

# §170.315(b)(4) Common Clinical Data Set summary record - create

2015 Edition CCGs

Version 1.4 Updated on 09-21-2018

## Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	01-05-2016
1.1	Clarification on testing and certification flexibility permitting leveraging test results from § 170.315(b)(1) for (b)(4).	04-22-2016
1.2	Provides notification of March 2017 Validator Update of C-CDA 2.1 Corrections adoption and compliance requirements for the entire criterion.	09-29-2017
1.3	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
1.4	Provides notification of August 2018 Validator Update of C-CDA 2.1	09-21-2018

Corrections adoption and compliance requirements for the entire criterion.

## Regulation Text

### Regulation Text

§170.315 (b)(4) *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).

## 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](#)

### Paragraph (b)(4)(i)

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

### Paragraph (b)(4)(ii)

§ 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(i) [ICD-10-CM](#)

### Additional Resources

§ 170.207(n)(1) Birth sex must be coded in accordance with [HL7 Version 3 Standard](#), Value Sets for [AdministrativeGender](#) and [NullFlavor](#) attributed as follows:

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

§ 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](#)

## Certification Companion Guide: Common Clinical Data Set summary record – create

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](#)

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

## 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.

### Table for Privacy and Security

- 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.

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.

### Table for Design and Performance

- [Quality management system \(§ 170.315\(g\)\(4\)\)](#)
- [Accessibility-centered design \(§ 170.315\(g\)\(5\)\)](#)
- [Consolidated CDA creation performance \(§ 170.315\(g\)\(6\)\)](#)

## Technical Explanations and Clarifications

### 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 (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, ONC assesses, approves, and incorporates corrections as part of required testing and certification to this criterion. [see [FAQ #51](#)] 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. Consistent with [FAQ 51](#), 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 consistent with [FAQ 51](#), 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 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]
- At the discretion of the ONC-ATL and ONC-ACB, the requirements of this criterion may be met through testing and certification to § 170.315(b)(1).

### Paragraph (b)(4)(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.

### Paragraph (b)(4)(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<sup>®</sup> codes.

**Clarifications:**

- In order to facilitate the translation of SNOMED CT<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>, 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](#)]

**Paragraph (b)(4)(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.

**Paragraph (b)(4)(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.

**Paragraph (b)(4)(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.

**Paragraph (b)(4)(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.

**Paragraph (b)(4)(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](#)]

Content last reviewed on May 20, 2020