

December 26, 2019

Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

***BY ELECTRONIC SUBMISSION***

**Re: Consumer Technology Association Public Comments in Response to Draft Guidance for Industry and Food and Drug Administration Staff on Clinical Decision Support (CDS) Software**

The Consumer Technology Association (CTA®) appreciates the opportunity to submit comments in response to the Food and Drug Administration (FDA) draft guidance entitled “Clinical Decision Support Software.” The guidance is intended to clarify the types of CDS functions that do not meet the definition of a device as amended by the 21st Century Cures Act (Cures), Public Law No: 114-255. It also seeks to describe a risk-based approach for regulatory oversight of CDS software functions and provide clarity on which FDA intends to focus its regulatory oversight for health care providers, patients, and caregivers. The guidance is a follow-up to FDA’s December 8, 2017 Draft Guidance on Clinical and Patient Decision Support Software.

As North America’s largest technology trade association, CTA® is the tech sector. Our members are the world’s leading innovators—from startups to global brands—helping support more than 18 million American jobs. CTA® owns and produces CES®—the largest, most influential tech event on the planet.

On the policy front, CTA’s® Health and Fitness Technology Division strives to advance the use of consumer-based technology enabled health solutions to deliver better health outcomes and reduce overall healthcare costs. The Division, which includes some of the most well-respected thought leaders in the health care and technology sectors, provides policy advocacy, health care market research, and standards initiatives that advance the appropriate use of consumer technologies in the health care context.

Unlike most trade associations, CTA® is accredited by the American National Standards Institute (ANSI) as a Standards Development Organization (SDO), and we have long history of voluntary national standards development. Among the wide range of topics addressed by our standards program are health, fitness & wellness, video, and drones. Both CTA® members and non-members can participate in the standards program. Just as significantly, CTA® partners with other standards developers and organizations to develop joint documents and other collaborative initiatives.

CTA® appreciates FDA’s continued leadership and transparency in interpreting Section 3060(a) of the Cures Act which amended the FD&C Act to add section 520(o)(1)(E) to exclude certain software functions from the definition of a device in section 201(h) of the FD&C Act.

## GENERAL COMMENT

The guidance attempts to provide clarity on the scope of FDA’s oversight of CDS software intended for health care professionals, patients, or caregivers—however, CTA® is concerned that basic definitions and concepts remain ambiguous, and that FDA’s message is lost in the complexity of the proposal.

### I. Comments on Revised Draft Guidance Sections II and IV—“Background” and “Scope”

In Section II(B), CTA® recommends FDA clarify that it only plans to apply the IMDRF Framework factors for CDS software functions to the extent they are consistent with the Federal Food, Drug, and Cosmetic Act (FDCA), as amended by Cures. As currently drafted, the guidance will likely create confusion regarding the statutory criteria and the IMDRF factors.

Related to the scope of the Revised Draft Guidance outlined in Section IV, several areas of clarification are likewise needed. Although the Revised Draft Guidance alludes to the nature of regulatory oversight applicable to Device CDS, it does not specify what requirements apply. It does not, for example, address classification, premarket review pathway, or the nature of applicable special controls for Device CDS. Additionally, FDA could provide clarity regarding patient/caregiver CDS that is *not* a device at all, and how those software tools intersect with those covered by FDA’s Wellness Guidance.<sup>1</sup>

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<sup>1</sup>FDA “Guidance for Industry and Food and Drug Administration Staff, General Wellness: Policy for Low Risk Devices” (Sept. 2019).

## II. Comments on Revised Draft Guidance Section V—“Interpretation of Criteria in Section 520(o)(1)(E) of the FD&C Act”

### A. Criterion 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.

Several terms within the first criterion for exempt CDS in section 520(o)(1)(E)—pursuant to which the software function must not be 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 to be considered CDS—lack clarity, may be misunderstood, or may be applied in an overly broad manner.

#### 1. *Medical Image*

The original Draft Guidance did not provide any interpretation or context for the reference to “medical image” that is part of the first criterion. As it stands, it will be difficult for developers, providers, and the agency to make consistent determinations about the applicability of this criterion. We recommend FDA clarify that an image or picture is not a “medical image” unless the tool that captures it is a medical device. This interpretation gives meaning to Congress’s explicit reference to “medical” images; otherwise, the statutory language would simply have referred to “image.” If an image generated by a consumer product, such as a smartphone, tablet, laptop, or digital camera is being used for a non-device purpose (*i.e.*, such that the platform is not transformed into a medical device),<sup>2</sup> such image should not reasonably constitute a “medical image.”

