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Clinical Decision Support Software

Guidance for Industry and Food and Drug Administration Staff

Document issued on January 29, 2026.

This document supersedes "Clinical Decision Support Software" issued on January 6, 2026.

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Preface

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Clinical Decision Support Software

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA) has long regulated software that meets the definition of a device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), including software that is intended to provide decision support for the diagnosis, treatment, prevention, cure, or mitigation of diseases or other conditions (often referred to as clinical decision support software). This guidance clarifies the scope of FDA's oversight of clinical decision support software intended for health care professionals (HCPs) as devices.[1] Not all clinical decision support software used in healthcare settings are devices and therefore subject to FDA oversight as a device.

FDA recognizes that the term "clinical decision support" or "CDS" is used broadly and in different ways, depending on the context.[2] In the Food and Drug Administration Safety and Innovation Act (FDASIA) Health IT Report of 2014, CDS is described as a variety of tools including, but not limited to: 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.[3] For the purposes of this guidance, 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. In accordance with section 201(h) of the FD&C Act, FDA uses criteria from section 520(o) of the FD&C Act, which was added to the FD&C Act by the 21st Century Cures Act

[1] For the purposes of this guidance, the FDA uses the term HCP to mean an individual who is licensed, registered, or certified by a State, territory, or other governing body, to administer health care, including but not limited to, nurse practitioner, registered nurse, licensed practical nurse, clinical social worker, dentist, occupational therapist, pharmacist, physical therapist, physician, physician assistant, psychologist, respiratory therapist, speech-language pathologist, technologist, or any other practitioner or allied health professional.

[2] For example, in one context CDS has been described as providing HCPs and patients with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care. See Office of the National Coordinator for Health Information Technology, "What is Clinical Decision Support (CDS)?" at https://www.healthit.gov/topic/safety/clinical-decision-support

[3] FDASIA Health IT Report, page 26, April 2014, available at https://web.archive.org/web/20150320102020/http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf

(Cures Act), to determine if a software function is Non-Device CDS (see Section III). Certain CDS software functions do not meet the criteria in section 520(o)(1)(E) of the FD&C Act and are therefore device functions. Furthermore, some multiple function device products may include both Non-Device CDS software functions and device software functions (CDS or otherwise). In such situations, FDA would use the approach outlined in FDA's guidance Multiple Function Device Products: Policy and Considerations,[4] when assessing the safety and effectiveness of the device software function, consistent with section 520(o)(2) of the FD&C Act.

The purpose of this guidance is to describe FDA's regulatory approach to CDS software functions. The Agency's approach reflects changes to the FD&C Act made by the Cures Act, which amended section 520 and excludes certain software functions from the device definition. The focus of this guidance is to clarify the types of CDS software functions that are excluded from the definition of device by the criteria in section 520(o)(1)(E) of the FD&C Act. This guidance further clarifies that FDA's existing digital health policies continue to apply to software functions that meet the definition of a device, including those that are intended for use by patients or caregivers.[5] For example, some decision support software functions may be identified in other guidance documents as software functions for which, based on our current understanding of the risks of these software functions, FDA does not intend at this time to enforce compliance with applicable device requirements of the FD&C Act, including, but not limited to, premarket clearance and approval requirements.

This guidance provides many examples of how FDA intends to consider different kinds of software functions, including Non-Device CDS software functions and device software functions.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

Section 3060(a) of the Cures Act amended the FD&C Act to add section 520(o) of the FD&C Act, which excludes certain software functions from the definition of device in section 201(h) of the FD&C Act. Certain 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:

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[4] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/multiple-function-device-products-policy-and-considerations.

[5] FDA intends to be consistent with existing policies, including the following documents: Policy for Device Software Functions and Mobile Medical Applications (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications), Software as a Medical Device (SaMD): Clinical Evaluation (https://www.imdrf.org/documents/software-medical-device-samd-clinical-evaluation), Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices), and General Wellness: Policy for Low Risk Devices (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices).

(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).[6]

To explain FDA's interpretation of section 520(o)(1)(E), in Section IV this guidance discusses each element of section 520(o)(1)(E) of the FD&C Act.

III. Scope

This guidance describes CDS software functions that do not meet the device definition (Non-Device CDS) based on the criteria in section 520(o) of the FD&C Act, which excludes certain software functions from the device definition, including certain CDS software functions intended for HCPs.

This guidance presents the Agency's current thinking on which CDS software functions are excluded from the definition of device by section 520(o)(1)(E) of the FD&C Act. The guidance does not address which other FDA statutory or regulatory requirements apply to device software functions, including which regulatory requirements may apply to a device software function that is part of a combination product, nor does it address labeling requirements for decision support software disseminated by or on behalf of a drug or biological product sponsor.

[6] The Cures Act provides that a software function described in section 520(o)(1)(E) of the FD&C Act will not be excluded from the device definition under section 201(h) if the software meets the criteria under section 513(a)(1)(C) of the FD&C Act or if the software is used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans (section 520(o)(4)(B) and (C) of the FD&C Act. In addition, the Cures Act provides that a software function will not be excluded if the Secretary of Health and Human Services issues a final order, after notification and a period for comment, that the software function would be reasonably likely to have serious adverse health consequences (section 520(o)(3) of the FD&C Act).

