A New Era for Clinical Decision Support Software

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In its latest embrace of software advancements and artificial intelligence, the FDA released updated guidance on Clinical Decision Support (CDS) software.[1] While the updated guidance leaves the overall CDS software framework intact, the Agency noted that certain updates were needed to "adapt to the times."[2] The primary goal of the updated guidance is to further clarify when CDS software is considered a medical device under the federal Food, Drug, and Cosmetic Act (FD&C Act) and when it is excluded from the device definition and, thus, not required to comply with the FDA's pre- and post-market device regulatory requirements. This clarity should open the door to new output capabilities for CDS software, but only for products that meet the FDA's criteria. CDS software that does not meet all four of the required elements outlined below will remain subject to the FDA's device regulations and can face enforcement and other potential liability for noncompliance.

What Criteria Must CDS Software Meet To Be Excluded From the Device Definition?

The 21st Century Cures Act amended Section 520 of the FD&C Act, in relevant part, by establishing four criteria that CDS software must meet to be excluded from the statutory definition of a "medical device."[3] The FDA explained that this guidance is intended to shed light on its interpretation of these provisions and the bounds of each criterion.

As a possible acknowledgement of the somewhat confusing statutory drafting, the FDA explains, first and foremost, that each of the following four elements must be met for CDS software to be deemed to have a "Non-Device CDS" function and excluded from the FDA regulation as a medical device:

1. The CDS software is 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. The CDS software is intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information.
3. The CDS software is intended for the purpose of supporting or providing recommendations to a Healthcare Provider (HCP) about prevention, diagnosis, or treatment of a disease or condition.
4. The CDS software is intended for the purpose of enabling an HCP to independently review the basis for the recommendations that such software presents so that it is not the intent that the HCP rely primarily on any such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

Read the full article here.

[1] FDA, Guidance for Industry: Clinical Decision Support Software (Jan. 6, 2026).

[2] Dr. Marty Makary (@DrMakaryFDA), X (Jan. 6, 2025, 10:55 AM), https://x.com/DrMakaryFDA/status/2008583173349974145.

[3] See Pub. L. 114-255; 21 U.S.C. § 360j(o)(1)(E).