# Test Criteria: 170.315.a.9 Clinical Decision Support

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| --- | --- |
| **Testing Result** |  |
| Participant and Product-with-version |  |
| Setting (Ambulatory or Inpatient) |  |
| Test Proctor |  |
| Test Date |  |
| Test Result | Pass:  Fail:  No Attempt: |
| Error Description (if applicable) |  |
| Modifications to Product Under Test |  |
| Additional Software Used |  |
| Additional Proctor Notes |  |

### Overview

In this document you will find:

* [Test Data and Test Tools](#_Test_Data_and_1)
* [Standards Support](#_Demonstrate_Standards_Support)
* [Drummond Test Report (Instructions, Expected Results, Points to Remember)](#_170.315.a.9_-_Clinical)
* [Test Procedures](#_Test_Procedures)
* [Appendix A: Testing Guide](#_Appendix_A:_Testing)
* [Appendix B: ONC Criteria](#_Appendix_B:_ONC)

### Version of ONC Test Method

1.2

### Scope of Proctoring Sheet

The ONC test method associated with this criterion is the only approved test method for EHR Meaningful Use certification. This Proctoring Sheet is not a replacement test method but a test procedure document for performing the ONC test method and recording the results. Proctoring Sheet describe test data, test criteria and expected results. It is assumed the Health IT Developer or Participant UnderTest is familiar with the associated ONC test method.

# Robustness and Reliability Requirement

To satisfy the module criteria, it is expected that the Product-Under-Test is able to complete the testing requirements reliably, including repeat testing with the same result without error, and with a satisfactory level of robustness. This includes unexpected error messages produced through normal operation, multiple unintended restarts of the application or any other “buggy” facets of the product displayed while testing. These errors are record in the Additional Proctor Notes of the proctor sheet. Lack of reliability and robustness of design will result in failure of the module.

# Test Data and Tools

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| **Test Data Source:** | ONC-Supplied  DG-Supplied:  Developer-Supplied: |
| **Pre-Test Data Setup:**  Health IT developer implements (7) Clinical Decision Support Interventions based on the elements described in test procedure below. | |
| **Test Data:**  Developer-supplied. | |
| **Test Tools:**  Not applicable. | |

# Demonstrate Standards Support

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| --- | --- |
| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **Instructions:** Implement standards below to demonstrate Clinical Decision Support Interventions. For additional references, click [here](https://www.healthit.gov/policy-researchers-implementers/meaningful-use-stage-2-0/standards-hub) for the ONC Standards Hub. | |

|  |  |  |
| --- | --- | --- |
|  | **Standard** | **Transition of Care/ Referral Summary\*** |
|  | §170.205(a)(3) | HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial |
|  | §170.205(a)(4) | HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, Release 2.1 |
|  | **Standard** | **Demographics (specified in 170.315(a)(5)(i))** |
|  | §170.207(f)(1) | OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No.15, as revised, October 30, 1997 |
|  | §170.207(f)(2) | Race and Ethnicity – CDC code system in the PHIN VADS Release 3.3.9 |
|  | §170.207(g)(2) | Request for Comments (RFC) 5646. “Tags for Identifying Languages, September 2009” <http://www.rfc-ditor.org/info/rfc5646> |
|  | §170.207(n)(1) | Birth sex must be coded in accordance with HL7 version 3 attributed as follows: Male (M), Female (F), Unknown (UKN) |
|  | **Standard** | **Infobutton -** (only method one required) |
|  | §170.204(b)(3) | HL7 Version 3 Standard: Context Aware Retrieval Application (“Infobutton”), Knowledge Request, Release 2. Implementation Specifications. HL7 Implementation Guide: **Service-Oriented Architecture** Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1 <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=283> |
|  | §170.204(b)(4) | HL7 Version 3 Standard: Context Aware Retrieval Application (“Infobutton”), Knowledge Request, Release 2. Implementation Specifications. HL7 Version 3 Implementation Guide: **Context-Aware Knowledge Retrieval** (Infobutton), Release 4  <http://www.hl7.org/implement/standards/product_brief.cfm?product_id=22> |

\*Transition of Care/Referral Summary required to be incorporated based on the standards cited above in order to demonstrate CDS Interventions.

