§170.315(b)(5) Common Clinical Data Set summary record – receive

2015 Edition Test Procedure

Version 1.1 Updated on 04-06-2018

Revision History

Version #	Description of Change	Version Date
1.0	Final Test Procedure	01-20-2016
1.1	Clarification of the "rejection" of an invalid C-CDA document in step 4 under the TLV of paragraph (b)(5)(i).	04-06-2018

Regulation Text

Regulation Text

§170.315 (b)(5) *Common Clinical Data Set summary record – receive—*

(i) Enable a user to receive a transition of care/referral summary formatted in accordance with the standards adopted in §170.205(a)(3) and §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:

(A) The Common Clinical Data Set.

(B) *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).

(C) Cognitive status.

(D) Functional status.

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

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

(ii) *Validate and display.* Demonstrate the following functionalities for the document received in accordance with paragraph (b)(5)(i) of this section:

(A) *Validate C-CDA conformance—system performance.* Detect valid and invalid transition of care/referral summaries including the ability to:

(1) Parse each of the document types formatted according to the following document templates: Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary.

(2) Detect errors in corresponding "document-templates," "section-templates," and "entry-templates," including invalid vocabulary standards and codes not specified in the

standards adopted in §170.205(a)(3) and §170.205(a)(4).

(3) Identify valid document-templates and process the data elements required in the corresponding section-templates and entry-templates from the standards adopted in §170.205(a)(3) and §170.205(a)(4).

(4) Correctly interpret empty sections and null combinations.

(5) Record errors encountered and allow a user through at least one of the following ways to:

(i) Be notified of the errors produced.

(ii) Review the errors produced.

(B) *Display.* Display in human readable format the data included in transition of care/referral summaries received and formatted according to the standards specified in §170.205(a)(3) and §170.205(a)(4).

(C) *Display section views.* Allow for the individual display of each section (and the accompanying document header information) that is included in a transition of care/referral summary received and formatted in accordance with the standards adopted in §170.205(a)(3) and §170.205(a)(4) in a manner that enables the user to:

(1) Directly display only the data within a particular section;

(2) Set a preference for the display order of specific sections; and

(3) Set the initial quantity of sections to be displayed.

Standard(s) Referenced

Paragraph (b)(5)(i)

§ 170.205(a)(3) HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012

§ 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(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

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)(5)(ii)

§ 170.205(a)(3) HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012. The use of the "unstructured document" document-level template is prohibited.

§ 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

Additional Resources

§ 170.207(a)(3) International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) International Release July 31, 2012 and US Extension to SNOMED CT® March 2012

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.

Testing components

				ONC Supplied Test Data

Paragraph (b)(5)(i)

System Under Test

Receive

1. Using the ETT: Message Validators – C-CDA R2.1 Validator, the health IT developer downloads the ONC-supplied CCDS xml documents through the receiver download selections of "170.315_b5_CCDS_ Amb" or "170.315_b5_CCDS_Inp" criteria and either a C-CDA R2 R1.1 or C-CDA R2 2.1 xml document and executes the download of the CCDS summary record xml file.
2. The user uses the Health IT Module to receive the downloaded CCDS summary record xml files from step 1, which are formatted as a CCD document in accordance with the standards adopted in § 170.205(a)(3) HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 or formatted with the following C-CDA transition of care/referral summary document types (CCDS summary record) and § 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1:
   - Continuity of Care Document;
   - Referral Note; and
   - *Inpatient setting only*: Discharge Summary.
3. Based upon the health IT setting(s) to be certified, a user repeats steps 1-2 for each ambulatory and/or inpatient CCDS summary record (xml) document in the ETT: Message Validators. All of the CCDS summary record documents for a given health IT setting must be received (both C-CDA R2 R1.1 and C-CDA R2 R2.1 formats).

Negative Test - Receive

4. Using the ETT: Message Validators – C-CDA R2.1 Validator, the health IT developer downloads each of the negative xml documents by selecting the ONC-supplied care plan xml documents through the receiver download selections of the "Negative Testing CCDS" criteria and one of the invalid C-CDA documents (for either a C-CDA R2 R2.1 and C-CDA R2 R1.1 file) and executes the download of the invalid C-CDA xml file.
5. Using the Health IT Module, the user receives the applicable C-CDA document types containing errors in the corresponding "document-templates," "section-templates," and "entry-templates," including invalid vocabulary standards and codes not specified in the standards adopted in § 170.205(a)(3) HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 or § 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1 and reports the error.
6. A user repeats steps 4-5 for each of the negative test samples in ETT: Message Validators "Negative_Testing_CCDS".

