

2015 Edition §170.315(b)(4) Common Clinical Data Set summary record - Create					
Testing Components:					
				Data	
Test Procedure Version 1.1 – Last Updated 10/30/15					

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.*

## Required Tests

### (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 standards specified in § 170.205(a)(4) using the Continuity of Care Document, Referral Note, and (for 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) or 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 date 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):**

- § 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](#)
- § 170.207(b)(3) [CDT](#)
- § 170.207(b)(2) [CPT-4](#)
- § 170.207(f)(2) [“Race & Ethnicity – CDC” code system in the PHIN Vocabulary Access and Distribution System \(VADS\), Release 3.3.9](#)
- § 170.207(e)(4) [National Drug Code Directory– Vaccine Codes, updates through August 3, 2015](#)
- § 170.207(b)(4) [ICD-10-PCS](#)
- § 170.207(i) [ICD-10-CM](#)
- § 170.207(e)(3) [HL7 Standard Code Set CVX—Vaccines Administered, updates through June 18, 2015](#)
- § 170.207(f)(1) [The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997](#)
- § 170.207(c)(3) [Logical Observation Identifiers Names and Codes \(LOINC®\) Database version 2.52](#)
- § 170.207(m)(1) [The Unified Code of Units of Measure, Revision 1.9](#)
- § 170.207(g)(2) [Request for Comments \(RFC\) 5646: Tags for Identifying Languages](#)
- § 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(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(d)(3) [RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release](#)
- § 170.207(h) Smoking status must be coded in one of the following SNOMED CT® codes:
  - (1) Current every day smoker. 449868002
  - (2) Current some day smoker. 428041000124106
  - (3) Former smoker. 8517006
  - (4) Never smoker. 266919005
  - (5) Smoker, current status unknown. 77176002
  - (6) Unknown if ever smoked. 266927001
  - (7) Heavy tobacco smoker. 428071000124103
  - (8) Light tobacco smoker. 428061000124105
- § 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. UNK

**Test Data:** [C-CDA Validator within the Edge Testing Tool](#)

Inpatient Setting - 170.315\_b4\_ccds\_create\_inp\_sample\*.pdf (all samples)

Ambulatory Setting - 170.315\_b4\_ccds\_create\_amb\_sample\*.pdf (all samples)

Test Tool: [C-CDA Validator within the Edge Testing Tool](#)

Criteria ¶	System Under Test	Test Lab Verification
	<ol style="list-style-type: none"> <li>1. Based upon the health IT setting(s) (i.e. ambulatory and/or inpatient), a user enters the Common Clinical Data Set (CCDS) summary record information for each of the ambulatory and/or inpatient test cases referenced from the CCDS summary record documents into the Health IT module. All test cases for a given health IT setting are required. The user retrieves the required CCDS instructions for entering data into the Health IT module from the top-level C-CDA Validator, one of the tool selections within the Edge Testing Tool.</li> <li>2. Using the C-CDA Validator, the user selects the ambulatory and/or inpatient CCDS documents (pdf) and selects download to download the required CCDS information documents.</li> <li>3. Using the Health IT module, the user creates a Common Clinical Data Set summary record with the minimum content specified in (b)(4)(i) – (b)(4)(vi) as a transition of care/referral summary document formatted in accordance with the standards specified in § 170.205(a)(4) to create each of the following document templates, as applicable: <ul style="list-style-type: none"> <li>• Continuity of Care Document;</li> <li>• Referral Note; and</li> <li>• Discharge Summary (for inpatient setting only).</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>1. The tester verifies that the CCDS summary record information entered into the Health IT module is accurate and without omission.</li> <li>2. Validation of a CCDS summary record is done using the top –level C-CDA Validator, one of the tool selections within the Edge Testing Tool. To validate the CCDS summary record (xml file) created by the Health IT module, the tester uses the C-CDA Validator Tool within the Edge Testing Tool to select the criteria to be verified based upon the originally downloaded test case document and upload the CCDS summary record (xml file) created by the Health IT module.</li> <li>3. For each test case, the tester uploads the CCDS summary record xml file into the top-level C-CDA Validator Tool within the Edge Testing Tool for validation based on each test case listed, and uses the Validation Report produced by the test tool to verify the Health IT module passes without error to confirm that the CCDS summary record is conformant to the standard adopted in § 170.205(a)(4). Each of the following document-template(s) must be verified: <ul style="list-style-type: none"> <li>• Continuity of Care;</li> <li>• Referral Note; and</li> <li>• Discharge Summary (for inpatient setting only).</li> </ul> </li> <li>4. As required by the test case, the tester uses the ONC-supplied CCDS summary record instructions and the CCDS summary record xml file from step 3 to verify through Visual Inspection the additional checks for equivalent text for content for all section level narrative text.</li> </ol>

