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Ringing in the New Year with Digital Health: FDA Updates Guidance Documents on Clinical Decision Support Software and General Wellness Products

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Key Takeaways

- FDA updated two key digital health guidance documents to align with the Administration's emphasis on deregulation and innovation in health care technology, including the use of generative AI.
- The agency will ease enforcement of medical device requirements for certain clinical decision support software that recommends a single diagnosis or treatment to a health care provider.
- In its revised policy for general wellness products, FDA indicates that it will not focus its oversight authority on products measuring physiological parameters, such as blood glucose, blood pressure and oxygen saturation, provided that the products meet certain criteria.

The U.S. Food and Drug Administration (FDA) wasted no time in kicking off the new year with changes to how it intends to regulate digital health products following the Trump Administration's promise to deregulate AI and promote its widespread use.[1] On January 6, 2026, without seeking public comment, FDA updated two guidance documents that address its regulation of Clinical Decision Support Software (CDS) and Low Risk General Wellness Products. In a series of posts on X, FDA Commissioner Martin Makary stated that the "[FDA] is cutting the red tape on wearables for general wellness" and "get[ing] out of the way" of CDS tools that doctors find useful. Although the updated guidance documents do not specifically focus on AI, the policies they contain are highly relevant to AI-enabled products used in the health care and wellness industries.

Generally, both updated guidance documents soften FDA's approach to regulating certain

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digital health products. These updated policies open the door for CDS to provide more targeted recommendations to health care providers (HCPs) without triggering FDA compliance oversight and for greater use of wearables that measure physiologic parameters like blood pressure, oxygen saturation and blood glucose, provided that they are intended solely for wellness uses. However, the new policies include guardrails that may make their impact more modest than many product developers would have hoped.

Clinical Decision Support Software Guidance

Background

CDS encompasses a variety of tools that are designed to augment decision-making within clinical workflows. Many CDS tools are integrated into or interact with providers' electronic health record (EHR) systems.

As part of the 21st Century Cures Act (Cures Act), Congress amended the statutory definition of an FDA-regulated "device" to exclude certain categories of software. One of those categories is for CDS that meets the following four criteria:

- **Criterion 1:** *Is not intended* to acquire, process or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system;
- **Criterion 2:** *Is intended* for the purpose of displaying, analyzing or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);
- **Criterion 3:** *Is intended* for the purpose of supporting or providing recommendations to an HCP about prevention, diagnosis or treatment of a disease or condition; *and*
- **Criterion 4:** *Is intended* for the purpose of enabling the HCP to independently review the basis for such recommendations that the software presents.

Software products that meet these criteria (the "CDS Criteria") are excluded from FDA's jurisdiction, significantly reducing barriers to market entry and compliance burden. In practice, FDA's interpretation of these criteria dictates the scope of products that qualify for the exemption, so its guidance on this topic is critically important for researchers, health care institutions and companies developing and deploying CDS products.

FDA first issued final guidance on the CDS Criteria in September 2022 (the "2022 Guidance"). Many viewed the 2022 Guidance as interpreting the CDS exemption from device regulation much more narrowly than Congress intended. For example, FDA made clear that if a CDS product recommended a single, specific preventative, diagnostic or treatment course for a patient or was intended for use in time-critical decision-making, then it would fail Criterion 3 and be regulated as a medical device. Some, including former FDA Commissioner Scott Gottlieb, raised concerns that certain policy positions in the 2022 Guidance would limit potentially valuable applications of generative AI in medical practice because developers may purposefully limit their products' capabilities to avoid uncertainty around costly device regulation. The 2022 Guidance also lacked clarity on several key issues that CDS developers must assess to determine if their products will be regulated as medical devices. For instance, the agency did not provide meaningful direction on the number and frequency of discrete physiological data points, e.g., blood pressure results, that CDS can analyze before FDA will regulate the CDS as a medical device because it is analyzing a "pattern."

2026 Updates

In its updated guidance on CDS (the "2026 Guidance") FDA makes several noteworthy

revisions, including the following:

