Test Procedure for §170.314 (b)(8) Optional – transitions of care

This document describes the test procedure for evaluating conformance of EHR technology to the certification criteria defined in 45 CFR Part 170 Electronic Health Record (EHR) Certification Criteria and the ONC Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange, 2014 Edition, Release 2, Final Rule September 11 2014. The test procedures may be updated to reflect on-going feedback received during the certification activities.

Questions or concerns regarding the ONC HIT Certification Program should be sent to: ONC.Certification@hhs.gov

CERTIFICATION CRITERIA

Refer to §170.314(b)(8) for the certification criteria.

Per the 2014 Edition, Release 2 Electronic Health Record (EHR) Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange Final Rule September 11, 2014, this certification criterion is added to the 2014 Edition test method and is designated as “optional” in regulation.

This certification criterion is a merge of §170.314(b)(1) and §170.314(b)(2) criteria for Transitions of Care (ToC) and reflects the same concepts from these two Test Procedures with the exception of the addition of testing of conformance to the Implementation Guide for Direct Edge Protocols v1.1, which is the only new functionality added in the §170.314(b)(8) criterion.

INFORMATIVE TEST DESCRIPTION

This section provides an informative description of how the test procedure is organized and conducted. It is not intended to provide normative statements of the certification requirements.

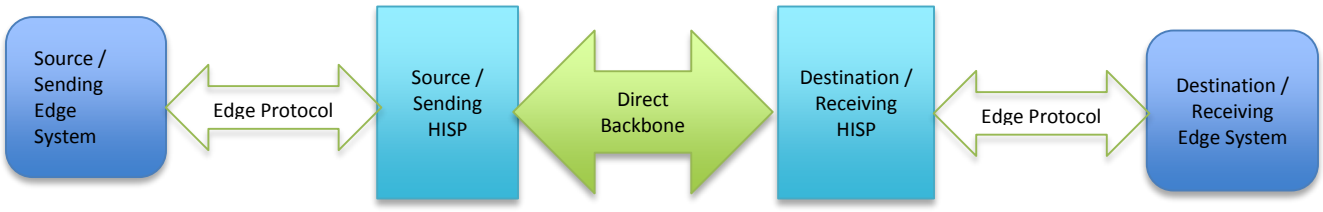
Note: The test tool functionality to support Edge Protocol Testing within the Edge Testing Tool is under development at the time of the release of this test procedure. As the Test Tool and User Guide develops, the information contained in the Test Tool, User Guide and Test Procedures will be streamlined in the Required Test Procedures section.

The 2014 Edition, Release 2 Final Rule proposed several changes to the “transitions of care” (ToC) certification criterion that includes an optional criterion for decoupling content and transport capabilities, and adopting the Direct Edge Protocol. This test evaluates the capability for EHR technology to electronically send and receive the transition of care/referral summary document (summary care record) via new Direct Edge Protocol testing using the transport protocol for Edge systems referenced in the Implementation Guide for Direct Edge Protocols, version 1.1.

The Direct Project’s Applicability Statement for Secure Health Transport (Direct Project Protocol) establishes the standard protocol by which Health Information Service Providers (HISPs) exchange data with other HISPs. While communication between the source HISP and the destination HISP has been

standardized using the Direct Project protocol, there was previously minimal implementation guidance on how EHR systems, referred to in this Test Procedure as the Edge System, should communicate with its respective HISP. The protocols used between HISPs are called "Direct Backbone Protocols," and the protocols used to send information to or receive information from HISPs are called "Direct Edge Protocols." The health IT systems (such as EHR systems) that send information to or receive information from HISPs referred to as Edge systems. Establishing standard transport protocols between Edge systems and HISPs will enable Certified Health Information Technology (IT) to interoperate with different HISP partners. Similarly, these standard transport protocols will enable HISPs to consistently integrate with edge systems (EHRs) using expected standards.

Edge protocols are used to exchange electronic health information between the Source Edge System and the Source HISP as well as the Destination HISP and the Destination Edge System. In Directed exchange, messages are sent from Source Edge systems to Destination Edge systems using the Edge and Direct Backbone protocols. The figure below shows the context and various actors involved in directed exchange using edge protocol.



