# §170.315(a)(9) Clinical decision support (CDS)

**2015 Edition Test Procedure**

**Version 1.3 Updated on 09-21-2017**

## Revision History

| Version # | Description of Change | Version Date |
|---|---|---|
| 1.0 | Final Test Procedure | 01-08-2016 |
| 1.1 | Updated the section referenced in paragraph (a)(9)(v)(A) from (iv) to the paragraph (a)(9)(i), and reference in paragraph (a)(9)(v)(B) from paragraph (a)(9)(ii) to paragraph (a)(9)(iv).<br><br>Added reference resources to the verification for step 3 of paragraph (a)(9)(ii)(A) in the test lab verification section. | 03-08-2016 |
| 1.2 | Add transition of care/referral summary configuration step for paragraph (a)(9)(ii)(B)(2).<br><br>Corrected small typos throughout:<br>i. TLV step 1.<br>ii. (A) SUT step 3.<br>iii. (B)(1) SUT<br>iv. (B) SUT and TLV<br>v. (A)(1-4) TLV<br>vi. Standard §170.207(n)(1) to UNK | 06-10-2016 |
| 1.3 | As of September 21, 2017, Test Procedure has been moved to | 09-21-2017 |

| | | |
|---|---|---|
| | Attestation/Developer self-declaration only. | |

## Regulation Text

### Regulation Text

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

(i) *CDS intervention interaction.* Interventions provided to a user must occur when a user is interacting with technology.

(ii) *CDS configuration.*

(A) 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.

(B) Enable interventions:

*(1)* Based on the following data:

*(i)* Problem list;

*(ii)* Medication list;

*(iii)* Medication allergy list;

*(iv)* At least one demographic specified in paragraph (a)(5)(i) of this section;

*(v)* Laboratory tests; and

*(vi)* Vital signs.

*(2)* 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.

(iii) *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.

(iv) *Linked referential CDS.*

*(A)* Identify for a user diagnostic and therapeutic reference information in accordance at least one of the following standards and implementation specifications:

*(1)* The standard and implementation specifications specified in §170.204(b)(3).

*(2)* The standard and implementation specifications specified in §170.204(b)(4).

*(B)* 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.

(v) *Source attributes.* Enable a user to review the attributes as indicated for all CDS resources:

(A) For evidence-based decision support interventions under paragraph (a)(9)(iii) of this section:

*(1)* Bibliographic citation of the intervention (clinical research/guideline);

*(2)* Developer of the intervention (translation from clinical research/guideline);

*(3)* Funding source of the intervention development technical implementation; and

*(4)* Release and, if applicable, revision date(s) of the intervention or reference source.

(B) 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).

## Standard(s) Referenced

### Cross Reference Criteria

§ 170.315(a)(5) (i) Enable a user to record, change, and access patient demographic data including race, ethnicity, preferred language, sex, sexual orientation, gender identity, and date of birth

§ 170.315(b)(2) (iii)(D) Upon a user's confirmation, automatically update the list, and incorporate the following data expressed according to the specified standard(s):

*(1)* Medications. At a minimum, the version of the standard specified in §170.207(d)(3);
*(2)* Medication allergies. At a minimum, the version of the standard specified in §170.207(d)(3); and
*(3)* Problems. At a minimum, the version of the standard specified in §170.207(a)(4).

### Paragraph (a)(9)(iv)

§ 170.204(b)(3) HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. (“Infobutton”), Knowledge Request, Release 2
HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1

§ 170.204(b)(4) HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. (“Infobutton”), Knowledge Request, Release 2
HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4

### Additional Resources

§ 170.205(a)(3) HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012

§ 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1, August 2015

## Testing components

Gap Eligible
Self-Declaration: As of September 21, 2017, the testing approach for this criterion is satisfied by self-declaration.

The archived version of the Test Procedure is attached below for reference.

| System Under Test | Test Lab Verification |
| --- | --- |
| The health IT developer submits their self- | The Tester verifies the self-declaration |

| | |
|---|---|
| declaration to the ONC-ATL. | document contains all of the required data elements. |

**Archived Version:**

§170.315(a)(9) Test Procedure

Content last reviewed on September 21, 2018