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For 2026, FDA signals shifts in digital health framework

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FDA seeks to modernize and enable innovation as it updates its General Wellness and Clinical Decision Support guidance documents, while also signaling future updates to its AI framework.

What's the impact?

- With its updated General Wellness guidance, the FDA has endeavored to provide clearer guidelines and has expanded the types of products that fall within the category of general wellness products that will not need FDA review prior to hitting the market, including certain sensor-based wearable technologies, so long as those products are intended for general wellness and are not making medical or clinical claims.
- For developers, the FDA's updated Clinical Decision Support guidance clarifies the FDA's interpretation of how software can qualify as "Non-Device CDS" under the 21st Century Cures Act. And in a notable shift from its prior approach, the FDA states that it will exercise enforcement discretion when evaluating software that produces a single clinically appropriate recommendation, provided all other criteria are met and the function is not intended for time-critical decision-making.

As part of an overall effort to modernize the FDA's procedures, enhance investment, and enable innovative digital health technology to timely reach the American public, the FDA recently

updated its General Wellness and Clinical Decision Support guidance documents. In stated remarks, the FDA Commissioner Martin Makary cited the need to enable clearer guidelines and reduce subjectivity and guesswork for developers, with the ultimate goal of improving the underlying health of Americans. The Commissioner also highlighted that FDA is in the process of developing a new, smarter, more forward-thinking framework for AI that will better deliver predictability.

The evolving road to 2026

On January 6, 2026, the US Food and Drug Administration (**FDA**) released revised guidance documents that recalibrate the regulatory lines for low-risk general wellness products and clinical decision support (**CDS**) software, signaling a marked shift in the agency's approach to digital health oversight. The recently issued "General Wellness: Policy for Low Risk Devices" and "Clinical Decision Support Software" guidance documents each supersede prior versions issued in 2019 and 2022, respectively. The updates reflect an evolving regulatory approach to digital health and software tools, balancing innovation with safety and clarity under the Federal Food, Drug, and Cosmetic Act **(FD&C Act)**.[1] These interpretations build on statutory exclusions enacted by the 21st Century Cures Act, which added FD&C Act section 520(o), excluding certain software functions from the definition of a medical device.

In January 6, 2026, remarks, FDA Commissioner Martin Makary cited key objectives driving the agency's actions: reduced subjectivity and guesswork for developers, increased certainty and clarity for investors deciding how to allocate capital, modernizing the agency so that the FDA is a leader in the space of AI and technology, and fostering market access to innovative products that will foster a healthier America.

Notably, as part of the agency's efforts to bring more clarity, Commissioner Makary cited the "27 different guidances that deal with software and digital health, some overlapping and some unclear" and expressed that the FDA will "cut that number by about 50% or more, make them more clear, concise, more modern, and more consistent."

Also clear in the Commissioner's remarks: medical products that require FDA approval will continue to be held to the FDA's review and compliance requirements. In his remarks, the Commissioner stated, "If your company does something that claims it is medical grade . . . then we're going to hold it to a different standard, because you're invoking an ancient, precious brand of our great medical profession, and we don't want people to be confused . . . [and don't want] people to be hurt at scale."

[1] 21 U.S.C. § 321(h); § 360j(o).

An expanded definition of general wellness devices

The 2026 General Wellness guidance emphasizes two threshold factors for determining if a product is a general wellness product: (1) the product is intended only for general wellness use as defined within the guidance, and (2) it presents low risk to the safety of users and other persons. The agency's reliance on these two factors remains unchanged from the 2019 guidance.

