Cooley

Automation Bias and Clinical Practice: FDA Makes Incremental Updates to Clinical Decision Support Software Guidance

January 20, 2026

On January 6, 2026, the US Food and Drug Administration (FDA) revised its final guidance on Clinical Decision Support Software (2026 CDS Software Guidance).[1] The 2026 guidance, which supersedes the 2022 version, clarifies the agency's interpretation of the four clinical decision support (CDS) statutory criteria.

To recap, with the passage of the 21st Century Cures Act in 2016, Congress exempted software from the device definition in the Federal Food, Drug, and Cosmetic Act (FDCA) if the software is:

1. 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.
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 healthcare professional about prevention, diagnosis or treatment of a disease or condition.
4. Intended for the purpose of enabling a healthcare professional to independently review the basis for recommendations that the software presents, but not rely primarily on those recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.[2]

In guidance documents issued since the FDCA was so amended, FDA has divided CDS software into two buckets: "non-device" CDS, which satisfies the statutory carve out and is exempted from regulation as a medical device, and "device" CDS, which FDA regulates as a medical device under the FDCA.

The 2026 CDS Software Guidance relies on this same statutory framework and uses the same general approach to identify non-device versus device CDS, though this latest guidance includes numerous real-world examples to highlight the distinction. For example, FDA explains that device CDS includes software that:

1. Provides recommendations requiring an immediate response from clinicians (e.g., within 24 hours).
2. Analyzes information from a separate device (e.g., a spectroscopy device or another device generating medical imagery).
3. Predicts a patient's response to clinical intervention.
4. Lacks verification and validation.
5. Is not derived from well-understood and accepted sources.

The 2026 CDS Software Guidance also addresses two of the more controversial points created by FDA's 2022 CDS Software Guidance, both of which relate to the third statutory criterion. First, FDA changes course from 2022 and explains that even software that provides a singular recommendation can be considered non-device CDS.[3] This is a significant departure from the 2022 guidance, where FDA stated that software had to offer more than one recommendation to be subject to enforcement discretion. Second, the 2026 guidance does not strictly prohibit risk "scoring" as a function that renders software ineligible for enforcement discretion. Although the 2026 guidance does not state that "scoring" is always permissible for non-device CDS, it provides several examples of products with risk scoring functions over which FDA intends to exercise enforcement discretion – e.g., software that presents the risk of a cardiovascular event given a patient's test results coupled with lifestyle and demographic information.

Aside from these significant updates, much of the 2026 CDS Software Guidance simply reframes FDA's previous interpretations of the CDS statutory criteria. For example, FDA clarified what it considers "medical information about a patient," moving away from only information "commonly discussed in a clinical conversation" to also include information supported by well-understood and accepted sources that is relevant to the patient. FDA continues to focus on its concerns about software functions that provide time-critical recommendations, though

FDA now spreads that analysis across the third and fourth statutory criteria.

Relatedly, FDA has relocated its reference to "automation bias" to the fourth statutory criterion. As with the 2022 iteration of the guidance, this point remains controversial, as physicians make critical, time-sensitive decisions throughout their practice, and FDA continues to support its concern about automation bias by citing only a 2004 journal article from the American Institute of Aeronautics and Astronautics, which was issued before ubiquitous use of smartphones and other related technology.[4] Finally, the 2026 CDS Software Guidance incorporates FDA's increased understanding of the value of "wearables" as articulated in the agency's revised final General Wellness Guidance, which was issued the same day as this guidance.[5] For example, in discussing what constitutes a "signal" and a "signal acquisition system" for the first statutory criterion, FDA references physiological monitoring, though the agency is careful to carve out products that monitor such parameters but do not meet the device definition. Consistent with FDA's revised General Wellness Guidance, FDA acknowledges that some such products that "are intended to monitor signals for medical purposes are considered medical devices, [though] some are not."[6]

While the 2026 CDS Software Guidance does not represent a sea change, the numerous real-world examples included in this iteration offer additional insight into FDA's enforcement discretion policy and may offer clarity in a somewhat gray area for industry. We anticipate, consistent with FDA's overall increased emphasis on transparency under Commissioner Martin Makary, that FDA will update its other digital health guidance documents, which can further inform regulatory strategy.

As FDA continues to update such policies, software developers will benefit from a reevaluation of their software functions, as we anticipate FDA will provide additional regulatory flexibility for certain categories of low-risk software. Cooley's life sciences and healthcare regulatory team closely monitors FDA's guidance documents and enforcement actions in this space and actively works with clients on their regulatory strategy and implementation. For assistance, please contact the authors listed below.

Notes

1. Clinical Decision Support Software – Guidance for Industry and Food and Drug Administration Staff.
2. 21 USC § 360j(o)(1)(E).
3. Clinical Decision Support Software – Guidance for Industry and Food and Drug Administration Staff at 10-11, 21.
4. See FDA's Latest Twist on Digital Health Oversight Brings Big Shift, Cooley client alert, January 3, 2023.
5. See FDA Opens Aperture for Wearables in Latest General Wellness Guidance, Cooley client alert, January 20, 2026.
6. Clinical Decision Support Software – Guidance for Industry and Food and Drug Administration Staff at 9.

Key Contacts

Sonia Nath Washington, DC	snath@cooley.com +1 202 776 2120

Son Nguyen Washington, DC	snguyen@cooley.com +1 202 728 7100
Wyatt Kernell Colorado	wkernell@cooley.com +1 720 566 4490