HIMSS Electronic Health Record Association

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

Dear Dr. Gottlieb,

On behalf of the more than 30 members of the Electronic Health Record Association (EHRA), we are pleased to share our comments regarding the Clinical and Patient Decision Support Software Draft Guidance for Industry and Food and Drug Administration Staff.

EHRA members serve the vast majority of hospitals and ambulatory care organizations that use electronic health records (EHRs) and other health information technology to deliver high quality, efficient care to their patients. Our core objectives focus on collaborative efforts to accelerate health IT adoption, advance interoperability, and improve the quality and efficiency of care through the use of these important technologies.

Our general impression is that three documents related to clinical decision support (CDS) were published in isolation, as there is a lack of harmonization among them. While EHRA appreciates publication of the International Medical Device Regulators Forum (IMDRF) Software as a Medical Device (SAMD): Clinical Evaluation as 'non-binding' insight into the current thinking of the FDA, it is puzzling as to why the Clinical Decision Support Draft Guidance includes no such risk-based strategy, but seems entirely based on transparency, which is not considered a determinant of risk in the IMDRF framework. Similarly, the Changes to Existing Medical Software Policies places significant emphasis on the timing of the clinical action relative to the CDS, a factor which is not mentioned in the Draft Guidance.

The lack of a unified strategy in these documents is of concern, as EHR developers may provide highly configurable tools that healthcare organizations might configure in a manner that could be seen as higher risk by regulatory authorities.

Conflicting language greatly broadens the scope in which EHR software could become regulated, which is contrary to the stated intent of the 21st Century Cures Act. EHRA recommends that FDA issue a less ambiguous guidance with internally consistent changes to existing Medical Software Policies. Also, EHRA recommends consideration of enforcement discretion for software tools where the risk may be created outside of the developers' control.

Our overall response to the CDS Draft Guidance is that while it includes many common-sense recommendations, some are overly broad, leading to potentially problematic ambiguity. Given the emphasis on transparency in the Guidance, EHRA has significant concerns over the absence of direction on the use of machine learning/artificial intelligence, which will play a key role in the future of CDS development.

EHRA would appreciate guidance from the FDA as to whether automated actions as a result of CDS will be regulated differently than suggestions/recommendation to a licensed clinician, which still require expert decision-making.

Patient decision support software, not intended for healthcare professionals, was described in the Guidance as "low risk devices" falling "outside of the set of functionalities upon which FDA intends to focus its regulatory oversight." We appreciate that FDA's pragmatic approach to this type of software. Additionally, we appreciate the FDA's decision to continue enforcement discretion for some clinician-facing mobile software as outlined in the 2015 Mobile Medical Applications (MMA) guidance, although the examples listed do not provide additional clarity on the regulation of CDS.

Where the Draft Guidance falls short is the absence of clear and unambiguous direction for software developers. While the examples provided for both non-devices and devices are helpful, the device examples rely solely on transparency and most lack applicability for EHR developers, a significant source of clinician-facing CDS.

More generally, the FDA has appropriately deemed all CDS that is based on published clinical guidelines and generally accepted clinical practice as non-regulatory; however, it is unclear what constitutes "generally accepted clinical practice." This could be interpreted to include medical or specialty guidelines, regional standards of care, or institutional practices. EHRA requests that the FDA provide additional detail as to the criteria defining this requirement.

The 21st Century Cures Act requires that supporting information for the CDS be available for review by the clinician, but does not specify that it be available to the public. However, the Guidance requires that supporting sources be "easily accessible to the intended user, understandable by the intended user (e.g., data points whose meaning is well understood by the intended user), and publicly available (e.g., clinical practice guidelines, published literature)." EHRA recommends striking the criterion for 'publicly available' data for transparency, as this is clearly expands beyond the scope of 21st Century Cures, resulting in additional ambiguity. For example:

- If the source is a published research study available to clinicians through a paid license, is that "easily accessible" and "publicly available," or will software vendors be expected to supply copyrighted content to their users?
- If a client healthcare organization incorporates the results of internal, non-published quality improvement studies to create custom CDS content, would the core EHR software and/or the custom CDS software tools be considered a regulated device?
- How are developers to determine "understandable by the intended user," given that a single CDS function could reasonably be expected to be used by a physician, nurse practitioner, physician's assistant, or other licensed clinician? Even when the intended user is a physician, there is a wide spectrum of training and experience (especially in academic settings and hospital inpatient environments), including between and within specialties. The regulatory status of the software should not be determined by a healthcare organization's decision to allow lesser trained, but still licensed, users of the software.

The guidelines published by the CDS Coalition attempted to address this issue, and we request that the FDA take those recommendations into consideration in its Final Guidance.

Moreover, the example of custom CDS by a healthcare organization illustrates a common paradigm for EHR developers. EHR developers provide software tools to clients who then take responsibility for the content of subsequent CDS recommendations to their clinical users. EHRA requests that FDA clarify the intent for regulating the software if the client creates clinical decision support rules which do not provide the transparency that the Guidelines indicate to be the primary determinant of regulatory oversight, regardless of risk.

We appreciate that the Guidance does not impose specific requirements for how CDS content is displayed, and we recommend continued flexibility. Healthcare organizations may choose to display CDS content differently depending on a variety of factors, such as the hardware or device on which it is likely to be viewed by the clinician, the clinical context, and how often it is expected to be triggered. Because best practices for software usability are continually evolving and improving, healthcare organizations and software developers should retain flexibility in how CDS content is displayed.

Thank you for this opportunity to comment. EHRA and its members are committed to identifying and capitalizing on opportunities to develop health IT into an even more effective tool in making health care safer.

Sincerely,

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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of more than 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.