Consolidated CDA creation performance | HealthIT.gov

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- Certification Companion Guide (CCG)
- Test Procedure

Updated on 03-21-2025

Regulation Text

Regulation Text

§ 170.315 (g)(6) *Consolidated CDA creation performance*—

The following technical and performance outcomes must be demonstrated related to Consolidated CDA creation. The capabilities required under paragraphs (g)(6)(i) through (v) of this section can be demonstrated in tandem and do not need to be individually addressed in isolation or sequentially.

1. This certification criterion's scope includes:
    1. The data classes expressed in the standard in § 170.213, and in accordance with § 170.205(a)(4) and (5), and the paragraphs (g)(6)(i)(*C*)(*1*)-(4) of this section for the time period up to and including December 31, 2025; or
    2. The data classes expressed in the standards in § 170.213, and in accordance with § 170.205(a)(4) and (6) and paragraphs (g)(6)(i)(C)(1) through (3) of this section
2. The following data classes:
    1. *Assessment and plan of treatment.* In accordance with the “Assessment and Plan Section (V2)” of the standard specified in § 170.205(a)(4); or in accordance with the “Assessment Section (V2)” and “Plan of Treatment Section (V2)” of the standard specified in § 170.205(a)(4).
    2. *Goals.* In accordance with the “Goals Section” of the standard specified in § 170.205(a)(4).
    3. *Health concerns.* In accordance with the “Health Concerns Section” of the standard specified in § 170.205(a)(4).
    4. *Unique device identifier(s) for a patient’s implantable device(s).* In accordance with the “Product Instance” in the “Procedure Activity Procedure Section” of the standard specified in § 170.205(a)(4)

3. *Reference C-CDA match*.
    1. For a health IT certified to (g)(6)(i)(A) of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) and (5) that matches a gold-standard, reference data file.
    2. For health IT certified to (g)(6)(i)(B*)* of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that matches a gold-standard, reference data file.
4. *Document-template conformance.*
    1. For a health IT certified to (g)(6)(i)(A) of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) and (5) that demonstrates a valid implementation of each document template applicable to the certification criterion or criteria within the scope of the certificate sought.
    2. For health IT certified to (g)(6)(i)(B*)* of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that demonstrates a valid implementation of each document template applicable to the certification criterion or criteria within the scope of the certificate sought.
5. *Vocabulary conformance.*
    1. For a health IT certified to (g)(6)(i)(A) of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) and (5) that demonstrates the required vocabulary standards (and value sets) are properly implemented.
    2. For health IT certified to (g)(6)(i)(B*)* of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that demonstrates the vocabulary standards (and value sets) are properly implemented.
5. *Completeness verification*. Create a data file for each of the applicable document templates referenced in paragraph (g)(6)(ii) of this section without the omission of any of the data included in either (g)(6)(i)(A) or (B) of this section, as applicable.

Standard(s) Referenced

Applies to entire criterion

§ 170.213(a) United States Core Data for Interoperability (USCDI), July 2020 Errata, Version 1 (v1) (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)(4) Health Level 7 (HL7®) Implementation Guide (IG) for CDA® Release 2 Consolidation CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1 C-CDA 2.1, August 2015, June 2019 (with Errata)

§ 170.205(a)(5) Health Level 7 (HL7®) CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019 (Adoption of this standard expires on January 1, 2026.)

§ 170.205(a)(6) Health Level 7 (HL7®) CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1 - US Realm (This standard is required by December 31, 2025.)

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 must update to the new versions of the standards for USCDI and C-CDA Companion Guide as outlined in the subparagraph (g)(6)(i)(A-B).

Certification Dependencies

This certification criterion was adopted at § 170.315(g)(6) and is required for all developers seeking certification to certification criteria with Consolidated Clinical Document Architecture (C-CDA) creation capabilities (i.e., § 170.315(b)(1), (b)(2), (b)(9), (e)(1), and (g)(9)).

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.

- 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, the QMS' need to be 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.

Privacy & Security Requirements

There are no associated required privacy and security criterion for this criterion at § 170.315(g)(6).

Revision History

Version #	Description of Change	Version Date
1.0	Initial publication	03-11-2024
1.1	Updated test steps with new SITE UI language	03-21-2025

Regulation Text

Regulation Text

§ 170.315 (g)(6) *Consolidated CDA creation performance*—

The following technical and performance outcomes must be demonstrated related to Consolidated CDA creation. The capabilities required under paragraphs (g)(6)(i) through (v) of this section can be demonstrated in tandem and do not need to be individually addressed in isolation or sequentially.

1. This certification criterion's scope includes:
    1. The data classes expressed in the standard in § 170.213, and in accordance with § 170.205(a)(4) and (5), and the paragraphs (g)(6)(i)(*C*)(*1*)-(4) of this section for the time period up to and including December 31, 2025; or
    2. The data classes expressed in the standards in § 170.213, and in accordance with § 170.205(a)(4) and (6) and paragraphs (g)(6)(i)(C)(1) through (3) of this section
2. The following data classes:
    1. *Assessment and plan of treatment.* In accordance with the “Assessment and Plan Section (V2)” of the standard specified in § 170.205(a)(4); or in accordance with the “Assessment Section (V2)” and “Plan of Treatment Section (V2)” of the standard specified in § 170.205(a)(4).
    2. *Goals.* In accordance with the “Goals Section” of the standard specified in § 170.205(a)(4).
    3. *Health concerns.* In accordance with the “Health Concerns Section” of the standard specified in § 170.205(a)(4).
    4. *Unique device identifier(s) for a patient’s implantable device(s).* In accordance with the “Product Instance” in the “Procedure Activity Procedure Section” of the standard specified in § 170.205(a)(4)

3. *Reference C-CDA match*.
    1. For a health IT certified to (g)(6)(i)(A) of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) and (5) that matches a gold-standard, reference data file.
    2. For health IT certified to (g)(6)(i)(B*)* of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that matches a gold-standard, reference data file.
4. *Document-template conformance.*
    1. For a health IT certified to (g)(6)(i)(A) of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) and (5) that demonstrates a valid implementation of each document template applicable to the certification criterion or criteria within the scope of the certificate sought.
    2. For health IT certified to (g)(6)(i)(B*)* of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that demonstrates a valid implementation of each document template applicable to the certification criterion or criteria within the scope of the certificate sought.
5. *Vocabulary conformance.*
    1. For a health IT certified to (g)(6)(i)(A) of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) and (5) that demonstrates the required vocabulary standards (and value sets) are properly implemented.
    2. For health IT certified to (g)(6)(i)(B*)* of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that demonstrates the vocabulary standards (and value sets) are properly implemented.
5. *Completeness verification*. Create a data file for each of the applicable document templates referenced in paragraph (g)(6)(ii) of this section without the omission of any of the data included in either (g)(6)(i)(A) or (B) of this section, as applicable.

