

<b>2015 Edition §170.315(b)(1) Transitions of Care</b>					
Testing Components:					
				Data	
Test Procedure Version 1.1 – Last Updated 10/30/15					

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

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

## Required Tests

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).

§ 170.210(g) [RFC 5905:Network Time Protocol Version 4: Protocol and Algorithms Specification, June 2010](#)

Tools: [Edge Testing Tool \(ETT\)](#)

[Transport Testing Tool \(TTT\)](#)

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

Criteria ¶	System Under Test	Test Lab Verification
(i)(A)	<ol style="list-style-type: none"> <li>1. The user shall execute XDR Tests using the ETT for “System as Sender.”</li> <li>2. Authentication: The user establishes a Mutual TLS session for the Health IT module to authenticate to the ETT (XDR Test 6).</li> <li>3. Authentication: The user authenticates the Health IT module to the ETT using an incorrect Mutual TLS session (XDR Test 7).</li> <li>4. Send: 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 following payloads created at (b)(1)(iii) should be sent as applicable: Continuity of Care Document (CCD), Referral Note, and a Discharge Summary (for inpatient setting only).</li> <li>5. Message Tracking Using Processed MDNs: The user shall send 3 messages to the ETT with unique message IDs for each XDR profile (XDR Test 19).</li> <li>6. Message Tracking Using Processed MDNs: The user shall send health information to multiple recipients including both valid (Endpoint 5) and invalid recipients (Endpoint 9) (XDR Test 20a, XDR Test 20b).</li> <li>7. Delivery Notification: The user shall send multiple messages (#TBD) 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 (Delivery Notification Test 48).</li> <li>8. Delivery Notification: The user shall send an XDR message to Endpoint 14 using the Edge Testing Tool with a valid Direct Address Block and Delivery Notifications header (Delivery Notification Test 49)</li> <li>9. Delivery Notification: The user shall send XDR messages to multiple recipients including both valid and invalid recipients within the same message to Endpoints 5 and 9 respectively (Delivery Notification Test 50).</li> </ol>	<ol style="list-style-type: none"> <li>1. Using the ETT, the tester verifies all XDR test cases for “System as Sender” are successful and valid.</li> <li>2. 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.</li> <li>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.</li> <li>4. Using the ETT, the tester verifies the Health IT module successfully performs message tracking using processed MDNs.</li> <li>5. 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 Test Labs shall verify message IDs in the ETT Logs.</li> <li>6. 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.</li> <li>7. 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 shall verify a Failure MDN for Endpoint 9 in the Health IT module’s ‘ogs. The tester verifies a processed MDN shall be sent for Endpoint 5.</li> </ol>

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

Criteria ¶	System Under Test	Test Lab Verification
(i)(A)	<ol style="list-style-type: none"> <li>1. The user shall execute SMTP Tests using the ETT for “System as Sender.”</li> <li>2. Start TLS Session: The user initiates a TLS session for the Health IT module with the ETT using email address <a href="mailto:wellformed2@edge.nist.gov">wellformed2@edge.nist.gov</a> (SMTP Test 14).</li> <li>3. Start TLS Session: The user initiates a TLS session for the Health IT module with the ETT using address 15 (SMTP Test 15 – not supported at this time).</li> <li>4. Authentication to SMTP Server: The user authenticates the Health IT module to the ETT using PLAIN SASL using email address <a href="mailto:wellformed1@edge.nist.gov">wellformed1@edge.nist.gov</a> (SMTP Test 18)</li> <li>5. Authentication to SMTP Server: The user authenticates the Health IT module to the ETT using DIGEST-MD5 SASL using email address <a href="mailto:wellformed1@edge.nist.gov">wellformed1@edge.nist.gov</a> (SMTP Test 19 – not supported at this time)</li> <li>6. Send: The user sends a document to the ETT using the email address <a href="mailto:wellformed1@edge.nist.gov">wellformed1@edge.nist.gov</a> (SMTP Tests 1-8) The following payloads created at (b)(1)(iii) should be sent as applicable: Continuity of Care Document (CCD), Referral Note and a Discharge Summary (for inpatient setting only).</li> <li>7. Message Tracking Using Processed MDNs: The user shall send 3 messages to the ETT with unique message IDs for each message to <a href="mailto:wellformed14@edge.nist.gov">wellformed14@edge.nist.gov</a> (Delivery Notification Test 17)</li> <li>8. Message Tracking Using Processed MDNs: The user shall send health information in a single SMTP message to <a href="mailto:processedonly5@edge.nist.gov">processedonly5@edge.nist.gov</a> and <a href="mailto:noaddressfailure@edge.nist.gov">noaddressfailure@edge.nist.gov</a> (Delivery Notification Test 18)</li> <li>9. Delivery Notification: The user shall send a series of SMTP mail messages (# TBD) to the ETT with unique message IDs specific to each message to <a href="mailto:wellformed14@hit-testing2.nist.gov">wellformed14@hit-testing2.nist.gov</a> The number</li> </ol>	<ol style="list-style-type: none"> <li>1. Using the ETT, the tester verifies all SMTP test cases for “System as Sender” are successful and valid.</li> <li>2. Using the ETT, the tester verifies the Health IT module initiates a TLS session and can authenticate using PLAIN SASL and DIGEST-MD5 SASL authentication.</li> <li>3. Using the ETT, the tester verifies the Health IT module can send an SMTP Message using §170.202(d): ONC Implementation Guide for Direct Edge Protocols v1.1.</li> <li>4. Using the ETT, the tester verifies the Health IT module successfully performs message tracking using processed MDNs.</li> <li>5. 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.</li> <li>6. Using the ETT Logs, the tester verifies: <ul style="list-style-type: none"> <li>● Multiple messages created with unique message ID</li> <li>● ETT processes Disposition-Notification-Options header appropriately and includes the header in the message</li> </ul> </li> <li>7. Using the Health IT module’s logs, the tester verifies the system has received, processed, and tracked a failure message (MDN) for Address 9 and successful MDN for Address 5.</li> </ol>