In evaluating the capability of the EHR technology to send or receive information during a transition of care, this test procedure will test the ability for an Edge system to support the various methods selected for edge protocol. From an implementation standpoint, Edge systems must support at least one of the following edge protocols for sending information to and receiving information from Edge systems to HISPs:

- IHE XDR profile for Limited Metadata Document Sources
- SMTP

In addition, Edge systems may optionally support one or more of the following edge protocols for transporting information from the HISP:

- Internet Message Access Protocol (IMAP4)
- Post Office Protocol (POP3)

IHE XDR and SMTP may be used as stand-alone edge protocols for both sending and receiving to and from HISPs. IMAP4 and POP3 may optionally be used for receiving messages from the HISP, however IMAP4 and POP3 may only be used when implemented in combination with SMTP. When using this

optional combination, SMTP will be used for sending information to HISPs and IMAP4/POP3 will be used for receiving information from HISPs.

ONC provides the test data for this test procedure utilizing TD 170.314(b)(1) and TD 170.314(b)(2). This test procedure is organized into four processes: 1) Creating a transition of care/referral summary document, 2) sending C-CDA document via Edge protocol to a third party, 3) receiving a C-CDA document via Edge protocol from a third party, and 4) displaying the transition of care/referral summary. The Test Steps are written based on the Test Case Document framework posted at: https://github.com/siteadmin/direct_smtp_edges/blob/master/smtptools/doc/DirectEdgeProtocols.xls *(Please note: Corresponding test case numbers are listed after each test step. Test Cases that are referenced as 'Optional' are not required for certification).*

- Create – evaluates the capability to create a transition of care/referral summary from the EHR in C-CDA format. Included in the test procedure is an evaluation of the capability to use specified vocabularies as defined by the referenced standards.
    - For both ambulatory and inpatient settings: the Common MU Data Set data with named standards as appropriate
        1) Patient name
        2) Sex
        3) Date of birth
        4) Race
        5) Ethnicity
        6) Preferred language
        7) Smoking status
        8) Problems
        9) Medications
        10) Medication Allergies
        11) Laboratory test(s)
        12) Laboratory value(s)/result(s)
        13) Vital signs – height, weight, blood pressure, BMI
        14) Care plan field(s), including goals and instructions
        15) Procedures
        16) Care team member(s)
    - For ambulatory settings only with named standards as appropriate if they associate with a vocabulary/code set: encounter diagnoses, immunizations, cognitive status, functional status, reason for referral, referring provider's name and contact information
    - For inpatient settings only with named standards as appropriate if they associate with a vocabulary/code set: encounter diagnoses, immunizations, cognitive status, functional status, and discharge instructions
    - The Vendor creates/accesses an existing patient record in the EHR technology with health information based on the ONC-provided test data
    - The Tester logs into the online application as a provider and creates a referral summary/transition of care

- Send -- evaluates the capability of EHR technology to allow a provider to electronically transmit the health information created in the "Create" section of the test procedure to another provider or next setting of care.
    - The Tester logs in to the EHR's online technology as the provider who created the information in the "Create" step
    - Using the Vendor-identified function(s), the Tester causes the health information in C-CDA format to be transmitted to a third party using either the Edge protocol for XDR or the Edge protocol for SMTP, based on ONC supplied test information
    - The Tester verifies successful transmission of the health information to the HISP (Edge Testing Tool)
    - Using the Vendor-identified function(s), the Tester verifies that the EHR technology is able to receive positive and negative delivery notification messages upon successful or unsuccessful delivery of a message to its intended destination using the Vendor-identified Edge protocol
    - The Tester verifies Message Disposition Notification tracking for SMTP Edge protocols based on the following:
        - An Edge system that supports tracking messages for SMTP Edge protocols via the Implementation Guide for Delivery Notification in Direct v1.0 must conform by including the Disposition-Notification-Options: X – DIRECT – FINAL – DESTINATION – DELIVERY = optional, true header in the message to be tracked
        - An Edge system that supports tracking messages for SMTP/IMAP4/POP3 Edge protocols via monitoring notifications associated with the sent message must conform by including a message-id header in the message to be tracked
    - The Tester verifies Message Disposition Notification tracking for IHE XDR Edge protocol based on the following:
        - An Edge system that supports tracking messages for IHE XDR Edge protocols via the Implementation Guide for Delivery Notification in Direct v1.0 must conform by including a SOAP header named X – DIRECT – FINAL – DESTINATION – DELIVERY with a value of 'true' as part of the direct address BLOCK header. The Edge system MUST also include the message-id WS-Addressing header in the message to be tracked
        - An Edge system that supports tracking messages for IHE XDR Edge protocols via monitoring notifications associated with the sent message must conform by including the message-ID WS-Addressing header in the message to be tracked
        - *Note: The Edge system has an option for tracking messages either by monitoring MDNs or by the Implementation Guide for notification delivery. Tracking messages by using processed MDNs or by using the IG for Delivery Notification standard is separated into 2 different categories in the MU2 test steps below*

