges identified in the engagement, and through interviews. The search included relevant regulations, executive orders, and other written guidance at the federal or state level; relevant policy literature including publications by academics, industry, and government agencies; white papers; conference proceedings; proposed legislation; and other domestic and international sources. The searches include the terms "wearable" or "digital health" plus the following: regulation,

review, approval, licensure, license, prescription, reimbursement, insurance, coverage, autonomy, artificial intelligence, machine learning, privacy, security, and ethics. Out of 58 potentially applicable articles identified, we selected 32 articles for review.

Interviews and site visits

We interviewed both government agency officials and non-governmental stakeholders. For government agencies, we interviewed officials from the Department of Health and Human Services, FDA, CMS, and the Department of Veterans Affairs. We also reviewed written responses from FDA and CMS.

We sorted nongovernment stakeholders into four groups: academia, manufacturers, clinicians, and associations (patient, medical, and industry). These categories were developed by assessing the available literature, as well as our own assessment of the various groups involved in the field of wearables for clinical decision-making. We developed a universe of 140 potential stakeholders in these categories based on available literature (authors, companies mentioned, peer review commentators, etc.), panelists or participants in topical panels or hearings the team watched, interactions at the DeviceTalks conference (see below), recommendations from agency entrance conferences, and recommendations from early interviews and site visits. We took this approach in order to gain a wide variety of perspectives relevant to the topic. Once the universe was identified, the team went about establishing criteria for selecting interviewees, including considering aspects such as regional, academic, or research variation, balance across perspectives (e.g., patients and manufacturers), disease variation, manufacturer size variation, device class variation, among others. The team reviewed the list of applicable stakeholders and identified any they intended to reserve for discussion group outreach (see below). Finally, the team balanced the number of interviews across the main four stakeholder groups, aiming for five to seven interviews with each group. These interviews are not generalizable to the entire stakeholder groups but provided sufficient information to answer the research objectives.

In total, we conducted 27 semi-structured interviews with stakeholders from all the above groups to get a wide variety of perspectives, including: six academics with experience in medical device usage; seven associations representing patients, medical groups, or industry; seven companies with experience in manufacturing or using wearable technology; clinicians from five health care facilities; and two agencies. We conducted these interviews between April and May of 2025. All stakeholders received a standardized set of core questions, and each of the stakeholder groups received an additional set of questions pertinent to their stakeholder designation. Semi-structured interviews were concluded when the team no longer obtained significant new information relevant to our research questions.

We categorized information as reported by "most" stakeholders if it was reported by fewer than 100 percent but more than 50 percent of respondents. We categorized any information that was reported by at least two respondents as coming from "some" stakeholders. In addition, when applicable, we broke stakeholder comments out by the

relevant respondent groups (e.g., clinicians, associations, etc.). In certain instances, "some" may have reflected a majority of stakeholder views, but we did not confirm that to be the case.

We also attended DeviceTalks 2025, an industry conference in the Boston area focused on medical devices and technology, to better understand these technologies. At DeviceTalks, we attended lectures, roundtables, and industry booths to learn about the state of the art in medical technology as it applies to wearables. Also in the Boston area, we visited an academic laboratory, a Department of Veterans Affairs medical center, a wearables manufacturer, a manufacturer with a wearable on the market, and a disease research center. We toured several of the facilities and viewed demonstrations of several wearables.

We also conducted two discussion groups with 10 stakeholders representing academia, wearables manufacturers, and both patient and medical associations to help inform policy options. We selected these participants to represent a balanced and diverse set of views for participation in the set of two 2-hour panel discussions.[34] Discussion groups had a set of questions and topics to guide the conversation around the team's proposed policy options, resulting in open discussion and back-and-forth engagement among participants. The intent was to solicit feedback on draft policy options from both discussion groups, with the second discussion group reviewing policy options that GAO revised based on the feedback from the first group. Participants in this set of panel discussions provided documentation of any potential conflicts of interest, and, upon review, we found the group of stakeholders as a whole did not have any inappropriate bias.