In applying the CDS exemption, what should be more important is how that information is used by the software function. If an image generated from a non-medical device is analyzed or manipulated by the software function for a clinically significant purpose, the software function would presumably fail to satisfy other CDS exemption criteria—rendering the software a medical device. In other words, if the source of the image is not intended to be used for a medical device purpose, the output is not a “medical image.” If a software leverages a non-device image for a diagnostic purpose, the software would be Device CDS (*i.e.*, would not qualify for the CDS exemption) and FDA would retain regulatory oversight. This approach is consistent with FDA’s treatment of regulated software devices, which may obtain and utilize data from non-device sources without rendering the source a medical device.<sup>3</sup>

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<sup>2</sup>In other circumstances, FDA has explained that a product or platform that is not otherwise a medical device can be transformed into a regulated medical device if intended for a purpose in the statutory definition of device. *See, e.g.*, FDA “Guidance for Industry and Food and Drug Administration Staff, Policy for Device Software Functions and Mobile Medical Applications” (Sept. 2019).

<sup>3</sup>For example, in a 2018 *de novo* classification of an ECG app, the device app gathers and analyzes data from a non-medical device.  
[https://www.accessdata.fda.gov/cdrh\\_docs/pdf18/DEN180044.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180044.pdf).

Defining a “medical image” as an image rendered by a medical device is the most reasonable and logical interpretation of the term. In fact, the examples FDA provides in defining the focus of the agency’s intended oversight mostly describe images gathered from traditional medical devices—generally radiological imaging systems like CT scans or MRIs (lines 180-81, 696, 701, 706). However, at least one example seems ambiguous in that it does not specify how or from what type of product the image was captured (*e.g.*, images of a skin lesion at lines 722-25). We urge FDA to clarify that example if the source of the image is indeed a medical device.<sup>4</sup>

## 2. *Signal from a Signal Acquisition System*

Like “medical image” within the same criterion (Section V(1)), the term “signal from a signal acquisition system” warrants further clarification. Consistent with our recommendation above, FDA should clarify whether a platform constitutes a “signal acquisition system” depends on if it is a medical device (lines 161-64). We believe that FDA does not intend to mean that receiving signals from non-medical (hardware) devices on its own, would disqualify a software function from the CDS exemption. This should be the case when a non-medical sensor comes into contact with the body. Smart physiologic sensors that may capture certain heart rate signals differ fundamentally from electrocardiogram devices. Platforms that measure physiologic parameters not intended for a medical purpose should not be considered signal acquisition systems.

Consistent with our suggestions above, FDA should specify that the term under these conditions (particularly the phrasing of the example at lines 189-98) is limited to signals from hardware signal acquisition systems that are medical devices. Further, while the Revised Draft Guidance does expand upon FDA’s thinking regarding what constitutes a physiological signal for purposes of this criterion, the two examples provided could be read as overly broad, as it is not clear that the source of the signal is a “signal acquisition system.”

Conversely, there is another complex scenario FDA must clarify. “Electronic patient records” such as electronic health records (EHRs) are real-time digital (software) repositories of patient information, bringing everything into one place (a patient’s medical history, diagnoses, medications, immunization dates, allergies, radiology images, lab and test results). EHRs often include physiologic data from a variety of medical devices whether within a medical facility or in non-facility or home settings. Cures excludes from the definition of a medical device software intended to serve as

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<sup>4</sup>FDA appears to allude to a similar line in the context of a signal acquisition device in its example at line 715: “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 narcoleptic episode. The software is a device function, because it is intended to analyze a medical signal and to aid in diagnosis.” In both cases, and as discussed in more detail below, FDA should clarify that both “medical image” and “signal acquisition system” should be tied to whether the underlying platform is itself a medical device.

electronic patient records.<sup>5</sup> Cures also codifies several FDA digital health guidance documents which grouped similar functions under enforcement discretion and are now not regulated, such as medical device data systems (MDDS) and certain other functions under mobile medical applications. Those are non-device software that are involved in the transfer, storage, conversion, or display of regulated medical device data. With that in mind, take the scenario when non-device software delivers regulated medical device data to a non-device CDS product. The non-device CDS may then “process” or “analyze” those physiologic medical device signals to potentially “inform” medical purposes—yet remain in compliance with this criterion, particularly since they are not directly acquiring a signal from a regulated medical device or “signal acquisition system” but rather from non-device software.