    - The Tester uploads the referral summary/transition of care document received by the Edge Testing Tool (HISP) to the Transport Testing Tool to perform validation for C-CDA conformance. Using the Validation Report produced by the Transport Test Tool, the Tester verifies that the Implementation Guide conformance requirements tested are met, and that the named standard vocabularies have been used where applicable for data in the transition of care/referral summary

- Using the provided test data, the Tester verifies that the data rendered in the C-CDA received by the Edge Testing Tool are complete and accurate (This may be accomplished by inspection of the C-CDA .xml).

- Receive – evaluates the capability of EHR technology to electronically receive a transition of care/referral summary for a test patient from both ambulatory and inpatient care settings:
  - Using the Vendor-identified function(s), the Tester causes the health information in C-CDA format to be transmitted from the Edge Testing Tool to the Edge system using one of the following edge protocols:
    - XDR protocol
    - SMTP protocol
    - IMAP4 protocol – in this case, the Edge system initiates the request to transmit the data from the HISP to the Edge system
    - POP3 protocol – in this case, the Edge system initiates the request to transmit the data from the HISP to the Edge system
  - (Optional) Using the Vendor-identified function(s), the Tester causes the health information in C-CDA format to be transmitted to the Edge System using the IMAP4 Edge protocol, based on ONC supplied test information
  - (Optional) Using the Vendor-identified function(s), the Tester causes the health information in C-CDA format to be transmitted to the Edge System using the POP3 Edge protocol, based on ONC supplied test information
  - The Tester verifies that the EHR technology does not accept receipt of messages when sent using an invalid certificate used for Mutual TLS authentication

- Display – evaluates the capability of the EHR technology to electronically display, in human readable format, the transition of care/referral summary that was received in the "Receive" step
  - The Tester logs in to the EHR technology as a provider
  - The Tester causes the EHR to display the transition of care/referral summary transmitted to the EHR in the "Receive" step
  - The Tester validates that the transition of care/referral summary received by the EHR system is electronically displayed for all three acceptable document conformance types: C-CDA, HITSP/C32, and ASTM CCR
  - The Tester verifies that the individual sections of the C-CDA conformant document for both the inpatient summary and ambulatory transition of care/referral summary records formatted to the C-CDA standard can be displayed
  - The Tester evaluates that the EHR technology individually displays all sections and accompanying document header information from the transition of care/referral summary received in the "Receive" step using the C-CDA standard and that the individual sections and header information is complete and accurate
  - The Tester verifies that the transition of care/referral summary information is accurate and complete, and verifies that the Common MU Data Set data are displayed in their English representation if they associate with a vocabulary/code set:
    1) Patient name
    2) Sex

3) Date of birth
4) Race
5) Ethnicity
6) Preferred language
7) Smoking status
8) Problems
9) Medications
10) Medication Allergies
11) Laboratory test(s)
12) Laboratory value(s)/result(s)
13) Vital signs – height, weight, blood pressure, BMI
14) Care plan field(s), including goals and instructions
15) Procedures
16) Care team member(s)
    - For ambulatory transition of care/referral summary C-CDA: encounter diagnoses, immunizations, cognitive status, functional status, reason for referral, referring provider's name and contact information
    - For inpatient transition of care C-CDA: encounter diagnoses, immunizations, cognitive status, functional status, and discharge instructions