Policy options

Based on the above, we derived three policy options that could address the challenges we identified associated with the use of wearables in clinical decision-making. These policy options are intended to provide policymakers with a broader base of information to inform their actions, based on their intended goals for the use of wearables in clinical decision-making. We consider policymakers to include legislative bodies, government agencies, standards-setting organizations, industry, and other groups. We listed our policy options in an order that did not rank them according to feasibility, effect, cost, or any other potential outcomes measures. Additionally, we limited policy options to those that fit the objective and fell within the report scope.

To develop our policy options, we compiled a list of possible options over the course of our work based on review of the literature, and interviews with government officials, stakeholders, and discussion groups. We further refined and assessed these options to ensure they were adequately supported by the evidence we collected, could be feasibly implemented, and fit into the overall scope of

[34]One participant was also interviewed as part of the semi-structured interview process, but the remaining 9 individuals were not included in those interviews.

our work to address the identified challenges. We then analyzed the information we collected to identify potential opportunities and considerations of implementing each policy option. We did not conduct work to assess how effective the options may be and express no view regarding the extent to which legal changes would be needed to implement them. The policy options and analyses were supported by documentary and testimonial evidence.

We conducted our work from September 2024 to August 2026 in accordance with all sections of GAO's Quality Assurance Framework that are relevant to technology assessments. The framework requires that we plan and perform the engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations to our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for the findings and conclusions in this product.

Appendix II: Current Federal Regulations and Guidance on Digital Health Technologies

Wearables, as discussed in this report, are part of a broader class of products known as digital health technologies (DHT), which are under the regulation and guidance of the Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS). While this report focused on the medical and wellness devices with the potential to be used in clinical decision-making, wearables are often subject to the regulations and guidance that govern the broader class of products. Below, we provide details about FDA and CMS's current regulations and guidance for DHTs, and how these may relate to or affect the use of wearables for health-related purposes. As noted below, some of these regulations and guidance may be evolving. This appendix complements the summary we provided about these agencies' roles in chapter 1 (p. 5).

FDA's definition of DHT

Beyond wearables, DHTs include products with sensors that are not worn on the body, such as sensors that are placed in the home environment, or health apps that have no worn component. FDA defines DHT as a system that uses computing platforms, connectivity, software, and sensors for health care and related uses. These technologies span a wide range of uses, from applications in general wellness to applications as a medical device. They include technologies intended for use as a medical product, in a medical product, or in support of other medical products (i.e., devices, drugs, and biologics). They may also be used to develop or study medical products.[35]

FDA discretion on "intended use"

In our report, we discussed wearables that are medical devices for which FDA intends to exercise regulatory oversight, wearables that may be medical devices but for which FDA does not intend to exercise regulatory oversight (such as when FDA has determined that the wearable is a low-risk general wellness device for which it will not be assessing compliance with the Federal Food, Drug, and Cosmetic (FD&C) Act), and wearables that are not medical devices and are therefore not subject to FDA oversight.

FDA's exercise of enforcement discretion is subject to change, and these changes can have far-reaching consequences. For instance, in January 2026 FDA modified its General Wellness: Policy for Low Risk Devices guidance, stating that, "FDA may consider certain products that use non-invasive sensing (e.g., optical sensing) to estimate, infer, or output physiologic parameters (e.g., blood pressure, oxygen saturation, blood

[35]For more on FDA terminology, see FDA, *Digital Health and Artificial Intelligence Glossary – Educational Resource*, available at https://www.fda.gov/science-research/artificial-intelligence-and-medical-products/fda-digital-health-and-artificial-intelligence-glossary-educational-resource#d. For a list of sensor-based digital health technology medical devices that have been authorized for marketing in the U.S., see FDA, *Medical Devices that Incorporate Sensor-based Digital Health Technology*, available at https://www.fda.gov/medical-devices/digital-health-center-excellence/medical-devices-incorporate-sensor-based-digital-health-technology.

