The Office of the National Coordinator for Health Information Technology

2015 Edition §170.315(a)(9) Clinical Decision Support

Testing Components: Health IT developer self-declaration to the testing outcomes

Test Procedure Version 1.3 – Last Updated 09/21/17

Please consult the Final Rule entitled: *2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications* for a detailed description of the certification criterion with which these testing steps are associated. We also encourage developers to consult the Certification Companion Guide in tandem with the test procedure as they provide clarifications that may be useful for product development and testing.

Note: The order in which the test steps are listed reflects the sequence of the certification criterion and does not necessarily prescribe the order in which the test should take place.

Required Tests

(a)(9)(i) *CDS intervention interaction*. Interventions provided to a user must occur when a user is interacting with technology.

Cross Reference Criteria: §170.315(a)(5)(i) Preferred language, sex, race, ethnicity, and date of birth

Standard(s): §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
§170.205(a)(4) - HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, Release 2.1
§170.207(f)(2) – CDC Race and Ethnicity Code Set Version 1.0 (March 2000)
§170.207(f)(1) - OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997
§170.207(g)(2) – Request for Comments (RFC) 5646
§170.207(n)(1) - Birth sex must be coded in accordance with HL7 Version 3 attributed as follows: Male (M), Female (F), Unknown (UNK)

Criteria ¶	System Under Test	Test Lab Verification
(i)	1. The user interacts with the Health IT Module, and clinical decision support (CDS) interventions are provided based on each data element and one combination of the following: (A) Problem list; (B) Medication list; (C) Medication allergy list; (D) At least one demographic specified in §170.315(a)(5)(i); (E) Laboratory tests; and (F) Vital signs. 2. The health IT developer demonstrates receiving a transition of care/referral summary to provide CDS interventions based on the incorporated data: • Medications; • Medication allergies; and • Problems.	1. The tester verifies that the CDS interventions are based on interactions with the system and based on all of the data elements listed (A-F) and one combination of the data elements. 2. The tester verifies that CDS interventions are provided when medications, medication allergies, and problems are received and incorporated into the patient's record from a transition of care/referral summary.

(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.

Standard(s): None

Criteria ¶	System Under Test	Test Lab Verification
(ii)(A)	1. The authorized user configures interventions and reference resources based on role for the user in section (i). 2. Negative Test: The unauthorized user attempts to configure interventions and resources. 3. Negative Test: The user with a role not configured for CDS interventions and reference resources interacts with the system that provides CDS intervention interaction and Linked Referential Clinical Decision Support.	1. The tester verifies that intervention and reference resource configuration is limited to a set of identified users and based on user role. 2. Negative Test: After the system is configured in step 1, the tester verifies that the unauthorized user is not granted access to configure interventions and resources. 3. Negative Test: After the system is configured in step 1, the tester verifies that the user with a role not configured for CDS interventions and references resources is not provided with CDS interventions and reference resources when interacting with the Health IT Module.
(ii)(B)(1)	The authorized user attempts to enable one electronic CDS intervention and reference resource based on each data element and one combination of the following: (A) Problem list; (B) Medication list; (C) Medication allergy list; (D) At least one demographic specified in §170.315(a)(5)(i); (E) Laboratory tests; and (F) Vital signs.	The tester verifies that the authorized user can enable interventions and reference resources based on all data elements (A-F) and one combination.

Criteria ¶	System Under Test	Test Lab Verification
(ii)(B)(2)	The authorized user attempts to enable electronic CDS intervention and reference resources for incorporated patient information from a transition of care/referral summary received as specified in §170.315(b)(2)(iii)(D), based on each of the following data elements: (A) Medication list; (B) Medication allergy list; and (C) Problem list.	The tester verifies that the authorized user can enable interventions and reference resources for incorporated patient information from a transition of care/referral summary received as specified in §170.315(b)(2)(iii)(D), based on all data elements (A-C).

(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.

Standard(s): None

Criteria ¶	System Under Test	Test Lab Verification
(iii)	1. The authorized user, configured in section (ii)(A) step 1, activates one electronic CDS intervention based on each data element and one combination of the following: (A) Problem list; (B) Medication list; (C) Medication allergy list; (D) At least one demographic specified in §170.315(a)(5)(i); (E) Laboratory tests; and (F) Vital signs. 2. Negative Test: The unauthorized user attempts to activate a CDS intervention.	1. The tester verifies that the authorized user, configured in section (ii)(A) step 1, is able to activate one CDS intervention, based on all of the listed data elements (A-F) and one combination of the data elements. 2. Negative Test: The tester verifies that the unauthorized user cannot activate the CDS intervention.

(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.

Cross Reference Criteria: §170.315(a)(5)(i) Preferred language, sex, race, ethnicity, and date of birth

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

Criteria ¶	System Under Test	Test Lab Verification
(iv)(A)	The Health IT Module identifies diagnostic and therapeutic reference information during the CDS intervention interaction testing in accordance with 170.204(b)(3) or 170.204(b)(4).	The tester verifies the diagnostic and therapeutic reference information is in accordance with 170.204(b)(3) or 170.204(b)(4).
(iv)(B)	The user with a role designated during the CDS configuration (ii)(A) step 1 has diagnostic and therapeutic reference information identified for them based on each data element and one combination: (A) Problem list; (B) Medication list; (C) At least one demographic specified in §170.315(a)(5)(i).	The tester verifies the diagnostic and therapeutic reference information is based on the problem list, medication list, at least one demographic specified in §170.315(a)(5)(i) and one combination of the required data elements for the user with a role designated during section (ii)(A) CDS configuration step 1.

(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).

Standards: None

Criteria ¶	System Under Test	Test Lab Verification
(v)(A)	The user is able to demonstrate that CDS interventions provided while testing section (i) includes or provides direct links to access: *(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.	The tester verifies that the CDS interventions in section (i) (have the ability to) include or provide direct links to access all of the outlined attributes (1-4).
(v)(B)	A user can review attributes for linked referential CDS demonstrated while testing section (iv) that include the following: • Developer of the intervention; and • Where clinically indicated, bibliographic citation of the intervention (clinical research/guideline).	The tester verifies that linked referential CDS in section (iv) includes the outlined attributes.
(v)(B)	A user can review attributes for drug-drug and drug-allergy interaction checks in §170.315(a)(4) that include the following: • Developer of the intervention; and • Where clinically indicated, bibliographic citation of the intervention (clinical research/guideline).	The tester verifies that the drug-drug and drug-allergy interaction checks include the outlined attributes.

Document History

Version Number	Description of Change	Date
1.0	Final Test Procedure	January 08, 2016
1.1	Updated the section referenced in (v)(A) from (iv) to section (i), and reference in (v)(B) from (ii) to section (iv). Added reference resources to the verification for step 3 of (ii)(A) in the test lab verification section.	March 08 ,2016
1.2	Add transition of care/referral summary configuration step for (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 Standard § 170.207(n)(1) to UNK	June 10, 2016
1.3	As of September 21, 2017, Test Procedure has been moved to Attestation/Developer self-declaration only	September 21, 2017

Dependencies: For all related and required criteria, please refer to the Master Table of Related and Required Criteria.