Clinical information reconciliation and incorporation

- Certification Companion Guide (CCG)
- Test Procedure

Updated on 03-21-2025

Regulation Text

Regulation Text

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

1. *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) through (5) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates, for time period up to and including December 31, 2025; or in accordance with the standards adopted in § 170.205(a)(3), (4), (6).
2. *Correct patient.* Upon receipt of a transition of care/referral summary formatted according to the standards adopted § 170.205(a)(3) through (5), for the time period up to and including December 31, 2025; or according to the standards adopted § 170.205(a)(3), (4), and (6), technology must be able to demonstrate that the transition of care/referral summary received can be properly matched to the correct patient.
3. *Reconciliation.* Enable a user to reconcile the data that represent a patient's active medication list, allergies and intolerance list, and problem list as follows. For each list type:
    1. 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.
    2. Enable a user to create a single reconciled list of each of the following: Medications; Allergies and Intolerances; and problems.
    3. Enable a user to review and validate the accuracy of a final set of data.
    4. Upon a user's confirmation, automatically update the list, and incorporate the following data expressed according to the specified standards:
        1. *Medications.* At a minimum, the version of the standard specified in § 170.213;
        2. *Allergies and intolerance.* At a minimum, the version of the standard specified in § 170.213; and
        3. *Problems.* At a minimum, the version of the standard specified in § 170.213.

4. *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 template and the standard specified in paragraph (a)(5) of this section for the time period up to and including December 31, 2025; or according to the standard specified in § 170.205(a)(4) using the Continuity of Care Document template and the standard specified in paragraph (a)(6) of this section.

Standard(s) Referenced

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

§ 170.213(a) United States Core Data for Interoperability (USCDI), July 2020 Errata, Version 1 (v1) (The adoption of this standard expires on January 1, 2026)

§ 170.213(b) United States Core Data for Interoperability (USCDI), October 2022 Errata, Version 3 (v3) (This standard is required by December 31, 2025)

§ 170.205(a)(3) Health Level 7 (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, June 2019 (with Errata)

§ 170.205(a)(5) HL7® CDA R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5) (the adoption of this standard expires on January 1, 2026)

§ 170.205(a)(6) HL7® CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1 - US Realm, June 2023 (required by December 31, 2025)

Paragraphs (b)(2)(iii)(B) – (D)

§ 170.213(a) United States Core Data for Interoperability (USCDI), July 2020 Errata, Version 1 (v1) (The adoption of this standard expires on January 1, 2026)

§ 170.213(b) United States Core Data for Interoperability (USCDI), October 2022 Errata, Version 3 (v3) (This standard is required by December 31, 2025)

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, June 2019 (with Errata)

§ 170.205(a)(5) HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5) (The adoption of this standard expires on January 1, 2026)

§ 170.205(a)(6) HL7® CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1 - US Realm, June 2023 (This standard is required by December 31, 2025)

Standards Version Advancement Process (SVAP) Version(s) Approved

United States Core Data for Interoperability (USCDI), Version 4, October 2023 Errata

HL7® CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes Edition 3.0 - US Realm, May 2024

For more information, please visit the Standards Version Advancement Process (SVAP) Version(s) page.

Required Update Deadlines

The following outlines deadlines for required updates for this criterion as they relate to changes published in recent ONC final rules. Developers must update their products to the requirements outlined and provide them to their customers by the stated deadlines. These represent one-time deadlines as set by recent regulatory updates and do not encompass ongoing deadlines related to the Conditions and Maintenance of Certification. Please review those requirements for additional compliance activities related to one's certification under Certification Dependencies.

Deadline: December 31, 2025

Action to be taken: Developers certified to this criterion must update their versions of USCDI and C-CDA Companion Guide as outlined in paragraphs (b)(2)(i) and (ii), (b)(2)(iii)(B) – (D), and (b)(2)(iv).

Certification Dependencies

Conditions and Maintenance of Certification

Real World Testing: Products certified to this criterion must complete requirements outlined for the Real World Testing Conditions and Maintenance of Certification.

Design and Performance: The following design and performance certification criteria (adopted in § 170.315(g)) must also be certified in order for the product to be certified.

- Safety-enhanced design (§ 170.315(g)(3)) must be explicitly demonstrated for this criterion.
- Quality management system (§ 170.315(g)(4)): When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, when different QMS are used, each QMS needs to be separately identified for every capability to which it was applied.
- Accessibility-centered design (§ 170.315(g)(5)): When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied; or, alternatively, the developer must state that no accessibility-centered design was used.
- Consolidated CDA creation performance (§ 170.315(g)(6)): Consolidated Clinical Document Architecture (C-CDA) creation performance (§ 170.315(g)(6)) does not need to be explicitly tested with this criterion unless it is the only criterion within the scope of the requested certification that includes C-CDA creation capabilities. Note that the application of § 170.315(g)(6) depends on the C-CDA templates explicitly required by the C-CDA-referenced criterion or criteria included within the scope of the certificate sought. Please refer to the C-CDA creation performance CCG for more details.

Privacy & Security Requirements

This certification criterion was adopted at § 170.315(b)(2). As a result, an ONC Authorized Certification Body (ONC-ACB) must ensure that a product presented for certification to a § 170.315(b) criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (b) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be tested once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, exceptions exist for § 170.315(e)(1) “View, download, and transmit to 3rd party (VDT)” and (e)(2) “Secure messaging”, which are explicitly stated.

For more information on the approaches to meet these Privacy and Security requirements, please review the Privacy and Security CCG.

If choosing Approach 2:

For each applicable privacy and security certification criterion not certified for Approach 1, the health IT developer may certify using system documentation which is sufficiently detailed to enable integration such that the Health IT Module has implemented service interfaces that enable the Health IT Module to access external services necessary to meet the requirements of the privacy and security certification criterion. Please see the ONC Cures Act Final Rule at 85 FR 25710 for additional clarification.

Revision History

Version #	Description of Change	Version Date
1.0	Initial publication	03-11-2024
1.1	Updated test tool link	12-02-2024
1.2	Updated test steps with 2024 SVAP approved standards and new SITE UI language	03-21-2025

Regulation Text

Regulation Text

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

1. *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) through (5) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates, for time period up to and including December 31, 2025; or in accordance with the standards adopted in § 170.205(a)(3), (4), (6).
2. *Correct patient.* Upon receipt of a transition of care/referral summary formatted according to the standards adopted § 170.205(a)(3) through (5), for the time period up to and including December 31, 2025; or according to the standards adopted § 170.205(a)(3), (4), and (6), technology must be able to demonstrate that the transition of care/referral summary received can be properly matched to the correct patient.

3. *Reconciliation.* Enable a user to reconcile the data that represent a patient's active medication list, allergies and intolerance list, and problem list as follows. For each list type:
    1. 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.
    2. Enable a user to create a single reconciled list of each of the following: Medications; Allergies and Intolerances; and problems.
    3. Enable a user to review and validate the accuracy of a final set of data.
    4. Upon a user's confirmation, automatically update the list, and incorporate the following data expressed according to the specified standards:
        1. *Medications.* At a minimum, the version of the standard specified in § 170.213;
        2. *Allergies and intolerance.* At a minimum, the version of the standard specified in § 170.213; and
        3. *Problems.* At a minimum, the version of the standard specified in § 170.213.
4. *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 template and the standard specified in paragraph (a)(5) of this section for the time period up to and including December 31, 2025; or according to the standard specified in § 170.205(a)(4) using the Continuity of Care Document template and the standard specified in paragraph (a)(6) of this section.

