# Test Criteria: 170.315.b.1 Transitions of Care - XDR

|  |  |
| --- | --- |
| **Testing Result** |  |
| Participant and Product-with-version |  |
| Setting (Ambulatory or Inpatient) |  |
| Test Proctor |  |
| Test Date |  |
| Test Result | Pass:  Fail:  No Attempt: |
| Error Description (if applicable) |  |
| Modifications to Product Under Test |  |
| Additional Software Used |  |
| Additional Proctor Notes |  |

### Overview

In this document you will find:

* [Test Data and Test Tools](#_Test_Data_and)
* [Standards Support](#_Demonstrate_Standards_Support)
* [Drummond Test Report (Instructions, Expected Results, Points to Remember)](#_170.315(b)(1)(i)(A)_–_Receive)
* [Test Procedures](#_Test_Procedures)
* [Appendix A: Testing Guide](#_Appendix_A:_Testing)
* [Appendix B: ONC Criteria](#_Appendix_B:_ONC)

### Version of ONC Test Method

1.9

### Scope of Proctoring Sheet

The ONC test method associated with this criterion is the only approved test method for EHR Meaningful Use certification. This Proctoring Sheet is not a replacement test method but a test procedure document for performing the ONC test method and recording the results. Proctoring Sheet describe test data, test criteria and expected results. It is assumed the Health IT developer or Participant under Test is familiar with the associated ONC test method.

# Robustness and Reliability Requirement

To satisfy the module criteria, it is expected that the Product-Under-Test is able to complete the testing requirements reliably, including repeat testing with the same result without error, and with a satisfactory level of robustness. This includes unexpected error messages produced through normal operation, multiple unintended restarts of the application or any other “buggy” facets of the product displayed while testing. These errors are record in the Additional Proctor Notes of the proctor sheet. Lack of reliability and robustness of design will result in failure of the module.

# Test Data and Tools

|  |  |
| --- | --- |
| **Test Data Source:** | ONC-Supplied  DG-Supplied:  Developer-Supplied: |
| **Pre-Test Data Setup:**  **RECEIVE:**   * Health IT Developer must supply Test Proctor with endpoints to be used for sending/receiving with the Edge Test Tool (ETT). * “Received” test data must be demonstrated during test event and is not to be pre-loaded. * “Negative Test Cases” (section 1.4 below) may be performed prior to test event depending on health IT implementation. Health IT developer must discuss this option with Test Proctor prior to test event. For expected negative results, see DG-supplied test file: “*170.315\_b.1-ReceiveValidation-NegativeTests-JurorDoc-CCDA\**” available for download in Zendesk. Note two separate documents exist – for CCDA R1.1 and R2.1.   **SEND:**   * Test Data is downloaded for the applicable setting from the ETT [C-CDA R2.1 Validator](https://ttpedge.sitenv.org/ttp/#/validators) using the “Sender SUT Test Data” selection. The test data should be loaded prior to test event:   Ambulatory:   * + 170.315\_b1\_Toc\_Amb (All Samples)   Inpatient:   * + 170.315\_b1\_Toc\_Inp (All Samples) * For expected results, see the DG-supplied test data files: “*170.315.b.1\_Transitions\_of\_Care\_\_SendCreate\_TestData*” and “*170.315.b.1\_Transitions\_of\_Care\_ReceiveParseDisplay\_TestData*”. | |
| **Test Data:**   * Test Data is downloaded for the applicable setting from the ETT [C-CDA R2.1 Validator](https://ttpedge.sitenv.org/ttp/#/validators) using the “Receiver SUT Test Data” and “Sender SUT Test Data” selections. | |
| **Test Tools:**   * Edge Testing Tool (ETT): <https://ttpedge.sitenv.org/ttp/#/certification/certb1> | |

