

Test Procedure for §170.314(a)(8) Clinical decision support

This document describes the test procedure for evaluating conformance of Complete EHRs or EHR modules 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 document¹ is organized by test procedure and derived test requirements with traceability to the normative certification criteria as described in the Overview document located at [available when final]. The test procedures may be updated to reflect on-going feedback received during the certification activities.

The HHS/Office of the National Coordinator for Health Information Technology (ONC) has defined the standards, implementation guides and certification criteria used in this test procedure. Applicability and interpretation of the standards, implementation guides and certification criteria to EHR technology is determined by ONC. Testing of EHR technology in the Permanent Certification Program, henceforth referred to as the ONC HIT Certification Program², is carried out by National Voluntary Laboratory Accreditation Program-Accredited Testing Laboratories (ATLs) as set forth in the final rule establishing the Permanent Certification Program (*Establishment of the Permanent Certification Program for Health Information Technology, 45 CFR Part 170; February 7, 2011.*)

Questions or concerns regarding the ONC HIT Certification Program should be directed to ONC at ONC.Certification@hhs.gov.

CERTIFICATION CRITERIA

This certification criterion is from 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 issued by the Department of Health and Human Services (HHS) on September 4, 2012.

§170.314(a)(8) Clinical decision support.

- (i) Evidence-based decision support interventions. Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data:
 - (A) Problem list;

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

² 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

- (B) Medication list;
 - (C) Medication allergy list;
 - (D) Demographics;
 - (E) Laboratory tests and values/results; and
 - (F) Vital signs.
- (ii) Linked referential clinical decision support.
- (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).
 - (B) For paragraph (a)(8)(ii)(A) of this section, EHR technology must be able to electronically identify for a user diagnostic and therapeutic reference information based on each one and at least one combination of the following data referenced in paragraphs (a)(8)(i)(A) through (F) of this section.
- (iii) Clinical decision support configuration.
- (A) Enable interventions and reference resources specified in paragraphs (a)(8)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role.
 - (B) EHR technology must enable interventions to be electronically triggered:
 - (1) Based on the data referenced in paragraphs (a)(8)(i)(A) through (F) of this section;
 - (2) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received pursuant to paragraph (b)(1)(iii) of this section.
 - (3) Ambulatory setting only. When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(5)(i)(A)(1) of this section.
- (iv) Automatically and electronically interact. Interventions triggered in accordance with paragraphs (a)(8)(i) through (iii) of this section must automatically and electronically occur when a user is interacting with EHR technology.
- (v) Source attributes. Enable a user to review the attributes as indicated for all clinical decision support resources:
- (A) For evidence-based decision support interventions under paragraph (a)(8)(i) 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 clinical decision support in paragraph (a)(8)(ii) of this section and drug-drug, drug-allergy interaction checks in paragraph(a)(2) of this section, the developer of the

intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).

Per 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, the 2014 Edition of this certification criterion is classified as revised from the 2011 Edition. This certification criterion meets at least one of the three factors of revised certification criteria: (1) the certification criterion includes changes to capabilities that were specified in the previously adopted certification criterion, (2) the certification criterion has a new mandatory capability that was not included in the previously adopted certification criterion, or (3) the certification criterion was previously adopted as “optional” for a particular setting and is subsequently adopted as “mandatory” for that setting.

Per 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 where the clinical decision support certification criterion is discussed:

- “...we intended for an identified set of limited users to be able to select CDS interventions (thus ...it should be apparent when these users have enabled certain interventions)...”
- “...the best method of tracking CDS interventions is to capture when they are enabled. So long as EHR technology is capable of recording such an event, then the EHR technology will be capable of generating a report that expresses the CDS interventions that were enabled across a given time-frame...”
- “We have adopted [HL7 Context-Aware Knowledge Retrieval Standard] as an alternative to a general capability for referential decision support that does not require a standard...we have expressed the HL7 Context-Aware Knowledge Retrieval Standard-enabled capability in the certification criterion with an “or”...”
- “CDS interventions must be triggered based on data that is already recorded and stored within EHR technology; CDS interventions must be triggered when a patient’s medications, medication allergies, and problems have been incorporated by EHR technology upon receipt of a transition of care/referral summary formatted in accordance with the Consolidated CDA; and, for the ambulatory setting only, CDS interventions must be triggered when laboratory test results/values are incorporated by EHR technology upon receipt of a laboratory test report formatted in accordance with the LRI specification.”
- “In a scenario where the EHR technology developer uses a third party content provider for a clinical reference or interventions it would be the third party from which the EHR technology developer would get this information.”
- “Drug-drug and drug-allergy interventions are clinical decision support resources.”
- “...a drug-allergy alert that warns a user not to prescribe a medication to which that patient is allergic may not merit the same scrutiny by the EP, EH, or CAH as an intervention that informs a

provider of an opportunity to prescribe a new medication for which a given patient may be a candidate. We therefore have modified this criterion to constrain the required information to a bibliographic citation and identification of the developer of the intervention, and further clarify that global citations are permitted in cases where all interventions of a given type are provided by the same reference.”