Standard(s) Referenced

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

§ 170.213(a) United States Core Data for Interoperability (USCDI), July 2020 Errata, Version 1 (v1) (The adoption of this standard expires on January 1, 2026)

§ 170.213(b) United States Core Data for Interoperability (USCDI), October 2022 Errata, Version 3 (v3) (This standard is required by December 31, 2025)

§ 170.205(a)(3) Health Level 7 (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, June 2019 (with Errata)

§ 170.205(a)(5) HL7® CDA R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5) (the adoption of this standard expires on January 1, 2026)

§ 170.205(a)(6) HL7® CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1 - US Realm, June 2023 (required by December 31, 2025)

Paragraphs (b)(2)(iii)(B) – (D)

§ 170.213(a) United States Core Data for Interoperability (USCDI), July 2020 Errata, Version 1 (v1) (The adoption of this standard expires on January 1, 2026)

§ 170.213(b) United States Core Data for Interoperability (USCDI), October 2022 Errata, Version 3 (v3) (This standard is required by December 31, 2025)

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, June 2019 (with Errata)

§ 170.205(a)(5) HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5) (The adoption of this standard expires on January 1, 2026)

§ 170.205(a)(6) HL7® CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1 - US Realm, June 2023 (This standard is required by December 31, 2025)

Standards Version Advancement Process (SVAP) Version(s) Approved

United States Core Data for Interoperability (USCDI), Version 4, October 2023 Errata

HL7® CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes Edition 3.0 - US Realm, May 2024

For more information, please visit the Standards Version Advancement Process (SVAP) Version(s) page.

Required Update Deadlines

The following outlines deadlines for required updates for this criterion as they relate to changes published in recent ONC final rules. Developers must update their products to the requirements outlined and provide them to their customers by the stated deadlines. These represent one-time deadlines as set by recent regulatory updates and do not encompass

ongoing deadlines related to the Conditions and Maintenance of Certification. Please review those requirements for additional compliance activities related to one's certification under Certification Dependencies.

Deadline: December 31, 2025

Action to be taken: Developers certified to this criterion must update their versions of USCDI and C-CDA Companion Guide as outlined in paragraphs (b)(2)(i) and (ii), (b)(2)(iii)(B) – (D), and (b)(2)(iv).

Certification Dependencies
Conditions and Maintenance of Certification

Real World Testing: Products certified to this criterion must complete requirements outlined for the Real World Testing Conditions and Maintenance of Certification.

Design and Performance: The following design and performance certification criteria (adopted in § 170.315(g)) must also be certified in order for the product to be certified.

- Safety-enhanced design (§ 170.315(g)(3)) must be explicitly demonstrated for this criterion.
- Quality management system (§ 170.315(g)(4)): When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, when different QMS are used, each QMS needs to be separately identified for every capability to which it was applied.
- Accessibility-centered design (§ 170.315(g)(5)): When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied; or, alternatively, the developer must state that no accessibility-centered design was used.
- Consolidated CDA creation performance (§ 170.315(g)(6)): Consolidated Clinical Document Architecture (C-CDA) creation performance (§ 170.315(g)(6)) does not need to be explicitly tested with this criterion unless it is the only criterion within the scope of the requested certification that includes C-CDA creation capabilities. Note that the application of § 170.315(g)(6) depends on the C-CDA templates explicitly required by the C-CDA-referenced criterion or criteria included within the scope of the certificate sought. Please refer to the C-CDA creation performance CCG for more details.

Privacy & Security Requirements
This certification criterion was adopted at § 170.315(b)(2). As a result, an ONC Authorized Certification Body (ONC-ACB) must ensure that a product presented for certification to a § 170.315(b) criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (b) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be tested once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, exceptions exist for § 170.315(e)(1) “View, download, and transmit to 3rd party (VDT)” and (e)(2) “Secure messaging”, which are explicitly stated.

For more information on the approaches to meet these Privacy and Security requirements, please review the Privacy and Security CCG.

- If choosing Approach 1:
  - Authentication, access control, and authorization (§ 170.315(d)(1))
  - Auditable events and tamper-resistance (§ 170.315(d)(2))
  - Audit reports (§ 170.315(d)(3))
  - Automatic access time-out (§ 170.315(d)(5))
  - Emergency access (§ 170.315(d)(6))
  - End-user device encryption (§ 170.315(d)(7))
  - Integrity (§ 170.315(d)(8))
  - Encrypt authentication credentials (§ 170.315(d)(12))
  - Multi-factor authentication (MFA) (§ 170.315(d)(13))
- If choosing Approach 2:

  For each applicable privacy and security certification criterion not certified for Approach 1, the health IT developer may certify using system documentation which is sufficiently detailed to enable integration such that the Health IT Module has implemented service interfaces that enable the Health IT Module to access external services necessary to meet the requirements of the privacy and security certification criterion. Please see the ONC Cures Act Final Rule at 85 FR 25710 for additional clarification.

Testing
Testing Tool

Standards Implementation & Testing Environment (SITE): C-CDA Validators

Test Tool Documentation

Test Tool Supplemental Guide

Criterion Subparagraph	Test Data

Criterion Subparagraph	Test Data
(b)(2)(ii)	170.315_b2_ciri_r11_sample*.xml (All Samples) 170.315_b2_ciri_r21_sample*.xml (All Samples)
(b)(2)(iii)	170.315_b2_ciri_r11_sample*.xml (All Samples) 170.315_b2_ciri_r11_ sample*_recon*.xml (All Samples) 170.315_b2_ciri_r21_sample*.xml (All Samples) 170.315_b2_ciri_r21_sample*_recon*.xml (All Samples)

Revision History

Version #	Description of Change	Version Date
1.0	Initial publication	03-11-2024
1.1	Updated test tool link	12-02-2024
1.2	Updated test steps with 2024 SVAP approved standards and new SITE UI language	03-21-2025

This Test Procedure illustrates the test steps required to certify a Health IT Module to this criterion. Please consult the most recent Final Rules on the Certification Regulations page for a detailed description of the certification criterion with which these testing steps are associated. ASTP/ONC also encourages developers to consult the Certification Companion Guide in tandem with the test procedure as it provides clarifications that may be useful for product development and testing.

Note: The tests step order does not necessarily prescribe the order in which the tests should take place.

Testing components

ONC Supplied Test Data

Paragraph (b)(2) – (Conditional – For Modules with Existing Certification to (b)(2))

System Under Test

Required by December 31, 2025
A Health IT Module currently certified to the § 170.315(b)(2) Clinical information reconciliation and incorporation will attest directly to the ONC-ACB to conformance with the updated § 170.315(b)(2) requirements outlined in the *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1)* Final Rule.

