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Clinical Decision Support Software

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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Preface

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Clinical Decision Support Software

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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 provides clarity on the scope of FDA's oversight of clinical decision support software intended for health care professionals, patients, or caregivers.

FDA recognizes that the term "clinical decision support" or "CDS" is used broadly and in different ways, depending on the context. CDS provides health care professionals (HCPs) and patients with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care.[1] 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.[2] For the purposes of this guidance, the term "CDS" is used to refer to functions that are either Device CDS or Non-Device CDS. FDA uses criteria from the 21st Century Cures Act (Cures Act) to determine if a software function is Device CDS or Non-Device CDS (see Section III).

The purpose of this guidance is to describe FDA's regulatory approach to CDS software functions. The agency's approach includes recent changes to the FD&C Act made by the Cures Act, which amended section 520 and excludes certain software functions from the device definition. This guidance clarifies the types of CDS software functions that: (1) do not meet the

[1] *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.

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

definition of a device as amended by the Cures Act; (2) may meet the definition of a device but for which, based on our current understanding of the risks of these devices, 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 premarket approval requirements; and (3) meet the definition of a device and on which FDA intends to focus its regulatory oversight. In its risk based approach to CDS regulation, FDA also intends to leverage the Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations (IMDRF Framework).[3]

This guidance provides many examples of how FDA intends to regulate different kinds of software functions, including:

- Non-Device CDS functions;
- Device CDS functions for which, based on our current understanding of the risks of these devices, FDA intends at this time not to enforce compliance with applicable requirements;
- Device CDS functions on which FDA intends to focus its regulatory oversight; and
- Non-CDS device functions on which FDA intends to focus its regulatory oversight.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidance documents 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 guidance documents means that something is suggested or recommended, but not required.

II. Background

A. 21st Century Cures Act

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. Specifically, this section excludes, from the definition of device, software functions that meet all of the following four criteria:

(1) not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system (section 520(o)(1)(E) of the FD&C Act);

(2) intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines) (section 520(o)(1)(E)(i) of the FD&C Act);

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

(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).[4]

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

B. International Medical Device Regulators Forum Framework

This guidance uses factors from the International Medical Device Regulators Forum (IMDRF) Framework to apply a risk-based policy for CDS software functions. This approach is consistent with FDA's commitment to implement IMDRF documents specifically and advance global medical device regulatory harmonization generally.

In September 2014, the IMDRF, of which FDA is a member, issued a final document entitled Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations (IMDRF Framework) based on international public comment on a proposed document.[5] The objective of the IMDRF Framework is to introduce a foundational approach, harmonized vocabulary, and general and specific considerations for manufacturers, regulators, and users to address the unique challenges associated with the use of software as a medical device (SaMD). The IMDRF Framework includes two factors important for SaMD characterization:

(A) the significance of the information provided by a SaMD to a health care decision: to treat or diagnose, to drive clinical management, or to inform clinical management; and

(B) the state of the patient's health care situation or condition: critical, serious, or non-serious.

[4] 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 software 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.

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

See Section VI of this guidance for additional information on the IMDRF Framework and how FDA applies the Framework to its risk-based policy for CDS software functions.

III. Definitions

As noted in the Introduction, the term CDS can be used more broadly to mean technology that provides HCPs and patients with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care. For the purposes of this guidance, FDA uses section 520(o)(1)(E) criteria to determine if a software function is Device CDS or Non-Device CDS. The term "CDS" is used to refer to functions that are either Device CDS or Non-Device CDS.

A software function is considered CDS, for the purposes of this guidance, if it meets the following:

- Not intended to acquire, process, or analyze [criterion (1)];
- Intended for the purpose of displaying, analyzing, or printing medical information [criterion (2)]; and
- Intended for the purpose of supporting or providing recommendations [part of criterion (3)].

CDS (as defined above) is not a device when the HCP can independently review the basis for the recommendation.[6] Thus, for the purposes of this guidance, CDS that meets all parts of the four section 520(o)(1)(E) criteria is Non-Device CDS. If CDS (as defined above) fails to meet part of criterion (3) and/or part or all of criterion (4), then it is Device CDS. This is illustrated in the following table.

Table 1. Is a CDS Software Function Device or Non-Device?

Is the Intended User an HCP? [part of criteria (3) and (4)]	Can the User Independently Review the Basis?* [part of criterion (4)]	Is it Device CDS?
Yes	Yes	No, it is Non-Device CDS because it meets all of section 520(o)(1)(E) criteria
	No	Yes, it is Device CDS
No, it is a patient or caregiver	Yes	Yes, it is Device CDS
	No	Yes, it is Device CDS

* "Can the user independently review the basis?" asks whether the function is intended for the purpose of enabling the user to independently review the basis for the recommendations so that it is not the intent that user rely primarily on any such recommendation (part of criterion (4)).

[6] That is, the CDS is intended for the purpose of enabling an HCP 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 (4)].

Non-Device CDS: Consistent with the Cures Act, for the purposes of this guidance, Non-Device CDS includes software functions that meet all four criteria of section 520(o)(1)(E) as listed in Section II.A above.[7] Non-Device CDS is intended for HCPs only, as required by criterion (3). Section V provides an explanation for each of the four criteria.

Device CDS: For the purposes of this guidance, Device CDS includes software functions that meet criteria (1) and (2) of section 520(o)(1)(E) as listed in Section II.A and are intended for the purpose of supporting or providing recommendations to an HCP, patient, or caregiver about prevention, diagnosis, or treatment of a disease or condition. These software functions may not meet parts of either criterion (3) or (4) (see Table 1 above).

