

2015 Edition §170.315(g)(6) Consolidated CDA Creation Performance					
Testing Components:					
				Data	
Test Procedure Version 1.1 – Last Updated 10/30/15					

Please consult the Final Rule entitled: *2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications* for a detailed description of the certification criterion with which these testing steps are associated. We also encourage developers to consult the Certification Companion Guide in tandem with the test procedure as they provide clarifications that may be useful for product development and testing.

Note: The order in which the test steps are listed reflects the sequence of the certification criterion and does not necessarily prescribe the order in which the test should take place.

Required Tests

(g)(6)(i) Reference C-CDA Match

Create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that matches a gold-standard, reference data file.

Standard(s): § 170.205(a)(4) [HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1](#) (incorporated by reference in § 170.299).

§ 170.207(b)(3) [CDI](#)

§ 170.207(b)(2) [CPT-4](#)

§ 170.207(f)(2) [“Race & Ethnicity – CDC” code system in the PHIN Vocabulary Access and Distribution System \(VADS\), Release 3.3.9](#)

§ 170.207(e)(4) [National Drug Code Directory– Vaccine Codes, updates through August 3, 2015](#)

§ 170.207(b)(4) [ICD-10-PCS](#)

§ 170.207(i) [ICD-10-CM](#)

§ 170.207(e)(3) [HL7 Standard Code Set CVX—Vaccines Administered, updates through June 18, 2015](#)

§ 170.207(f)(1) [The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997](#)

§ 170.207(c)(3) [Logical Observation Identifiers Names and Codes \(LOINC®\) Database version 2.52](#)

§ 170.207(m)(1) [The Unified Code of Units of Measure, Revision 1.9](#)

§ 170.207(g)(2) [Request for Comments \(RFC\) 5646: Tags for Identifying Languages](#)

§ 170.207(q)(1) [International Telecommunication Union E.123:Notation for national and international telephone numbers, e-mail addresses and web addresses and International](#) and [Telecommunication Union E. 164: The international public telecommunication numbering plan](#)

§ 170.207(a)(4) [International Health Terminology Standards Development Organisation \(IHTSDO\) Systematized Nomenclature of Medicine Clinical Terms \(SNOMED CT®\), U.S. Edition, September 2015 Release,](#)

§ 170.207(d)(3) [RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release](#)

§ 170.207(h) Smoking status must be coded in one of the following SNOMED CT® codes:

- (1) Current every day smoker. 449868002
- (2) Current some day smoker. 428041000124106
- (3) Former smoker. 8517006
- (4) Never smoker. 266919005
- (5) Smoker, current status unknown. 77176002
- (6) Unknown if ever smoked. 266927001
- (7) Heavy tobacco smoker. 428071000124103
- (8) Light tobacco smoker. 428061000124105

§ 170.207(n)(1) Birth sex must be coded in accordance with HL7 Version 3 attributed as follows:

- (i) Male. M
- (ii) Female. F
- (iii) Unknown. UNK

Test 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 CCD 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)

Test Tool: [C-CDA Validator tool](#)

The following technical and performance outcomes must be demonstrated related to Consolidated CDA creation. The capabilities required under paragraphs (g)(6)(i) through (iv) 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 Common Clinical Data Set definition.

Criteria ¶	System Under Test	Test Lab Verification
(i)	<ol style="list-style-type: none"> 1. Based upon the criteria for which the Health IT module is certifying (e.g. ambulatory transition of care, inpatient summary record), a user enters the appropriate clinical information for each of the ambulatory and/or inpatient test cases referenced in the certifying criteria into the Health IT module. All test cases for a given health IT setting are required. The user retrieves the required criteria instructions for entering data into the Health IT module from the top-level C-CDA Validator, one of the tool selections within the Edge Testing Tool. 2. Using the C-CDA Validator, the user selects the appropriate criteria and health IT settings (e.g. ambulatory and/or inpatient CCDS documents (pdf)) and selects download to download the required clinical information documents. 3. The user uses the Health IT module to create a data file formatted in accordance with the standard specified in § 170.205(a)(4), HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, Release 2.1, and includes the appropriate document templates and content for the certifying criteria being tested in order to match a gold-standard, reference data file for each applicable C-CDA document template, including variants to test optionality, matches a gold-standard reference data file for each applicable C-CDA document template. 	<ol style="list-style-type: none"> 1. For each test case, the tester verifies that the clinical summary information for the criteria entered into the Health IT module is accurate and without omission using visual inspection. 2. For each test case, the tester verifies that a document can be created for each of the certifying criteria using the Health IT module. 3. Validation of the record for each certifying criteria is done using the top – level C-CDA Validator, one of the tool selections within the Edge Testing Tool. To validate the certifying criteria document (xml file) created by the Health IT module, the tester uses the C-CDA Validator Tool within the Edge Testing Tool to select the criteria to be verified based upon the originally downloaded test case document and uploads the record (xml file) created by the Health IT module. 4. For each test case, the tester uploads the submitted certifying criteria record xml file into the top-level C-CDA Validator Tool within the Edge Testing Tool and uses the Reference Match feature for the criteria being certified for each test case listed and selects validate on the C-CDA Validator menu. 5. For each test case in step 4, the tester uses the Validation Report produced by the test tool to verify the validation report indicates the certifying criteria is conformant to the standard specified in § 170.205(a)(4) and includes the required data elements constrained according to the specified standard for the certifying criteria in order to match the gold-standard, reference data file. 6. As required by the test case, the tester uses the ONC-supplied certifying criteria instructions and the document uploaded in step 3 to verify through visual inspection the additional checks for equivalent text for content for all section level narrative text.

