EPSTEIN
BECKER
GREEN

Attorneys at Law

Bradley Merrill Thompson
t 202.861.1817
f 202.861.3517
bthompson@ebglaw.com

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Leslie Kux,
Assistant Commissioner for Policy
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Defining the Scope of FDA Regulation With Regard to
Clinical Decision Support ("CDS") Software
FDASIA Health IT Report Docket No. FDA–2014–N–0339

Dear Ms. Kux:

Thank you for the opportunity to provide comments on the Food and Drug Administration Safety and Innovation Act (FDASIA) Health IT Report: Proposed Risk Based Regulatory Framework (the "FDASIA Report"). We appreciate the tremendous amount of time and effort the Food and Drug Administration ("FDA"), the Office of The National Coordinator ("ONC"), the Federal Communications Commission ("FCC") and other government, public and industry stakeholders have put into the FDASIA Report. We applaud all those involved for the progress made**.**

We would like to assist the three agencies as they move from the initial FDASIA Report to the final one. In the preliminary FDASIA Report, the three agencies posed several questions and requested comment. The signatory organizations shown below have come together to offer a general framework for answering the following two questions posed in the FDASIA Report:

- What types of CDS functionality should be subject to the health management health IT framework?
- Which types should be the focus of FDA oversight?

We believe answering the question of whether a given piece of CDS software should be regulated by FDA involves a three-part test. To be regulated, the software must meet all three requirements.

1. Is the CDS a medical device?

To be regulated by FDA, a particular piece of software would first have to meet the statutory definition of a medical device (*i.e.*, generally be intended for use in the diagnosis or treatment of diseases or other conditions in man). We are excluding from the CDS category any software that

qualifies for FDA regulation by virtue of being an accessory to a medical device. Such software needs to be dealt with separately.

2. Is the CDS risky enough to merit regulation?

A specific CDS program should present sufficient potential risk to the patient to merit FDA regulation. Assessment of that risk would be a function of several factors:

a. The seriousness of the disease or condition being diagnosed or treated;

b. The role the software plays in that diagnosis or treatment; and

c. Other factors such as those outlined last summer by the FDASIA working group in its report to the agencies

A full discussion of these factors is beyond the scope of this letter.

3. If the potential risk is substantial, is that risk related to the CDS or to the practice of medicine?

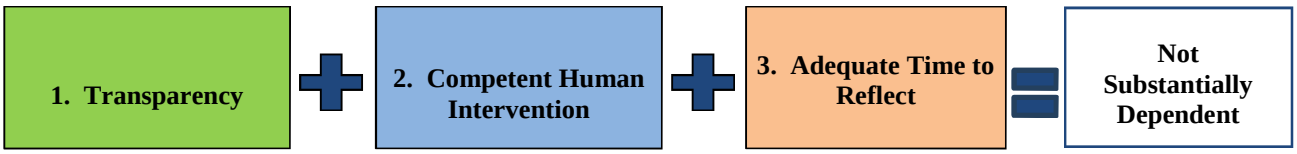
As you know, FDA's regulatory oversight does not extend to the practice of medicine. In the case of CDS, this means distinguishing risks that come from the practice of medicine (which are unregulated by the FDA) versus risks that come from a medical device (which FDA has responsibility for regulating.) In other words, we need to distinguish man from machine when it comes to assessing the source of the risk.

The undersigned groups would like to propose the following framework for distinguishing risks that come from medical devices versus those that come from the practice of medicine.

If the intended user is not substantially dependent on the CDS to make a diagnosis or treatment decision, a defect in that CDS will present little risk to the patient.

In our view, the need for FDA oversight of CDS depends entirely on whether the CDS is designed and marketed with an expectation that the user will be substantially dependent on the CDS in making a clinical decision. FDA should not regulate CDS that is not expected to create substantial user dependence.

FDA and industry can use three criteria to determine whether to expect the intended user to be substantially dependent on the CDS.



Each of these criteria would need to be met for user not to be substantially dependent on the software, as explained below.

1. **Transparency**. Does the software provide enough information for the user to understand and be able to evaluate the clinical basis for the software recommendation or other output? This may include disclosure of the following:

a. What the software does and does not do. It is important in this regard that the labeling for the software communicate to the user the limits of what the software's functionalities.

b. The information inputs used by the software. This includes (i) patient specific information, and (ii) the source of the clinical information or decision rules such as practice or professional guidelines that the software uses to analyze the patient information.

c. An indication of the certainty or reliability of the output, including as appropriate confidence levels and/or ranking of alternatives

d. The clinical rationale for the recommendations and rankings. This goes beyond merely identifying the source of the clinical rules, and includes an explanation of the clinical logic by which the software arrived at its recommendation based on patient specific information.

Most CDS will be intended to aid user decision-making, but not be a substitute for the user's expertise and judgment. The software needs to enable the intended user to understand the recommendation(s) made by the software and equally important, how the recommendations(s) were made for the user to be not substantially dependent.

2. **Competent Human Intervention**. Is the intended user competent – through training, experience or otherwise - to make the clinical decision in question without the software or to disregard the recommendation of the software? Competent intervention depends on the ability of the user and the nature of the decision. Thus, a consumer, primary care physician, and a specialist are each competent to make different types of decisions, as are nurses, pharmacists, home health aides and other health professionals and care-givers.

   Software intended to be used to extend a user's decision making ability beyond his/her abilities could create substantial dependence. However, software that assists the user in applying her competent judgment does not. Software which, for example, collects, calculates, sorts, or otherwise gathers and presents information which the user is competent in interpreting (while easing the burden of human data gathering or processing) should not result in substantial dependence so long as the other two conditions are also met.

   It is important to note that it may be prudent for decision-makers to also consider data outside of what the software has collected. Competent decision-makers will recognize that need and incorporate it into their decision making process.

3. **Sufficient Time to Reflect**. Based on the intended use, is the user expected to have enough time to reflect on the software output or recommendation before making a decision? The amount of time available to reflect will depend on the acuity of the condition, or how much time can lapse before the patient receives medical care without risk. The amount of time needed to reflect may also depend on the complexity of the decision.

If the intended user does not have opportunity to consider the software output or recommendation the user may be substantially dependent.

These criteria would need to be explained at a more detailed level in FDA guidance to be usable by industry. But at a high level, these criteria, taken together, would focus the agency on the risk associated with the software itself and assist CDS developers and manufacturers in determining whether the intended user is substantially dependent on their product, and thus whether their product is regulated (if their product also meets the medical device definition and risk threshold.)

We respectfully submit these ideas for consideration as the FDA, ONC and FCC finalize their approach to defining that portion of CDS that FDA should regulate. If you have any questions or would like to discuss any element of this recommendation, please contact me.

Respectfully Submitted,

Bradley Merrill Thompson

For the –

CDS Coalition

CDS Consortium

Continua Health Alliance

mHealth Regulatory Coalition

Wireless-Life Sciences Alliance