(i) The Common Clinical Data Set

Criteria ¶	System Under Test	Test Lab Verification
(i)	<p>Each of the documents created in (b)(4) includes at a minimum, the following data from the Common Clinical Data Set where applicable, and represent such data according to the additional constraints specified in Table 8 of the final rule:</p> <ul style="list-style-type: none"> <li>• Patient Name.</li> <li>• Sex constrained including birth sex</li> <li>• Date of Birth.</li> <li>• Race and Ethnicity</li> <li>• Preferred language</li> <li>• Smoking Status</li> <li>• Problems constrained</li> <li>• Medications constrained</li> <li>• Medication Allergies</li> <li>• Laboratory Tests constrained</li> <li>• Laboratory Values(s)/Result(s).</li> <li>• Vital Signs</li> <li>• Procedures constrained</li> <li>• Care Team Member(s)</li> <li>• Immunizations constrained</li> <li>• Unique Device Identifier(s) for a Patient’s Implantable Device(s)</li> <li>• Assessment and Plan of Treatment</li> <li>• Goals</li> <li>• Health Concerns</li> </ul> <p>The complete list of the Common Clinical Data Set and associated standards can be referenced in <a href="#">Table 8</a> of the Final Rule.</p>	<p>Using the C-CDA Validator within the Edge Test Tool as part of the verification done in (b)(4) steps 3 and 4, the tester verifies that the content of the Common Clinical Data Set summary record created in (b)(4) includes the Common Clinical Data Set.</p>

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

- (1) The standard specified in § 170.207(i).

(2) At a minimum, the standard specified in § 170.207(a)(4).

**Standard(s):**

§170.207(i) [ICD-10-CM](#).

§ 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](#)

**Test Data:** [C-CDA Validator within the Edge Testing Tool](#)

Inpatient Setting - 170.315\_b4\_ccds\_create\_inp\_sample\*.pdf (all samples)

Ambulatory Setting - 170.315\_b4\_ccds\_create\_amb\_sample\*.pdf (all samples)

**Test Tool:** [C-CDA Validator within the Edge Testing Tool](#)

Criteria ¶	System Under Test	Test Lab Verification
(ii)	<p>Each of the documents created in (b)(4)(i) include Encounter diagnoses using at least one standard, either the standard specified at §170.207(i), code set specified at 45 CFR 162.1002(c)(2) for the indicated conditions or the standard specified at § 170.207(a)(4). ICD-10-CM as maintained and distributed by HHS, for the following conditions:</p> <ul style="list-style-type: none"> <li>(i) Diseases;</li> <li>(ii) Injuries;</li> <li>(iii) Impairments;</li> <li>(iv) Other health problems and their manifestations;</li> <li>and</li> <li>(v) Causes of injury, disease, impairment, or other health problem.</li> </ul>	<p>The tester verifies that the content of the Common Clinical Data Set summary record created in (b)(4) includes the encounter diagnoses and is in accordance with the standard specified at § 170.207(i), or at a minimum the version of the standard specified at § 170.207(a)(4) ) by using the C-CDA Validator within the Edge Test Tool as part of the verification done in (b)(4) step 3.</p>

(iii) Cognitive status.

**Test Data:** [C-CDA Validator within the Edge Testing Tool](#)

Inpatient Setting - 170.315\_b4\_ccds\_create\_inp\_sample\*.pdf (all samples)

Ambulatory Setting - 170.315\_b4\_ccds\_create\_amb\_sample\*.pdf (all samples)

**Test Tool:** [C-CDA Validator within the Edge Testing Tool](#)

Criteria ¶	System Under Test	Test Lab Verification
(iii)	Each of the documents created in (b)(4)(i) includes Cognitive status.	The tester verifies that the content of the Common Clinical Data Set summary record created in (b)(4) includes the cognitive status when present in the Health IT module by using the C-CDA Validator within the Edge Test Tool as part of the verification done in (b)(4) step 3.

(iv) Functional status.

**Test Data:** [C-CDA Validator within the Edge Testing Tool](#)

Inpatient Setting - 170.315\_b4\_ccds\_create\_inp\_sample\*.pdf (all samples)

Ambulatory Setting - 170.315\_b4\_ccds\_create\_amb\_sample\*.pdf (all samples)

**Test Tool:** [C-CDA Validator within the Edge Testing Tool](#)

Criteria ¶	System Under Test	Test Lab Verification
(iv)	Each of the documents created in (b)(4)(i) includes Functional Status.	The tester verifies that the content of the Common Clinical Data Set summary record created in (b)(4) includes the functional status when present in the Health IT module by using the C-CDA Validator within the Edge Test Tool as part of the verification done in (b)(4) step 3.

