# Test Criteria: 170.315.b.2 Clinical Information Reconciliation

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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)
* [Standards Support](#_Demonstrate_Standards_Support)
* [Drummond Test Report (Instructions, Expected Results, Points to Remember)](#_170.315(b)(2)_Clinical_Information)
* [Test Procedures](#_Test_Procedures)
* [Appendix A: Testing Guide](#_Appendix_A:_Testing)
* [Appendix B: ONC Criteria](#_Appendix_B:_ONC)

### Version of ONC Test Method

1.1

### 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 under Test 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 pre-loads only the “**sample\*.xml**” files specified here from the ETT [C-CDA R2.1 Validator](https://ttpedge.sitenv.org/ttp/#/validators). Files within the ETT containing filename “recon” should not be pre-loaded.  Ambulatory files to pre-load:   * 170.315\_b2\_ciri\_r11\_sample1\*.xml * 170.315\_b2\_ciri\_r21\_sample1\_ccd\*.xml * 170.315\_b2\_ciri\_r21\_sample1\_rn\*.xml   Inpatient files to pre-load:   * + 170.315\_b2\_ciri\_r11\_sample1\*.xml   + 170.315\_b2\_ciri\_r21\_sample1\_ccd\*.xml   + 170.315.\_b2\_ciri\_r21\_sample1\_ds\*.xml   + 170.315\_b2\_ciri\_r21\_sample1\_rn\*.xml | |
| **Test Data:**   * Test Data is downloaded for the applicable setting from the ETT [C-CDA R2.1 Validator](https://ttpedge.sitenv.org/ttp/#/validators) using the “Receiver SUT Test Data” selection. The “\***recon\*.xml**” files will be loaded during test event:   + 170.315\_b2\_ciri\_r11\_\*recon\*.xml (All Samples)   + 170.315\_b2\_ciri\_r21\_\*recon\*.xml (All Samples) * For expected results, see the DG-supplied “170.315.b.2\_Clinical\_Information\_Reconciliation\_TestData” sheet. | |
| **Test Tools:**  Edge Test Tool – Message Validators: [C-CDA R2.1 Validator](https://ttpedge.sitenv.org/ttp/#/validators) | |

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# Demonstrate Standards Support

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| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **Instructions:** Implement support for RxNorm and SNOMED for medications and problems. RxNorm only needs to be displayed for allergies after the two lists have been reconciled. | |

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| **§170.205 Content Exchange Standards – Patient Summary Record** | | |
|  | §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 (US Realm), Draft Standard for Trial Use, Volume 1—Introductory Material, Release 2.1 and HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 2—Templates and Supporting Material, Release 2.1 (incorporated by reference in § 170.299). |
| **§170.207 Vocabulary standards for representing electronic health information** | | |
|  | §170.207(a)(3) | International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) International Release July 31, 2012 and US Extension to SNOMED CT® March 2012 |
|  | §170.207(a)(4) | IHTSDO SNOMED CT®, U.S. Edition, September 2015 Release. |
|  | §170.207(d)(2) | RxNorm, August 6, 2012 Full Release Update |
|  | §170.207(d)(3) | RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release. |

# 170.315(b)(2) Clinical Information Reconciliation

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| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **Instructions:** User matches to correct patient in health IT module and reconciles clinical information based upon the receipt of:   * **C-CDA 1.1**; * **C-CDA 2.1**; * **Referral Note 2.1**; and * *Inpatient setting only:* **Discharge Summary** **2.1** | |
| **Expected Test Result:**   * 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. * 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: * 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; * Enable a user to create a single reconciled list of medications, medication allergies, or problems; * 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, 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).  * Based on the data reconciled and incorporated, the health IT module 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. | |
| **Points to Remember:**   * The user must be able to confirm the reconciled list prior to saving it to the patient record’s active medications list. * Patient matching can be made automatically or manually. | |

### Test Procedures

**1.1 Clinical Information Reconciliation**

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|  | User imports the CCD R1.1 “*170.315\_b2\_ciri\_r11\_****sample\*****.xml*” file for the applicable setting. This will serve as the “base input”. |
|  | User imports corresponding “*170.315\_b2\_ciri\_r11\_sample1\_****recon\*.****xml*” reconciliation file and matches to correct patient. |
|  | User simultaneously views the specified elements side-by-side along with the source and last modification date from at least two sources (*i.e.,* *existing patient chart data compared to incoming C-CDA data*):   * Medications; * Medication Allergies; and * Problems |
|  | User reconciles data into a single, reconciled list for medications, allergies, and problems demonstrating that items can be merged, duplicates can be consolidated, and removed. |
|  | User reviews and is able to validate the accuracy of the list before confirming. Once confirmed, user accepts the reconciled list and health IT module updates the patient record. |
|  | Health IT module accurately incorporates reconciled medications, medication allergies, and problems into the patient record and expressed in the following (*for expected results,* *see the DG-supplied “170.315.b.2\_Clinical\_Information\_Reconciliation\_TestData” sheet):*   * Medications expressed in §170.207(d)(3) RxNorm codes * Problems expressed in §170.207(a)(4) SNOMED CT codes * Medication allergies expressed in §170.207(d)(3) RxNorm codes |
|  | User generates a CCD 2.1 document that includes the incorporated medications, medication allergies, and problems. |
|  | Proctor validates the C-CDA document using the Edge Test Tool [C-CDA R2.1 Validator](https://ttpedge.sitenv.org/ttp/#/validators) and visually inspects sections required for manual verification. All files should pass without error to confirm CCDS summary record(s) is compliant. |
|  | User will demonstrate same actions above for all test data samples for each additional type:   * **C-CDA 2.1**; * **Referral Note 2.1**; and * **Discharge Summary** **2.1** *(inpatient setting only)* |