- “...the system be capable of configuration based on the user’s role in the system. We expect that a physician, nurse, clerical worker, and patient would all have different settings, as the CDS interventions to which they should be exposed may differ – or may have different presentation formats.”

Per Section III.D of the preamble of the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule where the clinical decision support certification criterion is discussed:

- “The use of a pop-up message or sound was not a specified requirement in the regulation text. We agree with the commenters who explained that there may be better ways to provide alerts. For the purposes of testing and certification, we leave it entirely up to Complete EHR and EHR Module developers to innovate in this area and provide capabilities that are both easy to use and prevent medical errors. Additionally, we agree with the commenters who suggested that we replace “alert” with “notification,” and we have made that change globally across all certification criteria that used the term alert.”
- “...we clarify that with respect to notifications, that “real-time” means at the point of clinical decision making (i.e., notifications must be provided when an eligible professional is using Certified EHR Technology and not run overnight and provided in the morning, for instance).”
- “While this certification criterion is now the same as the certification criterion for Complete EHRs and EHR Modules designed for an ambulatory setting, we have not combined and moved the clinical decision support certification criteria to the general certification criteria section because the focus of the meaningful use objective is different and specific to eligible hospitals. We also believe that it is useful to keep these certification criteria separate because we anticipate that these certification criteria could in the future include different requirements, specific to the settings for which Complete EHRs and EHR Modules are developed.”

CHANGES FROM 2011 TO 2014 EDITION

Per 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 where the clinical decision support certification criterion is discussed:

- “We proposed to replace the term “clinical decision support rule” used in the 2011 Edition EHR certification criteria and the HITSC recommended criterion with the term “clinical decision support

intervention” to better align with, and clearly allow for, the variety of decision support mechanisms available that help improve clinical performance and outcomes.”

- “We appreciate the support for the more expansive term, “CDS intervention” and have used it in the final rule.”

INFORMATIVE TEST DESCRIPTION

This section provides an informative description of how the test procedure is organized and conducted. It is not intended to provide normative statements of the certification requirements.

This test evaluates the capability for a Complete EHR or EHR Module to:

- Enable a limited set of users to select (i.e., activate) one or more electronic clinical decision support interventions based on data from each one and at least one combination of data from two or more of the following data categories:
 - (A) Problem list;
 - (B) Medication list;
 - (C) Medication allergy list;
 - (D) Demographics;
 - (E) Laboratory tests and values/results; and
 - (F) Vital signs
- Enable interventions to be electronically triggered:
 - Based on data in the Problem list, Medication list, Medication allergy list, Demographics, Laboratory tests and values/results, and Vital signs; and based on at least one combination of data from two or more of these data categories
 - When a patient’s medications, medication allergies, and problems are electronically received and incorporated from a transition of care/referral summary, and in accordance with the ONC EHR certification criterion 170.314.b.1 Transitions of care, receive, display, and incorporate transition of care/referral summaries
 - Ambulatory setting only. When a patient’s laboratory tests and values/results are electronically received and incorporated in accordance with the ONC EHR certification criterion 170.314.b.5.i.A.1 Incorporate laboratory tests and values/results, Receive results, Ambulatory setting only
- Enable the clinical decision support interventions, triggered based on the capabilities and data elements listed above, to occur automatically and electronically when a user is interacting with the EHR technology
- Electronically identify for a user diagnostic and therapeutic reference information using a method identified by the EHR Vendor, or electronically identify for a user diagnostic and therapeutic reference information in accordance with the HL7 Version 3 Standard: Context-Aware Retrieval Application (Infobutton) standard and the HL7 Version 3 Implementation Guide: URL-Based Implementations of the Context-Aware Information Retrieval (Infobutton) Domain implementation guide, based on data from each one and at least one combination of data from two or more of the following data categories:

