# Test Criteria: 170.315.b.1 Transitions of Care – SMTP

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| --- | --- |
| **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)(B)_–_Receive)
* [Test Procedures](#_Test_Procedures)
* [Appendix A: Testing Guide](#_Appendix_A:_Testing)
* [Appendix B: ONC Criteria](#_Appendix_B:_ONC)
* [Appendix C: Receive (SMTP) Attestation Template](#_Appendix_C:_170.315(b)(1)_1)

### 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 UnderTest 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

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| **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). A “test” SMTP account may be set up by developer to prevent sharing SMTP username and password. * “Received” test data must be demonstrated during test event and is not to be pre-loaded. * “Negative Test Cases” (section 1.5 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*”. * Submit attestation letter (see [Appendix C](#_Appendix_C:_170.315(b)(1)) for template) to Test Proctor prior to test event. | |
| **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

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| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **Instructions:** Health IT module must support all standards listed below. | |

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| **§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)(B) – Receive Using Edge Protocol for SMTP

# 170.315(b)(1)(i)(B) – Receive Using Edge Protocol for IMAP

# 170.315(b)(1)(i)(B) – Receive Using Edge Protocol for POP3

# 170.315(b)(1)(i)(C) – XDM Processing (Received via Edge Protocol

|  |  |
| --- | --- |
| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **SMTP Protocol:** |  |
| **Instructions:**  Health IT developer must:   * Identify at least one SMTP protocol to be used for testing:   + SMTP alone;   + SMTP+IMAP; or   + SMTP+POP3 * Access <https://ttpedge.sitenv.org/ttp/#/certification/certb1> * Select the “Receive Using Edge Protocol - SMTP” option from the drop-down selector and execute the following Test Cases   + SMTP Test 9, 16, 20   + SMTP Test 25a – 25f, 26a – 26b, 27, 28, 29   + Negative CCDS Validation * *Optionally* select the “Receive Using Edge Protocol – IMAP” option from the drop-down selector and execute the following Test Cases   + IMAP Test 9, 16, 20   + IMAP Test 21, 25, 27, 28, 29a – 29b, 30, 31 * *Optionally* select the “Receive Using Edge Protocol – POP3” option from the drop-down selector and execute the following Test Cases   + POP Test 9, 16, 20   + POP Test 27, 28, 29a – 29b, 30, 31 * Select the “XDM Processing (Received via Edge Protocol)” option from the drop-down selector and execute all test cases   + SMTP Test 9, 16, 20 | |
| **Expected Test Result:**   * Pass all required and optionally applicable SMTP 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. * Health IT developer must submit a signed attestation document confirming health IT module functionality. See [Appendix C](#_Appendix_C:_170.315(b)(1)-) for an attestation template. | |
| **Points to Remember:**   * Refer to <https://ttpedge.sitenv.org/ttp/#/certification> for a list of the endpoints used for SMTP testing. * 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

For Test Steps 1.1 – 1.5, select the “Receive Edge Protocol – SMTP” option from the 170.315(b)(1) testing tool at <https://ttpedge.sitenv.org/ttp/#/certification/certb1>

**1.1 Receive Using Edge Protocol for SMTP: SMTP Test 9, 16, 20 (Receive)**

|  |  |
| --- | --- |
|  | Select one of the C-CDA Document Type payloads listed below and use the ETT to send the document to the Health IT module. |
|  | Using TLS, verify new email message received by the HIT module and that the subject of the email is STARTTLS & PLAIN SASL AUTHENTICATION and that the XML attachment is the C-CDA Document Type chosen in the prior step.  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. |
|  | Repeat previous steps for all required C-CDA Document Types. |
|  | All of the following C-CDA Document Type payloads must be received by Health IT module:  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>

**1.2 Receive Multiple Attachments**

|  |  |
| --- | --- |
|  | C-CDA and Text (SMTP Test 25(a)) |

<INSERT SCREEN SHOTS>

|  |  |
| --- | --- |
|  | PDF and C-CDA (SMTP Test 25(b)) |

<INSERT SCREEN SHOTS>

|  |  |
| --- | --- |
|  | Text and XDM Package (SMTP Test 25(c)) |

<INSERT SCREEN SHOTS/ETT LOGS>

|  |  |
| --- | --- |
|  | C-CDA and Text (SMTP Test 25(d)) |

<INSERT SCREEN SHOTS/ETT LOGS>

|  |  |
| --- | --- |
|  | C-CDA and PDF (SMTP Test 25(e)) |

<INSERT SCREEN SHOTS/ETT LOGS>

|  |  |
| --- | --- |
|  | XDM and Text (SMTP Test 25(f)) |

<INSERT SCREEN SHOTS/ETT LOGS>

**1.3 Negative Tests: Style Sheet/Header**

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| --- | --- |
|  | Bad Attachment - a bad C-CDA with a broken reference to the style sheet. (SMTP Test 26(a)) |
|  | Bad Attachment - a good C—CDA with a bad style sheet (SMTP Test 26(b)) |
|  | Receive XDM with bad XHTML (SMTP Test 27) |

