Clinical Decision Support Software, Final Guidance
March 11, 2026

Moderator: CAPT Kim Piermatteo
Presenters: Danielle Faruq and Aneesh Deoras

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CAPT Kim Piermatteo: Hello and welcome to this CDRH town hall. This is CAPT Kim Piermatteo of the United States Public Health Service, and I serve as the Education Program Administrator in the Division of Industry and Consumer Education within FDA's Center for Devices and Radiological Health. I'll be the moderator for today's event.

Today we will be discussing the update to the final guidance titled, Clinical Decision Support Software, issued on January 6, 2026 and re-issued on January 29, 2026. This guidance clarifies the FDA's thinking on the types of clinical decision support, or CDS, software functions that are excluded from the definition of a device by the criteria in section 520(o)(1)(E) of the Food, Drug and Cosmetic Act.

I'd now like to introduce our presenters from CDRH's Digital Health Center of Excellence, Danielle Faruq**,** Digital Health Specialist in the Division of Digital Health Policy, and Aneesh Deoras, Acting Division Director in the Division of Digital Health Technology Assessment.

We'll begin with a presentation from Danielle and Aneesh and then discuss some frequently asked questions regarding this final guidance.

Before I turn it over to Danielle to get us started, I'd like to remind everyone, the intended audience for this event is industry. National media and press members are encouraged to submit their questions through the FDA Newsroom at www.fda.gov/news-events/fda-newsroom.

Thank you all again for joining us. I'll now turn it over to Danielle.

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Danielle Faruq: Thank you Kim and thanks everyone for joining us today to learn more about the Clinical Decision Support Software final guidance.

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Danielle Faruq: This guidance document is available online on FDA's website as well as on regulations.gov under docket number FDA-2017-D-6569.

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Danielle Faruq: Our learning objectives today include briefly describing the 21st Century Cures Act and the history of the Clinical Decision Support Software final guidance. We'll also be explaining FDA's current thinking on clinical decision support, or CDS, including clarification on our interpretation of the criteria in section 520(o)(1)(E) of the Food, Drug and Cosmetic Act, or FD&C Act, for non-device CDS software functions. Then we'll describe FDA's Enforcement Discretion Policy for software functions that provide one clinically appropriate output and otherwise meet all other criteria in section 520(o)(1)(E) and give

examples of such functions. Finally, we'll give examples of non-device CDS software functions and CDS software functions that meet the device definition.

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Danielle Faruq: So let's start with learning objective number one.

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Danielle Faruq: As a reminder, in December 2016, the 21st Century Cures Act amended the definition of device in the FD&C Act to exclude certain software functions from the device definition. These software functions are described in section 520(o) of the FD&C Act and include five different categories of software functions, including clinical decision support.

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Danielle Faruq: The Clinical Decision Support Software guidance itself has gone through several iterations since the 21st Century Cures Act amended the device definition to exclude certain clinical decision support software functions from the device definition. Most recently, in January 2026, FDA issued a final guidance with updates, which are the topic of today's program.

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Danielle Faruq: So let's jump into the second learning objective.

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Danielle Faruq: This slide includes the four criteria that must be met for a software function to be considered non-device CDS software. Stated simply, these criteria describe the types of CDS that are not regulated as devices. It is important to note that these statutory criteria have not changed as part of updates to the guidance. We'll be talking about each of the individual criterion and clarifications we've made on our interpretation of these criteria next.

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Danielle Faruq: As described in criterion one, non-device CDS software functions do not acquire, process, or analyze medical images or signals from an in vitro diagnostic device, or IVD, or patterns or signals from a signal acquisition system. In our final guidance update, we've clarified our interpretation of the terms "signal acquisition system" and "pattern."

For signal acquisition system, we've clarified that such a system is one that measures a parameter from within, attached to, or external to the body for a medical purpose, for example, through continuous, near-continuous, or otherwise streaming measurement.