glucose, or heart rate variability) to be general wellness products to determine whether they are devices within the meaning of the FD&C Act or, if they are devices, whether they comply with the premarket review and post-market regulatory requirements for devices under the FD&C Act and implementing regulations."[36] An example of how this shift may have affected wearables manufacturers is that FDA had previously issued public warning letters to multiple wearables manufacturers. These letters stated that health features, which manufacturers claimed were wellness features, were instead medical and subject to FDA regulation. At least one manufacturer disputed this determination, and, according to news reports, the dispute is ongoing as of May 2026.[37] If FDA ultimately determines that the disputed health features are medical, manufacturers of such wearables may spend additional resources preparing marketing compliance materials.

Determining whether a wearable meets the definition of a medical device can depend on the device's intended use. Intent may be shown by what the manufacturer communicates about the device; the device's design; the circumstances surrounding its distribution, labeling, and advertising; or other oral or written statements.[38] The marketing pathway for a wearable that meets the statutory definition of a device under the FD&C Act is based on the risk of the device and the regulatory controls needed to ensure reasonable assurance of safety and effectiveness.

In commenting on the General Wellness: Policy for Low Risk Devices guidance, FDA officials told us they no longer intend to examine low-risk general wellness products to determine whether they are devices within the meaning of the FD&C Act, or if they are devices under the act, whether the devices comply with premarket and post-market regulatory requirements. According to FDA officials, these are products that are intended for only wellness use and present a low risk to the safety of users and other people. Wellness devices have (1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity or (2) an intended use that relates the role of a healthy lifestyle in helping to reduce the risk or affect of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.[39]

[36]See FDA, Guidance: *General Wellness: Policy for Low Risk Devices* (Rockville, MD: Jan. 2026), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices. In our report, "devices" does not refer only to those devices that are specifically defined by the Federal Food, Drug, and Cosmetic (FD&C) Act; we use the term more broadly. Not all wearables are "medical devices" that meet the definition of a device under section 201(h) of the FD&C Act. See chapter 1 for more detail on how we define wellness and medical devices in our report.

[37]Following the change in FDA guidance in Jan. 2026, the manufacturer revised its original marketing language. FDA has not issued a public comment regarding its dispute with the manufacturer since its original warning letter in July 2025.

[38]See 21 C.F.R. § 801.4.

[39]See FDA, Guidance: *General Wellness: Policy for Low Risk Devices* (Rockville, MD: Jan. 2026), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices

FDA guidance on multi-function devices

Some wearables may have multiple functions, some of which are subject to FDA's regulatory oversight as devices, while others are not. Generally, devices with at least one function that meets the definition of a medical device and one other function, are considered a multiple-function device product. For example, a smartwatch may include software that detects atrial fibrillation or sleep apnea that falls within the definition of a medical device, and therefore subject to FDA's oversight, while the smartwatch might also have other functions (e.g., promoting physical fitness) that are not subject to FDA's oversight. In 2020, FDA published guidance that explains FDA's regulatory approach and policy for multiple function device products.[40]

FDA guidance on clinical decision support tools

According to FDA documentation, software defined as "clinical decision support software" is exempt from FDA oversight under Section 520(o)(1)(E) of the FD&C Act.[41] The distinction we make in this report between clinical decision support software and wearables that may involve software that can be used in clinical decision-making aligns with FDA's interpretation of the FD&C Act criteria as of January 2026.[42] However, some policymakers have challenged FDA's interpretation of the law. For example, in February 2026 some federal legislators published a report that stated, "Congress, in the [amended FD&C] Act, explicitly carved out many [clinical decision support] tools from being defined as medical devices. This rejected FDA's authority to categorize [clinical decision support] tools as a medical device, except in limited circumstances." The policymakers stated that FDA should exercise its authority consistent with the FD&C Act amended by the 21st Century Cures Act.[43]

