

2015 Edition §170.315(b)(5) Common Clinical Data Set summary record - receive					
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)(5)(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 (for inpatient settings only) Discharge Summary document templates, and 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 version of 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

#### Standards:

- § 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](#), (incorporated by reference in § 170.299). 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, Draft Standard for Trial Use, Release 2.1](#) (incorporated by reference in § 170.299).
- § 170.207(b)(3) [CDI](#)
- § 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](#) and [Telecommunication Union E. 164: The international public telecommunication numbering plan](#)

§ 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,

§ 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\_b5\_ccds\_receive\_inp\_sample\*.xml (all samples)

Ambulatory Setting - 170.315\_b5\_ccds\_receive\_amb\_sample\*.xml (all samples)

Negative Tests: 170.315\_NT\_sample\*.xml

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

Criteria ¶	System Under Test	Test Lab Verification
(i)	<ol style="list-style-type: none"> <li>1. Based upon the health IT setting(s) (i.e. ambulatory and/or inpatient), a user receives into the Health IT module the Common Clinical Data Set (CCDS) for each of the ambulatory and/or inpatient test cases referenced from the CCDS summary record sample documents. All test cases for a given health IT setting are required.</li> <li>2. Using the top-level C-CDA Validator, one of the tool selections within the Edge Testing Tool, the user selects the CCDS summary record documents (xml) and selects download to download the required CCDS summary record xml files.</li> <li>3. The user uses the Health IT module to receive the downloaded CCDS summary record xml files with the following C-CDA transition of care/referral summary document types (CCDS summary record) formatted in accordance with the standards adopted in § 170.205(a)(3), CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 and § 170.205(a)(4), CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, Release 2.1: <ul style="list-style-type: none"> <li>• Continuity of Care Document</li> <li>• Referral Note</li> <li>• Discharge Summary (for inpatient setting only).</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>1. For each test case, the tester verifies that the Health IT module can successfully receive the applicable types of transitions of care/referral summaries according to the standard adopted in § 170.205(a)(3) and § 170.205(a)(4) and the content specified in (b)(5)(i)(A-F) as applicable, using Visual Inspection: <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> </ol>

Criteria ¶	System Under Test	Test Lab Verification
	<p>4. Negative Testing: Based upon the health IT setting(s) (i.e. ambulatory and/or inpatient), a user receives a series of invalid C-CDA document types referenced from the Negative sample documents into the Health IT module. All test cases for a given health IT setting are required.</p> <p>5. Negative Testing: Using the top-level C-CDA Validator, one of the tool selections within the Edge Testing Tool, the user selects the Negative Test documents (xml) and selects download to download the required care plan xml files.</p> <p>6. Negative Testing: Using the Health IT module, a user receives the Negative Test (xml files) for each of the test cases retrieved from the C-CDA Validator. All test cases are required.</p> <p>7. Negative Testing: 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) CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 and § 170.205(a)(4) for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU , Release 2.1 and reports the error.</p>	<p>2. Negative Test: For each test case, the tester uses visual inspection to verify that the Health IT module can successfully reject the C-CDA documents not specified in accordance with the standards adopted in § 170.205(a)(3) and § 170.205(a)(4) including:</p> <ul style="list-style-type: none"> <li>• “document –templates”</li> <li>• “section-templates”</li> <li>• “entry-templates”</li> <li>• invalid vocabulary standards</li> <li>• invalid codes</li> </ul>

(i)(A) The Common Clinical Data Set.

Criteria ¶	System Under Test	Test Lab Verification
(i)(A)	<p>Each of these documents includes, at a minimum, the Common Clinical Data Set, including:</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>The tester verifies the applicable types of transitions of care/referral summaries received in (b)(5)(i) include the following data element:</p> <ul style="list-style-type: none"> <li>• Clinical Common Data Set with associated standards</li> </ul>

**(i)(B) Encounter diagnoses.**

- (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](#)

Criteria ¶	System Under Test	Test Lab Verification
<b>(i)(B)</b>	<p>The transition of care/referral summary received in (5)(i)(A) includes at a minimum 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; and</li> <li>(v) Causes of injury, disease, impairment, or other health problems;</li> </ul> <p>or at a minimum the version of the standard specified at §170.205(a)(4) ( ICD-10-CM or SNOMED CT®).</p>	<p>The verification of the applicable types of transitions 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) and § 170.205(a)(4):</p> <ul style="list-style-type: none"> <li>• Encounter diagnoses.</li> </ul>

**(i)(C) Cognitive Status**

**Standards:**

§ 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](#), (incorporated by reference in § 170.299). 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, Draft Standard for Trial Use, Release 2.1](#) (incorporated by reference in § 170.299).

