33 W. Monroe, Suite 1700
Chicago, IL 60603
swillis@himss.org
Phone: 312-915-9518
Twitter: @EHRAssociation

Acumen Physician Solutions
AdvancedMD
AllMeds, Inc.
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June 30, 2017

Bradley Merrill Thompson, General Counsel
Clinical Decision Support Coalition
227 25th St NW #700
Washington, DC 20037

Dear Mr. Thompson,

The Electronic Health Record Association (EHRA) greatly appreciates the opportunity to review and provide feedback on the Clinical Decision Support Coalition's (CDS Coalition) Draft Industry Guidelines document. We represent our members, who are EHR developer companies that serve the vast majority of hospitals and ambulatory practices that use EHRs to deliver safer, more efficient care to their patients. These comments reflect our collective experiences in designing and supporting these complex technologies, including clinical decision support functionality.

We support the CDS Coalition's intent to ensure that CDS software, as much as possible, leaves the clinician in control of the clinical decision-making. However, within that context, we find these proposed guidelines to be overly complex, prescriptive, not practical, and inconsistent with the text or spirit of the applicable 21st Century Cures Act language.

As software developers who have worked to build clinical decision support functionality that both meets the stringent requirements of sound medical practice and the needs of the end-user in a variety of clinical settings, we are concerned that this perspective is not represented in the CDS Coalition guidelines.

While we appreciate the opportunity to comment, we urge the CDS Coalition to take a step back to reconsider these guidelines and further engage with additional experts and users who are experienced with how CDS works in practice.

General Comments

With regard to language in the 21st Century Cures Act (Cures) on clinical decision support (CDS) software, we have a number of specific comments on the Coalition's guidelines.

The guidelines indicate that they may, at times, exceed the requirements of the new law, and that these guidelines would become a basis for a higher level of validation and FDA oversight. We are concerned that this scope increase beyond the requirements of the 21st Century Cures Act is unnecessary and undesirable; and, we believe that the statute should form the basis for what might require additional validation or oversight and not these proposed guidelines.

In general, this proposal appears to be counter to the underlying intent of the Cures provisions to take a non-prescriptive and deregulatory approach to lower risk health IT.

One of the primary factors suggested by the guidelines is the ability for a clinician to perform independent review of the basis of the CDS recommendation. We agree that clinical decision support is not intended to replace a clinician's training and judgment, and that this is a key consideration. However, we see practical challenges with implementing the voluntary guidelines, especially around transparency as proposed and particularly in innovative areas such as the incorporation of machine learning and artificial intelligence (AI).
Product requirements should be driven by thoughtful design, while being mindful of regulatory impact. We do not believe that Cures intended to dictate design elements, but rather provide statutory guidelines regarding healthcare software that is not defined as a medical device or subject to FDA regulation; these certainly are *relevant* to design.

In many cases, third-party CDS software might coexist within the context of an EHR as a seamless user experience. This approach is widely recognized as an optimal delivery mechanism for this type of information. Given that expectation, we believe the CDS Coalition guidelines should account for a broader clinical environment than physician vs. non-physician users and generalist vs. specialist; also, recognize that the range of clinician users of CDS in an EHR can be very broad across specialty and profession, making detailed specification of the intended user impractical and undesirable.

The guidelines are also silent in regards to CDS created by healthcare organizations, which is very common in an EHR context, with the EHR providing a CDS context, rules, engine, etc., and end users acquiring or providing clinical content.

Scope of These Guidelines

- We suggest that a more accurate description of CDS would be that it, "Produces a particular actionable result ***relevant to*** the diagnosis…" The FDA has been consistent in determining that software that provides diagnoses are subject to regulatory oversight.
- We challenge the statement that CDS is specifically defined as returning a single option rather than multiple options; when, in our experience, multiple options may be appropriate under certain circumstances (e.g., medication order sets).
- "…is standalone software, and not an accessory to a medical device." EHRA understands the intent to define software that is not required to operate a medical hardware device. However, we suggest some may interpret this to mean that these guidelines only apply to standalone CDS software rather than CDS which is part of a more comprehensive software solution (e.g., EHR).

Overview of Voluntary Guidelines for Enabling Independent Review of the Basis for CDS Recommendations

- With regard to the recommendation that users be able to independently review the basis of the recommendations the software makes, what is meant by "independent review?" Does it mean, for example, review of all logic vs. ability to understand who developed the logic and the provenance of the CDS content? The EHRA questions the extent and practicality of such "review," and is concerned about the impact on clinical workflows. In general, we believe that the ONC approach that requires certified CDS provide links to sources is a better approach than the more prescriptive methods included in these draft guidelines.
- The three criteria recommended to determine if the CDS is intended to enable the healthcare professional user to independently review the basis of the software's recommendations -- transparency, competent human intervention, and adequate time to reflect -- seem appropriate, conceptually.
    - Related to transparency, we question the extent to which labeling the software can communicate to the user the limits of the software's functionalities as well as the feasibility of indicating the intended user when embedded within the workflow of an EHR that has a wide variety of users and clinical situations. It is particularly challenging to label configurable tools for all possible uses that are unique to a healthcare organization's environment.
    - With regard to competent human intervention, the EHRA has concerns about making intra-professional judgments -- that is, one physician specialty vs. another, or cross-clinician (NP vs. MD) for CDS that is included in an EHR designed for a general clinician audience.
    - The CDS Coalition guidelines are silent as to the implementation of CDS in environments of high acuity and in moderate and complex decision-making (e.g., in the context of a critical care unit or emergency department) environments. We acknowledge that there are challenges in implementing CDS in environments where the intended user does *not* have enough time to independently consider the data inputs and may not be able to independently review the basis of the recommendation. In general, even in such situations, most CDS clinicians are generally able to weigh a variety of inputs and make needed decisions, and there would still be the ability for their clinical organizations to evaluate CDS and associated clinical content prior to situations with limited decision-making time. In light of the impending implementation of CDS and Appropriate Use Criteria (AUC), it is inevitable that CDS will be required in these higher acuity clinical settings. The EHRA suggests further analysis, as we believe that there is an appropriate role for CDS within the context of these workflows, subject to clinician discretion, if designed and implemented appropriately. The EHRA does not believe that CDS should be regulated based on 'worst-case' scenarios.