# 

# Demonstrate Standards Support

|  |  |
| --- | --- |
| **Test Result:** | PASS:  FAIL:  No Attempt:  Not Applicable: |
| **Instructions:** Health IT module must support all standards listed below. | |

|  |  |  |
| --- | --- | --- |
| **§170.202 Transport standards.** | | |
|  | §170.202(a)(2) | [ONC Applicability Statement for Secure Health Transport, Version 1.2](https://www.healthit.gov/policy-researchers-implementers/direct-project) |
|  | §170.202(d) | [ONC Implementation Guide for Direct Edge Protocols (incorporated by reference in §170.299).](https://www.healthit.gov/sites/default/files/implementationguidefordirectedgeprotocolsv1_1.pdf) |
| **§170.205 Content Exchange Standards – Patient Summary Record** | | |
|  | §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](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258) |
|  | §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](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=379) |
|  | §170.205(p) | [XDM package processing—(1) Standard. IHE IT Infrastructure Technical Framework Volume 2b (ITI TF-2b) (incorporated by reference in § 170.299)](http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_Rev7-0_Vol2b_FT_2010-08-10.pdf) |
| **§170.207 Vocabulary standards for representing electronic health information \*** | | |
|  | §170.207(a)(4) | [IHTSDO SNOMED CT®, U.S. Edition, September 2015 Release](https://www.nlm.nih.gov/healthit/snomedct/us_edition.html) |
|  | §170.207(b)(2) | 45 CFR 162.1002(a)(5)—combination of HCPCS and CPT-4 |
|  | §170.207(b)(3) | 45 CFR 162.1002(a)(4)—Code on Dental Procedures and Nomenclature. |
|  | §170.207(b)(4) | 45 CFR 162.1002(c)(3)—ICD-10-PCS |
|  | §170.207(c)(3) | LOINC® Database version 2.52. |
|  | §170.207(d)(3) | RxNorm, September 8, 2015 Release. |
|  | §170.207(e)(3) | HL7 CVX—Vaccines Administered, updates through August 17, 2015. |
|  | §170.207(e)(4) | National Drug Code Directory—Vaccine Codes, updates through August 17, 2015. |
|  | §170.207(f)(1) | OMB as revised, October 30, 1997. |
|  | §170.207(f)(2) | CDC Race and Ethnicity Code Set Version 1.0 (March 2000) (incorporated by reference in § 170.299). |
|  | §170.207(g)(2) | Request for Comments (RFC) 5646 (incorporated by reference in § 170.299). |
|  | §170.207(h) | Smoking status constrained codes from SNOMED CT®. |
|  | §170.207(k)(1) | LOINC® version 2.51 (minimum codes: 8480-6, 8462-4, 8302-2, 3141-9, 8867-4, 9279-1, 8310-5, 59408-5, 39156-5, and 8478-0) |
|  | §170.207(m) | Numerical references—(1) Standard. The Unified Code of Units of Measure, Revision 1.9 (incorporated by reference in § 170.299). |
|  | §170.207(n)(1) | Birth sex must be coded in accordance with HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor (incorporated by reference in § 170.299), attributed as follows:  (i) Male. M (ii) Female. F  (iii) Unknown. nullFlavor UNK |
| **§170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.** | | |
|  | §170.210(g) | Synchronized clocks. The date and time recorded utilize a system clock that has been synchronized following (RFC 1305) Network Time Protocol, (incorporated by reference in §170.299) or (RFC 5905) Network Time Protocol Version 4, (incorporated by reference in §170.299). |

**CCDS Reference Table**

[2015 Common Clinical Data Set](https://www.healthit.gov/sites/default/files/2015Ed_CCG_CCDS.pdf)

