§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). 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). Corrected small typos throughout: i. TLV step 1. ii. (A) SUT step 3. iii. (B)(1) SUT iv. (B) SUT and TLV v. (A)(1-4) TLV 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.

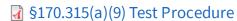
System Under Test	Test Lab Verification
The health IT developer submits their self-	The Tester verifies the self-declaration

5/26/2020

declaration to the ONC-ATL.

document contains all of the required data elements.

Archived Version:



Content last reviewed on September 21, 2018