REFERENCED STANDARDS

§170.202 Transport standards.	Regulatory Referenced Standard
The Secretary adopts the following transport standards:	
(a) Standard. ONC Applicability Statement for Secure Health Transport (incorporated by reference in § 170.299).	
(b) Standard. ONC XDR and XDM for Direct Messaging Specification (incorporated by reference in § 170.299).	
(d) Standard. ONC Implementation Guide for Direct Edge Protocols	
§170.205 Content exchange standards and implementation specifications for exchanging electronic health information.	**Regulatory Referenced Standard**
The Secretary adopts the following content exchange standards and associated implementation specifications:	
(a)(3) Standard. HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, (incorporated by reference in § 170.299). The use of the "unstructured document" document-level template is prohibited.	
§170.207 Vocabulary standards for representing electronic health information.	**Regulatory Referenced Standard**
The Secretary adopts the following code sets, terminology, and nomenclature as the vocabulary standards for the purpose of representing electronic health information:	

§170.207 Vocabulary standards for representing electronic health information.	Regulatory Referenced Standard
(a)(3) Standard. IHTSDO SNOMED CT® International Release July 2012 (incorporated by reference in § 170.299) and US Extension to SNOMED CT® March 2012 Release (incorporated by reference in § 170.299).	
(b)(8) Standard. The code set specified at 45 CFR 162.1002(a)(1).	45 CFR 162.1002 Medical data code sets The Secretary adopts the following code set maintaining organization's code sets as the standard medical data code sets: (a) International Classification of Diseases, 9th Edition, Clinical Modification, (ICD-9-CM), Volumes 1 and 2 (including The Official ICD-9-CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following conditions: (5) The combination of *Health Care Financing Administration Common Procedure Coding System (HCPCS),* as maintained and distributed by HHS, and *Current Procedural Terminology, Fourth Edition (CPT–4),* as maintained and distributed by the American Medical Association, for physician services and other health care services. These services include, but are not limited to, the following:
(b)(3) Standard. The code set specified at 45 CFR 162.1002(a)(1).	45 CFR 162.1002 Medical data code sets The Secretary adopts the following code set maintaining organization's code sets as the standard medical data code sets: (a) International Classification of Diseases, 9th Edition, Clinical Modification, (ICD-9-CM), Volumes 1 and 2 (including The Official ICD-9-CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following conditions: (4) *Code on Dental Procedures and Nomenclature,* as maintained and distributed by the American Dental Association, for dental services.
(4) Standard. The code set specified at 45 CFR 162.1002(c)(3) for the indicated procedures or other actions taken.	45 CFR 162.1002 Medical data code sets The Secretary adopts the following code set maintaining organization's code sets as the standard medical data code sets: (c)(3) International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) (including The Official ICD–10–PCS Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals: (i) Prevention. (ii) Diagnosis. (iii) Treatment. (iv) Management.

§170.207 Vocabulary standards for representing electronic health information.	Regulatory Referenced Standard
(c) Laboratory tests. (2) Standard. Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc. (incorporated by reference in § 170.299).	
(d) Medications. (2) Standard. RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release (incorporated by reference in § 170.299).	
(e) Immunizations. (2) Standard. HL7 Standard Code Set CVX -- Vaccines Administered, updates through July 11, 2012 (incorporated by reference in § 170.299).	
(f) Race and Ethnicity. Standard. 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 (see "Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity," available at http://www.whitehouse.gov/omb/fedreg_1997standards) .	
(g) Preferred language. Standard. As specified by the Library of Congress, ISO 639-2 alpha-3 codes limited to those that also have a corresponding alpha-2 code in ISO 639-1. (incorporated by reference in § 170.299).	
(h) Smoking status. Standard. 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	
(i) Encounter diagnoses. Standard. The code set specified at 45 CFR 162.1002(c)(2) for the indicated conditions.	45 CFR 162.1002 Medical data code sets. The Secretary adopts the following maintaining organization's code sets as the standard medical data code sets: (c)(2) International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) (including The Official ICD–10–CM Guidelines for Coding and Reporting), 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.

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.314(b)(8) – 1: Create Transition of Care/Referral Summary

DTR170.314(b)(8) – 2: Send Health Information to a Third Party Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources as the Edge system

DTR170.314(b)(8) – 3: Send Health Information to a Third Party Using Edge Protocol for SMTP as the Edge system

DTR170.314(b)(8) – 4: Receive Health Information from a Third Party Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources as the Edge system

DTR170.314(b)(8) – 5: Receive Health Information from a Third Party Using Edge Protocol for SMTP as the Edge system

DTR170.314(b)(8) – 6: Display Summary of Care Record

The following sections are optional. These DTRs will be written in parallel with Test Case development and published in a future release.