- (A) Problem list;
 - (B) Medication list;
 - (C) Medication allergy list;
 - (D) Demographics;
 - (E) Laboratory tests and values/results; and
 - (F) Vital signs
- Enable interventions and reference resources to be configured based on a user's clinical role by a limited set of identified users (e.g. system administrator)
 - Enable the user to review the following attributes for evidence-based clinical decision support interventions related to data in the Problem list, Medication list, Medication allergy list, Demographics, Laboratory tests and values/results, and Vital signs:
 - Bibliographic citation of the intervention (clinical research/guideline);
 - Developer of the intervention (translation from clinical research/guideline);
 - Funding source of the intervention development technical implementation; and
 - Release and, if applicable, revision date(s) of the intervention or reference source
 - Enable the user to review the following attributes for diagnostic and therapeutic reference resources and drug-drug/drug-allergy interaction checks:
 - Developer of the intervention
 - Bibliographic citation of the intervention (clinical research/guideline) where clinically indicated

The following points have been added as clarification for the Tester:

- The sequencing of the test steps was determined based on efficiency of testing and product workflow and does not follow the order of the criterion
- The structure of a clinical decision support intervention is not explicitly defined. The Vendor may choose to define an intervention in a variety of ways, including, but not limited to: automated workflow modifications, prompting or facilitation of clinical documentation (e.g., condition-specific flowsheets, highlighting or making available additional structured documentation based upon triggers, data-driven care plans and documentation templates), suggested orders/order sets, or user-facing messages, reminders, or warnings
- With regard to both Transition of Care/Referral Summary and Ambulatory Laboratory Tests and Values/Results, the Tester will be required to incorporate Vendor-supplied data into the appropriate document architecture (e.g. C-CDA, electronic lab results) and send the Transition of Care/Referral Summary and Ambulatory Laboratory Tests to the Vendor during the test
- With regard to linked referential clinical decision support, the Vendor may provide links or access to external, data-driven clinical reference information through the use of free (e.g. MedlinePlus®) or commercially available (e.g. UpToDate®) resources

The Vendor provides the test data for this test procedure.

This test procedure is organized into eight sections:

- Select/Activate – evaluates the capability for a limited set of identified users to select (i.e., activate) 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:
 - Problem list
 - Medication list
 - Medication allergy list
 - Demographics
 - Laboratory tests and values/results
 - Vital signs
 - The Vendor creates a patient record in their EHR and populates that patient's record with Vendor-supplied problems, medications, medication allergies, demographics, laboratory tests and values/results, and vital signs
 - The Vendor identifies and describes the clinical decision support interventions available 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:
 - Problem list
 - Medication list
 - Medication allergy list
 - Demographics
 - Laboratory tests and values/results
 - Vital signs
 - The Tester logs in to the EHR as a user that has the ability to select (i.e. activate) clinical decision support interventions and activates the available interventions based on data from each one and at least one combination of data from two or more of the following data categories:
 - Problem list
 - Medication list
 - Medication allergy list
 - Demographics
 - Laboratory tests and values/results
 - Vital signs
 - The Tester verifies that clinical decision support interventions are activated based on data from each one and at least one combination of data from two or more of the data categories listed above
 - The Tester logs in to the EHR as a user that does not have the ability to select (i.e. activate) clinical decision support interventions and verifies that the available interventions cannot be selected/activated
- Trigger – evaluates the capability for the EHR technology to electronically trigger interventions:

1. Based on data in the Problem list, Medication list, Medication allergy list, Demographics, Laboratory tests and values/results, and Vital signs; and based on at least one combination of data from two or more of these data categories
2. When a patient's medications, medication allergies, and problems are electronically received and incorporated from a transition of care/referral summary
3. Ambulatory setting only. When a patient's laboratory tests and values/results are electronically received and incorporated into the patient's record
 - The Tester verifies that clinical decision support interventions trigger electronically based on data from each one and at least one combination of data from two or more of the following data categories:
 - Problem list
 - Medication list
 - Medication allergy list
 - Demographics
 - Laboratory tests and values/results
 - Vital signs
 - The EHR receives a transition of care/referral summary, as referenced in 170.314(b)(1)
 - The Tester verifies that clinical decision support interventions trigger electronically when medications, medication allergies, and problems are electronically received and incorporated into the patient's record from a transition of care/referral summary
 - Ambulatory setting only: The EHR receives clinical laboratory tests and values/results, as referenced in 170.314.b.5
 - The Tester verifies that at least one clinical decision support intervention triggers electronically when clinical laboratory tests and values/results are electronically received and incorporated into the patient's record
- Occur – evaluates the capability of clinical decision support interventions, triggered based on the capabilities and data elements listed above, to occur automatically and electronically when a user is interacting with the EHR technology
 - The Tester verifies that clinical decision support interventions occur automatically and electronically based on data from each one and at least one combination of data from two or more of the following data categories:
 - Problem list
 - Medication list
 - Medication allergy list
 - Demographics
 - Laboratory tests and values/results
 - Vital signs