Criteria ¶	System Under Test	Test Lab Verification
	<p>of messages to be sent shall be determined by the Tester based upon the amount of rigor the testing requires (Delivery Notification Test 45).</p> <p>10. Delivery Notification: The user shall send an SMTP mail message to the ETT to <a href="mailto:wellformed14@edge.nist.gov">wellformed14@edge.nist.gov</a> 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 (Delivery Notification Test 46).</p> <p>11. Delivery Notification: The user shall send a C-CDA document in a single SMTP mail message to <a href="mailto:processedonly5@edge.nist.gov">processedonly5@edge.nist.gov</a> and <a href="mailto:noaddressfailure9@edge.nist.gov">noaddressfailure9@edge.nist.gov</a> (Delivery Notification Test 47).</p>	<p>8.</p>

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

Criteria ¶	System Under Test	Test Lab Verification
(i)(B)	<ol style="list-style-type: none"> <li>1. The user shall execute XDR Tests using the ETT for “System as Receiver.”</li> <li>2. Authentication: The user establishes authentication from the ETT to the Health IT module using Mutual TLS correctly (XDR Test 8).</li> <li>3. Authentication: The user establishes authentication from the ETT to the Health IT module using bad certificates (incorrect Mutual TLS configuration (XDR Test 9).</li> <li>4. Receive: 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 the Health IT module receives a properly formatted XDR message with limited metadata from the ETT (XDR Test 3).</li> <li>5. Receive: 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 the Health IT module receives a properly formatted XDR message with full metadata from the ETT (XDR Test 5).</li> <li>6. Incorrect XDR Message Receive: The Health IT module returns errors when the following incorrect messages are received from the ETT (XDR Test 4): <ul style="list-style-type: none"> <li>• Invalid SOAP envelope details;</li> <li>• Invalid SOAP body details;</li> <li>• Missing metadata elements;</li> <li>• Missing associations between eBRIM constructs; or</li> <li>• Missing Direct Address block.</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>1. Using the ETT, the tester verifies all XDR test cases for “System as Receiver” are successful and valid.</li> <li>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.</li> <li>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.</li> <li>4. Using logs, the tester verifies the Health IT module is capable of receiving and processing a valid XDR message with limited metadata.</li> <li>5. Using logs, the tester verifies the Health IT module is capable of receiving and processing a valid XDR message with full metadata.</li> <li>6. Using logs, the tester verifies the Health IT module does not accept invalid messages sent from the ETT.</li> </ol>

