

Alert | Digital Health/Health Care & FDA Practice



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FDA Updates Two Digital Health Final Guidance Documents

On Jan. 6, 2026, the U.S. Food and Drug Administration (FDA) updated the final guidance documents *General Wellness: Policy for Low Risk Devices* (the General Wellness Guidance) and *Clinical Decision Support Software* (the CDS Guidance), which supersede the previous versions of these final guidance documents issued in 2019 and 2022, respectively.

While FDA guidance documents do not establish legally enforceable responsibilities, they do describe the agency's current thinking on a topic and remain relevant for informing industry actions to comply with federal law. Stakeholders that have relied upon the prior versions of these final guidance documents may wish to closely review these updates to determine the potential impact on their products and business. Further, stakeholders may need to remember that, as it did here, FDA guidance is subject to change at any time, including with respect to whether the FDA intends to exercise enforcement discretion.

General Wellness Guidance

Regulatory Scheme for General Wellness Products

The FDA has a long-standing policy that it does not intend to examine "general wellness products" to determine whether they qualify as devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and, therefore, are subject to pre-market and post-market device compliance requirements. The updated

General Wellness Guidance does not change the “general wellness products” definition; however, certain changes suggest that more products may fall under this definition moving forward.

FDA Commentary on Wearables

The FDA included new commentary and criteria for determining whether **wearables** – described as “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)” – may be considered general wellness products.

For instance, the FDA indicated that a wearable that displays values, ranges, trends, baselines, or longitudinal summaries may be considered a general wellness product as long as such outputs are: (i) contextualized in relation to sleep, activity, stress, recovery, or similar wellness domains, and (ii) validated (e.g., via manufacturer testing, peer-reviewed clinical literature), though the FDA’s expectations for such validation remains unclear.

Where such outputs fall outside ranges appropriate for general wellness use, the wearable may notify users that an evaluation by a health care professional may be helpful as long as the notification does not: (i) identify or name a specific disease or medical condition; (ii) characterize the output as abnormal, pathological, or diagnostic; (iii) include clinical thresholds, diagnoses, or treatment recommendations; or (iv) provide ongoing alerts or monitoring intended to manage a disease or condition. The FDA has not clarified what it would consider a range appropriate for general wellness use. The agency has also not provided guidance on how product developers will navigate notifying a user to seek the advice of a health care professional without the ability to fully contextualize the rationale (e.g., an abnormal output).

CDS Guidance

The updated CDS Guidance provides the FDA’s current thinking on the interpretation of section 520(o)(1)(E) of the FD&C Act, which indicates that CDS software functions are excluded from the definition of device as long as those functions satisfy the following criteria:

1. 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;
2. 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);
3. Intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and
4. Intended for the purpose of enabling such health care professionals to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professionals rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

Criterion 1

The FDA clarified that signals from a signal acquisition system include those obtained through a “continuous, near-continuous, or otherwise streaming measurement.” The FDA also clarified that a pattern generally does not include “discrete, episodic, or intermittent point-in-time physiological measurements (e.g., routine vital signs obtained at discrete clinical encounters)” by themselves. While

these updates may provide helpful clarifications, they do not represent a material shift in the FDA's interpretation of this criterion.

Criterion 2

The FDA clarified that medical information about a patient refers broadly to information that is “used in, or that relates to, the clinical care of the patient, including patient specific information.” This somewhat departs from the prior language, which focused narrowly on whether the information is commonly discussed in a clinical conversation.

Criterion 3

The FDA stated that it intends to exercise enforcement discretion where a software function provides only one clinically appropriate recommendation but satisfies the other criteria under section 520(o)(1)(E) of the FD&C Act. To be clear, the FDA did not state that a software function providing only one clinically appropriate recommendation satisfies this criterion. The FDA's perspective on enforcement discretion may change in the future.

The FDA also moved the prior language on automation bias and time-critical nature of a health care provider's decision making from Criterion 3 to Criterion 4, which may signal that the agency no longer considers such matters in determining whether Criterion 3 is satisfied. However, certain examples provided by the FDA later in the updated guidance suggest that “time-critical” functions nonetheless do not satisfy Criterion 3 (or Criterion 4).

Criterion 4

The FDA clarified its interpretation regarding how and what level of information about an underlying algorithm should be presented to health care professionals to enable their independent review. These clarifications may suggest that the FDA has now favored a more practical approach, focused on avoiding information overload and prioritizing the most relevant information for decision making, rather than the comparably more detailed labeling expectations in the prior version of the guidance. Importantly, CDS developers may now have more flexibility in the level of specificity of the information on their proprietary algorithms to be disclosed to users. Nonetheless, the guidance may signal that the FDA intends to continue its evaluation of automated AI/machine learning-enabled functions, with a particular focus on Criterion 3 and Criterion 4.

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