

2015 Edition §170.315(b)(4) Common Clinical Data Set summary record – Create

| Testing Components: | | | | |
|--|---|---|---|------------------------------|
|  |  |  |  | ONC Supplied Test Data |
| Test Procedure Version 1.0 – Last Updated 1/20/16 | | | | |

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(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](#)

§ 170.207(n)(1) Birth sex must be coded in accordance with HL7 Version 3 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](#)

Data Elements and Vocabularies applicable to the Common Clinical Data Set (CCDS) – Outlined in the Common Clinical Data Set Reference Document

Test Data: [ETT: Message Validators](#)

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: [ETT: Message Validators](#)

| Criteria ¶ | System Under Test | Test Lab Verification |
|------------|--|---|
| (b)(4) | <p>Setup</p> <ol style="list-style-type: none"> Using the ETT: Message Validators – C-CDA R2.1 Validator, the health IT developer downloads the ONC-supplied data instructions through the sender download selections of the “170.315_b4_CCDS_Amb” or “170.315_b4_CCDS_Inp” criteria and one of the CCDS summary record – Create instruction documents and executes the download. <p>Data Entry</p> <ol style="list-style-type: none"> A user enters the Common Clinical Data Set (CCDS) summary record information downloaded in step 1 in order to create a patient record with the necessary information in the Health IT Module. <p>Create</p> <ol style="list-style-type: none"> Using the Health IT Module, the user creates a CCDS 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"> Continuity of Care Document; Referral Note; and (for inpatient setting only) Discharge Summary. The CCDS summary record created in step 3 is submitted to the tester for verification. Based upon the health IT setting(s) ambulatory and/or inpatient, a user repeats steps 1-4 for each of the ambulatory and/or inpatient CCDS summary record – Create instruction documents found in the ETT: Message Validators. The submission of a CCDS summary record document is required for all of the CCDS summary record instruction documents for a given health IT setting. | <p>Data Entry</p> <ol style="list-style-type: none"> Using the CCDS summary record instruction document downloaded in step 1 of the SUT, the tester verifies that the CCDS summary record information entered into the Health IT Module is accurate and without omission. <p>Create</p> <ol style="list-style-type: none"> Using the ETT: Message Validators – C-CDA R 2.1 Validator, the tester uploads the submitted CCDS summary record created by the Health IT Module, through the upload section of the “170.315_b4_CCDS_Amb” or “170.315_b4_CCDS_Inp” criteria and the file name, and executes the upload of the submitted file to the ETT: Message Validators. For each submitted CCDS summary record document, the tester uses the Validation Report produced by the ETT: Message Validators 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). As required by the ONC-supplied CCDS summary record instructions, the tester uses the ONC-supplied CCDS summary record instructions and the Message Content Report produced by the ETT: Message Validators to verify the additional checks for equivalent text for the content of all section level narrative text. Using the ETT: Message Validators Validation Report, the tester verifies that for each supported health IT setting, the following types of CCDS summary record summary documents have been created by the SUT: <ul style="list-style-type: none"> Continuity of Care Document; C-CDA R2 R2.1 Referral Note Document; and (for inpatient setting only) C-CDA R2 R2.1 Discharge Summary. |

| Criteria ¶ | System Under Test | Test Lab Verification |
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| (i) | <p>Common Clinical Data Set</p> <p>Each of the C-CDA R2 R2.1 documents created in (b)(4) includes at a minimum, the data from the CCDS where applicable, and represent such data in accordance with the standards specified in the CCDS Reference Document for C-CDA R2 R2.1 documents.</p> | <p>The tester performs verification that the CCDS data elements are in accordance with the CCDS Reference Document for a document specified in accordance with §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, as part of the Create verification in (b)(4) steps 3-5.</p> |
| (ii) | <p>Encounter diagnoses</p> <p>Each of the C-CDA R2 R2.1 documents created in (b)(4)(i) include Encounter diagnoses using at least one standard, either</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> (i) Diseases; (ii) Injuries; (iii) Impairments; (iv) Other health problems and their manifestations; and (v) Causes of injury, disease, impairment, or other health problem. <p>or at a minimum the version of the standard specified at §170.207(a)(4) (ICD-10-CM or SNOMED CT®).</p> | <p>The tester performs verification that the Encounter diagnoses data element is specified in accordance with the constrained standard specified at § 170.207(i), or at a minimum the version of the standard specified at § 170.207(a)(4), as part of the Create verification in (b)(4) steps 3-4.</p> |
| (iii) | <p>Cognitive status</p> <p>Each of the C-CDA R2 R2.1 documents created in (b)(4)(i) includes Cognitive status, when present, in the Health IT Module.</p> | <p>The verification of the Cognitive Status data element, when present in the Health IT Module, is performed as part of the Create verification in (b)(4) steps 3-4.</p> |