This is an area of ambiguity FDA must address. The agency should consider focusing on the device/signal acquisition system (as directed by Congress), *and* the type of data (medical vs. non-medical) that’s being fed into the CDS software. Such an approach would be consistent with the concepts detailed in the “Medical Device Accessories – Describing Accessories and Classification Pathways” guidance which focuses on the accessory and the risk of the accessory when used as intended with the parent device. Under that guidance FDA sought to determine the risks of accessories when used, as intended, with the parent device type. Doing so does not imply that all risks of a parent device are imputed to the accessory.

On a related front, CTA® recommends that, at lines 169-198, FDA should define the terms “physiologic” and “physiological,” and whether they are interchangeable. These terms have important significance for the digital health community, beyond the work related to this Revised Draft Guidance. For example, does “physiologic/physiological data” include keystroke interactions between a patient suffering PTSD and a mobile medical app that assesses those interactions to inform clinicians of psychological progress? Does “physiologic/physiological” include monitoring the use of short-acting beta-agonists of a patient as a potential marker for respiratory disease exacerbation? FDA’s insights regarding the terms “physiologic” and “physiological” would be helpful in advancing the nomenclature of digital medicine.

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<sup>5</sup>The 21st Cures Act (Public Law No: 114-255) amends Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) to add that section 201(h), shall not include a software function that is intended to “(C) serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as— ‘(i) such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals; ‘(ii) such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and ‘(iii) such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.”

**B. Criterion 3: Intended for the purpose of supporting or providing recommendations to a healthcare provider about prevention, diagnosis, or treatment of a disease or condition.**

Pursuant to Section 520(o)(1)(E)(ii) of the FDCA, to meet the statutory CDS exemption, software functions must be intended to support or provide recommendations to a health care professional (HCP) about prevention, diagnosis, or treatment of a disease or condition. We are concerned with the interpretation of the phrase “support or provide recommendations.” In particular, the words “provide recommendations” need further FDA clarification. In some disease use cases such as mental health, for example, diagnostic tools gather clinical information that could be construed as gathering information to “inform” a patient or caregiver. However, FDA also proposes that functions to “support or provide recommendations align with the IMDRF Framework category of [software as a medical device] SaMD functions that inform clinical management” (lines 232-33).

Consistent with Cures, the Revised Draft Guidance recognizes that so long as the other statutory exemption criteria are met, software that provides *recommendations* about prevention, diagnosis, or treatment of a disease or condition will not be considered a device. Based on FDA’s proposed application of the IMDRF factors, software that *aids* in treatment or diagnosis would be considered to “drive” clinical management and, therefore, would be treated as a device. The proposed exclusion of the IMDRF concept of “driving” clinical management from “support or providing recommendations” potentially conflicts with Cures criteria. If FDA is going to incorporate the IMDRF Framework factors, at minimum, the agency should explicitly confirm that “support or provide recommendations” does not constitute “driving clinical management” (line 217).

**C. Criterion 4: Intended for the purpose of enabling a healthcare provider to independently review the basis for the recommendations that such software presents so that it is not the intent that healthcare professionals rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.**

The final statutory criterion for the CDS exemption is the most problematic. It requires software to enable HCPs to independently review the basis for the recommendations presented by the software so that HCPs do not rely primarily on such recommendations. The HCPs would instead rely on their own judgment, to make a clinical diagnosis or treatment decision for a patient. As a preliminary matter, we question why providers would want to use such software. In today’s highspeed medical environment with large patient populations, shrinking numbers of providers, and other resources stretched thin, we have doubts regarding the ability for any HCP to independently review the basis for recommendations of software. This is not realistic. Moreover, the added responsibility of an independent review could subject any HCP to potential liability exposure.

However, this was the direction provided by Congress and what FDA must now interpret. In the Revised Draft Guidance, FDA states that for a software function to meet this criterion, developers should describe their software functions in plain language (line 249). The guidance goes on to explain that, “[t]he 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” (lines 257-262).

While we appreciate FDA providing more detail regarding the issue of independent review, much of the added detail will be difficult to apply to increasingly complex software. This is particularly the case for software functions that rely on machine learning/artificial intelligence (ML/AI). For such software, FDA should clarify that the independent review requirement would be satisfied by disclosing that a tool is based on an ML or AI algorithm (along with a basic description of the inputs and outputs), such that the HCP would be aware that a given recommendation is based on patterns and dependencies supported by ML or AI inputs (lines 257-262).

