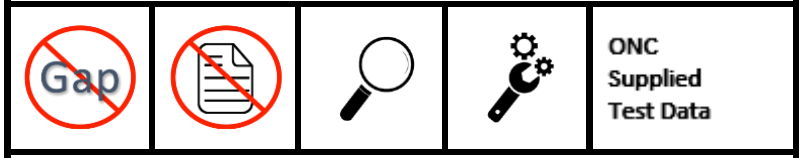
§ 170.315(g)(6) Consolidated CDA creation performance

Testing Components:



Test Procedure **Version 1.0** – Last **Updated on 01-03-2024**

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. 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.

Revision History

Version #	Description of Change	Version Date
1.0	Public Comment	01-03-2024

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.

(i) This certification criterion's scope includes:

(A) 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

(B) 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.

(C) 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).

(ii) *Reference C-CDA match*.

(A) 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.

(B) 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.

(iii) *Document-template conformance.*

(A) 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.

(B) 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.

(iv) *Vocabulary conformance.*

(A) 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.

(B) 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.

(v) *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), Version 1 (expires on January 1, 2026)

§ 170.213(b) United States Core Data for Interoperability (USCDI), October 2022 Errata, Version 3 (v3)

§ 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) 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). (expires on January 1, 2026)

§ 170.205(a)(6) HL7® CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes STU Companion Guide, Release 4.1 - US Realm

Required Tests

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).

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

December 31, 2025 Requirements

System Under Test	ONC-ACB Verification
The health IT developer of 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.	The ONC-ACB verifies the health IT developer of a 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)(A) Criteria scope

System Under Test	Test Lab Verification
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:	**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

System Under Test	Test Lab Verification
• 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)(4)(i) HL7® CDA® R2 IG: C-CDA Templates for Clinical Notes R1 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.	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.

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

System Under Test	Test Lab Verification
Current Requirements **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	**Current Requirements** **Data Entry** 1. Using the criteria instruction document downloaded in step 1, of the System Under Test, the tester verifies the clinical summary

System Under Test	Test Lab Verification
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 Edge Testing Tool (ETT): Message Validators – C-CDA R2.1 Validator for the criteria being certified. ***December 31, 2025 Requirements*** **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 §	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 ETT: Message Validators –C-CDA R2.1 Validator 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 ETT: Message Validators –C-CDA R2.1 Validator 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 ONC-supplied certifying criteria instructions and the Message Content Report produced by the ETT: Message Validators –C-CDA R2.1 Validator in step 2, to verify the additional checks for equivalent text for the content of all section level narrative text. ***December 31, 2025 Requirements*** **Data Entry** 5. Using the criteria instruction document downloaded in step 1, of the System Under Test, the tester verifies the clinical summary

System Under Test	Test Lab Verification
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)(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 Edge Testing Tool (ETT): Message Validators – C-CDA R2.1 Validator for the criteria being certified.	information for the criteria entered into the Health IT Module is accurate and without omission using visual inspection. **C-CDA Creation** 6. For each file submitted in step 3, of the System Under Test, the tester uses the ETT: Message Validators –C-CDA R2.1 Validator 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. 7. For each uploaded file in step 2, the tester uses the Validation Report produced by the ETT: Message Validators –C-CDA R2.1 Validator 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)(A) in order to match the gold-standard, reference data file. 8. As required by the criteria instruction document downloaded in step 1, of the System Under Test, the tester uses the ONC-supplied certifying criteria instructions and the Message Content Report produced by the ETT: Message Validators –C-CDA R2.1 Validator 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	Test Lab Verification
Current Requirement **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). ***December 31, 2025 Requirement*** **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).	**Current Requirement** **Data Entry** 3. 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)(A) step 1. **C-CDA Creation** 4. 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 ONC-supplied summary instructions and the Message Content Report produced by the ETT: Message Validators –C-CDA R2.1 Validator in section (g)(6)(ii)(A) step 2, to verify the additional checks for equivalent text for the content of all

System Under Test	Test Lab Verification
C-CDA Creation 1. 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)(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).	section-level narrative text. (This validation may have been done as part of the verification done in section (g)(6)(ii)(A) step ***December 31, 2025 Requirement*** **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)(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)(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)(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 ONC-supplied summary instructions and the Message Content Report produced by the ETT: Message Validators –C-CDA R2.1

System Under Test	Test Lab Verification
	Validator 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	Test Lab Verification
Current Requirements 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. ***December 31, 2025 Requirements*** 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)(6); and includes the appropriate document templates, content, vocabularies, and value-sets for the certifying criteria being tested, including at a	***Current Requirements*** 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). ***December 31, 2025 Requirements*** 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).

System Under Test	Test Lab Verification
minimum the data definition in section (g)(6)(i)(A), in order to demonstrate vocabulary conformance.	

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

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)(A) or (g)(6)(iii)(A), 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)(A) (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.

Testing Tab

Testing Tool

Edge Testing Tool (ETT): Message Validators

Test Tool Documentation

Test Tool Supplemental Guide

Test Tool 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)