Furthermore, the FDA's definition of a "general wellness" product remains unchanged. As defined by the FDA, a general wellness product "has (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 healthy lifestyle with helping to reduce the risk of impact 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."[2] As with the 2019 guidance document, if a "product's intended uses are not limited to [these] general wellness intended uses, the guidance does not apply." The FDA's approach to general wellness products is intended to be consistent with section 520(o)(1)(B) of the FD&C Act, under which software intended for maintaining or encouraging a healthy lifestyle and unrelated to disease diagnosis, cure, mitigation, prevention, or treatment is excluded from the definition of a medical device.[3]

The most meaningful change in the updated General Wellness guidance is the inclusion within the category of general wellness products of certain non-invasive, non-implanted products using, for example, optical sensing, that estimate, infer, or output physiologic parameters such as blood pressure, oxygen saturation, blood glucose, or heart rate variability when intended solely for wellness uses, provided they meet explicit guardrails, including not substituting for FDA-authorized, -cleared, or -approved devices, not including claims, functionality, or outputs that prompt or guide specific clinical action or medical management, and not including values that mimic clinically-used values unless validated. The guidance states that such products "may display values, ranges, trends, baselines, or longitudinal summaries, and may contextualize these outputs in relation to sleep, activity, stress, recovery, or similar wellness domains."

By contrast, products are not general wellness products when they are "intended to measure, estimate, or report physiologic values for medical or clinical purposes, including screening, diagnosis, monitoring, alerting, or management of a disease or condition," or when their labeling, advertising, user interface, or functionality includes, for example, references to specific diseases, clinical conditions, or diagnostic thresholds, treatment guidance intended to inform or direct clinical management, or claims of clinical equivalence/accuracy or medical-grade

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[2] US Food & Drug Administration, General Wellness: Policy for Low Risk Devices: Guidance for Industry and Food and Drug Administration Staff (Sept. 27, 2019), Section III.

[3] 21 U.S.C. § 360j(o)(1)(B); and *see* FDA, General Wellness Guidance (2026), Section II ("[S]ection 520(o)(1)(B) of the FD&C Act excludes software functions that are intended for maintaining or encouraging a healthy lifestyle and are unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition from the definition of device in section 201(h) of the FD&C Act.").

performance. The guidance provides that a limited "notification" may inform a user that evaluation by a healthcare professional may be helpful when outputs fall outside ranges appropriate for general wellness use, provided the notification does not identify a specific disease or medical condition; does not characterize outputs as abnormal, pathological, or diagnostic; does not include clinical thresholds, diagnoses, or treatment recommendations; and does not provide ongoing alerts, alarms, or prompts intended to manage a condition or require specific clinical action or medical management.

The General Wellness guidance also articulates a structured low-risk approach, noting that invasive, implanted, or higher-risk technologies that may pose a risk to the safety of users and other persons if specific regulatory controls are not applied (e.g., lasers, radiation) are outside the policy.

The guidance offers multiple examples of whether claims and technologies will be categorized as a general wellness product, including a wrist-worn wearable intended to assess activity and recovery that outputs multiple biomarkers, including hours slept, sleep quality, pulse rate, and blood pressure with validated blood pressure values, where sleep is measured via an accelerometer and pulse rate and blood pressure are measured via a photoplethysmogram (categorized as a general wellness product), versus a wearable, minimally invasive microneedle blood glucose estimator for monitoring nutritional impacts and which is explicitly contraindicated for use with diabetics and pre-diabetics and is marketed to users as a means of better understanding their insulin response to certain foods (not categorized as a general wellness product due to product penetrating the stratum corneum).

The FDA expands its approach with respect to clinical decision support software

Under federal law, software intended to diagnose, treat, cure, mitigate, or prevent disease is generally regulated as a medical device.[4] However, the 21st Century Cures Act added section 520(o)(1)(E) to the FD&C Act, which excludes from the "device" definition certain clinical decision support (CDS) software functions that meet the following four criteria:

- not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device (IVD) or a pattern or signal from a signal acquisition system;
- intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information;
- intended for the purpose of supporting or providing recommendations to a healthcare professional (**HCP**) about prevention, diagnosis, or treatment of a disease or condition; and
- intended for the purpose of enabling the HCP to independently review the basis for the

[4] 21 U.S.C. § 321(h).

recommendations that such software presents so that it is not the intent that the HCP rely primarily on any such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.[5]

While the statutory framework is unchanged, the 2026 CDS guidance provides important clarifications and updates:

CRITERION 1

Software that acquires, processes, or analyzes medical images or IVD signals or patterns or signals from a signal acquisition system remains a device. As the guidance explains, inputs of this type place a function within the scope of a medical device under section 201(h) of the FD&C Act.

