FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Welcome To Today's Webinar

Thanks for joining us!
We'll get started in a few minutes

Today's Topic:

Final Guidance on Clinical Decision Support Software

October 18, 2022

Clinical Decision Support Software
Final Guidance

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Center for Devices and Radiological Health
U.S. Food and Drug Administration

Final Guidance

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

Learning Objectives

- ✓ Describe purpose and scope of guidance
- ✓ Explain FDA's current thinking on Clinical Decision Support (CDS), including which CDS software functions are considered devices
- ✓ Identify how the guidance:
  - ➢ Clarifies criteria for non-device clinical decision support software functions
  - ➢ Provides examples of clinical decision support software functions
  - ➢ Complements other existing guidance documents

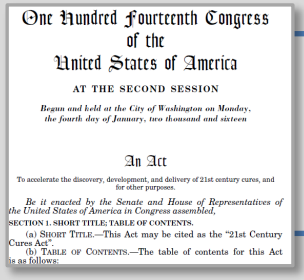
Cures Act built on FDA's digital health policies

On December 13, 2016, the 21st Century Cures Act amended the definition of "device" in the Federal Food, Drug, and Cosmetic Act (FD&C Act) to **exclude certain software functions** defined 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 with no reference to any disease or condition;**	**Electronic patient records;**	**Transferring, storing, converting formats, or displaying data and results;**	**Clinical decision support.**
520(o)(1)(A)	520(o)(1)(B)	520(o)(1)(C)	520(o)(1)(D)	520(o)(1)(E)

Guidance: Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act

Background


One Hundred Fourteenth Congress
of the
United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Monday, the fourth day of January, two thousand and sixteen

An Act

To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes.

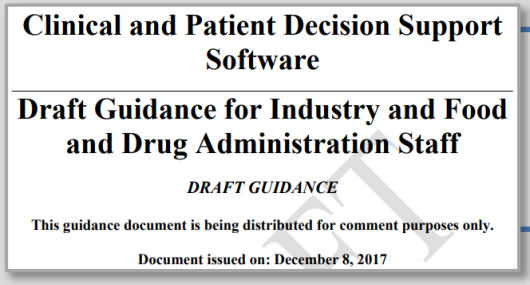
Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "21st Century Cures Act".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Dec 2016: 21st Century Cures Act:
Amended device definition


Clinical and Patient Decision Support Software

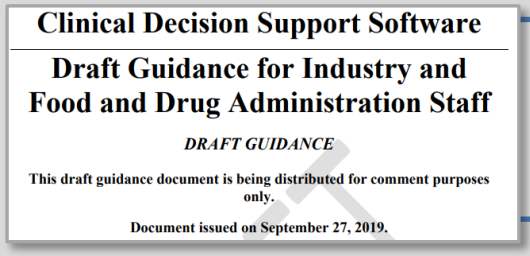
Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Document issued on: December 8, 2017

Dec 2017: First Draft Guidance:
"Clinical and Patient Decision Support Software"


Clinical Decision Support Software

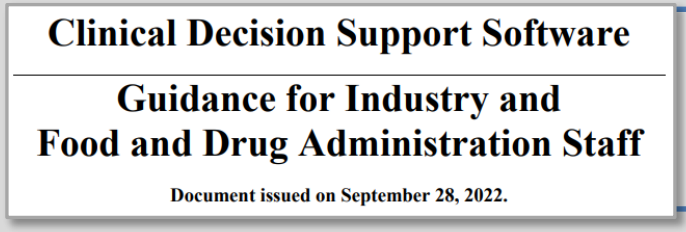
Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on September 27, 2019.

Sept 2019: Revised Draft Guidance:
"Clinical Decision Support Software"


Clinical Decision Support Software

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 28, 2022.

Sept 2022: Final Guidance:
"Clinical Decision Support Software"

What is Clinical Decision Support (CDS)?

Clinical Decision Support (CDS) is a tool that provides health care professionals and patients with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care.[1]

CDS includes:[2]

- computerized alerts and reminders for providers and patients;
- clinical guidelines;
- condition-specific order sets;
- focused patient data reports and summaries;
- documentation templates;
- diagnostic support;
- contextually relevant reference information.