Test Lab Verification

Setup

1. The tester creates a human readable version of the downloaded CCDS summary record from step 1 of the SUT to be used for verification for each CCDS summary record document received.

Receive

2. The tester uses visual inspection to verify that the Health IT Module can successfully receive the applicable types of transition of care/referral summaries for each CCDS summary record document received by the Health IT Module, either as a:
   - C-CDA R2 R1.1 document formatted as a CCD or a C-CDA with no specific document template according to the standard adopted in § 170.205(a)(3); or
   - C-CDA R2 R2.1 formatted in accordance with the standard specified in § 170.205(a)(4) as a Continuity of Care, Referral Note, or (*inpatient setting only*) as a Discharge Summary.
3. For each CCDS summary record document received by the SUT, the tester verifies the content specified in (b)(5)(i)(A-F) as applicable, using visual inspection.

Negative Test - Receive

4. For each negative test xml received, the tester uses visual inspection to verify that the Health IT Module can successfully notify the user of errors or allow the user to review the errors if the C-CDA documents not specified in accordance with the standards adopted in § 170.205(a)(3) and § 170.205(a)(4) including:
   - “document –templates”;
   - “section-templates”;
   - “entry-templates”;
   - invalid vocabulary standards; and
   - invalid codes.

Paragraph (b)(5)(i)(A)

System Under Test

The Common Clinical Data Set

Each of these documents includes, at a minimum, the Common Clinical Data Set as specified in the CCDS Reference Document for C-CDA R2 R1.1 or C-CDA R2 R2.1, as applicable.

Test Lab Verification

The tester verifies the applicable types of transition of care/referral summaries received in (b)(5)(i) include the following data elements, as applicable:

- Common Clinical Data Set in accordance with the CCDS Reference Document for either C-CDA R2 R1.1 or C-CDA R2 R2.1 based upon the document type received.

Paragraph (b)(5)(i)(B)

System Under Test

Encounter Diagnoses

The transition of care/referral summary received in (b)(5)(i) includes at a minimum encounter diagnoses using at least one standard, either

- the standard specified at § 170.207(i) ICD-10-CM for the following conditions:
  (i) Diseases;
  (ii) Injuries;
  (iii) Impairments;
  (iv) Other health problems and their manifestations; and
  (v) Causes of injury, disease, impairment, or other health problems;
- or at a minimum the version of the standard specified at § 170.207(a)(4) SNOMED CT®.

Test Lab Verification

The verification of the applicable types of transition of care/referral summaries received in (b)(5)(i) includes the following data element in accordance to the standard adopted in § 170.205(a)(3) or § 170.205(a)(4):

- Encounter diagnoses, formatted in accordance to one of the following standards:
  - The standard specified in § 170.207(i); or
  - At a minimum, the standard specified in § 170.207(a)(4).

Paragraph (b)(5)(i)(C)

System Under Test

Cognitive Status

The transition of care/referral summary received in (b)(5)(i) includes the Cognitive status, when present, in the C-CDA R2 R1.1 or C-CDA R2 R2.1 document.

Test Lab Verification

The verification of the applicable types of transition of care/referral summaries received in (b)(5)(i) includes the Cognitive status, when present, in accordance to the standard adopted in § 170.205(a)(3) or § 170.205(a)(4).

Paragraph (b)(5)(i)(D)

System Under Test

Functional Status

The transition of care/referral summary received in (b)(5)(i) includes the Functional status when present in the C-CDA R2 R1.1 or C-CDA R2 R2.1 document.

Test Lab Verification

The verification of the applicable types of transition of care/referral summaries received in (b)(5)(i) includes the Functional status when present in accordance to the standard adopted in § 170.205(a)(3) or § 170.205(a)(4) as applicable.