Criteria ¶	System Under Test	Test Lab Verification
(i)(C)	The transition of care/referral summary received in (5)(i)(A) includes the Cognitive Status.	The verification of the applicable types of transitions of care/referral summaries received in (b)(5)(i) includes the Cognitive status in accordance to the standard adopted in § 170.205(a)(3) and § 170.205(a)(4).

(i)(D) Functional Status

Standards:

§ 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](#), (incorporated by reference in § 170.299). 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, Draft Standard for Trial Use, Release 2.1](#) (incorporated by reference in § 170.299).

Criteria ¶	System Under Test	Test Lab Verification
(i)(D)	The transition of care/referral summary received in (5)(i)(A) includes the Functional Status.	The verification of the applicable types of transitions of care/referral summaries received in (b)(5)(i) includes the Functional Status in accordance to the standard adopted in § 170.205(a)(3) and § 170.205(a)(4).

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

**Standards:**

§ 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](#), (incorporated by reference in § 170.299). 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, Draft Standard for Trial Use, Release 2.1](#) (incorporated by reference in § 170.299).

Criteria ¶	System Under Test	Test Lab Verification
(i)(E)	<p>Ambulatory setting only, the transition of care/referral summary received in (5)(i)(A) includes, at a minimum:</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>	<p>Ambulatory setting only, the verification of the applicable types of transitions 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) and § 170.205(a)(4):</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>

(i)(F) **Inpatient setting only.** Discharge Instructions

**Standards:**

§ 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](#), (incorporated by reference in § 170.299). 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, Draft Standard for Trial Use, Release 2.1](#) (incorporated by reference in § 170.299).

Criteria ¶	System Under Test	Test Lab Verification
(i)(F)	<p>Inpatient setting only, the transition of care/referral summary received in (5)(i)(A) includes the discharge instructions.</p>	<p>Inpatient setting only, the verification of the applicable types of transitions of care/referral summaries received in (b)(5)(i) includes the discharge instructions in accordance to the standard adopted in § 170.205(a)(3) and § 170.205(a)(4).</p>

**(b)(5)(ii) Validate and display**

Demonstrate the 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; and
  - (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.

**Standards:**

- § 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](#), (incorporated by reference in § 170.299). 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, Draft Standard for Trial Use, Release 2.1](#) (incorporated by reference in § 170.299). § 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](#) and [Telecommunication Union E. 164: The international public telecommunication numbering plan](#)

§ 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,

§ 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\_b5\_ccds\_receive\_inp\_sample\*.xml (all samples)

170.315\_b5\_ccds\_receive\_inp\_sample\*.pdf (all samples)

Ambulatory Setting - 170.315\_b5\_ccds\_receive\_amb\_sample\*.xml (all samples)

170.315\_b5\_ccds\_receive\_amb\_sample\*.pdf (all samples)

Negative Test Inpatient Setting - 170.315\_NT\_sample\*.xml (all samples)

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

(ii)(A) Validate C-CDA conformance

Criteria ¶	System Under Test	Test Lab Verification
(ii)(A)	<ol style="list-style-type: none"> <li>1. Using the Common Clinical Data Set summary records received in (b)(5)(i) formatted in accordance with the standards specified in § 170.205(a)(3) CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 and § 170.205(a)(4) for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, Release 2.1, the Health IT module parses the document based on each of the following document types: <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>2. Negative Test: Using the Health IT module, the user receives 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) CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 and § 170.205(a)(4) for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, Release 2.1 and reports the errors. All test cases are required.</li> <li>3. 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) CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 and § 170.205(a)(4) for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, Release 2.1.</li> </ol>	<ol style="list-style-type: none"> <li>1. For each test case, the tester uses visual inspection to verify that the Common Clinical Data Set summary records received in (b)(5)(i) is formatted in accordance with both the standard specified in § 170.205(a)(3) and § 170.205(a)(4) can be successfully received and parsed using the Health IT module for each of the following document types as applicable: <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>2. Negative Test: Using visual inspection and ONC-supplied negative test data, the tester verifies that for each of the negative C-CDA document test cases not specified in the standards adopted in § 170.205(a)(3) and § 170.205(a)(4) the Health IT module correctly identifies errors in the C-CDA document and identifies the C-CDA document as invalid.</li> <li>3. Using visual inspection and the parsed data from step 1, 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 following applicable document types: <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. Using visual inspection and the processed data from step 3, 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: <ul style="list-style-type: none"> <li>• Continuity of Care;</li> </ul> </li> </ol>