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

**Test Data:** [C-CDA Validator within the Edge Testing Tool](#)

Inpatient Setting - 170.315\_b4\_ccds\_create\_inp\_sample\*.pdf (all samples)

Ambulatory Setting - 170.315\_b4\_ccds\_create\_amb\_sample\*.pdf (all samples)

**Test Tool:** [C-CDA Validator within the Edge Testing Tool](#)

Criteria ¶	System Under Test	Test Lab Verification
(v)	<p>Each of the documents created in (b)(4)(i) includes the following data:</p> <ul style="list-style-type: none"> <li>• reason for referral;</li> <li>• referring or transitioning provider’s name; and</li> <li>• office contact information.</li> </ul>	<ol style="list-style-type: none"> <li>1. Using the C-CDA Validator within the Edge Test Tool, as part of the verification done in (b)(4) step 3, the tester verifies that the content of the Common Clinical Data Set summary record created in (b)(4) include: <ul style="list-style-type: none"> <li>• Reason for referral</li> <li>• Referring or transitioning provider’s name</li> <li>• Office contact information.</li> </ul> </li> <li>2. Using visual inspection, as part of the verification done in (b)(4) step 4, the tester verifies that the unstructured data element, reason for referral, is present and correct.</li> </ol>

(vi) **Inpatient setting only.** Discharge instructions.

**Test Data:** [C-CDA Validator within the Edge Testing Tool](#)

Inpatient Setting - 170.315\_b4\_ccds\_create\_inp\_sample\*.pdf (all samples)

Ambulatory Setting - 170.315\_b4\_ccds\_create\_amb\_sample\*.pdf (all samples)

**Test Tool:** [C-CDA Validator within the Edge Testing Tool](#)

Criteria ¶	System Under Test	Test Lab Verification
(vi)	<p>The CCD and discharge summary documents created in (b)(4)(i) include discharge instructions.</p>	<ol style="list-style-type: none"> <li>1. The tester verifies that the content of the Common Clinical Data Set summary record created in (b)(4)(i) for the inpatient setting only includes the discharge instructions by using the C-CDA Validator within the Edge Test Tool as part of the verification done in (b)(4) step 2.</li> <li>2. Using Visual Inspection, as part of the verification done in (b)(4) step 3, the tester verifies that the unstructured data element, discharge instructions, is present and correct.</li> </ol>

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

Criteria ¶	System Under Test	Test Lab Verification
(vii)	<p>Each of the documents created in (b)(4)(i) includes the following data for patient matching data quality and, where applicable, represent such data according to the additional constraints specified below:</p> <ul style="list-style-type: none"> <li>• Name: First name, last name, previous name, middle name (including middle initial), suffix;</li> <li>• Date of birth including the year, month and date of birth must be present for a date of birth, when known, and null when unknown;</li> <li>• Optional: If the hour, minute and second are associated with a date of birth the technology must demonstrate that the correct time zone offset;</li> <li>• Address;</li> <li>• Phone number(s) which are constrained in accordance with the standard specified at § 170.207(q)(1), UTI-E.123 and UTI-E.124; and if multiple phone numbers are present within the Health IT module they are reflected in the transitions of care/referral summaries; and</li> <li>• Birth sex in accordance with the standard adopted in § 170.207(n)(1), birth sex coded in accordance with HL7 Version 3 attributed as follows: <ul style="list-style-type: none"> <li>(i) Male. M</li> <li>(ii) Female. F</li> <li>(iii) Unknown. UNK.</li> </ul> </li> </ul>	<ol style="list-style-type: none"> <li>1. The tester verifies that the patient matching data within the Common Clinical Data Set summary record created in (b)(4) includes the patients first name, last name, previous name, middle name (including middle initial), suffix, date of birth, address, phone number, and sex, by using the C-CDA Validator within the Edge Test Tool as part of the verification done in (b)(4) step 3.</li> <li>2. <u>Optional</u>: If the Health IT module supports the time of birth, the tester verifies that the Health IT module records the correct time zone offset as part of the time of birth using visual inspection.</li> </ol>

### Document History

Version Number	Description of Change	Date
1.0	Released for Comment - NPRM	March 31, 2015
1.1	Released for Comment - FR	October 30, 2015

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