

CLIENT ALERT | January 15, 2026

FDA Issues Updated Guidance Loosening Regulatory Approach to Certain Digital Health Tools

Two updated guidance documents aim to reduce “red tape” for certain digital health products.

Key Points:

- The updated guidance expands the scope of digital health tools, including certain types of wearables or clinical decision support software, that are legally exempt or otherwise free from FDA medical device oversight.
- The changes provide commercial opportunities for developers and manufacturers whose product offerings may previously have fallen outside the scope of FDA’s interpretation of the CDS exemption or general wellness policy.

On January 6, 2026, the Food and Drug Administration (FDA) issued updates to its guidance documents governing clinical decision support (CDS) software¹ and general wellness devices.² FDA Commissioner Marty Makary touted these changes as a way for FDA to “get out of the way as a regulator.”³ Department of Health and Human Services Secretary Robert F. Kennedy Jr. said the changes “[unlock] wearable devices for general wellness that have, for too long, been tied up in red tape.”⁴

This Client Alert summarizes the key changes to FDA’s approach to these product offerings and examines broader industry considerations.

CDS Guidance Updates

Background

Under the Federal Food, Drug, and Cosmetic Act (FDCA), software functions are excluded from the definition of a device if they meet the following criteria under 21 U.S.C. § 360j(o)(1)(E):

- not intended to acquire, process, or analyze a medical image or signal from an in vitro diagnostic device 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 (such as peer-reviewed clinical studies and clinical practice guidelines);

- intended for the purpose of supporting or providing recommendations to a healthcare professional about prevention, diagnosis, or treatment of a disease or condition; and
- intended for the purpose of enabling a healthcare professional to independently review the basis for recommendations that the software presents so that it is not the intent that such healthcare professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

Prior versions of the CDS guidance interpreting these statutory criteria drew substantial backlash from industry. For example, some commenters said that FDA's interpretation of the scope of CDS software exempt from the definition of a device was far more narrow than the statutory scope of exempt CDS software, evidencing a more conservative approach than Congress intended.

Other commenters, like the HIMSS Electronic Health Record Association, criticized the CDS guidance as falling short with respect to how FDA views CDS products that are intertwined with electronic health record software, many of which often issue decision alerts to clinicians configured by provider organizations and not software developers.⁵ In particular, the HIMSS Electronic Health Record Association disagreed with FDA's view that software that generates a single recommendation to the clinician could not qualify under the CDS exemption. Further, the HIMSS Electronic Health Record Association stated that FDA failed to account for the fact that in the vast majority of real-life cases, a single recommendation does not lead to an action by a clinician without the provider's necessary review and active, independent decision-making.⁶

Changes

The updated CDS guidance aims to clarify several key points, as described below.

Patterns, signals, and medical information

Whether a CDS tool is exempt from the device definition will depend, in part, on whether the input that the software analyzes, processes, acquires, prints, or displays is (i) a "signal" from an in vitro diagnostic device or a "pattern" or "signal" from a signal acquisition system, or (ii) "medical information."

If the CDS tool acquires, processes, or analyzes "patterns" or "signals," the software cannot be deemed exempt CDS as a threshold matter. However, if the CDS tool displays, analyzes, or prints "medical information," it can qualify for the exemption provided it satisfies the other statutory criteria.

FDA's distinction between patterns, signals, and medical information had created confusion for industry. In the updated guidance, FDA aims to clarify that signal acquisition systems measuring signals are those that measure parameters from the body for medical purposes such as through continuous, near-continuous, or streaming measures.

Similarly, FDA updated the guidance to state that patterns generally do not include discrete, episodic, or intermittent point-in-time physiological measurements like routine vital signs taken during a doctor's visit. Rather, such information from "a single, discrete test or measurement result" could be deemed "medical

information.” Further, FDA states that whether such information is communicated in a clinical conversation between a patient and a healthcare professional is not necessarily determinative of whether it satisfies the definition of “medical information.”

Taken together, the changes suggest that use of certain inputs which might previously have been thought of as signals or patterns may qualify as medical information that, if used as input in the CDS tool, will not preclude application of the exemption from the device definition.