Test Lab Verification

Required by December 31, 2025
The ONC-ACB verifies the Health IT Module certified to § 170.315(b)(2) Clinical information reconciliation and incorporation attests conformance to § 170.315(b)(2) criterion update requirements.

System Under Test	ONC-ACB Verification
Required by December 31, 2025 A Health IT Module currently certified to the § 170.315(b)(2) Clinical information reconciliation and incorporation will attest directly to the ONC-ACB to conformance with the updated § 170.315(b)(2) requirements outlined in the *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1)* Final Rule.	**Required by December 31, 2025** The ONC-ACB verifies the Health IT Module certified to § 170.315(b)(2) Clinical information reconciliation and incorporation attests conformance to § 170.315(b)(2) criterion update requirements.

Paragraph (b)(2)(ii) Correct patient

System Under Test

Expires on January 1, 2026
Setup

1. Using the ASTP Standards Implementation & Testing Environment (SITE): C-CDA Validator – USCDI v1 the user selects the receiver “170.315_b2_CIRI_Amb ” or “170.315_b2_CIRI_Inp” criteria, selects one of the C-CDA 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 R 2.1.
2. The user repeats step 1, but selects the corresponding CDA R1.1, 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 R1.1, or

Correct Patient

3. Using the xml files downloaded in step 1, 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, can be properly matched to a patient in the Health IT Module. Note that matches can be made automatically or manually.

4. Using the xml files downloaded in step 2, the user demonstrates that a transition of care summary/referral summary C-CDA document can be properly matched to a patient in the Health IT Module automatically or manually formatted according to the standards adopted at:
    - § 170.205(a)(4), HL7® Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1, and
    - § 170.205(a)(5), HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2 Companion Guide, Release 2
5. The user repeats steps 1-4, for each set of C-CDA R1.1, and C-CDA R2.1 xml files listed in the File Name for each of the health IT settings being certified.

Required by December 31, 2025
Setup

1. Using SITE: C-CDA Validator – USCDI v3 the user selects the receiver "170.315_b2_CIRI_Amb " or "170.315_b2_CIRI_Inp" criteria, selects one of the C-CDA 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 R 2.1.
2. The user repeats step 1, but selects the corresponding CDA R1.1, 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 R1.1.

Correct Patient

3. Using the xml files downloaded in step 1, 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, can be properly matched to a patient in the Health IT Module. Note that matches can be made automatically or manually.
4. Using the xml files downloaded in step 2, the user demonstrates that a transition of care summary/referral summary C-CDA document can be properly matched to a patient in the Health IT Module automatically or manually formatted according to the standards adopted at:

- § 170.205(a)(4), HL7® Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1, and
- § 170.205(a)(6), HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2 Companion Guide, Release 4.1

5. The user repeats steps 1-4, for each set of C-CDA R1.1, and C-CDA R2.1 xml files listed in the File Name for each of the health IT settings being certified.

Test Lab Verification

Expires on January 1, 2026

Setup

1. The tester creates a version in human readable format of the downloaded C-CDA R2 Release 2.1, in accordance with § 170.213 from step 1, of the System Under Test to be used for verification.
2. The tester creates a human readable version of the downloaded C-CDA R2 Release 1.1, files from step 2, of the System Under Test to be used for verification.

Correct Patient

3. The tester uses visual inspection to verify the Health IT Module can receive the C-CDA document downloaded in step 1, of the System Under Test 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.
4. The tester uses visual inspection to verify the Health IT Module can receive the C-CDA document downloaded in step 2, of the System Under Test as a C-CDA Release 2.1, document formatted according to the standard specified in § 170.205(a)(4) using one of the following document templates:
    - CCD;
    - Referral Note; and
    - *Inpatient setting only*: Discharge Summary.
5. Using the Health IT Module and the human readable xml files from steps 1 and 2, the tester verifies that each of the received C-CDA Release 1.1 and Release 2.1, documents can be properly matched to the correct patient record.

Required by December 31, 2025

Setup

1. The tester creates a version in human readable format of the downloaded C-CDA R2.1, in accordance with § 170.213 from step 1 of the System Under Test to be used for verification.
2. The tester creates a human readable version of the downloaded C-CDA R 1.1 files from step 2 of the System Under Test to be used for verification.

Correct Patient

3. The tester uses visual inspection to verify the Health IT Module can receive the C-CDA document downloaded in step 1 of the System Under Test as a C-CDA R1.1 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.

4. The tester uses visual inspection to verify the Health IT Module can receive the C-CDA document downloaded in step 2 of the System Under Test as a C-CDA R2.1 document formatted according to the standard specified in § 170.205(a)(4) using one of the following document templates:

- CCD;
- Referral Note; and
- *Inpatient setting only*: Discharge Summary.

5. Using the Health IT Module and the human readable xml files from steps 1 and 2, the tester verifies that each of the received C-CDA R1.1 and R2.1 documents can be properly matched to the correct patient record.

Paragraph (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) 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.

System Under Test

Expires on January 1, 2026
Setup

1. Using the ASTP Standards Implementation & Testing Environment (SITE): C-CDA Validator – USCDI v1 the user selects the receiver “170.315_b2_CIRI_Amb ” or “170.315_b2_CIRI_Inp” criteria, selects one of the C-CDA 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 R 2.1.
2. The user repeats step 1, but selects the corresponding CDA R1.1, 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 R1.1, or

Correct Patient

Test Lab Verification

Expires on January 1, 2026
Setup

1. The tester creates a version in human readable format of the downloaded C-CDA R2 Release 2.1, in accordance with § 170.213 from step 1, of the System Under Test to be used for verification.
2. The tester creates a human readable version of the downloaded C-CDA R2 Release 1.1, files from step 2, of the System Under Test to be used for verification.

Correct Patient

System Under Test

3. Using the xml files downloaded in step 1, 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, can be properly matched to a patient in the Health IT Module. Note that matches can be made automatically or manually.
4. Using the xml files downloaded in step 2, the user demonstrates that a transition of care summary/referral summary C-CDA document can be properly matched to a patient in the Health IT Module automatically or manually formatted according to the standards adopted at:
    - § 170.205(a)(4), HL7® Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1, and
    - § 170.205(a)(5), HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2 Companion Guide, Release 2
5. The user repeats steps 1-4, for each set of C-CDA R1.1, and C-CDA R2.1 xml files listed in the File Name for each of the health IT settings being certified.

Required by December 31, 2025
Setup

1. Using SITE: C-CDA Validator – USCDI v3 the user selects the receiver “170.315_b2_CIRI_Amb ” or “170.315_b2_CIRI_Inp” criteria, selects one of the C-CDA 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 R 2.1.
2. The user repeats step 1, but selects the corresponding CDA R1.1, 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 R1.1.

Correct Patient

Test Lab Verification

3. The tester uses visual inspection to verify the Health IT Module can receive the C-CDA document downloaded in step 1, of the System Under Test 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.
4. The tester uses visual inspection to verify the Health IT Module can receive the C-CDA document downloaded in step 2, of the System Under Test as a C-CDA Release 2.1, document formatted according to the standard specified in § 170.205(a)(4) using one of the following document templates:
    - CCD;
    - Referral Note; and
    - *Inpatient setting only*: Discharge Summary.
5. Using the Health IT Module and the human readable xml files from steps 1 and 2, the tester verifies that each of the received C-CDA Release 1.1 and Release 2.1, documents can be properly matched to the correct patient record.