- The Tester verifies that clinical decision support interventions occur automatically and electronically when a patient's medications, medication allergies, and problems are electronically received and incorporated from a transition of care/referral summary
- The Tester verifies that at least one clinical decision support intervention occurs automatically and electronically when clinical laboratory tests and values/results are incorporated into the patient record
- 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:
 - Problem list
 - Medication list
 - Medication allergy list
 - Demographics
 - Laboratory tests and values/results
 - Vital signs
 - The Vendor creates a patient record in their EHR and populates that patient's record with Vendor-supplied problems, medications, medication allergies, demographics, laboratory tests and values/results, and vital signs
 - The Tester performs the Vendor-identified EHR function(s) to access diagnostic and therapeutic reference information, using either general capability or the HL7 Context-Aware Knowledge Retrieval (Infobutton) Standard, based on data from each one and at least one combination of data from two or more of the following data categories:
 - Problem list
 - Medication list
 - Medication allergy list
 - Demographics
 - Laboratory tests and values/results
 - Vital signs
- Configure – evaluates the capability of a limited set of identified users to configure clinical decision support interventions and diagnostic and therapeutic reference resources into the EHR technology based on the user's clinical role
 - The Vendor creates a patient record in their EHR and populates that patient's record with Vendor-supplied problems, medications, medication allergies, demographics, laboratory tests and values/results, and vital signs
 - The Tester logs in to the EHR as a user that has the ability to configure clinical decision support interventions and diagnostic and therapeutic reference resources and configures the interventions based on a user's clinical role

- The Tester verifies that clinical decision support interventions occur automatically and electronically and that diagnostic and therapeutic reference resources are accessible electronically when logged in to the EHR as an authorized user
- The Tester verifies that clinical decision support interventions do not occur automatically and electronically and that diagnostic and therapeutic reference resources are not accessible electronically when logged in to the EHR as a user whose clinical role does not match the configuration
- The Tester logs in to the EHR as a user that does not have the ability to configure clinical decision support interventions nor diagnostic and therapeutic reference resources and verifies that interventions based on a user's clinical role cannot be configured
- Review – evaluates the capability of the EHR technology to enable a user to review the following information for evidence-based clinical decision support interventions associated with data in the Problem list, Medication list, Medication allergy list, Demographics, Laboratory tests and values/results, and Vital signs:
 - Bibliographic citation of the intervention (clinical research/guideline);
 - Developer of the intervention (translation from clinical research/guideline);
 - Funding source of the intervention development technical implementation; and
 - Release and, if applicable, revision date(s) of the intervention or reference source.
- The Tester performs the Vendor-identified EHR function(s) to review the attributes of at least one clinical decision support intervention
- The Tester verifies that the attribute contains the bibliographic citation of the intervention (clinical research/guideline), the developer of the intervention (translation from clinical research/guideline), the funding source of the intervention development technical implementation, and the release (and, if applicable, revision date(s)) of the intervention
- Review – evaluates the capability of the EHR technology to enable a user to review the following information for diagnostic and therapeutic reference resources associated with data in the Problem list, Medication list, Medication allergy list, Demographics, Laboratory tests and values/results, and Vital signs:
 - Developer of the intervention
 - Bibliographic citation of the intervention (clinical research/guideline)
- The Tester performs the Vendor-identified EHR function(s) to review the attributes of at least one diagnostic and therapeutic reference resource
- The Tester verifies that the attribute contains the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline)

- **Review** – 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):
 - Developer of the intervention
 - Bibliographic citation of the intervention (clinical research/guideline)
 - The Tester performs the Vendor-identified EHR function(s) to review the attributes of at least one drug-drug, drug-allergy interaction check
 - The Tester verifies that the attribute contains the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline)

REFERENCED STANDARDS

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

REFERENCED CERTIFICATION CRITERIA

§170.314 2014 Edition electronic health record certification criteria.	Referenced Standards
The Secretary adopts the following certification criteria for Complete EHRs or EHR Modules. Complete EHRs or EHR Modules 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) <u>Drug-drug, drug-allergy interaction checks.</u> <ul style="list-style-type: none">(i) <u>Interventions.</u> Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically and electronically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list.(ii) <u>Adjustments.</u><ul style="list-style-type: none">(A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.(B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.	