IV. Scope

This guidance describes CDS that does not meet the definition of a device (Non-Device CDS) in the context of and using language from 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 also describes FDA's risk-based enforcement discretion policy for software functions that are intended for HCPs, patients, or caregivers and may meet the definition of a device but for which, based on our current understanding of the risks of these devices, 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 premarket approval requirements.

This guidance presents the agency's current thinking on which CDS are and are not devices. The guidance does not address which FDA statutory or regulatory requirements apply to Device CDS, including which regulatory requirements may apply to a Device CDS that is part of a combination product, nor does it address labeling requirements for CDS disseminated by or on behalf of a drug or biological product sponsor.

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

For a software function to be Non-Device CDS, it must meet all of the following four criteria to be excluded from the device definition under section 520(o) of the FD&C Act. The functions excluded from the device definition are independent of the platform on which they might run.[8] The first criterion describes what CDS software functions must *not* be intended to do if they are to be excluded from the device definition under section 520(o) of the FD&C Act. The remaining

[7] Some software functions that have traditionally been considered CDS software functions never were considered device functions, because they are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease (section 201(h) of the FD&C Act). These CDS functions, such as software that presents best practices in an institution or facilitation of access to treatment guidelines, continue to not be device functions and are outside the scope of this draft guidance.

[8] The exclusions are subject to the limitations described in footnote 4.

three criteria describe purposes for which software functions must be intended in order to be excluded from the device definition under section 520(o) of the FD&C Act.

(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 in vitro diagnostic device, 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 continue to be subject to FDA oversight. Products that acquire an image or physiological signal from the body, or from a sample from the body, or that process or analyze such information, or both, have been regulated for many years as devices when such acquisition, processing, or analyzing is intended for a purpose identified in the statutory device definition.

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

- An in vitro diagnostic device, which typically includes 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:
    - 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.

Examples of this type of software function that are medical devices include software that process physiologic data to generate new data points (such as ST-segment measurements from ECG signals), analyze information within the original data (such as feature identification in image analysis), or analyze and interpret genomic data, such as identifying a patient's genetic variations for the purpose of determining a patient's risk for a particular disease. Other examples of device functions include use of an accelerometer for measuring tremors for early detection of Parkinson's disease or for measuring progression of other neurological disorders.

Although most physiological signal acquisition systems are intended to monitor physiological 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 physiological 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.

(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 medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines). FDA interprets this to include software functions that display, analyze, or print patient-specific information, such as demographic information, symptoms, test results, medical device outputs (such as heart rate or blood pressure), patient discharge summaries, and/or medical information (such as clinical practice guidelines, peer-reviewed clinical studies, textbooks, approved drug or medical device labeling, and government agency recommendations). In general, this is 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. 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. (Software functions that support or provide such recommendations to patients or caregivers – not HCPs –therefore remain in the definition of device.) Such functions are intended to assist HCPs in making patient-specific care decisions. These functions are evidence-based tools that support HCP decision-making when considering treatment options or diagnostic tests for a patient. They do not treat a patient, determine a patient's treatment, or provide a definitive diagnosis of a patient's disease or condition. Instead, these functions collate or develop recommendations based on an analysis of patient-specific information to an HCP, who may then use this information to make a decision about the care of a patient (e.g., treatment), along with other information and factors of which the HCP is aware. Examples of such recommendations include software that suggests possible diagnoses and recommends treatment plans or diagnostic tests based on patient-specific information that when combined with other information the intended HCP would generally use, would inform the HCP's decision regarding the prevention, diagnosis, or treatment of a patient's disease or condition.

Software functions intended to support or provide recommendations align with the IMDRF Framework category of SaMD functions that inform clinical management. (See Section VI for discussion of the IMDRF Framework.)

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. (See Section VII.A for additional examples.)

(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

Section 520(o)(1)(E)(iii) states that, in order to be excluded from the definition of a device by operation of section 520(o)(1)(E) of the FD&C Act, the CDS 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.

FDA interprets section 520(o)(1)(E)(iii) to mean that manufacturers of Non-Device CDS should describe their software functions in plain language, including:

1) The purpose or intended use of the software function;
2) The intended user (e.g., ultrasound technicians, vascular surgeons);
3) The inputs used to generate the recommendation (e.g., patient age and sex); and
4) The basis for rendering a recommendation.

In order to describe the basis for a recommendation, regardless of the complexity of the software and whether or not it is proprietary, the software developer should describe the underlying data used to develop the algorithm and should include plain language descriptions of the logic or rationale used by an algorithm to render a recommendation. The sources supporting the recommendation or the sources underlying the basis for the recommendation 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). A practitioner would be unable to independently evaluate the basis of a recommendation, and therefore would be primarily relying upon it, if the recommendation were based on information whose meaning could not be expected to be independently understood by the intended HCP user (e.g., the inputs used to generate the recommendation are not identified).

VI. Application of IMDRF Risk Categorization

FDA intends to apply a risk-based policy to its regulation of Device CDS functions by leveraging the IMDRF Framework.[9] The IMDRF Framework describes two major factors for the risk categorization of a SaMD (Table 2): (A) the significance of information provided by a SaMD to the health care decision, and (B) the state of the health care situation or condition. The IMDRF Framework applies to many more software functions than Device CDS and Non-Device CDS functions, as those terms are used in this guidance. The Framework is explained here, because FDA is using parts of the Framework in its CDS policy.