[1]*See Office of the National Coordinator for Health Information Technology, "What is Clinical Decision Support (CDS)?" at* www.healthit.gov/topic/safety/clinical-decision-support

[2]FDASIA Health IT Report, April 2014, available at www.fda.gov/about-fda/cdrh-reports/fdasia-health-it-report

2019 Revised Draft Guidance

Guidance Summary

FDA issued Draft Guidance in September 2019 to provide FDA's interpretation of the types of Clinical Decision Support (CDS) software excluded from the device definition by the 21st Century Cures Act. This draft guidance described:

(1) CDS software that is no longer under FDA's jurisdiction based on the Cures Act,

(2) CDS software for which FDA does not intend to enforce compliance with regulatory requirements, and

(3) CDS software for which FDA continues to focus its regulatory oversight.

67 Comments Received on Revised Draft

Summary of Comments

- Suggested changes to Enforcement Discretion Policy
- Requested explanation of difference between the terms "signal" and "medical information" for determining whether the software function is Device CDS or Non-device CDS
- Highlighted need to understand the application of the IMDRF Risk Categorization Framework, particularly in the difference between the categories of "Inform Clinical Management" and "Drive Clinical Management"
- Sought elaboration on how Artificial Intelligence/Machine Learning functions can be explained and understood

IMDRF = International Medical Device Regulators Forum

Summary of Changes from 2019 Revised Draft

- Additional clarity on each of the criteria from section 520(o)(1)(E) of the FD&C Act
  - Better explains distinction between “signal, pattern, medical image” (Criterion 1) and “medical information” (Criterion 2) for purposes of determining if Non-Device criteria are met
  - Provides information and examples to illustrate how healthcare professionals can independently review the basis of the software recommendations (including for AI/ML)
- IMDRF Risk Categorization Framework is not used in interpretation of Non-Device CDS criteria
- Does not include enforcement discretion policies proposed in draft guidance
- Additional explanation and examples to clarify these policies, including identifying complementary existing digital health guidances

Final Guidance Scope

This guidance presents the agency's current thinking on which CDS software functions are excluded from the definition of device by the criteria in section 520(o)(1)(E) of the FD&C Act.

- Guidance describes CDS that does not meet the definition of a device (Non-Device CDS) including certain CDS software functions intended for HCPs.
- Guidance does not address:
  - which FDA statutory or regulatory requirements apply to device software functions;
  - which regulatory requirements may apply to a device software function that is part of a combination product;
  - labeling requirements for decision support software disseminated by or on behalf of a drug or biological product sponsor.

Interpretation of Criteria in Section 520(o)(1)(E) of the FD&C Act

A software function must meet all of the four statutory criteria in section 520(o)(1)(E) of the FD&C Act to be excluded from the device definition.

- The functions excluded from the device definition are independent of the platform on which they might run.
- The term Non-Device CDS is used to refer to decision support software functions that do not meet the definition of device in section 201(h) of the FD&C Act.

21st Century Cures Criteria for Non-Device Clinical Decision Support (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);

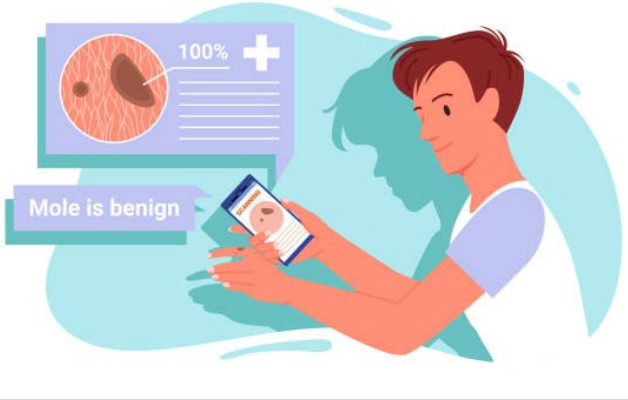
3) intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and

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)	*CDS Guidance*
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	If the type of data described in Criterion 1 (i.e., **medical image** or a **signal** from an IVD or a **pattern/signal** from a signal acquisition system) is **acquired, processed, or analyzed** (used as an input), then the software function **remains a device** within the meaning of section 201(h). Such products **have been regulated** as devices for many years.

