The Office of the National Coordinator for
Health Information Technology

2015 Edition §170.315(b)(1) Transitions of Care

Testing Components:

ONC Supplied Test Data

Test Procedure Version 1.2 – Last Updated 4/12/16

Please consult the Final Rule entitled: *2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications* for a detailed description of the certification criterion with which these testing steps are associated. We also encourage developers to consult the Certification Companion Guide in tandem with the test procedure as they provide clarifications that may be useful for product development and testing.

Note: The order in which the test steps are listed reflects the sequence of the certification criterion and does not necessarily prescribe the order in which the test should take place.

Required Tests

The testing depends on which edge protocol the Health IT Module chooses for certification.

(b)(1)(i) Send and Receive via Edge Protocol

Technology must be able to:

(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); 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.

Standards:

§170.202(a)(2) Direct Project: ONC Applicability Statement for Secure Health Transport, Version 1.2 (incorporated by reference §170.299).
§170.202(d) ONC Implementation Guide for Direct Edge Protocols (incorporated by reference in § 170.299).
§170.205(p)(1) XDM package processing. IHE IT Infrastructure Technical Framework Volume 2b (ITI TF-2b) (incorporated by reference in § 170.299).

Tools: Edge Testing Tool (ETT)
Transport Testing Tool (TTT)

Testing must be conducted for one of the Sending Alternatives outlined below to satisfy the requirements for this criterion.

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

Criteria ¶	System Under Test	Test Lab Verification
(i)(A) (Alternative)	<u>SUT Connection</u> 1. The user executes XDR Tests using the ETT for "System as Sender." 2. Authentication: The user establishes a Mutual TLS session for the Health IT Module to authenticate to the ETT (XDR Test 6). 3. Authentication: The user authenticates the Health IT Module to the ETT using an incorrect Mutual TLS session (XDR Test 7). <u>Send Payload</u> 4. The user provides the Health IT Module's Direct "From" address to generate endpoints for Limited Metadata (XDR Test 1) and Full Metadata (XDR Test 2). The payloads created at section(b)(1)(iii) shall be sent as applicable by the user selection of the criteria "170.315_b1_ToC_Amb" or "170.315_b1_ToC_Inp" based upon the health IT setting and the file name as a Continuity of Care Document (CCD), Referral Note, or a Discharge Summary (for inpatient setting only). Note: The user is required to send at least one payload using Limited Metadata and at least one payload using Full Metadata. <u>Message Tracking</u> 5. The user sends messages to the ETT with unique message IDs for each XDR profile (XDR MT Test 19). 6. The user sends health information to multiple recipients including both valid (Endpoint 5) and invalid recipients (Endpoint 9) (XDR MT Test 20a, XDR MT Test 20b). <u>Delivery Notification</u> 7. The user sends multiple messages to Endpoint 14 using the Edge Testing Tool in multiple sessions. The number of mail messages to be sent shall be determined by the tester based on the amount of rigor the testing requires (XDR MT Test 48). Continued on next page	<u>SUT Connection</u> 1. Using the ETT, the tester verifies the Health IT Module establishes a mutual TLS session prior to transmitting any data and disconnects when the ETT provides an invalid certificate and incorrect Mutual TLS configuration. <u>Send Payload</u> 2. Using the ETT, the tester verifies all XDR test cases for "System as Sender" are successful and valid. 3. Using the ETT, the tester verifies the Health IT Module can send an XDR Message using limited metadata and full metadata using §170.202(d): ONC Implementation Guide for Direct Edge Protocols v1.1. The verification of the payload is performed in section (b)(1)(iii). <u>Message Tracking</u> 4. Using the ETT, the tester verifies that each of the messages sent to the ETT is sent with a unique message id with no duplicates. 5. Using the ETT and inspection of Health IT Module logs, the tester verifies the Health IT Module successfully performs message tracking, including failure messages for invalid recipients. <u>Delivery Notification</u> 6. Using the ETT, the tester verifies the Health IT Module is able to create XDR messages with unique message IDs specific to each message and include it in the WS-Addressing header. The tester verifies the message IDs in the ETT Logs. Continued on next page

Criteria ¶	System Under Test	Test Lab Verification
(i)(A) (Alternative), continued	Continued from previous page 8. The user sends an XDR message to Endpoint 14 using the Edge Testing Tool with a valid Direct Address Block and Delivery Notifications header (XDR MT Test 49) 9. Delivery Notification: The user sends XDR messages to multiple recipients including both valid and invalid recipients within the same message to Endpoints 5 and 9 respectively (XDR MT Test 50).	Continued from previous page 7. Using the ETT, the tester verifies the Health IT Module is able to generate the Direct Address Block header including the Disposition Notifications header. The tester verifies the disposition header in the ETT Logs. 8. Using the Health IT Module's logs, the tester verifies the Health IT Module is able to accept failure notification messages from invalid recipients. The tester verifies a failure notification for Endpoint 9 in the Health IT Module's logs.