FDA may wish to clarify how the “basis for recommendation” may or may not be peer-reviewed literature validating the performance of machine learning-based CDS and highlight any constraints, limitations, and/or what levels of evidence are indicated as satisfying this requirement. If scientific studies were to measure the relative performance of consensus guidelines versus ML/AI-based CDS utilities in terms of relative benefit and risks of harm to patients, could this satisfy the “basis for recommendation”?

The “plain language” directive also remains unclear. In finalizing this guidance, FDA should clarify that plain language is satisfied if the inputs are appropriately described (for example, medical records, patient demographic information, and data sets). Many physicians, understandably, do not have a strong understanding of the underlying techniques associated with ML, so it does not make sense to differentiate between the comprehension levels of physicians and patients.<sup>6</sup> In other words, it may be appropriate to have the same expectations for plain language as it applies both to physicians and patients. We encourage FDA to provide concrete guidance its discussion of plain language and include examples on what level and extent of disclosure should be provided to the physician in each case.

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<sup>6</sup>For patient-facing instructions or labeling FDA has often identified a 6th to 8th grade reading comprehension level as the appropriate technical depth but this may be insufficient in this context. See, e.g., <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/device-labeling-guidance-g91-1-blue-book-memo> (7th grade reading level); <https://www.fda.gov/media/71030/download> (8th grade reading level); <https://www.fda.gov/media/88986/download> (6th to 8th); <https://www.fda.gov/media/72574/download> (6th to 8th); <http://www.fda.gov/media/75626/download> (8th); <https://www1.racgp.org.au/ajgp/2018/october/how-doctors-conceptualise-p-values>; <https://pubmed.ncbi.nlm.nih.gov/24404272-statistical-literacy-of-obstetrics-gynecology-residents/>; <https://annals.org/aim/article-abstract/1090696/do-physicians-understand-cancer-screening-statistics-national-survey-primary-care>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4695343/>.



Finally, the Revised Draft Guidance calls for software developers to explain the underlying data used to develop the algorithm regardless of the complexity of the software and “whether or not it is proprietary” (lines 254-55). This may be misinterpreted as *requiring* the disclosure of proprietary information, and worse, may establish an unreasonable expectation. Virtually all such algorithms will be proprietary or include proprietary specifications. Developers should never be made to share proprietary information in their descriptions, as is the case for complex hardware devices, biologics, or drugs. It should be enough for software developers to provide basic descriptions of the underlying data and logic or rationale of the algorithm without sharing proprietary information. We suggest that FDA simply strike the phrase, “whether or not it is proprietary” on line 255.

### **III. Comments on Revised Draft Guidance Section VI—“Application of IMDRF Risk Categorization”**

While we understand FDA’s efforts to pursue greater international harmonization by applying the IMDRF Risk Categorization to its regulation of Device CDS functions, FDA should carefully weigh the implications from adopting a framework new to the U.S. The terms used by the IMDRF Framework are not defined in the FDCA, nor in regulation. Nor have these terms been explained in guidance. It remains unclear exactly how they align with governing U.S. regulatory requirements.

If FDA intends to adopt IMDRF terminology, the agency should confirm so, address whether all the IMDRF examples and standards are appropriate and applicable, and elaborate on them in the guidance. Patients, device makers, and technologists will benefit if provided with clearer examples and definitions of the “seriousness of the condition” as laid out by the IMDRF risk categorizations—Critical, Serious, or Non-Serious. IMDRF examples and standards merit an appropriate and thorough analysis.

For example, Table 2, beginning at line 276, fails to adequately explain what the risk categorization means. Is FDA proposing to change the existing risk classifications and requirements for devices with software? If so, we are unclear as to the statutory or regulatory basis for doing so? We believe that introduction of this table of SaMD categories creates confusion regarding whether this risk stratification system is intended to somehow supersede the governing U.S. device classification system (with well-known types of controls applied to each of three device classes), and if not, how it affects the governing system, if at all.

We recommend FDA clarify the intent behind the table, and expand on the significance of the risk stratification, particularly if the agency intends this to play a role in the level of regulatory oversight for categories of SaMD beyond CDS.



**A. Significance of Information Provided by a SaMD to the Health Care Decision: Inform Clinical Management; Drive Clinical Management; Treat or Diagnose**

**1. *Inform Clinical Management***

The Revised Draft Guidance states that CDS functions inform clinical management. FDA defines “inform clinical management” as generating information that does not trigger an immediate or near-term action (lines 287-88). FDA does not define or elaborate on what constitutes “trigger[ing] an immediate or near term-action,” and should clarify several aspects of this phrase.

