Test Procedure for §170.314(a)(8) Clinical Decision Support

This document describes the test procedure for evaluating conformance of EHR technology to the certification criteria defined in 45 CFR Part 170 Subpart C of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule. The document[1] is organized by test procedure and derived test requirements with traceability to the normative certification criteria as described in the Overview document located at http://www.healthit.gov/certification (navigation: 2014 Edition Test Method). The test procedures may be updated to reflect on-going feedback received during the certification activities.

Questions or concerns regarding the ONC HIT Certification Program should be directed to opentestmethod@aing.com

Dependency Requirements

Related §170.314 2014 Edition electronic health record certification criteria.
The Secretary adopts the following certification criteria for EHR technology. EHR technology must include the capability to perform the following functions electronically, unless designated as optional, and in accordance with all applicable standards and implementation specifications adopted in this part:
(a)(2) Drug-drug, drug-allergy interaction checks. How does this relate to CDS test procedures?
(b)(1) Transitions of care – receive, display, and incorporate transition of care/referral summaries. How does this relate to CDS test procedures?
(b)(5) Incorporate laboratory tests and values/results.

Scenario Testing

[This section may be non-applicable for Clinical Decision Support.]

Informative Test Description

[The following is a starting point for the work group to expand upon and/or change.]

This test procedure is organized into eight sections:

- Select/Activate – evaluates the capability for a limited set of identified users to select (e.g., activate, enable) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) in the EHR technology based on data from each one and at least one combination of data from two or more of the following data categories. . .
- Trigger – evaluates the capability for the EHR technology to electronically trigger interventions to occur automatically and electronically. . .
- Identify – evaluates the capability for the EHR technology to electronically identify for a clinical user the diagnostic and therapeutic reference information based on data from each one and at least one combination of data from two or more of the following data categories. . .
- Configure – evaluates the capability of a limited set of identified users to configure the clinical decision support interventions and diagnostic and therapeutic reference resources into the EHR technology that will be triggered based upon a user's clinical role
- Review Evidence - Based CDS Attributes – evaluates the capability of the EHR technology to enable a user to review the following information for evidence-based clinical decision support

[1] Disclaimer: Certain commercial products may be identified in this document. Such identification does not imply recommendation or endorsement by ONC.

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Maybe clarify in preamble language or elsewhere in the TP... Special Considerations section?

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interventions associated with data in the Problem list, Medication list, Medication allergy list, Demographics, Laboratory tests and values/results, and Vital signs. . .

- Review Linked Referential CDS Attributes – evaluates the capability of the EHR technology to enable a user to review the following information for diagnostic and therapeutic reference resources (linked referential CDS) associated with data in the Problem list, Medication list, Medication allergy list, Demographics, Laboratory tests and values/results, and Vital signs. . .
- Review Drug Interaction Source Attributes – evaluates the capability of the EHR technology to enable a user to review the following information for drug-drug and drug-allergy interaction checks (specified in the ONC EHR certification criterion 170.314(a)(2)Drug-drug, drug-allergy interaction checks). . .

DTR-1: SETUP/ACTIVATION OF CDS INTERVENTIONS AND DIAGNOSTIC RESOURCES

1. VENDOR LOGS IN AS USER (INTERNALLY REFERRED TO AS USER#1) WITH ACCESS TO ACTIVATE/SETUP CDS INTERVENTIONS AND DIAGNOSTIC RESOURCES WITHIN THE EHR. AT A MINIMUM, THE FOLLOWING MUST BE SHOWN:

A. CDS INTERVENTIONS BASED ON DATA IN:

I. PROBLEM LIST

II. MEDICATION LIST

III. MEDICATION ALLERGY LIST

IV. DEMOGRAPHICS

V. LABORATORY TESTS AND VALUES/RESULTS

VI. VITAL SIGNS

VII. COMBINATION OF DATA FROM TWO OR MORE OF THE ABOVE-LISTED CATEGORIES.

B. DIAGNOSTIC RESOURCES BASED ON DATA IN

I. PROBLEM LIST

II. MEDICATION LIST

III. LABORATORY TESTS AND VALUES/RESULTS

IV. COMBINATION OF DATA FROM TWO OR MORE OF THE FOLLOWING: PROBLEM LIST, MEDICATION LIST, MEDICATION ALLERGY LIST, DEMOGRAPHICS, LABORATORY TESTS AND VALUES/RESULTS, VITALS

NOTE: DIAGNOSTIC RESOURCES CAN BE ASSOCIATED WITH CDS INTERVENTIONS OR ACTIVATED SEPARATELY.