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

The following sections explain FDA's interpretation of each of the four criteria in section 520(o)(1)(E) of the FD&C Act. In order for a software function to be excluded from the device definition by this provision, it must meet all four criteria. Stated simply, these criteria describe the types of CDS that are not regulated as devices. Non-Device CDS software functions do not acquire, process, or analyze images, signals from an in vitro diagnostic device (IVD), or patterns or signals from a signal acquisition system (Criterion 1). Non-Device CDS software functions display, analyze, or print medical information (Criterion 2) in order to provide recommendations about a patient's care to an HCP user (Criterion 3). Taken together, 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). Non-Device CDS software functions provide sufficient information about the basis for the recommendations to the HCP user, so that the user does not rely primarily on any of the recommendations to make a clinical decision about an individual patient (Criterion 4).

(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

Under section 520(o)(1)(E), software functions that are intended to acquire, process, or analyze a medical image, a signal from an IVD, or a pattern or signal from a signal acquisition system and are intended for a purpose identified in section 201(h) of the FD&C Act remain devices and therefore are subject to FDA oversight. In other words, 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 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.

We generally consider the term *medical image* to include those 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.

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 (e.g., through continuous, near-continuous, or otherwise streaming measurement) 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.

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. By contrast, discrete, episodic, or intermittent point-in-time physiological measurements (e.g., routine vital signs obtained at discrete clinical encounters) generally do not, by themselves, constitute a pattern. Examples of patterns include, but are not limited to:

- For ECG, an electrical signal acquired from the body is processed to create an ECG waveform and QRS complex, which are considered patterns;
- 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), are examples of patterns; or
- 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, which is considered a pattern.

FDA considers software functions that assess or interpret the clinical implications or clinical 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 include:

- 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, do not meet Criterion 1.
- 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, do not meet Criterion 1.
- Software functions that process or analyze the genetic sequence or patterns from an NGS analyzer to identify genetic variants or mutations or their clinical implications or relevance do not meet Criterion 1.
- 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, do not meet Criterion 1.

Although many signal acquisition systems are intended to monitor signals for medical purposes and, therefore, are considered medical devices, some are not. For example, 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.

We encourage manufacturers to engage with FDA if a signal acquisition system previously only considered for a medical purpose is intended to be used for a non-medical purpose. For example, software functions that use input from sensors and a signal acquisition system to measure physiological parameters for purposes of biometrics identification, such as retinal image analysis for secure access to a facility, are not devices within the meaning of section 201(h) of the FD&C Act.

(2) Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information

Section 520(o)(1)(E)(i) of the FD&C Act describes software functions that are intended to display, analyze, or print[7] medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines). In other words, if the type of data described in Criterion 2 (i.e., medical information) is used as an input, then the software function is not a device within the meaning of section 201(h) so long as it meets the other three criteria. FDA interprets Criterion 2 to include software functions that display, analyze, or print patient-specific information, such as demographic information, symptoms, certain test results, patient discharge summaries, and/or other medical information (such as clinical practice guidelines, peer-reviewed clinical studies, textbooks, approved drug or medical device labeling, and government agency recommendations). Taken together, 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).

FDA interprets *medical information about a patient* to be the type of information used in, or that relates to, the clinical care of the patient, including patient-specific information. Such information is that which may generally be communicated between HCPs in a clinical conversation or between HCPs and patients in the context of a clinical decision. Whether particular information is commonly discussed in a clinical conversation is 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[8] and can be appropriately understood in context. If Criterion 1 is met, data/results from devices (including IVD test(s)), when used in a manner consistent with the FDA-required labeling,[9] are generally considered "medical information about a patient" within the meaning of

[7] Software functions that solely display or print medical information as described in section 520(o)(1)(C) or (D) of the FD&C Act are not considered CDS.

[8] Generally, the kinds of information that are from "well-understood and accepted sources" are those that reflect knowledge and practices that are widely recognized and accepted within the medical or scientific community that are supported by scientific evidence, including peer-reviewed literature, clinical guidelines, or authoritative consensus documents. These can include information from sources such as medical textbooks or reference information developed by accredited medical institutions, government agencies, and professional organizations.

[9] For the purposes of this guidance, "used in a manner consistent with the FDA-required labeling" is use consistent with the FDA approved, cleared, or authorized uses of a product. The term "FDA-required labeling" as used in this

Criterion 2. 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.

A single, discrete test or measurement result[10] that is clinically meaningful (e.g., a blood glucose lab test result) is *medical information*, while a more continuous sampling of the same information (e.g., continuous glucose monitor readings) is a pattern/signal. As discussed above, a software function that is intended to acquire, process, or analyze a pattern/signal from a signal acquisition system fails Criterion 1 and remains a device (see Section IV (1)). FDA recognizes there is a continuum between a single sample and a continuous sample, and has included examples in Section V for reference.

The following are examples that describe types of medical information that can be displayed, analyzed, or printed about a patient:

- 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.

These software functions are not devices only if they also meet the other three criteria of section 520(o)(1)(E) of the FD&C Act.