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

Criteria ¶	System Under Test	Test Lab Verification
(i)(B)	<ol style="list-style-type: none"> <li>1. The user shall execute SMTP Tests using the ETT for “System as Receiver.”</li> <li>2. Start TLS Session: The user initiates a TLS session for the Health IT module with the ETT sent from email address <a href="mailto:wellformed3@edge.nist.gov">wellformed3@edge.nist.gov</a> to <a href="mailto:welformed1@edge.nist.gov">welformed1@edge.nist.gov</a> (SMTP Test 16).</li> <li>3. Start TLS Session: The user initiates a TLS session for the Health IT module with the ETT sent from <a href="mailto:badcommands4@edge.nist.gov">badcommands4@edge.nist.gov</a> to <a href="mailto:wellformed1@edge.nist.gov">wellformed1@edge.nist.gov</a> (SMTP Test 17).</li> <li>4. Authentication: The user authenticates the ETT with the Health IT module using PLAIN SASL as an SMTP server from <a href="mailto:wellformed3@edge.nist.gov">wellformed3@edge.nist.gov</a> to <a href="mailto:welformed1@edge.nist.gov">welformed1@edge.nist.gov</a> (SMTP Test 20).</li> <li>5. Authentication: The user authenticates the ETT using DIGEST-MD5 SASL as an SMTP server from <a href="mailto:wellformed3@edge.nist.gov">wellformed3@edge.nist.gov</a> to <a href="mailto:welformed1@edge.nist.gov">welformed1@edge.nist.gov</a> (SMTP Test 21 – cannot be tested at this time).</li> <li>6. Authentication: The Health IT module receives an authentication from the ETT using an Invalid PLAIN SASL username/password as an SMTP server from from <a href="mailto:wellformed3@edge.nist.gov">wellformed3@edge.nist.gov</a> to <a href="mailto:welformed1@edge.nist.gov">welformed1@edge.nist.gov</a> (SMTP Test 22).</li> <li>7. Authentication: The Health IT module receives an authentication from the ETT using an Invalid DIGEST-MD5 as an SMTP server from <a href="mailto:wellformed3@edge.nist.gov">wellformed3@edge.nist.gov</a> to <a href="mailto:welformed1@edge.nist.gov">welformed1@edge.nist.gov</a> (SMTP Test 23 – cannot be tested at this time).</li> <li>8. Receive: 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</li> </ol>	<ol style="list-style-type: none"> <li>1. Using the ETT, the tester verifies all SMTP test cases for “System as Receiver” are successful and valid.</li> <li>2. Using the ETT, the tester verifies a secure session was established with the Health IT module based upon TLS initiation using correct syntax.</li> <li>3. Using the ETT, the tester verifies the Health IT module does not accept the TLS session based upon incorrect syntax used.</li> <li>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.</li> <li>5. Using the ETT, the tester verifies a secure session was established with the Health IT module based upon successful DIGEST-MD5 authentication.</li> <li>6. 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.</li> <li>7. Using the ETT, the tester verifies the Health IT module does not accept the authentication request due to an DIGEST-MD5 value.</li> <li>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.</li> <li>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: <ul style="list-style-type: none"> <li>• Invalid DATA command;</li> <li>• Invalid SMTP commands; or</li> <li>• Invalid size limits of SMTP commands.</li> </ul> </li> </ol>

Criteria ¶	System Under Test	Test Lab Verification
	<p><a href="mailto:wellformed3@edge.nist.gov">wellformed3@edge.nist.gov</a> and establishes a connection with the ETT (SMTP Test 9).</p> <p>9. Receive: The user receives a document from the ETT using invalid data as part of the DATA command from <a href="mailto:badcommands@edge.nist.gov">badcommands@edge.nist.gov</a> to <a href="mailto:wellformed1@edge.nist.gov">wellformed1@edge.nist.gov</a> (SMTP Test 10).</p> <p>10. Receive: The user receives a document from the ETT using invalid SMTP commands as part of the DATA command from <a href="mailto:badcommands@edge.nist.gov">badcommands@edge.nist.gov</a> to <a href="mailto:wellformed1@edge.nist.gov">wellformed1@edge.nist.gov</a> (SMTP Test 11)</p> <p>11. Receive: The user receives a document from the ETT using data beyond allowable size limits from <a href="mailto:badcommands@edge.nist.gov">badcommands@edge.nist.gov</a> to <a href="mailto:wellformed1@edge.nist.gov">wellformed1@edge.nist.gov</a> (SMTP Test 12 – cannot be tested as these are not invalid per specification as RFC 2821 does not mandate any failure on large sizes).</p> <p>12. Receive: The user receives a document from the ETT from <a href="mailto:badcommands@edge.nist.gov">badcommands@edge.nist.gov</a> to <a href="mailto:wellformed1@edge.nist.gov">wellformed1@edge.nist.gov</a> beyond the allowable time period (SMTP Test 13).</p>	<p>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.</p>

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

Criteria ¶	System Under Test	Test Lab Verification
(i)(B)	<ol style="list-style-type: none"> <li>1. The user shall execute IMAP Tests using the ETT for “System as Receiver.”</li> <li>2. Authentication: The user shall initiate an IMAP session with STARTTLS and PLAIN SSL authentication with the ETT.</li> <li>3. The user shall demonstrate the Health IT module can use either the uppercase, lowercase, or mixed case mailbox names and access data.</li> <li>4. The user demonstrates the Health IT module’s capability to deal with exceptions for different commands, including bad commands from the ETT.</li> <li>5. The Health IT module is able to receive status and size updates from the IMAP4 server.</li> </ol>	<ol style="list-style-type: none"> <li>1. Using the ETT, the tester verifies all IMAP test cases for “System as Receiver” are successful and valid.</li> </ol>