Table 2. SaMD Categories established in IMDRF Framework

State of health care situation or condition	Significance of information provided by SaMD to health care decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

A. Significance of Information Provided by a SaMD to the Health Care Decision

The risk of a Device CDS function is based, in part, on significance of information provided by that software function. The IMDRF Framework defines three categories of significance of information for a SaMD function: (1) to inform clinical management, (2) to drive clinical management, or (3) to treat or diagnose.

(1) Inform Clinical Management

IMDRF describes the SaMD function to inform clinical management (IMDRF Framework Section 5.1.3) as "the information provided by the SaMD will not trigger an immediate or near-term action:

- To inform of options for treating, diagnosing, preventing, or mitigating a disease or condition.
- To provide clinical information by aggregating relevant information (e.g., disease, condition, drugs, medical devices, population, etc.)."

CDS functions, as defined in this guidance, inform clinical management, because the software functions intended to provide information, such as treatment or diagnostic options or aggregating

[9] The IMDRF framework is available at http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf. This guidance summarizes the IMDRF Framework and explains how it is applied for Device CDS. As explained later, the spectrum of software functions in the IMDRF Framework extends beyond Device CDS. FDA's interpretation of the IMDRF framework and its application to other software functions is outside the scope of this guidance.

clinical information, may support a recommendation to an HCP, patient, or caregiver. Such functions provide information that is not necessary to decision-making for a patient's care.

(2) Drive Clinical Management

IMDRF describes the SaMD function to drive clinical management (IMDRF Framework Section 5.1.2) as follows: "driving clinical management infers that the information provided by the SaMD will be used to aid in treatment, aid in diagnoses, to triage or identify early signs of a disease or condition will be used to guide next diagnostics or next treatment interventions:

- To aid in treatment by providing enhanced support to safe and effective use of medicinal products or a medical device.
- To aid in diagnosis by analyzing relevant information to help predict risk of a disease or condition or as an aid to making a definitive diagnosis.
- To triage or identify early signs of a disease or condition."

SaMD functions that drive clinical management are not CDS, as defined in the Cures Act and used in this guidance, because they go beyond supporting or providing recommendations to an HCP, patient, or caregiver (i.e., they do not meet criterion (3)). Drive functions provide enhanced support beyond simply supporting or providing a recommendation about prevention, diagnosis, or treatment of a disease or condition. Drive functions are relied on to guide next diagnostics or treatment interventions, and therefore are not CDS.

(3) Treat or Diagnose

IMDRF describes the SaMD function to treat or to diagnose (IMDRF Framework Section 5.1.1) as follows: "treating and diagnosing infers that the information provided by the SaMD will be used to take an immediate or near-term action:

- To treat/prevent or mitigate by connecting to other medical devices, medicinal products, general purpose actuators or other means of providing therapy to a human body.
- To diagnose/screen/detect a disease or condition (i.e., using sensors, data, or other information from other hardware or software devices, pertaining to a disease or condition)."

SaMD functions that treat or diagnose are not CDS, as defined in the Cures Act and used in this guidance, because they also go beyond supporting or providing recommendations to an HCP, patient, or caregiver (i.e., they do not meet criterion (3)). Rather, treatment or diagnosis functions provide the actual diagnosis or prompt an immediate or near-term action – functions that are well beyond the scope of supporting or providing recommendations.

B. State of the Health Care Situation or Condition

The risk of a Device CDS function also is based, in part, on the state of the health care situation or condition for which it is intended. The IMDRF Framework defines three categories for the state of the health care situation or condition: (1) non-serious, (2) serious, or (3) critical.

(1) Non-Serious Situations or Conditions

IMDRF defines non-serious situations or conditions (IMDRF Framework Section 5.2.3) as "situations or conditions where an accurate diagnosis and treatment is important but not critical for interventions to mitigate long term irreversible consequences on an individual patient's health condition or public health." Non-serious situations or conditions may also include situations or conditions where:

- An accurate and timely diagnosis, or timely treatment action or intervention is important, but not critical to prevent or mitigate long-term irreversible consequences on an individual patient's health condition, which may include short-lived or self-limiting disease processes, or temporary injury or impairment not requiring professional medical intervention (e.g., mild to moderate seasonal allergy symptoms); or
- An accurate and timely diagnosis, or timely treatment action or intervention is important, but not critical to mitigate long-term irreversible public health consequences.

(2) Serious Situations or Conditions

IMDRF defines serious situations or conditions (IMDRF Framework Section 5.2.2) as "situations or conditions where accurate diagnosis or treatment is of vital importance to avoid unnecessary interventions (e.g., biopsy) or timely interventions are important to mitigate long term irreversible consequences on an individual patient's health condition or public health." Serious situations or conditions may include situations or conditions where:

- Accurate and timely diagnosis, or timely treatment action or intervention is of importance to avoid unnecessary major interventions (e.g., biopsy, surgery); or
- Accurate and timely diagnosis, or timely treatment action or intervention is of importance to prevent or mitigate persistent or recurrent disease processes that have a substantial impact on day-to-day functioning; or
- Accurate and timely diagnosis, or timely treatment action or intervention is of importance to prevent progression of disease processes that have the potential to be substantially disabling or may result in injury or impairment requiring professional medical intervention to mitigate long-term irreversible consequences on an individual patient's health condition; or
- Accurate and timely diagnosis, or timely treatment action or intervention is of importance to mitigate long-term irreversible public health consequences.