(b)(1) Transitions of care – receive, display, and incorporate transition of care/referral summaries.

(iii) Incorporate. Upon receipt of a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(3), EHR technology must be able to:

(A) Correct patient. Demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient.

(B) Data incorporation. Electronically 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)(2);

(2) Problems. At a minimum, the version of the standard specified in §170.207(a)(3);

(3) Medication allergies. At a minimum, the version of the standard specified in §170.207(d)(2).

(C) Section views. Extract and allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary received and formatted in accordance with the standard adopted at § 170.205(a)(3).

§170.205 Content exchange standards and implementation specifications for exchanging electronic health information. The Secretary adopts the following content exchange standards and associated implementation specifications:

(a)(3) Standard. HL7

Implementation Guide for CDA[®] Release 2.0, Consolidated CDA Templates (US Realm), July 2012 (incorporated by reference in § 170.299). The use of the “unstructured document” document-level template is prohibited.

§170.207 Vocabulary standards for representing electronic health information.

The Secretary adopts the following code sets, terminology, and nomenclature as the vocabulary standards for the purpose of representing electronic health information

(a)(3) Standard. IHTSDO SNOMED CT[®] International Release July 2012 (incorporated by reference in § 170.299) and US Extension to SNOMED CT[®] March 2012 Release (incorporated by reference in § 170.299).

(d) Medications. (2) Standard. RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release (incorporated by reference in § 170.299).

(b)(5) Incorporate laboratory tests and values/results.

(i) Receive results.

(A) Ambulatory setting only.

(1) Electronically receive and incorporate clinical laboratory tests and values/results in accordance with the standard specified in § 170.205(j) and, at a minimum, the version of the standard specified in § 170.207(c)(2).

§170.205 Content exchange standards and implementation specifications for exchanging electronic health information. The Secretary adopts the following content exchange standards and associated implementation specifications:

(j) Electronic incorporation and transmission of lab results. Standard. HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, (incorporated by reference in § 170.299).

§170.207 Vocabulary standards for representing electronic health information.

The Secretary adopts the following code sets, terminology, and nomenclature as the vocabulary standards for the purpose of representing electronic health information

(c) Laboratory tests. (2) Standard. Logical Observation Identifiers Names and Codes (LOINC[®]) Database version 2.40, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc. (incorporated by reference in § 170.299).

DRAFT

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.314.a.8 – 1: Select/Activate Clinical Decision Support Interventions

DTR170.314.a.8 – 2: Trigger Clinical Decision Support Interventions

DTR170.314.a.8 – 3: Identify Diagnostic and Therapeutic Reference Resources

DTR170.314.a.8 – 4: Configure Clinical Decision Support Interventions and Diagnostic and Therapeutic Reference Resources

DTR170.314.a.8 – 5: Review Attributes

DTR170.314.a.8 – 1: Select/Activate Clinical Decision Support Interventions

Required Vendor Information

VE170.314.a.8 – 1.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test

VE170.314.a.8 – 1.02: Vendor shall populate the patient's record with Vendor-supplied problems, medications, medication allergies, demographics, laboratory tests and values/results, and vital signs

VE170.314.a.8 – 1.03: Vendor shall identify a user who has the ability to select (i.e. activate) clinical decision support interventions and shall identify a user who does not have the ability to select (i.e. activate) clinical decision support interventions

VE170.314.a.8 – 1.04: Vendor shall identify a user who has the ability to configure clinical decision support interventions and diagnostic and therapeutic reference resources and shall identify a user who does not have the ability to configure clinical decision support interventions nor diagnostic and therapeutic reference resources

VE170.314.a.8 – 1.05: Vendor shall identify users of the EHR whose clinical roles differ from one another

VE170.314.a.8 – 1.06: Vendor shall identify a user with the ability to enter orders via CPOE

VE170.314.a.8 – 1.07: Vendor shall provide the problems, medications, and medication allergies to be used by the Tester to populate the Consolidated Clinical Document Architecture transition of care/referral summary

VE170.314.a.8 – 1.08: Ambulatory setting only: Vendor shall provide the clinical laboratory tests and values/results to be used by the Tester to populate the Laboratory Results Interface document