(3) Intended for the purpose of supporting or providing recommendations to an HCP about prevention, diagnosis, or treatment of a disease or condition

Section 520(o)(1)(E)(ii) describes software functions that are intended to support or provide recommendations to an HCP about prevention, diagnosis, or treatment of a disease or condition.

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. As discussed below, 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

guidance includes the labeling reviewed and approved by FDA as part of the medical product marketing application review process. For products not subject to premarket approval, but instead subject to premarket notification (510(k)) requirements or exempt from premarket review, the term FDA-required labeling includes the labeling that provides adequate directions for use and other information required to appear on the label or in labeling.

[10] Software functions that process or analyze patterns or signals from chemical reactions generated by an assay and an instrument, such as an electrochemical or photometric response, to generate a clinical test result do not meet Criterion 1.

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.

The following examples are intended to illustrate software functions that otherwise meet the criteria but provide only one recommendation that is clinically appropriate, as well as sub-examples that would *not* be those for which FDA intends to exercise enforcement discretion.

- 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.
    - However, 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, would not fall under this example. Such a software function is a device software function that would remain the focus of FDA's oversight.
    - However, a software function with the same functionality, but predicts risk of a cardiovascular event in the next 24 hours, would not fall under this example. Such a software function is a device software function that would remain the focus of FDA's oversight.
- 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.
    - However, a software function with the same functionality, but also analyzes positron emission tomography (PET) scan images, would not fall under this example. Such a software function is a device software function that would remain the focus of FDA's oversight.
- 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.
    - However, a software function with the same functionality, but also analyzes spectroscopy data to diagnose bacterial infections, would not fall under this example. Such a software function is a device software function that would remain the focus of FDA's oversight.
- 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.
    - However, a software function with the same functionality, but also analyzes the image to generate the clinical findings and/or make measurements, would not fall under this example. Such a software function is a device software function that would remain the focus of FDA's oversight.
    - However, 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,

would not fall under this example. Such a software function is a device software function that would remain the focus of FDA's oversight.

- 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.
    - However, a software function that establishes a definitive diagnosis based on analysis of medical images, waveform data, or other signal-level inputs would not fall under this example. Such a software function is a device software function that would remain the focus of FDA's oversight.
- A software function that classifies patients with chronic low back pain into a single recommended appropriate clinical care pathway (e.g., 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.
    - However, 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, would not fall under this example. Such a software function is a device software function that would remain the focus of FDA's oversight.
- 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.
    - However, 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 would not fall under this example. Such a software function is a device software function that would remain the focus of FDA's oversight.
    - However, 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 would not fall under this example. Such a software function is a device software function that would remain the focus of FDA's oversight.

The following are examples of software functions that meet Criterion 3, because they are intended for the purpose of supporting or providing recommendations to an HCP about prevention, diagnosis, or treatment of a disease or condition. 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's orders; and
- Patient data reports and summaries (e.g., discharge papers).

FDA interprets Criterion 3 to describe software that:

a) Provides condition-, disease-, and/or patient-specific information and options to an HCP to enhance, inform and/or influence a health care 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.

Such software presents recommendations based on an analysis of patient-specific information to an HCP, who may then incorporate this information into their decision-making about the care of a patient, along with other information and factors of which the HCP is aware. For example, a software function that analyzes patient-specific medical information (e.g., atrial fibrillation (AF) diagnosis from Holter report) and provides the HCP with a prioritized list of treatment options for AF would meet Criterion 3.

Software functions that provide the following outputs may also be considered "supporting or providing recommendations to an HCP" and would meet Criterion 3, as long as they were not intended to replace or direct the HCP's judgment:

1. List of preventive, diagnostic or treatment options;
2. Prioritized list of preventive, diagnostic or treatment options; or
3. List of follow-up or next-step options for consideration (e.g., after a physician office visit, hospitalization, procedure).

The software functions described in this section as satisfying Criterion 3 are not devices only if they also meet the other three criteria of section 520(o)(1)(E) of the FD&C Act.

Software functions that support or provide recommendations to patients or caregivers – not HCPs – meet the definition of a device. FDA understands the importance of CDS for patients and caregivers and supports increased access to innovative, safe, and effective CDS for non-HCP users. FDA intends to be consistent with existing policies (including the following documents: Policy for Device Software Functions and Mobile Medical Applications,[11] Software as a Medical Device (SaMD): Clinical Evaluation,[12] Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices,[13] and General Wellness: Policy for Low Risk Devices)[14] in the regulation of CDS intended for non-HCPs. Further, FDA remains

[11] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications
[12] Available at https://www.imdrf.org/documents/software-medical-device-samd-clinical-evaluation
[13] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices
[14] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness- policy-low-risk-devices

committed to providing transparency and will update our existing policies, as appropriate, with additional examples as CDS for non-HCPs continues to evolve.

For additional information regarding risk categorization and considerations that may apply to certain software functions, please see the International Medical Device Regulators Forum (IMDRF) document Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations.[15]

(4) 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 be excluded from the definition of a device under section 520(o)(1)(E) of the FD&C Act, the software function must be 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.

