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.

The Department of Health and Human Services (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 Health Information Technology (HIT) Certification Program[2], is carried out by National Voluntary Laboratory Accreditation Program (NVLAP)-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. This certification criterion is included in the definition of a Base EHR.

§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)(B) or (b)(9)(ii)(D) 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 (September 4, 2012), 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.

2014 EDITION PREAMBLE LANGUAGE

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 such as during an EHR reporting period."
- "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."

2011 EDITION PREAMBLE LANGUAGE

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 (July 28, 2010) 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 EHR technology 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 an EHR technology 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 EHR technologies 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 September 4, 2012) 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.

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.

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.

This test evaluates the capability for an EHR technology to:

- Enable a limited set of users to select (e.g., activate, enable) 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 (summary care record) or clinical information reconciliation & incorporation, and in accordance with the ONC EHR certification criterion 170.314(b)(1)(B) or (b)(9)(ii)(D)
  - 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 of the following data categories:
    - Problem list
    - Medication list
    - Laboratory tests and values/results
  - Based on least one combination of data from two or more of the following data categories:
    - Problem list

    - Medication list
    - Laboratory tests and values/results
    - Demographics
    - Vital signs
    - Medication allergies
- 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, CDS rules engine, hard-coded interventions), 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 (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:

- 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 (e.g., activate, enable) 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 (e.g., trigger an intervention based upon age, gender such as a screening mammogram for a woman over 40)
        - Laboratory tests and values/results (e.g., trigger an intervention (for example, highlighting/change in color or font) that calls attention to an abnormal range value, prompt for entry of lab value prior to administration of a medication, suggest problem list entry)
        - Vital signs (e.g., trigger an intervention (for example, highlighting/change in color or font) that calls attention to an abnormal range value, suggest a diagnosis for the problem list (e.g. hypertension for blood pressure entry of 180/110), etc.)
    - 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 (e.g., activate, enable) clinical decision support interventions and verifies that the available interventions cannot be selected/activated
    - The Tester verifies that the EHR technology is capable of recording the time-frame for which CDS interventions are enabled (or disabled)

- Trigger – evaluates the capability for the EHR technology to electronically trigger interventions to occur automatically and electronically:
  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 (summary care record)
  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 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 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

- 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 of the following data categories:
    - Problem list
    - Medication list

        - Laboratory tests and values/results
    - Based on 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 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
    - 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 for clinical users with the appropriate role
    - 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 for the specific intervention(s)
    - 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 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 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 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:
  - 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 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):
  - 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) 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) 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 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. (i) Interventions. 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) Adjustments. (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).
(b)(9) *Optional—clinical information reconciliation and incorporation* (ii) *Reconciliation.* Enable a user to electronically reconcile the data that represent a patient's active medication, problem, and medication allergy list as follows. For each list type: (D) Upon a user's confirmation, automatically update the list, and 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).	

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 Source Attributes for Clinical Decision Support Resources

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

Required Vendor Information

VE170.314(a)(8) – 1.01: Vendor shall identify a user who has the ability to select (e.g., activate, enable) clinical decision support interventions and shall identify a user who does not have the ability to select clinical decision support interventions

VE170.314(a)(8) – 1.02: Vendor shall identify the EHR function(s) that are available to 1) select (e.g., activate, enable) clinical decision support interventions, and 2) recording when CDS interventions are enabled or disabled

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 (e.g., activate, enable) clinical decision support interventions

TE170.314(a)(8) – 1.02: Using the Vendor-identified EHR function(s), the Tester shall select (e.g., activate, enable) 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 (e.g., activate, enable) clinical decision support interventions and shall verify that the function(s) to select 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

IN170.314(a)(8) – 1.02: The Tester shall verify that the status and timing of the activated clinical decision support interventions is recorded by the EHR (e.g. by viewing a log, report)

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

Required Vendor Information

VE170.314(a)(8) – 2.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test

VE170.314(a)(8) – 2.02: 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) – 2.03: Vendor shall provide and identify, for a patient with an existing record in the EHR, a summary care record (Consolidated Clinical Document Architecture (C-CDA) document) received in the EHR that contains problems, medications, and medication allergies incorporated

VE170.314(a)(8) – 2.04: Ambulatory setting only: Vendor shall provide and identify, for a patient with an existing record in the EHR, clinical laboratory tests and values/results received in the EHR, available incorporated as structured data

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, with a Consolidated Clinical Document Architecture (C-CDA) summary care record with medications,

medication allergies, and problems information incorporated with Vendor-supplied data

TE170.314(a)(8) – 2.05: Using the Inspection Test Guide, the Tester shall verify that one or more clinical decision support interventions triggers electronically and occurs automatically based upon medications, medication allergies, and problems incorporated into the patient's record from a transition of care/referral summary (summary care record)

