U.S. FOOD & DRUG ADMINISTRATION

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Today's Topic:
Clinical Decision Support Software, Final Guidance

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Clinical Decision Support Software, Final Guidance

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Final Guidance

- **Clinical Decision Support Software**
  - www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software
  - Regulations.gov: FDA-2017-D-6569

Learning Objectives

- Objective #1: Briefly describe the 21st Century Cures Act and history of the Clinical Decision Support (CDS) software guidance

- Objective #2: Explain FDA's current thinking on CDS software, including clarification on our interpretation of the criteria in section 520(o)(1)(E) of the Food, Drug, and Cosmetic Act (FD&C Act)

- Objective #3: Describe FDA's Enforcement Discretion Policy for functions that provide one clinically appropriate output and examples

- Objective #4: Review examples of non-device CDS software functions and CDS software functions that meet the definition of device

Objective #1: Briefly explain the 21st Century Cures Act and history of the Clinical Decision Support (CDS) software guidance

21st Century Cures Act – Software Functions Excluded from Device Definition

On December 13, 2016, the 21st Century Cures Act amended the definition of "device" in the FD&C Act to exclude certain software functions described in section 520(o) of the FD&C Act. Specifically, 520(o) of the FD&C Act excludes software functions intended for:

Administrative support of a health care facility	Maintaining or encouraging a healthy lifestyle and unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition	Electronic patient records	Transferring, storing, converting formats, or displaying data and results	**Clinical Decision Support (CDS)**
520(o)(1)(A)	520(o)(1)(B)	520(o)(1)(C)	520(o)(1)(D)	520(o)(1)(E)

Background

21st Century Cures Act amended device definition in December 2016

First Draft Guidance and Revised Draft Guidance issued in December 2017 and September 2019, respectively

Final Guidance published in September 2022

Final Guidance published on January 6, 2026 (and re-issued on January 29, 2026)

Objective #2: Explain FDA's current thinking on CDS software, including clarification on our interpretation of the criteria in section 520(o)(1)(E) of the FD&C Act

21st Century Cures Criteria for Non-Device CDS

- The Cures Act excludes certain software functions from device definition if all four of these Criteria are met:

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;

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 health care professional about prevention, diagnosis, or treatment of a disease or condition; and

4) intended for the purpose of enabling a 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.

Criterion (1): Acquire, Process, Analyze

520(o)(1)(E): 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

- Medical image: images generated by use of medical imaging systems to view any part(s) of the body or images acquired for a medical purpose
- Signal from a(n):
  - An IVD; or
  - A signal acquisition system that measures a parameter from within, attached to, or external to the body for a medical purpose **(for example, through continuous, near-continuous, or otherwise streaming measurement)**
- Pattern: multiple, sequential, or repeated, measurements of a signal or from a signal acquisition system
  - **By contrast, discrete, episodic, or intermittent point-in-time physiological measurements (for example, routine vital signs obtained at discrete clinical encounters) generally do not, by themselves, constitute a pattern**

Criterion (1): Clinical relevance

520(o)(1)(E): 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

FDA considers software functions that assess or interpret the clinical implications or relevance of a signal, pattern, or medical image to be software functions that do not meet Criterion 1 because they *acquire*, *process*, or *analyze*. Examples:

- Image: Enhancing, manipulating, measuring, identifying structures
- ECG: Measuring repeated complexes, detecting arrhythmias
- NGS: Identifying genetic variants or clinical implications
- IVD: Generating a clinical test result

Criterion (2): Medical information

520(o)(1)(E)(i): 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)

- Non-device CDS are intended to display, analyze, or print medical information about a patient or other medical information.
- What is medical information?
  - demographic information
  - symptoms
  - certain test results
  - patient discharge summaries
  - other medical information such as clinical practice guidelines, peer-reviewed clinical studies, textbooks, approved drug or medical device labeling, and government agency recommendations

Criterion (2): Medical information

520(o)(1)(E)(i): 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)

- **Used in, or that relates to, the clinical care of the patient, including patient-specific information**
- **May generally be communicated between HCPs in a clinical conversation or between HCPs and patients in the context of a clinical decision**
  - **Not, by itself, determinative of whether it is "medical information about a patient" under Criterion 2, provided the information's relevance to patient care is supported by well-understood and accepted sources and can be appropriately understood in context**