The software and labeling recommendations in this section are based on FDA's experience evaluating device CDS and software functions that are Non-Device CDS. However, sponsors may use alternative approaches so long as their approach enables an HCP "to independently review the basis for such recommendations" (section 520(o)(1)(E)(iii) (Criterion 4). 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 and intended patient population. FDA does not consider software functions intended for a critical, time-sensitive task or decision to meet Criterion 4, because an HCP is unlikely to have sufficient time to independently review the basis of the recommendations. (As described in section IV (3), software functions that are intended to replace or direct the HCP's judgment would not meet Criterion 3.)
b) The software or labeling identify the required input medical information, with plain language instructions on how the inputs should be obtained, their relevance, and data quality requirements.
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, sufficient for the intended HCP user to understand the basis of the recommendation, including:
    i. A summary of the general approach relied upon to provide the recommendations (e.g., meta-analysis of clinical studies, expert panel, statistical modeling, AI/ML techniques), at a level of detail appropriate for the intended user and use environment, which could include, for example, the logic or methods relied upon;
    ii. A description of the data relied upon so that an HCP can assess whether the data is representative of their patient population (e.g., relevant sub-groups, disease conditions, collection sites, sex, ethnicity) and assess if best practices were

[15] Available at http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf

followed (e.g., independent development and validation datasets); and

iii. A description of the results from clinical studies conducted to validate the algorithm/recommendations so that an HCP can assess the potential performance and limitations when applied to their patients (e.g., sub-populations with untested or highly variable algorithm performance).

d) The software output provides the HCP user with relevant patient-specific information and other knowns/unknowns for consideration (e.g., missing, corrupted, or unexpected input data values) that will enable the HCP to independently review the basis for the recommendations and apply their judgment when making the final decision.

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.

The software output or labeling should be identified and available to the intended user (e.g., clinical practice guidelines with the date or version, published literature, or information that has been communicated by the CDS developer to the intended user) and understandable by the intended user (e.g., data points whose meaning is well understood by the intended user). In order to enable independent evaluation of its basis, the recommendation should be based on information whose meaning could be expected to be independently understood by the intended HCP user (e.g., the inputs used to generate the recommendations are identified, the recommendations are based on inputs that do not omit material information, and the quality and robustness of the datasets or clinical studies are described). FDA believes that relevant patient-specific information can also help the HCPs understand the basis of the recommendations. Beyond the input medical information relied upon, being able to clearly understand how the logic was applied for the patient (e.g., matching of patient-level data to criteria in practice guidelines, comparison to a reference/normal database, development and use of a prioritized schema for recommendation generation) will aid an HCP in understanding the basis of the recommendations. Providing the recommendations in the context of what is known/unknown for an individual patient may give HCPs an opportunity to assess the strength/limitations of the CDS software function recommendations when applying their judgment to the final decision.

In some cases, developers may need to perform usability testing to evaluate if their implementation meets Criterion 4.

Additionally, FDA considers the (a) level of software automation and (b) time-critical nature of the HCP's decision making 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.

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.[16] 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.

V. Examples

The following sections describe examples of software functions that are Non-Device CDS software functions (V.A and V.B) and examples of software functions that remain devices (V.C). This guidance, and these examples, are not intended to include all regulatory requirements for devices that may or may not apply to an individual software function. For additional information about applicable regulatory requirements, please see complementary, existing digital health policies described in the following: Policy for Device Software Functions and Mobile Medical Applications,[17] Software as a Medical Device (SaMD): Clinical Evaluation,[18] Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices,[19] and General Wellness: Policy for Low Risk Devices.[20]

A. Examples of Non-Device CDS Software Functions

The following 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.[21] (For examples focused on interpretation of Criterion 4, see section V.B below.)

Examples of non-device CDS software functions include software functions that provide:

1. Evidence-based clinician order sets for an HCP to choose from, tailored for a particular condition, disease, or clinician preference:
    a. Software function that provides groupings of standard order sets, consistent with clinical guidelines, for patient admission to critical care.
    b. Software function that provides a list of diagnostic and treatment order options to an HCP based on clinical guidelines for the care of adult patients presenting with pneumonia symptoms.

2. Matching patient-specific medical information from records or reports to reference information (e.g., clinical guidelines) that is routinely used in clinical practice:

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[16] M.L. Cummings. Automation Bias in Intelligent Time Critical Decision Support Systems. American Institute of Aeronautics and Astronautics 1st Intelligent Systems Technical Conference, Vol. 2, 2004, pp. 557-62.
[17] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications
[18] Available at https://www.imdrf.org/documents/software-medical-device-samd-clinical-evaluation
[19] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices
[20] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness- policy-low-risk-devices
[21] To be a non-device CDS software function, the software function would also need to be explained to the HCP user such that the user can independently review the basis for the recommendations presented by the software, and the user does not rely primarily on the outputs to make a clinical decision about an individual patient (Criterion 4).

a. Software function that matches patient-specific medical information (e.g., diagnosis, treatments, allergies, signs or symptoms) to reference information routinely uses in clinical practice (e.g., practice guidelines) to facilitate assessments of specific patients. For example, a software function that uses a patient's diagnosis and other medical information to provide an HCP with current practice treatment guidelines for common illnesses or conditions such as influenza, hypertension, and hypercholesterolemia.
b. Software function that matches patient-specific medical information to peer-reviewed literature publications on related topics.