|  |  |  |
| --- | --- | --- |
|  | **CCDS** | **Standard** |
|  | Patient Name | **<Not applicable>** |
|  | Sex; including Birth sex | **§170.207 (n)(1)** |
|  | Date of Birth | **<Not applicable>** |
|  | Race | **§170.207 (f)(2)** Mapped to **§170.207 (f)(1);**  **§170.207 (f)(2)** |
|  | Ethnicity | **§170.207 (f)(2)** Mapped to **§170.207 (f)(1);**  **§170.207 (f)(2)** |
|  | Preferred Language | **§170.207 (g)(2)** |
|  | Smoking Status | **§170.207 (h)** |
|  | Problems | **§170.207 (a)(4)** |
|  | Medications | **§170.207 (d)(3)** |
|  | Allergies | **§170.207 (d)(3)** |
|  | Lab Tests | **§170.207 (m)(1)** |
|  | Lab Values(s)/Results | **<Not applicable>** |
|  | Vital Signs | **§170.207 (k)(1), §170.207 (m)(1)** |
|  | BMI (Optional) | **§170.207 (c)(3), §170.207 (m)(1)** |
|  | Procedures | **§170.207 (a)(4)**  **§170.207 (b)(2)** |
|  | Procedures (Optional: for dental systems) | **§170.207 (b)(3)** |
|  | Procedures (Optional) | **§170.207 (b)(4)** |
|  | Care Team Member(s) | **<Not applicable>** |
|  | Immunizations | **§170.207 (e)(3), §170.207 (e)(4)** |
|  | Unique Device Identifier(s) for a Patient’s Implantable Device(s) | **“Product Instance” in the “Procedure Activity Procedure Section” of the standard specified in § 170.205(a)(4)** |
|  | Assessment and Plan of Treatment | **In accordance with the “Assessment and Plan Section (V2)” of the standard specified in § 170.205(a)(4); or**  **In accordance with the “Assessment Section (V2)” and “Plan of Treatment Section (V2)” of the standard specified in § 170.205(a)(4).** |
|  | Goals | **Goals Section” of the standard specified in § 170.205(a)(4) for certification to the 2015 Edition health IT certification criteria.** |
|  | Health Concerns | **In accordance with the “Health Concerns Section” of the standard specified in § 170.205(a)(4) for certification to the 2015 Edition health IT certification criteria.** |

# 170.315(b)(1)(i)(A) – Receive Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources

**170.315(b)(1)(ii) – Validate and Display**

|  |  |
| --- | --- |
| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **Instructions:**  Health IT developer must:   * Access <https://ttpedge.sitenv.org/ttp/#/certification/certb1> * Select “Receive using Edge Protocol - XDR” from the drop-down selector and execute the following Test Cases:   + XDR Test 3, 4a, 4b, 5, 8, and 9   + Negative CCDS Validation | |
| **Expected Test Result:**   * Pass all required XDR tests using the Edge Testing Tool (ETT) with no errors. * Receive a non-specified or CCD R1.1 C-CDA Document payload type in an Ambulatory and/or Inpatient setting as applicable * Receive CCD and Referral Note R2.1 C-CDA Document payload type in an Ambulatory and/or Inpatient setting as applicable * Receive Discharge Summary R2.1 C-CDA Document payload type in an Inpatient setting (if applicable) * Parse and display all data from the relevant C-CDA documents. * Validate and display any recorded errors for invalid C-CDA documents. | |
| **Points to Remember:**   * Refer to the ETT User Guide at <https://github.com/siteadmin/ett/raw/resources/documentation/guides/userguide.pdf> for a complete description and instructions for the setup and execution of all test cases. * ONC permits EHRs to implement their ETT validation tool code to perform CCDA validation and is available through GitHub: (<https://github.com/siteadmin/referenceccdavalidator/releases>). | |

### Test Procedures

**1.1 Edge System Establish TLS Connection with HISP (i)(B)**

|  |  |
| --- | --- |
|  | Positive TLS Authentication: **XDR Test 8** and Negative TLS Authentication **XDR Test 9**  OR  Secure Network (Alternative if not using TLS) – Developer demonstrates the ability to provide a secure connection to the SUT by providing evidence and demonstration that the system uses a “secure network” as described at 170.202(d) Implementation Guide for Direct Edge Protocols v1.1. |

