



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

- [AdvancedMD](#)
- [AllMeds](#)
- [Allscripts](#)
- [athenahealth](#)
- [BestNotes](#)
- [Bizmatic](#)
- [Cerner Corporation](#)
- [ChartLogic, A Division of](#)
- [Medsphere Systems](#)
- [CPSI](#)
- [CureMD Corporation](#)
- [eClinicalWorks, LLC](#)
- [eMDs](#)
- [EndoSoft](#)
- [Epic](#)
- [ezCaretch](#)
- [Flatiron Health](#)
- [FootHold Technology](#)
- [Greenway Health](#)
- [Harris Healthcare Group](#)
- [Lumeris](#)
- [MacPractice](#)
- [MEDHOST](#)
- [MEDITECH](#)
- [Modernizing Medicine](#)
- [Netsmart](#)
- [Nextech](#)
- [NextGen Healthcare](#)
- [Office Practicum](#)
- [Sevocity, A Division of](#)
- [Conceptual Mindworks](#)
- [SRS Health](#)
- [STI Computer Services](#)
- [Valant Medical Solutions](#)
- [Varian Medical Systems](#)

December 20, 2019

The Honorable Stephen Hahn, M.D.
Commissioner
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Commissioner Hahn,

On behalf of the 32 members of the Electronic Health Record Association (EHRA), we are pleased to share our comments regarding the *Clinical Decision Support Software Draft Guidance for Industry and Food and Drug Administration Staff*.

EHR Association members serve the vast majority of hospitals and ambulatory care organizations that use electronic health records (EHRs) and other health information and 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.

Among the suggestions the Association details in this document, we advise avoiding regulatory duplication by considering clinical decision support functionality certified to the Office of the National Coordinator for Health IT's 2015 Edition (or subsequent editions) to have demonstrated sufficient transparency of recommendations for independent review.

We request additional clarity to reduce ambiguity in the guidance. For example, to satisfy the test of "independently evaluate," what information is considered sufficient to enable independent review, and how, within the clinical workflow, must the basis for the recommendation be made available? How should developers differentiate between software functionality that "informs clinical management" and functionality intended to "drive clinical management?" What are the expectations for content to meet the four factors of intended use, intended user, inputs to generate the recommendation and the basis for rendering a recommendation? Providing additional examples will be key to ensuring developers are clear on expectations; by illustrating,

for example, what it means to meet the test of “independently evaluate” in terms of timeliness, context, form, content, and proximity to the clinical workflow.

Thank you for this opportunity to provide our perspective and expertise as you develop guidelines for FDA's oversight of clinical decision support software intended for health care professionals, patients, or caregivers. If the EHR Association can be of further assistance, please contact Jessie Bird at jbird@himss.org.

Sincerely,



Cherie Holmes-Henry
Chair, EHR Association
NextGen Healthcare



Hans J. Buitendijk
Vice Chair, EHR Association
Cerner Corporation

HIMSS EHR Association Executive Committee



David J. Bucciferro
Foothold Technology



Barbara Hobbs
MEDITECH, Inc.



Rick Reeves, RPh
CPSI



Emily Richmond, MPH
Practice Fusion Inc., a subsidiary of Allscripts



Sasha TerMaat
Epic



Courtney E. Tesvich, RN
Nextech

About the HIMSS 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.

HIMSS Electronic Health Record Association

Comments to the FDA on Clinical Decision Support Software Guidance for Industry and Food and Drug Administration Staff

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

The EHR Association suggests clarifying the word “analyze” in the context of applying the guidance in Part 2 (“Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information”). It is important to differentiate types of analysis. Simple analysis (for example, displaying data against a reference range) does not merit the same treatment as evaluation of data for purposes of diagnosis or treatment (evaluation of data sets for determination of clinical anomalies).

There is some ambiguity with respect to how patient portals would be impacted by this guidance. A frequent role of patient portals is to re-share information a clinician already reviewed with the patient in the context of the visit. The EHR Association suggests clarifying that displaying information to the patient in this content is outside the purview of this guidance. This information display is different from content provided to a patient directly for the patient’s independent assessment without a healthcare provider’s guidance.

Relationship to ONC HIT Certification

There are potential areas of overlap between the FDA draft guidance and the Office of the National Coordinator for Health Information Technology’s (ONC) Health Information Technology certification program. ONC certification is currently in the 2015 Edition, which includes [\(a\)\(9\) Clinical decision support](#)¹. ONC’s criteria include a requirement to support “source attributes” which seem similar to us to the expectation of transparency of recommendations enabling independent review that FDA identifies as factor 4 on page 12.