(3) Critical Situations or Conditions

IMDRF defines critical situations or conditions (IMDRF Framework Section 5.2.1) as "situations or conditions where accurate and/or timely diagnosis or treatment action is vital to avoid death, long-term disability or other serious deterioration of health of an individual patient or to mitigating impact to public health." Critical situations or conditions may include situations or conditions where:

- Accurate and timely diagnosis, or timely treatment action or intervention is vital to avoid death, permanent impairment, life-threatening injury, or other serious deterioration of health (e.g., paralysis) for an individual patient;

- Accurate and timely diagnosis, or timely treatment action or intervention is vital to mitigate a serious impact to public health (e.g., Ebola); or
- The intended target population is fragile with respect to the disease or condition (e.g., pediatrics, high risk populations, etc.).

Also included are situations or conditions in which inaccurate or misinterpreted diagnoses or treatment recommendations are likely to:

- Result in death, permanent impairment, life-threatening injury, or other serious deterioration of health for an individual patient (e.g., misdiagnosis of stroke); or
- Seriously or negatively impact public health for a pandemic or epidemiology situation (e.g., failure to recognize/diagnose Ebola).

C. Policy for Device CDS Functions

Using the IMDRF risk categorizations described above, FDA intends to apply a risk-based policy to its regulation of Device CDS functions. For two types of low risk Device CDS, informed by our current understanding of the risks of these devices, FDA does not intend at this time to enforce applicable device requirements.

As described in Section V.3 above, CDS software functions intended for the purpose of supporting or providing recommendations to patients or caregivers – not HCPs – to prevent, diagnose, or treat a disease or condition are still devices, because the Cures Act excludes only certain CDS functions intended for HCPs from the device definition. FDA considers such Device CDS functions, which are intended for patients or caregivers to inform clinical management for non-serious health care situations or conditions (i.e., inform x non-serious), to be low risk when the CDS function is intended for a patient or caregiver using the device to be able to independently review the basis for its recommendations. The software manufacturer should provide information to the patient about the inputs and basis of the recommendations made by the software, as described in Section V.4. Because these Device CDS functions are low risk, based on our current understanding of these devices, FDA does not intend at this time to enforce compliance with applicable device requirements of the FD&C Act for them. The recommendation for the type of decision to prevent, diagnose, or treat should be the type of decision a patient or caregiver would routinely make without the input of a health care professional, and the data used by the CDS function and the basis for its recommendations would be of a kind that patients or caregivers understand.

Device CDS functions also include functions intended for HCPs that do not meet criterion (4) of section 520(o)(1)(E) of the FD&C Act because they are not intended for the HCP to be able to independently review the basis for its recommendation, and therefore an HCP would primarily rely upon it. FDA also considers this category of Device CDS functions (i.e., inform x non-serious) to be low risk. Therefore, if an "inform x non-serious" CDS function that is intended for HCPs is not intended for the HCP to be able to independently review the basis for its recommendations, then based on our current understanding of these devices, FDA does not intend at this time to enforce compliance with the applicable device requirements of the FD&C Act.

FDA intends to focus its regulatory oversight on higher risk Device CDS software functions: Device CDS functions intended for patients, caregivers, or HCPs that inform clinical management for serious and critical health care situations or conditions. In Section VII.D, FDA also describes device software functions that are not CDS and on which FDA also intends to focus its regulatory oversight.

FDA encourages developers of CDS software functions that are not medical devices or are medical devices for which at this time FDA does not intend to enforce compliance with FD&C Act requirements to implement a quality system consistent with IMDRF's Software as a Medical Device (SaMD): Application of Quality Management System[10] and to apply good cyber hygiene, such as through software design and cyber vigilance, consistent with applicable FDA guidance.[11]

Table 3 summarizes FDA's approach to its regulation of CDS software functions. Those functions that are the focus of FDA's oversight are marked as "Oversight Focus," while those for which at this time FDA does not intend to enforce compliance with applicable device requirements based on our current understanding of the risks of these devices are marked as "Enforcement Discretion." Non-Device CDS functions are marked as "Not a Device."

Table 3. Summary of Regulatory Policy for CDS Software Functions

		Intended User is HCP		**Intended User is Patient or Caregiver**
IMDRF Risk Categorization	**Can the User Independently Review the Basis?***	**FDA Regulation**		**FDA Regulation**
Inform x Critical	Yes	Not a Device		Oversight Focus
	No	Oversight Focus		Oversight Focus
Inform x Serious	Yes	Not a Device		Oversight Focus
	No	Oversight Focus		Oversight Focus
Inform x Non-Serious	Yes	Not a Device		Enforcement Discretion**
	No	Enforcement Discretion**		Oversight Focus

[10] Available at http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-151002-samd-qms.pdf.

[11] Applicable guidance documents may include: General Principles of Software Validation (available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-principles-software-validation); Cybersecurity for Networked Medical Devices Containing Off-the-Shelf Software (available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-networked-medical-devices-containing-shelf-ots-software); Postmarket Management of Cybersecurity in Medical Devices (available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-management-cybersecurity-medical-devices); or Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices (available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-and-pre-market-submission-recommendations-interoperable-medical-devices).

* "Can the User Independently Review the Basis?" asks whether the function is intended for the purpose of enabling the user to independently review the basis for the recommendations so that it is not the intent that user relies primarily on any such recommendation (part of criterion (4)).
** "Enforcement Discretion" indicates that, based on our current understanding of the risks of these devices, FDA does not intend at this time to enforce compliance with applicable device requirements.