Criterion (1): Medical Image

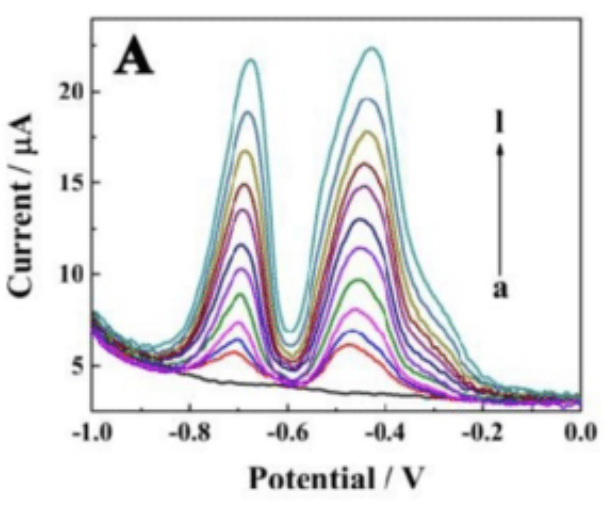


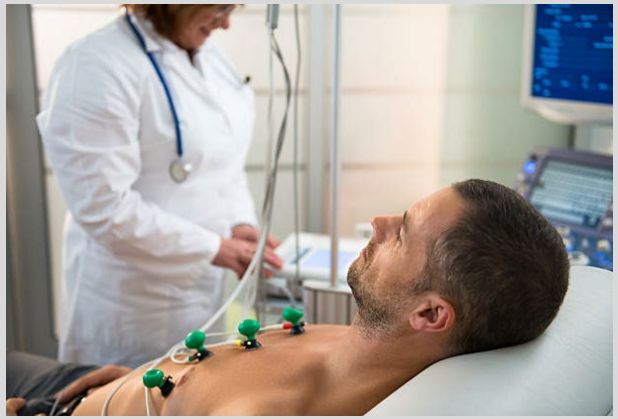
CDS Guidance

We generally consider the term **medical image** to include images generated by use of medical imaging systems (e.g., computed tomography (CT), x-ray, ultrasound, magnetic resonance imaging (MRI)) to view any part(s) of the body or images acquired for a medical purpose (e.g., pathology, dermatology).

Images that were not originally acquired for a medical purpose but are being processed or analyzed for a medical purpose are also considered medical images.

Criterion (1): Signal



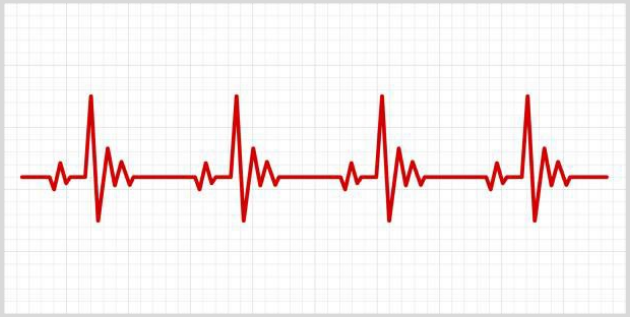


CDS Guidance

We generally consider the term **signal** to include those signals that typically require use of either:

- **An IVD**, which can include an electrochemical or photometric response generated by an assay and instrument that may be further processed by software to generate a clinical test result; or
- **A signal acquisition system** that measures a parameter from within, attached to, or external to the body **for a medical purpose** and often includes but is not limited to:
  - use of sensors (e.g., electrocardiogram (ECG) leads) along with electronics and software function that is used for signal generation (e.g., ECG);
  - collections of samples or specimens such as tissue, blood, or other fluids (e.g., conducting a pathological study using software such as digital pathology); or
  - use of radiological imaging systems (e.g., computed tomography (CT)) and a software function for image generation.