We suggest that clinical decision support functionality certified to ONC’s (a)(9) criterion (or subsequent similar criteria in future editions of ONC certification) be considered to have demonstrated sufficient transparency of recommendations for independent review. While this would not be the only method for enabling independent review (not all relevant products would pursue certification), it will avoid unnecessary regulatory duplication for certified products, and provide useful clarity for FDA’s expectations around independent review.

ONC has already recognized several important factors about source recommendations, including:

1. That the source attribute content does not have to (and often does not) originate from the EHR technology, as clinical decision support is often provided by expert sources or locally developed by healthcare organizations.
2. That source attributes do not need to be “automatically displayed” but simply available to end users; users could reasonably be expected to drill down or link out to find such information.

3. That it is reasonable to indicate if certain source attributes are unknown or unavailable (for example, if the funding source of a study is not known) for the healthcare provider to consider.

If FDA does not rely on ONC certification to (a)(9) as an indication of sufficient transparency to enable independent review as we recommend, then FDA will want to provide similar clarity on these areas in subsequent guidance.

Additionally, our recommendation is that CDS that achieves ONC certification not be regulated as a device. Because ONC certification includes use of a quality management system (§170.315(g)(4) Quality management system)¹, categorizing software that has achieved ONC certification in this way avoids duplicative regulatory frameworks.

Enabling Independent Review

Additional clarity on what is sufficient to enable independent review is necessary. As described in the section “Relationship to ONC HIT Certification” above, the EHR Association suggests that FDA accept a health IT module’s certification to the ONC 2015 Edition (a)(9) Clinical Decision Support criterion as an indication that sufficient information was provided to enable independent review, as certification requires health IT to display “source attributes” about clinical decision support.

If FDA does not accept HIT certification to (a)(9), further clarity will be necessary through other guidance. Also, this will be important for products that do not pursue ONC certification.

FDA indicates that information underlying the basis of the recommendation must be “available,” but what that means is not clear. We suggest that FDA adopt an approach similar to ONC, which has clarified how additional information can be provided in ways that do not detract from software usability. ONC says, “We do not require the automatic display of the source attributes, just the availability of the information to the end-user. For example, additional action may be required for a user to “drill down” or “link out” to view the source attributes of CDS. [see also [77 FR 54215](#)]²” and “For drug-drug, drug-allergy interaction checks, global citations are permitted in cases where all interventions of a given type are provided by the same reference. [see also [77 FR 54215](#)]³.” More prescriptive requirements for how guidance must be made available could have detrimental effects on the usability of clinical decision support and the ongoing refinement of how information is most effectively presented to different types of users.

Application of IMDRF Risk Categorization

“Inform” Clinical Management and “Drive” Clinical Management

¹ <https://www.healthit.gov/test-method/quality-management-system>

² <https://www.healthit.gov/test-method/clinical-decision-support-cds>

³ <https://www.healthit.gov/test-method/clinical-decision-support-cds>

The EHR Association suggests that FDA provide further guidance to differentiate between “informing” and “driving” clinical management. The guidance emphasizes that software functionality that “informs clinical management” meets the criteria of a recommendation in section 520(o) (1) (E) of the Cures Act. FDA indicates that software intended to “drive clinical management” is not considered CDS because it is providing “enhanced” information. We are uncertain how to assess whether functionality informs or drives clinical management based on the IMDRF definitions. FDA’s guidance should address how to make this distinction, particularly when the users interacting with a particular clinical decision support function might vary.

Examples need to speak to how the immediacy of an action to diagnose or to provide care matters to determining if something informs care versus directs care. It is in this area that we see particular ambiguity to some of the examples provided Section VII.

Policy for Device CDS Functions: Examples and How to Apply Framework

It would be helpful to see more of a connection from the FDA framework for CDS to the examples (such as the logic of the application of framework in the example cases). For example, it would be helpful for an example of CDS to be given and for the guidance document to outline how FDA would apply its analysis to determine the category of device or non-device (e.g. how should organizations apply the guidance in real life to determine categorization).

Many examples have a statement on how the criteria are met (“an HCP is not intended to be able to independently evaluate the basis for the software’s recommendations”) without explaining how FDA came to that conclusion. FDA appears to be using this statement as a proxy to denote that the transparency requirement is met, but doing so does not provide manufacturers with any window into how FDA evaluated the requirement. In particular, we would find clarity on independently evaluating the basis, the distinction between inform and drive, and determining the severity of the clinical context important to better using these examples.

