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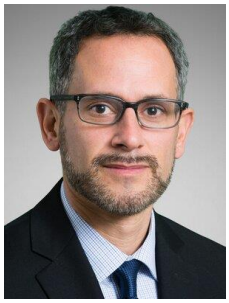
What FDA Guidance Means For The Future Of Health Software

By **Scott Danzis and Olivia Dworkin** (February 18, 2026, 6:46 PM EST)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The U.S. Food and Drug Administration kicked off 2026 by issuing two significant final guidance documents that the agency described[1] as part of an effort to "cut unnecessary regulation and promote innovation": one addressing clinical decision support software, and the other addressing general wellness products.[2]

The revisions are more measured than some had anticipated, although the updated guidances provide helpful clarification on areas that have challenged developers.

For some digital health innovators, understanding what these new guidances do and do not address is essential for strategic planning in this evolving regulatory landscape, although those hoping for more comprehensive and new artificial intelligence policies from the FDA will have to continue the wait.

Statutory and Policy Backdrop

Both guidances trace their roots to the 21st Century Cures Act, which sought to modernize FDA oversight of software by drawing clearer boundaries around what constitutes software that is regulated as a medical device.

With respect to clinical decision support, Congress excluded certain software functions from the device definition if four criteria are met: (1) the software must not analyze medical images, signals or patterns; (2) it must display or analyze medical information; (3) it must provide recommendations to healthcare professionals regarding prevention, diagnosis or treatment; and (4) it must enable those healthcare professionals to independently review the basis for the recommendations.

The FDA's 2022 guidance interpreting these criteria drew criticism from many stakeholders, including current U.S. Senate Committee on Health, Education, Labor and Pensions Chairman Bill Cassidy, R-La., who argued the agency imposed extrastatutory limitations that stifled innovation.[3] The revised guidance responds to some of these concerns, although through narrow adjustments rather than a broader reinterpretation of the statute.

Separately, the Cures Act — and FDA policy, last updated in 2019 — recognizes a nondevice category of general wellness products solely intended to maintain or encourage a healthy lifestyle, without claims tied to disease diagnosis, cure, mitigation or treatment.

The FDA's 2026 revisions to its general wellness policy focus heavily on sensor-based technologies, aligning with a broader push by the U.S. Department of Health and Human Services to promote the use of health-focused consumer wearables.

Clinical Decision Support: Course Corrections

Singular Recommendations

The most consequential change in the revised clinical decision support guidance concerns the FDA's treatment of software that provides a single recommendation.

The FDA's 2022 guidance provided that only software functions that output multiple recommendations in the form of a list of options to healthcare professionals could qualify as nondevice clinical decision support.

That interpretation drew significant criticism from industry and policymakers, who argued it forced developers to engineer artificial choice into tools even where clinical guidelines clearly pointed to a single optimal path.

In the recent update, the FDA now states that it intends to exercise enforcement discretion for clinical decision support tools that provide a singular output — such as recommending a particular FDA-approved drug for a clinician to consider based on patient-specific information — when only one recommendation is clinically appropriate, provided all other nondevice clinical decision support criteria are met.

Notably, the FDA has not revised its interpretation of the statute itself. Instead, the agency relies on enforcement discretion to soften the practical impact of its earlier position.

For developers, this provides near-term flexibility, but it also raises strategic questions about durability across administrations. Enforcement discretion, by definition, is policy rather than law, and companies must weigh how much to rely on it when making long-term product and investment decisions.

Open questions remain as well. The guidance does not define how a developer should determine when a single recommendation is clinically appropriate, leaving ambiguity around the boundaries of this carveout and the degree of judgment the FDA will apply in practice.

Clinical Documentation Tools

As global health regulators grapple with whether, whe, and how to regulate clinical documentation tools,[4] many in industry have been waiting for the FDA's perspective.

One example in the revised guidance offers limited insight into FDA's thinking: Software that analyzes a radiologist's written findings to generate a report summary and a specific diagnostic recommendation may fall within enforcement discretion if it does not analyze the underlying medical images, a healthcare professional remains in the loop, and the tool relies only on well-understood and accepted sources.

This example signals openness to innovation in documentation functionalities, but the guidance does not address the broader spectrum of documentation tools increasingly entering clinical workflows.

Developers will need to continue assessing whether particular documentation functions may fall within nondevice clinical decision support, enforcement discretion, or outside of the FDA's clinical decision support framework altogether, e.g., as administrative support.

General Wellness: Expanded Flexibility, With Tight Guardrails

A Shift From Biomarker-Based Exclusion to Claim-Based Analysis

The revised general wellness guidance reflects a notable evolution in FDA's treatment of sensor-based consumer wearables.