Criterion (1): Pattern

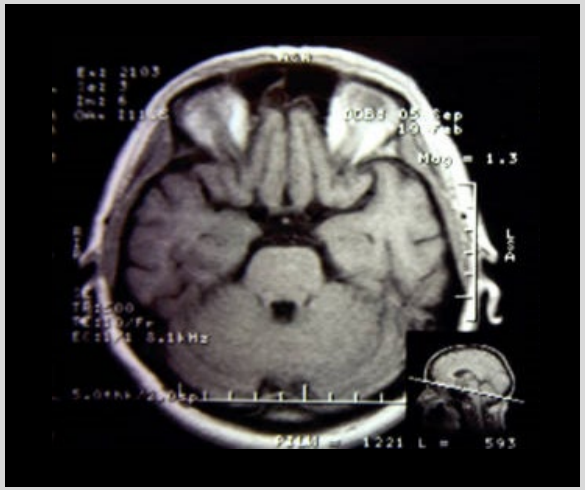


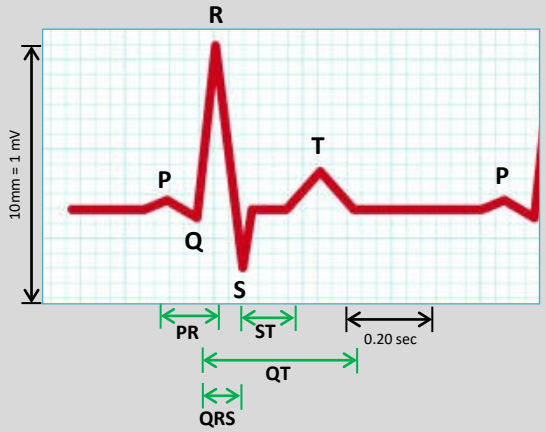
CDS Guidance

FDA interprets the term **pattern** in this provision to refer to multiple, sequential, or repeated, measurements of a signal or from a signal acquisition system. Examples of patterns include:

- For ECG, an electrical signal acquired from the body is processed to create an ECG waveform and QRS complex;
- For Next Generation Sequencing (NGS), a fluorescent signal on tagged DNA is processed by modification or transformation into base pairs and sequences. Genetic sequences, including datasets of sequence variants that differ from reference sequences and datasets filtered to represent disease-associated variations (such as variant call format files or VCFs); and
- For continuous glucose monitors (CGM), a photometric or electrochemical signal generated by an assay and instrument is processed to generate repeated glucose measurements over time.

Criterion (1): Clinical relevance





CDS Guidance

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)

CDS Guidance

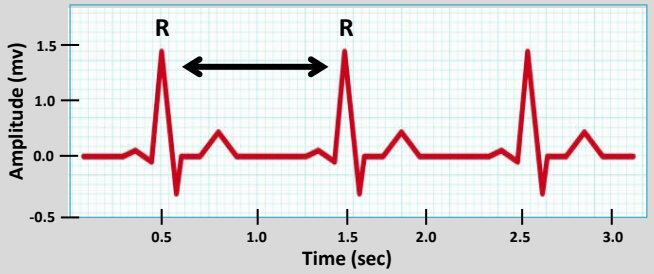
- Non-device CDS are intended to display, analyze, or print **medical information about a patient or other medical information**.
- What is medical information?
  - demographic information, symptoms,
  - test results, certain medical device outputs (such as a heart rate or blood pressure reading),
  - 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): What is Medical Information?

CDS Guidance

- The kind of information used by the intended user to make decisions about prevention, diagnosis, or treatment of a disease or condition for an individual patient.
  - Normally is, and generally can be, communicated between HCPs or HCPs/patients
- FDA interprets medical information about a patient to be information whose relevance to a clinical decision is well understood and accepted in the practice of medicine.

Criterion (2): What is Medical Information?



Electronic Health Record

"The patient shows sign of Atrial Fibrillation"

CDS Guidance

Sampling frequency is also an important consideration:

- A single, discrete test or measurement result that is clinically meaningful (e.g., a blood glucose lab test result) = *medical information*
- More continuous sampling of the same information (e.g., continuous glucose monitor readings) = a pattern/signal

Examples of medical information:

- The report from a radiology study or summary information about the output of legally marketed CAD software
- An ECG report annotated by an HCP with a description of an abnormal heart rhythm
- A blood pressure result from a legally marketed device
- A lab test result in an electronic health record

Criterion (3): Intended User is HCP

520(o)(1)(E)(ii)	*CDS Guidance*
Intended for the purpose of supporting or providing recommendations to an HCP about prevention, diagnosis, or treatment of a disease or condition	• Non-Device CDS software functions are intended to support or provide recommendations **to an HCP** about prevention, diagnosis, or treatment of a disease or condition. – **Software functions that support or provide such recommendations to patients or caregivers – not HCPs – therefore remain in the definition of device.** – FDA intends to be consistent with existing software policies in the regulation of CDS intended for non-HCPs. • Assist HCPs in making patient-specific care decisions.

