2015 Edition Certification Companion Guide

Common Clinical Data Set Summary Record – create - 45 CFR 170.315(b)(4)

Final Rule Preamble – **Test Procedure** – **Test Tool/Data**

Version 1.2 – Last Updated 9/29/2017

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

Privacy and Security: This certification criterion was adopted at §170.315(b)(4). As a result, an ONC-ACB must ensure that a product presented for certification to a §170.315(b) "paragraph (b)" criterion includes the privacy and security criteria (adopted in §170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in §170.315(d)) do not need to be explicitly tested with this specific paragraph (b) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be tested once to each applicable privacy and security criterion (adopted in §170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, exceptions exist for §170.315(e)(1) "VDT" and (e)(2) "secure messaging," which are explicitly stated.

Design and Performance: The following design and performance certification criteria (adopted in §170.315(g)) must also be certified in order for the product to be certified.

- When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, the QMS' need to be identified for every capability to which it was applied.
- When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied; or, alternatively the developer must state that no accessibility-centered design was used.
- C-CDA creation performance (§170.315(g)(6)) does not need to be explicitly tested with this criterion unless it is the only criterion within the scope of the requested certification that includes C-CDA creation capabilities. Note that the application of §170.315(g)(6) depends on the C-CDA templates explicitly required by the C-CDA-referenced criterion or criteria included within the scope of the certificate sought. Please refer to the C-CDA creation performance Certification Companion Guide for more details.

Privacy and Security (§170.315(d))	Design and Performance (§170.315(g))

• If choosing Approach 1:
  ○ Authentication, access control, and authorization (§170.315(d)(1))
  ○ Auditable events and tamper-resistance (§170.315(d)(2))
  ○ Audit reports (§170.315(d)(3))
  ○ Automatic access time-out (§170.315(d)(5))
  ○ Emergency access (§170.315(d)(6))
  ○ End-user device encryption (§170.315(d)(7))
  ○ Integrity (§170.315(d)(8))
• If choosing Approach 2:
  ○ For each applicable P&S certification criterion not certified for approach 1, the health IT developer may certify for the criterion using system documentation which provides a clear description of how the external services necessary to meet the P&S criteria would be deployed and used. Please see the 2015 Edition final rule correction notice at 80 FR 76870 for additional clarification.
	• Quality management system (§170.315(g)(4))
	• Accessibility-centered design (§170.315(g)(5))
	• Consolidated CDA creation performance (§170.315(g)(6))

Regulation Text

Common Clinical Data Set summary record – create. Enable a user to create a transition of care/referral summary formatted in accordance with the standard specified in §170.205(a)(4) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates that includes, at a minimum:

(i) The Common Clinical Data Set.

(ii) Encounter diagnoses. Formatted according to at least one of the following standards:

(A) The standard specified in §170.207(i).

(B) At a minimum, the version of the standard specified in §170.207(a)(4).

(iii) Cognitive status.

(iv) Functional status.

(v) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information.

(vi) Inpatient setting only. Discharge instructions.

(vii) Patient matching data. First name, last name, previous name, middle name (including middle initial), suffix, date of birth, address, phone number, and sex. The following constraints apply:

(A) Date of birth constraint—

(1) The year, month and day of birth must be present for a date of birth. The technology must include a null value when the date of birth is unknown.

(2) Optional. When the hour, minute, and second are associated with a date of birth the technology must demonstrate that the correct time zone offset is included.

(B) Phone number constraint. Represent phone number (home, business, cell) in accordance with the standards adopted in § 170.207(q)(1). All phone numbers must be included when multiple phone numbers are present.

(C) Sex constraint. Represent sex in accordance with the standard adopted in § 170.207(n)(1).