CRITERION 2

The FDA clarifies that "medical information about a patient"—including patient-specific information used in clinical care (e.g., demographics, symptoms, certain test results, patient discharge summaries)—need not be commonly discussed in a clinical conversation if its "relevance to patient care is supported by well-understood and accepted sources and can be appropriately understood in context." Additionally, "other medical information" includes "*peer-reviewed* clinical studies, clinical practice guidelines, and information that is similarly independently verified and validated as accurate, reliable, not omitting information, and supported by evidence" (emphasis added to reflect new language in 2026 guidance).

CRITERION 3

FDA continues to distinguish software that supports an HCPs' decision-making and software that replaces or directs it. Thus, "where a software function provides a specific preventive, diagnostic or treatment output or directive, the software function fails Criterion 3 because it is not intended for the purpose of supporting or providing recommendations" to an HCP.

- The most impactful change in the 2026 guidance is the change that if only one recommendation is clinically appropriate and all three other statutory criteria are met, the FDA intends to exercise enforcement discretion and will not require pre-market review, but not where the function supports time-critical decision-making or provides specific directives. The previous version of the guidance did not offer enforcement discretion if only one recommendation was provided.[6]

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[5] 21 U.S.C. § 360j(o)(1)(E)(i)–(iii); and *see also* US Food & Drug Administration, Clinical Decision Support Software: Guidance for Industry and Food and Drug Administration Staff (Jan. 6, 2026), Section II.

[6] US Food & Drug Administration, Clinical Decision Support Software: Guidance for Industry and Food and Drug Administration Staff (Sept. 28, 2022), Section IV(3).

- Notably, the 2026 guidance also removes the language from the prior guidance stating that any software providing a risk probability or risk score for a specific disease or condition is providing a specific preventive, diagnostic, or treatment output.[7]

CRITERION 4

The FDA emphasizes user understandability. The guidance continues to require that labeling include a plain-language description of the "underlying algorithm development and validation that forms the basis for the CDS implementation" and adds that this information must be "sufficient for the intended HCP user to understand the basis of the recommendation." For example, the guidance continues to require providing "a summary of the general approach relied upon to provide the recommendations (e.g., meta-analysis of clinical studies, expert panel, statistical modeling, AI/ML techniques)" and adds that this should be provided "at a level of detail appropriate for the intended user and use environment, which could include, for example, the logic or methods relied upon."

The guidance also reiterates that "[s]oftware functions that support or provide recommendations to patients and caregivers—not HCPs—meet the definition of a device," and that the FDA intends that its other existing digital health policies will continue to apply to such functions.

How can developers adapt to FDA's guidance?

While providing an updated framework and expanding the realm of digital health technology that is either outside the definition of a medical device or falls under enforcement discretion, the updated General Wellness and CDS guidance documents do not eliminate the need for developers to analyze how their technology fits within the FDA's updated framework, nor does the FDA's updated guidance documents provide a "free for all" that permits any and all digital health products to enter the US market without any FDA approval or oversight.

Developers who seek to utilize the pathways articulated in the General Wellness and Clinical Decision Support guidance documents to bring products to market that would either be excluded from the definition of a medical device or would fall under the FDA's enforcement discretion should take steps to ensure that they have a well-reasoned, defensible basis for utilizing these pathways. Doing so will position the developer and/or seller to effectively explain the product's classification should questions arise in the future from regulators or consumers. Furthermore, under the FDA's updated guidance documents, labeling, advertising, and promotion remain critical factors in assessing a product's intended use.

Commissioner Makary's statements also highlight continued work at the agency to formulate a smarter and more forward-thinking framework for AI products, suggesting that the FDA will be

[7] FDA, Clinical Decision Support Software Guidance (2022), Section IV(3).

issuing additional AI-related guidance in the future. Nixon Peabody attorneys are closely monitoring these developments. For more information on the content of this alert, please contact your Nixon Peabody attorney or:

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