<INSERT LINKS TO VALIDATION REPORTS>

**1.2 Receive Payload, Parse, and Display – Positive Test Cases**

|  |  |
| --- | --- |
|  | **XDR Test 5** (Full Metadata)  Health IT module must test one payload for Full Metadata. |
|  | **XDR Test 3** (Limited Metadata)  All of the following payloads must be received by health IT module using Limited Metadata:  For Ambulatory and/or Inpatient Settings:   * Either R1.1 non-specified C-CDA document *or* R1.1 CCD * Continuity of Care Document (CCD) R2.1 Sample 1 * Continuity of Care Document (CCD) R2.1 Sample 2 * Referral Note R2.1 Sample 1 * Referral Note R2.1 Sample 2   For Inpatient Settings only:   * Discharge Summary R2.1 Sample 1 * Discharge Summary R2.1 Sample 2 |
|  | Health IT module must test each of these requirements for the document types listed above in this table:   * Parsed and processed valid document-templates and required data elements (ii)(A) * Display human readable view (CCDS) (ii)(B) * Display section views (and document header information) (ii)(C)(1) * Data from particular sections (ii)(C)(2) * Set preference for order of specific sections (ii)(C)(3) * Set initial quantity of sections for display (ii)(C)(4) |

<INSERT LINK TO VALIDATION REPORTS>

<INSERT SCREENSHOTS>

### 1.3 Incorrect XDR Message Receive

|  |  |
| --- | --- |
|  | XDR Test 4:   * **XDR Test 4a**: Invalid SOAP header; and * **XDR Test 4b**: Invalid SOAP body details |

<INSERT SCREENSHOTS>

**1.4 Negative Testing C-CDA and Error Reporting**

|  |  |
| --- | --- |
|  | Using **XDR Test 3** and the “*NegativeTesting\_CCDS”* R1.1 and R2.1 Test Cases, for each invalid payload received, health IT module identifies and records the following errors and allows user to either (1) be notified of the errors produced; or (2) review the errors produced.   * “document-templates”; * “section-templates”; * “entry-templates”; * Invalid vocabulary standards; and * Invalid codes |

<INSERT SCREENSHOTS>

# 170.315(b)(1)(i)(A) – Send Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources

**170.315(b)(1)(iii)(A) - Create**

|  |  |
| --- | --- |
| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **Instructions:**  Health IT developer must:   * Access <https://ttpedge.sitenv.org/ttp/#/certification/certb1> * Select “Send Using Edge Protocol - XDR” from the drop-down selector to execute the following Test Cases:   + XDR Test 1, 2, 6, and 7   + XDR MT Test 20a, 20b, and 49 | |
| **Expected Test Result:**   * Pass all required XDR test cases using the Edge Testing Tool (ETT). * All C-CDA Document payloads in XDR Test 1 are sent using Limited XDR metadata. * One C-CDA Document payload in XDR Test 2 is sent using Full XDR metadata * **Ambulatory setting**: send a total of (4) R2.1 C-CDAs (2 CCDs and 2 Referral Notes) each using Limited Metadata and based upon the *170.315\_b1\_toc\_amb\_sample1* and *170.315\_b1\_toc\_amb\_sample2* ONC Test Patient Data * **Inpatient setting**: send a total of (6) R2.1 C-CDAs (2 CCDs, 2 Referral Notes, and 2 Discharge Summaries) each using Limited Metadata and based upon the *170.315\_b1\_toc\_inp\_sample1* and *170.315\_b1\_toc\_inp\_sample2* ONC Test Patient Data * Successfully validate all required C-CDA documents using the ETT. * Successfully validate all required C-CDA documents through visual inspection for a subset of CCDS data elements not verified by the ETT. Refer to the “170.315.b.1.Transitions\_of\_SendCreate\_TestData” document for visual inspection of relevant CCDS data elements. | |
| **Points to Remember:**   * Refer to the ETT User Guide at <https://github.com/siteadmin/ett/raw/resources/documentation/guides/userguide.pdf> for a complete description and instructions for the setup and execution of all test cases. | |

### Test Procedures

**2.1 Edge System Establish TLS Connection with HISP (i)(A)(2)**

|  |  |
| --- | --- |
|  | Positive TLS Authentication (**XDR Test 6**) and Negative TLS Authentication (**XDR Test 7**)  OR  Secure Network (Alternative if not using TLS) – Developer demonstrates the ability to provide a secure connection to the SUT by providing evidence and demonstration that the system uses a “secure network” as described at 170.202(d) Implementation Guide for Direct Edge Protocols v1.1. |