Required by December 31, 2025
Setup

1. The tester creates a version in human readable format of the downloaded C-CDA R2.1, in accordance with § 170.213 from step 1 of the System Under Test to be used for verification.

System Under Test

3. Using the xml files downloaded in step 1, 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, can be properly matched to a patient in the Health IT Module. Note that matches can be made automatically or manually.
4. Using the xml files downloaded in step 2, the user demonstrates that a transition of care summary/referral summary C-CDA document can be properly matched to a patient in the Health IT Module automatically or manually formatted according to the standards adopted at:

- § 170.205(a)(4), HL7® Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1, and
- § 170.205(a)(6), HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2 Companion Guide, Release 4.1

5. The user repeats steps 1-4, for each set of C-CDA R1.1, and C-CDA R2.1 xml files listed in the File Name for each of the health IT settings being certified.

Test Lab Verification

2. The tester creates a human readable version of the downloaded C-CDA R 1.1 files from step 2 of the System Under Test to be used for verification.

Correct Patient

3. The tester uses visual inspection to verify the Health IT Module can receive the C-CDA document downloaded in step 1 of the System Under Test as a C-CDA R1.1 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.
4. The tester uses visual inspection to verify the Health IT Module can receive the C-CDA document downloaded in step 2 of the System Under Test as a C-CDA R2.1 document formatted according to the standard specified in § 170.205(a)(4) using one of the following document templates:

- CCD;
- Referral Note; and
- *Inpatient setting only*: Discharge Summary.

5. Using the Health IT Module and the human readable xml files from steps 1 and 2, the tester verifies that each of the received C-CDA R1.1 and R2.1 documents can be properly matched to the correct patient record.

Paragraph (b)(2)(iii)(A) Reconciliation – simultaneous display

System Under Test

Expires on January 1, 2026
Simultaneous Display

1. Using SITE: C-CDA Validator – USCDI v1 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 R1.1 and R2.1 and executes the download.
2. The user simultaneously views data (including active medications, allergies and intolerances, 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 R1.1 and R2.1 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, and
    - § 170.205(a)(5) HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2 Companion Guide, Release 2, 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), § 170.205(a)(4), and will need to separately demonstrate each of the following document templates: CCD or C-CDA with no specific document template for C-CDA R1.1, and CCD, Referral Note, and (*inpatient setting only*) Discharge Summary document templates for C-CDA R2.1 in accordance with the standard specified at § 170.213 for the health IT setting(s) being certified.

Simultaneous Display (Approved SVAP Version)

- Complete steps above using SITE C-CDA Validator for USCDI v4 and;
- Reference United States Core Data for Interoperability (USCDI), Version 4, October 2023 Errata, and;
- Use HL7® CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes Edition 3.0 - US Realm, May 2024 for § 170.205(a)(4), (a)(5) or (a)(6).

Required by December 31, 2025

1. Using SITE: C-CDA Validator USCDI v3, 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 R1.1 and R2.1 and executes the download.
2. The user simultaneously views data (including active medications, allergies and intolerances, 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 R1.1 and R2.1 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, and
    - § 170.205(a)(6) HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2 Companion Guide, Release 4.1, 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), § 170.205(a)(4), and will need to separately demonstrate each of the following document templates: CCD or C-CDA with no specific document template for C-CDA R1.1, and CCD, Referral Note, and (*inpatient setting only*) Discharge Summary document templates for C-CDA R2.1 in accordance with the standard specified at § 170.213 for the health IT setting(s) being certified.

Simultaneous Display (Approved SVAP Version)

- Complete steps above using SITE C-CDA Validator for USCDI v4 and;
- Reference United States Core Data for Interoperability (USCDI), Version 4, October 2023 Errata, and;
- Use HL7® CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes Edition 3.0 - US Realm, May 2024 for § 170.205(a)(4), (a)(5) or (a)(6).

Test Lab Verification

Expires on January 1, 2026
Simultaneous Display

1. The tester verifies data from multiple sources can be simultaneously displayed in a single view for medications, allergies and intolerances, 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 allergies and intolerances were documented or edited.
2. Further, the tester must verify the Health IT Module can display the current patient record and a Transition of Care Summary/Referral Summary C-CDA R1.1 and R2.1, 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) and § 170.205(a)(5).

Note: The tester must verify this can be completed for the CCD or C-CDA with no specific document template for C-CDA R1.1; and CCD, Referral Note, and (*inpatient setting only*) Discharge Summary document templates for C-CDA R2.1.

Required by December 31, 2025
Simultaneous Display

1. The tester verifies data from multiple sources can be simultaneously displayed in a single view for medications, allergies and intolerances, 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 allergies and intolerances were documented or edited.
2. Further, the tester must verify the Health IT Module can display the current patient record and a Transition of Care Summary/Referral Summary C-CDA R1.1 and R2.1, 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) and § 170.205(a)(6).

Note: The tester must verify this can be completed for the CCD or C-CDA with no specific document template for C-CDA R1.1; and CCD, Referral Note, and (*inpatient setting only*) Discharge Summary document templates for C-CDA R2.1.

System Under Test	Test Lab Verification
Expires on January 1, 2026 **Simultaneous Display**	**Expires on January 1, 2026** **Simultaneous Display**

System Under Test

1. Using SITE: C-CDA Validator – USCDI v1 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 R1.1 and R2.1 and executes the download.
2. The user simultaneously views data (including active medications, allergies and intolerances, 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 R1.1 and R2.1 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, and
    - § 170.205(a)(5) HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2 Companion Guide, Release 2, 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), § 170.205(a)(4), and will need to separately demonstrate each of the following document templates: CCD or C-CDA with no specific document template for C-CDA R1.1, and CCD, Referral Note, and

Test Lab Verification

1. The tester verifies data from multiple sources can be simultaneously displayed in a single view for medications, allergies and intolerances, 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 allergies and intolerances were documented or edited.
2. Further, the tester must verify the Health IT Module can display the current patient record and a Transition of Care Summary/Referral Summary C-CDA R1.1 and R2.1, 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) and § 170.205(a)(5).

Note: The tester must verify this can be completed for the CCD or C-CDA with no specific document template for C-CDA R1.1; and CCD, Referral Note, and (*inpatient setting only*) Discharge Summary document templates for C-CDA R2.1.

Required by December 31, 2025
Simultaneous Display

System Under Test

(*inpatient setting only*) Discharge Summary document templates for C-CDA R2.1 in accordance with the standard specified at § 170.213 for the health IT setting(s) being certified.

Simultaneous Display (Approved SVAP Version)

- Complete steps above using SITE C-CDA Validator for USCDI v4 and;
- Reference United States Core Data for Interoperability (USCDI), Version 4, October 2023 Errata, and;
- Use HL7® CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes Edition 3.0 - US Realm, May 2024 for § 170.205(a)(4), (a)(5) or (a)(6).