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

Criteria ¶	System Under Test	Test Lab Verification
(i)(B)	<ol style="list-style-type: none"> <li>1. The user shall execute POP3 Tests using the ETT for “System as Receiver.”</li> <li>2. Authentication: The user shall initiate a POP session with STARTTLS and PLAIN SSL authentication with the ETT.</li> <li>3. The user demonstrates the Health IT module’s capability to deal with exceptions for different commands, including bad commands from the ETT.</li> </ol>	<ol style="list-style-type: none"> <li>1. Using the ETT, the tester verifies all POP3 test cases for “System as Receiver” are successful and valid.</li> </ol>

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

Criteria ¶	System Under Test	Test Lab Verification
(i)(C)	1. The user shall demonstrate that an XDM package received by the Health IT module using an Edge Protocol in (b)(1)(i)(B) is able to be successfully validated using the Transport Testing Tool (TTT) Message Validator.	1. Using the XDM payload returned by the ETT to the Contact Email address provided by the Health IT module user, the tester uploads the XDM payload to the TTT’s Message Validator to verify the XDM package is valid.

(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(b)(3) [CDT](#)

§ 170.207(b)(2) [CPT-4](#)

§ 170.207(f)(2) [“Race & Ethnicity – CDC” code system in the PHIN Vocabulary Access and Distribution System \(VADS\), Release 3.3.9](#)

§ 170.207(e)(4) [National Drug Code Directory– Vaccine Codes, updates through August 3, 2015](#)

§ 170.207(b)(4) [ICD-10-PCS](#)

§ 170.207(i) [ICD-10-CM](#)

§ 170.207(e)(3) [HL7 Standard Code Set CVX—Vaccines Administered, updates through June 18, 2015](#)

§ 170.207(f)(1) [The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997](#)

§ 170.207(c)(3) [Logical Observation Identifiers Names and Codes \(LOINC®\) Database version 2.52](#)

§ 170.207(m)(1) [The Unified Code of Units of Measure, Revision 1.9](#)

§ 170.207(g)(2) [Request for Comments \(RFC\) 5646: Tags for Identifying Languages](#)

§ 170.207(q)(1) [International Telecommunication Union E.123:Notation for national and international telephone numbers, e-mail addresses and web addresses and International and Telecommunication Union E. 164: The international public telecommunication numbering plan](#)

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

§ 170.207(d)(3) [RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release](#)

§ 170.207(h) Smoking status must be coded in one of the following SNOMED CT® codes:

- (1) Current every day smoker. 449868002
- (2) Current some day smoker. 428041000124106
- (3) Former smoker. 8517006
- (4) Never smoker. 266919005
- (5) Smoker, current status unknown. 77176002
- (6) Unknown if ever smoked. 266927001
- (7) Heavy tobacco smoker. 428071000124103
- (8) Light tobacco smoker. 428061000124105

§ 170.207(n)(1) Birth sex must be coded in accordance with HL7 Version 3 attributed as follows:

- (i) Male. M
- (ii) Female. F
- (iii) Unknown. UNK

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

Inpatient setting 170.315\_b1\_toc\_inp\_sample\*.pdf (All Samples)

Outpatient setting 170.315\_b1\_toc\_amb\_sample\*.pdf (All Samples)

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

Criteria ¶	System Under Test	Test Lab Verification
(ii)(A)	<ol style="list-style-type: none"> <li>1. The Health IT module receives transition of care/referral summary payloads via the Edge Protocol (b)(1)(i)(B) for each of the required test cases.</li> <li>2. The Health IT module parses each of the following ambulatory and/or inpatient setting applicable C-CDA document types formatted in accordance with the standards specified in § 170.205(a)(3) CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 and § 170.205(a)(4) for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU , Release 2.1: <ul style="list-style-type: none"> <li>• Continuity of Care;</li> <li>• Referral Note; and</li> <li>• Discharge Summary (for inpatient setting only).</li> </ul> </li> <li>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, the Common Clinical Data Set, including: <ul style="list-style-type: none"> <li>• Patient Name</li> <li>• Sex constrained including birth sex</li> <li>• Date of Birth</li> <li>• Race and Ethnicity</li> <li>• Preferred language</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>1. For each test case, the tester uses visual inspection to verify that the Health IT module can successfully receive, parse, and process the applicable types of transitions of care/referral summaries according to the standard adopted in § 170.205(a)(3) and § 170.205(a)(4) including the Common Clinical Content Set as applicable: <ul style="list-style-type: none"> <li>• Continuity of Care;</li> <li>• Referral Note; and</li> <li>• Discharge Summary (for inpatient setting only).</li> </ul> </li> <li>2. Negative Test: For each test case, 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: <ul style="list-style-type: none"> <li>• “document –templates”</li> <li>• “section-templates”</li> <li>• “entry-templates”</li> <li>• invalid vocabulary standards</li> <li>• invalid codes</li> </ul> </li> <li>3. The tester verifies that valid empty sections and null combinations in valid C-CDA documents with corresponding section-templates and entry-templates from the standards adopted in § 170.205(a)(3) and § 170.205(a)(4) are successfully interpreted for each of the following document types: <ul style="list-style-type: none"> <li>• Continuity of Care;</li> <li>• Referral Note; and</li> <li>• Discharge Summary (for inpatient setting only).</li> </ul> </li> </ol>