FDA guidance on device modifications

With Predetermined Change Control Plans (PCCPs), manufacturers can prospectively specify and seek premarket authorization for intended modifications to a device, including to artificial-intelligence-enabled device software functions, without needing to submit additional marketing submissions or obtain further authorization before implementing such modifications—provided the changes are implemented consistent with the PCCP that has been reviewed and established through a device marketing authorization. While there are circumstances that clearly trigger a new review, such as a significant change in the intended use of a wearable to indicate new conditions that it

[40]See FDA, Guidance: *Multiple Function Device Products: Policy and Considerations* (Rockville, MD: July 2020), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/multiple-function-device-products-policy-and-considerations.

[41]21 U.S.C. § 360j(o)(1)(E).

[42]See FDA, *Clinical Decision Support Software: Guidance for Industry and Food and Drug Administration Staff*, (January 29, 2026), available at https://www.fda.gov/media/109618/download.

[43]See Office of Senator Bill Cassidy, Chair, U.S. Senate Committee on Health, Education, Labor, and Pension, Report: *Patient and Families First: Building the FDA of the Future* (2026). https://www.help.senate.gov/imo/media/doc/fda_report.pdf.

previously could not, and circumstances that do not require a new marketing submission, such as certain planned and previously authorized AI modifications, there also may be situations where manufacturers have questions about whether a new review is needed. In such cases, the manufacturer can consult with FDA.[44]

FDA's review of "safe and effective" compared to CMS's review of "reasonable and necessary"

As agencies with distinct legal authorities and missions, FDA and CMS use different criteria to evaluate DHTs, such as medical wearables. FDA's premarket review standard is that it must be able to determine that the device is "safe and effective" when used as intended.[45] By contrast, CMS determines coverage using the criteria of whether the device is "reasonable and necessary" for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed part of the body. Additionally, for CMS, the DHT under review must also not be specifically excluded by the Social Security Act and must fall within at least one benefit category established in Section 1861 of the Social Security Act.[46] Wearable devices that have completed FDA review are not guaranteed coverage by Medicare.[47] In the *Federal Register*, a CMS Notice described the difference between FDA and CMS reviews: "Clinical studies that are conducted to gain FDA market authorization are not necessarily required to include participants with similar demographics and characteristics of the Medicare population…[A] device's potential benefits and harms for older patients with more comorbidities may not be well understood at the time of FDA market authorization."[48]

[44]See FDA, Guidance: *Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions* (Rockville, MD: Aug. 2025), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence.

[45]Under the FD&C Act, FDA classifies medical devices based on risk and the controls necessary to provide reasonable assurance of the device's safety and effectiveness. 21 U.S.C. § 360c. FDA's standard for "safe and effective" is described in 21 C.F.R.§ 860.7.

[46]See 42 U.S.C. § 1395x, 42 U.S.C. § 1395y(a)(1)(A).

[47]CMS, Medicare Program; Revised Process for Making Medicare National Coverage Determinations, 68 Fed. Reg. 55,634 (Sept. 26, 2003).

[48]CMS, Medicare Program; Transitional Coverage for Emerging Technologies, 89 Fed. Reg. 65,724, 65,726 (Aug. 12, 2024). In a guidance document, CMS further explained, "Even well-designed and well conducted trials may not supply evidence relevant for CMS if study results do not apply to the Medicare beneficiary population, typical clinical settings, or to health outcomes that would be meaningful to Medicare beneficiaries. CMS may consider evidence that provides accurate information about a population or setting not well represented in the Medicare program but would also consider whether the information is sufficiently applicable to the Medicare beneficiaries who would be receiving the service or technology." See CMS, CMS National Coverage Analysis Evidence Review Guidance Document, (Aug. 7, 2024). https://www.cms.gov/files/document/cms-evidence-review2024pdf.pdf.

Appendix III: GAO Contact and Staff Acknowledgements

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