Criterion (3): Supporting/Providing Recommendations

520(o)(1)(E)(ii): Intended for the purpose of supporting or providing recommendations to an HCP about prevention, diagnosis, or treatment of a disease or condition

- FDA interprets Criterion 3 to refer to software that is intended for an HCP and:
  - provides condition-, disease-, and/or patient-specific information and options to an HCP to enhance, inform and/or influence a health care decision;
  - does not provide a specific preventive, diagnostic or treatment output or directive; and
  - is not intended to replace the HCP's judgment.
- Outputs that meet Criterion 3:
  - List of preventive, diagnostic or treatment options;
  - Prioritized list of preventive, diagnostic or treatment options; or
  - List of follow-up or next-step options for consideration (e.g., after a physician office visit, hospitalization, procedure)
- While our interpretation that software that "is not intended to support time-critical decision-making" has been removed from Criterion 3, it is still a consideration when deciding whether a software function meets Criterion 4

Criterion (4): Independent Review

520(o)(1)(E)(iii): 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 of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient

Non-Device CDS are intended to enable HCPs to independently review the basis for the recommendations presented by the software so that they do not rely primarily on such recommendations, but rather on their own judgment, to make clinical decisions for individual patients.

Criterion (4): Enabling Independent Review

520(o)(1)(E)(iii): 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 of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient

In order to satisfy Criterion 4, FDA recommends that:

a) The software or labeling include the purpose or intended use of the product, including the intended HCP user

b) The software or labeling identify the required input medical information

c) The software or labeling provide a plain language description of the underlying algorithm development and validation that forms the basis for the CDS implementation

   i. Summary of the general approach relied upon to provide the recommendations (for example, AI/ML techniques)

   ii. Description of the data relied upon

   iii. Description of results from clinical validation studies

d) The software output provide relevant patient-specific information and other knowns/unknowns for consideration

In order to describe the basis for the recommendations, regardless of the complexity of the software and whether or not it is proprietary, the software or associated labeling should provide adequate background information about underlying sources in plain language. Information that enables an HCP to independently review the basis of provided recommendations is presented in a manner that promotes usability and avoids information overload, including prioritizing the most decision-relevant information and making additional detail available as appropriate.

Criterion (4): Level of Automation and Time-Critical Nature

520(o)(1)(E)(iii): 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 of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient

FDA considers the following when determining whether a software function allows an HCP to independently review the basis for the recommendations presented by the software so that they do not rely primarily on such recommendations:

(a) level of software automation and

(b) time-critical nature of the HCP's decision making

Automation bias is the propensity of humans to over-rely on a suggestion from an automated system. In the context of CDS, automation bias can result in errors of commission (following incorrect advice) or omission (failing to act because of not being prompted to do so). In situations that require urgent action, automation bias increases because there is not sufficient time for the user to adequately consider other information. This understanding of automation bias informs FDA's interpretation that Non-Device CDS software functions allow an HCP to independently review the basis for the recommendations presented by the software so that they do not rely primarily on such recommendations.

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Objective #3: Describe FDA's Enforcement Discretion Policy for functions that provide one clinically appropriate output and examples

Enforcement Discretion Policy for Certain Software Functions with One Clinically Appropriate Output

- 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 health care decision but is not intended to replace or direct the HCP's judgment.
- In cases where a software function provides a specific preventive, diagnostic or treatment output or directive, the software function fails Criterion 3 because it is not intended for the purpose of supporting or providing recommendations under section 520(o)(1)(E)(ii).
- If only one option is clinically appropriate and the software function otherwise meets all criteria under section 520(o)(1)(E), FDA intends to exercise enforcement discretion for such functions.