Standard(s) Referenced

Applies to entire criterion

§ 170.213(a) United States Core Data for Interoperability (USCDI), July 2020 Errata, Version 1 (v1) (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)(4) Health Level 7 (HL7®) Implementation Guide (IG) for CDA® Release 2 Consolidation CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1 C-CDA 2.1, August 2015, June 2019 (with Errata)

§ 170.205(a)(5) Health Level 7 (HL7®) CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019 (Adoption of this standard expires on January 1, 2026.)

§ 170.205(a)(6) Health Level 7 (HL7®) CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1 - US Realm (This standard is required by December 31, 2025.)

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 must update to the new versions of the standards for USCDI and C-CDA Companion Guide as outlined in the subparagraph (g)(6)(i)(A-B).

Certification Dependencies

This certification criterion was adopted at § 170.315(g)(6) and is required for all developers seeking certification to certification criteria with Consolidated Clinical Document Architecture (C-CDA) creation capabilities (i.e., § 170.315(b)(1), (b)(2), (b)(9), (e)(1), and (g)(9)).

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.

- 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, the QMS' need to be 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.

Privacy & Security Requirements

There are no associated required privacy and security criterion for this criterion at § 170.315(g)(6).

Testing

Testing Tool

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

Test Tool Documentation

Test Tool Supplemental Guide

Criterion Subparagraph	Test Data
(g)(6)(i)	Sample gold standard C-CDA documents are available on an ONC-maintained repository: https://github.com/onc-healthit/2015-edition-cures-update-data The C-CDA Data set to be used corresponds to the criteria for which the Health IT Module is certifying. For example, if the Health IT Module is certifying to § 170.315(b)(1) Transitions of care, the following C-CDA validation documents would be used: Inpatient Setting: 170.315_b1_toc_inp_sample*.pdf (All Samples) Ambulatory Setting: 170.315_b1_toc_amb_sample*.pdf (All Samples)

Revision History

Version #	Description of Change	Version Date
1.0	Initial publication	03-11-2024
1.1	Updated test steps with 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 ONC Final Rule 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 test step order does not necessarily prescribe the order in which the tests should take place.

Testing components

ONC Supplied Test Data

Paragraph (g)(6) – (Conditional – For Modules with existing certification to (g)(6))

System Under Test

Required by December 31, 2025
A Health IT Module currently certified to the §170.315(g)(6) C-CDA creation performance will attest directly to the ONC-ACB to conformance with the updated § 170.315(g)(6) 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(g)(6) C-CDA creation performance attests conformance to updated § 170.315(g)(6) criteria requirements.

The verification of the § 170.315(g)(6) Consolidated CDA (C-CDA) Creation Performance criteria for a given criterion is performed in conjunction with the specific criteria. No additional tests need to be executed to certify for § 170.315(g)(6) C-CDA Creation Performance. The § 170.315(g)(6) C-CDA Creation Performance Test Procedure is provided to illustrate the tests which are performed as part of certifying for § 170.315(g)(6) C-CDA Creation Performance.

The following technical and performance outcomes must be demonstrated related to C-CDA creation. The capabilities required under paragraphs (g)(6)(ii) through (v) of this section can be demonstrated in tandem and do not need to be individually addressed in isolation or sequentially. This certification criterion's scope includes only data expressed within the definition provided in section (g)(6)(i).

System Under Test	ONC-ACB Verification
Required by December 31, 2025 A Health IT Module currently certified to the §170.315(g)(6) C-CDA creation performance will attest directly to the ONC-ACB to conformance with the updated § 170.315(g)(6) 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(g)(6) C-CDA creation performance attests conformance to updated § 170.315(g)(6) criteria requirements.

Paragraph (g)(6)(i) Criteria scope

System Under Test

Expires on January 1, 2026
Criteria Data Definition

1. Based upon the criteria for which the health IT developer is certifying (e.g. transition of care, care plan), the appropriate clinical information for the certifying criteria at a minimum must include the following data elements and data classes as applicable:
    - The data classes expressed in the standard in § 170.213, and in accordance with § 170.205(a)(4) HL7® Implementation Guide for CDA® Release 2: C-CDA Templates for Clinical Notes, DSTU Release 2.1 (with Errata) and § 170.205(a)(5) HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2.
    - The "Assessment and plan of treatment, specified in accordance with the "Assessment and Plan Section (V2)" of the standard specified in § 170.205(a)(4); or in accordance with the "Assessment Section (V2)" and "Plan of Treatment Section (V2)" of the standard specified in § 170.205(a)(4). At a minimum, the Assessment and Plan of Treatment data includes the narrative text.
    - The Goals, specified in accordance with the standard specified in § 170.205(a)(4). At a minimum, the Goals data includes narrative text.
    - The Health Concerns, specified in accordance with the standard specified at § 170.205(a)(4). At a minimum, the Health Concerns data includes narrative text.
    - Unique device identifier(s), specified in accordance with the "Product Instance" in the "Procedure Activity Procedure Section" of the standard specified in § 170.205(a)(4).

Required by December 31, 2025
Criteria Data Definition

1. Based upon the criteria for which the health IT developer is certifying (e.g. transition of care, care plan), the appropriate clinical information for the certifying criteria at a minimum must include the following data elements and data classes as applicable:

- The data classes expressed in the standard in § 170.213, and in accordance with § 170.205(a)(4) HL7® Implementation Guide for CDA® Release 2: C-CDA Templates for Clinical Notes, DSTU Release 2.1 (with Errata) and § 170.205(a)(6) HL7® CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes STU Companion Guide, Release 4.1.
- The Assessment and Plan of Treatment, specified in accordance with the "Assessment and Plan Section (V2)" of the standard specified in § 170.205(a)(4); or in accordance with the "Assessment Section (V2)" and "Plan of Treatment Section (V2)" of the standard specified in § 170.205(a)(4). At a minimum, the Assessment and Plan of Treatment data includes the narrative text.
- The Goals, specified in accordance with the standard specified in § 170.205(a)(4). At a minimum, the Goals data includes narrative text.
- The Health Concerns, specified in accordance with the standard specified at § 170.205(a)(4). At a minimum, the Health Concerns data includes narrative text.

- Unique device identifier(s), specified in accordance with the “Product Instance” in the “Procedure Activity Procedure Section” of the standard specified in § 170.205(a)(4).

Test Lab Verification

Expires on January 1, 2026
Criteria Data Definition

1. The tester verifies the clinical summary information for the criteria includes at a minimum the following data definition:
    - All of the United States Core Data for Interoperability (USCDI) data elements as specified in the standard at § 170.213 with the data classes expressed in accordance with the implementation guides at § 170.205(a)(4) and § 170.205(a)(5).
    - The Assessment and Plan or both the Assessment and Plan of Treatment are specified in accordance with the standard specified in § 170.205(a)(4) as narrative text;
    - The Goals are specified in accordance with the standard specified in § 170.205(a)(4) as narrative text; and
    - The Health Concerns are specified in accordance with the standard specified in § 170.205(a)(4) as narrative text.
    - Unique device identifier(s), specified in accordance with the “Product Instance” in the “Procedure Activity Procedure Section” of the standard specified in § 170.205(a)(4).