(i)(A) – Send Using Edge Protocol for SMTP

Criteria ¶	System Under Test	Test Lab Verification
(i)(A) (Alternative)	<u>SUT Connection</u> 1. The user executes SMTP Tests using the ETT for "System as Sender." 2. Start TLS Session: The user initiates a TLS session for the Health IT Module with the ETT (SMTP Test 14). 3. The Health IT Module provides documentation of the Heath IT module's ability to reject the connection for a TLS session initiated with a HISP due to an invalid certificate. 4. Authentication to SMTP Server: The user authenticates the Health IT Module to the ETT using PLAIN SASL (SMTP Test 18). 5. The Health IT Module provides documentation of the Heath IT module's ability to authenticate using DIGEST-MD5 SASL. <u>Send Payload</u> 6. The user sends a document to the ETT (SMTP Tests 1-8) The payloads created at (b)(1)(iii) shall be sent as applicable by the user selection of the criteria "170.315_b1_ToC_Amb" or "170.315_b1_ToC_Inp" based upon the health IT setting and the file name as a Continuity of Care Document (CCD), Referral Note or a Discharge Summary (for inpatient setting only). Note: The user is required to send at least one payload using Limited and at least one payload using Full Metadata. <u>Message Tracking</u> 7. The user sends messages to the ETT with unique message IDs for each message (SMTP MT Test 17). 8. The user sends health information in a single SMTP message (SMTP MT Test 18). Continued on next page	<u>SUT Connection</u> 1. Using the ETT, the tester verifies the Health IT Module initiates a TLS session. and can authenticate using PLAIN SASL authentication. 2. The tester verifies evidence of the Health IT Module's capability to initiate a TLS session, but reject the connection with a HISP due to an invalid certificate. 3. The tester verifies evidence of the Health IT Module's capability to authenticate using DIGEST-MD5 SASL. <u>Send Payload</u> 4. Using the ETT, the tester verifies the Health IT Module can send a message using the SMTP Edge Protocol with STARTTLS and PLAIN SASL Authentication. The verification of the payload is performed in section (b)(1)(iii). <u>Message Tracking</u> 5. Using the ETT, the tester verifies that each of the messages sent to the ETT is sent with a unique message id with no duplicates. 6. Using the ETT and inspection of Health IT Module logs, the tester verifies the Health IT Module successfully performs message tracking, including failure messages for invalid recipients. <u>Delivery Notification</u> 7. Using the ETT, the tester verifies the Health IT Module successfully performs delivery notification handling per the ONC Implementation Guide for Delivery Notification in Direct v1.0.

Criteria ¶	System Under Test	Test Lab Verification
(i)(A) (Alternative), continued	Continued from previous page <u>Delivery Notification</u> 9. The user sends a series of SMTP mail messages to the ETT with unique message IDs specific to each message. The number of messages to be sent shall be determined by the Tester based upon the amount of rigor the testing requires (SMTP MT Test 45). 10. The user sends an SMTP mail message to the ETT with a valid Disposition-Notifications-Options Header that provides an extensible mechanism for required information and additional control over how and what MDNs are generated per section 1.3 of the ONC Implementation Guide for Delivery Notification in Direct v1.0 (SMTP MT Test 46). 11. The user sends a C-CDA document in a single SMTP mail message (SMTP MT Test 47).	See previous page

Testing must be conducted for one of the Receiving Alternatives outlined below to satisfy the requirements for this criterion.

(i)(B) – Receive Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources

Criteria ¶	System Under Test	Test Lab Verification
(i)(B) Alternative	<u>SUT Connection</u> 1. The user executes XDR Tests using the ETT for "System as Receiver." 2. Authentication: The user establishes authentication from the ETT to the Health IT Module using Mutual TLS correctly (XDR Test 8). Continued on the next page	<u>SUT Connection</u> 1. Using the ETT, the tester verifies all XDR test cases for "System as Receiver" are successful and valid. 2. Using the ETT, the tester verifies the Health IT Module is capable of accepting and validating a Mutual TLS session when authenticating to the ETT. Continued on the next page

Criteria ¶	System Under Test	Test Lab Verification
(i)(B) Alternative, continued	Continued from previous page 3. Authentication: The user establishes authentication from the ETT to the Health IT Module using bad certificates (incorrect Mutual TLS configuration (XDR Test 9). <u>Receive Payload</u> 4. For each required payload specified in (b)(1)(ii), the user selects the appropriate criteria "170.315_b1_ToC_Amb," "170.315_b1_ToC_Inp," "NegativeTesting_CCDS" and then selects the file name to be received by the Health IT Module as a properly formatted XDR message with limited metadata from the ETT (XDR Test 3). Note: The user is required to receive a single payload using both Limited and Full Metadata. 5. For each required payload specified in (b)(1)(ii), the user selects the appropriate criteria "170.315_b1_ToC_Amb" "170.315_b1_ToC_Inp" "NegativeTesting_CCDS" and then selects the file name to be received by the Health IT Module receives a properly formatted XDR message with full metadata from the ETT (XDR Test 5). Note: The user is required to receive at least payload one payload using Limited Metadata and at least one payload using Full Metadata. The full set of required payloads only need to be received using either Limited or Full Metadata. All of the files within a specific criterion need to be received by the Health IT Module. <u>Incorrect XDR Message Receive</u> 6. The Health IT Module returns errors when the following incorrect messages are received from the ETT (XDR Test 4): • Invalid SOAP envelope details; • Invalid SOAP body details; • Missing address information.	Continued from previous page 3. Using the logs, the tester verifies the Health IT Module does not accept connections due to incorrect Mutual TLS configuration and an invalid certificate published by the ETT. <u>Receive Payload</u> 4. Using logs, the tester verifies the Health IT Module is capable of receiving and processing a valid XDR message with limited metadata. The verification of the payload is performed in section (b)(1)(ii). 5. Using logs, the tester verifies the Health IT Module is capable of receiving and processing a valid XDR message with full metadata. <u>Incorrect XDR Message Receive</u> 6. Using logs, the tester verifies that the Health IT Module recognizes that the messages sent from the ETT are invalid messages. This test does not specify how invalid messages are handled by the Health IT Module.