Single recommendation

In the prior guidance, FDA made clear that a CDS tool would not be exempt if it did not provide multiple options or recommendations to the clinician. This was ostensibly to ensure that a CDS tool did not substitute the clinical judgment of a healthcare professional and that the recommendations provided were meant to provide more context and information to enable a more refined treatment decision for a patient without the risk of automation bias.⁷

In the updated guidance, FDA indicates that it intends to exercise enforcement discretion even where only one option is provided to the clinician, provided that only one recommendation is clinically appropriate. Notably, instead of stating that CDS tools with such functions may be exempt from device regulation, FDA refers to an application of its enforcement discretion, thereby appearing to take the position that such functions with a single recommendation do not qualify for non-device status.

Although this new category of CDS tools is expected to be free from FDA regulation as a matter of enforcement discretion, FDA does not explain how it will determine that a single recommendation is “clinically appropriate,” leaving such standard open to interpretation.

General Wellness Guidance Updates

Background

Under the FDCA, software functions intended for “maintaining or encouraging a healthy lifestyle and [that are] unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition” are excluded from the definition of a device under 21 U.S.C. § 360j(o)(1)(B).

Under previous guidance, FDA expanded on the scope of this exemption (limited by statute to software) and extended its enforcement discretion to “low risk general wellness products” (i.e., the policy applied beyond software products), stating that it did not intend to determine whether these products were devices so long as they were only for general wellness use and presented a low risk to the safety of users and other persons.⁸

Changes

The updated general wellness guidance leaves this approach unchanged, but seemingly expands the scope of products that qualify as “wellness products” to include those 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) when such outputs are intended solely for wellness use.

Specifically, FDA explains 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.” Such products may also notify a user that evaluation by a healthcare professional may be helpful when outputs fall outside normal ranges and remain subject to the policy in the guidance.

Thus, the changes suggest a broadening of the scope of products subject to the wellness policy and arguably free from FDA oversight.

Considerations for Industry

With these changes, FDA expands and clarifies the scope of CDS and general wellness products either subject to exemption from the definition of a device (and thus not regulated as such) or eligible for enforcement discretion (and thus not subject to device regulations even if the product would otherwise meet the definition of a device).

These changes provide commercial opportunities for developers and manufacturers whose product offerings may previously have fallen outside the scope of FDA’s interpretation of the CDS exemption or general wellness policy. For example, companies may be able to get their products to market earlier without the need to comply with FDA device regulations. This is particularly the case for certain wearables that measure physiologic parameters like blood pressure or oxygen saturation, which FDA might have previously considered to be regulated devices.

Moreover, CDS developers struggling to adhere to FDA’s interpretation of the CDS exemption by ensuring their tools produced multiple outputted options or recommendations for clinicians may now have more freedom to limit those recommendations to only one option or recommendation to the clinician in certain circumstances while still benefitting from speed to market as a result of lack of FDA oversight.

Despite these new flexibilities, developers and manufacturers should continue to monitor FDA’s evolving regulatory approach to digital health tools and keep in mind that FDA’s legal authorities remain unchanged. Critically, the use of medical claims, therapeutic uses, or “medical grade” readings are likely to trigger FDA regulatory scrutiny and subject the product to FDA’s device authority, including the potential requirement for premarket review.

Careful product design and attention to marketing claims enables earlier access to the market with reduced risk of enforcement. As digital health regulatory frameworks attempt to catch up to the novel digital health technologies that typically outpace them, industry has substantial opportunity to educate regulators and shape the resulting regulatory schemes.

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Endnotes

- ¹ FDA, Clinical Decision Support Software — Guidance for Industry and Food and Drug Administration Staff (Jan. 2026), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software> (CDS Guidance).
- ² FDA, General Wellness: Policy for Low Risk Devices — Guidance for Industry and Food and Drug Administration Staff (Jan. 2026), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices> (GW Guidance).
- ³ OncoDaily, U.S. Food and Drug Administration (FDA) Commissioner Marty Makary Used the 2026 Consumer Electronics Show (CES) to Frame a Deregulatory Message, <https://oncoday.com/industry/fda-8>.
- ⁴ X, HHS Secretary Robert F. Kennedy, Jr. (Jan. 6, 2026), <https://x.com/SecKennedy/status/2008606670067232894>.
- ⁵ Letter from HIMSS Electronic Health Record Ass'n to Food & Drug Admin., Re: Clinical Decision Support Software Guidance, Docket No. FDA-2017-D-6569 (FDA-2017-D-6569-0115, attachment 1) (Dec. 6, 2022).
- ⁶ *Id.*
- ⁷ See FDA, Clinical Decision Support Software: Guidance for Industry and Food and Drug Administration Staff (Sept. 2022).
- ⁸ See GW Guidance, at 2.