VII. Examples

The following sections describe examples of CDS software functions that are not devices (VII.A), Device CDS functions that remain devices for which, based on our current understanding of the risks of these devices, 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 premarket approval requirements (VII.B), and Device CDS functions that remain devices and on which FDA intends to focus its regulatory oversight (VII.C). These examples apply section 520(o)(1)(E) criteria and the IMDRF risk categorization to evaluate whether the software function is not a device, is a function for which FDA does not intend to enforce compliance with applicable requirements at this time, or is a function on which FDA intends to focus its regulatory oversight. Note that while a particular health care situation or condition may be described as "critical," "serious," or "non-serious" for a particular example of a software function, it may be considered differently for another software function given the context of use. Section VII.D provides examples of device software functions that are not CDS and on which FDA intends to focus its regulatory oversight.

A. Examples of Non-Device CDS Functions

Below are examples of CDS functions that do not meet the definition of device in section 201(h), as amended by the Cures Act, because they meet all four criteria described in section 520(o)(1)(E). Provided that the CDS function meets the criteria described in section 520(o)(1)(E) of the FD&C Act, as described in Section V of this guidance, the function is Non-Device CDS regardless of the healthcare situation or condition (i.e., "critical," "serious," or "non-serious").

- Software that provides recommendations to HCPs by matching patient-specific information (e.g., diagnosis, treatments, allergies, signs or symptoms) to reference information the medical community routinely uses in clinical practice (e.g., practice guidelines) to facilitate assessments of specific patients. The software explains that the basis of the recommendation is developed from authoritative medical sources, as recognized by the field or discipline that is the subject of the software and provides or cites those materials. Examples include:
    - Software that uses a patient's diagnosis to provide an HCP with current practice treatment guidelines for common illnesses or conditions such as influenza, and provides the source of the guidelines; and
    - Software that helps to identify drug-drug interaction and drug-allergy contraindications, based on the current version of FDA-approved drug or medical device labeling or other up-to-date and reliable sources and patient-specific information, to attempt to prevent adverse drug events.

- Software that provides HCPs with recommendations on the use of a prescription drug[12] that are consistent with the FDA-required labeling.[13,14] The software describes that the recommendations are based on FDA-required labeling, such that the HCP does not rely primarily on the software's recommendation.

- Software that provides HCPs with recommendations on the use of a medical device that are consistent with the FDA-required labeling or that are described in other sources, such as those identified in the definition of CDS, such that the HCP does not rely primarily on the software's recommendation.

- Software that suggests an intervention or test, consistent with clinical guidelines and/or drug labeling, based on or in response to a physician's order, such as, for example, software suggesting that an HCP order G6PD deficiency tests before starting an antimalarial. The software describes the inputs and basis for the recommendations – i.e., the physician's order for medication, drug labeling, and clinical guidelines – that are made available to the HCP or cited by the software, such that the HCP does not rely primarily on the software's recommendation.

- Software that makes chemotherapeutic suggestions to an HCP based on patient history, test results, and patient characteristics, including, for example, software suggesting a FDA-approved chemotherapy for BRCA-positive individuals, that is consistent with clinical guidelines and/or the drug labeling, which are described as the basis for the recommendation and provided for the HCP to review, based on available information in the patient's electronic health record, such that the HCP does not rely primarily on the software's recommendation.

- Software that compares patient signs, symptoms, or results with available practice guidelines (institutions-based or academic/clinical society-based) to recommend condition-specific diagnostic tests, investigations, or therapy. The practice guidelines are described as the basis for the recommendation and provided for the HCP to review, such that the HCP does not rely primarily on the software's recommendation.

- Software that contains tools, calculators, guidelines, and protocols for ordering total parenteral nutrition (TPN), enteral nutrition, or other alimentation procedures. This would include, for example, software recommending increased protein in TPN for patients with active infection, consistent with generally accepted clinical practice, which is described

[12] 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)).

[13] Drug labeling includes prescribing information (also referred to as package insert or physician labeling); patient labeling, including patient package inserts and Medication Guides; the Drug Facts Label; the product's immediate container label; outer container; the outside package; and other written, printed, or graphic information that accompanies the product. For more information, see the notice issued by FDA in the Federal Register regarding Prescription Drug-Use-Related Software (83 FR 58574).

[14] 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.

as the basis for the recommendation and provided for the HCP to review, such that the HCP does not rely primarily on the software's recommendation.

- Software that provides HCPs with a report based on arterial blood gas results that includes a calculated anion gap and recommends whether the patient has high anion gap metabolic acidosis and possible next steps, based on practice guidelines, which are described as the basis for the recommendation and provided for the HCP to review, such that the HCP does not rely primarily on the software's recommendation.
- Software that presents and prioritizes alternatives to the HCP's orders, drugs, or therapies using practice guidelines and other generally accepted practices, such as rule-based tools allowing HCPs to efficiently select diagnostic tests, drugs, devices, or therapies in accordance with clinical practice guidelines, peer-reviewed clinical studies, textbooks, or other appropriate sources, and their approved or cleared labeling. The software describes the logic for the rule-based tools and provides or cites the sources, such that the HCP does not rely primarily on the software's recommendation.
    - A specific example is software that uses data from a ventilator to facilitate patient status assessments by the clinician based on hospital practice guidelines or clinical literature.
- Software intended for use by HCPs to provide options for diagnosing patients suspected to have diabetes mellitus. The HCP enters patient parameters and laboratory test results (e.g., fasting plasma glucose, oral glucose tolerance test results, and/or hemoglobin A1c test results), and the device suggests whether the patient's condition meets the definition of diabetes based on established guidelines, which are described as the basis for the recommendation and provided for the HCP to review, such that the HCP does not rely primarily on the software's recommendation.
- Software tools that analyze a patient's stored clinical information based on specific clinical parameters to make recommendations to an HCP for opportunities for complementary tests, and the basis for the recommendation is provided so that the HCP does not rely primarily on the recommendation.
- Software that allows for simple and detailed calculation of the volume of intravenous fluids estimated for the patient based on the total surface area of burns and the Parkland formula, which is described as the basis for the recommendation, so that the HCP does not rely primarily on the recommendation.