A pattern is multiple, sequential, or repeated, measurements of a signal or from a signal acquisition system. In our final guidance update, we've clarified that, by contrast, discrete, episodic, or intermittent point-in-time physiological measurements, for example, routine vital signs obtained at discrete clinical encounters, generally do not, by themselves, constitute a pattern. Again, the updates we've made do not fundamentally change our understanding of the criterion itself.

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Danielle Faruq: As a reminder, FDA considers software functions that assess or interpret the clinical implications or relevance of a signal, pattern, or medical image to be software functions that do not meet criterion one. So for example, a software function that's processing or analyzing an ECG waveform or

QRS complex, which can be a continuous, near-continuous, or otherwise streaming measurement, and measuring repeated complexes or detecting heart rate arrhythmias, are the kinds of signal processing and analyzing that do not meet criterion one.

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Danielle Faruq: As described in criterion two, non-device CDS functions are intended to display, analyze, or print medical information about a patient or other medical information. The CDS final guidance explains that, in other words, if medical information is used as an input, then the software function is not a device so long as it meets the other three criteria. The CDS final guidance explains that such medical information includes patient-specific information, such as demographic information, symptoms, certain test results, or 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.

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Danielle Faruq: In our final guidance, we've made updates to clarify how we interpret the term "medical information." Medical information is the type of information used in, or that relates to, the clinical care of the patient, including patient-specific information. It may generally be communicated between healthcare providers, or HCPs, in a clinical conversation or between HCPs and patients in the context of a clinical decision. However, 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 two, provided the information's relevance to patient care is supported by well-understood and accepted sources and can be appropriately understood in context.

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Danielle Faruq: So now let's jump into criterion three. Specifically, criterion three states that software functions must be intended for the purpose of supporting or providing recommendations to an HCP about prevention, diagnosis, or treatment of a disease or condition. So when thinking about what it means when a software function is supporting or providing recommendations, FDA interprets criterion three to refer to software that is intended for an HCP and that provides condition, disease, or patient-specific information and options to an HCP to enhance, inform, and/or influence a health care decision, but does not provide a specific preventive, diagnostic, or treatment output or directive and is not intended to replace the HCP's judgement.

Software functions that provide the following outputs would meet criterion three, as long as they were not intended to replace or direct the HCP's judgment. The first is a list of preventive, diagnostic, or treatment options to the HCP, or a prioritized list of preventive, diagnostic, or treatment options to the HCP, or finally a list of follow-up or next-step options for the HCP to consider.

While our interpretation that software that is not intended to support time-critical decision-making has been removed from criterion three, it is still a consideration when deciding whether a software function meets criterion four, which we'll go over when we discuss that criterion next.

As part of the updates in this final guidance, we communicate an enforcement discretion policy for software functions that fail criterion three because they provide a specific preventive, diagnostic, or treatment output or directive, but for which only one clinically appropriate recommendation exists and the software 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. We will describe this enforcement discretion policy in more detail later in our presentation.

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Danielle Faruq: So now let's discuss criterion four, which states that software functions must be intended for the purpose of enabling an HCP to independently review the basis for the recommendations that such software presents so that the HCP does not rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

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Danielle Faruq: When thinking about how to satisfy criterion four to enable independent review, we've included software and labeling recommendations in the guidance. Sponsors may use alternative approaches as long as the approach enables an HCP to independently review the basis for the recommendations so that they don't rely primarily on such recommendations.

These recommendations have not fundamentally changed as part of the updates, though we do communicate additional recommendations that the software or associated labeling should provide adequate background information about underlying sources in plain language. Furthermore, we recommend that information that enables an HCP to independently review the basis of provided recommendations from the software 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.

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Danielle Faruq: We have also clarified that, in determining whether a software function meets criterion four, FDA considers both the level of automation and 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.

As we discussed in the clarification of our interpretation of criterion three, the time-critical nature of the HCP's decision making is now only a consideration for criterion four. The updated final guidance also clarifies that automation bias is the propensity of humans to over-rely on a suggestion from an automated system. In the context of CDS, automation bias can result in errors of commission, following incorrect advice, or omission, failing to act because of not being prompted to do so.