VE170.314.a.8 – 1.09: Vendor shall identify the EHR function(s) that are available to 1) select (i.e. activate) clinical decision support interventions, 2) identify diagnostic and therapeutic reference resources, 3) configure clinical decision support interventions and diagnostic and therapeutic reference resources, and 4) review attributes

Required Test Procedures

TE170.314.a.8 – 1.01: Tester shall log in to the EHR as a user who has the ability to select (i.e. activate) clinical decision support interventions

TE170.314.a.8 – 1.02: Using the Vendor-identified EHR function(s), the Tester shall select (i.e. activate) clinical decision support interventions based on data from each one and at least one combination of data from two or more of the following data categories:

- Problem list
- Medication list
- Medication allergy list
- Demographics
- Laboratory tests and values/results
- Vital signs

TE170.314.a.8 – 1.03: Tester shall log in to the EHR as a user who does not have the ability to select (i.e. activate) clinical decision support interventions and shall verify that the function(s) to select (i.e. activate) the interventions is (are) not available

TE170.314.a.8 – 1.04: Using the Inspection Test Guide, the Tester shall verify that clinical decision support interventions are activated based on data in the Problem list, Medication list, Medication allergy list, Demographics, Laboratory tests and values/results, and Vital signs; and based on at least one combination of data from two or more of these data categories

Inspection Test Guide

IN170.314.a.8 – 1.01: Using the Vendor-supplied test data, the Tester shall verify that clinical decision support interventions are activated based on data in the Problem list, Medication list, Medication allergy list, Demographics, Laboratory tests and values/results, and Vital signs; and based on at least one combination of data from two or more of these data categories

DTR170.314.a.8 – 2: Trigger Clinical Decision Support Interventions

Required Vendor Information

- Information as defined in DTR170.314.a.8 – 1, no additional information is required

Required Test Procedures

TE170.314.a.8 – 2.01: Tester shall log in to the EHR and shall select a patient record identified by the Vendor and populated with Vendor-supplied test data

TE170.314.a.8 – 2.02: Using the Inspection Test Guide, the Tester shall verify that clinical decision support interventions trigger electronically based on data from each one and at least one combination of data from two or more of the following data categories:

- Problem list
- Medication list
- Medication allergy list

- Demographics
- Laboratory tests and values/results
- Vital signs

TE170.314.a.8 – 2.03: Using the Inspection Test Guide, the Tester shall verify that the clinical decision support interventions, triggered based on the capabilities and data elements listed above, occur automatically and electronically when a user is interacting with the EHR technology

TE170.314.a.8 – 2.04: Tester shall select a patient record identified by the Vendor and shall send a transition of care/referral summary populated with Vendor-supplied data

TE170.314.a.8 – 2.05: Tester shall verify that a transition of care/referral summary populated with Vendor-supplied data is received by the EHR

TE170.314.a.8 – 2.06: Using the Inspection Test Guide, the Tester shall verify that clinical decision support interventions trigger electronically when medications, medication allergies, and problems are electronically received and incorporated into the patient's record from a transition of care/referral summary

TE170.314.a.8 – 2.07: Using the Inspection Test Guide, the Tester shall verify that the clinical decision support interventions, triggered when data elements are incorporated into the patient's record from a transition of care/referral summary, occur automatically and electronically when a user is interacting with the EHR technology

TE170.314.a.8 – 2.08: Ambulatory setting only. Tester shall select a patient record identified by the Vendor and shall send Vendor-supplied clinical laboratory tests and values/results

TE170.314.a.8 – 2.09: Ambulatory setting only. Tester shall verify that Vendor-supplied laboratory tests and values/results are received by the EHR

TE170.314.a.8 – 2.10: Ambulatory setting only. Using the Inspection Test Guide, the Tester shall verify that at least one clinical decision support intervention triggers electronically when clinical laboratory tests and values/results are electronically received and incorporated into the patient's record

TE170.314.a.8 – 2.11: Ambulatory setting only. Using the Inspection Test Guide, the Tester shall verify that the clinical decision support interventions, triggered when clinical laboratory tests and values/results are incorporated into the patient's record, occur automatically and electronically when a user is interacting with the EHR technology

Inspection Test Guide

IN170.314.a.8 – 2.01: Using the Vendor-supplied test data, the Tester shall verify that at least one clinical decision support intervention is triggered based on data in the Problem list, Medication list, Medication allergy list, Demographics, Laboratory tests and values/results, and Vital signs; and based on at least one combination of data from two or more of these data categories