Required by December 31, 2025

1. The tester verifies the clinical summary information for the criteria includes at a minimum the following data definition:
    - All of the United States Core Data for Interoperability (USCDI) data elements as specified in the standard at § 170.213 with the data classes expressed in accordance with the implementation guides at § 170.205(a)(4) and § 170.205(a)(6).
    - The Assessment and Plan or both the Assessment and Plan of Treatment are specified in accordance with the standard specified in § 170.205(a)(4) as narrative text;
    - The Goals are specified in accordance with the standard specified in § 170.205(a)(4) as narrative text; and
    - The Health Concerns are specified in accordance with the standard specified in § 170.205(a)(4) as narrative text.
    - Unique device identifier(s), specified in accordance with the “Product Instance” in the “Procedure Activity Procedure Section” of the standard specified in § 170.205(a)(4).

System Under Test

Expires on January 1, 2026
Criteria Data Definition

1. Based upon the criteria for which the health IT developer is certifying (e.g. transition of care, care plan), the appropriate clinical information for the certifying criteria at a minimum must include the following data elements and data classes as applicable:
    - The data classes expressed in the standard in § 170.213, and in accordance with § 170.205(a)(4) HL7® Implementation Guide for CDA® Release 2: C-CDA Templates for Clinical Notes, DSTU Release 2.1 (with Errata) and § 170.205(a)(5) HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2.
    - The “Assessment and plan of treatment, specified in accordance with the “Assessment and Plan Section (V2)” of the standard specified in § 170.205(a)(4); or in accordance with the “Assessment Section (V2)” and “Plan of Treatment Section (V2)” of the standard specified in § 170.205(a)(4). At a minimum, the Assessment and Plan of Treatment data includes the narrative text.
    - The Goals, specified in accordance with the standard specified in § 170.205(a)(4). At a minimum, the Goals data includes narrative text.
    - The Health Concerns, specified in accordance with the standard specified at § 170.205(a)(4). At a minimum, the Health Concerns data includes narrative text.
    - Unique device identifier(s), specified in accordance with the “Product Instance” in the “Procedure Activity Procedure Section” of the standard specified in § 170.205(a)(4).

Required by December 31, 2025
Criteria Data Definition

Test Lab Verification

Expires on January 1, 2026
Criteria Data Definition

1. The tester verifies the clinical summary information for the criteria includes at a minimum the following data definition:
    - All of the United States Core Data for Interoperability (USCDI) data elements as specified in the standard at § 170.213 with the data classes expressed in accordance with the implementation guides at § 170.205(a)(4) and § 170.205(a)(5).
    - The Assessment and Plan or both the Assessment and Plan of Treatment are specified in accordance with the standard specified in § 170.205(a)(4) as narrative text;
    - The Goals are specified in accordance with the standard specified in § 170.205(a)(4) as narrative text; and
    - The Health Concerns are specified in accordance with the standard specified in § 170.205(a)(4) as narrative text.
    - Unique device identifier(s), specified in accordance with the “Product Instance” in the “Procedure Activity Procedure Section” of the standard specified in § 170.205(a)(4).

System Under Test

1. Based upon the criteria for which the health IT developer is certifying (e.g. transition of care, care plan), the appropriate clinical information for the certifying criteria at a minimum must include the following data elements and data classes as applicable:

- The data classes expressed in the standard in § 170.213, and in accordance with § 170.205(a)(4) HL7® Implementation Guide for CDA® Release 2: C-CDA Templates for Clinical Notes, DSTU Release 2.1 (with Errata) and § 170.205(a)(6) HL7® CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes STU Companion Guide, Release 4.1.
- The Assessment and Plan of Treatment, specified in accordance with the “Assessment and Plan Section (V2)” of the standard specified in § 170.205(a)(4); or in accordance with the “Assessment Section (V2)” and “Plan of Treatment Section (V2)” of the standard specified in § 170.205(a)(4). At a minimum, the Assessment and Plan of Treatment data includes the narrative text.
- The Goals, specified in accordance with the standard specified in § 170.205(a)(4). At a minimum, the Goals data includes narrative text.
- The Health Concerns, specified in accordance with the standard specified at § 170.205(a)(4). At a minimum, the Health Concerns data includes narrative text.
- Unique device identifier(s), specified in accordance with the “Product Instance” in the “Procedure Activity Procedure Section” of the standard specified in § 170.205(a)(4).

Test Lab Verification

Required by December 31, 2025

1. The tester verifies the clinical summary information for the criteria includes at a minimum the following data definition:
    - All of the United States Core Data for Interoperability (USCDI) data elements as specified in the standard at § 170.213 with the data classes expressed in accordance with the implementation guides at § 170.205(a)(4) and § 170.205(a)(6).
    - The Assessment and Plan or both the Assessment and Plan of Treatment are specified in accordance with the standard specified in § 170.205(a)(4) as narrative text;
    - The Goals are specified in accordance with the standard specified in § 170.205(a)(4) as narrative text; and
    - The Health Concerns are specified in accordance with the standard specified in § 170.205(a)(4) as narrative text.
    - Unique device identifier(s), specified in accordance with the “Product Instance” in the “Procedure Activity Procedure Section” of the standard specified in § 170.205(a)(4).

Paragraph (g)(6)(ii)(A) and (B) Reference C-CDA match

System Under Test

Expires on January 1, 2026
Data Entry

1. Based upon the criteria for which the Health IT Module is certifying (e.g. transition of care, care plan), the user enters the appropriate clinical information for the certifying criteria into the Health IT Module.

C-CDA Creation

2. Using the Health IT Module, the user creates a data file formatted in accordance with the standard specified in § 170.205(a)(4) and § 170.205(a)(5) and includes the appropriate document templates and content for the certifying criteria, being tested, including at a minimum the data definition in (g)(6)(i)(A), in order to match a gold-standard, reference data file for each applicable C-CDA document-template.
3. The C-CDA document created in step 2, is submitted to the tester for verification.
4. Based upon the health IT settings (i.e. ambulatory and/or inpatient), the user repeats steps 1-3, for each of the instruction documents found in ASTP's Standards Implementation & Testing Environment (SITE): C-CDA Validators - USCDI v1 for the criteria being certified.

Required by December 31, 2025
Data Entry

1. Based upon the criteria for which the Health IT Module is certifying (e.g. transition of care, care plan), the user enters the appropriate clinical information for the certifying criteria into the Health IT Module.

C-CDA Creation

2. Using the Health IT Module, the user creates a data file formatted in accordance with the standard specified in § 170.205(a)(4) and § 170.205(a)(6) and includes the appropriate document templates and content for the certifying criteria, being tested, including at a minimum the data definition in (g)(6)(i)(B), in order to match a gold-standard, reference data file for each applicable C-CDA document-template.
3. The C-CDA document created in step 2 is submitted to the tester for verification.
4. Based upon the health IT settings (i.e. ambulatory and/or inpatient), the user repeats steps 1-3, for each of the instruction documents found in ASTP's Standards Implementation & Testing Environment (SITE): C-CDA Validators – USCDI v3 for the criteria being certified.

