

The HITSC recommended a revised clinical decision support (CDS) certification criterion for the 2014 Edition EHR certification criteria. We have refined the recommended certification criterion to provide a clearer understanding of the capabilities that must be tested and certified and to provide greater flexibility to EHR technology developers in designing EHR technology to meet this proposed certification criterion. We also propose to require the use of the HL7 Context-Aware Knowledge Retrieval (“Infobutton”) Standard, International Normative Edition 2010, for retrieving diagnostic or therapeutic reference information and specifically require the use of CDS with the incorporation of a summary care record.

We have replaced the term “clinical decision support rule” used in the 2011 Edition EHR certification criteria and the HITSC recommended criterion with the term “clinical decision support intervention” to better align with, and clearly allow for, the variety of decision support mechanisms available that help improve clinical performance and outcomes. A CDS intervention is not simply an alert, notification, or explicit care suggestion. Rather, it should be more broadly interpreted as the user-facing representation of evidence-based clinical guidance. Our goal in clarifying the nomenclature is to focus more on the representation of the guidance (the CDS intervention) that the EHR technology should offer to the user rather than prescribe the form of either the logical representation of the clinical guidance or how the intervention interacts with the user.

Referential sources such as medical texts, primary research articles, and clinical practice guidelines have long been available in electronic form, but the means and manner of accessing them have historically been disconnected from the

points in providers' patient care workflows when the immediate availability of the reference sources would optimize clinical decisions. Increasingly, these tools are being made available through links in EHRs, offering information at relevant points within the clinical workflow. The Infobutton standard has been in active use for several years with many reference content vendors now providing their products in this form, and we propose to adopt its most recent edition (International Normative Edition 2010) in order to enable a user to retrieve diagnostic or therapeutic reference information. The use of standard reference information retrieval formats will accelerate the delivery of content to providers and hospitals, and will enhance the flexibility of such implementations because these formats reduce the need to "hard wire" the content databases to installed EHR technology. This flexibility allows EPs, EHRs, and CAHs more choices and easier migration across content providers, encouraging innovation and competitiveness among these content providers.

We believe it is important for CDS interventions to be triggered when new information is incorporated into EHR technology as a result of a care transition. Therefore, we are proposing that EHR technology enable interventions to be triggered when the specified data elements are incorporated into a summary care record pursuant to the capability specified at § 170.314(b)(1) (transitions of care – incorporate summary care record). We are also considering whether EHR technology should be capable of importing or updating value sets for the expression of CDS vocabulary elements using the HL7 Common Terminology Services, Revision

1, standard. We request comment on industry readiness to adopt this standard and on the benefits it could provide if required as a part of this certification criterion.

Consistent with the HITSC stated intent, for EHR technology to be certified to this criterion it must be capable of providing interventions and the reference resources in paragraph (a)(8)(ii)(A) by leveraging each one or any combination of the patient-specific data elements listed in paragraphs (a)(8)(i) and (ii) as well as one or any combination of the user context data points listed in paragraph (a)(8)(iii)(A). EHR technology must also be capable of generating interventions automatically and electronically when a user is interacting with the EHR technology. Last, the HITSC recommended that the source attributes of suggested interventions be displayed or available for users. We agree that this capability is important, but believe further clarification is necessary regarding what types of information must be provided for EHR technology to meet this criterion. We believe that, at a minimum, a user should be able to review the: bibliographic citation (i.e., the clinical research/guideline) including publication; developer of the intervention (i.e., the person or entity who translated the intervention from a clinical guideline into electronic form, for example, Company XYZ or University ABC); funding source of the intervention development; and release and, if applicable, revision date of the intervention. The availability of this information will enable the user to fully evaluate the intervention. The availability of this information will also enhance the transparency of all CDS interventions, and thus improve their utility to healthcare professionals and patients.

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**MU Objective**

Use clinical decision support to improve performance on high-priority health conditions.

**2014 Edition EHR Certification Criterion****Clinical decision support.**

- (i) **Evidence-based decision support interventions.** Enable a user to select (or activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in each one or any combination of the following:
  - (A) Problem list;
  - (B) Medication list;
  - (C) Medication allergy list;
  - (D) Demographics;
  - (E) Laboratory tests and values/results; and
  - (F) Vital signs.
- (ii) **Linked referential clinical decision support.**
  - (A) Enable a user to retrieve diagnostic or therapeutic reference information in accordance with the standard specified at § 170.204(b)(1).
  - (B) Enable a user to access the reference information specified in paragraph (ii)(A) relevant to patient context based on the data elements included in each one or any combination of the following:
    - (1) Problem list;
    - (2) Medication list;
    - (3) Medication allergy list;
    - (4) Demographics;
    - (5) Laboratory tests and values/results; and
    - (6) Vital signs.
- (iii) **Configure clinical decision support.**
  - (A) Enable interventions and reference resources specified in paragraphs (a)(8)(i) and (ii) to be configured by an identified set of users (e.g., system administrator) based on each one of the following:
    - (1) A user's role;
    - (2) Clinical setting; and
    - (3) Identified points in the clinical workflow.
  - (B) Enable interventions to be triggered, based on the data elements specified in paragraph (a)(8)(i), when a summary care record is incorporated pursuant to § 170.314(b)(1).
- (iv) **Automatically and electronically interact.** Interventions selected and configured in accordance with paragraphs (a)(8)(i)-(iii) must automatically and electronically occur when a user is interacting with EHR technology.
- (v) **Source attributes.** Enable a user to review the attributes for each intervention or reference source for all clinical decision support resources including:
  - (A) Bibliographic citation (clinical research/guideline) including publication;
  - (B) Developer of the intervention (translation from clinical research/guideline);
  - (C) Funding source of the intervention development technical implementation; and
  - (D) Release and, if applicable, revision date of the intervention.

**Standard**

§ 170.204(b)(1) (HL7 Context-Aware Knowledge Retrieval ("Infobutton") Standard, International Normative Edition 2010)