In prior enforcement actions, including a high-profile warning letter and safety communication in 2025, the FDA took the position that products intended to measure or estimate certain physiological parameters — most prominently blood pressure — were inherently medical devices because of their close association with clinical conditions such as hypertension.

The 2026 guidance retreats from that categorical framing. Under the revisions, no physiological parameter is automatically disqualifying for general wellness status. Instead, the regulatory analysis turns on intended use, claims and risk profile.

Noninvasive products that estimate or output physiological parameters traditionally associated with medical devices, including blood pressure, may qualify as general wellness products if their claims are strictly wellness-oriented and all other conditions of the policy are satisfied. These revisions signal that the FDA is no longer drawing bright lines based solely on what is being measured, but rather on how and why it is being measured.

The FDA does, however, draw a firm line at invasiveness: Even minimally invasive products, such as microneedle-based glucose wearables, are not low-risk for purposes of the general wellness policy, regardless of how carefully their claims are framed.

Guardrails That May Complicate Messaging

The revised policy also sharpens the guardrails around what general wellness products may not do, suggesting that the FDA may still police the line between wearables intended solely for general wellness purposes and those potentially intended for clinical use.

The FDA emphasizes that manufacturers should avoid displaying values that mimic those used clinically, unless validated, claiming clinical accuracy or medical-grade performance, prompting specific clinical actions or otherwise informing or directing medical management, or making disease-specific references.

These guardrails may require careful calibration by developers. For example, the guidance seemingly permits values that mimic clinical values if they are validated, but simultaneously prohibits claims of clinical accuracy or equivalence. This tension raises a practical question many developers will face: how to communicate validation or reliability without crossing into prohibited clinical performance claims.

User Notifications and the Edge of Clinical Meaning

The revised guidance also acknowledges that sensor-based wellness products may include limited user

notifications, such as informing a user that evaluation by a healthcare professional may be helpful when outputs "fall outside ranges appropriate for general wellness use."

But the guidance tightly cabins the permissible scope of such notifications. The notifications may not reference diseases or conditions, characterize outputs as abnormal or diagnostic, identify clinical thresholds, diagnose users, recommend treatments, or engage in ongoing monitoring or alerts for disease management.

For developers, this may create a delicate design challenge. How can a product flag out-of-range values without implying abnormality or clinical significance? How should manufacturers define "ranges appropriate for general wellness use" in a way that is both informative for users and compliant?

The AI Question

Although the agency framed both guidances in the context of AI innovation, neither guidance substantively engages on AI.

Although some examples in the revised guidances could encompass AI-enabled tools, the FDA does not directly address many of the novel technologies surfacing today, such as clinician- and consumer-facing medical chatbots, AI tools that leverage data from health wearables, or tools such as AI-generated prescription renewals and referral letters.

Moreover, the revised clinical decision support guidance emphasizes the use of well-understood and accepted sources to inform evidence-based recommendations and enable human review.

For traditional, rule-based software, this framework is relatively straightforward. For more advanced AI systems, such as those designed to surface insights from complex patterns, proprietary datasets, or emerging evidence not yet reflected in consensus guidelines, the fit is less clear.

As AI increasingly challenges conventional notions of explainability and evidentiary grounding, the FDA's approach may evolve to accommodate these technologies.

This silence on AI may reflect several possibilities. For example, the FDA may still be grappling with when and how to regulate AI-enabled tools or preserving flexibility in a rapidly evolving space. This omission also may itself be a signal that more comprehensive, AI-specific guidance is forthcoming.

Looking Ahead

Taken together, the FDA's early 2026 guidances reflect a targeted effort to ease innovation friction around specific areas — such as singular clinical decision support recommendations and sensor-based wearables — while maintaining established regulatory boundaries.

Companies should continue to monitor how the FDA applies these policies in practice and watch for additional guidance, particularly as digital health and AI technologies continue to advance.

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[1] https://x.com/drmakaryfda/status/2008583173349974145?s=46&t=2F87A5L8ZNIhYGJKdzModA.

[2] See FDA, Clinical Decision Support Software, Guidance for Industry and Food and Drug Administration Staff (Jan. 6, 2025); FDA, General Wellness: Policy for Low Risk Devices, Guidance for Industry and Food and Drug Administration Staff (Jan. 6, 2025); Dr. Marty Makary (@DrMakaryFDA), X (Jan. 6, 2026, 8:55 AM), https://x.com/drmakaryfda/status/2008583173349974145?s=46&t=2F87A5L8ZNIhYGJKdzModA.

[3] https://www.help.senate.gov/rep/newsroom/press/ranking-member-cassidy-rebukes-fda-policy-limiting-access-to-innovative-medical-technology.

[4] https://www.england.nhs.uk/long-read/guidance-on-the-use-of-ai-enabled-ambient-scribing-products-in-health-and-care-settings/.