In situations that require urgent action, automation bias increases because there is not sufficient time for the user to adequately consider other information. This understanding of automation bias informs FDA's interpretation that non-device CDS software functions allow an HCP to independently review the basis for the recommendations presented by the software so that they, again, do not rely primarily on such recommendations.

I will now pass it off to Aneesh to speak to learning objectives three and four.

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Aneesh Deoras: Thank you Danielle.

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Aneesh Deoras: We'd now like to shift to talking about our third learning objective.

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Aneesh Deoras: As a reminder, FDA interprets criterion three to refer to software that provides condition-, disease-, and/or patient-specific recommendations to an HCP to enhance, inform and/or influence a

health care decision but is not intended to replace or direct the HCP's judgment. In cases where a software function provides a specific preventive, diagnostic or treatment output or directive, the software function fails criterion three because it is not intended for the purpose of supporting or providing recommendations under section 520(o)(1)(E)(ii).

As Danielle mentioned, if only one recommendation 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. In the updated final guidance, we include examples of software functions that otherwise meet the criteria but provide only one recommendation that's clinically appropriate and are those for which we intend to exercise enforcement discretion, as well as sub-examples that would not be those for which FDA intends to exercise enforcement discretion. We will go through these examples now.

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Aneesh Deoras: First, we have 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. Assuming that this software function meets all criteria except for criterion three, and has one clinically appropriate output, it is a software function for which we intend to exercise enforcement discretion.

However, a software function with the same functionality, but also utilizes variant genomic data as an input that does not have an established relevance to the diagnostic recommendation, would not fall under this example because it fails criterion one and two. Therefore, such a software function is a device software function that would remain the focus of FDA's oversight.

Also, 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 because it fails criterion four. Such a software function is also a device software function that would remain the focus of FDA's oversight.

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Aneesh Deoras: Moving to our next example, we have a software function that creates a recommended treatment plan, including possible medications, 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. Assuming this software function meets all criteria except for criterion three and has one clinically appropriate output, it is a software function for which we intend to exercise enforcement discretion.

However, a software function with the same functionality, but also analyzes positron emission tomography, PET, scan images, would not fall under this example because it fails criterion one. Such a software function is a device software function that would remain the focus of FDA's oversight.

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Aneesh Deoras: Next, we have 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. Assuming this software function meets all criteria except for criterion three and has one clinically appropriate output, it is a software function for which we intend to exercise enforcement discretion.

However, a software function with the same functionality, but also analyzes spectroscopy data to diagnose bacterial infections, would not fall under this example because it fails criterion one. Such a software function is a device software function that would remain the focus of FDA's oversight.

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Aneesh Deoras: Next, we have 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. This software function meets all criteria except for criterion three and has one clinically appropriate output. Therefore, it is a software function for which we intend to exercise enforcement discretion.

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 because it fails criterion one. Such a software function is a device software function that would remain the focus of FDA's oversight.

Also, 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 because it fails criterion two. Again, such a software function is a device software function that would remain the focus of FDA's oversight.

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Aneesh Deoras: Next, we have 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. This software function meets all criteria except for criterion three and has one clinically appropriate output. Therefore, it is a software function for which we intend to exercise enforcement discretion.

However, a software function that establishes a definitive diagnosis based on an analysis of medical images, waveform data, or other signal-level inputs would not fall under this example because it fails criterion one and because it directs an HCP's judgement instead of recommending a differential diagnosis. Such a software function is a device software function that would remain the focus of FDA's oversight.

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Aneesh Deoras: Next, we have a software function that classifies patients with chronic low back pain into a single recommended appropriate clinical care pathway, for example, conservative management or referral to a surgical spine specialist, based on patient history, symptom duration, and documented clinical findings, where the recommendation is intended to be reviewed and acted upon by an HCP. This software function meets all criteria except for criterion three and has one clinically appropriate output. Therefore, it is a software function for which we intend to exercise enforcement discretion.

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 because it fails criterion four. Such a software function is a device software function that would remain the focus of FDA's oversight.