First, we recommend that “triggering” be defined as directly ordering an action. It excludes aiding or supporting decision-making, even if followed by an immediate or near-term action or decision by an HCP. For example, FDA identifies software that contains tools, calculators, guidelines, and protocols for ordering total parenteral nutrition, enteral nutrition, and other alimentation procedures as Non-Device CDS (lines 501-06). Given the lack of clarity regarding the concept of “triggering” an immediate or near-term action, it is unclear why this type of function would be deemed to “drive” clinical management if, for example, it recommended increased protein.

Second, “near-term action,” is undefined (lines 287-88). A person’s receipt of virtually any type of information that may potentially be related to a diagnosis could trigger that person to seek a diagnostic test or consult a physician. A less subjective approach would be to evaluate whether it is the developer’s intent that the information produced by the CDS function would trigger an immediate or “near-term action.”

We urge FDA to clarify these definitions in Section VI(A)(1) and provide context-specific examples illustrating those concepts.

**2. *Drive Clinical Management***

FDA must define, with specificity, the ways in which software “drives clinical management” (lines 297-312) and how that differs from software that “informs clinical management” (lines 286-296). In many instances, it is unclear how software that may meet the statutory criterion of “supporting or providing recommendations . . . about prevention, diagnosis, or treatment,” as described in the CDS criteria discussion (lines 213-236) would differ from software that FDA would consider to be driving clinical management.

The distinction between “inform” and “drive” is particularly relevant not only because it separates Device CDS from Non-Device CDS, but also because it defines the band of enforcement discretion related to non-serious conditions. In this guidance, and as discussed in more detail below, FDA has

introduced new criteria for enforcement discretion, without sufficiently explaining the distinction between inform and drive. It would be helpful for FDA to provide additional examples differentiating between clinical information versus information that aids in diagnosis in specific disease areas. In the diabetes space, for example, certain clinical symptoms increase the likelihood that a patient has diabetes, but there are particular blood tests that serve as “diagnostic clinchers.” This equivalent does not exist in mental health, where survey responses sometimes serve as the primary basis for the diagnosis. These types of distinctions among diseases and conditions, and among medical specialties, require further explanation and consideration.

Finally, FDA categorizes software that identifies early signs of a condition or triages patients as software that drives clinical management (lines 304-06). We disagree with this categorization. Software that can risk stratify or identify early signs of a disease or condition should not necessarily be presumed to drive clinical management—particularly in the case of low-risk conditions.

**B. State of the Health Care Situation or Condition**

In Section VI(B), FDA provides descriptions and examples of three categories for the state of the health care situation or condition for which the Device CDS is intended. In sections VI(B)(2) and (B)(3), we urge FDA to provide more examples and factors in ways to distinguish serious situations and conditions (lines 344-61) versus critical situations or conditions (lines 362-80). FDA should also clarify this is not relevant to the exemption, and specify how, if at all, the agency proposes to apply it—either for enforcement discretion or in classifying devices that will be actively regulated.

**C. Policy for Device CDS Functions**

The Revised Draft Guidance narrows enforcement discretion for patient-oriented CDS functions (formerly patient decision support or “PDS”). In the initial Draft Guidance, FDA stated it did not intend to enforce requirements for what it termed PDS if those devices were analogous to devices excluded from the definition of device software for HCPs that satisfy 520(0)(1)(E) of the Cures Act. In the Revised Draft Guidance, FDA appears to be shifting its approach, stating that the agency will not only enforce compliance requirements, but that many of these devices will be the subject of the FDA’s oversight focus. Lines 414-16 of the Revised Draft Guidance provides that CDS functions used by patients or caregivers that inform clinical management of serious or critical conditions will remain under regulatory oversight. Moving much of patient-oriented CDS outside of FDA regulation and under the umbrella of regulatory oversight would be a drastic change, particularly when made without explanation.

Patient-facing CDS when “the user can independently review the basis” (a level of transparency FDA will need to define), should be treated and analyzed the same way FDA plans to treat HCP software

that can be independently reviewed. We request FDA consider the clarifications discussed above regarding Criterion 4 as applicable for patient- and consumer-facing CDS. Specifically, we urge FDA to clarify that CDS should not be considered a device if the software functions meet the FDA’s four criteria when the user may be an HCP, consumer, patient, and/or caregiver as stated in criteria 3 and 4.

