Clinical Decision Support Coalition

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**VIA ELECTRONIC SUBMISSION**

December 13, 2019

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

**Re: Clinical Decision Support Software: Draft Guidance for Industry and FDA Staff, Docket Number FDA-2017-D-6569**

Dear Sir or Madam:

On September 27, 2019, FDA requested comments on a reproposed draft of the agency's guidance on clinical decision support ("CDS") software, originally proposed on December 8, 2017. The reproposed guidance clarifies the types of clinical decision support functions that do not meet the definition of a device under the Federal Food, Drug, and Cosmetic Act, as amended by the 21st Century Cures Act (Cures Act).

This guidance describes a risk-based approach for regulatory oversight of CDS software functions that remain devices using the categories defined by the International Medical Device Regulators Forum (IMDRF) final document entitled "Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations." The guidance also seeks to provide clarity on the types of CDS software functions intended for healthcare providers, patients, and caregivers that will be the focus of FDA's regulatory oversight.

By way of background, the CDS Coalition is a diverse group of stakeholders consisting of software providers, IT infrastructure manufacturers, healthcare providers, medical device and pharmaceutical manufacturers, trade groups, and members of the clinical community. Focused on clinical decision support software, the coalition's goal is to ensure a risk-based and clearly defined regulatory system for such software that appropriately balances the need for regulatory oversight with the need for innovation and access to new technology, so we are well aligned with FDA's purposes.

The CDS Coalition offers the following three comments broadly on the reproposed CDS guidance.

1. FDA should exclude more software as low risk.
2. FDA should not try to limit the scope of the statutory transparency exclusion found in the Cures Act to only software which, in the IMDRF terminology, merely informs or provides options regarding clinical management of patients.

3. FDA should not limit its offer of enforcement discretion to only patient-directed software that informs clinical management for non-serious situations or conditions.

We will explain each of those in turn.

**1. FDA should exclude from regulation more software as low risk.**

We want to start this topic by expressing appreciation for FDA moving from an approach that was not risk-based in the prior CDS guidance draft, to one that is. That is a change in a positive direction. We understand that many organizations recommended, in response to the first draft of the CDS guidance, that FDA do this, and we appreciate FDA listening to those comments. That is to FDA's credit.

But at the same time, we need to observe that FDA took a very small step in this positive direction. We understand that prior comments recommended that FDA go much further to exempt other low risk software. For example, comments submitted by the CDS Coalition on February 5, 2018 specifically recommended that the agency use the IMDRF framework for risk stratification, and extend the exemption of low risk software to all software that merely informs clinical management and is considered to be of low impact. In appendix A to those comments, we included a list of 22 low risk software products already on the market that the coalition recommended be exempt.

Using the IMDRF framework, that appendix laid out the three subcategories of the "inform clinical management" category as follows:

> These nontransparent software programs should nonetheless be exempt under FDA enforcement discretion because they meet the following criteria:
>
> 1. SaMD that provides information to drive clinical management of a disease or conditions in a non-serious situation or condition is a Category I and is considered to be of low impact.
> 2. SaMD that provides information to inform clinical management for a disease or conditions in a serious situation or condition is a Category I and is considered to be of low impact.
> 3. SaMD that provides information to inform clinical management for a disease or conditions in a non-serious situation or condition is a Category I and is considered to be of low impact.

In its newly revised CDS guidance, FDA only extends the exemption to the third of those three subcategories. More revealing, the effect is to only exempt <u>one out of the 22 products</u> listed in that appendix A. That is a very small step indeed. And the agency offers absolutely no justification or explanation as to why the first two subcategories – categories that contain the other 21 products – should not also be exempt.

We think it is incumbent upon FDA to explain, in a data-driven manner, why exactly the agency is drawing the line where it proposes. There should be data underlying FDA's decision, and it would help the public discourse if FDA identified those data so that they could be discussed. FDA's policymaking should be both data-driven and transparent. Otherwise we are left with

arbitrary distinctions built on opinion. Exempting one product category out of 22 proposed in the CDS Coalition comment letter is not a meaningful improvement. In other words, the change did not truly produce a risk-based approach when the only exclusion is de minimis.

2. **FDA should not try to limit the scope of the statutory transparency exclusion found in the Cures Act to only software which, in the IMDRF terminology, merely informs or provides options regarding clinical management of patients**.