In particular, EHR Association members found examples regarding device data puzzling. Line 519 suggested analysis of device data could fall within non-device CDS. One recommendation could be for the guidance to clearly state that if CDS is using device information as one input to the recommendation, that alone won’t be interpreted as analysis of device data in a way that it wouldn’t meet the first criteria.

Another example of ambiguity is line 533, which blurs the line with respect to what is meant around “relying primarily” on the recommendation for making the clinical decision. We note that technology can enable the independent review such that a clinician would not need to rely on the recommendation, but we cannot determine to what degree a provider is relying or not.

Overall, we would find the examples in the guidance more useful if it were further explained how FDA is applying the guidance and framework to each of the examples. Applying the new guidance to existing product codes would be helpful.

Serious vs Non-Serious Conditions

The IMDRF speaks of the importance of the immediacy of the care situation to a diagnosis or treatment action as a distinguishing factor between what is deemed as non-serious or serious care situations. In the application of this to the classification of a CDS function as a medical device, non-serious situations are ones where the timely diagnosis or intervention is important, but not critical, to prevent or mitigate disease. Following this line of thinking, the CDS function that may inform care may not have to be “timely” in terms of immediacy to a care decision for a non-serious situation. Additionally, it would seem reasonable that the basis for the CDS recommendation is not one that must be immediately reviewable or at hand when its purpose may only be to inform.

In the list in Section VII.A for Non-Device CDS Functions, the example is given for identifying drug-drug interactions and drug-allergy contraindications. In the list in Section VII.B.1 for Device CDS intended for HCP use, there is an example of providing recommendations of potential allergens or cold symptoms. On the face of it, these seem like similar examples, however FDA classifies them differently. In the former example, the immediacy of the CDS to a determination of a possible contraindication seems imminent to a prescribing decision and yet the function is classified as non-device CDS, with presumably the role of the CDS being to inform. In the latter example, the determination of an allergen seems important to know and it is hard to understand if the determination of an allergen bears immediacy to care, and no indication is given whether the healthcare scenario in which this is deployed in is serious or non-serious. Further, if the determination of a contraindication bears consequence for another care action, such as a prescribing decision interaction that could be triggered by that same allergen, does it do more than inform?

The EHR Association encourages the FDA to take several examples from the lists in Section VII to show how the risk-based policy discussed in Section VI.C is applied, to give light to how the independently evaluate test is applied considering such factors as how the basis of recommendation is provided, how the immediacy of the care action differentiates a CDS function from “informing” or “driving,” and the role of the CDS function in relation to how its clinical significance could be laid out.

Definition of “Independently Evaluate”

The FDA should offer clarity on how the basis for the recommendation is to be made available to the end user to satisfy the test of enabling “independent evaluation.”

The Association urges the FDA to provide answers to the significance of how, in what manner, and how timely to the clinical act being able to access the basis of the CDS recommendation is to an HCP’s ability to independently evaluate the basis. In particular:

- Is it an expectation that the basis be available to the HCP as an end user of the CDS function in the context of that use?
- Is there a timeliness factor to the point of use of the CDS function that must be observed to satisfy “independently evaluate?” For example, if the user can access reference materials about the basis of the recommendation adjunct to the use of the CDS function directory from within

clinical workflow, does that satisfy the test of “independently evaluate?” Or if the user later accesses support guides or accesses reference information in a user manual and independently validates its veracity on the internet, is that a valid means of “independently evaluate”?

We suggest FDA allow for this “enable” requirement to be met by providing information at various levels of engagement with the user and taking into consideration the expected clinical training.

Additionally, we suggest that following ONC’s guidance (cited above) should be considered sufficient. For example, providing a basis for independent evaluation through a link or click to drill down should be sufficient in this guidance as it is in ONC’s source attributes. Similarly, if the basis for a portion of clinical decision support (for example, all drug interactions) is the same, providing a universal citation or basis should be sufficient without repetition. Overly prescriptive expectations will jeopardize usability of health IT products as they evolve to meet user needs.

Comments regarding “basis for software’s recommendation”

The FDA should give more clarity as to what content is presented to meet the four factors described under this criterion as to intended use, intended user, inputs to generate the recommendation and the basis for rendering a recommendation. It would be useful to developers to understand examples of how this is to be done. And, if done in the context of clinical workflow, how that may be presented to the end user so they may be able to independently evaluate the basis of the recommendation.

