Official Website of The Office of the National Coordinator for Health Information Technology (ONC)

HealthIT.gov

§170.315(b)(2) Clinical information reconciliation and incorporation

2015 Edition Test Procedure

Updated on 09-29-2017

Revision History

Version #	Description of Change	Version Date
1.0	Final Test Procedure	01-20-2016
1.1	Updated paragraph (b)(2)(iii)(A) under TLV to remove ordered, prescribed, refilled, dispensed from last medication bullet.	08-01-2016
1.2	Addition of statement – reconciliation process must be completed in a simultaneous view.	07-07-2017
1.3	Clarified paragraph (b)(2)(iii)(B) TLV requirements for displaying and reconciling a list for each list type.	09-29-2017

Regulation Text

Regulation Text

§ 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.

Standard(s) Referenced

Paragraphs (b)(2)(i) and (ii)

§ 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 Release 2.1, August 2015

Paragraphs (b)(2)(iii)(B) – (D)

§ 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

§ 170.207(d)(3) RxNorm, September 8, 2015 Full Release Update

Paragraph (b)(2)(iv)

§ 170.205(a)(4) HL7® Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1, August 2015

Additional Resources

§ 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(d)(2) RxNorm, August 6, 2012 Full Release Update

Resource Documents

Resource Document

- Privacy and Security Certification Companion Guide [PDF - 281 KB]
- 2015 Edition Network Time Protocol (NTP) [PDF - 157 KB]
- CHPL SED Guide [PDF - 690 KB]
- Master Table of Related and Required Criteria [PDF-251 KB]

Revision History

Version #	Description of Change	Version Date

1.0	Final Test Procedure	01-20-2016
1.1	Updated paragraph (b)(2)(iii)(A) under TLV to remove ordered, prescribed, refilled, dispensed from last medication bullet.	08-01-2016
1.2	Addition of statement – reconciliation process must be completed in a simultaneous view.	07-07-2017
1.3	Clarified paragraph (b)(2)(iii)(B) TLV requirements for displaying and reconciling a list for each list type.	09-29-2017

Regulation Text

Regulation Text

§ 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.

Standard(s) Referenced

Paragraphs (b)(2)(i) and (ii)

§ 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 Release 2.1, August 2015

Paragraphs (b)(2)(iii)(B) – (D)

§ 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

§ 170.207(d)(3) RxNorm, September 8, 2015 Full Release Update

Paragraph (b)(2)(iv)

§ 170.205(a)(4) HL7® Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1, August 2015

Additional Resources

§ 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(d)(2) RxNorm, August 6, 2012 Full Release Update

Testing

Testing Tool

Edge Testing Tool (ETT): Message Validators

Test Tool Documentation

Test Tool Supplemental Guide

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.

Testing components

Paragraph (b)(2)(ii)

System Under Test

Setup

1. Using the ETT: Message Validators – C-CDA R2.1 Validator, the user selects the receiver “170.315_b2_CIRI_Amb ” or “170.315_b2_CIRI_Inp” criteria, selects one of the C-CDA R2 Release 2.1 xml files, and executes the download of the required Clinical Information Reconciliation document 170.315_b2_ciri_r21_sample*.xml file for C-CDA R2 Release 2.1.
2. The user repeats step 1, but selects the corresponding CDA R2 Release 1.1 xml file from the File Name and executes the download of the required Clinical Information Reconciliation document 170.315_b2_ciri_r11_sample*.xml file for C-CDA R2 Release 1.1.

Correct Patient

3. Using the xml files downloaded in steps 1 and 2, the user demonstrates that a transition of care summary/referral summary Consolidated-Clinical Document Architecture (C-CDA) document, formatted according to the standard adopted at § 170.205(a)(3) HL7® Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1, and a transition of care summary/referral summary C-CDA document, formatted according to the standard adopted at § 170.205(a)(4) HL7® Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1, can be properly matched to a patient in the Health IT Module. Note that matches can be made automatically or manually.
4. The user repeats steps 1-3 for each set of C-CDA R2 Release 1.1 and C-CDA R2 Release 2.1 xml files listed in the File Name for each of the health IT settings being certified.

Test Lab Verification

Setup

1. The tester creates a human readable version of the downloaded C-CDA R2 Release 2.1 and C-CDA R2 Release 1.1 files from step 1 of the SUT to be used for verification.