As FDA has recognized, there is value in certain software tools that help patients live well with conditions that are beyond non-serious, such as heart disease.<sup>7</sup> Allowing patient-facing tools broader enforcement discretion would be consistent with FDA’s approach in the wellness space. We recommend that FDA clarify that the wellness guidance, including the enforcement discretion criteria applied therein, continues to apply to products that meet those criteria (in line 390, or within the paragraph discussing patient-facing CDS at lines 387-402). This will ensure FDA policy is consistent with patient-centric healthcare to enable patients, consumers, and caregivers to become actively involved in managing their health in partnership with HCPs.

We commend FDA for including Table 3 in the Revised Draft Guidance. It very clearly and succinctly summarizes the regulatory approach for CDS software functions used by HCPs and patients or caregivers. It accurately depicts whether CDS software functions are a device, or under FDA regulation and the subject of oversight. It bases those determinations on whether the intended user (i.e., HCP or patient/caregiver) could independently review the basis for the CDS.

Table 3 helps underscore why FDA must clarify IMDRF concepts and terminology. Doing so will help explain how CDS functions “inform clinical management.” More specifically, Table 3 shows how all CDS that informs clinical management intended for an HCP that cannot be independently reviewed is subject to FDA’s regulatory oversight focus—regardless of the IMDRF Risk Categorization level (non-serious, serious, and critical).<sup>8</sup>

This begs the question as to why FDA is proposing to introduce the IMDRF Risk Categorization levels—non-serious, serious, and critical. We believe that the agency should instead focus on the meaning of “informing” versus “driving” clinical management. As provided under Table 3, all CDS that informs clinical management intended for the patient or caregiver, regardless of whether the user can independently review the basis, is subject to FDA regulation and the focus of oversight.<sup>9</sup> If this is indeed FDA’s vision, we are unclear why the agency is relying on the IMDRF Risk Categorizations.

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<sup>7</sup>See FDA “Guidance for Industry and Food and Drug Administration Staff, General Wellness: Policy for Low Risk Devices” (Sept. 2019).

<sup>8</sup>The lowest risk “Non-Serious” CDS used to inform clinical management intended for an HCP who cannot independently review the basis is still under FDA regulation, albeit under enforcement discretion (meaning FDA will not enforce requirements under the FD&C Act).

<sup>9</sup>The lowest risk “Non-Serious” CDS used to inform clinical management intended for patient/caregiver who cannot independently review the basis is still under FDA regulation, albeit under enforcement discretion (meaning FDA will not enforce requirements under the FD&C Act).

#### IV. Comments on Revised Draft Guidance Section VII—“Examples”

##### A. Examples Not Addressed in Discussion Above

In general, FDA should include more examples and should consider posting the document online with updates to the examples as the agency learns of new and interesting scenarios and use cases. We have identified additional situations that would benefit from examples.

First, the examples FDA provides in Section VII of the Revised Draft Guidance do not address software products intended specifically for disease prevention. Stakeholders would benefit from understanding how software that predicts medical conditions in order to prevent acute episodes would be characterized under this guidance.

Second, the examples provided by FDA fail to address software that does not diagnose a disease or condition, but rather characterizes a symptom’s similarity (captured by image, for example) to symptoms of other patients diagnosed with a disease or condition. Assuming other CDS exemption criteria were met, such software would be intended to assist patients to self-educate about their condition, at which point they would seek professional consultation. We believe that this category of software functionality would presumably qualify as Non-Device CDS.

Finally, one of FDA’s examples of a Non-Device CDS Function describes software intended for use by HCPs to provide options for diagnosing patients suspected to have diabetes mellitus (line 522). The HCP would enter patient parameters and lab test results, and the software then suggests whether the patient’s condition meets the definition of diabetes based on established guidelines. This example illustrates the challenges in evaluating “informing” versus “driving” clinical management. While we agree that this example describes a Non-Device CDS, it appears that the software is aiding in diagnosing whether the patient has diabetes, based on established guidelines, and, therefore, driving clinical management. FDA even uses the words “aid in diagnos[is]” for the same example in the original Draft Guidance. In this example, the line between providing clinical information and aiding in diagnosis are blurred. FDA should not only clarify this example in future iterations of the guidance, but also, as discussed above in detail, thoroughly address situations like these that may blur the lines of “informing” versus “driving” clinical management.

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CTA® thanks FDA for the opportunity to comment, and we welcome discussing these issues in more depth. In the meantime, if you have any questions, please do not hesitate to contact us.

Respectfully submitted,

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