| Criteria ¶ | System Under Test | Test Lab Verification |
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| (iv) | <p><u>Functional status</u> Each of the C-CDA R2 R2.1 documents created in (b)(4)(i) includes Functional Status, when present, in the Health IT Module.</p> | <p>The verification of the Functional Status data element, when present in the Health IT Module, is performed as part of the Create verification in (b)(4) steps 3-4.</p> |
| (v) | <p><u>Ambulatory setting only</u> Each of the C-CDA R2 R2.1 documents created in (b)(4)(i) for the ambulatory health IT setting includes the following data:</p> <ul style="list-style-type: none"> • reason for referral; • referring or transitioning provider’s name; and office contact information. | <p>The verification of the data element requirements for the Ambulatory setting is performed as part of the Create verification in (b)(4) steps 3-5. This includes verifying that the content of the CCDS summary record created in (b)(4) includes: Reason for referral, Referring or transitioning provider’s name and Office contact information. Additional verification is done in (b)(4) step 5, to verify that the unstructured data element reason for referral is correct.</p> |
| (vi) | <p><u>Inpatient setting only</u> Each of the C-CDA R2 R2.1 documents created in (b)(4)(i) for the inpatient health IT setting includes discharge instructions.</p> | <p>The verification of the data element requirements for the Inpatient setting is performed as part of the Create verification in (b)(4) steps 3-5. This includes tester verifies that the content of the CCDS summary record created in (b)(4)(i) includes the discharge instructions. Additional verification is done in (b)(4) step 5, to verify that the unstructured data element, discharge instructions, is present and correct.</p> |
| (vii) | <p><u>Patient matching data</u> Each of the C-CDA R2 R2.1 documents created in (b)(4)(i) includes the following data for patient matching data quality and, where applicable, represent such data as specified below:</p> <ul style="list-style-type: none"> • Name: First name, last name, previous name, middle name (including middle initial), suffix; • 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; • Address; <p style="text-align: right;">continued on the next page</p> | <p>The verification of the data element requirements for patient data matching is performed as part of the Create verification in (b)(4) steps 3-5. The verification of the patient matching data within the CCDS summary record created in (b)(4) includes the presence of the patient’s first name, last name, previous name, middle name (including middle initial), suffix; date of birth, address, all phone number (s) present in the Health IT Module and sex, as applicable. Furthermore, the phone number(s) are constrained in accordance with the standard specified at § 170.207(q)(1) and the birth sex is in accordance with the standard adopted in § 170.207(n)(1).</p> |

| Criteria ¶ | System Under Test | Test Lab Verification |
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| (vii) continued | <p>Continued from previous page</p> <ul style="list-style-type: none"> • 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 when multiple phone numbers are present within the Health IT Module they are reflected in the transitions of care/referral summaries; and • Birth sex in accordance with the standard adopted in § 170.207(n)(1), birth sex coded in accordance with HL7 Version 3 Value Sets for AdministrativeGender and NullFlavor attributed as follows: <ul style="list-style-type: none"> (i) Male. M (ii) Female. F (iii) Unknown. nullFlavor UNK | See previous page |
| (vii)(A)(ii) (Optional) | <p><u>Date of Birth with hours, minutes and seconds</u> If the hour, minute, and second are associated with a date of birth the technology must demonstrate the correct time zone offset.</p> | The tester verifies that the Health IT Module records the correct time zone offset as part of the time of birth, using visual inspection. |

Document History

| Version Number | Description of Change | Date |
|----------------|-----------------------|------------------|
| 1.0 | Final Test Procedure | January 20, 2016 |

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