Slide 28

Aneesh Deoras: Next, we have a software function that classifies patients with chronic low back pain into a single recommended appropriate clinical care pathway. For example, conservative management or referral to a surgical spine specialist based on patient history, symptom duration and documented clinical

findings where the recommendation is intended to be reviewed and acted upon by an HCP. This software function meets all criteria except for criterion three and has one clinically appropriate output. Therefore, it is a software function for which we intend to exercise enforcement discretion.

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 because it fails criterion four. Such a software function is a device software function that would remain the focus of FDA's oversight.

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Aneesh Deoras: Finally, we will cover our fourth learning objective to review examples of non-device CDS software functions and CDS software functions that meet the device definition.

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Aneesh Deoras: First, we will review an example that was included in the updated final guidance for non-device CDS software. Please note that the other examples of non-device CDS software in section V.A. of the updated final guidance were not updated or revised. The new example, number 12 in section V.A. of the guidance, is a software function that identifies to an HCP that a patient, consistent with the current version of FDA-approved drug labeling, is within 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. This example meets criterion one, two and three and is non-device CDS, provided that it also meets criterion four.

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Aneesh Deoras: We will now move to examples of device software functions, which are functions that meet the definition of a device and, in the context of section 520(o)(1)(E), that do not meet all four criteria.

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 three is referenced, as discussed previously, if only one option is clinically appropriate and the software function otherwise meets all criteria under section 520(o)(1)(E), then FDA intends to exercise enforcement discretion, meaning that FDA does not intend to enforce requirements under the FD&C Act, for such functions.

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Aneesh Deoras: First, in example number four, we have a software function that analyzes multiple signals, for example, perspiration rate, heart rate, eye movement, breathing rate, from wearable products to monitor whether a person is having a heart attack or narcolepsy episode. The software is a device function. It does not meet criterion one because it is intended to analyze signals. It does not meet criterion two because it is not intended to display, analyze, or print medical information. It does not meet criterion three or four because it provides a specific diagnostic output and supports time-critical decision making.

Next, in example five, we have a 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 one because it is intended to analyze a signal. It does not meet criterion two because it is not intended to display, analyze, or print medical information.

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Aneesh Deoras: Next, in example nine, we have a 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 one because it is intended to analyze a medical signal. It does not meet criterion two because it is not intended to display, analyze, or print medical information. It does not meet criterion three or four because it provides a specific, time-critical treatment output or directive for a disease or condition.

Then, in example 11, we have a 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 three or four because it is intended to provide a specific diagnostic output or directive, including an alarm which supports time-critical decision-making.

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Aneesh Deoras: Now, in example 22, we have a software function that analyzes patient-specific measurements, for example, ST-segment elevation or depression as reported on an ECG report and cardiac enzyme laboratory results from the electronic health record, to identify patients potentially experiencing myocardial ischemia or infarction. This software is a device function. It does not meet criterion three or four because it provides a specific diagnostic output or directive and supports time-critical decision-making.

Next, in example 23, we have a software function intended for HCP management of heart failure patients that analyzes patient-specific medical information, for example, daily heart rate, SpO2, blood pressure, or other output from wearable product, to predict heart failure hospitalization. This software is a device function. It does not meet criterion three or four because it provides a specific diagnostic output or directive and supports time-critical decision making.

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Aneesh Deoras: Next, in example 24, we have a software function that analyzes hourly pulse oximetry and heart rate measurements, for example, from a patient’s electronic health record, to identify signs of patient deterioration and alert an HCP. This software is a device function. It does not meet criterion one because it analyzes a pattern. It does not meet criterion two because it is not intended to display, analyze, or print medical information. It does not meet criterion three or four because it provides a specific diagnostic output or directive and supports time-critical decision making.

Then, in example 25, we have a software function that analyzes glucose measurement outputs from a continuous glucose monitor every 30 minutes to detect periods of potential hypoglycemia and notify the patient’s HCP. This software function is a device function. It does not meet criterion one because it analyzes a pattern. It does not meet criterion two because it is not intended to display, analyze, or print medical information. It does not meet criterion three or four because it provides a specific diagnostic output or directive and supports time-critical decision making.