(i)(B) – Receive Using Edge Protocol for SMTP

Criteria ¶	System Under Test	Test Lab Verification
(i)(B) (Alternative)	<u>SUT Connection</u> 1. The user executes SMTP Tests using the ETT for "System as Receiver." 2. Start TLS Session: The user initiates a valid TLS session for the Health IT Module with the ETT sent from email address the user name supplied by the Health IT Module email account being authenticated to the Health IT Module SMTP email address (SMTP Test 16). 3. Start TLS Session: The user initiates an invalid TLS session for the Health IT Module with the ETT sent from the user name supplied by the Health IT Module email account being authenticated to the Health IT Module SMTP email address (SMTP Test 17). 4. Authentication: The user authenticates the ETT with the Health IT Module using PLAIN SASL as an SMTP server from the user name supplied by the Health IT Module email account being authenticated to the Health IT Module SMTP email address (SMTP Test 20). 5. The Health IT Module provides documentation of the ability to authenticate to a HISP using DIGEST-MD5 SASL as an SMTP server and reject authentication due to an invalid DIGEST-MD5 value. 6. Authentication: The Health IT Module receives an authentication from the ETT using an Invalid PLAIN SASL username/password as an SMTP server from the user name supplied by the Health IT Module email account being authenticated (SMTP Test 22). Continued on the next page	<u>SUT Connection</u> 1. Using the ETT, the tester verifies all SMTP test cases for "System as Receiver" are successful and valid. 2. Using the ETT, the tester verifies a secure session was established with the Health IT Module based upon TLS initiation using correct syntax. 3. Using the ETT, the tester verifies the Health IT Module does not accept the TLS session based upon incorrect syntax used. 4. Using the ETT with a predetermined username and password, the tester verifies a secure session was established with the Health IT Module with PLAIN SASL authentication. 5. The tester verifies evidence of the capability to establish a secure session with the Health IT Module based upon successful DIGEST-MD5 authentication. 6. The tester verifies evidence of the capability to reject an authentication request due to an invalid DIGEST-MD5 value. 7. Using the ETT, the tester verifies the Health IT Module does not accept the authentication request due to an invalid PLAIN SASL username and password. Continued on the next page

Criteria ¶	System Under Test	Test Lab Verification
(i)(B) (Alternative), continued	<u>Receive Payload</u> 7. For each of the applicable ambulatory and/or inpatient setting transition of care/referral summary payloads (continuity of care, referral note, and discharge summary) and the Negative C-CDA tests, the user selects the payload type and receives a document from the ETT using valid SMTP commands from the user name supplied by the Health IT Module email account being authenticated and establishes a connection with the ETT (SMTP Test 9). 8. The user receives a document from the ETT using invalid data as part of the DATA command from the user name supplied by the Health IT Module email account being authenticated to the Health IT Module SMTP email address (SMTP Test 10). 9. The user receives a document from the ETT using invalid SMTP commands as part of the DATA command from the user name supplied by the Health IT Module email account being authenticated to the Health IT Module SMTP email address (SMTP Test 11). 10. The user receives a document from the ETT using data beyond allowable size limits from the user name supplied by the Health IT Module email account being authenticated to the Health IT Module SMTP email address (SMTP Test 12 – cannot be tested as these are not invalid per specification as RFC 2821 does not mandate any failure on large sizes). 11. The user receives a document from the ETT from the user name supplied by the Health IT Module email account being authenticated to the Health IT Module SMTP email address beyond the allowable time period (SMTP Test 13). Continued on next page	<u>Receive Payload</u> 8. Using the ETT, the tester verifies the Health IT Module can receive an SMTP Message using §170.202(d): ONC Implementation Guide for Direct Edge Protocols v1.1, and the Validation Report indicates the successful sequence of commands for SMTP protocols for each of the required payloads. 9. Using the ETT Logs, the tester verifies a secure connection cannot be established based upon invalid data provided and does not accept the data by using appropriate responses: • Invalid DATA command; • Invalid SMTP commands; or • Invalid size limits of SMTP commands. 10. Using the ETT, the tester verifies the Health IT Module has kept the transaction open for beyond the specified time constraints found with RFC 2821, Section 4.5.3.2, and therefore cannot accept the incoming message. <u>Receive Multiple Attachments</u> 11. Using the ETT logs for Tests 25 a-f, the tester uses visual inspection to verify that the Health IT Module can successfully receive the multiple attachments types as received by the SUT in step 13, and that the Validation Report indicates the successful sequence of commands for SMTP protocols for each of the attachment types. Continued on next page