3. Contextually relevant reference information about a disease or condition:
    a. Software function that provides HCPs with recommendations on the use of a prescription drug[22] for a disease (as indicated in the patient's medical record) that are consistent with the current version of the drug's FDA-approved labeling.[23,24]
    b. Software function that provides HCPs with available treatment options, including drug, device, surgical and/or lifestyle changes for heart failure patients based on their disease stage and clinical guidelines.

4. Drug-drug interaction and drug-allergy contraindication notifications to avert adverse drug reactions:
    a. Software function that identifies drug-drug interactions and drug-allergy contraindications, based on the current version of FDA-approved drug or device labeling or other up-to-date and peer-reviewed sources and patient-specific information, to attempt to prevent adverse drug reactions.
    b. Software function that enables an HCP to enter multiple drug names and provides information regarding known drug-drug interactions.
    c. 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.

5. Drug formulary guidelines:
    a. Software function that provides HCPs with a list of medications on a formulary for a given disease or condition.
    b. Software function that provides alerts to HCPs regarding changes in a formulary and recommends alternatives.

[22] Information relied upon by the software should be kept up-to-date while prominently displaying the source of the information (e.g., FDA-approved labeling), and provide options to users to obtain up-to-date information. (For example, software that provides alerts for potential drug-drug interactions should provide a link directly to a trusted and up-to-date source for that information (e.g., DailyMed for drug labeling)).

[23] Includes prescribing information (also referred to as package insert or physician labeling); patient labeling, including patient package inserts and Medication Guides; the product's immediate container label; outer container; the outside package; and other written, printed, or graphic information that accompanies the product.

[24] See FDA guidance entitled "Medical Product Communications that are Consistent with FDA-Required Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-product-communications-are-consistent-fda-required-labeling-questions-and-answers

6. Duplicate testing or medication error prevention notifications (e.g., medication reconciliations and test reconciliations):
    a. Software function that provides an alert to notify an HCP of redundant test orders and advise discontinuation of the order.
    b. Software function that flags patient results for an HCP based on specific clinical parameters (e.g., out of range test results where the reference ranges are predetermined by the lab or HCP) in response to a medication order. Example:
        - Software function that flags low potassium and/or magnesium levels in a patient in response to a prescription for digoxin.

7. Reminders for preventive care or clinician's orders:
    a. Software function that provides an HCP with reminders for preventive care (e.g., breast cancer screening or immunizations) for a patient based on practice guidelines using medical information in the patient's medical record.
    b. Software function that provides an HCP with reminders for orders for Hemoglobin A1C tests for diabetic patients using patient-specific medical information from the medical record (e.g., the patient's diagnosis, date of prior Hemoglobin A1C test) based on practice guidelines.

8. Patient data reports and summaries (e.g., discharge papers):
    a. Software function that uses medical information from the patient's medical records to provide an HCP with recommended assessments prior to discharge, such as a pain assessment.
    b. Software function that aggregates possible post-operative care instructions, medication needs, and follow-up instructions to assist an HCP in assembling discharge papers for a patient.

9. List of preventive, diagnostic or treatment options:
    a. Software function that provides a list of appropriate cholesterol-lowering drugs to HCPs to consider based on a patient's cholesterol levels and demographics found in the electronic health record (EHR).
    b. Software function that 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.
    c. Software function that provides to an HCP a list of FDA-approved chemotherapeutic agents for a cancer type identified through analysis of medical information on the patient's diagnosis and pathologist confirmed biopsy result.
    d. Software function that analyzes family history, prior mammogram results, and BRCA1 status from the medical record and recommends that an HCP consider increased mammography frequency or supplemental breast ultrasound for the patient.
    e. Software function that enables an HCP to input the specific mutation results of an FDA-authorized Epidermal Growth Factor Receptor Mutation (EGFR) test for a patient with non-small cell lung cancer (the same clinical condition for which the FDA-authorized EGFR test was clinically validated) and identifies FDA-approved treatments for non-small cell lung cancer indicated for use with the FDA-authorized EGFR test.

10. Prioritized list of preventive, diagnostic or treatment options:
    a. Software function that analyzes the type of arthritis diagnosis in the patient's medical record and identifies prioritized treatment options available for that condition.
    b. Software function that analyzes patient-specific symptoms to provide a prioritized list of diagnostic tests for the HCP to consider.
    c. Software intended for HCPs that analyzes patient-specific medical information to determine which over-the-counter (OTC) allergy drug class is likely to be most effective in alleviating the patient's seasonal allergies and provides a list of available medications in that drug class.
    d. Software function that analyzes information on a patient's glaucoma diagnosis in the patient's medical record and provides the HCP with a list of prioritized treatment options to consider for that patient.

