February 6, 2018

Scott Gottlieb, M.D.
Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Commissioner Gottlieb:

The College of Healthcare Information Management Executives (CHIME) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) draft guidance, "Clinical and Patient Decision Support Software," published December 7, 2017. CHIME is an executive organization serving more than 2,500 chief information officers (CIOs) and other senior health information technology leaders at hospitals and clinics across the nation. CHIME members are responsible for the selection and implementation of clinical and business technology systems that are facilitating healthcare transformation.

The FDA has long regulated software that is used as a device. The 21st Century Cures Act signed into law in 2016 excludes from the agency's oversight purview various types of software applications. Section 3060(a) of the 21st Century Cures Act amended Section 520 of the Federal Food, Drug and Cosmetic Act (FD&C Act) to exclude certain software functions that either do not meet the definition of a device pursuant to the changes in the Cures Act, or for which the agency does not plan to enforce compliance.

CHIME Recommendations

As detailed below, overall, we are supportive of much of the draft FDA has published. There are three areas, however, where we recommend changes:

1. **Greater clarification around what software is included under FDA oversight authority;**
2. **Revising the definition under item 3, Section III to include emulated decision-making and predictive modeling (page 7, lines 198-200); and**
3. **Clarification is needed around whether the FDA would consider intensive care unit (ICU) dashboards and electronic health records (EHRs) within or outside their enforcement authority.**

College of Healthcare Information Management Executives (CHIME)
710 Avis Drive, Suite 200 | Ann Arbor, MI 48108 | 734.665.0000 | chimecentral.org

Section II – "Background"

The law is prescriptive with respect to the software functions for which FDA oversight is excluded. It precludes software functions as falling under the definition of a device and thus are outside the scope of FDA oversight if the function meets all four below criteria:

(1) not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system (section 520(o)(1)(E) of the FD&C Act);
(2) intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines) (section 520(o)(1)(E)(i) of the FD&C Act);
(3) intended for the purpose of supporting or providing recommendations to a healthcare professional about prevention, diagnosis, or treatment of a disease or condition (section 520(o)(1)(E)(ii) of the FD&C Act); and
(4) intended for the purpose of enabling such healthcare professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient (section 520(o)(1)(E)(iii) of the FD&C Act).

Section III – "Interpretation of Criteria in Section 520(o)(1)(E) of the FD&C Act

Subsection 2 – "Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information"

Overall, CHIME is pleased with most of the guidance especially if you consider the majority of clinical decision support (CDS) used today typically requires a human to take an action based upon recommendations made by the software. Our members appreciate the need for a lighter regulatory touch which can be helpful in a rapidly evolving area like healthcare technology. However, we are unclear if it is FDA's intent to include or exclude the more futuristic types of CDS like machine learning and predictive modeling. **CHIME recommends that the FDA offer more clarification around what types of CDS software they plan on overseeing and whether this is intended to include machine learning and predictive modeling.**

Subsection 3 – "Intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition

To our recommendation above, if this guidance is not intended to cover more futuristic and evolving CDS rather than what is typically found is most hospitals today, then we believe the guidance strikes the appropriate level of oversight. However, given that CDS will increasingly rely on machine learning and predictive modeling, more oversight around these areas is warranted. Our members need assurances that when purchasing this type of software there is adequate oversight. Thus, if there is any area of the guidance that presents concerns to us, it centers around item 3 (starting line 198) under Section III, "Interpretation of Criteria in Section 520(o)(1)(E) of the FD&C Act." Section 3060(a) of the Cures Act.

Our members facilitate patient care using technology and their primary concern hinges around patient safety. Presently, most CDS in EHRs requires direct clinical input whether from a physician or someone else and a human must say "yes" to the CDS to trigger an action. However, as technology is rapidly evolving and machine learning evolves – we will see more decisions being made automatically by the computer without the opportunity for a clinician's review.

We have among the CHIME membership those working at institutions that use cutting-edge CDS. These entities feel confident that they have adequate staff and internal controls in place around testing, maintenance and evaluation of CDS; for them, further oversight would be superfluous if not outright burdensome. However, there are many others – including several entities outside the healthcare space – that are using or designing CDS for which patient safety may not be the top concern.

While well-designed CDS has been proven to be safe and can help improve patient care, research – including studies funded by the federal government – has found current generation CDS systems can also be prone to malfunction creating patient safety issues. For instance, one study published in the *Journal of the American Medical Informatics Association (JAMIA)* and funded by Office of the National Coordinator for Health IT (ONC) found

variations among drug-drug interactions (DDIs) due to the present lack of standards.[1] There was substantial variation among different EHR vendors and only four of the 19 systems displayed the most severe alert to users. With an estimated 1.5 million adverse drug events occurring annually – many of which stem from DDIs – this is cause for concern.