# 170.315.a.9 - Clinical Decision Support

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| --- | --- |
| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **CDS Interventions** (to be completed by Test Proctor): | |
| Problem List: |  |
| Medication List: |  |
| Medication Allergy List: |  |
| Demographic: |  |
| Laboratory Test: |  |
| Vital Signs: |  |
| Combination: |  |
| **Instructions:** Demonstrate the following actions for Clinical Decision Support:   * CDS Intervention Interaction * CDS Configuration * Evidence-based Decision Support Intervention * Linked Referential CDS (Diagnostic and Therapeutic Reference Resources) using HL7 “Infobutton” Standard * Source Attributes | |
| **Expected Test Result:**   * Interactions provided to a user must occur when interacting with technology. * Enable interventions and reference resources to be configured by a limited set of users and based on role. * Enable a limited set of users to select (i.e., activate) CDS interventions (in addition to drug-drug, drug-allergy interaction checks) based on six elements identified below and at least one combination. Seven (7) interventions in total will be demonstrated. * Identify for a user diagnostic and therapeutic reference information in accordance with at least one of the following Infobutton standards: §170.204(b)(3) or §170.204(b)(4). * Enable a user to review attributes as indicated for all clinical decision support resources. | |
| **Points to Remember:**   * Health IT developers are encouraged to use standards to retrieve CDS content from external sources rather than “hard coding” CDS interventions to static data in the system. * Interventions based on demographics only need to be based on one of the demographics data types (e.g., sex or date of birth). | |

### Test Procedures

### 1.1 CDS Configuration

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|  | Log in as authorized user (e.g., system administrator) to verify access to configure intervention and reference resources is limited to a set of identified users based on role. |
|  | Log in as unauthorized user to verify user has no access to configure interventions and reference resources. |
|  | Log in as authorized user to enable interventions and reference resources for the following (7) elements:   1. Problem List; 2. Medication List; 3. Medication allergy list; 4. At least one demographic (*specified in 170.315(a)(5)(i)*); 5. Laboratory tests; 6. Vital Signs; and 7. Combination *(based on at least two of the elements listed above)* |
|  | Authorized user enables interventions and reference resources for incorporated patient information from a transition of care summary based on:   1. Problem List; 2. Medication List; and 3. Medication allergy list |

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### 1.2 CDS Intervention Interaction

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|  | Authorized user logs in and activates CDS interventions when interacting with health IT module for the (7) elements listed in section 1.1 above. |
|  | Health IT module identifies for user the diagnostic and therapeutic reference resource information using the HL7 V3 Context Aware Knowledge Retrieval Application (“Infobutton”) standard based for the following elements:   * + Problem list;   + Medication list;   + At least one demographic (*specified in 170.315(a)(5)(i)*); and   + One combination of problem list, medication list, and demographics |

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**1.3 Source Attributes**

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| --- | --- |
|  | Evidence-based decision support interventions provided must have the following attributes accessible to the user:   * Bibliographic citation (clinical research/guideline) * Developer of the intervention * Funding source of the intervention development technical implementation; and * Release and, if applicable, revision date(s) of the intervention or reference source |
|  | Linked Referential decision support interventions provided must have the following attributes accessible to the user:   * Developer of the intervention * Bibliographic citation (clinical research/guideline) |

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**1.4 Source Attributes – Drug-Drug, Drug-Allergy Interaction Checks**

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|  | Authorized user reviews drug-drug and drug-allergy interaction checks and verifies the following attributes are accessible:   * Developer of the intervention; and * Where clinically indicated, bibliographic citation of the intervention (clinical/research guideline) |

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### 1.5 CDS Intervention Interaction – Unauthorized User

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|  | Unauthorized user(s) log in to same patient record demonstrated in section 1.2 and verifies that user(s) has:   * No access to activate CDS interventions * No access to activate Diagnostic and Therapeutic reference resources |

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**1.6 CDS Intervention Based on Receipt of Summary**

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|  | Authorized user logs in and interacts with health IT module to receive a transition of care/referral summary and demonstrates CDS interventions are provided based on the following incorporated data:   * Problems; * Medications; and * Medication allergies |

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# Appendix A: Testing Guide

*This appendix contains more details and background on the testing requirements, including explanation on underlying standards, notable issues and best practice suggestions.*

Rev 03-Apr-2017 Additions

* If health IT module is not certifying to (b.3) and plans to use a 3rd party eRx provider to demonstrate compliance to Source Attributes for drug-drug, drug-allergy checks, this is permissible. In this case, the 3rd party eRx provider will not need to be listed as ‘relied upon software’.

Rev 01-Mar-2016 Additions

* A CDS intervention is not simply an alert, notification, or explicit care suggestion. Rather, it should be more broadly interpreted as the user-facing representation of evidence-based clinical guidance.
* The National Library of Medicine hosts a publicly available repository of value sets for use in CDS and clinical quality measures that are available as a resource to developers. Please see: <https://vsac.nlm.nih.gov/>.
* For drug-drug, drug-allergy interaction checks, global citations are permitted in cases where all interventions of a given type are provided by the same reference.
* “Bibliographic citation” is a reference (if available) to a publication of clinical research that documents the clinical value of the intervention. If no such reference exists (e.g., locally developed intervention), the health IT product should indicate so.
* “Developer of the intervention (translation from clinical research/guideline)” is the team, person, organization, department or other entity that interpreted the clinical research and translated it into computable form (sometimes the knowledge Health IT Developer).
* “Funding source of the intervention development technical implementation” is the source of funding for the work performed by the “developer of the intervention.” If this information is unknown, the user should have access to know that it is unknown.