Test Lab Verification

Expires on January 1, 2026
Data Entry

1. Using the criteria instruction document downloaded in step 1, of the System Under Test, the tester verifies the clinical summary information for the criteria entered into the Health IT Module is accurate and without omission using visual inspection.

C-CDA Creation

2. For each file submitted in step 3, of the System Under Test, the tester uses the SITE: C-CDA Validator – USCDI v1 to upload the submitted C-CDA document through the sender upload selection of the criteria being certified along with the file name and executes the upload of the submitted file.
3. For each uploaded file in step 2, the tester uses the Validation Report produced by the SITE: C-CDA Validator- USCDI v1 to verify the validation report indicates the certifying criteria is conformant to the standard specified in § 170.205(a)(4) and § 170.205(a)(5), and includes the required data elements specified by the standard for the certifying criteria, including at a minimum the data definition in (g)(6)(i)(A) in order to match the gold-standard, reference data file.
4. As required by the criteria instruction document downloaded in step 1, of the System Under Test, the tester uses the ASTP/ONC-supplied certifying criteria instructions and the Message Content Report produced by the SITE: C-CDA Validators - USCDI v1 in step 2, to verify the additional checks for equivalent text for the content of all section level narrative text.

Required by December 31, 2025
Data Entry

1. Using the criteria instruction document downloaded in step 1, of the System Under Test, the tester verifies the clinical summary information for the criteria entered into the Health IT Module is accurate and without omission using visual inspection.

C-CDA Creation

2. For each file submitted in step 3, of the System Under Test, the tester uses the SITE: C-CDA Validator – USCDI v3 to upload the submitted C-CDA document through the sender upload selection of the criteria being certified along with the file name and executes the upload of the submitted file.

3. For each uploaded file in step 2, the tester uses the Validation Report produced by the SITE: C-CDA Validator – USDCI v3 to verify the validation report indicates the certifying criteria is conformant to the standard specified in § 170.205(a)(4) and § 170.205(a)(6), and includes the required data elements specified by the standard for the certifying criteria, including at a minimum the data definition in (g)(6)(i)(B) in order to match the gold-standard, reference data file.
4. As required by the criteria instruction document downloaded in step 1, of the System Under Test, the tester uses the ASTP/ONC-supplied certifying criteria instructions and the Message Content Report produced by the SITE: C-CDA Validator – USCDI v3 in step 2, to verify the additional checks for equivalent text for the content of all section level narrative text.

System Under Test

Expires on January 1, 2026
Data Entry

1. Based upon the criteria for which the Health IT Module is certifying (e.g. transition of care, care plan), the user enters the appropriate clinical information for the certifying criteria into the Health IT Module.

C-CDA Creation

2. Using the Health IT Module, the user creates a data file formatted in accordance with the standard specified in § 170.205(a)(4) and § 170.205(a)(5) and includes the appropriate document templates and content for the certifying criteria, being tested, including at a minimum the data definition in (g)(6)(i)(A), in order to match a gold-standard, reference data file for each applicable C-CDA document-template.
3. The C-CDA document created in step 2, is submitted to the tester for verification.

Test Lab Verification

Expires on January 1, 2026
Data Entry

1. Using the criteria instruction document downloaded in step 1, of the System Under Test, the tester verifies the clinical summary information for the criteria entered into the Health IT Module is accurate and without omission using visual inspection.

C-CDA Creation

2. For each file submitted in step 3, of the System Under Test, the tester uses the SITE: C-CDA Validator – USCDI v1 to upload the submitted C-CDA document through the sender upload selection of the criteria being certified along with the file name and executes the upload of the submitted file.
3. For each uploaded file in step 2, the tester uses the Validation Report produced by the SITE: C-CDA Validator-USCDI v1 to verify the validation report indicates the certifying criteria is conformant to the standard specified in § 170.205(a)(4) and § 170.205(a)(5), and includes the required data elements specified by the standard for the certifying criteria, including at a minimum the data definition in (g)(6)(i)(A) in order to match the gold-standard, reference data file.

System Under Test

4. Based upon the health IT settings (i.e. ambulatory and/or inpatient), the user repeats steps 1-3, for each of the instruction documents found in ASTP's Standards Implementation & Testing Environment (SITE): C-CDA Validators - USCDI v1 for the criteria being certified.

Required by December 31, 2025
Data Entry

1. Based upon the criteria for which the Health IT Module is certifying (e.g. transition of care, care plan), the user enters the appropriate clinical information for the certifying criteria into the Health IT Module.

C-CDA Creation

2. Using the Health IT Module, the user creates a data file formatted in accordance with the standard specified in § 170.205(a)(4) and § 170.205(a)(6) and includes the appropriate document templates and content for the certifying criteria, being tested, including at a minimum the data definition in (g)(6)(i)(B), in order to match a gold-standard, reference data file for each applicable C-CDA document-template.
3. The C-CDA document created in step 2 is submitted to the tester for verification.
4. Based upon the health IT settings (i.e. ambulatory and/or inpatient), the user repeats steps 1-3, for each of the instruction documents found in ASTP's Standards Implementation & Testing Environment (SITE): C-CDA Validators – USCDI v3 for the criteria being certified.

Test Lab Verification

4. As required by the criteria instruction document downloaded in step 1, of the System Under Test, the tester uses the ASTP/ONC-supplied certifying criteria instructions and the Message Content Report produced by the SITE: C-CDA Validators - USCDI v1 in step 2, to verify the additional checks for equivalent text for the content of all section level narrative text.

Required by December 31, 2025
Data Entry

1. Using the criteria instruction document downloaded in step 1, of the System Under Test, the tester verifies the clinical summary information for the criteria entered into the Health IT Module is accurate and without omission using visual inspection.

C-CDA Creation

2. For each file submitted in step 3, of the System Under Test, the tester uses the SITE: C-CDA Validator – USCDI v3 to upload the submitted C-CDA document through the sender upload selection of the criteria being certified along with the file name and executes the upload of the submitted file.
3. For each uploaded file in step 2, the tester uses the Validation Report produced by the SITE: C-CDA Validator – USDCI v3 to verify the validation report indicates the certifying criteria is conformant to the standard specified in § 170.205(a)(4) and § 170.205(a)(6), and includes the required data elements specified by the standard for the certifying criteria, including at a minimum the data definition in (g)(6)(i)(B) in order to match the gold-standard, reference data file.

System Under Test	Test Lab Verification
	4. As required by the criteria instruction document downloaded in step 1, of the System Under Test, the tester uses the ASTP/ONC-supplied certifying criteria instructions and the Message Content Report produced by the SITE: C-CDA Validator – USCDI v3 in step 2, to verify the additional checks for equivalent text for the content of all section level narrative text.

