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regarding the Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act Draft Guidance for Industry and Food and Drug Administration Staff.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 while there are many proposals for which the FDA is to be commended, overall the Changes to Existing Medical Software Policies (Changes) is predicated far more on the timeliness of the CDS interventions, while the CDS Draft Guidance relies solely on transparency. Both factors are important, however, this discontinuity between the two simultaneously released documents results in ambiguity and uncertainty.

We commend FDA for exercising common sense with its decision to exclude from its enforcement discretion low-risk "general wellness intended uses relates to sustaining or offering general improvement to functions associated with a general state of health while making reference to help reduce the risk of or help living well with certain chronic diseases or conditions."

Also, we are pleased to see that software such as Laboratory Information Management Systems (LIMS) and Mobile apps that meet the definition of Medical Device Data Systems are being removed from the Draft Guidance, as they are not within the definition of the term "device" under the 21st Century Cures Act.

Regarding EHRs, the proposed Changes state that FDA does not intend to enforce "requirements for software functions that are not certified by ONC." This is another common sense provision that we support. Additionally, we are supportive of the acknowledgement that software functions in personal health record (PHR) systems that "are not intended for use in the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition are not devices." FDA has widely recognized that mobile apps that enable individuals to communicate with ONC-certified EHRs are not devices.

EHRA is very interested in the timeline for the release of the FDA strategy indicated in the notation that "FDA's approach to oversight of software functions that meet the definition of a device in a system with software functions that do not meet the definition of a device (products with multiple functions) will be addressed in a separate guidance document."

The proposed Changes state that enforcement discretion applies for "software tools that analyze stored clinical information to flag patient results based on specific clinical parameters (e.g. out of range results, potential drug interactions opportunities for complementary tests, create disease registries, summarize patient-specific information in an integrated report, and/or track a patient's treatment or diseases outcome) provided that the analysis performed by these software is not intended for immediate clinical action and does not represent a unique interpretation function (emphasis added)." The qualifier of "intended for immediate clinical action" is of particular interest for EHR developers in the acute-care setting, as the same CDS functions may be used by licensed clinical professionals in all areas of the healthcare facility. The acuity of the patient/care environment is the variable, rather than the inherent risk of the CDS function.

Interpretation of "immediate clinical action" could mean an action by a clinician on the patient (e.g. administering a medication). The timing of interactions between clinician and patient exist outside of the software and are not determined or guided by the software. The time frame in which a clinical intervention needs to occur varies by patient, acuity, comorbidities and other factors. If the FDA plans to regulate CDS that may be used on critically ill patients (as the riskiest scenario), then by default they will regulate most, if not all, CDS used in the acute-care setting.

Alternatively, if "immediate clinical action" is interpreted as an action which a clinical user must take within the software to proceed, that will also greatly expand the scope of regulation as many CDS "hard stops" exist but are not necessarily high risk scenarios.

While time and situational acuity are factors in a risk-based framework, in the absence of the FDA formally implementing such a framework, EHRA has serious concerns with partially including "immediacy" as the ultimate criterion within the actual regulatory language. The 21st Century Cures Act does not require that CDS be intended for non-immediate clinical action in order to satisfy the

exemption. Therefore, we recommend that FDA remove that requirement from the proposed Changes and add a reference to the criteria for exemption until such time as a fully implemented risk-based framework is established.

Of similar concern to EHRA is the following:

> *Section 520(o)(1)(D) of the FD&C Act does not capture software functions intended to generate alarms or alerts or prioritize multi-patient displays, because these functions involve analysis or interpretation of laboratory test or other device data and results. For example, if a software function is intended to prioritize patients in an Intensive Care Unit based on their clinical status, then this function is intended to interpret or analyze device data, results, and findings and is, therefore, not excluded from the definition of device under section 520(o)(1)(D) of the FD&C Act. Similarly, software functions that analyze medical device data in order to provide a notification or flag (e.g., that a parameter is out of range) are not excluded from the definition of device under subsection (D). However, FDA does not intend to enforce requirements under the FD&C Act and implementing regulations for these low risk software functions, such as the analysis of data to provide a notification, for which immediate clinical action is not needed.*

While we appreciate the FDA's stated intent to exercise enforcement discretion, the determination that the cited example of sorting an ICU patient list based on acuity could be construed as a contradiction to the separate Draft CDS Guidance if the basis for evaluating the clinical status of patients was generally accepted clinical practice/published guidelines such as Apache II scoring.

The 'out of range' flag cited as an example of a device subject to enforcement discretion is inherently contradictory in the EHR environment where many such flags are transmitted from some other system--e.g. LIMS, which are now not considered devices--and do not represent any EHR-based analysis. By qualifying enforcement discretion with the need for immediate clinical action, one could infer that an EHR which displays a critical lab result flag would be subject to regulatory oversight.

While both of these examples are subject to enforcement discretion, this discretion is predicated upon the time-based criterion and could be rescinded in the future. By designating these types of functions as medical devices, the FDA has greatly broadened the scope of medical device definition to include functions which have been safely implemented in EHRs for many years.

EHRA requests that the FDA harmonize the CDS Guidance with the proposed Changes to eliminate contradictory and ambiguous language, as well as remove or better define the "immediate clinical action" criterion.

Thank you for this opportunity to comment.

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.