Enforcement Discretion Policy for Certain Software Functions with One Clinically Appropriate Output: Examples

A software function that predicts risk of future cardiovascular events for an HCP to consider based on a patient's weight, current and historical smoking status, blood pressure, and brain natriuretic peptide (BNP) IVD test results.	✓ Meets all criteria except for Criterion 3, and has one clinically appropriate output
A software function with the same functionality, but also utilizes variant genomic data as an input that does not have established relevance to the diagnostic recommendation.	X Device software function that would remain the focus of FDA's oversight (fails Criteria 1,2)
A software function with the same functionality, but predicts risk of a cardiovascular event in the next 24 hours.	X Device software function that would remain the focus of FDA's oversight (fails Criterion 4)

Enforcement Discretion Policy for Certain Software Functions with One Clinically Appropriate Output: Examples

A software function that creates a recommended treatment plan, including possible medication(s), for patients diagnosed with cognitive impairment for an HCP to consider based on the patient's diagnosis related to cognitive impairment as well as potential comorbidities, age, sex, and patient preferences, and that should be reviewed, revised, and finalized by an HCP.

✓ Meets all criteria except for Criterion 3, and has one clinically appropriate output

A software function with the same functionality, but also analyzes positron emission tomography (PET) scan images.

✗ Device software function that would remain the focus of FDA's oversight (fails Criterion 1)

Enforcement Discretion Policy for Certain Software Functions with One Clinically Appropriate Output: Examples

A software function that recommends a specific FDA-approved antibiotic agent for an HCP to consider based on the patient's symptoms, recent hospitalizations, and previous antibiotic exposure.

✓ Meets all criteria except for Criterion 3, and has one clinically appropriate output

A software function with the same functionality, but also analyzes spectroscopy data to diagnose bacterial infections.

✗ Device software function that would remain the focus of FDA's oversight (fails Criterion 1)

Enforcement Discretion Policy for Certain Software Functions with One Clinically Appropriate Output: Examples

A software function that analyzes a radiologist's clinical findings of an image to generate a proposed summary of the clinical findings for a patient's radiology or pathology report, including a specific diagnostic recommendation based on clinical guidelines that should be reviewed, revised, and finalized by an HCP.	✓ Meets all criteria except for Criterion 3, and has one clinically appropriate output
A software function with the same functionality, but also analyzes the image to generate the clinical findings and/or make measurements.	✗ Device software function that would remain the focus of FDA's oversight (fails Criterion 1)
A software function with the same functionality, but utilizes information that cannot be verified and validated to be from well-understood and accepted sources to generate a specific diagnostic recommendation.	✗ Device software function that would remain the focus of FDA's oversight (fails Criterion 2)

Enforcement Discretion Policy for Certain Software Functions with One Clinically Appropriate Output: Examples

A software function that provides an HCP with a differential diagnosis based on a patient's symptoms, vital signs, and laboratory values, and that, depending on the clinical context, may present either multiple diagnostic considerations or a single clinically appropriate diagnostic recommendation when alternative diagnoses are highly improbable. The output is intended to support clinical reasoning and to be reviewed, revised, and finalized by the HCP.

✓ Meets all criteria except for Criterion 3, and has one clinically appropriate output

A software function that establishes a definitive diagnosis based on analysis of medical images, waveform data, or other signal-level inputs.

✗ Device software function that would remain the focus of FDA's oversight (fails Criterion 1 and directs HCP's judgement)

Enforcement Discretion Policy for Certain Software Functions with One Clinically Appropriate Output: Examples

A software function that classifies patients with chronic low back pain into a single recommended appropriate clinical care pathway (for example, conservative management or referral to a surgical spine specialist) based on patient history, symptom duration, and documented clinical findings, where the recommendation is intended to be reviewed and acted upon by an HCP.

✓ Meets all criteria except for Criterion 3, and has one clinically appropriate output

A software function that provides care pathway recommendations for patients with acute back pain due to trauma or other emergent conditions, where immediate clinical intervention may be required.

✗ Device software function that would remain the focus of FDA's oversight (fails Criterion 4)

Enforcement Discretion Policy for Certain Software Functions with One Clinically Appropriate Output: Examples

A software function that estimates 90-day and 1-year postoperative mortality and complication risk following lung transplantation based on patient specific clinical characteristics and published clinical evidence, where the output is intended to support pre-transplant planning and shared decision-making and is reviewed by an HCP.	✓ Meets all criteria except for Criterion 3, and has one clinically appropriate output
A software function that predicts intraoperative or in-hospital mortality based on near real-time physiologic measurements and is intended to guide immediate escalation of care.	✗ Device software function that would remain the focus of FDA's oversight (fails Criterion 4)
A software function that incorporates medical images, genomic data, or other data sources that are not well-understood and accepted for the stated clinical use.	✗ Device software function that would remain the focus of FDA's oversight (fails Criteria 1,2)

Objective #4: Review examples of non-device CDS software functions and CDS software functions that meet the definition of device

Examples: Non-Device CDS

Software function that identifies to an HCP that a patient, consistent with the current version of FDA-approved drug labeling, is within a specific indicated population for an FDA-approved chemotherapeutic agent based on analysis of patient specific medical information, such as patient diagnosis and pathologist confirmed biopsy results.

