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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.

Criterion 1 and 2: CDS Software Inputs

Criterion 1 and 2 concern the data inputs used for CDS software, describing the types of input functions that are within the scope of the medical device definition and that are Non-Device CDS functions, respectively. In other

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[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).

words, software that serves one of the input functions described in Criterion 1 is a device under the FD&C Act, while software that functions for one of the purposes in Criterion 2 is excluded from the device definition.

A. *Criterion 1*

If the input for the software is a medical image, signal from an IVD, or pattern or signal from a signal acquisition system, the software is likely a device under the FD&C Act. This means that software acquiring or analyzing MRIs, x-rays, CT scans, or ECG waveforms are likely devices subject to the FDA's pre- and post-market regulatory requirements. In addition, input that results from continuous or repeated measurements of a signal or from a signal acquisition system—as opposed to discrete, point-in-time physiological measurements—indicates that the software is a medical device.

For example, the following software does not meet criterion 1:

- Software functions that process or analyze a medical image, such as enhancement, manipulation, making measurements, identifying normal/abnormal structures, determining size/shape/location of a suspected nodule, or functions within computer aided diagnostics (CADx) or computer-aided detection (CADe) systems

- Software functions that process or analyze an ECG waveform or QRS complex, such as measuring repeated complexes, measuring variation from baseline, or detecting heart rate, arrhythmias, or structural abnormalities

- Software functions that process or analyze an electrochemical or photometric response generated by an assay and instrument to generate a clinical test result, such as determining a potassium level

It should be noted, however, that signal acquisition systems measuring physiological parameters can be used for nonmedical purposes, such as for the purpose of biometric identification. Software using inputs from such systems for nonmedical purposes are not devices under the FD&C Act.

B. *Criterion 2*

In contrast, software intended to display, analyze, or print *medical information about a patient* or other medical information can be software excluded from the device definition. The FDA defines *medical information about a patient* as information "used in, or that relates to, the clinical care of the patient, including patient-specific information." The updated guidance further clarifies that this includes "information which may generally be communicated between HCPs in a clinical conversation or between HCPs and patients in the context of a clinical decision." This may include patient demographic information, symptoms, certain test results, and discharge summaries. Notably, however, whether the information is commonly discussed in a clinical conversation is not, by itself, determinative of whether Criterion 2 is satisfied, as long as the information's relevance to patient care is "supported by well-understood and accepted sources." The FDA provides the following examples of software meeting Criterion 2:

- The report from a radiology study (e.g., "a BIRADS category 4 lesion is present") or summary information about the output of legally marketed CAD software (e.g., "twelve CAD annotations are present")

- An ECG report annotated by an HCP with a description of an abnormal heart rhythm (e.g., "the patient shows signs of Atrial Fibrillation")

- A blood pressure result (e.g., "120/80 mmHg") from a legally marketed device

- A lab test result (e.g., "potassium level of 4.0 mmol/L or glucose level of 95 mg/dL") in an electronic health record

Other medical information, such as clinical practice guidelines, peer-reviewed clinical studies, textbooks, or approved drug or medical device labeling, may also be used as an input under Criterion 2.

Criterion 3: Intended To Support or Provide Recommendations to HCPs

The most significant update to the FDA's guidance is described in Criterion 3, as it contains a key substantive change from the prior version of this guidance, rather than just additional clarity.

The FDA considers software meeting the requirements of Criterion 3 as software that: (a) provides condition-, disease-, and/or patient-specific information and options to an HCP to enhance, inform, and/or influence a healthcare decision; (b) does not provide a specific preventive, diagnostic, or treatment output or directive; and (c) is not intended to replace or direct the HCP's judgment.

The 2022 guidance seemed to require that CDS software provide HCPs with multiple treatment, diagnostic, or preventive options to satisfy Criterion 3. However, the updated guidance loosens its restriction by noting that the Agency intends to exercise enforcement discretion for software providing a single recommendation *if only one option is clinically appropriate.* For example, under the updated guidance, software may:

- Create a recommended treatment plan based on patient diagnoses and comorbidities

- Recommend a specific diagnosis based on a patient's symptoms, vital signs, and laboratory values when alternative diagnoses are "highly improbable"

- Recommend a diagnosis while summarizing a clinician's report, such as a radiologist or pathologist report

- Predict the risk of complications based on patient-specific information (i.e., age, sex, weight, etc.)

While the updated guidance opens the door to more capabilities for CDS software, the FDA did not elaborate on when only one option is "clinically appropriate," leaving lingering questions about the updated guidance's utility in real-world scenarios.

In addition, the updated guidance also removed the limitation that software could not provide information that a patient "may exhibit signs" of a specific disease or identify a risk probability for a specific disease. Instead, under the updated guidance, such outputs may fall within the bounds of Criterion 3.

Criterion 4: Intended To Enable Independent Review of Recommendations by HCPs

To ensure the software does not replace or direct decisions made by HCPs, software must be intended to enable independent review of the basis for the recommendations. Otherwise, the software is a device under the FD&C Act, and subject to pre- and post-market device regulatory requirements.

The FDA recommends the following to ensure HCPs remain the final decision-maker and software functions satisfy Criterion 4:

- Software or labeling should include the intended use of the product, including the intended HCP user and patient population

- Software or labeling should identify the required input(s) medical information, as well as how the input(s) should be obtained, its relevance, and the data quality requirements

- Software or labeling should provide a description of the underlying algorithm, and accompanying validation, sufficient for the intended HCP user to identify the basis of the recommendation. This should include:
    - A summary of the general approach relied upon to provide the recommendations
    - A description of the data relied upon to such that an HCP can ensure the data represents their patient population
    - A description of the clinical studies and results used to validate the algorithm and/or recommendations

- The output provides HCPs with relevant patient-specific information and other knowns/unknowns to enable HCPs to independently review the accuracy of the recommendations

In addition, the Agency will continue to consider the level of software automation, as well as the time-critical nature of the HCP's decision to determine whether the software satisfies Criterion 4. For example, in urgent situations, HCPs are less likely to independently review the software's output, which increases the risk that the software will replace or direct the HCP's decision. As such, software used to support time-sensitive decisions are more likely to be considered devices under the FD&C Act based on failure to meet Criterion 4.

Conclusion

The updated guidance provides new output capabilities for the CDS software, potentially opening the door to more innovation in the space. However, the limits of the exclusion for Non-Device CDS software remain subject to some level of uncertainty and discretion. Even with the additional regulatory flexibility and clarity provided by the updated guidance, careful analysis is recommended for developers relying (or planning to rely) on the statutory exclusion in Section 520(o) of the FD&C Act to market CDS software without complying with applicable device regulations.