11. List of follow-up or next-step options for consideration (e.g., after a physician office visit, hospitalization, procedure):
    a. Software function that analyzes a patient's age, sex, and radiologist's report for findings of low bone density and micro cervical fractures in order to provide an HCP with a list of follow-up options for consideration, such as performance of periodic bone-densitometry scans, nonpharmacological management (e.g., weight-bearing exercise), or referral of the patient to a specialist.
    b. Software function that tracks and analyzes a chronic obstructive pulmonary disease (COPD) patient's age and average number of steps walked per day in order to provide a list of follow-up options for the HCP to consider (e.g., office visit, chest CT, spirometry) to evaluate disease progression.
    c. Software function that 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.
    d. Software function that interprets daily results of a basic metabolic panel for a hospitalized patient and recommends several options for IV fluids that may be beneficial to ensure proper hydration and to prevent acidosis. In some cases, this software function may also provide recommendations for potential follow-up testing options.
    e. Software function that inputs information about a patient's cancer progression and treatment history and other medical information from a patient's medical record and recommends, in addition to prioritized treatments, that the healthcare practitioner also consider one or more legally marketed companion diagnostic tests.

12. 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.

B. Examples of Non-Device CDS Software Functions - Criterion 4

The following examples are intended to clarify FDA's interpretation of the fourth criterion in section 520(o)(1)(E) of the FD&C Act: software functions considered Non-Device CDS if they also meet Criteria 1, 2, and 3.

1. Software function that analyzes patient-specific medical information (e.g., end stage renal disease (ESRD) diagnosis, lab test results, and patient demographics from the patient's medical record) and provides an HCP with a list of treatment options for ESRD based on implementation of practice guidelines. To enable the HCP 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 software labeling and function provide the following information to the HCP:
    a. The intended use, HCP user, and patient population are clearly identified. The intended use is not time-critical, and the intended HCP is expected to have sufficient time and training to understand the practice guidelines that are the basis of the recommendations;
    b. The input medical information is clearly identified and relevant, with data quality requirements to ensure compatibility to enable relevant medical information to be extracted from the EHR;
    c. A plain language description of the underlying algorithm development and validation that forms the basis for any recommendations is provided. In addition, the practice guidelines being implemented are clearly identified to the HCP, and the guidelines contain sufficient information on their development and clinical studies underlying the recommendations for ESRD treatment options; and
    d. The recommendations are provided to the HCP with relevant patient-specific information including a description of how the patient-specific information matches the criteria for treatment options in the practice guidelines. The output indicates whether any expected input medical information from the medical record was missing.

2. 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:
    a. 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;
    b. The cancer diagnosis and patient demographics are clearly identified as the inputs being used in the database search and analysis;
    c. 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;

   d. 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.

3. Software function that analyzes a COPD patient's age and average number of steps walked per day in order to provide a list of follow-up options for the HCP to consider (e.g., office visit, chest CT, spirometry) to evaluate disease progression. 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:
   a. 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;
   b. The patient's age and average number of steps walked per day and the date of the measurement are clearly identified as the input information. The software also describes how this information is collected;
   c. A plain language summary is provided to the HCP describing how the algorithm is analyzing patient age and steps walked to assess activity and any validation studies, as appropriate;
   d. The list of follow-up options is provided to the HCP to consider. The average metrics of the patient over time are shown in comparison with a subset of subjects from the underlying database with similar age, disease severity and demographics. The algorithm identifies limitations to consider, such as number of days with missing step information or high variability in daily measurements, which could impact the analysis or the follow-up recommendation based on the HCP's judgement.

C. Examples of Device Software Functions

The following examples illustrate FDA's interpretation of the criteria in section 520(o)(1)(E) of the FD&C Act and describe device software functions which do not meet all four criteria and for which FDA intends to focus its regulatory oversight. Certain examples focus on the first three criteria in section 520(o)(1)(E). Others focus on the interpretation of Criterion 4 to demonstrate scenarios where the software function does not enable the HCP to independently review the basis for the recommendations presented by the software. 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, as discussed in more detail in section IV(3) above, 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.

1. Software function that uses a patient's image sets (e.g., CT, magnetic resonance (MR)) to create an individual treatment plan for review by an HCP for patients undergoing radiation therapy treatment with external beam or brachytherapy. This software is a device function. It does not meet Criterion 1 because it is intended to analyze a medical image. It does not meet

Criterion 2 because it is not intended to display, analyze, or print medical information. It does not meet Criterion 3 because it generates the treatment plan, which is intended to provide a specific treatment directive.