Criteria ¶	System Under Test	Test Lab Verification
(ii)(A)	<ul style="list-style-type: none"> <li>• Smoking Status</li> <li>• Problems constrained</li> <li>• Medications constrained</li> <li>• Medication Allergies</li> <li>• Laboratory Tests constrained</li> <li>• Laboratory Values(s)/Result(s)</li> <li>• Vital Signs</li> <li>• Procedures constrained</li> <li>• Care Team Member(s)</li> <li>• Immunizations constrained</li> <li>• Unique Device Identifier(s) for a Patient’s Implantable Device(s)</li> <li>• Assessment and Plan of Treatment</li> <li>• Goals</li> <li>• Health Concerns</li> </ul> <p>The complete list of the Common Clinical Data Set and associated standards can be referenced in <a href="#">Table 8</a> of the Final Rule.</p> <p>4. Negative Testing: Based upon the health IT setting(s) (i.e. ambulatory and/or inpatient), a user receives a series of invalid C-CDA document types via the Edge Protocol (b)(1)(i)(B). All test cases for a given health IT setting are required.</p> <p>5. The Health IT module receives and parses 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</p>	<p>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.</p>

Criteria ¶	System Under Test	Test Lab Verification
(ii)(A)	<p>Templates for Clinical Notes, DSTU, Release 2.1 and reports the errors.</p> <p>6. The user receives valid document-templates with empty sections and null combinations in accordance with document-templates from the standards adopted in § 170.205(a)(3) CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 and § 170.205(a)(4) for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU, Release 2.1; and interprets them correctly.</p> <p>7. A user is notified or can review the recorded errors encountered during the parsing and processing of C-CDA documents.</p>	

(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(b)(3) [CDT](#)
- § 170.207(b)(2) [CPT-4](#)
- § 170.207(f)(2) [“Race & Ethnicity – CDC” code system in the PHIN Vocabulary Access and Distribution System \(VADS\), Release 3.3.9](#)
- § 170.207(e)(4) [National Drug Code Directory– Vaccine Codes, updates through August 3, 2015](#)
- § 170.207(b)(4) [ICD-10-PCS](#)
- § 170.207(i) [ICD-10-CM](#)
- § 170.207(e)(3) [HL7 Standard Code Set CVX—Vaccines Administered, updates through June 18, 2015](#)
- § 170.207(f)(1) [The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997](#)
- § 170.207(c)(3) [Logical Observation Identifiers Names and Codes \(LOINC®\) Database version 2.52](#)
- § 170.207(m)(1) [The Unified Code of Units of Measure, Revision 1.9](#)
- § 170.207(g)(2) [Request for Comments \(RFC\) 5646: Tags for Identifying Languages](#)

§ 170.207(q)(1) [International Telecommunication Union E.123:Notation for national and international telephone numbers, e-mail addresses and web addresses and International and Telecommunication Union E. 164: The international public telecommunication numbering plan](#)

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

§ 170.207(d)(3) [RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release](#)

§ 170.207(h) Smoking status must be coded in one of the following SNOMED CT® codes:

- (1) Current every day smoker. 449868002
- (2) Current some day smoker. 428041000124106
- (3) Former smoker. 8517006
- (4) Never smoker. 266919005
- (5) Smoker, current status unknown. 77176002
- (6) Unknown if ever smoked. 266927001
- (7) Heavy tobacco smoker. 428071000124103
- (8) Light tobacco smoker. 428061000124105

§ 170.207(n)(1) Birth sex must be coded in accordance with HL7 Version 3 attributed as follows:

- (i) Male. M
- (ii) Female. F
- (iii) Unknown. UNK

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

Inpatient setting 170.315\_b1\_toc\_inp\_sample\*.pdf (All Samples)

Outpatient setting 170.315\_b1\_toc\_amb\_sample\*.pdf (All Samples)

