

# 2015 Edition Certification Companion Guide

## Consolidated CDA Creation Performance - 45 CFR 170.315(g)(6)

Links will be updated as available: [Final Rule Preamble](#) – [Correction Notice Preamble](#) – [Test Procedure](#) – [Test Tool/Data](#) – [Test Tool User Guide](#)

Version 1.1 – Last Updated 1/5/2016

New/Revised/Unchanged Compared to 2014 Edition	Gap Certification Eligible	Base EHR Definition	In Scope for Certified EHR Technology Definition	Associated EHR Incentive Program Objective(s)
New	No	No	No	N/A

### Certification Requirements

This certification criterion was adopted at § 170.315(g)(6), and is required for all developers seeking certification to 2015 Edition certification criteria with C-CDA creation capabilities (i.e., § 170.315(b)(1), (b)(2), (b)(4), (b)(6), (b)(9), (e)(1), and (g)(9)). There are no associated required privacy and security criterion for this criterion at § 170.315(g)(6).

### Regulation Text

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 (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.

- (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.
- (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.
- (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.
- (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.

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion	<p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>The specific requirements in provisions (i)-(iv) can be demonstrated in tandem.</li> <li>This certification criterion focuses on the data expressed in the Common Clinical Data Set definition.</li> <li>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 CCD template would <u>not</u> 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 <a href="#">80 FR 62674</a>]</li> <li>C-CDA files created during testing (using test data) will be retained by NVLAP-Accredited Testing Labs and contributed to an ONC-maintained repository. [see also <a href="#">80 FR 62675</a>]</li> </ul>	N/A
(i)	<ul style="list-style-type: none"> <li>Technical outcome – The health IT can create a C-CDA file in accordance with the HL7 C-CDA Release 2.1 Implementation Guide (IG) that matches a gold-standard, reference data file.</li> </ul> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>We will publish sample gold standard C-CDA documents on <a href="http://www.healthit.gov">www.healthit.gov</a> or another ONC-maintained repository for the public to review and provide comment. [see also <a href="#">80 FR 62675</a>]</li> <li>We anticipate there will be multiple gold standard documents for each C-CDA document template with variations in each to test optionality allowed by the C-CDA standard. [see also <a href="#">80 FR 62674</a>]</li> <li>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.</li> </ul>	§ 170.205(a)(4) <a href="#">HL7 Implementation Guide for CDA<sup>®</sup> Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1, August 2015</a>
(ii)	<ul style="list-style-type: none"> <li>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.</li> </ul> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>No additional clarifications available.</li> </ul>	§ 170.205(a)(4) <a href="#">HL7 Implementation Guide for CDA<sup>®</sup> Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1, August 2015</a>

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(iii)	<ul style="list-style-type: none"> <li>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.</li> </ul> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>No additional clarifications available.</li> </ul>	§ 170.205(a)(4) <a href="#">HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1, August 2015</a>
(iv)	<ul style="list-style-type: none"> <li>Technical outcome – The health IT can create a C-CDA file in accordance with the HL7 C-CDA Release 2.1 IG that includes all of the data in the Common Clinical Data Set definition.</li> </ul> <p><b>Clarifications:</b></p> <ul style="list-style-type: none"> <li>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 <a href="#">80 FR 62675</a>]</li> </ul>	§ 170.205(a)(4) <a href="#">HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1, August 2015</a>

**Note:** This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the 2015 Edition final regulation. It extracts key portions of the rule’s preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the 2015 Edition final rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

### Version History

Version #	Change(s) Summary	Date Made
1.0	Initial Publication	Oct 30, 2015
1.1	Revised to note that § 170.315(b)(9) care plan and § 170.315(g)(9) application access – all data request also require C-CDA creation performance demonstration. Revised regulation text per the 2015 Edition final rule correction notice to remove the text that stated the scope of this criterion would not exceed the CCD, Referral Note, and Discharge Summary document templates. Added clarification regarding testing to match a gold standard C-CDA file.	Jan 5, 2016