B. Examples of Device CDS for which, based on our current understanding of the risks of these devices, FDA does not intend at this time to enforce compliance with applicable device requirements

(1) Device CDS intended for HCPs

Based on our current understanding of the risks of these devices, FDA does not intend at this time to enforce compliance with applicable requirements of the FD&C Act for Device CDS

software functions intended for HCPs that (using the IMDRF Framework) are intended to "inform clinical management" for "non-serious situations or conditions."

- Software that provides recommendations of potential allergens and common cold symptoms based on location-specific electronic health records, environmental conditions, and patient-reported outcomes to provide the HCP with options for different diagnoses (e.g., seasonal allergic rhinitis vs. common cold). This software is a Device CDS function, because the HCP is not intended to be able to independently evaluate the basis for the software's recommendations. At this time, FDA does not intend to enforce compliance with applicable requirements of the FD&C Act for this Device CDS, because it is an aggregation of data intended to provide clinical information for a non-serious situation or condition (i.e., "inform x non-serious").
- Machine-learning algorithm, for which the logic and inputs are not explained, that trends and classifies patient-specific data (e.g., blood test results, weight) to alert HCPs to potential triggers that may be indicative of cholesterol management issues. At this time, FDA does not intend to enforce compliance with applicable requirements of the FD&C Act for this Device CDS, because it is an aggregation of data intended to provide clinical information for a non-serious situation or condition (i.e., "inform x non-serious").
- Software intended for HCPs where the basis for the recommendation is not disclosed to the user to analyze patient information to determine which over-the-counter (OTC) allergy drug class is likely to be most effective in alleviating the patient's seasonal allergies. This software is a Device CDS function, because the HCP is not intended to be able to independently evaluate the basis for the recommendation. At this time, FDA does not intend to enforce compliance with applicable requirements of the FD&C Act for this Device CDS, because it provides treatment options for a non-serious situation or condition (i.e., "inform x non-serious").

(2) Device CDS intended for patients

Based on our current understanding of the risks of these devices, FDA does not intend at this time to enforce compliance with applicable requirements of the FD&C Act for Device CDS software functions intended for patients that (using the IMDRF Framework) are intended to "inform clinical management" for "non-serious situations or conditions" and that, in addition, are intended for the patient to be able to independently evaluate the basis for the software's recommendations.

- Software that provides information to a patient about the use of a prescription drug that is consistent with the FDA-required labeling15 and the patient's prescription, such as reminding the patient how or when to take a prescribed drug. Such software does not recommend changes in dose or drug discontinuation that HCPs do not oversee (unless drug labeling includes such recommendations). This software is Device CDS, because it is intended for a patient. At this time, FDA does not intend to enforce compliance with

[15] 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).

applicable requirements of the FD&C Act for this software function, because it is an aggregation of data intended to provide clinical information for a non-serious situation or condition (i.e., "inform x non-serious") and because the basis for the recommendation (FDA-required labeling) is described to the user, so that the software is intended for the patient to be able to independently evaluate the basis for the software's recommendations.

- Software that assists a patient in identifying OTC cold or allergy medications to consider purchasing based on symptoms. For example, once a patient or non-HCP caregiver inputs the symptoms of the person needing a cold or allergy medication, the software provides a prioritized list of OTC medications that match the person's symptoms. In this example, inclusion of appropriate warnings about products with overlapping active ingredients (e.g., multiple products containing acetaminophen) would be an important mechanism to prevent risks to patients that might arise from using this software. This software is Device CDS, because it is intended for a patient. At this time, FDA does not intend to enforce compliance with applicable requirements of the FD&C Act for this software function, because it is intended to provide options for the treatment of a non-serious situation or condition (i.e., "inform x non-serious") and because it is intended for the patient to be able to independently evaluate the basis for the software's recommendations.16

- Software that provides information or general instructions to patients or non-HCP caregivers that are not specific to any drug, biological product, or medical device labeling, such as general pre- and post-surgical care preparation and instructions. This software is Device CDS, because it is intended for a patient. At this time, FDA does not intend to enforce compliance with applicable requirements of the FD&C Act for this software function because it is an aggregation of data intended to provide clinical information for a non-serious situation (i.e., "inform x non-serious") and because it is intended for the patient to be able to independently evaluate the basis for the software's recommendations.17

- Software that assists patients with choosing OTC sunscreen (based on use, time, ingredients, etc.), as well as best practices for selection and application to prevent sunburn. This software is Device CDS, because it is intended for a patient. At this time, FDA does not intend to enforce compliance with applicable requirements of the FD&C Act for this software function, because it is an aggregation of data intended to provide clinical information for a non-serious situation or condition (i.e., "inform x non-serious") and because it is intended for the patient to be able to independently evaluate the basis for the software's recommendations.[18]

[16] Such information sources (identified by the software) may include FDA-approved labeling or DailyMed for drug labeling.