Correct Patient

2. The tester uses visual inspection to verify the Health IT Module can receive the C-CDA document downloaded in step 1 of the SUT as a C-CDA Release 1.1 document formatted according to the standard specified in § 170.205(a)(3) as either a CCD or a C-CDA with no specific document template.
3. The tester uses visual inspection to verify the Health IT Module can receive the C-CDA document downloaded in step 2 of the SUT as a C-CDA Release 2.1 documents formatted according to the standard specified in § 170.205(a)(4) using one of the following document templates:
   - Continuity of Care Document (CCD);
   - Referral Note; and
   - *Inpatient setting only*: Discharge Summary.
4. Using the Health IT Module and the human readable xml files from step 1, 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.

Paragraph (b)(2)(i)

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) HL7® Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 and § 170.205(a)(4) HL7® Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1 using the Continuity of Care Document (CCD), Referral Note, and (*inpatient setting only*) Discharge Summary document templates.

Paragraph (b)(2)(iii)(A)

System Under Test

Simultaneous Display

1. Using the ETT: Message Validators – C-CDA R2.1 Validator, the user downloads the Clinical Information Reconciliation documents (xml) by selecting the receiver "170.315_b2_CIRI_Amb" or "170.315_b2_CIRI_Inp" criteria and the required Clinical Information Reconciliation documents xml files for both C-CDA Release 1.1 and Release 2.1 and executes the download.
2. The user simultaneously views data (including active medications, medication allergies, and problems) along with the source and last modification date attributes from at least two sources:
   - The current patient record which includes the base input received in section (b)(2)(ii); and
   - The 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) HL7® Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 AND § 170.205(a)(4) HL7® Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1 which includes the reconciliation data 170.315_b2_ciri_r11_ sample*_recon*.xml or 170.315_b2_ciri_r21_ sample*_recon*.xml.

Note that Health IT Module will need to separately demonstrate the ability to reconcile summary of care documents formatted according to § 170.205(a)(3) HL7® Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 and § 170.205(a)(4) HL7® Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1, and they will need to separately demonstrate each of the following document templates: CCD or C-CDA with no specific document template for C-CDA Release 1.1; and CCD, Referral Note, and (*inpatient setting only*) Discharge Summary document templates for C-CDA Release 2.1 for the health IT setting(s) being certified.

Test Lab Verification

Simultaneous Display

1. 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:
   - Last date medication was documented, or edited;
   - Last date the problem was documented or edited; and
   - Last date the medication allergy was documented or edited.

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).

The tester must verify that this can be completed for the CCD or C-CDA with no specific document template for C-CDA Release 1.1; and CCD, Referral Note, and (*inpatient setting only*) Discharge Summary document templates for C-CDA Release 2.1.

Paragraph (b)(2)(iii)(B)

System Under Test

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:

- Medications;
- Medication allergies; and
- Problems.

Test Lab Verification

The tester verifies that, for each list type: a simultaneous display (i.e. a single view), 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. The entire reconciliation process must occur within a simultaneous view.

Paragraph (b)(2)(iii)(C)

System Under Test

The user reviews the details of the reconciled list and validates its accuracy.

Test Lab Verification

The tester verifies that, for each list type, a user is able to review and verify the accuracy of the final list.

Paragraph (b)(2)(iii)(D)

System Under Test

The user accepts the reconciled list and the patient record in the Health IT Module is updated.

Test Lab Verification

The tester verifies that reconciled medications, medication allergies, and problems data are accurately incorporated into the patient record and expressed in the following:

- Medications are expressed according to the standard specified in § 170.207(d)(3) RxNorm;
- Medication allergies are expressed according to the standard specified in § 170.207(d)(3); and
- Problems are expressed according to the standard specified in § 170.207(a)(4) SNOMED CT®.

Paragraph (b)(2)(iv)

System Under Test

1. For each reconciliation in (b)(2)(iii), a user creates a CCD that includes the reconciled and incorporated data, in accordance with the standard adopted at § 170.205(a)(4) HL7® Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1, for each of the following:
    - Medications;
    - Medication allergies; and
    - Problems.

Test Lab Verification

1. Using the reconciled CCD document submitted by the SUT, the tester uses the ETT: Message Validators –C-CDA R2.1 Validator to upload the submitted CCD by selecting the sender “170.315_b2_CIRI_Amb” or “170.315_b2_CIRI_Inp” criteria, and the file name corresponding to the reconciliation input samples. The tester executes the upload.
2. The tester uses the ETT: Message Validators Validation Report created as a result of the upload in step 1 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 has been performed. Furthermore, the tester verifies that it meets the standard specified in § 170.205(a)(4). This verification is only for C-CDA Release 2.1 CCD documents.

Content last reviewed on February 17, 2023