DTR170.314(b)(8) – 7: Receive Health Information from a Third Party Using Edge Protocol for IMAP4 as an Edge System (Optional)

DTR170.314(b)(8) – 8: Receive Health Information from a Third Party Using Edge Protocol for POP3 as an Edge System (Optional)

DTR170.314(b)(8) – 1: Create Transition of Care/Referral Summary

Required Vendor Information

VE170.314(b)(8) – 1.01: Using ONC-supplied test data, the Vendor shall create a test patient in the EHR to be used for this test as indicated in TD170.314(b)(2) – 1: Ambulatory (ambulatory only) or TD170.314(b)(2) – 2: Inpatient (inpatient only)

VE170.314(b)(8) – 1.02: Vendor shall identify a provider with privileges to access the patient's record

VE170.314(b)(8) – 1.03: Vendor shall identify the EHR function(s) that are available for a provider to view health information including the named data elements as well as the Common MU Data Set with associated vocabulary standards and create a transition of care/referral summary document in C-CDA format

Required Test Procedure

TE170.314(b)(8) – 1.01: Using the Vendor-identified EHR function(s), the Tester shall access the ONC-supplied test patient's record as the provider

TE170.314(b)(8) – 1.02: Using the Vendor-identified EHR function(s), the Tester creates the patient encounter and summary care record using the ONC-supplied test data and tester selected values for ranges as indicated in TD170.314(b)(2) – 1:

Ambulatory (ambulatory only) or TD170.314(b)(2) – 2: Inpatient (inpatient only) for the patient created in VE170.314(b)(2) – 1.01 that conforms to the minimum requirements for the:

- Ambulatory Summary Care Record: Common MU Data Set and the following data elements: encounter diagnoses, immunizations, cognitive status, functional status, reason for referral, referring provider's name and contact information (Ambulatory EHR Only)
- Inpatient Summary Care Record: Common MU Data Set and encounter diagnoses, immunizations, cognitive status, functional status, and discharge instructions (Inpatient EHR Only)

TE170.314(b)(8) – 1.03: Using the Inspection Test Guide, the Tester shall verify that the created Ambulatory Summary Care Record/Inpatient Summary Care Record is complete and accurate and in accordance with TD170.314(b)(2) – Ambulatory (ambulatory only) or TD170.314(b)(2) – Inpatient (inpatient only)

Inspection Test Guide

IN170.314(b)(8) – 1.01: Using the ONC-provided test data, the Tester shall inspect the content of the C-CDA conformant document is complete and accurate, is equivalent to the provided test data (TD170.314(b)(2)) and equivalent to the information contained in the patient's EHR record

DTR170.314(b)(8) – 2: Send Health Information Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources as the Edge system

Required Vendor Information *(To be refined as the Test Tool is developed)*

VE170.314(b)(8) – 2.01: The Vendor shall identify the edge protocol to be used to send health information from the Edge system to the HISP for testing: IHE XDR profile for Limited Metadata Document Sources edge protocol

VE170.314(b)(8) – 2.02: Using the same host and port, the Vendor shall configure the Edge Testing Tool HISP configuration for:

- Endpoint 5: Provides regular processed Message Disposition Notifications (MDNs) when messages are received (No Dispatched MDN)
- Endpoint 6: Provides both processed and dispatched MDNs when messages are received
- Endpoint 7: Provides processed MDNs when messages are received, dispatched MDNs [60 minutes time] after messages are received. The default time for the Edge Test Tool is 60 minutes but is configurable by the tester/vendor/lab at run time
- Endpoint 8: No MDNs are provided when the Implementation Guide for Delivery Notification is invoked
- Endpoint 9: Non-existent final address (need to send a Failure MDN)
- Endpoint 15: Receiving messages from the Edge system when errors are encountered

VE170.314(b)(8) – 2.03: Additionally, the Vendor shall configure secondary HISP domain Endpoints:

- Endpoints 10-12: Used by the Edge system
- Endpoint 14: Successful/good destination