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

Criteria ¶	System Under Test	Test Lab Verification
(ii)(B)	<p>1. The user is able to view the processed C-CDA documents in (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 and § 170.205(a)(4) for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, DSTU , Release 2.1.</p>	<p>1. The tester retrieves the transition of care/referral summary information in order to validate the display of the transition of care/referral summaries received and validated in (b)(1)(i)(B) and (b)(1)(ii)(A) respectively. This is accomplished by using the top-level C-CDA Validator, one of the tool selections within the Edge Testing Tool to download the ambulatory and/or inpatient test cases referenced transition of care/referral summary record sample information documents (pdfs). The tester selects the criteria that is the appropriate transition of care/referral summary record information documents (pdf) and then selects download to download the transition of care/referral summary sample information documents (pdfs). All test cases need to be verified.</p> <p style="padding-left: 40px;">Note: The required transition of care/referral summary information documents may already be available if they were downloaded to send transition of care/referral summaries via Edge Protocol (b)(1)(i)(A).</p> <p>2. Using the transition of care/referral summary information documents downloaded in step 1, the tester verifies that transitions of care /referral summaries received in (b)(1)(ii)(A)(1), (b)(1)(ii)(A)(3), and (b)(1)(ii)(A)(4) 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.</p>

**(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).

§ 170.207(b)(3) [CDT](#)

§ 170.207(b)(2) [CPT-4](#)

§ 170.207(f)(2) [“Race & Ethnicity – CDC” code system in the PHIN Vocabulary Access and Distribution System \(VADS\), Release 3.3.9](#)

§ 170.207(e)(4) [National Drug Code Directory– Vaccine Codes, updates through August 3, 2015](#)

§ 170.207(b)(4) [ICD-10-PCS](#)

§ 170.207(i) [ICD-10-CM](#)

§ 170.207(e)(3) [HL7 Standard Code Set CVX—Vaccines Administered, updates through June 18, 2015](#)

§ 170.207(f)(1) [The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997](#)

§ 170.207(c)(3) [Logical Observation Identifiers Names and Codes \(LOINC®\) Database version 2.52](#)

§ 170.207(m)(1) [The Unified Code of Units of Measure, Revision 1.9](#)

§ 170.207(g)(2) [Request for Comments \(RFC\) 5646: Tags for Identifying Languages](#)

§ 170.207(q)(1) [International Telecommunication Union E.123: Notation for national and international telephone numbers, e-mail addresses and web addresses and International](#) and [Telecommunication Union E. 164: The international public telecommunication numbering plan](#)

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

§ 170.207(d)(3) [RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release](#)

§ 170.207(h) Smoking status must be coded in one of the following SNOMED CT® codes:

- (1) Current every day smoker. 449868002
- (2) Current some day smoker. 428041000124106
- (3) Former smoker. 8517006
- (4) Never smoker. 266919005
- (5) Smoker, current status unknown. 77176002

(6) Unknown if ever smoked. 266927001

(7) Heavy tobacco smoker. 428071000124103

(8) Light tobacco smoker. 428061000124105

§ 170.207(n)(1) Birth sex must be coded in accordance with HL7 Version 3 attributed as follows:

(i) Male. M

(ii) Female. F

(iii) Unknown. UNK

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

Inpatient setting 170.315\_b1\_toc\_inp\_sample\*.pdf (All Samples)

Outpatient setting 170.315\_b1\_toc\_amb\_sample\*.pdf (All Samples)

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

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

**(b)(i)(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(b)(3)[CDT](#)
- § 170.207(b)(2) [CPT-4](#)
- § 170.207(f)(2) [“Race & Ethnicity – CDC” code system in the PHIN Vocabulary Access and Distribution System \(VADS\), Release 3.3.9](#)
- § 170.207(e)(4) [National Drug Code Directory– Vaccine Codes, updates through August 3, 2015](#)
- § 170.207(b)(4)[ICD-10-PCS](#)
- § 170.207(i) 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(e)(3) [HL7 Standard Code Set CVX—Vaccines Administered, updates through June 18, 2015](#)
- § 170.207(f)(1) [The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997](#)
- § 170.207(c)(3) [Logical Observation Identifiers Names and Codes \(LOINC®\) Database version 2.52](#)
- § 170.207(m)(1) [The Unified Code of Units of Measure, Revision 1.9](#)
- § 170.207(g)(2) [Request for Comments \(RFC\) 5646: Tags for Identifying Languages](#)
- § 170.207(q)(1) [International Telecommunication Union E.123:Notation for national and international telephone numbers, e-mail addresses and web addresses and International and Telecommunication Union E. 164: The international public telecommunication numbering plan](#)
- § 170.207(a)(4) [International Health Terminology Standards Development Organisation \(IHTSDO\) Systematized Nomenclature of Medicine Clinical Terms \(SNOMED CT®\), U.S. Edition, September 2015 Release,](#)

§ 170.207(d)(3) [RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release](#)

§ 170.207(h) Smoking status must be coded in one of the following SNOMED CT® codes:

- (1) Current every day smoker. 449868002
- (2) Current some day smoker. 428041000124106
- (3) Former smoker. 8517006
- (4) Never smoker. 266919005
- (5) Smoker, current status unknown. 77176002
- (6) Unknown if ever smoked. 266927001
- (7) Heavy tobacco smoker. 428071000124103
- (8) Light tobacco smoker. 428061000124105