Examples: Device Software Functions

- Device software functions are those that meet the definition of device
  - Do not meet all four criteria and for which FDA intends to focus its regulatory oversight
- If an example does not include a statement reflecting that the software function fails a specific criterion, then for the purposes of the example, it can be assumed that the criterion is satisfied.
- Note that where Criterion 3 is referenced, if only one option is clinically appropriate and the software function otherwise meets all criteria under section 520(o)(1)(E), FDA intends to exercise enforcement discretion (meaning that FDA does not intend to enforce requirements under the FD&C Act) for such functions.

Examples: Device Software Functions

Function Description	Rationale
Software function that analyzes multiple signals (for example, perspiration rate, heart rate, eye movement, breathing rate) from wearable products to monitor whether a person is having a heart attack or narcolepsy episode.	**This software is a device function because:** **X Criterion 1** It analyzes signals. **X Criterion 2** It is not intended to display, analyze, or print medical Information. **X Criterion 3 and 4 I**t provides a specific diagnostic output and supports time-critical decision making.
Software function that analyzes near-infrared camera images of a patient intended for use in determining or diagnosing a brain hematoma.	**This software is a device function because:** **X Criterion 1** It analyzes a signal. **X Criterion 2** It is not intended to display, analyze, or print medical Information.

Examples: Device Software Functions

Function Description	Rationale
Software function that analyzes signals from a trans-abdominal electromyography device, a fetal heart rate monitor, and an intrauterine pressure catheter to determine timing of a C-section intervention for an “at term” pregnant woman.	**This software is a device function because:** **X Criterion 1** It analyzes a medical image. **X Criterion 2** It is not intended to display, analyze, or print medical Information. **X Criterion 3 and 4** It provides a specific, time-critical treatment output or directive for a disease or condition.
Software function that analyzes patient-specific medical information to detect a life-threatening condition, such as stroke or sepsis, and generate an alarm or an alert to notify an HCP.	**This software is a device function because:** **X Criterion 3 and 4** It is intended to provide a specific diagnostic output or directive, including an alarm which supports time-critical decision-making.

Examples: Device Software Functions

Function Description	Rationale
Software function that analyzes patient-specific measurements (for example, ST-segment elevation or depression as reported on ECG reports and cardiac enzyme laboratory results from the EHR) to identify patients potentially experiencing myocardial ischemia or infarction.	**This software is a device function because:** **X Criterion 3 and 4** It provides a specific diagnostic output or directive and supports time-critical decision-making.
Software function intended for HCP management of heart failure patients that analyzes patient-specific medical information (for example, daily heart rate, SpO2, blood pressure, or other output from wearable product) to predict heart failure hospitalization.	**This software is a device function because:** **X Criterion 3 and 4** It provides a specific diagnostic output or directive and supports time-critical decision-making.

Examples: Device Software Functions

Function Description	Rationale
Software function that analyzes hourly pulse oximetry and heart rate measurements (for example, from a patient's EHR) to identify signs of patient deterioration and alert an HCP.	**This software is a device function because:** **X Criterion 1** It analyzes a pattern. **X Criterion 2** It is not intended to display, analyze, or print medical Information. **X Criterion 3 and 4** It provides a specific diagnostic output or directive and supports time-critical decision-making.
Software function that analyzes glucose measurements output from a CGM every 30 minutes to detect periods of potential hypoglycemia and notify the patient's HCP.	**This software is a device function because:** **X Criterion 1** It analyzes a pattern. **X Criterion 2** It is not intended to display, analyze, or print medical Information. **X Criterion 3 and 4** It provides a specific diagnostic output or directive and supports time-critical decision making.