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion	***Clarifications:*** • The scope of this criterion is limited to the Consolidated CDA (C-CDA) Continuity of Care Document (CCD), Referral Note, and (for the inpatient setting only) Discharge Summary document templates. [see also 80 FR 62633] • We recommend health IT developers and providers follow the guidance provided in the HL7 Implementation Guide: S&I Framework Transitions of Care Companion Guide to Consolidated-CDA for Meaningful Use Stage 2, Release 1 – US Realm. This Companion Guide includes industry best practices guidance for consistent implementation of the C-CDA Release 1.1 standard, including mapping Common MU Data Set elements into the C-CDA standard. [see also 80 FR 62633] We understand that HL7 is developing a Companion Guide for C-CDA Release 2.1 and intend to update this document once it becomes publicly available. In the meantime, we recommend developers follow the guidance provided by the HL7 CDA Example Task Force for implementation of the C-CDA Release 2.1 standard. • 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. (C-CDA R2.1 IG), in March, 2017 and previously, ONC assessed, approved and incorporated the following errata as part of required testing and certification to this criterion: C-CDA 2.1 ERRATA [Effective in testing with the C-CDA 2.1 Validator, March 2017; Surveillance compliance date is September 1, 2018] [see also FAQ 51] • At the discretion of the ATL and ONC-ACB, the requirements of this criterion may be met through testing and certification to § 170.315(b)(1).	§ 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
(i)	• Technical outcome – The health IT can create a C-CDA (formatted to Release 2.1) that includes the Common Clinical Data Set. ***Clarifications:*** • Please refer to the standards required for the 2015 Edition Common Clinical Data Set.	Please refer to the standards required for the 2015 Edition Common Clinical Data Set.

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(ii)	• Technical outcome – The health IT can create a C-CDA (formatted to Release 2.1) that includes encounter diagnoses using either ICD-10-CM or SNOMED CT® codes. ***Clarifications:*** • In order to facilitate the translation of SNOMED CT® codes to ICD-10-CM in administrative systems, developers are encouraged to reference the publicly available mapping that the National Library of Medicine provides. [see also 77 FR 54220] • We provide the following OIDs to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards. ▪ ICD-10 Procedure Coding System OID: 2.16.840.1.113883.6.4 ▪ SNOMED CT® OID: 2.16.840.1.113883.6.96 [see also 80 FR 62612] • Health IT Modules can present for certification to a more recent version of SNOMED CT®, U.S. Edition than the September 2015 Release per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62620]	§ 170.207(i) ICD-10-CM § 170.207(a)(4) International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, September 2015 Release
(iii)	• Technical outcome – The health IT can create a C-CDA (formatted to Release 2.1) that includes cognitive status. ***Clarifications:*** • The C-CDA Cognitive Status Observation template has been deprecated in Release 2.1 and has been replaced with the Mental Status Observation template. Developers should use the Mental Status Observation template for cognitive status and be aware that the C-CDA validator will issue an error if the deprecated Cognitive Status Observation is used instead.	N/A
(iv)	• Technical outcome – The health IT can create a C-CDA (formatted to Release 2.1) that includes functional status. ***Clarifications:*** • No additional clarifications available.	N/A

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(v)	Technical outcome – In the ambulatory setting only, the health IT can create a C-CDA (formatted to Release 2.1) that includes the reason for referral and the referring or transitioning provider's name and office contact information. ***Clarifications:*** • No additional clarifications available.	N/A
(vi)	Technical outcome – In the inpatient setting only, the health IT can create a C-CDA (formatted to Release 2.1) that includes discharge instructions. ***Clarifications:*** • No additional clarifications available.	N/A

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(vii)	• Technical outcome – The health IT can create a C-CDA (formatted to Release 2.1) that includes certain data to assist with patient matching. Unless otherwise specified, the developer should follow the guidance in C-CDA Release 2.1 for formatting the data. ***Clarifications:*** • These requirements concern only the ability to create a transition of care/referral summary document that contains the data elements in accordance with the specified standards/constraints. The health IT is not required to demonstrate how it performs patient matching with these data for certification. [see also 80 FR 62637] • C-CDA Release 2.1 allows suffix to be included as an additional qualifier to the last name field. [see also 80 FR 62636] • We recommend receiving systems follow the guidance in CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0 for normalizing last name before sending ToC/referral summary documents. [see also 80 FR 62636] • "Previous name" is intended to capture situations where a patient may use an alias (e.g., maiden name, family name, legally changed last name). [see also 80 FR 62636] • C-CDA Release 2.1 cannot distinguish between historical and current address, but can accommodate more than one address. [see also 80 FR 62637] • The C-CDA validation tool will test adherence to the use of the HL7 postal format for address. [see also 80 FR 62637]	§ 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 § 170.207(q)(1) International Telecommunication Union E.123: Notation for national and international telephone numbers, e-mail addresses and web addresses and International Telecommunication Union E.164: The international public telecommunication numbering plan. § 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. nullFlavor UNK

Version History

Version #	Change(s) Summary	Date Made
1.0	Initial Publication	Jan 5, 2016
1.1	Clarification on testing and certification flexibility permitting leveraging test results from § 170.315(b)(1) for (b)(4).	Apr 22, 2016
1.2	Provides notification of C-CDA2.1 errata adoption and compliance requirements within the entire criterion row.	Sep 29, 2017