Required by December 31, 2025

1. Using SITE: C-CDA Validator USCDI v3, 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 R1.1 and R2.1 and executes the download.
2. The user simultaneously views data (including active medications, allergies and intolerances, 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

Test Lab Verification

1. The tester verifies data from multiple sources can be simultaneously displayed in a single view for medications, allergies and intolerances, 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 allergies and intolerances were documented or edited.
2. Further, the tester must verify the Health IT Module can display the current patient record and a Transition of Care Summary/Referral Summary C-CDA R1.1 and R2.1, 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) and § 170.205(a)(6).

Note: The tester must verify this can be completed for the CCD or C-CDA with no specific document template for C-CDA R1.1; and CCD, Referral Note, and (*inpatient setting only*) Discharge Summary document templates for C-CDA R2.1.

System Under Test

- The Transition of Care Summary/Referral Summary C-CDA R1.1 and R2.1 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, and
  - § 170.205(a)(6) HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2 Companion Guide, Release 4.1, 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), § 170.205(a)(4), and will need to separately demonstrate each of the following document templates: CCD or C-CDA with no specific document template for C-CDA R1.1, and CCD, Referral Note, and (*inpatient setting only*) Discharge Summary document templates for C-CDA R2.1 in accordance with the standard specified at § 170.213 for the health IT setting(s) being certified.

Simultaneous Display (Approved SVAP Version)

- Complete steps above using SITE C-CDA Validator for USCDI v4 and;
- Reference United States Core Data for Interoperability (USCDI), Version 4, October 2023 Errata, and;

Test Lab Verification

System Under Test	Test Lab Verification
• Use HL7® CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes Edition 3.0 - US Realm, May 2024 for § 170.205(a)(4), (a)(5) or (a)(6).	

Paragraph (b)(2)(iii)(B) Reconciliation – single reconciled list

System Under Test

The user creates a single, reconciled list using the data reviewed from the multiple medications, problems, or allergies and intolerances list sources in step one for each of the following:

- Medications;
- Allergies and Intolerances; 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.

System Under Test	Test Lab Verification
The user creates a single, reconciled list using the data reviewed from the multiple medications, problems, or allergies and intolerances list sources in step one for each of the following: • Medications; • Allergies and Intolerances; and • Problems.	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) Reconciliation – user review

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, the user is able to review and verify the accuracy of the final list.

System Under Test	Test Lab Verification
The user reviews the details of the reconciled list and validates its accuracy.	The tester verifies that, for each list type, the user is able to review and verify the accuracy of the final list.

Paragraph (b)(2)(iii)(D) Reconciliation – user confirmation

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, allergies and intolerances, and problems data are accurately incorporated into the patient record and expressed in the following:

- Medications are expressed according to the standard specified in § 170.213;
- Allergies and intolerances are expressed according to the standard specified in § 170.213; and
- Problems are expressed according to the standard specified in § 170.213.

System Under Test	Test Lab Verification
The user accepts the reconciled list and the patient record in the Health IT Module is updated.	The tester verifies that reconciled medications, allergies and intolerances, and problems data are accurately incorporated into the patient record and expressed in the following: • Medications are expressed according to the standard specified in § 170.213; • Allergies and intolerances are expressed according to the standard specified in § 170.213; and • Problems are expressed according to the standard specified in § 170.213.

Paragraph (b)(2)(iv) System verification

System Under Test

Expires on January 1, 2026

1. For each reconciliation in section (b)(2)(iii), the user creates a CCD that includes the reconciled and incorporated data, in accordance with the standard adopted at § 170.205(a)(4) and § 170.205(a)(5), for each of the following:
    - Medications;
    - Allergies and Intolerances; and
    - Problems.

Required by December 31, 2025

2. For each reconciliation in section (b)(2)(iii), the user creates a CCD that includes the reconciled and incorporated data, in accordance with the standard adopted at § 170.205(a)(4) and § 170.205(a)(6), for each of the following:

- Medications;
- Allergies and Intolerances; and
- Problems.

Test Lab Verification

Expires on January 1, 2026

Using the reconciled CCD document submitted by the System Under Test, the tester uses SITE: C-CDA 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. The tester uses the 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, allergies and intolerances, and/or problems has been performed. Furthermore, the tester verifies that the Health IT Module meets the standard specified in § 170.205(a)(4) and § 170.205(a)(5).

This verification is only for C-CDA R2.1 CCD documents.

Required by December 31, 2025

Using the reconciled CCD document submitted by the System Under Test, the tester uses the SITE: C-CDA 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. The tester uses the 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, allergies and intolerances, and/or problems has been performed. Furthermore, the tester verifies that the Health IT Module meets the standard specified in § 170.205(a)(4) and § 170.205(a)(6).

This verification is only for C-CDA R2.1 CCD documents.

System Under Test	Test Lab Verification
Expires on January 1, 2026 1. For each reconciliation in section (b)(2)(iii), the user creates a CCD that includes the reconciled and incorporated data, in accordance with the standard adopted at § 170.205(a)(4) and § 170.205(a)(5), for each of the following: ◦ Medications; ◦ Allergies and Intolerances; and ◦ Problems. **Required by December 31, 2025** 2. For each reconciliation in section (b)(2)(iii), the user creates a CCD that includes the reconciled and incorporated data, in accordance with the standard adopted at § 170.205(a)(4) and § 170.205(a)(6), for each of the following: • Medications; • Allergies and Intolerances; and • Problems.	**Expires on January 1, 2026** Using the reconciled CCD document submitted by the System Under Test, the tester uses SITE: C-CDA 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. The tester uses the 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, allergies and intolerances, and/or problems has been performed. Furthermore, the tester verifies that the Health IT Module meets the standard specified in § 170.205(a)(4) and § 170.205(a)(5). This verification is only for C-CDA R2.1 CCD documents. **Required by December 31, 2025** Using the reconciled CCD document submitted by the System Under Test, the tester uses the SITE: C-CDA 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. The tester uses the 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, allergies and intolerances, and/or problems has been performed. Furthermore, the tester verifies that the Health IT Module meets the standard specified in § 170.205(a)(4) and § 170.205(a)(6). This verification is only for C-CDA R2.1 CCD documents.

Archived Version:
§170.315(b)(2) Clinical information reconciliation and incorporation Test Procedure

Updated on 03-27-2025

Regulation Text

Regulation Text

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

1. *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) through (5) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates, for time period up to and including December 31, 2025; or in accordance with the standards adopted in § 170.205(a)(3), (4), (6).
2. *Correct patient.* Upon receipt of a transition of care/referral summary formatted according to the standards adopted § 170.205(a)(3) through (5), for the time period up to and including December 31, 2025; or according to the standards adopted § 170.205(a)(3), (4), and (6), technology must be able to demonstrate that the transition of care/referral summary received can be properly matched to the correct patient.
3. *Reconciliation.* Enable a user to reconcile the data that represent a patient's active medication list, allergies and intolerance list, and problem list as follows. For each list type:
    1. 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.
    2. Enable a user to create a single reconciled list of each of the following: Medications; Allergies and Intolerances; and problems.
    3. Enable a user to review and validate the accuracy of a final set of data.
    4. Upon a user's confirmation, automatically update the list, and incorporate the following data expressed according to the specified standards:
        1. *Medications.* At a minimum, the version of the standard specified in § 170.213;
        2. *Allergies and intolerance.* At a minimum, the version of the standard specified in § 170.213; and
        3. *Problems.* At a minimum, the version of the standard specified in § 170.213.