Examples: Device Software Functions

Function Description	Rationale
Software function that analyzes a radiologist's score/report of regional contrast discrepancies measured from a head CT of a suspected stroke patient to identify whether the HCP should initiate a specific drug therapy based on a scoring algorithm.	**This software is a device function because:** **X Criterion 3 and 4** It provides a specific treatment output or directive and supports time-critical decision making.
Software function that analyzes the radiologist's reported imaging findings and other patient-specific medical information taken by an HCP upon admission as input to a stroke triage algorithm that indicates whether to transfer the patient to a major stroke center for an intervention.	**This software is a device function because:** **X Criterion 3 and 4** It provides a specific, time-critical diagnostic or treatment output or directive.

Examples: Device Software Functions

Function Description	Rationale
Software function that helps a diabetic patient manage their blood sugars by calculating bolus insulin dose based on carbohydrate intake, pre-meal blood glucose, and anticipated physical activity reported to adjust carbohydrate ratio and basal insulin.	**This software is a device function because:** **X Criterion 3** It is not intended for an HCP. **X Criterion 4** It supports time-critical decision-making.
Software function that analyzes a patient's symptoms, prior diagnosis, and serum digoxin level from the medical record to assess a patient's likelihood for digoxin toxicity and indicates treatment with digoxin immune antigen binding fragments (digibind) for those at high risk.	**This software is a device function because:** **X Criterion 3 and 4** It provides a specific diagnostic or treatment output or directive and supports time-critical decision-making.

Summary

- Briefly explained the 21st Century Cures Act and history of the Clinical Decision Support guidance
- Explained FDA's current thinking on Clinical Decision Support (CDS), including clarification on our interpretation of criteria
- Described FDA's Enforcement Discretion Policy for functions that provide one clinically appropriate output and examples
- Reviewed examples of non-device CDS software functions and CDS software functions that meet the definition of device


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Frequently Asked Questions

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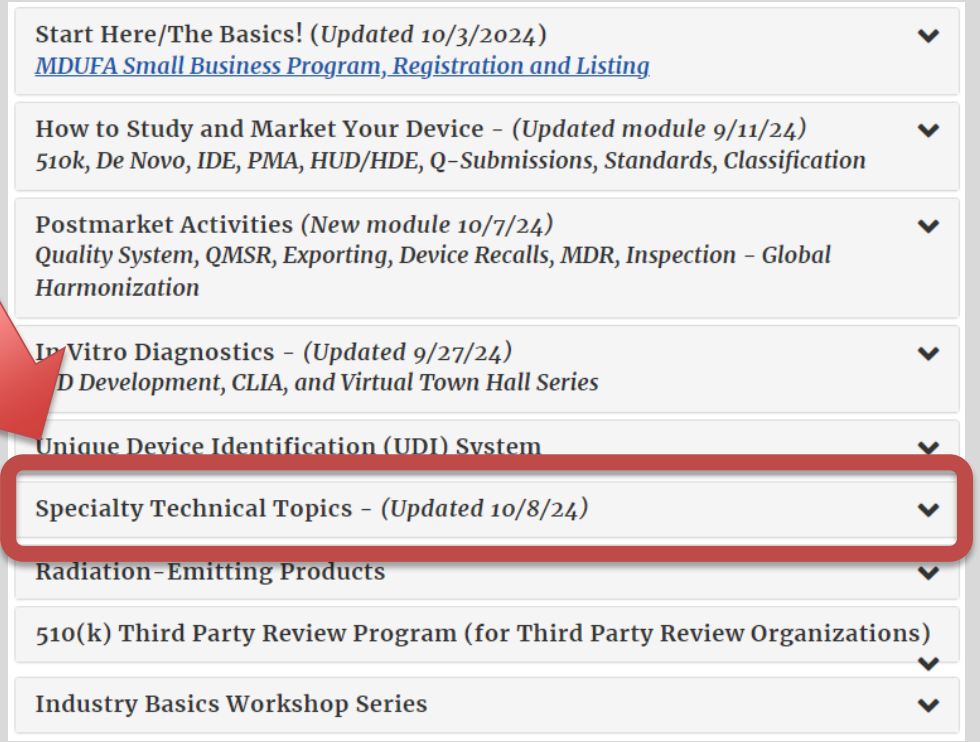


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