Criteria ¶	System Under Test	Test Lab Verification
(i)(B) (Alternative), continued	<u>Receive Multiple Attachments</u> 12. The user receives multiple attachments (with appropriate MIME type) by running each of the following ETT Test Cases: • C-CDA and Text (SMTP Test 25(a)) • PDF and C-CDA (SMTP Test 25(b)) • Text and XDM Package (SMTP Test 25(c)) • C-CDA and Text (SMTP Test 25(d)) • C-CDA and PDF (SMTP Test 25(e)) • XDM and Text (SMTP Test 25(f)) <u>Negative Tests: Style Sheet/Header</u> 13. The user receives a bad attachment by running each of the following ETT Test Cases: • a bad C-CDA with a broken reference to the style sheet. (SMTP Test 26(a)) • a good C—CDA with a bad style sheet (SMTP Test 26(b)) 14. The user receives an XDM package with a bad XHTML by running the ETT: SMTP Test 27. <u>MIME Type</u> 15. The user receives an XDM package with a MIME type of 'application/octet-stream' (SMTP layer) by running the SMTP Test 28. 16. The user receives an XDM package containing a C-CDA with a MIME type of 'application/xml' (XDM layer) by running the SMTP Test 29.	<u>Negative Tests: Style Sheet/Header</u> 12. Using the ETT logs for Tests 26 a-b and the Health IT Module identified functions, the tester verifies that the Health IT Module rejects a C-CDA with a broken reference to a style sheet and a C-CDA with a good reference but a bad style sheet as received by the SUT in step 14 and that the Validation Report indicates the unsuccessful sequence of commands for SMTP protocols for each bad C-CDA. 13. Using the ETT logs for SMTP Test 27 and the Health IT Module identified functions, the tester verifies that the Health IT Module accepts the XDM package with the bad XHTML. <u>Negative Tests: Style Sheet/Header</u> 14. Using the ETT logs for SMTP Tests 28 and the Health IT Module identified functions, the tester uses visual inspection to verify that the Health IT Module can successfully receive an XDM package with a MIME type of 'application/octet-stream' as received by the SUT in step 16. 15. Using the ETT logs for SMTP Test 29 and the Health IT Module identified functions, the tester uses visual inspection to verify that the Health IT Module can successfully receive an XDM package with a MIME type of 'application/xml' as received by the SUT in step 17 and accepts the C-CDA within the XDM package.

(i)(B) – Receive Using Edge Protocol for IMAP (Optional)

Criteria ¶	System Under Test	Test Lab Verification
(i)(B) (Optional)	<u>SUT Connection</u> 1. The user executes Edge IMAP Tests using the ETT for "System as Receiver." 2. The user initiates an IMAP session with STARTTLS and PLAIN SSL authentication with the ETT. (IMAP Tests 19, 20, 24) 3. The Health IT Module provides documentation of the ability to initiate a STARTTLS connection and reject the connection upon receiving an invalid certificate from a HISP. 4. The Health IT Module provides documentation of the ability to connect to the valid TLS_RSA_WITH_RC4_128_MD5 cipher suite. <u>IMAP Receive</u> 5. The user demonstrates the Health IT Module can use either the uppercase, lowercase, or mixed case mailbox names and access data. (IMAP Test 21) 6. The Health IT Module is able to receive status and size updates from the IMAP4 server. (IMAP Test 25) 7. The user demonstrates the Health IT Module's capability to accept XDM packages sent using appropriate MIME types. (IMAP Test 27) 8. The user demonstrates the Health IT Module's capability to receive multiple attachments in varying order from the ETT. (IMAP Test 28) 9. The user demonstrates the Health IT Module's capability to receive a bad attachment (C-CDA where the style sheet is bad or missing) from the ETT. (IMAP Test 29) 10. The user demonstrates the Health IT Module's capability to receive an XDM package with a bad XHTML from the ETT. (IMAP Test 30) 11. The user demonstrates the Health IT Module's capability to receive different attachments. (IMAP Test 31)	<u>SUT Connection</u> 1. Using the ETT, the tester verifies the Health IT Module is able to successfully initiate an IMAP4 session with the ETT: a. IMAP Tests 19, 20, 24 b. IMAP Test 21 c. IMAP Test 25 2. The tester verifies evidence of the capability of the Health IT Module to reject a STARTTLS connection upon receiving an invalid certificate from the server. 3. The tester verifies evidence of the capability to connect only using the valid cipher suite (TLS_RSA_WITH_RC4_128_MD5 only when offered by the HISP). <u>IMAP Receive</u> 4. Using the ETT and Health IT Module logs, the tester verifies the Health IT Module accepts the XDM with the specified MIME type. (IMAP Test 27) 5. The tester verifies the Health IT Module accepts attachments sent from the ETT (IMAP Test 28) in the correct order: a. Text then C-CDA (or reverse if selected in the tool) b. PDF then C-CDA (or reverse if selected in the tool) 6. The tester verifies the Health IT Module accepts the C-CDA sent from the ETT with: (1) broken reference to a style sheet, or (2) a good reference to the style sheet but a bad style sheet. (IMAP Test 29) 7. The tester verifies the Health IT Module accepts an XDM package sent from the ETT with bad XHTML (IMAP Test 30). 8. The tester verifies the Health IT Module accepts different attachment types sent from the ETT (IMAP Test 31).