[17] Such information sources (identified by the software) may aggregate general instructions and recommendations from the National Institutes of Health (NIH), the Agency for Healthcare Research and Quality (AHRQ), among others.

[18] Sources (identified by the software) may include information from OTC sunscreen from multiple manufacturers and recommendations by clinical practice guidelines, for example.

C. Device CDS on which FDA intends to focus its regulatory oversight

(1) Device CDS intended for HCPs

FDA intends to focus its regulatory oversight on Device CDS functions intended for HCPs that are intended (using the IMDRF Framework) to "inform clinical management" for "serious or critical situations or conditions" and that, in addition, are not intended for the HCP to be able to independently evaluate the basis for the software's recommendations.

- Machine-learning algorithm, for which the logic and inputs are not explained, that categorizes likely symptoms of seasonal influenza for each flu season based on location and current electronic health records of patients diagnosed or suspected to have influenza to assist HCPs in differentiating between common flu symptoms and other illnesses (e.g., common cold) in a particular season. This software is a Device CDS function, because the HCP is not expected to be able to independently evaluate the basis for the software's recommendations. FDA intends to focus its regulatory oversight on this software, because it is intended to inform clinical management for a serious situation or condition.
    - Note: If the HCP could evaluate the basis for the software's recommendations, because the logic and inputs for the machine-learning algorithm and data inputs used for the algorithm were explained and available to the HCP, then this software would be considered Non-Device CDS (Section VII.A).
- Software, for which the inputs are not explained, that identifies patients who may exhibit signs of opioid addiction based on patient-specific data, family history, electronic health records data, prescription patterns, and geographical data. This software is a Device CDS function, because the HCP is not expected to be able to independently evaluate the basis for the software's recommendations. FDA intends to focus its regulatory oversight on this software, because it is intended to inform clinical management for a critical situation or condition.
- Machine learning algorithm, for which the logic and inputs are not explained, that identifies hospitalized, type 1 diabetic patients at increased risk of postoperative cardiovascular events. This software is a Device CDS function, because the HCP is not expected to be able to independently evaluate the basis for the software's recommendations. FDA intends to focus its regulatory oversight on this software, because it is intended to inform clinical management for a critical situation or condition.
    - Note: If the HCP could evaluate the basis for the software's recommendations, because the logic and data inputs for the machine learning algorithm and criteria for risk of cardiovascular events were explained and available to the HCP, then this software would be considered Non-Device CDS (Section VII.A).

(2) Device CDS intended for patients

FDA intends to focus its regulatory oversight on Device CDS functions intended for patients that (using the IMDRF framework) are intended to "inform clinical management" for a "non-serious situation or condition" and that, in addition, are not intended for the patient to be able to independently evaluate the basis for the software's recommendations. FDA also intends to focus

its regulatory oversight on Device CDS functions intended for patients that are intended to "inform clinical management" for "a serious or critical situation or condition," whether or not the software is intended for the patient to be able to independently evaluate the basis for the software's recommendations.

- Software that aggregates data from continuous glucose monitoring, activity trackers, and food logs to help insulin-dependent type 2 diabetic patients identify potential lifestyle triggers for hypoglycemic events and recommends corrective treatment options (e.g., timing of insulin dosing). This software is a Device CDS function, because it is intended for patients and to inform clinical management. FDA intends to focus its regulatory oversight on this software, because it is intended to inform clinical management for a serious situation or condition.
- Software intended for patients that provides a questionnaire to assess a patient's level of stress and anxiety (prior to any diagnosis of general anxiety disorder) and recommends treatment options based on the output of the assessment. This software is a Device CDS function, because it is intended for patients and to inform clinical management. FDA intends to focus its regulatory oversight on this software, because it is intended to inform clinical management for a non-serious situation or condition, but the patient is not expected to be able to independently evaluate the basis for the software's recommendations.
    - Note: If the patient could understand the software's recommendation, for example, if the software provided the basis of the recommendation that is understandable to the patient of how the questionnaire assesses stress and anxiety, and how the recommendation is based on peer-reviewed publications and/or clinical practice guidelines and the patient's answers, then this software would be considered Device CDS, but for which, based on our current understanding of the risks of these devices, FDA does not intend at this time to enforce compliance with applicable device requirements (Section VII.B.2).
- A software function that provides recommendations to caregivers of pediatric patients with cystic fibrosis by aggregating information on when they should bring such children to the emergency room, based on patient-specific symptoms and care guidelines. This software is a Device CDS function, because it is intended for caregivers and to inform clinical management. FDA intends to focus its regulatory oversight on this software, because it is intended to inform clinical management for a critical situation or condition, because the target population is fragile with respect to the disease or condition.

D. Examples of device software functions that are not CDS on which FDA intends to focus its regulatory oversight

FDA intends to focus its regulatory oversight on device functions that do not meet the definition of Device CDS, as defined by the Cures Act and used in this guidance, but are devices.

- Software 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, because this software is intended to analyze a medical image and to generate the treatment plan, which is intended to guide the next treatment intervention.

- Software that manipulates or analyzes images and other data obtained from a radiological device (e.g., CT, bone density, and distance) 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, because this software is intended to analyze a medical image and to generate the models for planning treatment.

- Software 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 lung tissue; and placement of markers into soft lung tissue to guide radiosurgery and thoracic surgery. This software is a device function, because it is intended to analyze a medical image and to guide surgery.

- Software that helps create custom implants and/or instrumentation based on analysis of imaging and device characteristics for orthopedic or dental implant procedures. This software is a device function, because it is intended to analyze a medical image and to guide treatment through the design of custom implants.