Paragraph (b)(5)(i)(E)

System Under Test

Ambulatory Setting Only

The transition of care/referral summary received in (b)(5)(i) includes, at a minimum:

- reason for referral;
- referring or transitioning provider's name; and
- office contact information.

Test Lab Verification

For the *ambulatory setting only*, the verification of the applicable types of transition of care/referral summaries received in(b)(5)(i) includes the following data elements in accordance to the standard adopted in § 170.205(a)(3) or § 170.205(a)(4) as applicable:

- reason for referral;
- referring or transitioning provider's name; and
- office contact information.

Paragraph (b)(5)(i)(F)

System Under Test

Inpatient Setting Only

The transition of care/referral summary received in (b)(5)(i) includes the discharge instructions.

Test Lab Verification

For the *inpatient setting only*, the verification of the applicable types of transition of care/referral summaries received in (b)(5)(i) includes the discharge instructions in accordance to the standard adopted in § 170.205(a)(3) or § 170.205(a)(4) as applicable.

Paragraph (b)(5)(ii)(A)

System Under Test

Validate (Parse, Identify, and Interpret)

1. Using the Common Clinical Data Set summary records received in (b)(5)(i), the Health IT Module parses the document formatted as a CCD or a C-CDA with no specific document template in accordance with the standards specified in § 170.205(a)(3) HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 or as a C-CDA § 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1, as one of the following document types:
   - Continuity of Care;
   - Referral Note; and
   - *Inpatient setting only*: Discharge Summary.
2. Using the C-CDA documents parsed in step 1, the Health IT Module processes the data elements required in the corresponding section-templates and entry-templates from the standards adopted in § 170.205(a)(3) HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 or § 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1 as applicable.
3. Using the C-CDA documents parsed in step 1, the Health IT Module processes empty sections and null combinations in accordance with document-templates from the standards adopted in § 170.205(a)(3) HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 and § 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1 and interprets them correctly.

Detect Errors

4. Using the invalid Common Clinical Data Set summary records received in (b)(5)(i), the Health IT Module detects the C-CDA document types containing errors for the negative test cases referenced from the C-CDA negative testing sample documents corresponding to “document-templates” errors, “section-templates” errors, and “entry-templates” errors including invalid vocabulary standards and codes not specified in the standards adopted in § 170.205(a)(3) HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 and § 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1 and the Health IT Module reports the errors.

Error Handling

5. In the Health IT Module, the user is notified and/or can review the recorded errors encountered during the parsing and processing of C-CDA documents.

Test Lab Verification

Validate (Parse, Identify, and Interpret)

1. For each document received and parsed by the SUT in step 1, the tester uses visual inspection and the human readable document version created in step 1 of the receive setup, to verify that the Common Clinical Data Set summary records received in (b)(5)(i) are formatted in accordance with either the standard specified in § 170.205(a)(3) as a CCD or C-CDA or § 170.205(a)(4) as a C-CDA with one of the following document types as applicable:
   - Continuity of Care;
   - Referral Note; and
   - *Inpatient setting only*: Discharge Summary.
2. Using visual inspection and the parsed data from step 1 of the SUT, the tester verifies that all of the required data elements from valid C-CDA documents with corresponding section-templates and entry-templates from the standards adopted in § 170.205(a)(3) and § 170.205(a)(4) are successfully processed for each of the appropriate document types.
3. Using visual inspection and the processed data from step 2 of the SUT, the tester verifies that valid empty sections and null combinations in valid C-CDA documents with corresponding section-templates and entry-templates from the standards adopted in § 170.205(a)(3) and § 170.205(a)(4) are successfully interpreted for each of the following applicable document types.

Detect Errors

4. Using visual inspection and ONC-supplied negative test data, the tester verifies that for each of the negative C-CDA document test files not specified with the standards adopted in § 170.205(a)(3) or § 170.205(a)(4) the Health IT Module correctly identifies errors in the C-CDA document and identifies the C-CDA document as invalid.

Error Handling

5. Using visual inspection, the tester verifies that errors encountered during the parsing and processing of the C-CDA documents are recorded, and that a user is either notified of the errors produced OR can review all of the recorded errors using the Health IT Module.