2. Software function that manipulates or analyzes images and other data obtained from a radiological device (e.g., CT, bone density, and distance between structures) to create 3D models of the region intended to be used in planning orthopedic/dental surgical treatments with a device. This software is a device function. It does not meet Criterion 1 because it is intended to analyze a medical image. It does not meet Criterion 2 because it is not intended to display, analyze, or print medical information. It does not meet Criterion 3 because it generates the models for planning treatment, which is intended to provide a specific treatment directive.
3. Software function that manipulates or interpolates data from a patient's CT scan, providing 3D reconstruction for visualization of the interior of the bronchial tree to aid in the placement of catheters in the bronchial tree and placement of markers into soft lung tissue to guide radiosurgery and thoracic surgery. This software is a device function. It does not meet Criterion 1 because it is intended to analyze a medical image. It does not meet Criterion 2 because it is not intended to display, analyze, or print medical information. It does not meet Criterion 3 because it provides a specific treatment directive.
4. Software function that analyzes multiple signals (e.g., perspiration rate, heart rate, eye movement, breathing rate) from wearable products to monitor whether a person is having a heart attack or narcolepsy episode. The software is a device function. It does not meet Criterion 1 because it is intended to analyze signals. It does not meet Criterion 2 because it is not intended to display, analyze, or print medical information. It does not meet Criterion 3 or 4 because it provides a specific diagnostic output and supports time-critical decision making.
5. Software function that analyzes near-infrared camera images of a patient intended for use in determining or diagnosing a brain hematoma. The software is a device function. It does not meet Criterion 1 because it is intended to analyze a signal. It does not meet Criterion 2 because it is not intended to display, analyze, or print medical information.
6. Software function that calculates the fractal dimension of a lesion and surrounding skin image and builds a structural map to provide a diagnosis or identify whether the lesion is malignant or benign. This software is a device function. It does not meet Criterion 1 because it is intended to analyze a medical image. It does not meet Criterion 2 because it is not intended to display, analyze, or print medical information. It does not meet Criterion 3 because it provides a specific diagnostic output for a disease or condition.
7. Software function that analyzes CT images to compute and/or approximate fractional flow reserve. The intended use is to determine the likelihood that the stenosis impedes oxygen delivery to the heart muscle (myocardial ischemia). This software is a device function. It does not meet Criterion 1 because it is intended to analyze a medical image. It does not meet Criterion 2 because it is not intended to display, analyze, or print medical information. It does not meet Criterion 3 because it provides a specific diagnostic output for a disease or condition.
8. Software function that is intended to perform image analysis for diagnostically differentiating between ischemic and hemorrhagic stroke. This software is a device function. It does not meet Criterion 1 because it is intended to analyze a medical image. It does not meet Criterion 2 because it is not intended to display, analyze, or print medical information. It does not meet Criterion 3 because it provides a specific diagnostic output for a disease or condition.

9. 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. It does not meet Criterion 1 because it is intended to analyze a medical signal. It does not meet Criterion 2 because it is not intended to display, analyze, or print medical information. It does not meet Criterion 3 or 4 because it provides a specific, time-critical treatment output or directive for a disease or condition.
10. Software that performs analysis of cerebrospinal fluid (CSF) spectroscopy data to diagnose tuberculosis meningitis or viral meningitis in children. This software is a device function. It does not meet Criterion 1 because it is intended to analyze a signal. It does not meet Criterion 2 because it is not intended to display, analyze, or print medical information. It does not meet Criterion 3 because it provides a specific diagnostic output for a disease or condition.
11. 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. It does not meet Criterion 3 or 4 because it is intended to provide a specific diagnostic output or directive, including an alarm which supports time-critical decision-making
12. Software function that provides a prioritized list of possible diagnoses of a patient's abnormality based on analysis of its size, shape, appearance, or other functional aspects visible in an image. This software is a device function. It does not meet Criterion 1 because it is intended to analyze a medical image. It does not meet Criterion 2 because it is not intended to display, analyze, or print medical information.
13. Software function that detects and highlights abnormalities (CADe) and assesses associated disease severity (CADx) in an image. This software is a device function. It does not meet Criterion 1 because it is intended to analyze a medical image. It does not meet Criterion 2 because it is not intended to display, analyze, or print medical information. It does not meet Criterion 3 because it provides a specific diagnostic output or directive for a disease or condition
14. Software function that analyzes sound waves captured when users cough or recite certain sentences to diagnose bronchitis or sinus infection. This software is a device function. It does not meet Criterion 1 because it is intended to analyze a signal or pattern. It does not meet Criterion 2 because it is not intended to display, analyze, or print medical information. It does not meet Criterion 3 because it provides a specific diagnostic output or directive for a disease or condition.
15. Software function that analyzes breathing patterns from a sleep apnea monitor to diagnose sleep apnea or other conditions in patients. This software is a device function. It does not meet Criterion 1 because it is intended to analyze a pattern. It does not meet Criterion 2 because it is not intended to display, analyze, or print medical information. It does not meet Criterion 3 because it provides a specific diagnostic output for a disease or condition.
16. Software function that analyzes images of body fluid preparations or digital slides (digital pathology) to perform cell counts and morphology reviews to identify patients with low white blood cell counts. This software is a device function. It does not meet Criterion 1 because it is intended to analyze a medical image. It does not meet Criterion 2 because it is not intended to display, analyze, or print medical information. It does not meet Criterion 3 because it provides a specific diagnostic output for a disease or condition.