Criteria ¶	System Under Test	Test Lab Verification
(ii)(A)	<p>4. 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) CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 and § 170.205(a)(4) for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, Release 2.1; and interprets them correctly.</p> <p>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.</p>	<ul style="list-style-type: none"> <li>• Referral Note; and</li> <li>• Discharge Summary (for inpatient setting only).</li> </ul> <p>5. Using visual inspection, the tester verifies that errors encountered during the parsing and processing of the C-CDA documents are recorded, and that user is either notified of the errors produced OR can review all of the recorded errors using the Health IT Module.</p>

**(ii)(B) Display-** Display in human readable format the data included in transition of care/referral summaries received:

Criteria ¶	System Under Test	Test Lab Verification
(ii)(B)	<p>1. Using Health IT module and the processed C-CDA documents in (b)(5)(ii)(A), the user displays the transitions 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) CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 and § 170.205(a)(4) for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, Release 2.1 and includes, at a minimum, the following content in English (i.e., non-coded) representation if they associate with a vocabulary/code set) as applicable in the Common Clinical Data Set including:</p> <ul style="list-style-type: none"> <li>• The following content from the Common Clinical Data Set: <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> </ul> </li> </ul>	<p>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 top-level C-CDA Validator, one of the tool selections within the Edge Testing Tool to download the ambulatory and/or inpatient test cases referenced CCDS summary record sample information documents (pdfs). The tester selects the criteria that is the appropriate CCDS summary record information documents (pdf) and then selects download to download the CCDS summary record sample information documents (pdfs). All test cases need to be verified.</p> <p>2. For each test case, the tester uses the corresponding CCDS summary record information documents and the Health IT module to verify through visual inspection that the transitions 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) and § 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:</p> <ul style="list-style-type: none"> <li>• Common Clinical Data Set</li> <li>• Encounter diagnoses</li> <li>• Cognitive status;</li> <li>• Functional Status;</li> <li>• For ambulatory setting only: reason for referral, referring or transitioning provider's name, and office contact information; and</li> <li>• For inpatient setting only: discharge instructions.</li> </ul>

Criteria ¶	System Under Test	Test Lab Verification
(ii)(B)	<ul style="list-style-type: none"> <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> <ul style="list-style-type: none"> <li>● Encounter diagnoses in the standard specified at §170.207(i), code set specified at 45 CFR 162.1002(c)(2) for the indicated conditions ICD-10-CM as maintained and distributed by HHS, for the following conditions: <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>(v) Causes of injury, disease, impairment, or other health problems</li> </ul> </li> </ul> <p>or at a minimum the version of the standard specified at §170.205(a)(4) (ICD-10-CM or SNOMED CT®)</p> <ul style="list-style-type: none"> <li>● Cognitive status;</li> <li>● Functional Status;</li> <li>● Ambulatory setting only: reason for referral, referring or transitioning provider’s name, and office contact information;</li> <li>● Inpatient setting only: discharge instructions.</li> </ul>	

**(ii)(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.

Criteria ¶	System Under Test	Test Lab Verification
(ii)(C)	<ol style="list-style-type: none"> <li>1. Using the Common Clinical Data Set summary record(s) received and processed in (b)(5)(i), (b)(5)(ii)(A), and (B)(5)(ii)(B), 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, formatted according to the standards specified in § 170.205(a)(3) and § 170.205(a)(4).</li> <li>2. Using the Common Clinical Data Set summary record(s) received and processed in (b)(5)(i), and (b)(5)(ii)(A), and (B)(5)(ii)(B), the user uses the Health IT module to directly display only the data within a particular section.</li> <li>3. The user uses the Health IT module to set the preference for the display order of specific sections.</li> <li>4. The user uses the Health IT module to set the initial quantity of sections to be displayed.</li> </ol>	<ol style="list-style-type: none"> <li>1. Using visual inspection, the tester verifies that for that transitions 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.</li> <li>2. Using visual inspection, the tester verifies that for the transitions of care/referral summaries being displayed in step 1, the user can select data from an additional individual section or sections to be displayed, along with its accompanying document header information.</li> <li>3. Using visual inspection the tester verifies that data first displayed in step 1 is for one particular section of the document for each document type.</li> <li>4. Using visual inspection, the tester verifies that transitions of care/referral summary data displayed in steps 1 and 2 are accurate and without omission.</li> <li>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.</li> <li>6. Using visual inspection, the tester verifies that the sections displayed for transitions 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 step 4. The sections are displayed in the preferred order.</li> <li>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.</li> <li>8. Using visual inspection, the tester verifies that the number of transition of care/referral summary sections initially displayed in step 1 corresponds to the quantity of sections to be displayed in step 7.</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](#).