EHRA
HIMSS ELECTRONIC HEALTH RECORD ASSOCIATION

350 North Orleans Street, Suite S10000
Chicago, IL 60654

@EHRAssociation | ehra.org

December 6, 2022

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

RE: Docket number FDA-2017-D-6569

Dear Dr. Califf and team,

The HIMSS Electronic Health Record (EHR) Association is a national trade association of EHR developers serving the vast majority of hospital, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs and other health IT across the United States. Together, we work to improve the quality and efficiency of care through the adoption and use of innovative, interoperable, and secure health information technology.

On behalf of our 30 member companies, we are herein submitting commentary in response to the Food and Drug Administration's recently released Guidance for Clinical Decision Support (CDS) Software *(docket number FDA-2017-D-6569)*. We appreciate the FDA's efforts in producing this guidance. Our members have long awaited its release, contributing input on the subject to the Administration over the past years.

While we are generally aligned with much of the guidance presented, we offer five key elements about which we have specific questions or concerns, based on our experience supporting healthcare providers in their use of EHRs and other health IT.

1. In many cases, CDS is highly intertwined with EHR technology and is sourced from a number of different places: our companies, third-party publishers, and the providers who are using it. ONC's health information technology certification program sets the expectation that clinical decision support is configurable by administrators at a healthcare organization. However, the FDA's guidance does not appropriately reflect the reality that decision alerts are frequently created and configured by provider organizations and that for many health IT solutions, the developer asserts little or no control over CDS configuration. It is unclear who ultimately has an obligation to enforce compliance

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when a provider is using the solution to deliver CDS they have developed themselves or purchased and implemented directly from a third party. We request clarification and additional guidance as to how this should work in practicality.

2. Extensive functionality exists within EHRs already in use across the market that seems to directly or in part bump up against the FDA's new guidance. Clinical decision support has been part of ONC's EHR certification requirements since 2011 and is widely deployed. We are highly concerned that this guidance could lead to disruption in the availability of solutions that clinicians rely upon to maximize both the usability of their EHRs, as well as to help them sift through the massive amounts of patient data they have gathered when making decisions about diagnosis and treatment plans. As one example, does the FDA intend to designate as a device CDS the legacy Sepsis CDS functionality that is widely in use across healthcare organizations today and provides a clinician alert within EHRs? Or existing functionality that leads a system to create a list for review of patients who might potentially be at risk of substance use disorder based on criteria identified by the provider organization? If this type of existing functionality is, indeed, intended to be classified as device CDS, a few additional questions:
    - How does the FDA plan to address the long list of CDS tools already on the market and in active use by hospitals and providers that the FDA has now essentially classified as device CDS through this guidance?
    - Does the FDA mean to say that the CDS functionality needs to be removed from the EHR, is it allowed to remain in the EHR if it is somehow divided or separated in such a way that it does not impact other EHR functionality, or can the module remain as is, as long as it is managed as CDS?
    - Is there an expected effective date, or a transition period the FDA has in mind?

3. The FDA guidance expresses concern and makes recommendations regarding scenarios in which software provides a user with a single recommendation in a CDS alert rather than a list of options. This appears to ignore the fact that even where a single recommendation is made, in the vast majority of the instances, no action is taken to affect the patient without the provider's review and active decision-making. The provider has a choice to follow or not follow the CDS recommendation based on other knowledge s/he has separate from what the CDS alert is presenting within the EHR. For example, an EHR would not automatically send a script to the pharmacy based on the single recommendation provided; a provider would issue the prescription after considering the recommendation and deciding whether it was the right course of action.

   We believe the FDA is missing a critical distinction between CDS (Clinical Decision Support) and what we are terming "CDM" (Clinical Decision Making). CDS brings information to the clinical provider at the point of care, with the final treatment or diagnostic decision ultimately made by the provider based on the presented information and their additional knowledge. Software-driven "CDM," conversely, would utilize Artificial Intelligence (AI) to institute decisions from the information presented in the system based on programming without input, review, or interaction from the clinician at the point of care. This latter scenario happens very rarely in

terms of the EHR software we develop, and while we agree that it is an important area of consideration due to rapidly changing technologies, it would be better addressed in separate AI

guidance from the FDA instead of the conflation with CDS that occurs in the guidance we are discussing here. If the FDA believes this scenario is one that should be addressed in the FDA CDS guidance, the difference between CDS and "CDM" would seem to be a natural distinction between device CDS and non-device CDS.

Further, we note that there are scenarios in which it is entirely appropriate that a single recommendation is presented, as opposed to a list of choices. For example, the hospital or practice might have a preferred care pathway for that condition that they want to be delivered in an alert to clinicians, or the treatment recommended may be the only one covered by the patient's insurance. Even here, a provider still has the option not to follow the recommendation.

The approach suggested in the CDS guidance wherein alerts would always need to include options would significantly impair the helpfulness of clinical decision support alerts that significantly aid in decision-making today. If software developers were to remove functionality offering a single option in order not to offer device CDS, provider workflow would be adversely impacted, forcing them to search for information rather than having the system present it for use, as would patient care.

4. The guidance appears arbitrary in making distinctions to determine what constitutes device CDS. For example, the guidance does not categorize a medication/allergy alert as device CDS, while similar alerts designed to bring information from a patient's record to the clinician's attention are seemingly deemed device CDS. If the FDA finds the first example acceptable, others that are configured similarly to inform providers of relevant facts from the patient's record for consideration but leave the decision to the clinician should be treated the same in terms of risk assessment. Criteria should be clearly and consistently applied, which would require the published guidance to be revised.

5. The function or purpose of CDS within EHRs is to provide clinical information and options to the clinician. However, the guidance interprets many common scenarios as automation bias. As EHR developers, our role is to design systems that provide ease and efficiency for our clients. Therefore, the fact that an alert has been successfully designed to be easily interpreted seems an unreasonable criterion for identifying it as automation bias. The EHR Association recommends the FDA revisit this issue.

Thank you for this opportunity to share our experiences and expertise. We would welcome an opportunity to speak with the FDA team that has worked on the CDS guidance in order to share more real-world examples of where the recently published document is unclear, inconsistent, or risks negatively impacting the clinician's maximization of our software. We appreciate the FDA's ongoing collaboration to leverage health IT and bring to the market innovations to support clinicians and the patients they serve.

Sincerely,

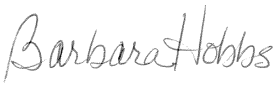
Hans J. Buitendijk
Chair, EHR Association
Cerner Corporation

David J. Bucciferro
Vice Chair, EHR Association
Foothold Technology

HIMSS EHR Association Executive Committee

Pamela Chapman
Experity

William J. Hayes, M.D., M.B.A.
CPSI



Barbara Hobbs
MEDITECH, Inc.

Cherie Holmes-Henry
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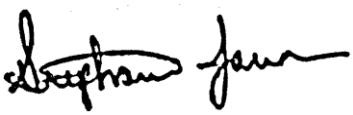

Stephanie Jamison
Greenway Health

Sasha TerMaat
Epic

Established in 2004, the Electronic Health Record (EHR) Association is comprised of 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.