CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

December 23, 2019

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

Subject: Docket Number FDA-2017-D-6569, Draft Guidance for Industry and Food and Drug Administration Staff: Clinical Decision Support Software

Dear Dockets Management Staff:

On behalf of more than 400 member hospitals and health systems, the California Hospital Association (CHA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) revised draft guidance for industry and FDA staff on clinical decision support (CDS) software as part of the agency's ongoing efforts to implement Section 3060(a) of the 21st Century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).

CHA strongly supports the goals of the Cures Act, which is aimed at driving innovation in health care and accelerating new treatments to lead to cures. Notably, Section 3060(a) of the Cures Act sought to deter over-regulation by establishing four criteria to exempt certain low-risk CDS software from FDA regulation, fostering bedside innovation by allowing clinicians to use CDS algorithms that analyze large amounts of clinical data to support their patient-specific decision-making. We continue to support the FDA's important authority to regulate software that replaces — rather than supports — health care provider decision-making. **However, we share concerns expressed by the American Hospital Association (AHA) and the Federation of American Hospitals that, under the draft guidance, the FDA's interpretation of certain criteria established by the Cures Act could result in many existing CDS algorithms being subject to the FDA approval process, ultimately slowing the pace of innovation and development of new software tools that support better patient care and outcomes**.

Recognizing the origin of the ultimate clinical treatment or action — the health care provider or the software algorithm — is critical to ensuring the statute is accurately applied. **While we provide comments specific to each of the Cures Act criteria below, we urge the FDA to continue to seek clarification and stakeholder feedback — in particular from providers who interact with CDS tools in the hospital — as it continues to refine its regulatory approach to device and non-device CDS functions**.

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

The first criterion established by the Cures Act describes what CDS software functions must **not** be intended to do if they are to be excluded from the device definition. We believe this statutory

499 So. Capitol Street SW, Suite 410, Washington, DC 20003 • *Telephone:* 202.488.3740 • *Facsimile:* 202.488.4418
1215 K Street, Suite 800, Sacramento, CA 95814 • *Telephone:* 916.443.7401 • *Facsimile:* 916.552.7596 • www.calhospital.org
Corporate Members: Hospital Council of Northern and Central California, Hospital Association of Southern California, and Hospital Association of San Diego and Imperial Counties

requirement is appropriate, as it is critical to ensure that data obtained from these devices and systems are created accurately. However, the draft guidance lacks clarity regarding the definition of "a signal from an IVD device" or "a pattern or signal from a signal acquisition system," and could cause confusion for hospitals and health systems as they seek to determine which CDS software meets this criterion.

For example, hospitals utilize CDS software that take data generated by medical devices to identify and alert clinicians to possible cases of sepsis. The data from these devices must be accepted by a clinician into the medical record before the CDS algorithm uses them to process any alerts the clinician may use as a source of information to determine a diagnosis or treatment.

We support the AHA's recommendation that the FDA should draw 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 health care providers 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)

CHA appreciates the 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 of the statute.

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

Under the third exemption criterion established by the Cures Act, the software function must be intended for the purpose of "supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition." As stated earlier in this letter, we agree that algorithms that take the ultimate decision-making authority out of the hands of the health care provider should be appropriately regulated as medical devices. However, we are concerned that the draft guidance introduces unnecessary confusion with its proposed use of the International Medical Device Regulators Forum (IMDRF) framework to implement this criterion.

Specifically, the FDA proposes to define software functions intended to "support or provide recommendations," and thus exempted from device regulation, as those that align with the IMDRF framework category of functions that "inform clinical management." CDS software 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. The IMDRF describes functions that **drive** clinical management as software that provides information that "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." This would include CDS software used to "**identify** early signs of a disease or condition" or "**aid** in diagnosis by analyzing

relevant information to help predict risk of a disease or condition." **However, in clinical practice, these types of CDS functions are just one of several sources of information that a health care provider will use to independently determine diagnosis and course of treatment.**

We urge the FDA to reconsider applying this distinction between CDS functions that "inform" versus those that "drive" clinical management, and instead propose a policy that is consistent with the statutory exemption for software functions that support or provide recommendations about prevention, diagnosis, or treatment. The FDA could draw a much clearer line — if an algorithm takes the agency and decision-making authority away from the clinician and dictates the next course of diagnostic testing or treatment without any reasonable opportunity for intervening clinical judgment, then such software functions should be regulated as devices.

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

Under the draft guidance, the FDA interprets the final criterion to require that CDS software functions subject to the Cures Act exemption be described in plain language to providers, including:

- The purpose or intended use of the software function
- The intended user (e.g., ultrasound technicians, vascular surgeons)
- The inputs used to generate the recommendation (e.g., patient age and sex)
- The basis for rendering a recommendation

CHA supports the FDA's interpretation of this criterion and the underlying intent that the health care provider has access to understandable information upon which to evaluate the basis of the recommendation. However, we urge the FDA to further clarify the format in which this information may be provided. While we agree that the information described by the FDA in the CDS draft guidance should be made available to health care providers, it is not necessary to embed all of this information within the algorithmic output, nor is it necessary to affirmatively require or confirm that providers review this information each time the algorithm is used. **We urge the FDA to clarify that as long as the information is accessible as part of the software function (e.g., through a link to a separate web page) — regardless of whether the health care provider chooses to access the information — the conditions of this criterion have been met.**

CHA appreciates the opportunity to share our comments. If you have additional questions, please contact me at akeefe@calhospital.org or (202) 488-4688, or my colleague Megan Howard, senior policy analyst, at mhoward@calhospital.org or (202) 488-3742.

Sincerely,

/s/
Alyssa Keefe
Vice President, Federal Regulatory Affairs