Paragraph (g)(6)(iii)(A) and (B) Document-template conformance

System Under Test

Expires on January 1, 2026
Data Entry

1. Based upon the criteria for which the Health IT Module is certifying, the user enters the appropriate clinical information into the Health IT Module. (This data was entered in section (g)(6)(ii)(A) step 1).

C-CDA Creation

2. The user uses the Health IT Module to create data files formatted in accordance with the standard specified in § 170.205(a)(4) and § 170.205(a)(5) HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, and includes the appropriate document templates and content for the certifying criteria being tested, including at a minimum the data definition in section (g)(6)(i)(A), for the applicable C-CDA document templates. (These C-CDA documents were created and submitted to the Test Lab for verification in section (g)(6)(ii)(A) step 3).

Required by December 31, 2025
Data Entry

1. Based upon the criteria for which the Health IT Module is certifying, the user enters the appropriate clinical information into the Health IT Module. (This data was entered in section (g)(6)(ii)(B) step 1).

C-CDA Creation

2. The user uses the Health IT Module to create data files formatted in accordance with the standard specified in § 170.205(a)(4) and § 170.205(a)(6) HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1, and includes the appropriate document templates and content for the certifying criteria being tested, including at a minimum the data definition in section (g)(6)(i)(B), for the applicable C-CDA document templates. (These C-CDA documents were created and submitted to the Test Lab for verification in section (g)(6)(ii)(B) step 3).

Test Lab Verification

Expires on January 1, 2026
Data Entry

1. For each file submitted, the tester verifies that the certifying criteria information entered into the Health IT Module is accurate and without omission using visual inspection. This validation may have been done as part of the verification done in section (g)(6)(ii)(A) step 1.

C-CDA Creation

2. For each uploaded file in section (g)(6)(ii)(A) step 3, the tester verifies a certifying criteria document can be created for the certifying criteria using the validation report to review the document-templates and that:
    - The validation report indicates passing without error to confirm that a C-CDA Release 2.1, document can be created, that each document type is conformant to the standard specified in § 170.205(a)(4) and § 170.205(a)(5), and that the document contains the applicable data elements for the certifying criteria, including at a minimum the data definition in section (g)(6)(i)(A). (This validation may have been done as part of the verification done in section (g)(6)(ii)(A) step 3).
    - As required by the criteria instruction document downloaded in section (g)(6)(ii)(A) step 1, of the System Under Test, the tester uses the ASTP/ONC-supplied summary instructions and the Message Content Report produced by the SITE: C-CDA Validator - USCDI v1 in section (g)(6)(ii)(A) step 2, to verify the additional checks for equivalent text for the content of all section-level narrative text. (This validation may have been done as part of the verification done in section (g)(6)(ii)(A) step 4).

Required by December 31, 2025
Data Entry

1. For each file submitted, the tester verifies the certifying criteria information entered into the Health IT Module is accurate and without omission using visual inspection. This validation may have been done as part of the verification done in section (g)(6)(ii)(B) step 1.

C-CDA Creation

2. For each uploaded file in section (g)(6)(ii)(A) step 3, the tester verifies a certifying criteria document can be created for the certifying criteria using the validation report to review the document-templates and that:

- The validation report indicates passing without error to confirm that a C-CDA Release 2.1, document can be created, that each document type is conformant to the standard specified in § 170.205(a)(4) and § 170.205(a)(6), and that the document contains the applicable data elements for the certifying criteria, including at a minimum the data definition in section (g)(6)(i)(A). (This validation may have been done as part of the verification done in section (g)(6)(ii)(B) step 3).
- As required by the criteria instruction document downloaded in section (g)(6)(ii)(A) step 1, of the System Under Test, the tester uses the ASTP/ONC-supplied summary instructions and the Message Content Report produced by the SITE: C-CDA Validator – USCDI v3 in section (g)(6)(ii)(A) step 2, to verify the additional checks for equivalent text for the content of all section-level narrative text. (This validation may have been done as part of the verification done in section (g)(6)(ii)(A) step 4).

System Under Test

Expires on January 1, 2026
Data Entry

1. Based upon the criteria for which the Health IT Module is certifying, the user enters the appropriate clinical information into the Health IT Module. (This data was entered in section (g)(6)(ii)(A) step 1).

C-CDA Creation

Test Lab Verification

Expires on January 1, 2026
Data Entry

1. For each file submitted, the tester verifies that the certifying criteria information entered into the Health IT Module is accurate and without omission using visual inspection. This validation may have been done as part of the verification done in section (g)(6)(ii)(A) step 1.

C-CDA Creation

System Under Test

2. The user uses the Health IT Module to create data files formatted in accordance with the standard specified in § 170.205(a)(4) and § 170.205(a)(5) HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, and includes the appropriate document templates and content for the certifying criteria being tested, including at a minimum the data definition in section (g)(6)(i)(A), for the applicable C-CDA document templates. (These C-CDA documents were created and submitted to the Test Lab for verification in section (g)(6)(ii)(A) step 3).

Required by December 31, 2025
Data Entry

1. Based upon the criteria for which the Health IT Module is certifying, the user enters the appropriate clinical information into the Health IT Module. (This data was entered in section (g)(6)(ii)(B) step 1).

C-CDA Creation

2. The user uses the Health IT Module to create data files formatted in accordance with the standard specified in § 170.205(a)(4) and § 170.205(a)(6) HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1, and includes the appropriate document templates and content for the certifying criteria being tested, including at a minimum the data definition in section (g)(6)(i)(B), for the applicable C-CDA document templates. (These C-CDA documents were created and submitted to the Test Lab for verification in section (g)(6)(ii)(B) step 3).

Test Lab Verification

2. For each uploaded file in section (g)(6)(ii)(A) step 3, the tester verifies a certifying criteria document can be created for the certifying criteria using the validation report to review the document-templates and that:
    - The validation report indicates passing without error to confirm that a C-CDA Release 2.1, document can be created, that each document type is conformant to the standard specified in § 170.205(a)(4) and § 170.205(a)(5), and that the document contains the applicable data elements for the certifying criteria, including at a minimum the data definition in section (g)(6)(i)(A). (This validation may have been done as part of the verification done in section (g)(6)(ii)(A) step 3).
    - As required by the criteria instruction document downloaded in section (g)(6)(ii)(A) step 1, of the System Under Test, the tester uses the ASTP/ONC-supplied summary instructions and the Message Content Report produced by the SITE: C-CDA Validator - USCDI v1 in section (g)(6)(ii)(A) step 2, to verify the additional checks for equivalent text for the content of all section-level narrative text. (This validation may have been done as part of the verification done in section (g)(6)(ii)(A) step 4).

Required by December 31, 2025
Data Entry

System Under Test

Test Lab Verification

1. For each file submitted, the tester verifies the certifying criteria information entered into the Health IT Module is accurate and without omission using visual inspection. This validation may have been done as part of the verification done in section (g)(6)(ii)(B) step 1.