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Aneesh Deoras: Next, in example 26, we have a 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 three or four because it provides a specific treatment output or directive and supports time-critical decision making.

Then, in example 27, we have a 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 three or four because it provides a specific, time-critical diagnostic or treatment output or directive.

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Aneesh Deoras: Next, in example 28, we have a 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 function is a device function. It does not meet criterion three because it is not intended for an HCP. It does not meet criterion four because it supports time-critical decision-making.

Finally, in example 29, we have a 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 that treatment with digoxin immune antigen binding fragments, digibind, for those at high risk. This software is a device function. It does not meet criterion three or four because it provides a specific diagnostic or treatment output or directive and supports time-critical decision-making.

If you have questions about how to use the guidance or the non-device CDS criteria, please reach out to us at DigitalHealth@fda.hhs.gov. You may also consider submitting a 513(g) for device determination or Q-Submission to talk with us about how to apply the criteria.

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Aneesh Deoras: To summarize, here are the topics we covered today, we briefly explained the 21st Century Cures Act and history of the Clinical Decision Support guidance, we explained FDA's current thinking on clinical decision support or CDS, including clarification on our interpretation of the statutory criteria, we described FDA's Enforcement Discretion Policy for software functions that provide one clinically appropriate output and examples, and we reviewed examples of non-device CDS software functions and CDS software functions that meet the device definition.

And with that, I think we can move on to questions.

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CAPT Kim Piermatteo: Thank you Aneesh and Danielle for your presentations on the update to the Clinical Decision Support Software final guidance.

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CAPT Kim Piermatteo: We will now transition to the portion of today's town hall where we address some frequently asked questions about the final guidance. I'll read a question aloud and then ask Aneesh to provide a response.

Aneesh, our first question is, would a software function that analyzes voice characteristics in a short recording to make recommendations to the healthcare provider, or HCP, about the prevention, diagnosis, or treatment of mental health diseases or conditions, based on recommendations that were validated in a peer-reviewed published clinical study, meet all four criteria and therefore be non-device CDS?

Aneesh Deoras: Thanks Kim and I'm sorry about my audio quality earlier. For the answer, similar to the product in example 14 in section V.C. of the guidance, this software function would likely fail criterion one because it analyzes a signal or pattern and would likely fail criterion two because it is not intended to display, analyze, or print medical information. Therefore, it likely would not meet all four criteria to be non-device CDS.

CAPT Kim Piermatteo: Thanks Aneesh. Our next question is, could you clarify how criteria four of the non-device CDS relates to the qualification of large language models?

Aneesh Deoras: Criterion four states that a non-device CDS software function is 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. A large language model- or, LLM-enabled software function may meet this criterion if it can sufficiently enable an HCP to independently review the basis for the recommendations. The guidance includes software and labeling recommendations for sponsors to consider to enable independent review.

CAPT Kim Piermatteo: Thanks Aneesh. Alright, our next question is, how would a software function embedded in a diagnostic ultrasound medical device that is administered by a patient under medical oversight, be considered by the FDA under the policies in this guidance?

Aneesh Deoras: If this software function is intended to support or provide recommendations to a patient, it would fail criterion three and would not be non-device CDS.

CAPT Kim Piermatteo: Thanks again. Our next question is, would a software function intended to generate an alarm or alert be non-device CDS or meet the definition of a device?

Aneesh Deoras: Section 520(o)(1) of the FD&C Act does not explicitly carve out software functions intended to generate alarms or alerts or prioritize patient-related information from the device definition. However, alerts that inform the user of recommendations that meet all the criteria in section 520(o)(1)(E) may be considered non-device CDS. In evaluating whether an alert may be non-device CDS, we recommend referring to our interpretation of criterion four, and specifically whether the time-critical nature of the recommendation provides sufficient time for the HCP to consider the basis of the recommendation.