Appendix A: Transparency Guidelines

- Under Medical Knowledge, #6 refers to machine learning.
    - Regarding the recommended Transparency Elements, the approach to validation seems reasonable.

- Similarly under Machine Learning Outputs, it may be difficult to represent the full and precise mathematical formula used in a complex calculation or machine learning/AI. Is the intention of the CDS Coalition that such representation would be in laymen's terms, so easily understood by non-technical clinicians?
- In general, we believe that CDS using AI/machine learning should provide links to the applicable studies/research that bears on methods, validation, etc., and that users would be able to evaluate the sources of these algorithms and approaches, similar to what is done for other CDS but adjusted to the specifics of machine learning.

- Regarding the Proposed Disclosures by Number of Required Clicks, we question whether the number of clicks is really used as described in this section or just as an artifact. The number of clicks can vary across products and change as usability processes are applied. As user-centered design methods have evolved, multi-layer presentation has, in many places, been flattened in order to reduce clicks while still minimizing cognitive load.
- Relative to the reference to software that is designed to require the user to review an input page before getting to the recommendations, articles that need to be purchased may not be "reasonably accessible" to the user at the point of care. We encourage validation with the end-user community regarding actual value vs. perceived value, and whether there is a more targeted focus for implementation that would be reasonable to undertake and feasible to maintain.
  - How is "reasonably accessible" to be balanced with copyright infringement requirements? By extension, is just providing a pointer to send users to a place to purchase the article truly providing access to the basis for the recommendation?
  - EHRs are not in a position to control whether the fees required to access articles make them inaccessible to certain users.

Appendix B: Competent Human Intervention Guidelines

- Under Competent Human Categories, the EHRA suggests that "General Practitioner" is an outdated term. The healthcare industry uses "Family Practitioner" or "Primary Care Professional." Also, it is not at all clear that intended use should be designated based on primary care and specialty care, or physicians and everyone else. While for some categories of CDS, stratification by specialty is appropriate, there are many clinical areas where there is significant overlap between specialties and credentialing.
- The EHRA does not agree that Clinical Decision Support Categories, as described, are appropriate or are comprehensive enough to address the complex healthcare provider environment. The categories do not address advanced practice nurses or other limited license practitioners. The distinction between generalists and specialists as written also seem inappropriate to be applied to all forms of CDS.
- Regarding Intended Use Requirements in Labeling and Promotional Activities, these requirements are much too restrictive in the context of CDS as part of an EHR. Clinical users of CDS span multiple specialties and credentialing. Requiring marketing materials specifically targeted and labeled for every specialty and credential profile would be overly prescriptive. The FDA provides similar Labeling and Marketing cautions for regulated medical devices, and we do not see benefits in going beyond the FDA guidance in this regard.

Appendix C: Time to Reflect Guidelines

- The challenge in this general area is that most CDS will cross a range of clinical conditions, including acuity. It is very difficult to establish reasonable guidelines without delving into these variations. While standalone CDS software may be used in primarily non-urgent situations, as the industry moves toward API-based integration, e.g., the implementation of AUC, providing the benefit of CDS in urgent/emergency care areas is both inevitable and valuable and should be accounted for in these guidelines.

Appendix D: Background: Understanding the Statute

- #1 under (iii), enabling such health professional review seems to imply that EHR CDS or other CDS would focus on the specialty of the user. This is unrealistic.
- We also disagree that there must be information external to the software on which the provider can base clinical decisions. All available information may, in fact, be part of the CDS basis for recommendation when provided in the context of the EHR. In those situations, it should be sufficient to understand who developed the CDS and how it was developed and validated, vs. presenting the actual logic in detail.

Again, on behalf of the EHRA, we appreciate this opportunity to provide input on this important topic, and urge the CDS Coalition to rework these guidelines to better reflect how healthcare professionals use CDS.

CDS is based on complex functionality that has evolved through real-world experience and feedback from our customers over many years. We look forward to working closely with the Clinical Decision Support Coalition to further refine and improve our EHRs to support CDS.

Sincerely,

Sasha TerMaat
Chair, EHR Association
Epic

Richard Loomis, MD
Vice Chair, EHR Association
Practice Fusion

HIMSS EHR Association Executive Committee

Hans J. Buitendijk
Cerner Corporation

Leigh Burchell
Allscripts

Cherie Holmes-Henry
NextGen Healthcare

Nadeem Dhanani, MD, MPH
Modernizing Medicine

Joseph M. Ganley
McKesson Corporation

Rick Reeves, RPh
Evident

About the EHR Association

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