VE170.314(b)(8) – 2.04: The Vendor shall use the Edge Testing Tool to generate Endpoints for use in XDR testing

VE170.314(b)(8) – 2.05: The Vendor shall identify the C-CDA conformant document(s) created in TE170.314(b)(8) - 1.02

Required Test Procedures

The following test steps will test the ability of an Edge system to authenticate to the HISP:

TE170.314(b)(8) – 2.01: The Tester shall establish a Mutual TLS session to authenticate to the Edge Testing Tool (HISP) (XDR-6)

TE170.314(b)(8) – 2.02: The Tester shall use an incorrect Mutual TLS session to authenticate to the Edge Testing Tool (HISP) (XDR-7)

The following test steps will test the Edge system as a Sender (sending data to the HISP)

TE170.314(b)(8) – 2.03: The Tester shall cause the Edge system to send the C-CDA document (Ambulatory/Inpatient), created in TE170.314(b)(8) - 1.02 in an XDR message to the Edge Testing Tool (HISP) with limited metadata and a Direct Address block using the Implementation Guide for Direct Edge Protocols, version 1.1 (XDR-1)

TE170.314(b)(8) – 2.04: The Tester shall cause the Edge system to send the C-CDA document (Ambulatory/Inpatient), created in TE170.314(b)(8) - 1.02 in an XDR message to the Edge Testing Tool (HISP) with full metadata using the standard edge protocol (optional XDR-2)

TE170.314(b)(8) – 2.05: The Tester shall obtain the C-CDA document received by the Edge Testing Tool (HISP) and upload it to the Transport Testing Tool to validate conformance of the Consolidated CDA standard with named vocabulary standards

TE170.314(b)(8) – 2.06: Using the Inspection Test Guide, the Tester shall verify that the Transition of Care/Referral Summary is transmitted according to the Implementation Guide for Direct Edge Protocols v1.1 and formatted according to the Consolidated CDA standard tested and the named vocabulary standards, and is complete and accurate

The following steps will test XDR Edge system message tracking using processed MDNs:

TE170.314(b)(8) – 2.07: The Tester shall send multiple messages (# TBD) to the Edge Testing Tool with unique message IDs for each XDR profile to Endpoint 8 in multiple sessions. The number of messages to be sent shall be determined by the Tester based upon the amount of rigor the testing requires (MU2-19)

TE170.314(b)(8) – 2.08: The Tester shall send the C-CDA document to the Edge Testing Tool to multiple recipients including both valid (Endpoint 5) and invalid recipients (Endpoint 9) (MU2-20)

The following test steps will test XDR Edge system message tracking using the "Implementation Guide for Delivery Notification" standard:

TE170.314(b)(8) – 2.09: The Tester (System Under Test) 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 (MU2-48)

TE170.314(b)(8) – 2.10: The Tester (System Under Test) shall send and XDR message to Endpoint 14 using the Edge Testing Tool with a valid Direct Address Block and Delivery Notifications header (MU2-49)

TE170.314(b)(8) – 2.11: The Tester (System Under Test) shall send XDR messages to multiple recipients including both valid and invalid recipients within the same message to Endpoints 5 and 9 respectively (MU2-50)

Inspection Test Guide

IN170.314(b)(8) – 2.01: The Tester shall verify that a mutual TLS session is established between the Edge system (sender) and the Edge Testing Tool (receiver) (XDR-6)

IN170.314(b)(8) – 2.02: The Tester shall verify that the Edge system (sender) disconnects when the Edge Testing Tool provides an invalid certificate and incorrect mutual TLS configuration (XDR-7)

IN170.314(b)(8) – 2.03: The Tester shall verify that the Edge system produces the correct message with limited metadata and conforms to the Implementation Guide for Direct Edge Protocols, version 1.1 standard (XDR-1)

IN170.314(b)(8) – 2.04: The Tester shall verify that the Edge system produces the correct message with full metadata and conforms to the Implementation Guide for Direct Edge Protocols, version 1.1 standard (Optional XDR-2)

IN170.314(b)(8) – 2.05: Using the provided test data and the Validation Report produced by the Transport Testing Tool identified in the Conformance Test Tools section of this test procedure**,** the Tester shall verify that

- The C-CDA Implementation Guide conformance requirements tested are met by the electronically generated (Ambulatory/Inpatient) Transition of Care/Referral Summary
- The standards for the named vocabularies for the Common MU Data Set, Encounter diagnoses, and Immunizations are met by the electronically generated Transition of Care/Referral Summary

IN170.314(b)(8) – 2.06: The Tester shall identify the C-CDA conformant .xml files within the transmitted documents (This may involve reviewing EHR logs to access the transmitted documents, parsing files and inspecting the header to identify the C-CDA conformant document .xml (vs. style sheet, human readable document, etc.))