<INSERT LINKS TO VALIDATION REPORTS>

**Refer to the “170.315.b.1.Transitions\_of\_SendCreate\_TestData” document for visual inspection of relevant CCDS data elements.**

**2.2 Send Using Edge Protocol for IHE XDR Profile for Limited Metadata (i)(A)(4)**

|  |  |
| --- | --- |
|  | **Send: XDR Test 1 (Limited Metadata)**  Using both Sample 1 and Sample 2 ONC Test Patient Data from the applicable Ambulatory and/or Inpatient settings, all of the following C-CDA Release 2.1 Document Template Types must be sent by the Health IT module:   * Continuity of Care Document (CCD) R2.1 Sample 1 * Continuity of Care Document (CCD) R2.1 Sample 2 * Referral Note R2.1 Sample 1 * Referral Note R2.1 Sample 2 * *Inpatient setting only*: Discharge Summary R2.1 Sample 1 * *Inpatient setting only*: Discharge Summary R2.1 Sample 2 |
|  | **Send: XDR Test 2 (Full Metadata)**  The user must send one vendor-supplied C-CDA document type as XDR-based payloads with Full Metadata. |

<INSERT LINK TO VALIDATION REPORTS>

<INSERT SCREEN SHOTS>

**2.3 Message Tracking Using Processed MDNs**

|  |  |
| --- | --- |
|  | (i)(A)(6)Message Tracking Using Processed MDNs: XDR Test 20a |

<INSERT LINK TO VALIDATION REPORT>

**2.4 Message Tracking Using Processed MDNs**

|  |  |
| --- | --- |
|  | (i)(A)(5) Message Tracking Using Processed MDNs: XDR Test 20b |

<INSERT LINK TO VALIDATION REPORT>

**2.5 Message Tracking Using Processed MDNs**

|  |  |
| --- | --- |
|  | (i)(A) 8. Delivery Notification: XDR Test 49 |

<INSERT LINK TO VALIDATION REPORT>

# Appendix A: Testing Guide

*This appendix contains more details and background on the testing requirements, including explanation on underlying standards, notable issues and best practice suggestions.*

Rev 01-Mar-2016 Additions

* <NONE>

# Appendix B: ONC Criteria and Standards

*This appendix contains copy of the relevant ONC criteria and standards for this proctor sheet as a reference. In the event of a discrepancy with the ONC Final Rule, the ONC Final Rule takes precedence.*

**§170.315(b)(1) *Transitions of care***—(i) *Send and receive via edge protocol*—(A) Send transition of care/referral summaries through a method that conforms to the standard specified in § 170.202(d) and that leads to such summaries being processed by a service that has implemented the standard specified in § 170.202(a)(2); and

(B) Receive transition of care/referral summaries through a method that conforms to the standard specified in § 170.202(d) from a service that has implemented the standard specified in § 170.202(a)(2).

(C) *XDM processing.* Receive and make available the contents of a XDM package formatted in accordance with the standard adopted in § 170.205(p)(1) when the technology is also being certified using an SMTP-based edge protocol.

(ii) *Validate and display*—(A) *Validate C-CDA conformance—system performance.* Demonstrate the ability to detect valid and invalid transition of care/referral summaries received and formatted in accordance with the standards specified in § 170.205(a)(3) and § 170.205(a)(4) for the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates. This includes the ability to:

(*1*) Parse each of the document types.

(*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.

(iii) *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:

(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.

(G) *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:

(*1*) *Date of birth constraint*—(*i*) 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.

(*ii*) *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.

(*2*) *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.

(*3*) *Sex constraint.* Represent sex in accordance with the standard adopted in § 170.207(n)(1).

**§170.102 – Definitions**

***Common Clinical Data Set*** means the following data expressed, where indicated, according to the specified standard(s):

(1) *Patient name.*

(2) *Sex.* (ii) The standard specified in § 170.207(n)(1).

(3) *Date of birth.*

(4) *Race.* (ii) For certification to the 2015 Edition health IT certification criteria:

(A) The standard specified in § 170.207(f)(2);

(B) The standard specified in § 170.207(f)(1) for each race identified in accordance § 170.207(f)(2).