4. *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 template and the standard specified in paragraph (a)(5) of this section for the time period up to and including December 31, 2025; or according to the standard specified in § 170.205(a)(4) using the Continuity of Care Document template and the standard specified in paragraph (a)(6) of this section.

Standard(s) Referenced

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

§ 170.213(a) United States Core Data for Interoperability (USCDI), July 2020 Errata, Version 1 (v1) (The adoption of this standard expires on January 1, 2026)

§ 170.213(b) United States Core Data for Interoperability (USCDI), October 2022 Errata, Version 3 (v3) (This standard is required by December 31, 2025)

§ 170.205(a)(3) Health Level 7 (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, June 2019 (with Errata)

§ 170.205(a)(5) HL7® CDA R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5) (the adoption of this standard expires on January 1, 2026)

§ 170.205(a)(6) HL7® CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1 - US Realm, June 2023 (required by December 31, 2025)

Paragraphs (b)(2)(iii)(B) – (D)

§ 170.213(a) United States Core Data for Interoperability (USCDI), July 2020 Errata, Version 1 (v1) (The adoption of this standard expires on January 1, 2026)

§ 170.213(b) United States Core Data for Interoperability (USCDI), October 2022 Errata, Version 3 (v3) (This standard is required by December 31, 2025)

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, June 2019 (with Errata)

§ 170.205(a)(5) HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5) (The adoption of this standard expires on January 1, 2026)

§ 170.205(a)(6) HL7® CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1 - US Realm, June 2023 (This standard is required by December 31, 2025)

Standards Version Advancement Process (SVAP) Version(s) Approved

United States Core Data for Interoperability (USCDI), Version 4, October 2023 Errata

HL7® CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes Edition 3.0 - US Realm, May 2024

For more information, please visit the Standards Version Advancement Process (SVAP) Version(s) page.

Required Update Deadlines

The following outlines deadlines for required updates for this criterion as they relate to changes published in recent ONC final rules. Developers must update their products to the requirements outlined and provide them to their customers by the stated deadlines. These represent one-time deadlines as set by recent regulatory updates and do not encompass ongoing deadlines related to the Conditions and Maintenance of Certification. Please review those requirements for additional compliance activities related to one's certification under Certification Dependencies.

Deadline: December 31, 2025

Action to be taken: Developers certified to this criterion must update their versions of USCDI and C-CDA Companion Guide as outlined in paragraphs (b)(2)(i) and (ii), (b)(2)(iii)(B) – (D), and (b)(2)(iv).

Certification Dependencies

Conditions and Maintenance of Certification

Real World Testing: Products certified to this criterion must complete requirements outlined for the Real World Testing Conditions and Maintenance of Certification.

Design and Performance: The following design and performance certification criteria (adopted in § 170.315(g)) must also be certified in order for the product to be certified.

- Safety-enhanced design (§ 170.315(g)(3)) must be explicitly demonstrated for this criterion.
- Quality management system (§ 170.315(g)(4)): When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, when different QMS are used, each QMS needs to be separately identified for every capability to which it was applied.
- Accessibility-centered design (§ 170.315(g)(5)): When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied; or, alternatively, the developer must state that no accessibility-centered design was used.
- Consolidated CDA creation performance (§ 170.315(g)(6)): Consolidated Clinical Document Architecture (C-CDA) creation performance (§ 170.315(g)(6)) does not need to be explicitly tested with this criterion unless it is the only criterion within the scope of the requested certification that includes C-CDA creation capabilities. Note that the application of § 170.315(g)(6) depends on the C-CDA templates explicitly required by the C-CDA-referenced criterion or criteria included within the scope of the certificate sought. Please refer to the C-CDA creation performance CCG for more details.

Privacy & Security Requirements

This certification criterion was adopted at § 170.315(b)(2). As a result, an ONC Authorized Certification Body (ONC-ACB) must ensure that a product presented for certification to a § 170.315(b) criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (b) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be tested once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, exceptions exist for § 170.315(e)(1) “View, download, and transmit to 3rd party (VDT)” and (e)(2) “Secure messaging”, which are explicitly stated.

For more information on the approaches to meet these Privacy and Security requirements, please review the Privacy and Security CCG.

- If choosing Approach 1:
  - Authentication, access control, and authorization (§ 170.315(d)(1))
  - Auditable events and tamper-resistance (§ 170.315(d)(2))
  - Audit reports (§ 170.315(d)(3))
  - Automatic access time-out (§ 170.315(d)(5))
  - Emergency access (§ 170.315(d)(6))
  - End-user device encryption (§ 170.315(d)(7))
  - Integrity (§ 170.315(d)(8))
  - Encrypt authentication credentials (§ 170.315(d)(12))
  - Multi-factor authentication (MFA) (§ 170.315(d)(13))
- If choosing Approach 2:

  For each applicable privacy and security certification criterion not certified for Approach 1, the health IT developer may certify using system documentation which is sufficiently detailed to enable integration such that the Health IT Module has implemented service interfaces that enable the Health IT Module to access external services necessary to meet the requirements of the privacy and security certification criterion. Please see the ONC Cures Act Final Rule at 85 FR 25710 for additional clarification.

Revision History

Version #	Description of Change	Version Date
1.0	Initial publication	03-11-2024
1.1	Updated test tool link	12-02-2024
1.2	Updated test steps with 2024 SVAP approved standards and new SITE UI language	03-21-2025

Regulation Text

Regulation Text

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

1. *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) through (5) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates, for time period up to and including December 31, 2025; or in accordance with the standards adopted in § 170.205(a)(3), (4), (6).
2. *Correct patient.* Upon receipt of a transition of care/referral summary formatted according to the standards adopted § 170.205(a)(3) through (5), for the time period up to and including December 31, 2025; or according to the standards adopted § 170.205(a)(3), (4), and (6), technology must be able to demonstrate that the transition of care/referral summary received can be properly matched to the correct patient.
3. *Reconciliation.* Enable a user to reconcile the data that represent a patient's active medication list, allergies and intolerance list, and problem list as follows. For each list type:
    1. 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.
    2. Enable a user to create a single reconciled list of each of the following: Medications; Allergies and Intolerances; and problems.
    3. Enable a user to review and validate the accuracy of a final set of data.
    4. Upon a user's confirmation, automatically update the list, and incorporate the following data expressed according to the specified standards:
        1. *Medications.* At a minimum, the version of the standard specified in § 170.213;
        2. *Allergies and intolerance.* At a minimum, the version of the standard specified in § 170.213; and
        3. *Problems.* At a minimum, the version of the standard specified in § 170.213.
4. *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 template and the standard specified in paragraph (a)(5) of this section for the time period up to and including December 31, 2025; or according to the standard specified in § 170.205(a)(4) using the Continuity of Care Document template and the standard specified in paragraph (a)(6) of this section.