§ 170.207(n)(1) Birth sex must be coded in accordance with HL7 Version 3 attributed as follows:

- (i) Male. M
- (ii) Female. F
- (iii) Unknown. UNK

**Test Data Instructions**

Inpatient setting 170.315\_b1\_toc\_inp\_sample\*.pdf (All Samples)

Outpatient setting 170.315\_b1\_toc\_inp\_sample\*.pdf (All Samples)

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

Criteria ¶	System Under Test	Test Lab Verification
(iii)	<ol style="list-style-type: none"> <li>1. Based upon the health IT setting(s) (i.e. ambulatory and/or inpatient), a user retrieves the transition of care/referral summary information which needs to be entered into the Health IT module from the top-level C-CDA Validator in the Edge Testing Tool. All test cases for a given health IT setting are required.</li> <li>2. To download the transition of care/referral summary information document (pdf), the user first selects the appropriate test criteria(s) for the transitions of care/referral summary information and then selects download.</li> <li>3. The user uses the downloaded transition of care/referral summary instruction documents to enter the data into the Health IT module for each supported health IT setting to create transitions of care/referral summaries formatted according to the standard adopted in § 170.205(a)(4) in the following formats as applicable: <ul style="list-style-type: none"> <li>• Continuity of Care;</li> <li>• Referral Note; and</li> <li>• Discharge Summary (for inpatient setting only),</li> </ul> with at a minimum the following content constrained to the specified standards as applicable: <ul style="list-style-type: none"> <li>• Common Clinical Data Set as specified in (b)(1)(iii)(A);</li> <li>• Encounter Diagnoses as specified in (b)(1)(iii)(B);</li> <li>• Cognitive status as specified in (b)(1)(iii)(C);</li> <li>• Functional status as specified in (b)(1)(iii)(D);</li> <li>• For the Ambulatory setting only: <ul style="list-style-type: none"> <li>○ The reason for referral; and</li> <li>○ Referring or transitioning provider’s name and office contact information</li> </ul> as specified in (b)(1)(iii)(E);</li> <li>• For the inpatient setting only the discharge instructions as specified in (b)(1)(iii)(F); and</li> <li>• Patient match data as specified in (b)(1)(iii)(G).</li> </ul> </li> </ol>	<ol style="list-style-type: none"> <li>1. For each test case, using the transition of care/referral summary information document and visual inspection, the tester verifies that the transitions of care/referral summary record information entered into the Health IT module is accurate and without omission.</li> <li>2. As part of the sending of a transitions of care/referral summary via Edge Protocol (b)(1)(i)(A), the tester verifies the content of the transitions of care/referral summary using the Content Validation Report within the ETT. For each test case, the tester verifies that for each applicable payload no errors exist in the Content Validation 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.</li> <li>3. Using the Message Content within the ETT and the transition of care/referral summary instruction documents used to create the payload, the tester verifies through visual inspection, the additional checks for equivalent text for content for all section level narrative text.</li> </ol>

(iii)(A) The Common Clinical Data Set

Criteria ¶	System Under Test	Test Lab Verification
(iii)(A)	<p>The content of the transitions of care/referral summaries created in (b)(1)(iii) contains the Common Clinical Data Set, including:</p> <ul style="list-style-type: none"> <li>• Patient Name</li> <li>• Sex constrained including birth sex</li> <li>• Date of Birth</li> <li>• Race and Ethnicity</li> <li>• Preferred language</li> <li>• Smoking Status</li> <li>• Problems constrained</li> <li>• Medications constrained</li> <li>• Medication Allergies</li> <li>• Laboratory Tests constrained</li> <li>• Laboratory Values(s)/Result(s)</li> <li>• Vital Signs</li> <li>• Procedures constrained</li> <li>• Care Team Member(s)</li> <li>• Immunizations constrained</li> <li>• Unique Device Identifier(s) for a Patient's Implantable Device(s)</li> <li>• Assessment and Plan of Treatment</li> <li>• Goals</li> <li>• Health Concerns</li> </ul> <p>The complete list of the Common Clinical Data Set and associated standards can be referenced in <a href="#">Table 8</a> of the Final Rule.</p>	<p>The tester verifies the Common Clinical Data Set content of transition of care/referral summaries by using the C-CDA Validator within the Edge Test Tool as part of the verification done in (b)(1)(iii).</p>

**(iii)(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).

**Test Data:**

Inpatient Setting - 170.315\_b1\_toc\_receive\_inp\_sample\*.xml (all samples)

Ambulatory Setting - 170.315\_b1\_toc\_receive\_amb\_sample\*.xml (all samples)