(i)(B) – Receive Using Edge Protocol for POP3 (Optional)

Criteria ¶	System Under Test	Test Lab Verification
(i)(B) (Optional)	<u>SUT Connection</u> 1. The user executes Edge POP3 Tests using the ETT for "System as Receiver." 2. The user initiates POP3 sessions with the ETT. (POP Test 19, 20, 24) 3. The Health IT Module provides documentation of the ability to initiate a STARTTLS connection and reject the connection upon receiving an invalid certificate from a HISP. 4. The Health IT Module provides documentation of the ability to connect to the valid cipher suite (TLS_RSA_WITH_RC4_128_MD5). <u>POP3 Receive</u> 5. The user demonstrates the Health IT Module's ability to accept XDM packages sent using appropriate MIME Types. (POP Test 27) 6. The user demonstrates the Health IT Module's capability to receive multiple attachments in varying order from the ETT. (POP Test 28) 7. The user demonstrates the Health IT Module's capability to receive a bad attachment (C-CDA where the style sheet is bad or missing) from the ETT. (POP Test 29) 8. The user demonstrates the Health IT Module's capability to receive an XDM package with a bad XHTML from the ETT. (POP Test 30) 9. The user demonstrates the Health IT Module's capability to receive different attachments. (POP Test 31)	<u>SUT Connection</u> 1. Using the ETT, the tester verifies the Health IT Module is able to successfully initiate POP3 sessions with the ETT: • POP Tests 19, 20, 24 2. The tester verifies evidence of the capability of the Health IT Module to reject a STARTTLS connection upon receiving an invalid certificate from the server. 3. The tester verifies evidence of the capability to connect only using the valid cipher suite (TLS_RSA_WITH_RC4_128_MD5 only when offered by the HISP). <u>POP3 Receive</u> 4. Using the ETT and Health IT Module logs, the tester verifies the Health IT Module accepts the XDM with the specified MIME type. (POP Test 27) 5. The tester verifies the Health IT Module accepts attachments sent from the ETT (POP Test 28) in the correct order: • Text then C-CDA (or reverse if selected in the tool) • PDF then C-CDA (or reverse if selected in the tool) 6. The tester verifies the Health IT Module accepts the C-CDA sent from the ETT with: (1) broken reference to a style sheet, or (2) a good reference to the style sheet but a bad style sheet. (POP Test 29) 7. The tester verifies the Health IT Module accepts an XDM package sent from the ETT with bad XHTML (POP Test 30). 8. The tester verifies the Health IT Module accepts different attachment types sent from the ETT (POP Test 31).

(i)(C) – XDM Processing (Received via Edge Protocol)

Criteria ¶	System Under Test	Test Lab Verification
(i)(C)	1. The user selects the XDM payload attachment within the ETT (SMTP Test 9, 16, 20) and receives an XDM document from the ETT using valid SMTP commands from the user name supplied by the Health IT Module email account being authenticated. 2. The user downloads the XDM payload from the ETT validation report and uploads it to the Transport Testing Tool (TTT) to perform validation of the XDM package.	1. Using the TTT validation report, the tester verifies the XDM payload received by the Health IT Module successfully passes XDM validation.

(b)(1)(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), and at a minimum to the Continuity of Care Document, Referral Note, and (for 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.

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

§ 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(i) ICD-10-CM
Data Elements and Vocabularies applicable to the Common Clinical Data Set (CCDS) for both C-CDA R2 R1.1 and C-CDA R2 R2.1 – Outlined in the Common Clinical Data Set Reference Document

Test Data Instructions: ETT: Message Validators
Inpatient setting 170.315_b1_toc_inp_sample*.pdf (All Samples)
Outpatient setting 170.315_b1_toc_amb_sample*.pdf (All Samples)

Test Data (Payload):
Inpatient setting 170.315_b1_toc_inp_*_r11_sample*.xml
170.315_b1_toc_inp_*_r21_sample*.xml
Outpatient setting 170.315_b1_toc_amb_*_r11_sample*.xml
170.315_b1_toc_amb_*_r21_sample*.xml
Negative Tests: NT_*_r11*.xml
NT_*_r21*.xml

Test Tool: ETT: Edge

Criteria ¶	System Under Test	Test Lab Verification
(ii)(A)	Receive Payload 1. The Health IT Module receives transition of care/referral summary payloads via the Edge Protocol as specified in (b)(1)(i)(B) for the inpatient and/or ambulatory setting. Parse and Process 2. The Health IT Module parses each of the following ambulatory and/or inpatient setting applicable C-CDA document types formatted as a CCD document in accordance with the standards specified in § 170.205(a)(3) CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 or a C-CDA § 170.205(a)(4) for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, Release 2.1 with one of following document-templates: Continued on next page	Receive Payload 1. Using the ETT: Message Validators - C-CDA R2.1 Validator, the tester downloads the appropriate ONC-Supplied Transition of Care instruction documents by selecting the "170.315_b1_ToC_Amb", "170.315_b1_ToC_Inp", "NegativeTesting_CCDS" criteria and the file name. Parse and Process 2. For each payload received in step 1 of the SUT, the tester uses the downloaded ONC-Supplied Transition of Care instruction document downloaded in step 1 and visual inspection to verify that the Health IT Module can successfully receive, parse, and process the applicable types of transitions of care/referral summaries containing the Common Clinical Content Set, and formatted as a CCD or a C-CDA with Continued on next page

