

2015 Edition §170.315(g)(6) Consolidated CDA Creation Performance				
Testing Components:				
 Gap				ONC Supplied Test Data
Test Procedure Version 1.0 – Last Updated 1/20/16				

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.

The verification of the §170.315(g)(6) Consolidated 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) Consolidated CDA Creation Performance. The §170.315(g)(6) Consolidated CDA Creation Performance Test Procedure is provided to illustrate the tests which are performed as part of certifying for §170.315(g)(6) Consolidated CDA Creation Performance.

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).
 Data Elements and Vocabularies applicable to the C-CDA Criteria being certified

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 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)

Test Tool: ETT: Message Validators

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)	<p>Data Entry</p> <ol style="list-style-type: none"> Based upon the criteria for which the Health IT Module is certifying (e.g. transition of care, common clinical data set summary record, care plan), a user enters the appropriate clinical information for the certifying criteria into the Health IT Module. <p>C-CDA Creation</p> <ol style="list-style-type: none"> Using the Health IT Module, the user creates 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. The C-CDA document created in step 2 is submitted to the tester for verification. Based upon the health IT setting(s) (i.e. ambulatory and/or inpatient), a user repeats steps 1-3 for each of the instruction documents found in ETT: Message Validators for the criteria being certified. 	<p>Data Entry</p> <ol style="list-style-type: none"> Using the criteria instruction document downloaded in step 1 of the SUT, 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. <p>C-CDA Creation</p> <ol style="list-style-type: none"> For each file submitted in step 3 of the SUT, the tester uses the ETT: Message Validators – C-CDA R 2.1 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. For each uploaded file in step 2, the tester uses the Validation Report produced by the ETT: Message Validators 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 specified by the standard for the certifying criteria in order to match the gold-standard, reference data file. As required by the criteria instruction document downloaded in step 1 of the SUT, the tester uses the ONC-supplied certifying criteria instructions and the Message Content Report produced by the ETT: Message Validators in step 2 to verify the additional checks for equivalent text for the content of 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.

Criteria ¶	System Under Test	Test Lab Verification
(ii)	<p><u>Data Entry</u></p> <p>1. Based upon the criteria for which the Health IT Module is certifying, a user enters the appropriate clinical information into the Health IT Module. (This data was entered in section (g)(6)(i) step 1.)</p> <p><u>C-CDA Creation</u></p> <p>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 for the certifying criteria being tested 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)(i) step 3.)</p>	<p><u>Data Entry</u></p> <p>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)(i) step 1.</p> <p><u>C-CDA Creation</u></p> <p>2. For each uploaded file in section (g)(6)(i) step 3, the tester verifies that a certifying criteria document can be created for the certifying criteria using the Validation Report to review the document-templates.</p> <p>3. For each uploaded file in section (g)(6)(i) step 3, the tester uses the Validation Report produced by the ETT: Message Validators 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. (This validation may have been done as part of the verification done in section (g)(6)(i) step 3.)</p> <p>4. As required by the criteria instruction document downloaded in section (g)(6)(i) step 1 of the SUT, the tester uses the ONC-supplied summary instructions and the Message Content Report produced by the ETT: Message Validators in section (g)(6)(i) 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)(i) step 4.)</p>

(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 sections (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 the certifying criteria documents into the Health IT Module. 2. If the certifying criteria documents were not already created in section (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, vocabularies and value-sets for the certifying criteria being tested in order to demonstrate vocabulary conformance. 	<p>The validation of the vocabulary conformance is done as part of the document template conformance performed in section (g)(6)(ii) step 3 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).</p>

(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>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)(i) or (g)(6)(ii), a 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 (e.g. CCDS summary record or care plan), where applicable.</p>	<p>The validation of the completeness verification is done as part of the document template conformance performed in section (g)(6)(ii) steps 3 and 4 and verifies that the content of the submitted document is complete and without omission.</p>

Document History

Version Number	Description of Change	Date
1.0	Final Test Procedure	January 20, 2016

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