

2015 Edition §170.315(b)(2) Clinical Information Reconciliation					
Testing Components:					
				Data	
Test Procedure Version 1.1 – Last Updated 10/29/2015					

Please consult the Final Rule entitled: *2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications* for a detailed description of the certification criterion with which these testing steps are associated. We also encourage developers to consult the Certification Companion Guide in tandem with the test procedure as they provide clarifications that may be useful for product development and testing.

*Note: The order in which the test steps are listed reflects the sequence of the certification criterion and does not necessarily prescribe the order in which the test should take place.*

## Required Tests

### (b)(2)(i) General requirements

Paragraphs (b)(2)(ii) and (iii) of this section must be completed based on the receipt of a transition of care/referral summary formatted in accordance with the standards adopted in § 170.205(a)(3) and § 170.205(a)(4) using the Continuity of Care Document, Referral Note, and (for inpatient setting only) Discharge Summary document templates.

### (b)(ii) Correct Patient

Upon receipt of a transition of care/referral summary formatted according to the standards adopted at § 170.205(a)(3) and § 170.205(a)(4), technology must be able to demonstrate that the transition of care/referral summary received can be properly matched to the correct patient.

**Standards:** §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 Use July 2012](#)

§170.205(a)(4) [HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1](#)

**Test Data:** [C-CDA Validator within the Edge Testing Tool](#)

170.315\_b2\_ciri\_r1.1\_sample\*.xml (All Samples)

170.315\_b2\_ciri\_r2.1\_sample\*.xml (All Samples)

**Test Tool:** [C-CDA Validator within the Edge Testing Tool](#)

Criteria ¶	System Under Test	Test Lab Verification
(ii)	<ol style="list-style-type: none"> <li>1. Using the top-level C-CDA Validator, one of the tool selections within the Edge Testing Tool, the user selects the Clinical Information Reconciliation documents (xml) and selects download to download the required Clinical Information Reconciliation documents xml files for both C-CDA Release 1.1 and Release 2.1.</li> <li>2. The user demonstrates that a transition of care summary/referral summary C-CDA document, formatted according to the standard adopted at §170.205(a)(3) and a transition of care summary/referral summary C-CDA document formatted according to the standard adopted at §170.205(a)(4), can be properly matched to a patient in the Health IT Module. Matches can be made automatically or manually.</li> </ol>	<p>The tester verifies that the received C-CDA Release 1.1 and Release 2.1 documents can be properly matched to the correct patient record.</p> <p>Visual inspection of test data (C-CDA Release 1.1 and Release 2.1 documents formatted in both the §170.205(a)(3) and §170.205(a)(4). standards). Each of the following document templates will be visually inspected:</p> <ul style="list-style-type: none"> <li>• Continuity of Care Document (CCD);</li> <li>• Discharge Summary; and</li> <li>• Referral Note.</li> </ul>

### (iii) Reconciliation

Enable a user to reconcile the data that represent a patient's active medication list, medication allergy list, and problem list as follows. For each list type:

- (A) Simultaneously display (i.e., in a single view) the data from at least two 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;
- (B) Enable a user to create a single reconciled list of medications, medication allergies, or problems;
- (C) Enable a user to review and validate the accuracy of a final set of data; and
- (D) Upon a user's confirmation, automatically update the list, and 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) Medication allergies. At a minimum, the version of the standard specified in § 170.207(d)(3); and
  - (3) Problems. At a minimum, the version of the standard specified in § 170.207(a)(4).

**Standards:** §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 Use July 2012](#)

§170.205(a)(4) [HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1](#)

§170.207(d)(3) [RxNorm](#), a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release

§ 170.207(a)(4) [International Health Terminology Standards Development Organisation \(IHTSDO\) Systematized Nomenclature of Medicine Clinical Terms \(SNOMED CT®\)](#), U.S. Edition, September 2015 Release

**Test Data:** [C-CDA Validator within the Edge Testing Tool](#)

170.315\_b2\_ciri\_R1.1\_sample\*.xml (All Samples)

170.315\_b2\_ciri\_R1.1\_sample\*\_recon.xml (All Samples)

170.315\_b2\_ciri\_R2.1\_sample\*.xml (All Samples)

170.315\_b2\_ciri\_R2.1\_sample\*\_recon.xml (All Samples)