C-CDA Creation

2. For each uploaded file in section (g)(6)(ii)(A) step 3, the tester verifies a certifying criteria document can be created for the certifying criteria using the validation report to review the document-templates and that:

- The validation report indicates passing without error to confirm that a C-CDA Release 2.1, document can be created, that each document type is conformant to the standard specified in § 170.205(a)(4) and § 170.205(a)(6), and that the document contains the applicable data elements for the certifying criteria, including at a minimum the data definition in section (g)(6)(i)(A). (This validation may have been done as part of the verification done in section (g)(6)(ii)(B) step 3).
- As required by the criteria instruction document downloaded in section (g)(6)(ii)(A) step 1, of the System Under Test, the tester uses the ASTP/ONC-supplied summary instructions and the Message Content Report produced by the SITE: C-CDA Validator – USCDI v3 in section (g)(6)(ii)(A) step 2, to verify the additional checks for equivalent text for the content of all section-level narrative text. (This validation may have been done as part of the verification done in section (g)(6)(ii)(A) step 4).

Paragraph (g)(6)(iv)(A) and (B) Vocabulary conformance

System Under Test

Expires on January 1, 2026
If the certifying criteria information was not already entered in sections (g)(6)(ii)(A) or (g)(6)(iii)(A), based upon the health IT setting(s) (i.e. ambulatory and/or inpatient), the user: enters the appropriate clinical information for the certifying criteria documents into the Health IT Module; creates a data file formatted in accordance with the standard specified in § 170.205(a)(4) and § 170.205(a)(5); and includes the appropriate document templates, content, vocabularies, and value-sets for the certifying criteria being tested, including at a minimum the data definition in section (g)(6)(i)(A), in order to demonstrate vocabulary conformance.

Required by December 31, 2025
If the certifying criteria information was not already entered in sections (g)(6)(ii)(B) or (g)(6)(iii)(B), based upon the health IT setting(s) (i.e. ambulatory and/or inpatient), the user: enters the appropriate clinical information for the certifying criteria documents into the Health IT Module; creates a data file formatted in accordance with the standard specified in § 170.205(a)(4) and § 170.205(a)(6); and includes the appropriate document templates, content, vocabularies, and value-sets for the certifying criteria being tested, including at a minimum the data definition in section (g)(6)(i)(B), in order to demonstrate vocabulary conformance.

Test Lab Verification

Expires on January 1, 2026
The validation of the vocabulary conformance is done as part of the document template conformance performed in section (g)(6)(iii)(A) step 2 and verifies the validity of the vocabularies associated with the data elements as well as the data element value being from the required value-set(s).

Required by December 31, 2025
The validation of the vocabulary conformance is done as part of the document template conformance performed in section (g)(6)(iii)(B) step 2 and verifies the validity of the vocabularies associated with the data elements as well as the data element value being from the required value-set(s).

System Under Test	Test Lab Verification

System Under Test	Test Lab Verification
Expires on January 1, 2026 If the certifying criteria information was not already entered in sections (g)(6)(ii)(A) or (g)(6)(iii)(A), based upon the health IT setting(s) (i.e. ambulatory and/or inpatient), the user: enters the appropriate clinical information for the certifying criteria documents into the Health IT Module; creates a data file formatted in accordance with the standard specified in § 170.205(a)(4) and § 170.205(a)(5); and includes the appropriate document templates, content, vocabularies, and value-sets for the certifying criteria being tested, including at a minimum the data definition in section (g)(6)(i)(A), in order to demonstrate vocabulary conformance. **Required by December 31, 2025** If the certifying criteria information was not already entered in sections (g)(6)(ii)(B) or (g)(6)(iii)(B), based upon the health IT setting(s) (i.e. ambulatory and/or inpatient), the user: enters the appropriate clinical information for the certifying criteria documents into the Health IT Module; creates a data file formatted in accordance with the standard specified in § 170.205(a)(4) and § 170.205(a)(6); and includes the appropriate document templates, content, vocabularies, and value-sets for the certifying criteria being tested, including at a minimum the data definition in section (g)(6)(i)(B), in order to demonstrate vocabulary conformance.	**Expires on January 1, 2026** The validation of the vocabulary conformance is done as part of the document template conformance performed in section (g)(6)(iii)(A) step 2 and verifies the validity of the vocabularies associated with the data elements as well as the data element value being from the required value-set(s). **Required by December 31, 2025** The validation of the vocabulary conformance is done as part of the document template conformance performed in section (g)(6)(iii)(B) step 2 and verifies the validity of the vocabularies associated with the data elements as well as the data element value being from the required value-set(s).

Paragraph (g)(6)(v) Completeness verification

System Under Test

In order to demonstrate the completeness of the created C-CDA document, if the certifying criteria information was not already entered in sections (g)(6)(ii) or (g)(6)(iii), the user enters the certifying criteria information for the certifying criteria documents into the Health IT Module. The information entered into the Health IT Module must include all of the required data elements for the certifying criteria including at a minimum the data definition in section (g)(6)(i) (e.g., transitions of care summary record or care plan), where applicable.

Test Lab Verification

The validation of the completeness verification is done as part of the document template conformance performed in section (g)(6)(iii) steps 3 and 4 and verifies that the content of the submitted document is complete and without omission.

System Under Test	Test Lab Verification
In order to demonstrate the completeness of the created C-CDA document, if the certifying criteria information was not already entered in sections (g)(6)(ii) or (g)(6)(iii), the user enters the certifying criteria information for the certifying criteria documents into the Health IT Module. The information entered into the Health IT Module must include all of the required data elements for the certifying criteria including at a minimum the data definition in section (g)(6)(i) (e.g., transitions of care summary record or care plan), where applicable.	The validation of the completeness verification is done as part of the document template conformance performed in section (g)(6)(iii) steps 3 and 4 and verifies that the content of the submitted document is complete and without omission.

Archived Version:
§ 170.315(g)(6) Consolidated CDA creation performance TP

Updated on 03-27-2025

Regulation Text

Regulation Text

§ 170.315 (g)(6) *Consolidated CDA creation performance—*

The following technical and performance outcomes must be demonstrated related to Consolidated CDA creation. The capabilities required under paragraphs (g)(6)(i) through (v) of this section can be demonstrated in tandem and do not need to be individually addressed in isolation or sequentially.