CAPT Kim Piermatteo: Great, thanks Aneesh. Next the question is, in acute care, does the context itself make predictive or screening CDS more likely to be considered a device, even if the software provides transparent risk information and does not recommend a specific intervention? If so, what factors drive that determination?

Aneesh Deoras: So the acute care context alone does not necessarily mean that a software function meets the definition of a device. If the software function meets all four criteria, it is non-device CDS. For this scenario, we recommend referring to our interpretation of criterion four, and specifically the 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 recommendation presented by the software so that they do not rely primarily on such recommendations.

CAPT Kim Piermatteo: Thanks again Aneesh. Our next question is, if a CDS provides a single risk score as output, would it be a non-device under criterion three, or a device subject to enforcement discretion?

Aneesh Deoras: As demonstrated by the criterion three examples in the guidance, a CDS software function that provides a single risk score as an output, and meets all other criteria, is a software function for which FDA intends to exercise enforcement discretion where providing a single risk score is clinically appropriate.

CAPT Kim Piermatteo: Thanks Aneesh, alright next question, would software that provides risk scores for hospitalized patients, including intensive care unit patients, be more likely considered a device, even if the score does not address a life-threatening condition, and it is not intended to drive time-critical decisions?

Aneesh Deoras: So the indicated population alone does not entirely dictate whether a software function meets the definition of device. In the context of CDS, if a software function meets all four criteria, it is non-device CDS. If a software function has one clinically appropriate output, meaning it fails criterion three, but otherwise meets the other criteria, it is a software function for which FDA intends to exercise enforcement discretion.

CAPT Kim Piermatteo: Great, thanks Aneesh. I have two more questions for you today, and the next one is, can FDA clarify why the example on page 11 of the updated guidance, for "a software function predicting risk of a cardiovascular event in the next 24 hours", does not fall under the enforcement discretion policy for certain software functions that have one clinically appropriate output but meet otherwise or sorry, but otherwise meet other criteria?

Aneesh Deoras: Thanks we should have caught that. While this software function has one clinically appropriate output, it fails criterion four because of the time-critical nature of the HCP's decision-making for this intended use, in that there is not sufficient time for the HCP to consider the basis of the recommendation. However, not all software functions that provide a recommendation for harm that may occur within 24 hours necessarily fail criterion four.

CAPT Kim Piermatteo: Thanks Aneesh. Alright the last question I have for today's town hall is, page 15 notes that usability testing may be needed to evaluate whether implementation meets criterion four. If a product is ultimately considered non-device CDS, could FDA suggest the types of usability evidence that are appropriate to document and whether any public frameworks or standards are recommended for demonstrating adequate independent review by HCPs.

Aneesh Deoras: So first please note that this recommendation wasn't changed in either of the recent updates. Second, FDA does not have specific recommendations on what usability testing may demonstrate that an implementation meets criterion four. However, FDA may request information on usability testing if there is a question about whether a software function fails criterion four and therefore could be a device software function.

CAPT Kim Piermatteo: Thank you Aneesh for addressing those frequently asked questions. I hope our attendees found this information useful.

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CAPT Kim Piermatteo: As we wrap up today's town hall, I'd like to turn it back over to Aneesh for some closing remarks regarding today's topic. Aneesh…

Aneesh Deoras: Thank you all for the questions and for joining our discussion on the clinical decision support software guidance. Again, please reach out if you have any questions and we look forward to seeing you for the next town hall. Kim…

CAPT Kim Piermatteo: Thanks Aneesh and thanks again Danielle for being a part of today's town hall. I want to let everyone know a recording of today's event, a copy of the slides and a transcript will be posted as soon as possible to the event page, as well as to CDRH Learn under the section titled "Specialty Technical Topics," and the sub-section "Digital Health." A screen shot of where you will be able to find these materials has been provided on this slide.

If you have additional questions regarding today's town hall, feel free to reach out to DICE at DICE@fda.hhs.gov.

And lastly, I encourage you to monitor our CDRH Events webpage at www.fda.gov/CDRHevents, for a listing of upcoming CDRH Events.

Thank you all again joining. This concludes our CDRH Town Hall.

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