Standard(s) Referenced

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

§ 170.213(a) United States Core Data for Interoperability (USCDI), July 2020 Errata, Version 1 (v1) (The adoption of this standard expires on January 1, 2026)

§ 170.213(b) United States Core Data for Interoperability (USCDI), October 2022 Errata, Version 3 (v3) (This standard is required by December 31, 2025)

§ 170.205(a)(3) Health Level 7 (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, June 2019 (with Errata)

§ 170.205(a)(5) HL7® CDA R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5) (the adoption of this standard expires on January 1, 2026)

§ 170.205(a)(6) HL7® CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1 - US Realm, June 2023 (required by December 31, 2025)

Paragraphs (b)(2)(iii)(B) – (D)

§ 170.213(a) United States Core Data for Interoperability (USCDI), July 2020 Errata, Version 1 (v1) (The adoption of this standard expires on January 1, 2026)

§ 170.213(b) United States Core Data for Interoperability (USCDI), October 2022 Errata, Version 3 (v3) (This standard is required by December 31, 2025)

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, June 2019 (with Errata)

§ 170.205(a)(5) HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019, IBR approved for § 170.205(a)(5) (The adoption of this standard expires on January 1, 2026)

§ 170.205(a)(6) HL7® CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1 - US Realm, June 2023 (This standard is required by December 31, 2025)

Standards Version Advancement Process (SVAP) Version(s) Approved

United States Core Data for Interoperability (USCDI), Version 4, October 2023 Errata

HL7® CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes Edition 3.0 - US Realm, May 2024

For more information, please visit the Standards Version Advancement Process (SVAP) Version(s) page.

Required Update Deadlines

The following outlines deadlines for required updates for this criterion as they relate to changes published in recent ONC final rules. Developers must update their products to the requirements outlined and provide them to their customers by the stated deadlines. These represent one-time deadlines as set by recent regulatory updates and do not encompass ongoing deadlines related to the Conditions and Maintenance of Certification. Please review those requirements for additional compliance activities related to one's certification under Certification Dependencies.

Deadline: December 31, 2025

Action to be taken: Developers certified to this criterion must update their versions of USCDI and C-CDA Companion Guide as outlined in paragraphs (b)(2)(i) and (ii), (b)(2)(iii)(B) – (D), and (b)(2)(iv).

Certification Dependencies

Conditions and Maintenance of Certification

Real World Testing: Products certified to this criterion must complete requirements outlined for the Real World Testing Conditions and Maintenance of Certification.

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- Safety-enhanced design (§ 170.315(g)(3)) must be explicitly demonstrated for this criterion.
- Quality management system (§ 170.315(g)(4)): When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, when different QMS are used, each QMS needs to be separately identified for every capability to which it was applied.
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- Consolidated CDA creation performance (§ 170.315(g)(6)): Consolidated Clinical Document Architecture (C-CDA) creation performance (§ 170.315(g)(6)) does not need to be explicitly tested with this criterion unless it is the only criterion within the scope of the requested certification that includes C-CDA creation capabilities. Note that the application of § 170.315(g)(6) depends on the C-CDA templates explicitly required by the C-CDA-referenced criterion or criteria included within the scope of the certificate sought. Please refer to the C-CDA creation performance CCG for more details.

Privacy & Security Requirements

This certification criterion was adopted at § 170.315(b)(2). As a result, an ONC Authorized Certification Body (ONC-ACB) must ensure that a product presented for certification to a § 170.315(b) criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (b) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be tested once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, exceptions exist for § 170.315(e)(1) “View, download, and transmit to 3rd party (VDT)” and (e)(2) “Secure messaging”, which are explicitly stated.

For more information on the approaches to meet these Privacy and Security requirements, please review the Privacy and Security CCG.

If choosing Approach 2:

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Revision History

Version #	Description of Change	Version Date
1.0	Initial publication	03-11-2024

Version #	Description of Change	Version Date
1.1	Standards Referenced updated to reflect 2024 Approved SVAP Standards	08-19-2024
1.2	For entire criterion, added clarification regarding compliance with EO 14168 and OPM guidance	03-27-2025

Testing
Testing Tool

Standards Implementation & Testing Environment (SITE): C-CDA Validators

Test Tool Documentation

Test Tool Supplemental Guide

Criterion Subparagraph	Test Data
(b)(2)(ii)	170.315_b2_ciri_r11_sample*.xml (All Samples) 170.315_b2_ciri_r21_sample*.xml (All Samples)
(b)(2)(iii)	170.315_b2_ciri_r11_sample*.xml (All Samples) 170.315_b2_ciri_r11_ sample*_recon*.xml (All Samples) 170.315_b2_ciri_r21_sample*.xml (All Samples) 170.315_b2_ciri_r21_sample*_recon*.xml (All Samples)

Certification Companion Guide: Clinical information reconciliation and incorporation

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product certification. The CCG is not a substitute for the requirements outlined in regulation and related ONC final rules. It extracts key portions of ONC final rules' preambles and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the Certification Regulations page for links to all ONC final rules or consult other regulatory references as noted. The CCG is for public use and should not be sold or redistributed.

The below table outlines whether this criterion has additional Maintenance of Certification dependencies, update requirements and/or eligibility for standards updates via SVAP. Review the Certification Dependencies and Required Update Deadline drop-downs above if this table indicates “yes” for any field.

Base EHR Definition	Real World Testing	Insights Condition	SVAP	Requires Updates
Not Included	Yes	Yes	Yes	Yes

Certification Requirements

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:

- The scope of this criterion is limited to the C-CDA Continuity of Care Document (CCD), Referral Note, and (inpatient setting only) Discharge Summary document templates. [see also 80 FR 62639]
- In combination with the C-CDA R2.1 standard, developers certifying to the USCDI must follow the guidance and templates provided in the HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 until December 31, 2025, deadline; or HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1, for implementation of the C-CDA Release 2.1 standard. For example, details on how to structure and exchange Clinical Notes are included in the C-CDA Companion Guide.
- “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. [see also 77 FR 54168 and 77 FR 54218]

- In order to mitigate potential interoperability errors and inconsistent implementation of the HL7® Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1, ONC assesses, approves, and incorporates corrections as part of required testing and certification to this criterion. [see the ONC Health IT Certification Program Overview] Certified health IT adoption of, and compliance with, the corrections are necessary because they update vocabularies, update rules for cardinality and conformance statements, and promote proper exchange of C-CDA documents. There is a 90-day delay from the time the CCG has been updated with the ONC-approved corrections to when compliance with the corrections will be required to pass testing (i.e., ETT Message Validator). Similarly, there will be an 18-month delay before a finding of a correction's absence in certified health IT during surveillance would constitute a non-conformity under the Certification Program.
- Consistent with Executive Order (EO) 14168 and OPM guidance, Health IT Modules certifying and/or currently certified to certification criteria that cross-reference the USCDI standard at 45 CFR 170.213 are only required to demonstrate the capability to categorize data on individuals for the sex data element in accordance with the following SNOMED CT® codes:
    - 248152002 |Female (finding)| and
    - 248153007 |Male (finding)|
- Further, these Health IT Modules are no longer required to support the following USCDI data elements for purposes of certification:
    - Sexual orientation in USCDI version 4;
    - Gender identity in USCDI version 4;
    - Sex parameter for clinical use in USCDI version 5;
    - Name to use in USCDI version 5;
    - Pronouns in USCDI version 5.