For example, in the 2015 Edition Certification Criteria published by the HHS Office of the National Coordinator for Health IT (ONC), there are specific statements made as to requirements⁴ both for the bibliographic source of the CDS function as well as for how its basis is to be represented and described. We do not mean to suggest a prescriptive set of requirements for how the four factors are to be met, but we do ask for illustrative examples. Also, we reiterate that flexibility will be critical here as providers and their technology partners look to implement any forthcoming guidance or regulations.

Device CDS intended for HCPs (FDA does not intend to enforce compliance)

In the examples given in this section, there appears to be more information about how the framework is applied that isn’t described in previous sections. We appreciate this additional information; but, we request that if there are specific considerations that would determine surveillance versus non-surveillance (e.g. presence of reference information), those be described earlier in the framework.

Also, EHR Association members request clarification on FDA’s intention with respect to the presence of reference information as the determining factor between device/non-device CDS, as it appears in the example in this section (line 624-631). We request additional clarification on how to meet the transparency requirement with respect to the reference recommendation (timely, format, etc.).

⁴ <https://www.healthit.gov/sites/default/files/170%20315%28a%29%289%29%20CDS.pdf>

Device CDS intended for patients (FDA does not intend to enforce compliance)

The EHR Association recommends that FDA exercise enforcement discretion on patient-facing apps that are overseen by the provider.

Device CDS intended for HCPs (FDA intends to focus regulatory oversight)

Similarly to the previous section, EHR Association members would find the examples in the guidance more useful if FDA provided more details around how the guidance and framework were applied to each of the scenarios. For example, it seems that transparency provides a key distinguisher for how examples are categorized. However, it is not clear how a manufacturer would meet that criterion for providing transparency. In a second example, the guidance repeats “not expected to be able to independently evaluate the basis” but does not give an explanation.

Device CDS intended for patients (FDA intends to focus regulatory oversight)

The EHR Association recommends that FDA exercise enforcement discretion on patient-facing apps overseen by the provider.

Examples of device software functions that are not CDS on which FDA intends to focus its regulatory oversight

Similarly to the previous section, EHR Association members would find the examples in the guidance more useful if FDA provided more details around how the guidance and framework were applied to each of the scenarios.

In the example of software intended to generate an alarm or alert (Line 746), FDA seems to be stating a policy for the low-risk example of a Laboratory Information System functionality that is not intended to analyze the signal for immediate clinical action or to uniquely interpret laboratory test data. We recommend that FDA consider changes to existing guidance by propagating or referencing the enforcement discretion decision for this functionality in the “Policy for Device Software Functions and Mobile Medical Applications” final guidance.

ⁱ <https://www.healthit.gov/test-method/clinical-decision-support-cds>

§170.315 (a)(9) *Clinical decision support (CDS)*—

- *CDS intervention interaction.* Interventions provided to a user must occur when a user is interacting with technology.
- *CDS configuration.*
 - Enable interventions and reference resources specified in paragraphs (a)(9)(iii) and (iv) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role.
 - Enable interventions:
 - Based on the following data:
 - Problem list;
 - Medication list;
 - Medication allergy list;
 - At least one demographic specified in paragraph (a)(5)(i) of this section;
 - Laboratory tests; and
 - Vital signs.

-
- When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received and pursuant to paragraph (b)(2)(iii)(D) of this section.
 - *Evidence-based decision support interventions.* Enable a limited set of identified users to select (i.e., activate) electronic CDS interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the data referenced in paragraphs (a)(9)(ii)(B)(1)(i) through (vi) of this section.
 - *Linked referential CDS.*
 - Identify for a user diagnostic and therapeutic reference information in accordance with at least one of the following standards and implementation specifications:
 - The standard and implementation specifications specified in §170.204(b)(3).
 - The standard and implementation specifications specified in §170.204(b)(4).
 - For paragraph (a)(9)(iv)(A) of this section, technology must be able to identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (a)(9)(ii)(B)(1)(i), (ii), and (iv) of this section.
 - *Source attributes.* Enable a user to review the attributes as indicated for all CDS resources:
 - For evidence-based decision support interventions under paragraph (a)(9)(iii) of this section:
 - Bibliographic citation of the intervention (clinical research/guideline);
 - Developer of the intervention (translation from clinical research/guideline);
 - Funding source of the intervention development technical implementation; and
 - Release and, if applicable, revision date(s) of the intervention or reference source.
 - For linked referential CDS in paragraph (a)(9)(iv) of this section and drug-drug, drug-allergy interaction checks in paragraph (a)(4) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).