17. Software function that uses a variant call format (VCF) file containing patient-specific genetic variants and mutations identified from an NGS Analyzer and provides recommendations for FDA-approved treatment options based on those findings. This software is a device function. It does not meet Criterion 1 because it is analyzing a pattern from a signal acquisition system (NGS analyzer). It does not meet Criterion 2 because it is not intended to display, analyze, or print medical information.
18. Software function that acquires and analyzes electrical signals from ECG leads to generate an ECG waveform. This software is a device function. It does not meet Criterion 1 because it acquires, processes, and analyzes a signal. It does not meet Criterion 2 because it is not intended to display, analyze, or print medical information.
19. Software function that analyzes an ECG waveform output from an FDA-cleared device to detect or diagnose arrhythmias (e.g., atrial fibrillation). This software is a device function. It does not meet Criterion 1 because it analyzes a pattern. It does not meet Criterion 2 because it is not intended to display, analyze, or print medical information. It does not meet Criterion 3 because it provides a specific diagnostic output.
20. Software function that analyzes and interprets five sequential RR interval measurements from Holter monitor data in a patient medical record to diagnose atrial fibrillation. This software is a device function. It does not meet Criterion 1 because it analyzes a pattern (due to the sampling frequency of RR interval measurements). It does not meet Criterion 2 because it is not intended to analyze medical information. It does not meet Criterion 3 because it provides a specific diagnostic output.
21. 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. This software is a device function. It does not meet Criterion 1 because it analyzes a pattern (due to the sampling frequency of RR interval measurements). It does not meet Criterion 2 because it is not intended to display, analyze, or print medical information. It does not meet Criterion 3 because it provides a specific diagnostic output or directive.
22. Software function that analyzes patient-specific measurements (e.g., 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. It does not meet Criterion 3 or 4 because it provides a specific diagnostic output or directive and supports time-critical decision-making.
23. 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. This software is a device function. It does not meet Criterion 3 or 4 because it provides a specific diagnostic output or directive and supports time-critical decision making.
24. Software function that analyzes hourly pulse oximetry and heart rate measurements (e.g., from a patient's EHR) to identify signs of patient deterioration and alert an HCP. This software is a device function. It does not meet Criterion 1 because it analyzes a pattern. It does not meet Criterion 2 because it is not intended to display, analyze, or print medical information. It does not meet Criterion 3 or 4 because it provides a specific diagnostic output or directive and supports time-critical decision making.

25. 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. It does not meet Criterion 1 because it analyzes a pattern. It does not meet Criterion 2 because it is not intended to display, analyze, or print medical information. It does not meet Criterion 3 or 4 because it provides a specific diagnostic output or directive and supports time-critical decision making.
26. 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. It does not meet Criterion 3 or 4 because it provides a specific treatment output or directive and supports time-critical decision making.
27. 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. It does not meet Criterion 3 or 4 because it provides a specific, time-critical diagnostic or treatment output or directive.
28. 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. It does not meet Criterion 3 because it is not intended for an HCP. It does not meet Criterion 4 because it supports time-critical decision-making.
29. 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. It does not meet Criterion 3 or 4 because it provides a specific diagnostic or treatment output or directive and supports time-critical decision-making.
30. Software function that analyzes serial cardiac troponin readings over 24 hours to estimate the size of a myocardial infarction. This software is a device function. It does not meet Criterion 1 because it analyzes a pattern. It does not meet Criterion 2 because it is not intended to display, analyze, or print medical information. It does not meet Criterion 3 because it provides a specific diagnostic output.
31. Software function that analyzes patient-specific medical information found in the medical record, including the most recent mammography report findings, in order to provide a list of follow-up options for the HCP to consider following a patient's annual mammogram. The software algorithm is trained on a large dataset of 100,000 cases from 10 clinical sites, with summary performance based on subsequent cancer detection rates with supplemental imaging and biopsy. The product labeling provides information on the purpose of the software, the intended user and patient population, and a description of the software outputs. 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 studies that are the basis of the recommendations. However, this software is a device function since it does not meet Criterion 4 because:
    a. The input medical information is not adequately disclosed to the HCP to be able to understand what information is being considered from the patient's medical record or from the radiologist's report;

b. While the HCP is informed that an algorithm was trained on a large dataset with supplemental imaging and biopsy, specific details on the independence of the development and validation datasets, such as the distribution of cases from different sites, breast density, ethnicity, or other important factors, are not available to the HCP. Without this information, the HCP will not be able to assess if the results are generalizable; and
c. The recommendations are provided to the HCP; however, no additional information is available to the HCP to understand the key variables that influenced the recommendations.

Taken together, an HCP is not able to independently review the basis for the recommendations that the software function provides. As a result, the software function is a device.

32. Software function that provides a prioritized list of FDA-authorized depression treatment options to an HCP based on an analysis of reported outcomes in a database of clinical studies using medical information (e.g., diagnosis and demographics) from the patient's medical record. 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 studies that are the basis of the recommendations. The medical information from the patient's medical record is clearly identified to the HCP to be able to understand what information is being considered. However, this software is a device function since it does not meet Criterion 4 because:

    a. The full report of the clinical studies being relied upon is not made available to the user; and
    b. The prioritized list of FDA-authorized depression treatment options is provided to the user; however, the software does not identify the studies that most closely matched the patient-specific diagnosis and demographics and other considerations, such as the warning/contraindications from the labeling.

    Taken together, an HCP is not able to independently review the basis for the recommendations that the software function provides. As a result, the software function is a device.

Guidance History*	Date	Description
Revisions to Final Guidance	January 2026	Revisions issued under Level 2 guidance procedures (21 CFR 10.115(g)(4)). Minor correction on p.13 & 14 to delete reference to time-critical decision-making for alignment with January 6, 2026, update.

*This table was implemented, beginning January 2026 and previous guidance history may not be captured in totality.