IN170.314.a.8 – 2.02: Using the Vendor-supplied test data, the Tester shall verify that incorporation of the summary care record, referenced in §170.314.b.1, functions as described by the Vendor

IN170.314.a.8 – 2.03: Using the Vendor-supplied test data, the Tester shall verify that incorporation of the clinical laboratory tests and values/results, referenced in §170.314.b.5, functions as described by the Vendor

IN170.314.a.8 – 2.04: Using the Vendor-supplied test data, the Tester shall verify that at least one clinical decision support intervention is indicated when medications, medication allergies, and problems are electronically received and incorporated into the patient's record from a transition of care/referral summary

IN170.314.a.8 – 2.05: Ambulatory setting only: Using the Vendor-supplied test data, the Tester shall verify that at least one clinical decision support intervention is indicated when clinical laboratory tests and values/results are electronically received and incorporated into the patient's record

IN170.314.a.8 – 2.06: Using the Vendor-supplied test data, the Tester shall verify that the clinical decision support interventions occur automatically and electronically as described by the Vendor when a user is interacting with the EHR technology

DTR170.314.a.8 – 3: Identify Diagnostic and Therapeutic Reference Resources

Required Vendor Information

- Information as defined in DTR170.314.a.8 – 1, no additional information is required

Required Test Procedures

TE170.314.a.8 – 3.01: Tester shall select a patient record identified by the Vendor and populated with Vendor-supplied test data

TE170.314.a.8 – 3.02: Using the Vendor-identified EHR function(s), the Tester shall access diagnostic and therapeutic reference information, using either general capability or the HL7 Context-Aware Knowledge Retrieval (Infobutton) Standard, based on data from each one and at least one combination of data from two or more of the following data categories:

- Problem list
- Medication list
- Medication allergy list
- Demographics
- Laboratory tests and values/results
- Vital signs

Inspection Test Guide

IN170.314.a.8 – 3.01: Using the Vendor-supplied test data, the Tester shall verify that the diagnostic and therapeutic reference resources function as described by the Vendor

DTR170.314.a.8 – 4: Configure Clinical Decision Support Interventions and Diagnostic and Therapeutic Reference Resources

Required Vendor Information

- Information as defined in DTR170.314.a.8 – 1, no additional information is required

Required Test Procedures

- TE170.314.a.8 – 4.01: Tester shall log in to the EHR as a user (e.g. system administrator) who has the ability to configure clinical decision support interventions
- TE170.314.a.8 – 4.02: Using the Vendor-identified EHR function(s), the Tester shall configure at least one clinical decision support intervention based on a user's clinical role
- TE170.314.a.8 – 4.03: Using the Inspection Test Guide, the Tester shall log in to the EHR as a user whose clinical role has been configured to allow for indication of clinical decision support interventions, shall select a patient record identified by the Vendor and populated with Vendor-supplied test data, and shall verify that the clinical decision support interventions occur automatically and electronically when a user is interacting with the EHR technology
- TE170.314.a.8 – 4.04: Using the Inspection Test Guide, the Tester shall log in to the EHR as a user whose clinical role does not allow for indication of clinical decision support interventions and shall verify that the clinical decision support interventions do not occur automatically and electronically
- TE170.314.a.8 – 4.05: Tester shall log in to the EHR as a user (e.g. system administrator) who has the ability to configure diagnostic and therapeutic reference resources
- TE170.314.a.8 – 4.06: Using the Vendor-identified EHR function(s), the Tester shall configure at least one diagnostic and therapeutic reference resource based on a user's clinical role
- TE170.314.a.8 – 4.07: Using the Inspection Test Guide, the Tester shall log in to the EHR as a user whose clinical role has been configured to allow access to diagnostic and therapeutic reference resources and shall verify that the reference resources can be accessed electronically
- TE170.314.a.8 – 4.08: Using the Inspection Test Guide, the Tester shall log in to the EHR as a user whose clinical role does not allow access to diagnostic and therapeutic reference resources and shall verify that the reference resources cannot be accessed electronically
- TE170.314.a.8 – 4.09: Using the Inspection Test Guide, the Tester shall log in to the EHR as a user who does not have the ability to configure clinical decision support interventions nor diagnostic and therapeutic reference resources and shall verify that the functions to configure clinical decision support interventions and diagnostic and therapeutic reference resources are not available