Criteria ¶	System Under Test	Test Lab Verification
(ii)(A), continued	Continued from previous page • Continuity of Care; • Referral Note; and • Discharge Summary (for inpatient setting only). 3. The Health IT Module processes the valid document-templates and 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. Each of these documents includes, at a minimum, as applicable, the following: • Common Clinical Data Set; • Encounter Diagnoses; • Cognitive status; • Functional status; • For the Ambulatory setting only the following data elements: reason for referral; and referring or transitioning provider's name and office contact information; and • For the inpatient setting only the discharge instructions. 4. The Health IT Module further processes the document for valid document-templates with empty sections and null combinations in accordance with document-templates from the standards adopted in § 170.205(a)(3) continued on next page	Continued from previous page no specific document template according to the standard adopted in § 170.205(a)(3) or as a C-CDA according to the standard adopted in § 170.205(a)(4) with the following document –templates as applicable: • Continuity of Care; • Referral Note; and • Discharge Summary (for inpatient setting only). 3. The tester verifies that valid empty sections and null combinations in valid the C-CDA documents processed in step 2 with corresponding section-templates and entry-templates are successfully interpreted in accordance with the standards adopted in § 170.205(a)(3), or § 170.205(a)(4) for each of the following document types: • Continuity of Care; • Referral Note; and • Discharge Summary (for inpatient setting only). <u>Negative Testing</u> 4. Negative Test: For each invalid payload received in step 6 of the SUT, the tester uses visual inspection to verify that the Health IT Module can identify errors in the C-CDA documents not specified in accordance with the standards adopted in § 170.205(a)(3) and § 170.205(a)(4) including: • "document –templates" • "section-templates" • "entry-templates" • invalid vocabulary standards • invalid codes continued on next page

Criteria ¶	System Under Test	Test Lab Verification
(ii)(A), continued	Continued from previous page 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. 5. Based upon the health IT setting(s) to be certified, a user repeats steps 1 -3 for each ambulatory and/or inpatient Transition of Care (xml) document in the ETT: Edge. All of the Transitions of Care documents for a given health IT setting must be received (both C-CDA R2 Release 1.1 and C-CDA R2 Release 2.1 formats). Negative Testing 6. The Health IT Module receives a series of invalid C-CDA document types via the Edge Protocol (b)(1)(i)(B) for C-CDA R2 Release 1.1 and C-CDA R2 Release 2.1 documents. The Health IT Module parses the invalid documents received in step 6, where 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 errors. Error Reporting 7. A user is notified or can review the recorded errors encountered during the parsing and processing of C-CDA documents.	Continued from previous page Error Reporting 5. Using Visual Inspection, the tester verifies that errors encountered during the parsing and processing of the C-CDA documents are recorded, and that users are either notified of errors encountered OR a mechanism is provided for users to review all of the recorded errors encountered.

(ii)(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).

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(a)(3) International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) International Release July 31, 2012 and US Extension to SNOMED CT® March 2012
§ 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(i) ICD-10-CM
Data Elements and Vocabularies applicable to the Common Clinical Data Set (CCDS) for both C-CDA R2 R1.1 and C-CDA R2 R2.1 – Outlined in the Common Clinical Data Set Reference Document

Test Data Instructions: ETT: Message Validators
Inpatient setting 170.315_b1_toc_inp_sample*.pdf (All Samples)
Ambulatory setting 170.315_b1_toc_amb_sample*.pdf (All Samples)

Test Tool: ETT: Edge

Criteria ¶	System Under Test	Test Lab Verification
(ii)(B)	The user is able to view the processed C-CDA documents in section (b)(1)(ii)(A), 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 or § 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 for the • Common Clinical Data Set • Encounter diagnoses • Cognitive status • Functional Status • For Ambulatory setting only: reason for referral, and referring or transitioning provider's name and office contact information • For Inpatient setting only: discharge instructions.	Using transition of care/referral summary information retrieved in section (b)(1)(ii)(A) step 1 the tester verifies that for each transitions of care /referral summaries received in section (b)(1)(ii)(A)(1), section (b)(1)(ii)(A)(3), and section (b)(1)(ii)(A)(4), the transition of care/referral summaries are displayed accurately and are complete, and that the data is formatted in accordance with the standards specified in § 170.205(a)(3) and § 170.205(a)(4) using visual inspection and includes at a minimum the applicable English (i.e., non-coded) representation if they associate with a vocabulary/code set) content from the: • Common Clinical Data Set • Encounter diagnoses • Cognitive status; • Functional Status; • For ambulatory setting only: reason for referral, referring or transitioning provider's name, and office contact information; and • For inpatient setting only: discharge instructions.

(ii)(C) Display section views. Allow for the individual display each additional section or sections (and the accompanying document header information) that were 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).