(5) *Ethnicity.* (ii) For certification to the 2015 Edition health IT certification criteria:

(A) The standard specified in § 170.207(f)(2);

(B) The standard specified in § 170.207(f)(1) for each ethnicity identified in accordance § 170.207(f)(2).

(6) *Preferred language.* (ii) The standard specified in § 170.207(g)(2).

(7) *Smoking status.* The standard specified in § 170.207(h).

(8) *Problems.* (ii) At a minimum, the standard specified in § 170.207(a)(4).

(9) *Medications.* (ii) At a minimum, the standard specified in § 170.207(d)(3).

(10) *Medication allergies.* (ii) At a minimum, the standard specified in § 170.207(d)(3).

(11) *Laboratory test(s).* (ii) At a minimum, the standard specified in § 170.207(c)(3).

(12) *Laboratory value(s)/result(s).*

(13) *Vital signs.* (ii) For certification to the 2015 Edition Health IT certification criteria:

(A) The patient's diastolic blood pressure, systolic blood pressure, body height, body weight, heart rate, respiratory rate, body temperature, pulse oximetry, and inhaled oxygen concentration must be exchanged in numerical values only; and

(B) In accordance with the standard specified in § 170.207(c)(3) and with the associated applicable unit of measure for the vital sign measurement in the standard specified in § 170.207(m)(1).

(C) *Optional.* The patient's BMI percentile per age and sex for youth 2-20 years of age, weight for age per length and sex for children less than 3 years of age, and head occipital-frontal circumference for children less than 3 years of age must be recorded in numerical values only in accordance with the standard specified in § 170.207(c)(3) and with the associated applicable unit of measure for the vital sign measurement in the standard specified in § 170.207(m)(1). For BMI percentile per age and sex for youth 2-20 years of age and weight for age per length and sex for children less than 3 years of age, the reference range/scale or growth curve should be included as appropriate.

(15) *Procedures*—(i)(A) At a minimum, the version of the standard specified in § 170.207(a)(4), or § 170.207(b)(2); or

(B) For technology primarily developed to record dental procedures, the standard specified in § 170.207(b)(3).

(ii) *Optional.* The standard specified in § 170.207(b)(4).

(16) *Care team member(s).*

(17) *Immunizations.* In accordance with, at a minimum, the standards specified in § 170.207(e)(3) and (4).

(18) *Unique device identifier(s) for a patient's implantable device(s).* In accordance with the “Product Instance” in the “Procedure Activity Procedure Section” of the standard specified in § 170.205(a)(4).

(19) *Assessment and plan of treatment.* (i) In accordance with the “Assessment and Plan Section (V2)” of the standard specified in § 170.205(a)(4); or

(ii) In accordance with the “Assessment Section (V2)” and “Plan of Treatment Section (V2)” of the standard specified in § 170.205(a)(4).

(20) *Goals.* In accordance with the “Goals Section” of the standard specified in § 170.205(a)(4).

(21) *Health concerns.* In accordance with the “Health Concerns Section” of the standard specified in § 170.205(a)(4).

**§170.202 Transport standards.**

**(a)(2) *Standard.*** ONC Applicability Statement for Secure Health Transport, Version 1.2 (incorporated by reference in § 170.299).

**(d) *Standard.*** ONC Implementation Guide for Direct Edge Protocols (incorporated by reference in §170.299).

**§170.205 Content Exchange Standards – Patient Summary Record.**

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

**(a)(4) *Standard.*** HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 1—Introductory Material, Release 2.1 and HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 2—Templates and Supporting Material, Release 2.1 (incorporated by reference in § 170.299).

**(p) *XDM package processing*—(1) *Standard.*** IHE IT Infrastructure Technical Framework Volume 2b (ITI TF-2b) (incorporated by reference in § 170.299).