Clarifications:

- The scope of this criterion is limited to the C-CDA Continuity of Care Document (CCD), Referral Note, and (inpatient setting only) Discharge Summary document templates. [see also 80 FR 62639]
- In combination with the C-CDA R2.1 standard, developers certifying to the USCDI must follow the guidance and templates provided in the HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 until December 31, 2025, deadline; or HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1, for implementation of the C-CDA Release 2.1 standard. For example, details on how to structure and exchange Clinical Notes are included in the C-CDA Companion Guide.
- "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. [see also 77 FR 54168 and 77 FR 54218]
- In order to mitigate potential interoperability errors and inconsistent implementation of the HL7® Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1, ONC assesses, approves, and incorporates corrections as part of required testing and certification to this criterion. [see the ONC Health IT Certification Program Overview] Certified health IT adoption of, and compliance with, the corrections are necessary because they update vocabularies, update rules for cardinality and conformance statements, and promote proper exchange of C-CDA documents. There is a 90-day delay from the time the CCG has been updated with the ONC-approved corrections to when compliance with the corrections will be required to pass testing (i.e., ETT Message Validator). Similarly, there will be an 18-month delay before a finding of a correction's absence in certified health IT during surveillance would constitute a non-conformity under the Certification Program.
- Consistent with Executive Order (EO) 14168 and OPM guidance, Health IT Modules certifying and/or currently certified to certification criteria that cross-reference the USCDI standard at 45 CFR 170.213 are only required to demonstrate the capability to categorize data on individuals for the sex data element in accordance with the following SNOMED CT® codes:
    - 248152002 |Female (finding)| and
    - 248153007 |Male (finding)|
- Further, these Health IT Modules are no longer required to support the following USCDI data elements for purposes of certification:
    - Sexual orientation in USCDI version 4;
    - Gender identity in USCDI version 4;
    - Sex parameter for clinical use in USCDI version 5;
    - Name to use in USCDI version 5;
    - Pronouns in USCDI version 5.

Paragraph (b)(2)(i) General requirements

Technical outcome – The health IT can complete the requirements in paragraphs (b)(2)(ii) and (iii) of this criterion upon receipt of a transition of care/referral C-CDA (for both Releases 1.1 and 2.1).

Clarifications:

> ONC is requiring Health IT Modules to be able to reconcile and incorporate information from C-CDAs formatted to both C-CDA Releases 1.1 and 2.1. While Release 2.1 largely ensures compatibility between C-CDA Release 1.1 and 2.0, it does not guarantee compatibility without further development effort. [see also 80 FR 62639]

Technical outcome – The health IT can complete the requirements in paragraphs (b)(2)(ii) and (iii) of this criterion upon receipt of a transition of care/referral C-CDA (for both Releases 1.1 and 2.1).

Clarifications:

> ONC is requiring Health IT Modules to be able to reconcile and incorporate information from C-CDAs formatted to both C-CDA Releases 1.1 and 2.1. While Release 2.1 largely ensures compatibility between C-CDA Release 1.1 and 2.0, it does not guarantee compatibility without further development effort. [see also 80 FR 62639]

Paragraph (b)(2)(ii) Correct patient

Technical outcome – The health IT can properly match a received transition of care/referral summary (for both Releases 1.1 and 2.1) to the correct patient.

Clarifications:

> Health IT Modules do not have to auto-match the patient. Manual patient match is acceptable as long as the received C-CDA can be matched to the correct patient. [see also 80 FR 62640 and 77 FR 54219]

Technical outcome – The health IT can properly match a received transition of care/referral summary (for both Releases 1.1 and 2.1) to the correct patient.

Clarifications:

> Health IT Modules do not have to auto-match the patient. Manual patient match is acceptable as long as the received C-CDA can be matched to the correct patient. [see also 80 FR 62640 and 77 FR 54219]

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

Technical outcome – A user can simultaneously display a patient's active data, and its attributes, from at least two of the following sources: a patient's medication list, allergies and intolerances list, and problem list. Displayed data attributes must include the source and the last modification date.

Clarifications:

> A vendor 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, then this does not constitute a single view and does not meet the requirements for the certification criterion.

Technical outcome – A user can simultaneously display a patient's active data, and its attributes, from at least two of the following sources: a patient's medication list, allergies and intolerances list, and problem list. Displayed data attributes must include the source and the last modification date.

Clarifications:

> A vendor 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, then this does not constitute a single view and does not meet the requirements for the certification criterion.

Paragraphs (b)(2)(iii)(B) - (D) Reconciliation

Technical outcome – A user can review, validate, and incorporate a patient's medication list (using RxNorm), allergies and intolerances list (Medication using RxNorm, Drug Class using SNOMED CT®, and Reaction using SNOMED CT®), and problem list (using SNOMED CT®).

Clarifications:

- 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. [see also 80 FR 62639]
- 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. [see also 80 FR 62639]
- ONC encourages health IT developers to incorporate data in a structured format. [see also 77 FR 54219]
- Incorporation does not have to be automated. [see also 77 FR 54219]

- Health IT Modules can present for certification to more recent versions of RxNorm and/or SNOMED CT®, U.S. Edition, than what is currently in USCDI per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62620]
- ONC provides the following object identifiers (OIDs) to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards.
    - RxNorm OID: 2.16.840.1.113883.6.88.
    - SNOMED CT® OID: 2.16.840.1.113883.6.96. [see also 80 FR 62612]

Technical outcome – A user can review, validate, and incorporate a patient's medication list (using RxNorm), allergies and intolerances list (Medication using RxNorm, Drug Class using SNOMED CT®, and Reaction using SNOMED CT®), and problem list (using SNOMED CT®).

Clarifications:

- 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. [see also 80 FR 62639]
- 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. [see also 80 FR 62639]
- ONC encourages health IT developers to incorporate data in a structured format. [see also 77 FR 54219]
- Incorporation does not have to be automated. [see also 77 FR 54219]
- Health IT Modules can present for certification to more recent versions of RxNorm and/or SNOMED CT®, U.S. Edition, than what is currently in USCDI per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62620]
- ONC provides the following object identifiers (OIDs) to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards.
    - RxNorm OID: 2.16.840.1.113883.6.88.
    - SNOMED CT® OID: 2.16.840.1.113883.6.96. [see also 80 FR 62612]

Paragraph (b)(2)(iv) System verification

Technical outcome – The health IT can create a C-CDA document (using the CCD template in C-CDA Release 2.1) that includes the reconciled and incorporated data.

Clarifications:

No additional clarifications.

Technical outcome – The health IT can create a C-CDA document (using the CCD template in C-CDA Release 2.1) that includes the reconciled and incorporated data.

Clarifications:

No additional clarifications.

Archived Version:

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