Inspection Test Guide

- IN170.314.a.8 – 4.01: Using the Vendor-supplied test data, the Tester shall verify that the clinical decision support interventions and the diagnostic and therapeutic reference resources can be configured based on a user's clinical role
- IN170.314.a.8 – 4.02: Using the Vendor-supplied test data, the Tester shall verify that, once configured, the clinical decision support interventions occur automatically and electronically based on a user's clinical role as described by the Vendor
- IN170.314.a.8 – 4.03: Using the Vendor-supplied test data, the Tester shall verify that, once configured, the diagnostic and therapeutic reference resources can be accessed electronically based on a user's clinical role as described by the Vendor

DTR170.314.a.8 – 5: Review Attributes

Required Vendor Information

- Information as defined in DTR170.314.a.8 – 1, no additional information is required

Required Test Procedures

- TE170.314.a.8 – 5.01: Tester shall log in to the EHR as a user whose role is configured to allow for indication of clinical decision support interventions and shall select a patient record identified by the Vendor and populated with Vendor-supplied test data
- TE170.314.a.8 – 5.02: Using the Vendor-identified EHR function(s), the Tester shall interact with the EHR technology and cause a clinical decision support intervention to trigger electronically and occur electronically and automatically
- TE170.314.a.8 – 5.03: Using the Vendor-identified EHR function(s), the Tester shall display the bibliographic citation of the intervention (clinical research/guideline), the developer of the intervention (translation from clinical research/guideline), the funding source of the intervention development technical implementation, and the release (and, if applicable, revision date(s)) of the intervention
- TE170.314.a.8 – 5.04: Using the Inspection Test Guide, the Tester shall verify that the attributes for clinical decision support interventions are accessed and viewed as described by the Vendor
- TE170.314.a.8 – 5.05: Tester shall log in to the EHR as a user whose role is configured to allow for access to diagnostic and therapeutic reference resources and shall select a patient record identified by the Vendor and populated with Vendor-supplied test data
- TE170.314.a.8 – 5.06: Using the Vendor-identified EHR function(s), the Tester shall access diagnostic and therapeutic reference information, using either general capability or the HL7 Context-Aware Knowledge Retrieval (Infobutton) Standard
- TE170.314.a.8 – 5.07: Using the Vendor-identified EHR function(s), the Tester shall display the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention

- TE170.314.a.8 – 5.08: Using the Inspection Test Guide, the Tester shall verify that the attributes for diagnostic and therapeutic references are accessed and viewed as described by the Vendor
- TE170.314.a.8 – 5.09: Tester shall log in to the EHR as a user with the ability to enter orders via CPOE and shall select a patient record identified by the Vendor and populated with Vendor-supplied test data
- TE170.314.a.8 – 5.10: Using the Vendor-identified EHR function(s), the Tester shall automatically and electronically indicate a drug-drug or drug-allergy contraindication intervention based on the patient's Medication list or Medication allergy list, respectively, before a medication order is completed and acted upon during CPOE
- TE170.314.a.8 – 5.11: Using the Vendor-identified EHR function(s), the Tester shall display the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention
- TE170.314.a.8 – 5.12: Using the Inspection Test Guide, the Tester shall verify that the attributes for drug-drug and drug-allergy interaction checks are accessed and viewed as described by the Vendor

Inspection Test Guide

- IN170.314.a.8 – 5.01: Using the Vendor-supplied test data, the Tester shall verify that the attributes for diagnostic and therapeutic references are accessed and viewed as described by the Vendor
- IN170.314.a.8 – 5.02: Using the Vendor-supplied test data, the Tester shall verify that the attributes for diagnostic and therapeutic references are accessed and viewed as described by the Vendor
- IN170.314.a.8 – 5.03: Using the Vendor-supplied test data, the Tester shall verify that the attributes for drug-drug and drug-allergy interaction checks are accessed and viewed as described by the Vendor

TEST DATA

This test procedure requires the vendor to supply the test data. The Tester shall address the following:

- Vendor-supplied test data shall ensure that the functional requirements identified in the criterion can be adequately evaluated for conformance
- Vendor-supplied test data shall strictly focus on meeting the basic capabilities required of an EHR relative to the certification criterion rather than exercising the full breadth/depth of capability that an installed EHR might be expected to support
- Tester shall record as part of the test documentation the specific Vendor-supplied test data that was utilized for testing

CONFORMANCE TEST TOOLS

None

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Document History

Version Number	Description	Date Published
1.0	Released for public comment	September 21, 2012

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