Clinical Decision Support (CDS) Software Final Rule

A Practical Guidance® Article by Kyle Faget, Foley & Lardner LLP

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This article discusses final guidance issued by the U.S. Food and Drug Administration (FDA) addressing clinical decision support (CDS) software. Software intended for medical diagnosis or treatment, including CDS software, has historically been considered a medical device subject to FDA regulation. CDS software includes computerized alerts and reminders for providers and patients, clinical guidelines, condition-specific order sets, focused patient data reports and summaries, documentation templates, diagnostic support, and contextually relevant reference information.

On September 28, 2022, FDA issued *Guidance for Industry and Food and Drug Administration Staff: Policy for Device Software Functions and Mobile Medical Applications*. The Guidance is available on the FDA's website.

Software intended for medical diagnosis or treatment, including CDS software, has historically been considered a medical device subject to FDA regulation.

In the final guidance, FDA clarifies that certain types of CDS software functions are excluded from the definition of a medical device when such products meet all four of the criteria articulated in Section 520(o)(1)(E) of the FD&C Act. Such non-device CDS are:

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 (Criterion 1)
2. Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (e.g., peer-reviewed clinical studies and clinical practice guidelines) (Criterion 2)
3. Intended for the purpose of supporting or providing recommendations to an HPC about prevention, diagnosis, or treatment of a disease or condition (Criterion 3)
4. Intended for the purpose of enabling such HCPs to independently review the basis for such recommendations that such software presents so that it is not the intent that such HCPs rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient (Criterion 4).

FDA interprets the statutory criteria that exclude mobile health (sometimes referred to as mHealth) software from the definition of a medical device, which FDA refers to as "non-device CDS."

FDA explains the four criteria in the final guidance.

Criterion 1

FDA noted that if a medical image or a signal from an IVD or a pattern/signal from a signal acquisition system is used as input, then the software function remains a regulated medical device.

FDA considers a "medical image" to include images generated by medical imaging systems (e.g., computed

tomography, x-ray, ultrasound, and magnetic resonance imaging) to view any part(s) of the body or images acquired for a medical purpose. Images not originally acquired for a medical purpose but that are processed or analyzed for a medical purpose are also considered "medical images."

FDA considers "signal" to refer to signals that typically require use of either an IVD (such as photometric response generated by an assay and instrument that is further processed by software to generate a clinical test result) or a signal acquisition system such as an ECG lead that measures a parameter from within, attached to, or external to the body for a medical purpose.

FDA interprets "pattern" to refer to multiple, sequential, or repeated measurements of a signal or from a signal acquisition system.

Note, however, that activity monitors or other signal acquisition systems that measure physiological parameters that are not specifically intended or marketed for a purpose identified in the device definition are not medical devices.

Criterion 2

Software functions intended to display, analyze, or print/ medical information about a patient or other medical information (e.g., peer-reviewed clinical studies or clinical practice guidelines) meet Criterion 2 and are not medical devices subject to FDA regulation and oversight.

FDA considers "medical information about a patient" to be the type of information that normally is, and generally can be, communicated between health care providers (HCPs) in a clinical conversation or between HCPs and patients in the context of a clinical decision, meaning that the relevance of the information to the clinical decision being made is well understood and accepted. Medical information, as defined in the final guidance, would exclude potentially relevant information that is not yet "well understood and accepted," which may limit the type of inputs that can be used by non-device CDS software.

FDA interprets "other medical information" to include information such as peer-reviewed clinical studies, clinical practice guidelines, and information that is similarly independently verified and validated as accurate, reliable, not omitting material information, and supported by evidence.

FDA notes that frequency is important when determining if information is considered "medical information" or a "signal" or "pattern." A single test or measurement result (e.g., from a blood glucose test) is considered medical information but continuous sampling of the same would be considered a pattern or signal subject to FDA regulation as a medical device.

FDA explains that Criterion 1 and Criterion 2 describe the types of data inputs used in devices (Criterion 1) and the types of data inputs used in non-device CDS (Criterion 2).

Criterion 3

Criterion 3 software functions support or present recommendations to HCPs. HCPs may then incorporate this information into their decision-making about the care of a patient, with other information and factors of which the HCP is aware. FDA interprets Criterion 3 to refer to software that:

- Provides condition-, disease-, and/or patient-specific recommendations to an HCP to enhance, inform, and/ or influence a healthcare decision (e.g., drug-drug interaction and drug-allergy contraindication notifications to avert adverse drug events)
- Does not provide specific preventative, diagnostic, or treatment output or directive
- Is not intended to replace or direct an HCP's judgment –and–
- Does not include in time-critical decision-making

Such functions are not intended for the purpose of supporting or providing recommendations to HCPs.

FDA considers software functions that provide the following outputs to be non-device CDS as long as they are not intended to support time-critical decision-making and/ or replace or direct an HCP's judgment:

- A list of preventive, diagnostic or treatment options
- A prioritized list of preventive, diagnostic or treatment options –or–
- A list of follow-up or next-step options for consideration

FDA notes that two aspects of software functionality may affect whether a software function is being used to support or provide recommendations to an HCP:

- The level of software automation –and–
- The time-critical nature of the HCP's decision-making

Automation bias may occur if software provides an HCP with a single, specific, selected output or solution as opposed to a list of options or complete information for the HCP's consideration.

Criterion 4

Under Criterion 4, the software function must be intended to enable HCPs to independently review the basis for the recommendations presented by the software so that HCPs do not rely primarily on such recommendations, but rather on their own judgment, to make clinical decisions for individual patients. FDA notes that software functions intended for critical, time-sensitive decisions will not meet Criterion 4 because the HCP will not be able to independently review the basis for the recommendation.

FDA recommends that software or labeling:

- Include the purpose or intended use of the product, including the intended HCP user and patient population
- Identify the required medical inputs with plain language instructions on how the inputs should be obtained, their relevance, and data quality requirements
- Provide a plain language description of the underlying algorithm development and validation that forms the basis for CDS implementation, including a summary of the logic or methods used to provide the recommendation, a description of the underlying data relied upon so the HCP can assess whether the data is representative of their specific population, and a description of the results from clinical studies conducted to validate the algorithm/recommendations so the HCP can assess the performance and limitations as applied to their patient population –and–
- Provide, in the software output, patient-specific information and other knowns/unknowns, such as missing or corrupted data, so the HCP can independently review the basis for the recommendations and apply their own judgment

According to the FDA, regardless of the complexity of the software and whether or not it is proprietary, the software output or labeling should provide adequate background information in plain language on the input(s), algorithm logic or methods, datasets, and validation. Additionally, relevant sources should be identified and available to and understandable by the HCP user.

Note that earlier draft guidance on CDS opined upon CDS intended for use by patients and caregivers, as opposed to HCPs. Importantly, the final guidance noted that software functions that support or provide recommendations to patients or caregivers—not HCPs—meet the definition of a device.

The final guidance released by FDA also includes several examples of device and non-device CDS. When in doubt, keep in mind that through the 513(g) Request for Information process, 21 U.S.C. § 360c(g), the FDA provides an avenue for clarifying whether a product is a regulated medical device. Further information about the 513(g) process is located on the FDA's website.

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