HealthIT.gov

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

2015 Edition CCGs

Updated on 09-21-2018

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	10-30-2015
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.	01-05-2016
1.2	Added hyperlinks to the ONC maintained repository for 1) C-CDA's created to support (g)(6); and 2) "gold standard" C-CDAs.	04-22-2016
1.3	Provides notification of March 2017 Validator Update of C-CDA 2.1 Corrections adoption and compliance requirements for entire criterion.	09-29-2017
1.4	Provides notification of April 2018 Validator Update of C-CDA 2.1 Corrections adoption and compliance requirements for the entire criterion. Note: Due to an error in calculation ONC is also updating the dates for compliance with the March 2017 Validator	05-02-2018

	Update of C-CDA 2.1 Corrections that were adopted September 29, 2017.	
1.5	Provides notification of August 2018 Validator Update of C-CDA 2.1 Corrections adoption and compliance requirements for the entire criterion.	09-21-2018

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 (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.

Standard(s) Referenced

Applies to entire criterion

§ 170.205(a)(4) 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

Please refer to the Data Elements and Vocabularies applicable to the Common Clinical Data Set (CCDS) as outlined in the Common Clinical Data Set Reference Document

Resource Documents

Resource Document

- Privacy and Security Certification Companion Guide [PDF - 281 KB]
- 2015 Edition Network Time Protocol (NTP) [PDF - 157 KB]
- CHPL SED Guide [PDF - 690 KB]
- Master Table of Related and Required Criteria [PDF-251 KB]
- CCDS Reference [PDF - 655 KB]
- CCDS Guide [PDF - 349 KB]

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	10-30-2015
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.	01-05-2016
1.2	Added hyperlinks to the ONC maintained repository for 1) C-CDA's created to support (g)(6); and 2) "gold standard" C-CDAs.	04-22-2016
1.3	Provides notification of March 2017 Validator Update of C-CDA 2.1 Corrections adoption and compliance requirements for entire criterion.	09-29-2017
1.4	Provides notification of April 2018 Validator Update of C-CDA 2.1 Corrections adoption and compliance requirements for the entire criterion. Note: Due to an error in calculation ONC is also updating the dates for compliance with the March 2017 Validator Update of C-CDA 2.1 Corrections that were adopted September 29, 2017.	05-02-2018
1.5	Provides notification of August 2018 Validator Update of C-CDA 2.1 Corrections adoption and compliance requirements for the entire criterion.	09-21-2018

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 (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.

Standard(s) Referenced

Applies to entire criterion

§ 170.205(a)(4) 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

Please refer to the Data Elements and Vocabularies applicable to the Common Clinical Data Set (CCDS) as outlined in the Common Clinical Data Set Reference Document

Testing

Testing Tool

Edge Testing Tool (ETT): Message Validators

Test Tool Documentation

Test Tool Supplemental Guide

Certification Companion Guide: Consolidated CDA creation performance

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.

Link to Final Rule Preamble

Link to Correction Notice Preamble

Edition Comparision	Gap Certification Eligible	Base EHR Definition	In Scope for CEHRT Definition
New	No	Not Included	No

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 Consolidated Clinical Document Architecture (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).

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 CCDS definition.
- 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 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 order to mitigate potential interoperability errors and inconsistent implementation of the HL7® Implementation Guide 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 ONC 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., C-CDA 2.1 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.
  - March 2017 Validator Update of C-CDA 2.1 Corrections [Effective for testing on December 28, 2017; Surveillance compliance date is March 29, 2019]
  - April 2018 Validator Update of C-CDA 2.1 Corrections [Effective for testing on July 31, 2018; Surveillance compliance date is November 2, 2019]
  - August 2018 Validator Update of C-CDA 2.1 Corrections [Effective for testing on December 20, 2018; Surveillance compliance date is March 21, 2020]
- 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]

Paragraph (g)(6)(i)

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.

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)(ii)

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)(iii)

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)

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.

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]

Content last reviewed on February 17, 2023