<INSERT SCREEN SHOTS – Reconciliation – CCD R1.1 Sample 1>

<INSERT SCREEN SHOTS – Reconciled Data Incorporated CCD R1.1 Sample 1>

<INSERT SCREEN SHOTS – CCD R2.1 generated based on CCD R1.1 Sample 1>

<INSERT SCREEN SHOTS – ETT Validation Report>

<INSERT SCREEN SHOTS – Reconciliation – CCD R2.1 Sample 1>

<INSERT SCREEN SHOTS – Reconciled Data Incorporated CCD R2.1 Sample 1>

<INSERT SCREEN SHOTS –CCD R2.1 generated based on CCD R2.1 Sample 1>

<INSERT SCREEN SHOTS – ETT Validation Report>

<INSERT SCREEN SHOTS – Reconciliation – RN R2.1 Sample 1>

<INSERT SCREEN SHOTS – Reconciled Data Incorporated – RN R2.1 Sample 1>

<INSERT SCREEN SHOTS – CCD R2.1 generated based on RN R2.1 Sample 1>

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*INPATIENT ONLY:*

<INSERT SCREEN SHOTS – Reconciliation – DischargeSummary R2.1 Sample 1>

<INSERT SCREEN SHOTS – Reconciled Data Incorporated – DS R2.1 Sample 1>

<INSERT SCREEN SHOTS – CCD R2.1 generated based on DS R2.1 Sample 1>

<INSERT SCREEN SHOTS – ETT Validation Report>

# 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 01-Mar-2016 Additions

* The scope of this criterion is limited to the Consolidated CDA (C-CDA) Continuity of Care Document (CCD), Referral Note, and (inpatient setting only) Discharge Summary document templates.
* “Incorporation” means to electronically process structured information from another source such that it is combined (in structured form) with information maintained by health IT and is subsequently available for use within the health IT system by a user.
* Health IT module must enable a user to electronically and simultaneously display (that is in a single view) the data from at least two list sources. If the two lists cannot be displayed in the tool at the same time this does not constitute a single view and does not meet the requirements for the certification criterion.
* The health IT can enable a user to review, validate, and incorporate medications, medication allergies, and problems in distinct functions, or combined, as long as all three can be demonstrated.
* Testing will evaluate health IT ability to incorporate data from C-CDA documents with variations in the data elements to be reconciled to test real-world variation that may be found in C-CDA documents.

# 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(b)(2) *Clinical information reconciliation and incorporation*—**(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 (inpatient setting only) Discharge Summary document templates.

(ii) *Correct patient.* Upon receipt of a transition of care/referral summary formatted according to the standards adopted § 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.

(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 each of the following: Medications; medication allergies; and problems.

(C) Enable a user to review and validate the accuracy of a final set of data.

(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).

(iv) *System verification.* Based on the data reconciled and incorporated, the technology must be able to create a file formatted according to the standard specified in § 170.205(a)(4) using the Continuity of Care Document document template.

**§170.205 Content Exchange Standards – Patient Summary Record.**

**(a)(3) *Standard.*** HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012.

**(a)(4) *Standard.*** HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 1—Introductory Material, Release 2.1 and HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 2—Templates and Supporting Material, Release 2.1 (incorporated by reference in § 170.299).

**§170.207 Vocabulary standards for representing electronic health information.**

**(a)(4) *Standard*.** IHTSDO SNOMED CT®, U.S. Edition, September 2015 Release.

**(d)(3) *Standard.*** RxNorm, September 8, 2015 Release.

# Change Log

|  |  |
| --- | --- |
| Revision | Change Description |
| 01-Mar-2017 | Updated test data references to align with NIST ETT’s test data updates. |
| 01-Oct-2016 | Updated hyperlinks for ONC-hosted ETT. Corrected patient matching test procedure under section 1.1. |
| 01-Jun-2016 | Updated test data filenames to align with ONC updates. Added reference to the DG-supplied “170.315\_b.2\_Clinical\_Information\_Reconciliation\_TestData” sheet. |
| 01-Mar-2016 | Initial Release. |
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**About Drummond Group LLC**

Drummond Group LLC is a global software test and certification lab that serves a wide range of vertical industries.  In healthcare, Drummond Group tests and certifies Controlled Substance Ordering Systems (CSOS), Electronic Prescription of Controlled Substances (EPCS) software and processes, and Electronic Health Records (EHRs) – designating the trusted test lab as the only third-party certifier of all three initiatives designed to move the industry toward a digital future. Founded in 1999, and accredited for the Office of the National Coordinator Health IT Certification Program as an Authorized Certification Body (ACB) and an Authorized Test Lab (ATL), Drummond Group continues to build upon its deep experience and expertise necessary to deliver reliable and cost-effective services. For more information, please visit <http://www.drummondgroup.com> or email [ehr@drummondgroup.com](mailto:ehr@drummondgroup.com)

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