Test Data Instructions: ETT: Message Validators
Inpatient setting 170.315_b1_toc_inp_sample*.pdf (All Samples)
Ambulatory setting 170.315_b1_toc_amb_sample*.pdf (All Samples)
Test Tool: ETT: Edge

Criteria ¶	System Under Test	Test Lab Verification
(ii)(C)	<u>Display Section Views</u> 1. Using the transitions of care/referral summaries received and processed in section (b)(1)(ii)(A), the user displays each individual section or additional sections (and the accompanying document header information) of the received transitions of care/referral summaries displayed in section (b)(1)(ii)(B) formatted according to the standards specified in § 170.205(a)(3) and § 170.205(a)(4). 2. Using the transitions of care/referral summaries received and processed in section (b)(1)(ii)(A), the user can display data from a particular section. <u>Section Order</u> 3. The user uses the Health IT Module to set the preference for the display order of specific sections. <u>Quantity of Sections</u> 4. The user uses the Health IT Module to set the initial quantity of sections to be displayed.	<u>Display Section Views</u> 1. Using visual inspection, the tester verifies that the transitions of care/referral summaries received and processed in section (b)(1)(ii)(A) can display the data from an individual section and its accompanying document header information. 2. Using visual inspection, the tester verifies that for the transitions of care/referral summaries 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. 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. 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. <u>Section Order</u> 5. Using visual inspection, the tester verifies the user has the ability to set the order in which the transitions of care/referral summary sections are displayed for each of the supported document-types. 6. Using visual inspection, the tester verifies that the sections displayed for the transitions of care/referral summaries received and processed in section (b)(1)(ii)(A) are ordered correctly based upon the section order set in the previous step (step 5 above). The sections are displayed in the preferred order. <u>Quantity of Sections</u> 7. Using visual inspection, the tester verifies the user has the ability to set the initial quantity of sections for a transitions of care/referral summary to be displayed. 8. Using visual inspection, the tester verifies that the number of transition of care/referral summary sections initially displayed in step 1 corresponds to the quantity of sections to be displayed in step 7.

(b)(1)(iii) Create

Enable a user to create a transition of care/referral summary: formatted according 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.

(i) 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).

Standards:

§ 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(i) Encounter diagnoses: The 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:

(i) Diseases.

(ii) Injuries.

(iii) Impairments.

(iv) Other health problems and their manifestations.

(v) Causes of injury, disease, impairment, or other health problems.

§ 170.207(a)(4) International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), U.S. Edition, September 2015 Release,

§ 170.207(n)(1) Birth sex must be coded in accordance with HL7 Version 3 Value Sets for AdministrativeGender and NullFlavor attributed as follows:

(i) Male. M

(ii) Female. F
(iii) Unknown. NullFlavor UNK

§ 170.207(q)(1) International Telecommunication Union E.123:Notation for national and international telephone numbers, e-mail addresses and web addresses and International and Telecommunication Union E. 164: The international public telecommunication numbering plan
Data Elements and Vocabularies applicable to the Common Clinical Data Set (CCDS)– Outlined in the Common Clinical Data Set Reference Document

Test Data Instructions: ETT: Message Validators
Inpatient setting 170.315_b1_toc_inp_sample*.pdf (All Samples)
Ambulatory setting 170.315_b1_toc_amb_sample*.pdf (All Samples)

Test Tool: ETT: Edge

Criteria ¶	System Under Test	Test Lab Verification
(iii)	Data Entry 1. Based upon the health IT setting, the health IT developer uses the ETT: Message Validators -C-CDA R2.1, to download the appropriate ONC-Supplied Transition of Care instruction documents by selecting the "170.315_b1_ToC_Amb", "170.315_b1_ToC_Inp" criteria selecting the file name and executes the download. 2. The user enters the Transition of Care information downloaded in step 1 in order to create a patient record with the necessary information. Create 3. Using the Health IT Module, the user sends a Transitions of Care document using one of the transport mechanisms specified in section (b)(1)(i)(A) as a C-CDA document, which contains a transitions of care/referral summaries formatted according to the standard adopted in § 170.205(a)(4) in the following formats as applicable: • Continuity of Care; • Referral Note; and Continued on next page	Data Entry 1. For each transition of care payload sent by the SUT, the tester uses the transition of care/referral summary information document downloaded in step 1 of the SUT and visual inspection to verify that the transitions of care/referral summary record information entered into the Health IT Module is accurate and without omission. Create 2. For each transition of care payload sent by the SUT via Edge Protocol as specified in section (b)(1)(i)(A), the tester verifies the content of the transitions of care/referral summary using the Message Content Report within the ETT. The tester verifies that for each applicable payload no errors exist in the Message Content Report indicating the Health IT Module can successfully create a payload which conforms to the transition of care/referral summary in accordance with the standard specified at § 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, and that the document sent is either a CCD document, a Referral Note or (for inpatient setting only) a Discharge Summary. Continued on next page

Criteria ¶	System Under Test	Test Lab Verification
(iii), continued	• (for inpatient setting only) Discharge Summary. 4. At a minimum, the C-CDA document created in step 4 includes the following content in accordance with the specified standards as applicable: 5. Common Clinical Data Set as specified in section (b)(1)(iii)(A); 6. Encounter Diagnoses as specified in section (b)(1)(iii)(B); 7. Cognitive status as specified in section (b)(1)(iii)(C); 8. Functional status as specified in section(b)(1)(iii)(D); 9. For the Ambulatory setting only the following data elements as specified in section(b)(1)(iii)(E): a. The reason for referral; and b. Referring or transitioning provider's name and office contact information 10. For the inpatient setting only the discharge instructions as specified in section (b)(1)(iii)(F); and 11. Patient match data as specified in section(b)(1)(iii)(G). 12. Based upon the supported health IT setting(s), the user repeats steps1-4 or each of the ambulatory and/or inpatient Transition of Care instruction documents found in the ETT: Message Validators. A transition of care document must be sent for every transition of care instruction document for a given health IT setting.	3. Using the Message Content Report from the ETT: Edge and the transition of care/referral summary instruction documents used to create the payload, the tester uses visual inspection to verify the additional checks for equivalent text for the content of all section level narrative text. The content of each narrative text data element must match the content specified in the transition of care/referral summary instruction document. 4. Using the Validation Report from the ETT: Edge the tester verifies that for each supported health IT setting, the following type of CCDS summary record summary documents have been created by the SUT: • Continuity of Care Document; • C-CDA R2 R2.1 Referral Note Document and • (for inpatient setting only) C-CDA R2 R2.1 Discharge Summary.
(iii)(A)	<u>The Common Clinical Data Set</u> The content of the transitions of care/referral summaries created in Data Elements and Vocabularies applicable to the Common Clinical Data Set (CCDS) section (b)(1)(iii) contains the Common Clinical Data Set where applicable, and represent such data in accordance with the standards specified in the CCDS Reference Document for C-CDA R2 R2.1 documents.	The verification that the Common Clinical Data Set content is in accordance with the standards specified in the CCDS Reference Document for a document specified in accordance with §170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1 is performed as part of the verification done in section(b)(1)(iii) steps 2-3.

