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@ainq.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

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[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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Commented [1]: Consider adding a definitions section.

Commented [2]: e.g. the term "trigger"

Commented [3]: Is there room in the TP to define something that isn't defined in the rule? ONC's thinking is no; go with what's in the rule and create FAQs for clarity around confusing terms.

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). . .

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

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Commented [8]: Add clarity into Special Considerations around these terms.

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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