# Appendix B: ONC Criteria and Standards

*This appendix contains copy of the relevant ONC criteria and standards for this proctor sheet as a reference. In the event of a discrepancy with the ONC Final Rule, the ONC Final Rule takes precedence.*

**§170.315(a)(9) Clinical decision support**

1. CDS Intervention Interaction. Interventions provided to a user must occur when a user is interacting with technology.
2. CDS configuration.
   1. Enable interventions and reference resources specified in paragraphs (a)(9)(iii) and (iv) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user’s role.
   2. Enable interventions:
      1. Based on the following data
         * 1. Problem List
           2. Medication List
           3. Medication allergy list
           4. At least one demographic specified in paragraph (a)(5)(i) of this section;
           5. Laboratory tests; and
           6. Vital Signs
      2. When a patient’s medications, medication allergies, and problems are incorporated from a transition of care/referral summary received pursuant to **§170.315(b)(2)(iii)(D).**
3. Evidence-based decision support interventions. Enable a limited set of identified users to select (i.e., activate) electronic CDS interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data:
   * 1. Problem list;
     2. Medication list;
     3. Medication allergy list;
     4. At least one demographic specified in **§170.315(a)(5)(i)** (preferred language, sex, race, ethnicity, and date of birth);
     5. Laboratory tests; and
     6. Vital signs.
4. Linked referential CDS.
   1. Identify for a user diagnostic and therapeutic reference information in accordance at least one of the following standards and implementation specifications:
      1. The standard and implementation specifications specified in **§170.204(b)(3).**
      2. The standard and implementation specifications specified in **§170.204(b)(4).**
   2. For paragraph (a)(9)(ii)(A) of this section, technology must be able to identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the following data referenced in paragraphs (a)(9)(ii)(B)(1)(i), (ii), and (iv) of this section.
5. Source attributes. Enable a user to review the attributes as indicated for all CDS resources:
   1. For evidence-based decision support interventions under paragraph (a)(9)(iii) of this section:
      1. Bibliographic citation of the intervention (clinical research/guideline);
      2. Developer of the intervention (translation from clinical research/guideline);
      3. Funding source of the intervention development technical implementation; and
      4. Release and, if applicable, revision date(s) of the intervention or reference source.
   2. For linked referential CDS in paragraph (a)(9)(iv) of this section and drug-drug, drug-allergy interaction checks in paragraph (a)(4) of this section: the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).

**§170.204(b)(3)** HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. (“Infobutton”), Knowledge Request, Release 2. Implementation specifications. HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1

**§170.204(b)(4)** HL7 Version 3 Standard: Context Aware Retrieval Application (“Infobutton”), Knowledge Request, Release 2. Implementation specifications. HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4.

**§170.315(b)(2) Clinical Information Reconciliation and Incorporation – receive, display, reconcile, and incorporate transition of care/referral summaries.**

1. Reconcile. Upon receipt of a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(3) and § 170.205(a)(4), EHR technology must be able to:
   1. Correct patient. Demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient.
   2. 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:

(i) Electronically and simultaneously display (that is, in a single view) the data from at least two list sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date.

(ii) Enable a user to create a single reconciled list of medications, medication allergies, or problems.

(iii) Enable a user to review and validate the accuracy of a final set of data and, upon a user’s confirmation, automatically update the list.

* 1. 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)(3);
     2. Problems. At a minimum, the version of the standard specified in § 170.207(a)(4);
     3. Medication allergies. At a minimum, the version of the standard specified in §170.207(d)(3).
  2. Create. Enable a user to electronically create a transition of care/referral summary that includes the reconciled and incorporated data formatted according to the standard adopted at § 170.205(a)(4).

**§170.205(a). Content Exchange Standards – Patient Summary Record**

1. Standard: HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation. The use of the “unstructured document” document-level template is prohibited.

**§170.207(a). Vocabulary standards – Problems**

(3) IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release.

**§170.207(d). Vocabulary standards – Medications**

(2) RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release.

# Change Log

|  |  |
| --- | --- |
| Revision | Change Description |
| 03-Apr-2017 | Under Appendix A, clarified that 3rd party eRx provider may be used to supply content for drug-drug, drug-allergy check source attributes. Restructured test procedures to reduce number of users required. Corrected reference resource (“Infobutton”) query to include ‘one combination’ under section 1.2. |
| 01-Dec-2016 | Added fields for CDS interventions tested to be recorded by Proctor. Renumber sections. Updated workflow for unauthorized users to occur after enabling interventions. |
| 01-Oct-2016 | Corrected Info button standard identifiers under “Expected  Test Result” section. |
| 01-Apr-2016 | Added section numbering. Associated “where clinically indicated” with bibliographic citation bullet in section 4.2. |
| 01-Mar-2016 | Initial Release. |
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**About Drummond Group LLC**

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