2. FOR EACH CDS INTERVENTIONS AND DIAGNOSTIC RESOURCES, VENDOR SHOWS THE FOLLOWING INFORMATION OR EXPLAINS THIS INFORMATION CONTAINED IN THE CDS INTERVENTIONS:

A. CDS INTERVENTIONS:

I. INTERVENTION / ALERT / CARE SUGGESTION GIVEN TO A USER (E.G., "ORDER LAB TEST X").

II. METHOD OR LOGIC WHICH TRIGGERS THE INTERVENTION (E.G., "IF PATIENT HAS PROBLEM Y, ENGAGE INTERVENTION").

III. USER/ROLE WHO CAN RECEIVE INTERVENTION / ALERT / CARE SUGGESTION WHEN ENGAGING PATIENT DATA.

IV. USER/ROLE WHO CANNOT RECEIVE INTERVENTION / ALERT / CARE SUGGESTION WHEN ENGAGING PATIENT DATA.

V. ALL NECESSARY SOURCE ATTRIBUTES SUCH AS:

1. BIBLIOGRAPHIC CITATION OF THE INTERVENTION (CLINICAL RESEARCH/GUIDELINE)

2. THE DEVELOPER OF THE INTERVENTION (TRANSLATION FROM CLINICAL RESEARCH/GUIDELINE)

3. THE FUNDING SOURCE OF THE INTERVENTION DEVELOPMENT TECHNICAL IMPLEMENTATION

4. THE RELEASE (AND, IF APPLICABLE, REVISION DATE(S)) OF THE INTERVENTION

B. DIAGNOSTIC RESOURCES:

I. Resource material accessible to a user.

II. Reference source of diagnostic resources.

3. Vendor show how EHR logs the status and timing of the activated clinical decision support interventions is recorded by the EHR (e.g. by viewing a log, report).

4. Vendor logs in as a different User than in Step DTR-1.1. This second user (internally referred to as User#2) is unable to activate/setup CDS Interventions and Diagnostic Resources.

DTR-2: Interaction with CDS Interventions and Diagnostic Resources

1. Vendor logs in as user who has been configured to access CDS Interventions as setup in in Step DTR-1.1. This user (internally referred to as User#3) accesses a patient record(s) which will trigger a CDS Intervention shown in Step DTR-1.1.

NOTE: The patient data to trigger the CDS Intervention may be pre-loaded or added during the test event.

2. For each CDS Intervention, User#3 sees the intervention / alert / care suggestion and also the source attributes of the respective intervention as shown previously in Step DTR-1.2.

3. Vendor logs in as user who has been configured to access Diagnostic Resources as setup in in Step DTR-1.1. This user (internally referred to as User#4) accesses a patient record(s) which will allow access to Diagnostic Resources shown in Step DTR-1.1.

NOTE: The patient data to trigger the Diagnostic Resources may be pre-loaded or added during the test event.

NOTE: User#4 may be the same as User# depending on configuration of EHR

4. For each Diagnostic Resource, User#3 sees the resource material suggestion, either by Infobutton or other method, and also the source attributes of the respective intervention as shown previously in Step DTR-1.2.

5. Vendor logs in as user who has NOT BEEN configured to access CDS Interventions and Diagnostic Resources as setup in in Step DTR-1.1. This user (internally referred to as User#5) accesses same patient record(s) from Step DTR-2.1 and DTR-2.3 and does NOT receive access to CDS Interventions or Diagnostic Resources previously shown.

DTR-3: CDS and Other Criteria

NOTE: The following test steps in this section are dependent upon other functionality employed within the EHR.

A. Drug-drug/Drug-allergy

1. In performing testing for Drug-drug/Drug-allergy (314.a.2), EHR displays the following source attributes to user for drug-drug/drug-alert interaction checking:

I. Intervention developer and

II. Bibliographic citation of the intervention (clinical research/guideline)

NOTE: Global citations are permitted in cases where all interventions of a given type are provided by the same reference

B. Incorporation of Lab Results

1. IN PERFORMING TESTING FOR INCORPORATE LAB RESULTS (314.B.5) IN AMBULATORY SETTING ONLY, EHR CAN PROVIDE CDS INTERVENTIONS AND DIAGNOSTIC RESOURCES FOR INCORPORATED LABORATORY TESTS AND VALUES/RESULTS AS REQUIRED IN DTR-1 AND DTR-2 OF THIS TEST PROCEDURE.