Criterion (3): Supporting/Providing Recommendations

CDS Guidance

FDA interprets Criterion 3 to refer to software that:

- ❑ 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;
- ❑ is not intended to support time-critical decision-making; and
- ❑ is not intended to replace the HCP's judgment.

Criterion (3): Supporting/Providing Recommendations

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)

Outputs that do not meet Criterion (3)

- Provides a specific preventative, diagnostic or treatment course;
- Provides a specific follow-up directive;
- Provides time-critical alarms or alerts intended to trigger potential clinical intervention to assure patient safety; or
- Provides a treatment plan for a specific patient's disease or condition.

Criterion (3): Supporting/Providing Recommendations

CDS Guidance

Examples of Non-Device CDS software functions include software functions that provide:

- Evidence-based clinician order sets for an HCP to choose from, tailored for a particular condition, disease, or clinician preference;
- Matching patient-specific medical information from records or reports to reference information (e.g., clinical guidelines);
- Contextually relevant reference information about a disease or condition;
- Drug-drug interaction and drug-allergy contraindication notifications to avert adverse drug events;
- Drug formulary guidelines;
- Duplicate testing or prescription product prevention notifications (e.g., medication reconciliations and test reconciliations);
- Reminders for preventive care or clinician orders; and
- Patient data reports and summaries (e.g., discharge papers).

Criterion (4): Independent Review

520(o)(1)(E)(iii)	*CDS Guidance*
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

CDS Guidance

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 [can't be time-critical]

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 logic or methods (e.g., 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

Examples: Non-Device CDS

Some examples of non-device CDS include a software function that …

… identifies drug-disease interactions and contraindications, such as notifying an HCP that a patient with asthma should not be prescribed a non-selective beta-blocking drug.

… aggregates possible post-operative care instructions, medication needs, and follow-up instructions to assist an HCP in assembling discharge papers for a patient.

… provides alerts to HCPs regarding changes in a formulary and recommends alternatives.

… analyzes medical information on a patient's asthma diagnosis and demographics from the patient's medical record and provides an HCP with a list of FDA-approved treatment options for asthma.

… analyzes blood glucose laboratory test results and pre-diabetes diagnosis from a patient's medical record and provides an HCP with a list of next-step options to consider, such as more frequent office visits or referral to a specialist.

These examples are intended to illustrate FDA's interpretation of the first three criteria in section 520(o)(1)(E) of the FD&C Act: software functions considered Non-Device CDS provided that they also meet Criterion 4.

Example: Non-Device CDS that meets Criterion 4

Software function that recommends a prioritized list of FDA-approved chemotherapeutic agents (approved for the patient's diagnosed cancer type) to an HCP based on analysis of reported outcomes in a database of clinical studies using the patient's diagnosis and demographics from the medical record. 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, the following information is provided to the HCP:

The intended use, HCP user, and patient population are clearly identified. The use is not time-critical and the intended HCP is expected to have sufficient time and training to assess the clinical studies that are the basis of the recommendations;

The cancer diagnosis and patient demographics are clearly identified as the inputs being used in the database search and analysis;

Information about how the clinical studies included were selected, the full reports of the clinical studies being relied upon are clearly identified, with a brief summary of the strength of each study (e.g., number of patients, outcome metrics, randomization, comparison arm), and the key elements of the diagnosis or demographics searched for in the medical record are noted; and

The prioritized list of FDA-approved chemotherapeutic agents and the basis of the prioritization is provided to the HCP, and the studies that most closely matched the patient-specific diagnosis and demographics are identified. Other considerations, such as the warnings and contraindications from the current version of the FDA-approved drug labeling, are also provided to the HCP for consideration prior to making a final decision.