- *Easing enforcement of medical device requirements for certain CDS products*. Officially, FDA is standing by its position that providing a single, preventive, diagnostic or treatment recommendation for a patient (as opposed to multiple options) will subject software to medical device regulation, but with a significant caveat: The 2026 Guidance announces that FDA does not intend to enforce medical device requirements for CDS products that present only one such recommendation to an HCP, provided that (1) the recommendation is the only clinically appropriate option and (2) the product at issue meets all other CDS criteria. By way of example, FDA indicates that it would not enforce medical device requirements for software that meets all other CDS Criteria but "recommends a specific FDA-approved antibiotic agent for an HCP to consider based on the patient's symptoms, recent hospitalizations and previous antibiotic exposure." Other examples of CDS that would fall under this new policy include a product that estimates longer-term, post-operative mortality and complication risk after lung transplantation based on certain factors. Notably, however, the guidance is silent on how FDA will judge whether a CDS-provided recommendation represents the *only* clinically appropriate option.
- *Time-critical decision making*. In the 2026 Guidance, FDA has removed most of the language indicating that software intended for use in time-critical clinical decision-making will *automatically* fail Criterion 3 and thus be subject to regulation as a medical device. However, the guidance still indicates in at least one place that software intended to support time-critical decision-making does not meet Criterion 3. Retaining that language may simply have been an oversight, but FDA has also added specific new language to its discussion of Criterion 4 indicating that it will consider both the time-critical nature of the intended HCP user's decision-making and the level of software automation when determining if a CDS product permits the HCP to independently review the basis for the software's recommendations. Therefore, CDS intended for use in scenarios that FDA might consider "time-critical"—which could encompass many health care contexts—still presents higher risk of being considered a medical device under the updated guidance.
- *Attempt to clarify the term "pattern."* The 2026 Guidance notes that "discrete, episodic or intermittent point-in-time physiological measurements" like routine vitals taken at discrete clinical encounters "generally do not, by themselves, constitute a pattern" that would cause a CDS product to fail Criterion 1. This new language does little to identify where, on the continuum between a single measurement and continuous readings, a set of data points becomes a "pattern." However, given that the 2026 Guidance was also revised to remove language stating that "sampling frequency" is an important consideration when determining if information analyzed by CDS constitutes a "pattern," FDA may be signaling that it is less likely to consider multiple measurements that stop short of being truly "continuous" to be a pattern.
- *Transparency for HCP users.* FDA previously recommended that to provide appropriate transparency to HCPs and satisfy Criterion 4, CDS should supply plain-language information on the software's "input(s), algorithm logic or methods, datasets and validation." As AI tools have become increasingly sophisticated, some questioned the feasibility and practicality of providing these details to users, prompting concerns that it would be difficult for such tools to qualify as CDS exempt from device regulation. The 2026 Guidance appears to indicate more clearly that providing information on the "logic or methods" relied upon to develop recommendations for an HCP is one way to help meet Criterion 4, but that other descriptions of the "general approach" used to provide those recommendations may be acceptable. In sum, while the guidance does not depart from the criterion that CDS needs to provide HCPs enough information to independently understand the basis for the recommendation, software developers may have more ways to satisfy it.

General Wellness Guidance

Background

The Cures Act also removed software functions intended to maintain or encourage a healthy lifestyle that are unrelated to the diagnosis, cure, mitigation, prevention or treatment of a disease or condition from the definition of a "device." Unchanged from previous versions of FDA's General Wellness Guidance, FDA defines general wellness products as low-risk products (including some wearables) that fit into one of two categories:

1. A product with an intended use that relates to maintaining and encouraging a general state of health or a healthy activity (and for which there are no marketing claims that reference diseases or conditions).
2. A product with an intended use that relates to the role of a healthy lifestyle while helping to reduce the risk or 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.

2026 Update

In the updated General Wellness Guidance, FDA now indicates that it "may" consider products that use non-invasive sensing, e.g., optical sensing, to estimate, infer or output physiologic parameters, e.g., blood pressure, oxygen saturation, blood glucose, heart rate variability, to be general wellness products, provided that (1) such outputs are intended solely for wellness uses and (2) the products meet the following criteria:

- are non-invasive and not-implanted;
- do not involve an intervention or technology that may pose a risk to the safety of users or other persons if specific regulatory controls are not applied;
- are not intended for the diagnosis, cure, mitigation, prevention or treatment of a disease or condition;
- are not intended to substitute for an FDA-authorized, cleared or approved device;
- do not include claims, functionality or outputs that prompt or guide specific clinical action or medical management; and
- do not include values that mimic those used clinically unless validated, e.g. manufacturer testing, peer-reviewed clinical literature, to reflect those values.

Despite these limitations, the policy appears to significantly broaden the scope of digital health products that can live in this unregulated wellness space. FDA previously took the position that measurement or estimation of blood pressure is "*inherently associated*" with the diagnosis of a disease or a condition (hypo-and hypertension) and, therefore, products providing blood pressure estimations are medical devices. The agency has also indicated previously that products providing blood pressure estimation are not low-risk and thus are outside the scope of FDA's policy on general wellness products. One can imagine FDA applying a similar rationale to products that provide blood glucose or certain other measurements.

However, the agency now states that some products offering these types of readings to users *may* be general wellness products. Indeed, the updated guidance indicates that, in some cases, such products could qualify as general wellness products even if they notify a user that evaluation by an HCP may be helpful based on out-of-range measurements. However, product developers who wish to incorporate such notifications should carefully consult the new General Wellness Guidance to understand the parameters FDA has placed on them. FDA also makes clear that a product will *not* be a general wellness

product if its labeling or functionality:

- Makes references to specific diseases, clinical conditions or diagnostic thresholds;
- Provides alerts, alarms or prompts that recommend or require specific clinical action or medical management;
- Provides treatment guidance intended to inform or direct medical management;
- Includes claims of clinical equivalence, clinical accuracy, medical or clinical grade or substitution for an FDA-authorized, cleared or approved medical device; or
- Includes intended-use statements that explicitly target diagnosis, screening, monitoring or management of a disease or condition.

For example, FDA indicates that a wearable product intended to evaluate activity and recovery and that provides biomarker outputs to the user on sleep quality, pulse rate and blood pressure could be a general wellness product for which FDA would not expect compliance with medical device requirements. This presumes claims about the wearable do not refer to specific diseases or medical conditions and the product meets the other criteria outlined above.

Looking Ahead

The updates to FDA's guidance documents mark a shift in the landscape of digital health regulation to align with the Administration's goals of promoting the use of AI and encouraging innovation in consumer wearables. However, the new policies incorporate a number of changes—both allowances and limitations—that it will be important to navigate with care. Companies developing software for the health care or wellness space should seek legal counsel during the development process to mitigate potential risks of misalignment with FDA policy and assess whether they can benefit from new flexibilities.

If you have questions about how these updated FDA guidance documents may apply to your products, please contact Polsinelli's Food, Drug and Device team.

[1] Exec. Order, Ensuring a National Policy Framework for Artificial Intelligence (Dec. 11, 2025).