C. INCORPORATION OF CCDA

1. IN PERFORMING TESTING FOR TRANSITIONS OF CARE – RECEIVE, DISPLAY, AND INCORPORATE TRANSITION OF CARE/REFERRAL SUMMARIES (314.B.1) IN AMBULATORY SETTING ONLY, EHR CAN PROVIDE CDS INTERVENTIONS AND DIAGNOSTIC RESOURCES FOR INCORPORATED MEDICATIONS, MEDICATION ALLERGIES AND PROBLEMS AS REQUIRED IN DTR-1 AND DTR-2 OF THIS TEST PROCEDURE.

TEST DATA

[Contents and description of this section are to be determined by the work group.]

CONFORMANCE TEST TOOLS

[There is currently no NIST test tool associated with this test procedure, but if there is a test tool that you would like to use, please describe it here.]

SPECIAL CONSIDERATIONS

On December 7, 2012, ONC issued clarifications on testing of this criterion via Frequently Asked Questions (FAQ) - Question [12-12-034-1]: Will the demonstration/use of vital signs and/or medication allergies data be individually required for testing and certification of the linked referential clinical decision support (CDS) capability specified in the certification criterion adopted at 45 CFR 170.314(a)(8)?

Answer:
The specific capability for linked referential CDS is found at 45 CFR 170.314 (a)(8)(ii)(A), which states:

> "(A) EHR technology must be able to:
>
> (1) Electronically identify for a user diagnostic and therapeutic reference information; or
>
> (2) Electronically identify for a user diagnostic and therapeutic reference information in accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204 (b)(1) or (2).

and, further 45 CFR 170.314 (a)(8)(ii)(B) states:

> (B) For paragraph (a)(8)(ii)(A) of this section, EHR technology must be able to electronically 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)(8)(i)(A) through (F) of this section."

Based on analysis and stakeholder feedback (with which we agree), we clarify that testing for the linked referential CDS capability will not require the individual demonstration/use (i.e, the "each one" requirement) of vital signs or medication allergies data.

We understand that for the Infobutton-enabled capability at (a)(8)(ii)(A)(2), the implementation guides do not support either of these two data. Thus, we do not intend for testing or compliance with this specific capability within the certification criterion to be based on the individual assessment of vital signs or medication allergies data (i.e., the "each one" requirement) to meet the capability specified at (a)(8)(ii)(A)(1) or (a)(8)(ii)(A)(2).

We also understand and clarify that with respect to demographics data that certain demographic data (e.g., age) can and should be used as a modifier. We intend for testing and certification to evaluate this specific capability in that way. Similar to the prior clarification we do not intend for

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demographic data to be individually tested or required for certification as part of the "each one" requirement of this specific capability.

In summary, for the purposes of testing and compliance with the capability specified at (a)(8)(ii)(A)(1) or (a)(8)(ii)(A)(2) in the CDS certification criterion, demographics, vital signs, and medication allergies data are not expected to be individually tested or required for certification as part of the "each one" requirement of this specific capability.

The Centers for Medicare and Medicaid Services (CMS) Clinical Decision Support: More than Just 'Alerts' Tipsheet: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/ClinicalDecisionSupport_Tipsheet-.pdf

REFERENCED STANDARDS

§170.204 Functional standards.	Regulatory Referenced Standards
The Secretary adopts the following functional standards:	
(b) Reference source. Standard. HL7 Version 3 Standard: Context-Aware Retrieval Application (Infobutton) (incorporated by reference in § 170.299). (1) Implementation specifications. HL7 Version 3 Implementation Guide: URL-Based Implementations of the Context-Aware Information Retrieval (Infobutton) 170.299).	

CERTIFICATION CRITERIA

§170.314(a)(8) Clinical decision support

2014 EDITION PREAMBLE LANGUAGE

Additional information about this certification criterion can be found in Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule (September 4, 2012).

CHANGES FROM 2011 TO 2014 EDITION

The 2014 edition of this certification criterion is classified as revised from the 2011 edition.

Document History

Version Number	Description of Change	Date Published