Criteria ¶	System Under Test	Test Lab Verification
(iii)(B)	<u>Encounter diagnoses</u> The content of the transitions of care/referral summaries created in section (b)(1)(iii) contains the 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 ICD-10-CM as maintained and distributed by HHS, for the following conditions: (i) Diseases. (ii) Injuries. (iii) Impairments. (iv) Other health problems and their manifestations. (v) Causes of injury, disease, impairment, or other health problems • or at a minimum the version of the standard specified at §170.205(a)(4) (ICD-10-CM or SNOMED CT®).	The verification that the Encounter diagnoses content is specified in accordance with the constrained standard specified at § 170.207(i), or at a minimum the version of the standard specified at § 170.207(a)(4) is performed as part of the verification done in section (b)(1)(iii) steps 2-3.
(iii)(C)	<u>Cognitive Status</u> The content of the transitions of care/referral summaries created in section (b)(1)(iii) contains the Cognitive status when present.	The verification the Cognitive status content of the transitions of care/referral summaries is performed as part of the verification done in section (b)(1)(iii).
(iii)(D)	<u>Functional Status</u> The content of the transitions of care/referral summaries created in section (b)(1)(iii) contains the Functional Status when present.	The verification the Functional status content of the transitions of care/referral summaries is performed as part of the verification done in section (b)(1)(iii).
(iii)(E)	<u>Ambulatory Setting Only</u> For ambulatory setting only: The content of the transitions of care/referral summaries created in section (b)(1)(iii) contains the reason for referral, referring or transitioning provider's name, and office contact information.	The verification of the data element requirements for the ambulatory setting within a transitions of care/referral summaries is performed as part of the verification done in section (b)(1)(iii). This includes verifying that the transitions of care/referral summaries record includes: the Referring or transitioning provider's name and Office contact information. Additional verification is done in section (b)(1)(ii) step 3 to verify the unstructured text data element Reason for Referral.

Criteria ¶	System Under Test	Test Lab Verification
(iii)(F)	<u>Inpatient Setting Only</u> For inpatient setting only: The content of the transitions of care/referral summaries created in section (b)(1)(iii) contains the discharge instructions.	The verification of the required discharge instructions content for the inpatient setting within a transitions of care/referral summaries is performed as part of the verification done in section (b)(1)(iii) steps 2-3.
(iii)(G)	<u>Patient matching data</u> The content of the transitions of care/referral summaries created in section (b)(1)(iii) contains the following patient matching data: • Full name including first name, last name, previous name, middle name (including middle initial) and suffix; • Date of birth including the year, month and day when known, and null when unknown. • Address; • Phone number(s) which are constrained in accordance with the standard specified at § 170.207(q)(1), UTI-E.123 and UTI-E.124; and if multiple phone numbers are present within the Health IT Module they are reflected in the transitions of care/referral summaries; and • Birth sex which is constrained in accordance with the standard specified at § 170.207(n)(1): birth sex coded in accordance with HL7 Version 3 Value Sets for AdministrativeGender and NullFlavor attributed as follows: (i) Male. M (ii) Female. F (iii) Unknown. NullFlavor UNK.	The verification the patient matching data within the transitions of care/referral summaries created in section (b)(1)(iii) includes the following checks presence of the patient's first name, last name, previous name, middle name (including middle initial), suffix; date of birth, address, all phone number (s) present in the Health IT Module and sex, as applicable. Furthermore, the phone number(s) are constrained in accordance with the standard specified at § 170.207(q)(1) and the birth sex is in accordance with the standard adopted in § 170.207(n)(1).
(iii)(G)(1)(i) (Optional)	<u>Birth with Time</u> If the time of birth (hours, minutes and seconds) is included the correct time zone offset is used;	If the Health IT Module supports the time of birth, the tester verifies that the Health IT Module can demonstrate the correct time zone offset as part of the time of birth.

Document History

Version Number	Description of Change	Date
1.0	Final Test Procedure	January 29, 2016
1.1	Section (i)(A) removed the reference to the actual number of message (3) sent. Removed email addresses throughout test procedure. Section (i)(A) Updated language within note related to payload testing. Removed reference to IMAP and POP test 22.	March 21 , 2016
1.2	Removed references to "processed MDNs"	April 12, 2016

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