Criteria ¶	System Under Test	Test Lab Verification
(iii)(B)	<p>The content of the transitions of care/referral summaries created in (b)(1)(iii) contains the Encounter diagnoses in accordance with 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:</p> <ul style="list-style-type: none"> <li>(i) Diseases.</li> <li>(ii) Injuries.</li> <li>(iii) Impairments.</li> <li>(iv) Other health problems and their manifestations.</li> <li>(v) Causes of injury, disease, impairment, or other health problems</li> </ul> <p>or at a minimum the version of the standard specified at §170.205(a)(4) ( ICD-10-CM or SNOMED CT®)</p>	<p>The tester verifies the Encounter diagnoses content of a transitions of care/referral summaries by using the C-CDA Validator within the Edge Test Tool as part of the verification done in (b)(1)(iii).</p>

**(iii)(C) Cognitive Status**

**Test Data:**

Inpatient Setting - 170.315\_b1\_toc\_receive\_inp\_sample\*.xml (all samples)

Ambulatory Setting - 170.315\_b1\_toc\_receive\_amb\_sample\*.xml (all samples)

Criteria ¶	System Under Test	Test Lab Verification
(iii)(C)	<p>The content of the transitions of care/referral summaries created in (b)(1)(iii) contains the Cognitive status when present.</p>	<p>The tester verifies the Cognitive status content of the transitions of care/referral summaries by using the C-CDA Validator within the Edge Test Tool as part of the verification done in (b)(1)(iii).</p>

**(iii)(D) Functional Status**

**Test Data:**

Inpatient Setting - 170.315\_b1\_toc\_receive\_inp\_sample\*.xml (all samples)

Ambulatory Setting - 170.315\_b1\_toc\_receive\_amb\_sample\*.xml (all samples)

Criteria ¶	System Under Test	Test Lab Verification
(iii)(D)	The content of the transitions of care/referral summaries created in (b)(1)(iii) contains the Functional Status when present.	The tester verifies the Functional status content of the transitions of care/referral summaries by using the C-CDA Validator within the Edge Test Tool as part of the verification done in (b)(1)(iii).

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

**Test Data:** Ambulatory Setting - 170.315\_b1\_toc\_receive\_amb\_sample\*.xml (all samples)

Criteria ¶	System Under Test	Test Lab Verification
(iii)(E)	For ambulatory setting only: The content of the transitions of care/referral summaries created in (b)(1)(iii) contains the reason for referral, referring or transitioning provider's name, and office contact information.	The tester verifies the required content for the ambulatory setting within a transitions of care/referral summaries is present by using the C-CDA Validator within the Edge Test Tool as part of the verification done in (b)(1)(iii), and visual inspection of the unstructured text data element for the ambulatory setting which includes: <ul style="list-style-type: none"> <li>Reason for Referral</li> </ul>

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

**Test Data:** Inpatient Setting - 170.315\_b1\_toc\_receive\_inp\_sample\*.xml (all samples)

Criteria ¶	System Under Test	Test Lab Verification
(iii)(F)	For inpatient setting only: The content of the transitions of care/referral summaries created in (b)(1)(iii) contains the discharge instructions.	The tester verifies the required content for the inpatient setting within a transitions of care/referral summaries by using the C-CDA Validator within the Edge Test Tool as part of the verification done in (b)(1)(iii), and visual inspection of the unstructured text data element for the inpatient setting which includes: <ul style="list-style-type: none"> <li>For Inpatient Setting only: Discharge Instructions</li> </ul>

**(iii)(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).

**Test Data:**

Inpatient Setting - 170.315\_b1\_toc\_receive\_inp\_sample\*.xml (all samples)

Ambulatory Setting - 170.315\_b1\_toc\_receive\_amb\_sample\*.xml (all samples)

Criteria ¶	System Under Test	Test Lab Verification
(iii)(G)	<p>The content of the transitions of care/referral summaries created in (b)(1)(iii) contains the following patient matching data:</p> <ul style="list-style-type: none"> <li>• Full name including first name, last name, previous name, middle name (including middle initial) and suffix;</li> <li>• Date of birth including the year, month and day when known, and null when unknown. <u>Optional:</u> If the time of birth (hours, minutes and seconds) is included the correct time zone offset is used;</li> <li>• Address;</li> <li>• 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</li> <li>• 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 attributed as follows: <ul style="list-style-type: none"> <li>(i) Male. M</li> <li>(ii) Female. F</li> <li>(iii) Unknown. UNK.</li> </ul> </li> </ul>	<ol style="list-style-type: none"> <li>1. The tester verifies the patient matching data within the transitions of care/referral summaries by using the C-CDA Validator within the Edge Test Tool as part of the verification done in (b)(1)(iii).</li> <li>2. <u>Optional:</u> 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.</li> </ol>

### Document History

Version Number	Description of Change	Date
1.0	Released for Comment - NPRM	March 31, 2015
1.1	Released for Comment - FR	October 30, 2015

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