- Software that analyzes multiple physiological signals (e.g., sweat, heart rate, eye movement, breathing – from FDA-regulated devices) to monitor whether a person is having a heart attack or narcolepsy episode. The software is a device function, because it is intended to analyze medical signals and to aid in diagnosis.

- Software that analyzes near-infrared camera signals of a patient intended for use in determining and/or diagnosing brain hematoma. The software is a device function, because it is intended to analyze a medical signal and to aid in diagnosis.

- Software that calculates the fractal dimension of a lesion and surrounding skin image and builds a structural map to provide diagnosis or identify whether the lesion is malignant or benign. This software is a device function, because it is intended to analyze a medical image and to diagnose a disease or condition.

- Software that analyzes CT images to compute and/or approximate fractional flow reserve. In this case, the software performs and provides the HCP an image analysis that the HCP could not independently derive. 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, because it is intended to analyze a medical image and to aid in diagnosis of a disease or condition.

- Software that is intended to perform image analysis for diagnostically differentiating between ischemic and hemorrhagic stroke. In this case, the software performs and provides the HCP an image analysis that the HCP could not independently derive. This software is a device function, because it is intended to analyze a medical image and to aid in diagnosis of a disease or condition.

- Software that analyzes signals from an FDA-cleared trans-abdominal electromyography device and an FDA-cleared fetal heart rate, intrauterine pressure catheter intended to determine a C-section intervention for an "at term" pregnant woman. This software is a device function, because it is intended to analyze a medical signal and to aid in treatment of a disease or condition.

- 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, because it is intended to analyze a medical signal and to diagnose a disease or condition.

- Software intended to generate an alarm or an alert to notify a caregiver of a life-threatening condition, such as stroke, and the caregiver relies primarily on this alarm or alert to make a treatment decision. This software is a device function, because it is intended to analyze a medical signal and to aid in treatment of a disease or condition.
    - Note the following low-risk example, which is also a device function but not Device CDS, and for which, based on our current understanding of the risks of these devices, FDA does not intend at this time to enforce compliance with the applicable requirements of the FD&C Act: Software intended to analyze or interpret laboratory test or other device data and results to flag patient results based on specific clinical parameters (e.g., out of range test results where the reference ranges are predetermined by the lab) provided that the analysis performed by these software is not intended for immediate clinical action and does not represent a unique interpretation function but rather summarizes standard interpretation of individual variables that healthcare practitioners could do themselves. This software is a device function, because it is intended to analyze a medical signal. However, in accordance with current practice, FDA does not intend to enforce compliance with the applicable device requirements of the FD&C Act for this flag/notification software function, because it is low risk. The example immediately above of an alarm or an alert that a caregiver relies on to make a treatment decision remains the focus of FDA's regulatory oversight, because it is high risk.
- Software function that provides a characterization of a patient's abnormality based on its size, shape, appearance, or other functional aspects visible in the image. This software is a device function, because it is intended to analyze a medical image and to aid in diagnosis of a disease or condition.
- Software that detects and highlights abnormalities (Computer-Assisted Detection, CADe) and assesses associated disease severity (Computer-Assisted Diagnosis, CADx). This software is a device function, because it is intended to analyze a medical image and to aid in diagnosis of a disease or condition.
- Software that analyzes sound waves captured when users recite certain sentences to diagnose bronchitis or sinus infection. This software is a device function, because it is intended to analyze a medical signal and to diagnose a disease or condition.

- Software that analyzes breathing patterns from a sleep apnea monitor to diagnose sleep apnea or other conditions in patients. This software is a device function, because it is intended to analyze a medical signal and to diagnose a disease or condition.

- Software that analyzes images of body fluid preparations or digital slides (digital pathology) to perform cell counts and morphology reviews. This software is a device function, because it is intended to analyze a medical image.

- Software that helps diabetic patients by calculating bolus insulin dose based on carbohydrate intake, pre-meal blood glucose, and anticipated physical activity reported to adjust carbohydrate ratio and basal insulin. This software is a device function, because it is intended to aid in treatment of a disease or condition.

- Bioinformatics software products used to process high volume "omics" data (e.g., genomics, proteomics, metabolomics) process a signal from an in vitro diagnostic (IVD) and are generally not considered to be CDS. Software products that provide patient-specific information based on "omics" data often drive diagnostic and treatment decisions. These software products are device functions, because they are intended to aid in treatment of a disease or condition and because they process a signal from an IVD.

- Bioinformatics software products that query multiple genetic variants against reference databases or other information sources to make patient-specific recommendations about the significance of a patient's variants are devices, because the HCP is not expected to be able to independently evaluate the basis for the software's recommendations. The information excluded in the process of making an assertion about a genetic variant is not provided to the user; therefore, the user cannot verify that the determination to exclude such information was appropriate. These software products are device functions, because they are intended to aid in treatment of a disease or condition and because the HCP is not expected to be able to independently evaluate the basis for the software products' recommendations.

VIII. Conforming Changes to Existing Guidance

Once this guidance is finalized, FDA intends to make conforming edits to the FDA Guidance Policy for Device Software Functions and Mobile Medical Applications[19] to make it consistent with the interpretations and policies in this guidance. For example, software functions that use patient characteristics such as age, sex, and behavioral risk factors to provide patient-specific screening, counseling, and preventative recommendations from well-known and established authorities (listed in Appendix B of the guidance) are not devices.

[19] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications.