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December 20, 2019

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

RE: Docket Number FDA-2017-D-6569, Draft Guidance for Industry and Food and Drug Administration Staff: Clinical Decision Support Software

To the Dockets Management Staff:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) draft guidance for industry and FDA staff on clinical decision support (CDS) software as part of the agency's ongoing efforts to implement Section 3060(a) of the 21st Century Cures Act (Cures Act). This draft guidance significantly revises a previous version released by the FDA on Dec. 8, 2017.

The AHA strongly supports the underlying goals of the Cures Act aimed at accelerating new treatments that lead to cures and driving innovation in health care. In recent years, hospitals and health systems have increasingly brought innovation to the bedside by implementing CDS software algorithms to analyze large amounts of clinical data to generate patient-specific recommendations. These recommendations can support provider decision making, but ultimately are only one of many inputs, including the health care professional's (HCP) own clinical judgement.

Section 3060(a) of the Cures Act sought to deter over-regulation by establishing criteria to exempt this type of low-risk decision support software from FDA regulation while at the same time appropriately ensuring continued authority for the FDA to regulate software that replaces rather than supports the decision making of the HCP. **Patient safety is the top priority for hospitals and health systems, and the AHA strongly**

supports FDA's continued oversight of any software that automatically determines clinical treatment or action.

Recognition of this distinction between the origin of the action (the HCP or the software algorithm) is critical to ensuring accurate implementation of the statutory provision. And while we appreciate the FDA undertaking an iterative process to develop this guidance, we believe the draft would benefit from further revision, clarification and stakeholder feedback with special emphasis on providers who interact with CDS tools in a care environment. **In particular, we are concerned that the FDA's interpretation of certain criteria could result in many existing CDS algorithms being subject to the FDA approval process and ultimately slow the pace of innovation and development of new software tools to support better patient care and outcomes.** We offer specific comments and recommendations below.

Criterion 1. *Not Intended to Acquire, Process or Analyze a Medical Image or Signal from an IVD Device or a Pattern or Signal from a Signal Acquisition System*

Under criterion one, the statute appropriately does <u>not</u> exempt a software function from FDA regulation if it analyzes "a signal from an in vitro (IVD) device or a pattern or signal from a signal acquisition system" as it is critical to ensure that data obtained from these devices and systems are created accurately. However, the lack of clarity in the draft guidance regarding the definition of "a signal from an IVD device" or "a pattern or signal from a signal acquisition system" could cause confusion for hospitals and health systems as they seek to determine which CDS software meets this criterion.

We recommend drawing a clear distinction between an algorithm that analyzes data from an electronic health record or other similar real-time source from one that generates the original data within the device. **Specifically, the FDA should clarify that once the data are created by an FDA-regulated device, any software that further collects, collates and analyzes the data "downstream" to provide insights and recommendations to HCPs would be exempt from FDA regulation under this criterion.**

Criterion 2. *Displaying, Analyzing, or Printing Medical Information about a Patient or other Medical Information (such as peer-reviewed clinical studies and clinical practice guidelines)*

The AHA appreciates FDA's recognition of the broad types of patient-specific information that may be utilized in CDS software subject to this exemption criteria and supports the agency's proposed interpretation.

Criterion 3. *Supporting or Providing Recommendations to a Health Care Professional (HCP) about Prevention, Diagnosis or Treatment of a Disease or Condition*

The FDA proposes to define software functions intended to "support or provide recommendations" as those that align with the International Medical Device Regulators Forum (IMDRF) Framework category of functions that "inform clinical management." CDS that falls under the additional two categories of the IMDRF Framework – "drive clinical management" and "treat or diagnose" – would, in turn, be subject to FDA regulation.

While the AHA strongly agrees that any CDS algorithm that takes independent review and action out of the hands of the HCP should be regulated, we are concerned that the FDA's interpretation of this criterion could apply an arbitrary distinction between "informing clinical management" and "driving clinical management" that is not directly supported by the statute and does not accurately reflect how CDS is used in a patient care environment.

For example, the IMDRF Framework describes the "inform" function as information "not triggering an immediate or near-term action." However, according to our members, almost all CDS output is intended to do just that – be one of several sources of information that support an HCP's decision of whether to take action – action that could be time-sensitive and critical to achieving a positive health outcome for a patient. Along the same lines, under the proposed construct, CDS software used to "<u>identify</u> early signs of a disease or condition" or "<u>aid</u> in diagnosis by analyzing relevant information to help predict risk of a disease or condition" would fall under "driving clinical management" and therefore <u>not</u> be exempt from FDA regulation under this criterion. Yet, these examples highlight some of the most compelling use cases for decision support as they create one of many inputs for the HCP to independently consider when determining diagnosis and treatment.

We urge FDA to reconsider applying this arbitrary distinction of "informing" vs. "driving" clinical management to criterion three, and instead, propose policy that is consistent with the statute's focus on <u>supporting or providing recommendations</u> about prevention, diagnosis or treatment.

<u>Criterion 4</u>. *Enabling an HCP to <u>Independently Review</u> the Basis for the Recommendations that the Software Presents, so that it is NOT the intent that such HCP Rely <u>Primarily</u> on any of such Recommendations to Make a Clinical Diagnosis or Treatment Decision Regarding an Individual Patient*

The FDA interprets this criterion in the draft guidance to require that exempt software functions be transparent and described in plain language to HCPs, including:

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

The AHA supports FDA's interpretation of this criterion and the underlying intent that the HCP has access to understandable information upon which to evaluate the basis of the recommendation. However, we request further specificity on the format in which the plain language information should be made available. Flexibility to provide easy access to the information through a mechanism other than the algorithmic output itself should be considered. **Specifically, FDA should clarify that as long as the information is accessible as part of the software function (e.g., through a link to a separate webpage), and regardless of whether the HCP chooses to access the information, the conditions of this criterion have been met.**

Thank you for your consideration of our comments. We look forward to working with the FDA to ensure the agency's regulatory approach to implementing Section 3060(a) is consistent with the language and intent of the Cures Act and prioritizes patient safety while at the same time allowing hospitals and health systems to continue to implement innovative decision support tools. Please contact me if you have questions or feel free to have a member of your team contact Samantha Burch, director of health information technology policy, at sburch@aha.org or 202-626-2313.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development