United States Senate
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
WASHINGTON, DC 20510–6300

April 17, 2024

**VIA ELECTRONIC TRANSMISSION**

The Honorable Robert Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20933

Dear Commissioner Califf:

Clinical decision support (CDS) software is a helpful tool for providers to deliver personalized care to patients. CDS software can improve health care outcomes by analyzing a patient's health records to determine risk of complications from a medical procedure and potential treatment options based on individual histories. FDA, however, threatens to undermine the effective use of these tools with its September 2022 final guidance that seeks to regulate CDS software as a medical device.

In the 21st Century Cures Act, Congress exempted CDS software from being categorized as a medical device, provided the software supplements and does not direct a provider's delivery of care.[1] FDA's guidance, however, ignores this congressional directive and expands its authority over CDS software without identifying the likelihood that these tools are "reasonably likely to have serious adverse health consequences." This guidance unnecessarily calls into question the safety of these tools and expands the universe of entities regulated by FDA, many of which are small provider practices who have developed their own CDS tools. FDA has failed to raise specific safety concerns with CDS software that would justify expanding FDA's oversight over these tools. FDA's decision to expand its authority over CDS software through guidance and not by going through notice and comment rulemaking is also concerning, as it fails to give stakeholders opportunity to share feedback on the proposed changes.

FDA's guidance not only runs contrary to an explicit congressional directive but may jeopardize access to advanced tools that improve patient care. To that end, I ask that you answer the following questions on a question-by-question basis by **May 1, 2024**:

[1] *See 21st Century Cures Act*, Section 3060(a).

1. What did FDA's review of CDS software from publication of its September 2019 draft guidance to the publication of its September 2022 final guidance find to justify the expansion of its authority to regulate CDS software?

2. In the final guidance, FDA raised concerns about providers defaulting to "automation bias," where a provider assumes CDS outputs to be correct, when using CDS software to support care delivery.[2] What evidence has FDA reviewed on automation bias? Please describe any adverse event reports highlighting the impact to patient safety, if any.

3. Why did FDA pursue this major policy shift in its approach to CDS software through guidance as opposed to rulemaking and how does FDA intend to integrate stakeholder feedback into implementing the final guidance?

4. What stakeholder engagement does FDA plan to offer to assist in compliance with the final guidance, particularly for those who have never previously engaged with FDA?

5. How many CDS tools, if any, did FDA determine to be a medical device prior to finalizing its CDS software guidance?

6. Should FDA determine that a particular CDS software tool is a device, will the developing entity be required to comply with all medical device regulations, including participation in the user fee program?

7. Many CDS tools are developed within health care practices to maximize clinical resources. How did FDA consider CDS usage by small providers and their current engagement with FDA in developing the final guidance?

8. What engagement has FDA had with other agencies, such as the Office of the National Coordinator for Health Information Technology (ONC) or the Centers for Medicare and Medicaid Services (CMS) in implementing its final guidance?

[2] *Clinical Decision Support Software*, Food and Drug Administration (Sept. 28, 2022), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software, at 11.

Sincerely,

Bill Cassidy, M.D.

Bill Cassidy, M.D.
Ranking Member
Senate Committee on Health,
Education, Labor, and Pensions

CC:
Dr. Micky Tripathi
National Coordinator for Health Information Technology, Office of the National Coordinator for Health Information Technology