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Update - Clinical Decision Support Software Final Guidance

The Food and Drug Administration has published final guidance on determining whether clinical decision support (CDS) software is considered a medical device.

Overview: Certain Clinical Decision Support (CDS) software functions are excluded from the definition of device by section 520(o)(1)(E) of the FD&C Act if the software functions meet all of the following four 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 (section 520(o)(1)(E) of the FD&C Act);
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) (section 520(o)(1)(E)(i) of the FD&C Act);
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 (section 520(o)(1)(E)(ii) of the FD&C Act); and
4. Intended for the purpose of enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient (section 520(o)(1)(E)(iii) of the FD&C Act).

There were significant changes from the 2019 draft guidance with some parts being completely rewritten. Some notable changes:

- Removed discussion of CDS software intended to be used by patients or caregivers and instead refers to other FDA guidance documents for analysis of patient-directed decision support tools, which include: Policy for Device Software Functions and Mobile Medical Applications, Software as a Medical Device (SaMD): Clinical Evaluation, Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices, and General Wellness: Policy for Low Risk Devices
- Removed discussion of using the International Medical Device Regulators Forum's (IMDRF) risk-based framework as a way to decide which software to regulate (comments said it was too confusing)
- Addition of examples to identify FDA's views on non-device CDS software functions and device software functions

Some controversy: Software products previously not regulated by FDA under the 2019 draft guidance may now be subject to FDA oversight under the Final Guidance.

Some new decision-making tools from FDA:

- Graphic: Your Clinical Decision Support Software - Is It a Medical Device?
- Digital Health Policy Navigator: A tool to help in determining whether a product's software functions are potentially the focus of the FDA's oversight.

Suggested Reading Materials:

- Slides from 10/18/22 FDA Webinar: Clinical Decision Support Software Final Guidance (webinar recording has not been posted yet)
- Your clinical decision support software may now be regulated by FDA as a medical device (DLA Piper)
- Is Your Clinical Decision Support Software a Medical Device? Final Guidance Details FDA's Latest Thinking (Ropes & Gray)