<INSERT SCREEN SHOTS>

**1.4 MIME Type**

|  |  |
| --- | --- |
|  | XDM package with a MIME type of ‘application/octet-stream’ (SMTP layer) (SMTP Test 28) |
|  | XDM package containing a C-CDA with a MIME type of ‘application/xml’ (XDM layer) (SMTP Test 29) |

<INSERT SCREEN SHOTS>

**1.5 Negative Test Cases: C-CDA Error Reporting**

|  |  |
| --- | --- |
|  | Using **XDR Test 9, 16, 20 (Receive)** 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/LOG FILES>

For Test Steps 1.6, select the “XDM Processing (Received via Edge Protocol)” option from the 170.315(b)(1) testing tool at <https://ttpedge.sitenv.org/ttp/#/certification/certb1>

**1.6 Validation of XDM package**

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|  | Validation of XDM package: The SUT receives an XDM document payload from the ETT using valid SMTP commands (SMTP Test 9, 16, 20) |

<INSERT SCREEN SHOTS>

For the following *optional* Test Step 1.7, select the “Receive Using Edge Protocol - IMAP” option from the 170.315(b)(1) testing tool at <https://ttpedge.sitenv.org/ttp/#/certification/certb1>

**1.7 IMAP Test cases (Alternative)** **(i)(B)**

|  |  |
| --- | --- |
|  | SUT Connection: The user shall initiate an IMAP session with STARTTLS and PLAIN SSL authentication with the ETT (IMAP Tests 19 STARTTLS and IMAP Test 20 SASL)  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. |
|  | IMAP receive: (IMAP Test 24) |
|  | IMAP receive: The user shall demonstrate the Health IT module can use either the uppercase, lowercase, or mixed case mailbox names and access data (IMAP Test 21). |
|  | IMAP receive: The Health IT module is able to receive status and size updates from the IMAP4 server (IMAP Test 25). |
|  | IMAP receive: XDM packages sent using appropriate MIME types. (IMAP Test 27). |
|  | IMAP receive: Multiple attachments in varying order from the ETT. (IMAP Test 28). |
|  | IMAP receive: Bad attachment (C-CDA where the style sheet is bad or missing) from the ETT. (IMAP Tests 29a and 29b). |
|  | IMAP receive: XDM package with a bad XHTML from the ETT. (IMAP Test 30). |
|  | IMAP receive: Different attachments. (IMAP Test 31). |

<INSERT SCREENSHOTS>

For the following *optional* Test Step 1.8, select the “Receive Using Edge Protocol – POP3” option from the 170.315(b)(1) testing tool at <https://ttpedge.sitenv.org/ttp/#/certification/certb1>

**1.8 POP3 Test cases (Alternative)**

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|  | (i)(B) 2. SUT Connection: (POP Test 19 and 24) The user shall initiate a POP session the ETT using TLS.  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. |
|  | POP3 Receive: (POP Test 24) |
|  | (i)(B) 6. POP3 Receive: XDM Packages sent using appropriate MIME Types. (POP Test 27) |
|  | (i)(B) 7. POP3 Receive: Multiple attachments in varying order from the ETT. (POP Test 28) |
|  | (i)(B) 8. POP3 Receive: Bad attachment (C-CDA where the style sheet is bad or missing) from the ETT. (POP Test 29a and 29b) |
|  | (i)(B) 9. POP3 Receive: XDM package with a bad XHTML from the ETT. (POP Test 30) |
|  | (i)(B) 10. POP3 Receive: Different attachments. (POP Test 31) |

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# 170.315(b)(1)(i)(A) – Send Using Edge Protocol for SMTP