TE170.314(a)(8) – 2.06: Ambulatory setting only. Tester shall select a patient record identified by the Vendor with clinical laboratory tests and values/results received electronically and incorporated as structured data

TE170.314(a)(8) – 2.07: Ambulatory setting only. Using the Inspection Test Guide, the Tester shall verify that one or more clinical decision support intervention triggers electronically and occurs automatically based upon clinical laboratory tests and values/results incorporated into the patient's record

Inspection Test Guide

IN170.314(a)(8) – 2.01: Using the Vendor-supplied test data, the Tester shall verify that clinical decision support intervention(s) are triggered based on data in the each of the following categories (minimum of 7 combinations):

- Problem list
- Medication list
- Medication allergy list
- Demographics
- Laboratory tests and values/results
- Vital signs
- Combination of data from two or more of the above-listed categories

IN170.314(a)(8) – 2.02: 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 incorporated into the patient's record from a transition of care/referral summary

IN170.314(a)(8) – 2.03: 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 incorporated into the patient's record as structured data

IN170.314(a)(8) – 2.04: 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

VE170.314(a)(8) – 3.01: Vendor shall identify the EHR function(s) that are available to identify diagnostic and therapeutic reference resources

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 (used with the applicable implementation guide),
  - Based on data from each one of the following data categories:
    - Problem list
    - Medication list
    - Laboratory tests and values/results
  - Based on 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

VE170.314(a)(8) – 4.01: 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) – 4.02: Vendor shall identify two or more users of the EHR whose clinical roles differ from one another (e.g. physician, nurse, office staff)

VE170.314(a)(8) – 4.03: Vendor shall identify the EHR function(s) that are available to configure clinical decision support interventions and diagnostic and therapeutic reference resources

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 that is inclusive of one of the roles in VE170.314(a)(8) (e.g., triggered for a physician role but not triggered for nurse or office staff roles)

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 (e.g. physician), 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 (e.g., nurse, office staff) 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 Source Attributes for Clinical Decision Support Resources

Required Vendor Information

VE170.314(a)(8) – 5.01: Vendor shall identify a user with the ability to enter orders via CPOE (e.g. a user with a clinical role that will allow display of drug-drug or drug-allergy contraindications)

VE170.314(a)(8) – 5.02: Vendor shall identify the EHR function(s) that are available to review source attributes for CDS resources

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 (used with the applicable implementation guide) using the approach(es) indicated in TE170.314(a)(8) – 3.02

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 (clinical research/guideline)

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 source attributes for evidenced-based clinical decision support interventions 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 source 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 source attributes for drug-drug and drug-allergy interaction checks are accessed and viewed as described by the Vendor

TEST DATA

The Vendor shall supply the test data for this test procedure.

Vendor supplied test data are provided with the test procedure to ensure that the applicable requirements identified in the criteria can be adequately evaluated for conformance, as well as to provide consistency in the testing process across multiple National Voluntary Laboratory Accreditation Program (NVLAP) - Accredited Testing Labs (ATLs). The provided test data focus on evaluating the basic capabilities of required EHR technology, rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support. The test data are formatted for readability of use within the testing process. The format is not prescribing a particular end-user view or rendering. No additional requirements should be drawn from the format.

Any test data provided shall focus on meeting the basic capabilities required of EHR technology relative to the certification criterion rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support.

The test procedures require that the Tester enter the applicable test data into the EHR technology being evaluated for conformance. The intent is that the Tester fully controls the process of entering the test data in order to ensure that the data are correctly entered as specified in the test procedure. If a situation arises where it is impractical for a Tester to directly enter the test data, the Tester, at the Tester's discretion, may instruct the Vendor to enter the test data, so long as the Tester remains in full control of the testing process, directly observes the test data being entered by the Vendor, and validates that the test data are entered correctly as specified in the test procedure.

For Vendor-supplied test data, the Tester shall address the following:

- Vendor-supplied test data shall ensure that the 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.

Test Data for §170.314(a)(8) Clinical Decision Support available at http://www.healthit.gov/certification (navigation: 2014 Edition Test Method)

CONFORMANCE TEST TOOLS

None

Document History

Version Number	Description of Change	Date Published
1.0	Released for public comment	November 19, 2012
1.1	Delivered for National Coordinator Approval	December 3, 2012
1.2	Posted Approved Test Procedure	December 14, 2012
1.3	Clarify and add the cross reference to TOC and CIRI: Change from (b)(1)(iii) to(b)(1)(iii)(B) or (b)(9)(ii)(D)	December 24, 2014