Another study also published in *JAMIA* and funded by the National Institutes of Health (NIH) found alert malfunctions are commonplace across different health systems.[2] They also discussed who should be responsible for updating CDS content. They state, "Although we believe that provider organizations are ultimately responsible for their CDS content, we also believe that EHR vendors and content suppliers should provide tools for monitoring CDS in real time (or as near to real time as possible) and consider enhancements to their content-authoring and knowledge-management tools to prevent the common issues observed in our study (e.g., better environment migration tools to ensure content integrity, or automated dependency checking tools to mitigate potential issues when new codes are changed)." As CDS software evolves into a higher state of machine learning and the data derived from algorithms is increasingly driven by the software, the solutions presented to clinicians could be opaque. Adequate oversight is thus needed to ensure transparency for clinicians and prioritizing patient safety.

Given some of the patient safety issues that have been highlighted in CDS systems, it is even more important that as we move into the increased use of next-generation CDS software that there is adequate oversight and that patient safety remains a top priority. **Therefore, we recommend the following changes to lines 198-200 with the underlined text reflecting our suggested, revised language:**

> **(3) Intended for the purpose of supporting or providing recommendations <u>emulated decision making or predictive modeling</u> to a healthcare professional about prevention, diagnosis, or treatment of a disease or condition**

Along these lines, we seek clarification from the FDA around how they would treat data warehouses and data analytics associated with machine learning. These areas are perceived by our members as "gray areas" and warrant a greater oversight. Among the criteria for exclusion from FDA oversight is when a clinician is not relying solely on software recommendations to make a clinical diagnosis. Data warehousing and analytics could be used as the sole source of clinical decision-making. We seek greater clarification from the FDA around the agency's plans for handling machine learning as it relates to the criteria that excludes CDS when it is relied upon as the only source of information for making a clinical decision.

<u>Reference to "Changes to Existing Medical Software Policies Resulting from Section 3060 of 2 the 21st Century Cures Act" Guidance Document</u>

The FDA released two other guidance documents the same day they released the CDS guidance. The FDA references the second guidance on lines 341-344 of the CDS document. In the second draft guidance, "Changes to Existing Medical Software Policies Resulting from Section 3060 of 2 the 21st Century Cures Act," we received questions concerning how the agency plans to handle EHRs.

This second guidance clarifying provisions found at 520(o)(1)(A-D). Among the software the law has excluded in Section 520(o)(1)(C) are "electronic patient records." Specifically, in this second draft guidance FDA states (lines 347-342):

> *Software functions excluded from the device definition by section 520(o)(1)(C) of the FD&C Act may be contained in electronic health record (EHR) systems, PHR systems, and other health information technology. Such systems may also contain other software functions that could meet the definition of a device. FDA's approach to oversight of software functions that meet the definition of a device in a system*

---

[1] McEvoy DS, Sittig DF, Hickman T-T, Aaron K, Ai A, Amato M, Bauer DW, Fraser GM, Harper J, Kennemer A, Krall MA, Lehmann CU, Malhotra S, Murphy DR, O'Kelley B, Samal L, Schreiber R, Singh H, Thomas EJ, Vartian CV, Westmorland J, McCoy AB, Wright A. Variation in High Priority Drug-Drug Interaction Alerts Across Institutions and Electronic Health Records. J Am Med Inform Assoc. DOI: http://dx.doi.org/10.1093/jamia/ocw114 First published online: 28 August 2016. PMID: 27570216.

[2] Wright A, Ai A, Ash J, Wiesen JF, Hickman TT, Aaron S, McEvoy D, Borkowsky S, Dissanayake PI, Embi P, Galanter W, Harper J, Kassakian SZ, Ramoni R, Schreiber R, Sirajuddin A, Bates DW, Sittig DF. Clinical decision support alert malfunctions: analysis and empirically-derived taxonomy. J Am Med Inform Assoc. 2017 Oct 16; PMID: 29045651. https://doi.org/10.1093/jamia/ocx106

with software functions that do not meet the definition of device (products with multiple functions) will be addressed in a separate guidance document.

First, our members asked since the lines outlined above appear to reference back to the CDS guidance concerning software with multiple functions, does that mean that EHRs are now considered devices if any part or function of the EHR is a regulated device? Second, throughout the second guidance document there is reference to "immediate clinical action." On lines 450-456 the agency references active patient monitoring and alarms. Our members have requested clarification on whether dashboards used in an intensive care unit that track patient data and that send alarms alerting a clinician to take an action would qualify as a device? Most EHRs have functions that handle this type of alerting and thus this has raised questions.

With our above comments in mind, we offer the following recommendations:

1. **Clarification on whether the FDA would consider ICU dashboard and EHRs within or outside their enforcement authority is needed.**
2. **ICU dashboards should be excluded from FDA oversight.**
3. **EHRs as a whole should not be regulated just because one function within the EHR is considered a device; rather, the focus should be on the individual function.**

Conclusion

CHIME appreciates the opportunity to comment on this guidance and welcomes to opportunity to further inform these policies. Should you have any questions please contact my staff, Mari Savickis, vice president, federal affairs, at msavickis@chimecentral.org.

Sincerely,

Russell Branzell, FCHIME, CHCIO
CEO & President, CHIME

Cletis Earle
Chair, CHIME Board of Trustees
Vice President and CIO Information Technology
Kaleida Health