Example: Non-Device CDS that meets Criterion 4

Software function that recommends a prioritized list of FDA-approved chemotherapeutic agents (approved for the patient's diagnosed cancer type) to an HCP based on analysis of reported outcomes in a database of clinical studies using the patient's diagnosis and demographics from the medical record. 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, the following information is provided to the HCP:

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The prioritized list of FDA-approved chemotherapeutic agents and the basis of the prioritization is provided to the HCP, and the studies that most closely matched the patient-specific diagnosis and demographics are identified. Other considerations, such as the warnings and contraindications from the current version of the FDA-approved drug labeling, are also provided to the HCP for consideration prior to making a final decision.

Example: Non-Device CDS that meets Criterion 4

Software function that recommends a prioritized list of FDA-approved chemotherapeutic agents (approved for the patient's diagnosed cancer type) to an HCP based on analysis of reported outcomes in a database of clinical studies using the patient's diagnosis and demographics from the medical record. 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, the following information is provided to the HCP:

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The prioritized list of FDA-approved chemotherapeutic agents and the basis of the prioritization is provided to the HCP, and the studies that most closely matched the patient-specific diagnosis and demographics are identified. Other considerations, such as the warnings and contraindications from the current version of the FDA-approved drug labeling, are also provided to the HCP for consideration prior to making a final decision.

Example: Device Software Function

Function Description	Rationale
Software function that analyzes sound waves when users cough or recite certain sentences to diagnose bronchitis or sinus infection. (Example #15 in guidance)	**This software is a device function because:** **X Criterion 1** It analyzes a signal or pattern. **X Criterion 2** It is not intended to display, analyze, or print Medical Information. **X Criterion 3** It provides a specific diagnostic output or directive.
Software function that uses a variant call format (VCF) file containing patient-specific genetic variants and mutations identified from a Next Generation Sequencing (NGS) Analyzer and provides recommendations for FDA-approved treatment options based on those findings. (Example #18 in guidance)	**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. ✔ **Criterion 3**

These examples focus on the first three criteria in section 520(o)(1)(E). Other examples focus on the interpretation of criterion 4.

Example: Device Software Function

Function Description	Rationale
Software function that analyzes an ECG waveform output from an FDA cleared device to detect or diagnose arrhythmias (e.g., atrial fibrillation). (Example #20 in guidance)	**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** It provides a specific diagnostic output.
Software function that analyzes five sequential RR interval measurements from Holter monitor data in a patient medical record to identify a possible heart rhythm irregularity and recommend follow-up testing. (Example #22 in guidance)	**This software is a device function because:** **X Criterion 1** It analyzes a pattern (due to sampling frequency of RR interval measurements). **X Criterion 2** It is not intended to display, analyze, or print Medical Information. **X Criterion 3** It provides a specific diagnostic output or directive.

These examples focus on the first three criteria in section 520(o)(1)(E). Other examples focus on the interpretation of criterion 4.

Example: Device Software Function

Function Description	Rationale
Software function intended for HCP management of heart failure patients that analyzes patient-specific medical information (e.g., daily heart rate, SpO2, blood pressure, or other output from wearable product) to predict heart failure hospitalization. (Example #24 in guidance)	**This software is a device function because:** ✔ **Criterion 1** ✔ **Criterion 2** ✘ **Criterion 3** It provides a specific diagnostic output or directive and supports time-critical decision making.
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. (Example #27 in guidance)	**This software is a device function because:** ✔ **Criterion 1** ✔ **Criterion 2** ✘ **Criterion 3** It provides a specific treatment output or directive and supports time-critical decision making.

These examples focus on the first three criteria in section 520(o)(1)(E). Other examples focus on the interpretation of criterion 4.

Example: Device Software Function

Function Description	Rationale
Software function that identifies a specific FDA-approved chemotherapeutic agent to an HCP based on analysis of patient diagnosis and pathologist confirmed biopsy results. (Example #29 in guidance)	**This software is a device function because:** ✔ **Criterion 1** ✔ **Criterion 2** ✘ **Criterion 3** It provides a specific treatment output or directive.
Software function that helps a diabetic patient manage their blood sugar 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. (Example #30 in guidance)	**This software is a device function because:** ✔ **Criterion 1** ✔ **Criterion 2** ✘ **Criterion 3** It is not intended for an HCP and it provides a specific treatment output or directive and supports time-critical decision-making.