In its new proposed CDS guidance, FDA seeks to limit the scope of the statutory transparency exclusion despite the clear statutory language of the Cures Act. As revealed in lines 68 and 69 of the proposed guidance, FDA recognizes full well that the scope of the act encompasses software "intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition." It's important to dissect that language a bit, and to appreciate that the language includes both information that merely supports a diagnostic or therapeutic decision, as well as information that "recommends" such things as a diagnostic or treatment decision.

On the top of page 14, in lines 307 through 312, among other places, FDA advances the rather convoluted argument that somehow software that "drives" clinical management does not fall within that statutory language of "recommending" diagnostic or therapeutic decision making by healthcare professionals. In lines 299 through 306, FDA expresses (in a grammatically incorrect and confusing way) the broad definition of what, according to IMDRF, it means to drive clinical management 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."

One of the keys to understanding the IMDRF framework is understanding that none of the software that we are discussing in this "software as a medical device" framework is part of a closed-loop system. All SaMD merely informs a human who then makes the decision. So the keyword in that just quoted passage is "guide," because that word is describing the relationship of the information to the human healthcare professional who is receiving the advice.

So FDA wants to argue, apparently, that software that "guides" human decision-making is somehow not included within statutory language that encompasses software that "recommends" decisions for humans to make. That's a distinction without substance.

According to Merriman Webster's Dictionary, the word "recommend" means, among other things: "to suggest an act or course of action."

According to that same dictionary, the word "guide" means, among other things: to "direct in a way or course." How could these terms possibly be construed as different?

FDA is apparently drawing a distinction between the words "suggest" and "direct," because those are the only different words of significance. While in a human context there may be a difference between suggesting and directing, because perhaps of the authority of the person speaking (a boss or someone in greater authority can direct a subordinate to do something), in the context of software, there is no difference. Software is not the boss of a human. No software can "direct" a human to do anything. Software by its very nature can only suggest. So the distinction FDA proposes makes no sense whatsoever in the context of software.

Indeed, if we look at FDA's own definition of "guiding," the agency and IMDRF give three examples of "aiding" healthcare professional decision-making. It's significant that the word "aiding" is synonymous with "supporting" (the statutory term that partially defines the scope of the exemption), according to the same dictionary. Perhaps even more revealing, the IMDRF/FDA definition of "guiding" incorporates the very words of the statute. For example, "[t]o aid in treatment by providing enhanced support" makes specific reference to the statutory term "support," while "[t]o aid in diagnosis by analyzing relevant information" makes specific reference to the statutory term "analyzing" as the cornerstone of the definition of CDS. There is simply no substance to the FDA assertion that somehow by using the terms "supporting or providing recommendations to a health care professional" that Congress did not intend to extend the exemption to software that provides guidance to healthcare professionals on these topics.

FDA apparently wants to limit what Congress has previously authorized, but that's not the way it works. Congress, not FDA, has the final word. It is not within the agency's discretion to try to undo what Congress has done.

**3. FDA should not limit its offer of enforcement discretion to only patient-directed software that informs clinical management for non-serious situations or conditions.**

In the original draft CDS guidance, FDA proposed to extend enforcement discretion to CDS software directed at patients or caregivers (rather than healthcare professionals) that, in general, meets the definition of exempt CDS software for healthcare professionals under the Cures Act. The agency, however, noted that this is not open-ended because it means, among other things, that the "kinds of explanations that a healthcare professional may be able to understand and apply are different than the kinds of explanations that a patient may be able to understand and apply, given the differences in clinical education and experience." That observation greatly reduces the potential candidates of software that may be exempt when directed to patients.

But now, without explanation, FDA retreats from that position. Starting on line 309, FDA now proposes:

> "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 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."

That passage adds significant limitations to the previously proposed enforcement discretion affecting patient-directed software. Under the newly proposed language, the use would have to be low risk and the recommendation would have to relate to a type of decision "routinely" made without a doctor's input.

We do not understand the factual basis for the need for either of those additional limitations. If the software relates to a decision where the patient or other caregiver can fully understand the basis for the recommendation, it is not clear to us why these additional limitations are necessary.

Please let us know if you have any questions or need any further information.

Yours truly,

Bradley Merrill Thompson
General Counsel, CDS Coalition