(ii) Document Template Conformance

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. The scope of this certification criterion will not exceed the evaluation of the CCD, Referral Note, and Discharge Summary document templates.

Criteria ¶	System Under Test	Test Lab Verification
(ii)	<ol style="list-style-type: none"> 1. Based upon the criteria for which the Health IT module is certifying (e.g. ambulatory transition of care, care plan, etc.), a user enters the appropriate clinical information for each of the ambulatory and/or inpatient test cases referenced from the certifying criteria documents into the Health IT module. All test cases for a given health IT setting are required. (This data was entered in (g)(6)(i) step 1.) 2. The user uses the Health IT module to create data files formatted in accordance with the standard specified in § 170.205(a)(4), HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, Release 2.1, and includes the appropriate document templates, and content and constraints for the certifying criteria being tested for the applicable C-CDA document templates: <ul style="list-style-type: none"> • Continuity of Care (CCD); • Referral Note; and/or • Discharge Summary. 	<ol style="list-style-type: none"> 1. For each test case, 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 (g)(6)(i) step 1. 2. For each test case, the tester verifies that a certifying criteria document can be created for the certifying criteria using the Health IT module. 3. Validation of the certifying criteria record is done using the top-level C-CDA Validator Tool, one of the tool selections within the Edge Testing Tool. To validate the document (xml file) created by the Health IT module, the tester uses the C-CDA Validator Tool within the Edge Testing Tool to select the criteria to be verified based upon the originally downloaded test case document and uploads the certifying criteria record (xml file) created by the Health IT module. 4. For each test case, the tester uploads the submitted record-based xml file into the top-level C-C-CDA Validator Tool within the Edge Testing Tool and selects the certifying criteria test case to run the validation. 5. For each test case in step 4, the tester uses the Validation Report produced by the test tool to verify 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 contains the applicable data elements for the certifying criteria. 6. As required by the test case, the tester uses the ONC-supplied summary instructions and the document uploaded in step 3 to verify through visual inspection the additional checks for equivalent text for content for all section level narrative text.

(iii) Vocabulary Conformance

Create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) that demonstrates the required vocabulary standards (and value sets) are properly implemented

Criteria ¶	System Under Test	Test Lab Verification
(iii)	<ol style="list-style-type: none"> 1. If the certifying criteria information was not already entered in (g)(6)(i) or (g)(6)(ii), based upon the health IT setting(s) (i.e. ambulatory and/or inpatient), a user enters the appropriate clinical information for each of the ambulatory and/or inpatient test cases referenced from the certifying criteria documents into the Health IT module. All test cases for a given health IT setting are required. 2. If the certifying criteria documents were not already created in (g)(6)(ii), the user uses the Health IT module to create a data file formatted in accordance with the standard specified in § 170.205(a)(4), HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, Release 2.1, and includes the appropriate document templates, content, and constraints for the certifying criteria being tested in order to demonstrate vocabulary conformance. <ul style="list-style-type: none"> • Health Concerns in accordance with the “Health Concerns Section” accordance with the standard specified in § 170.205(a)(4) CDA® Release 2: DSTU, Release 2.1 	<ol style="list-style-type: none"> 1. The validation of the vocabulary conformance is done as part of the document template conformance performed in (g)(6)(ii).

(iv) 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 the Common Clinical Data Set definition.

Criteria ¶	System Under Test	Test Lab Verification
(iv)	<p>1. In order to demonstrate the completeness of the created C-CDA document, if the certifying criteria information was not already entered in (g)(6)(i) or (g)(6)(ii), a user enters the certifying criteria information for each of the ambulatory and/or inpatient test cases referenced from the certifying criteria documents into the Health IT module. All test cases for a given health IT setting are required. The information entered into the Health IT module must include all of the required Common Clinical Data Set (CCDS) data elements, where applicable, constrained as follows:</p> <ul style="list-style-type: none"> • Patient Name • Sex constrained including birth sex • Date of Birth • Race and Ethnicity • Preferred language • Smoking Status • Problems constrained • Medications constrained • Medication Allergies • Laboratory Tests constrained • Laboratory Values(s)/Result(s) • Vital Signs • Procedures constrained • Care Team Member(s) • Immunizations constrained • Unique Device Identifier(s) for a Patient’s Implantable Device(s) • Assessment and Plan of Treatment • Goals • Health Concerns <p>The complete list of the Common Clinical Data Set and associated standards can be referenced in Table 8 of the Final Rule.</p>	<p>1. The validation of the completeness verification is done as part of the document template conformance performed in (g)(6)(ii), but may need to be repeated to include without omission any of the data included in the Common Clinical Data Set definition.</p>

Document History

Version Number	Description of Change	Date
1.0	Released for Comment - NPRM	March 20, 2015
1.1	Released for Comment - FR	October 30, 2015

Dependencies: For all related and required criteria, please refer to the [Master Table of Related and Required Criteria](#).