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

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| --- | --- |
| **Test Result:** | PASS:  FAIL:  No Attempt: |
| **Instructions:**  Health IT developer must:   * Access <https://ttpedge.sitenv.org/ttp/#/certification/certb1> * Select “Send using Edge Protocol - SMTP” from the drop-down selector to execute the following Test Cases:   + SMTP Test 8, 14, and 18 (Send)   + SMTP MT Test 46 (Generate Disposition Notification Options Header). | |
| **Expected Test Result:**   * Pass all required SMTP test cases using the Edge Testing Tool (ETT). * **Ambulatory setting**: send a total of (4) R2.1 C-CDAs (2 CCDs and 2 Referral Notes) each 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 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 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. * Health IT developer must submit a signed attestation document confirming health IT module functionality. See Appendix C for an attestation template. | |
| **Points to Remember:**   * Refer to <https://ttpedge.sitenv.org/ttp/#/certification> for a list of the endpoints used for SMTP testing. * 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

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

**2.1 Send Using Edge Protocol for SMTP**

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| --- | --- |
|  | **SMTP Tests 8 and 14** (STARTTLS, Authentication)  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. |
|  | SMTP 18 (Send)  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 |

<INSERT LINK TO VALIDATION REPORTS>

**2.2 Send Using Edge Protocol for SMTP**

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| --- | --- |
|  | Generate Disposition Notification Options Header: SMTP MT Test 46 |

<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).

### Appendix C: 170.315(b)(1) – SMTP Attestation Template

*This appendix contains a template for submitting the 170.315(b)(1) attestation requirements. The attestation letter should be returned on company letterhead addressing the required functionality. References listed in gray serve as an aide in evaluation. All are not required to be included in the attestation letter itself. This attestation may be combined and submitted with “Receive (SMTP) Attestation Template” within 170.315b.1\_SMTP\_TOC\_ReceiveValidateDisplay” proctor sheet.*

[Name of Authorized Senior Company Representative]

[Title of Company Representative]

[Company Contact Information]

[Company Name] attests that the System Under Test provides the functionality identified below for the associated ONC 2015 Edition criteria 170.315(b)(1) requirements.

*Identify all that apply for Transitions of Care - Receive:*

* *Authenticate to a HISP using DIGEST-MD5 SASL as an SMTP server.*
* *Initiate a STARTTLS connection and reject the connection upon receiving an invalid certificate from a HISP using IMAP.*
* *Initiate a STARTTLS connection and reject the connection upon receiving an invalid certificate from a HISP using POP3.*
* *Connect to the valid cipher suite (TLS\_RSA\_WITH\_RC4\_128\_MD5) using IMAP.*
* *Connect to the valid cipher suite (TLS\_RSA\_WITH\_RC4\_128\_MD5) using POP3.*

*Identify all that apply for Transitions of Care - Send:*

* *Can reject the connection for a TLS session initiated with a HISP due to an invalid certificate.*
* *Can authenticate using DIGEST-MD5 SASL.*

**I hereby attest that all above statements are true, as an authorized signing authority on behalf of my organization.**

[Signature]

[Signature Block of Authorized Senior Company Representative]

[Date signed]

# Change Log

|  |  |
| --- | --- |
| 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. Removed redundant test case 25d.  Added “Secure Network” Alternative for providing secure connection to sections 1.1, 1.7, 1.8, and 2.1. Removed negative authentication due to invalid DIGEST-MD5 value. |
| 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. |
| 01-Dec-2016 | Added option for developer to set up “test” (e.g., fake) SMTP account for ETT testing under Pretest Data Setup. |
| 01-Oct-2016 | Updated “Test Data and Tools” section for pre-test activities and reference test data sheet. Also updated section 1.11 to clarify expected errors to be recorded. Updated hyperlinks for ONC-hosted ETT. |
| 01-Aug-2016 | Updated IMAP and POP test procedure sections from “Optional” to “Alternative”. |
| 01-July-2016 | Removed SMTP test case 12. |
| 01-Jun-2016 | Updated test tool and test data filenames. Updated section numbering. Removed irrelevant test cases. Added SMTP Test 27 to section 1.9. Added reference to the DG-supplied “170.315.b.1\_Transitions\_of\_Care\_TestData” sheet. Added hyperlinks to standards list. |
| 01-May-2016 | Added comment clarifying one of 3 SMTP protocols may be tested: SMTP, SMTP+IMAP, or SMTP+POP. Corrected Race and Ethnicity entries on “CCDS Reference Table” to clarify 170.207(f)(2) should be mapped to 170.207(f)(1). |
| 01-Apr-2016 | Removed erroneous references to “IMAP Test 22” and “POP3 Test 22”. |
| 01-Mar-2016 | Initial Release. |

**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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