Paragraph (b)(5)(ii)(B)

System Under Test

Display

1. Using the Health IT Module and the processed C-CDA documents in (b)(5)(ii)(A), the user displays the transition of care/referral summaries received in human readable format including the data which is formatted in accordance to the standards specified in § 170.205(a)(3) HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 or § 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1, as applicable, and includes, at a minimum, the following content in English (non-coded) representation if they associate with a vocabulary/code set as applicable for the:
   - Common Clinical Data Set as specified in (b)(5)(i)(A);
   - Encounter diagnoses as specified in (b)(5)(i)(B);
   - Cognitive status as specified in (b)(5)(i)(C);
   - Functional status as specified in (b)(5)(i)(D);
   - *Ambulatory setting only*: data elements as specified in (b)(5)(i)(E); and
   - *Inpatient setting only*: data elements as specified in (b)(5)(i)(F).

Test Lab Verification

Display

1. The tester retrieves the CCDS summary record information in order to validate the display of the CCDS summary records received and validated in (b)(5)(i) and (b)(5)(ii)(A) respectively. This is accomplished by using the human readable versions of the downloaded CCDS summary record created in (b)(5)(i) step 1 of the SUT.
2. For each CCDS summary record received in (b)(5)(i), the tester uses the corresponding CCDS summary record information documents and the Health IT Module to verify through visual inspection that the transition of care/referral summaries received in (b)(5)(ii)(B), are displayed accurately and without omission, and that the data is formatted in accordance with the standards specified in § 170.205(a)(3) or § 170.205(a)(4) and includes at a minimum the applicable English (i.e., non-coded) representation if they associate with a vocabulary/code set content from the:
   - Common Clinical Data Set;
   - Encounter diagnoses;
   - Cognitive status;
   - Functional status;
   - *Ambulatory setting only*: the reason for referral, referring or transitioning provider's name, and office contact information; and
   - *Inpatient setting only*: the discharge instructions.

Paragraph (b)(5)(ii)(C)

System Under Test

Display Section Views

1. Using the Common Clinical Data Set summary record(s) received and processed in (b)(5)(i) and (b)(5)(ii)(A), the user uses the Health IT Module to display each individual section or additional sections (and the accompanying document header information) of the received transition of care/referral summaries displayed, that are formatted according to the standards specified in § 170.205(a)(3) HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 and § 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU Release 2.1.
2. Using the Common Clinical Data Set summary record(s) received and processed in (b)(5)(i), and (b)(5)(ii)(A), the user uses the Health IT module to directly display only the data within a particular section.

Section Order

3. The user uses the Health IT Module to set the preference for the display order of specific sections.

Quantity of Sections

4. The user uses the Health IT Module to set the initial quantity of sections to be displayed.

Test Lab Verification

Display Section Views

1. Using visual inspection, the tester verifies that for transition of care/referral summaries received and processed in (b)(5)(ii)(A)(*1*), (b)(5)(ii)(A)(*3*), and (b)(5)(ii)(A)(*4*) the Health IT Module can display the data from an individual section and its accompanying document header information.
2. Using visual inspection, the tester verifies that for the transition of care/referral summaries being displayed in step 1 of the SUT, the user can select data from an additional individual section or sections to be displayed, along with its accompanying document header information.
3. Using visual inspection, the tester verifies that data first displayed in step 1 of the SUT is for one particular section of the document for each document type.
4. Using visual inspection, the tester verifies that transitions of care/referral summary data displayed in steps 1 and 2 of the SUT are accurate and without omission.

Section Order

5. Using visual inspection, the tester verifies the user has the ability to set the order in which the transitions of care/referral summary sections are displayed for each of the supported document-types.
6. Using visual inspection, the tester verifies that the sections displayed for transition of care/referral summaries received and processed in (b)(5)(ii)(A)(*1*), (b)(5)(ii)(A)(*3*) and (b)(5)(ii)(A)(*4*) are ordered correctly based upon the section order set in the previous step (step 5 of the TLV). The sections are displayed in the preferred order.

Quantity of Sections

7. Using visual inspection, the tester verifies the user has the ability to set the initial quantity of sections for a transitions of care/referral summary to be displayed.
8. Using visual inspection, the tester verifies that the number of transition of care/referral summary sections initially displayed in step 1 of the SUT corresponds to the quantity of sections to be displayed in step 7 of the TLV.

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