These examples focus on the first three criteria in section 520(o)(1)(E). Other examples focus on the interpretation of criterion 4.

Your Clinical Decision Support Software: Is It a Device?

Your software function must meet all four criteria to be considered Non-Device CDS.

Summary interpretation of CDS criteria

1. Your software function does **NOT** acquire, process, or analyze medical images, signals, or patterns.
2. Your software function displays, analyzes, or prints medical information normally communicated between health care providers.
3. Your software function provides information and/or options to a health care provider rather than a specific output or directive.
4. Your software function provides the basis of the recommendations so that the HCP does not rely on any recommendations in order to make a decision.

Your software function is non-device CDS.

Non-Device Examples

Non-Device examples display, analyze, or print the following examples of medical information, which must also not be images, signals, or patterns:

- Information whose relevance to a clinical decision is well understood
- A single discrete test result that is clinically meaningful
- Report from imaging study

AND

Non-Device Examples provide:

- Lists of preventive, diagnostic, or treatment options
- Clinical guidelines matched to patient-specific medical info
- Relevant reference information about a disease or condition

AND

Non-Device Examples provide:

- Plain language descriptions of the software purpose, medical input, underlying algorithm
- Relevant patient-specific information and other knowns/unknowns for consideration

Device Examples

Device examples acquire, process, or analyze:

- Signal acquisition systems
- In vitro diagnostics
- Magnetic resonance imaging (MRI)
- Next Generation Sequencing (NGS)
- Continuous Glucose Monitoring (CGM)
- Computer aided detection/diagnosis (CADe/CADx)

Device examples display, analyze or print:

- Continuous signals/patterns
- Medical images
- Waveforms (ECG)
- More continuous sampling (aka – a signal or pattern)

Device Examples provide:

- Risk scores for disease or condition
- Probability of disease or condition
- Time-critical outputs

Device Examples provide:

- Basis of recommendations is not provided

Your software function is a device.

*Disclaimer: This graphic gives a general overview of the policies in Section IV of the guidance. Consult the guidance for the complete policies. The device examples identified in this graphic are illustrative only. Other software functions that are not listed may also be device software functions.

We have made corresponding changes through Level 2 Updates to other Digital Health Guidances

GUIDANCE DOCUMENT

Policy for Device Software Functions and Mobile Medical Applications

GUIDANCE DOCUMENT

Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices

GUIDANCE DOCUMENT

Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act

We have issued an interactive tool to introduce digital health policies to stakeholders

This tool incrementally introduces policy considerations with plain language to establish baseline understanding of policies and pathways

Interactive accessible format with simplified questions and YES or NO answers; and layered supporting information.

www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-policy-navigator

Summary

- CDS Final Guidance focuses on the statutory criteria describing Non-Device clinical decision support software functions
  - Clarifies scope of FDA oversight of clinical decision support software intended for health care professionals as devices

- Guidance provides examples of how FDA intends to consider different kinds of software functions, including non-device clinical decision support functions and device functions

- If unsure of how to apply the guidance/Non-Device CDS criteria:
  - Reach out to DigitalHealth@fda.hhs.gov
  - Consider submitting 513(g) for device determination or Q-Sub for discussion


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Additional Panelist

Brendan O'Leary

Acting Director

CDRH Digital Health Center of Excellence

Office of Strategic Partnerships and Technology Innovation

Center for Devices and Radiological Health

U.S. Food and Drug Administration

Let's Take Your Questions

- **To Ask a Question:**
  1. Raise your hand in Zoom 

  2. Moderator will announce your name and invite you to ask your question
  3. Unmute yourself when prompted in Zoom to ask your question

- **When Asking a Question:**
  - Ask one question only
  - Keep question short
  - No questions about specific submissions

- **After Question is Answered:**
  - Mute yourself and lower your hand
  - If you have more questions - raise your hand again

Thanks for Joining Today!

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