**Test Tool:** [C-CDA Validator within the Edge Testing Tool](#)

Criteria ¶	System Under Test	Test Lab Verification
(iii)(A)	<p>1. Using the top-level C-CDA Validator, one of the tool selections within the Edge Testing Tool, the user selects the Clinical Information Reconciliation documents (xml) and selects download to download the required Clinical Information Reconciliation documents xml files for both C-CDA Release 1.1 and Release 2.1.</p> <p>2. The user simultaneously views data (including active medications, medication allergies, and problems) that includes the source and last modification date data from at least two sources:</p> <ul style="list-style-type: none"> <li>• The current patient record AND</li> <li>• Transition of care summary/referral summary C-CDA Release 1.1 and Release 2.1 document, formatted according to the standard adopted at §170.205(a)(3) AND §170.205(a)(4).</li> </ul> <p>Note that Health IT technology will need to separately demonstrate the ability to reconcile summary of care documents formatted according to §170.205(a)(3) and §170.205(a)(4), and they will need to separately demonstrate each of the following document templates: CCD, Discharge Summary, and Referral Note.</p>	<p>The tester verifies that data from multiple sources can be simultaneously displayed in a single view for medications, medication allergies, and problems, including both the source and last modification date. The last modification date is defined for each list as:</p> <ul style="list-style-type: none"> <li>• Last date medication was documented, ordered, prescribed, refilled, dispensed, or edited;</li> <li>• Last date the problem was documented or edited; and</li> <li>• Last date the medication allergy was documented or edited.</li> </ul> <p>Further, the tester must verify that the Health IT Module can display the current patient record and a transition of care summary/referral summary C-CDA Release 1.1 and Release 2.1 document, formatted according to the standard adopted at §170.205(a)(3) and separately the current patient record and a transition of care summary/referral summary C-CDA document, formatted according to the standard adopted at §170.205(a)(4).</p> <p>The tester must also verify that this can be completed for the CCD, Discharge Summary, and Referral Note document templates.</p>

Criteria ¶	System Under Test	Test Lab Verification
(iii)(B)	<p>The user creates a single, reconciled list using the data reviewed from the multiple medications, problems or medication allergies list sources in step one for each of the following:</p> <ul style="list-style-type: none"> <li>• Medications;</li> <li>• Medication allergies; and</li> <li>• Problems.</li> </ul>	<p>The tester verifies that, for each list type, the lists can be merged, duplicates can be consolidated into a single representation, list items can be removed, and any other methods the Health IT Module may use to reconcile the list.</p>
(iii)(C)	<p>The user reviews the details of the reconciled list and validates its accuracy.</p>	<p>The tester verifies that, for each list type, a reconciled list including:</p> <ul style="list-style-type: none"> <li>• the use of medication vocabularies, where applicable, according to the standard adopted at §170.207(d)(3); and</li> <li>• The use of problem vocabularies, where applicable, according to the standard adopted at §170.207(a)(4).</li> </ul>
(iii)(D)	<p>The user accepts the reconciled list and the patient record in the Health IT module is updated.</p>	<p>The tester verifies that reconciled medications, medication allergies, and problems data are accurately incorporated into the patient record expressed in the following:</p> <ul style="list-style-type: none"> <li>• medications are expressed according to the standard specified in §170.207(d)(3);</li> <li>• medication allergies are expressed according to the standard specified in §170.207(d)(3); and</li> <li>• problems are expressed according to the standard specified in §170.207(a)(4).</li> </ul>

#### (iv) System Verification

Based on the data reconciled and incorporated, the technology must be able to create a file formatted according to the standard adopted at § 170.205(a)(4) using the Continuity of Care Document template.

Standard(s): §170.205(a)(4) [HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1](#)

Test Tool: [C-CDA Validator within the Edge Testing Tool](#)

Criteria ¶	System Under Test	Test Lab Verification
(iv)	<p>A user creates a CCD that includes the reconciled and incorporated data, in accordance with the standard adopted at §170.205(a)(4), for each of the following:</p> <ul style="list-style-type: none"> <li>• medications</li> <li>• medication allergies</li> <li>• problems</li> </ul>	<ol style="list-style-type: none"> <li>1. Validation of a CCD document is done using the top-level C-CDA Validator, one of the tool selections within the Edge Testing Tool. To validate the Clinical Information Reconciliation CCD (xml file) created by the Health IT module, the tester uses the C-CDA Validator Tool within the Edge Testing Tool to select the criteria to be verified, in this case the Clinical Information Reconciliation CCD document(s).</li> <li>2. For each test case, the tester uploads the corresponding Clinical Information Reconciliation CCD xml file, created by the Health IT module, into the C-CDA Validator for validation and uses the Validation Report produced by the test tool to verify the Health IT module passes without error to confirm that the Clinical Information Reconciliation CCD document is conformant when it is created after a reconciliation of medications, medication allergies and/or problems reconciliation has been performed, and meet the standard specified in § 170.207(a)(4). This verification is only for C-CDA Release 2.1 CCD documents.</li> </ol>

### Document History

Version Number	Description of Change	Date
1.0	Released for Comment - NPRM	March 20, 2015
1.1	Released for Comment- FR	October 29, 2015

Dependencies: For all related and required criteria, please refer to the [Master Table of Related and Required Criteria](#).