1. This certification criterion's scope includes:
    1. The data classes expressed in the standard in § 170.213, and in accordance with § 170.205(a)(4) and (5), and the paragraphs (g)(6)(i)(*C*)(*1*)-(4) of this section for the time period up to and including December 31, 2025; or
    2. The data classes expressed in the standards in § 170.213, and in accordance with § 170.205(a)(4) and (6) and paragraphs (g)(6)(i)(C)(1) through (3) of this section

2. The following data classes:
    1. *Assessment and plan of treatment.* In accordance with the “Assessment and Plan Section (V2)” of the standard specified in § 170.205(a)(4); or in accordance with the “Assessment Section (V2)” and “Plan of Treatment Section (V2)” of the standard specified in § 170.205(a)(4).
    2. *Goals.* In accordance with the “Goals Section” of the standard specified in § 170.205(a)(4).
    3. *Health concerns.* In accordance with the “Health Concerns Section” of the standard specified in § 170.205(a)(4).
    4. *Unique device identifier(s) for a patient’s implantable device(s).* In accordance with the “Product Instance” in the “Procedure Activity Procedure Section” of the standard specified in § 170.205(a)(4)
3. *Reference C-CDA match*.
    1. For a health IT certified to (g)(6)(i)(A) of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) and (5) that matches a gold-standard, reference data file.
    2. For health IT certified to (g)(6)(i)(B*)* of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that matches a gold-standard, reference data file.
4. *Document-template conformance.*
    1. For a health IT certified to (g)(6)(i)(A) of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) and (5) that demonstrates a valid implementation of each document template applicable to the certification criterion or criteria within the scope of the certificate sought.
    2. For health IT certified to (g)(6)(i)(B*)* of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that demonstrates a valid implementation of each document template applicable to the certification criterion or criteria within the scope of the certificate sought.
5. *Vocabulary conformance.*
    1. For a health IT certified to (g)(6)(i)(A) of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) and (5) that demonstrates the required vocabulary standards (and value sets) are properly implemented.
    2. For health IT certified to (g)(6)(i)(B*)* of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that demonstrates the vocabulary standards (and value sets) are properly implemented.
5. *Completeness verification*. Create a data file for each of the applicable document templates referenced in paragraph (g)(6)(ii) of this section without the omission of any of the data included in either (g)(6)(i)(A) or (B) of this section, as applicable.

Standard(s) Referenced

Applies to entire criterion

§ 170.213(a) United States Core Data for Interoperability (USCDI), July 2020 Errata, Version 1 (v1) (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)(4) Health Level 7 (HL7®) Implementation Guide (IG) for CDA® Release 2 Consolidation CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1 C-CDA 2.1, August 2015, June 2019 (with Errata)

§ 170.205(a)(5) Health Level 7 (HL7®) CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019 (Adoption of this standard expires on January 1, 2026.)

§ 170.205(a)(6) Health Level 7 (HL7®) CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1 - US Realm (This standard is required by December 31, 2025.)

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 must update to the new versions of the standards for USCDI and C-CDA Companion Guide as outlined in the subparagraph (g)(6)(i)(A-B).

Certification Dependencies

This certification criterion was adopted at § 170.315(g)(6) and is required for all developers seeking certification to certification criteria with Consolidated Clinical Document Architecture (C-CDA) creation capabilities (i.e., § 170.315(b)(1), (b)(2), (b)(9), (e)(1), and (g)(9)).

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.

- 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, the QMS' need to be 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.

Privacy & Security Requirements

There are no associated required privacy and security criterion for this criterion at § 170.315(g)(6).

Revision History

Version #	Description of Change	Version Date
1.0	Initial publication	03-11-2024
1.1	Updated test steps with new SITE UI language	03-21-2025

Regulation Text

Regulation Text

§ 170.315 (g)(6) *Consolidated CDA creation performance*—

The following technical and performance outcomes must be demonstrated related to Consolidated CDA creation. The capabilities required under paragraphs (g)(6)(i) through (v) of this section can be demonstrated in tandem and do not need to be individually addressed in isolation or sequentially.

1. This certification criterion's scope includes:
    1. The data classes expressed in the standard in § 170.213, and in accordance with § 170.205(a)(4) and (5), and the paragraphs (g)(6)(i)(*C*)(*1*)-(4) of this section for the time period up to and including December 31, 2025; or
    2. The data classes expressed in the standards in § 170.213, and in accordance with § 170.205(a)(4) and (6) and paragraphs (g)(6)(i)(C)(1) through (3) of this section

2. The following data classes:
    1. *Assessment and plan of treatment.* In accordance with the “Assessment and Plan Section (V2)” of the standard specified in § 170.205(a)(4); or in accordance with the “Assessment Section (V2)” and “Plan of Treatment Section (V2)” of the standard specified in § 170.205(a)(4).
    2. *Goals.* In accordance with the “Goals Section” of the standard specified in § 170.205(a)(4).
    3. *Health concerns.* In accordance with the “Health Concerns Section” of the standard specified in § 170.205(a)(4).
    4. *Unique device identifier(s) for a patient’s implantable device(s).* In accordance with the “Product Instance” in the “Procedure Activity Procedure Section” of the standard specified in § 170.205(a)(4)
3. *Reference C-CDA match*.
    1. For a health IT certified to (g)(6)(i)(A) of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) and (5) that matches a gold-standard, reference data file.
    2. For health IT certified to (g)(6)(i)(B*)* of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that matches a gold-standard, reference data file.
4. *Document-template conformance.*
    1. For a health IT certified to (g)(6)(i)(A) of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) and (5) that demonstrates a valid implementation of each document template applicable to the certification criterion or criteria within the scope of the certificate sought.
    2. For health IT certified to (g)(6)(i)(B*)* of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that demonstrates a valid implementation of each document template applicable to the certification criterion or criteria within the scope of the certificate sought.
5. *Vocabulary conformance.*
    1. For a health IT certified to (g)(6)(i)(A) of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) and (5) that demonstrates the required vocabulary standards (and value sets) are properly implemented.
    2. For health IT certified to (g)(6)(i)(B*)* of this section, create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that demonstrates the vocabulary standards (and value sets) are properly implemented.
5. *Completeness verification*. Create a data file for each of the applicable document templates referenced in paragraph (g)(6)(ii) of this section without the omission of any of the data included in either (g)(6)(i)(A) or (B) of this section, as applicable.

Standard(s) Referenced

Applies to entire criterion

§ 170.213(a) United States Core Data for Interoperability (USCDI), July 2020 Errata, Version 1 (v1) (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)(4) Health Level 7 (HL7®) Implementation Guide (IG) for CDA® Release 2 Consolidation CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1 C-CDA 2.1, August 2015, June 2019 (with Errata)

§ 170.205(a)(5) Health Level 7 (HL7®) CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019 (Adoption of this standard expires on January 1, 2026.)

§ 170.205(a)(6) Health Level 7 (HL7®) CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1 - US Realm (This standard is required by December 31, 2025.)

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 must update to the new versions of the standards for USCDI and C-CDA Companion Guide as outlined in the subparagraph (g)(6)(i)(A-B).

Certification Dependencies

This certification criterion was adopted at § 170.315(g)(6) and is required for all developers seeking certification to certification criteria with Consolidated Clinical Document Architecture (C-CDA) creation capabilities (i.e., § 170.315(b)(1), (b)(2), (b)(9), (e)(1), and (g)(9)).

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.

- 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, the QMS' need to be 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.

Privacy & Security Requirements

There are no associated required privacy and security criterion for this criterion at § 170.315(g)(6).