**§170.207 Vocabulary standards for representing electronic health information.**

**(a)(4) *Standard*.** IHTSDO SNOMED CT®, U.S. Edition, September 2015 Release.

**(b)(2) *Standard*.** 45 CFR 162.1002(a)(5)—combination of HCPCS and CPT-4

**(b)(3) *Standard.*** 45 CFR 162.1002(a)(4)—Code on Dental Procedures and Nomenclature.

**(b)(4) *Standard.*** 45 CFR 162.1002(c)(3)—ICD-10-PCS

**(c)(3) *Standard.*** LOINC® Database version 2.52.

**(d)(3) *Standard.*** RxNorm, September 8, 2015 Release.

**(e)(3) *Standard.*** HL7 CVX—Vaccines Administered, updates through August 17, 2015.

**(e)(4) *Standard.*** National Drug Code Directory—Vaccine Codes, updates through August 17, 2015.

**(f)(1) *Standard.*** OMB as revised, October 30, 1997.

**(f)(2) *Standard.*** CDC Race and Ethnicity Code Set Version 1.0 (March 2000) (incorporated by reference in § 170.299).

**(g)(2) *Standard.*** Request for Comments (RFC) 5646 (incorporated by reference in § 170.299).

**(h) *Standard.*** Smoking status constrained codes from SNOMED CT®.

**(k)(1) *Standard.*** LOINC® version 2.51 (minimum codes: 8480-6, 8462-4, 8302-2, 3141-9, 8867-4, 9279-1, 8310-5, 59408-5, 39156-5, and 8478-0)

***(m) Numerical references—(1) Standard.*** The Unified Code of Units of Measure, Revision 1.9 (incorporated by reference in § 170.299).

**(n)(1) *Standard*.** Birth sex must be coded in accordance with HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor (incorporated by reference in § 170.299), attributed as follows:

(i) Male. M

(ii) Female. F

(iii) Unknown. nullFlavor UNK

**§170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.**

(g) Synchronized clocks. The date and time recorded utilize a system clock that has been synchronized following (RFC 1305) Network Time Protocol, (incorporated by reference in §170.299) or (RFC 5905) Network Time Protocol Version 4, (incorporated by reference in §170.299).

# Change Log

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| Revision | Change Description |
| 05-Jun-2017 | Added note that ONC permits EHR vendors to use validation tool code to perform CCDA validation under “points to remember”. Corrected section numbering. Added “Secure Network” Alternative for providing secure connection to sections 1.1 and 2.1. |
| 03-May-2017 | Reflects significant changes to ETT test cases in the new “2015 Certification Testing” path for 170.315(b)(1). Combined “Receive” and “Send” TOC proctor sheets into one document. |
| 03-Jan-2017 | Removed test case 4c from section 1.3. |
| 01-Oct-2016 | Updated “Test Data and Tools” section for pre-test activities and reference test data sheet. Also updated section 1.4 to clarify expected errors to be recorded. Updated hyperlinks for ONC-hosted ETT. |
| 01-Jun-2016 | Updated test tool and test data filenames. Added reference to the DG-supplied “170.315.b.1\_Transitions\_of\_Care\_TestData” sheet. Updated section numbering. Removed irrelevant test cases under section 2.1. Added hyperlinks to standards list. |
| 01-May-2016 | Corrected Race and Ethnicity entries on “CCDS Reference Table” to clarify 170.207(f)(2) should be mapped to 170.207(f)(1). |
| 01-Mar-2016 | Initial Release. |
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**About Drummond Group LLC**

Drummond Group LLC is a global software test and certification lab that serves a wide range of vertical industries.  In healthcare, Drummond Group tests and certifies Controlled Substance Ordering Systems (CSOS), Electronic Prescription of Controlled Substances (EPCS) software and processes, and Electronic Health Records (EHRs) – designating the trusted test lab as the only third-party certifier of all three initiatives designed to move the industry toward a digital future. Founded in 1999, and accredited for the Office of the National Coordinator Health IT Certification Program as an Authorized Certification Body (ACB) and an Authorized Test Lab (ATL), Drummond Group continues to build upon its deep experience and expertise necessary to deliver reliable and cost-effective services. For more information, please visit <http://www.drummondgroup.com> or email [ehr@drummondgroup.com](mailto:ehr@drummondgroup.com)

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