Revision History

Version #	Description of Change	Version Date
1.0	Initial publication	03-11-2024
1.1	Removed reference to removed criteria § 170.315(b)(4) and (b)(6) in the Design and Performance Certification Dependencies, which were previously included in error.	03-27-2024
1.2	Added Design and Performance requirements under Certification Dependencies, as they were excluded in error from the initial publication.	05-31-2024
1.3	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

Criterion Subparagraph	Test Data
(g)(6)(i)	Sample gold standard C-CDA documents are available on an ONC-maintained repository: https://github.com/onc-healthit/2015-edition-cures-update-data The C-CDA Data set to be used corresponds to the criteria for which the Health IT Module is certifying. For example, if the Health IT Module is certifying to § 170.315(b)(1) Transitions of care, the following C-CDA validation documents would be used: Inpatient Setting: 170.315_b1_toc_inp_sample*.pdf (All Samples) Ambulatory Setting: 170.315_b1_toc_amb_sample*.pdf (All Samples)

Certification Companion Guide: Consolidated CDA creation performance

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	No	No	No	Yes

Certification Requirements

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:

- The specific requirements in provisions (g)(6)(i)-(iv) can be demonstrated in tandem.
- This certification criterion focuses on the data expressed in the USCDI.

- If the scope of the certification includes more than one certification criterion with C-CDA creation required, C-CDA creation performance only has to be demonstrated once for each C-CDA document template (e.g., C-CDA creation performance to the Continuity of Care Document (CCD) template would not have to be demonstrated twice if the Health IT Module presents for certification to both the Transitions of care and Data export criteria). [see also 80 FR 62674]
- In combination with the C-CDA R2.1 standard, developers certifying to the USCDI must follow the guidance and templates provided in HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2 Companion Guide, Release 2, for implementation of the C-CDA Release 2.1 standard for the period leading up to and including December 31, 2025 or must follow guidance and templates provided in HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2 Companion Guide, Release 4.1. For example, details on how to structure and exchange Clinical Notes are included in the C-CDA Companion Guide.
- In order to mitigate potential interoperability errors and inconsistent implementation of the HL7® IG 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 Health IT Certification Program Overview] Certified health IT adoption and compliance with the following corrections are necessary because they implement updates to 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.
- C-CDA files created during testing (using test data) will be retained by National Voluntary Laboratory Accreditation Program (NVLAP)-Accredited Testing Labs and contributed to an ONC-maintained repository. [see also 80 FR 62675]
- 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 specific requirements in provisions (g)(6)(i)-(iv) can be demonstrated in tandem.
- This certification criterion focuses on the data expressed in the USCDI.
- If the scope of the certification includes more than one certification criterion with C-CDA creation required, C-CDA creation performance only has to be demonstrated once for each C-CDA document template (e.g., C-CDA creation performance to the Continuity of Care Document (CCD) template would not have to be demonstrated twice if the Health IT Module presents for certification to both the Transitions of care and Data export criteria). [see also 80 FR 62674]
- In combination with the C-CDA R2.1 standard, developers certifying to the USCDI must follow the guidance and templates provided in HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2 Companion Guide, Release 2, for implementation of the C-CDA Release 2.1 standard for the period leading up to and including December 31, 2025 or must follow guidance and templates provided in HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R2 Companion Guide, Release 4.1. For example, details on how to structure and exchange Clinical Notes are included in the C-CDA Companion Guide.
- In order to mitigate potential interoperability errors and inconsistent implementation of the HL7® IG 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 Health IT Certification Program Overview] Certified health IT adoption and compliance with the following corrections are necessary because they implement updates to 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.
- C-CDA files created during testing (using test data) will be retained by National Voluntary Laboratory Accreditation Program (NVLAP)-Accredited Testing Labs and contributed to an ONC-maintained repository. [see also 80 FR 62675]
- 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 (g)(6)(i) Certification scope

Technical outcome – The health IT can create a C-CDA file in accordance with the HL7® C-CDA Release 2.1 IG for each document template applicable to the certification criteria within the scope of the certification.

Clarifications:

No additional clarifications.

Technical outcome – The health IT can create a C-CDA file in accordance with the HL7® C-CDA Release 2.1 IG for each document template applicable to the certification criteria within the scope of the certification.

Clarifications:

No additional clarifications.

Paragraph (g)(6)(ii) Reference C-CDA match

Technical outcome – The health IT can create a C-CDA file in accordance with the HL7® C-CDA Release 2.1 IG that matches a gold-standard, reference data file.

Clarifications:

- Sample gold standard C-CDA documents are available on an ONC-maintained repository. [see also 80 FR 62675]
- On the gold standard match, the exact match is expected for the coded test data provided to the system under test for creation. In other words, the developer-submitted C-CDA will be matched with a gold standard C-CDA for the test data that is provided to the developer.

Technical outcome – The health IT can create a C-CDA file in accordance with the HL7® C-CDA Release 2.1 IG that matches a gold-standard, reference data file.

Clarifications:

- Sample gold standard C-CDA documents are available on an ONC-maintained repository. [see also 80 FR 62675]
- On the gold standard match, the exact match is expected for the coded test data provided to the system under test for creation. In other words, the developer-submitted C-CDA will be matched with a gold standard C-CDA for the test data that is provided to the developer.

Paragraph (g)(6)(iii) Document-template conformance

Technical outcome – The health IT can create a C-CDA file in accordance with the HL7® C-CDA Release 2.1 IG that shows the required vocabulary standards and that value sets are properly implemented.

Clarifications:

No additional clarifications.

Technical outcome – The health IT can create a C-CDA file in accordance with the HL7® C-CDA Release 2.1 IG that shows the required vocabulary standards and that value sets are properly implemented.

Clarifications:

No additional clarifications.

Paragraph (g)(6)(iv) Vocabulary conformance

Technical outcome – The health IT can create a C-CDA file in accordance with the HL7® C-CDA Release 2.1 IG that includes at a minimum all of the data classes in the USCDI.

Clarifications:

This provision intends to ensure that the data entered into the health IT system (via whatever workflow and functionality) can be reflected in a C-CDA file created by the system and not be missing data a user otherwise recorded. [see also 80 FR 62675]

Technical outcome – The health IT can create a C-CDA file in accordance with the HL7® C-CDA Release 2.1 IG that includes at a minimum all of the data classes in the USCDI.

Clarifications:

This provision intends to ensure that the data entered into the health IT system (via whatever workflow and functionality) can be reflected in a C-CDA file created by the system and not be missing data a user otherwise recorded. [see also 80 FR 62675]

Paragraph (g)(6)(v) Completeness verification

Technical outcome – The health IT can create a data file for each of the applicable document templates referenced in paragraph (g)(6)(iii) of this section without the omission of any of the data included in (g)(6)(i)(A) or (B) of this section, as applicable.

Clarifications:

No additional clarifications.

Technical outcome – The health IT can create a data file for each of the applicable document templates referenced in paragraph (g)(6)(iii) of this section without the omission of any of the data included in (g)(6)(i)(A) or (B) of this section, as applicable.

Clarifications:

No additional clarifications.

Archived Version:

§ 170.315(g)(6) Consolidated CDA creation performance CCG