IN170.314(b)(8) – 2.07: Using the ONC-provided test data, the Tester shall verify that the content of the created C-CDA conformant Ambulatory Summary of Care Record displays completely and accurately, including section headings and at a minimum, the following data elements (Ambulatory Only):

1) Encounter diagnoses

2) Immunizations
3) Cognitive status
4) Functional status
5) Reason for referral
6) Referring or transitioning provider's name
7) Provider name
8) Provider office contact information
9) Common MU Data Set (in their English representation if they associate with a vocabulary/code set)
    1) Patient name
    2) Sex
    3) Date of birth
    4) Race
    5) Ethnicity
    6) Preferred language
    7) Smoking status
    8) Problems
    9) Medications
    10) Medication Allergies
    11) Laboratory test(s)
    12) Laboratory value(s)/result(s)
    13) Vital signs – height, weight, blood pressure, BMI
    14) Care plan field(s), including goals and instructions
    15) Procedures
    16) Care team member(s)

IN170.314(b)(8) – 2.08: Using the ONC-provided test data, the Tester shall verify that the content of the created C-CDA conformant Inpatient Summary of Care Record displays completely and accurately, including section headings and at a minimum, the following data elements (Inpatient Only):

1) Encounter diagnoses
2) Immunizations
3) Cognitive status
4) Functional status
5) Discharge instructions
6) Common MU Data Set (in their English representation if they associate with a vocabulary/code set)
    1) Patient name
    2) Sex
    3) Date of birth
    4) Race
    5) Ethnicity
    6) Preferred language
    7) Smoking status

8) Problems
9) Medications
10) Medication Allergies
11) Laboratory test(s)
12) Laboratory value(s)/result(s)
13) Vital signs – height, weight, blood pressure, BMI
14) Care plan field(s), including goals and instructions
15) Procedures
16) Care team member(s)

IN170.314(b)(8) – 2.09: The Tester shall verify that the Edge system is able to create multiple messages with unique message IDs specific to each message. Each unique message ID shall be included in the MessageID field of the WS-Addressing Header element. The Test Labs shall verify that the message IDs are unique in the Edge Testing Tool Logs (MU2-19)

IN170.314(b)(8) – 2.10: The Tester shall verify that the Edge system is able to accept failure messages for invalid recipients from the Edge Testing Tool. Failure messages to invalid recipients have to be processed/tracked appropriately. The Test Labs shall verify in the System Under Test (SUT) logs that the Failure MDN is sent for Endpoint 9 and the Processed MDN is sent for Endpoint 5 (MU2-20)

IN170.314(b)(8) – 2.11: The Tester shall verify that the Edge system 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 Edge Testing Tool Logs (MU2-48)

IN170.314(b)(8) – 2.12: The Tester shall verify that the Edge system is able to generate the Direct Address Block header including the Disposition Notifications header. The Test Labs shall verify the disposition header in the Edge Testing Tool Logs (MU2-49)

IN170.314(b)(8) – 2.13: The Tester shall verify that the Edge system is able to accept failure notification messages from invalid recipients. The Test Labs shall verify a Failure MDN for Endpoint 9 in the SUT Logs. A processed MDN shall be sent for Endpoint 5 (MU2-50)

IN170.314(b)(8) – 2.14: After the end of the testing cycle, the Tester shall review the Validation Report to verify that all tests have been completed with a status of Pass or Fail

DTR170.314(b)(8) – 3: Send Health Information Using Edge Protocol for SMTP as the Edge system

Required Vendor Information (*To be refined as the Test Tool is developed)*

VE170.314(b)(8) – 3.01: The Vendor shall identify the edge protocol to be used to send health information from the Edge system to the HISP for testing: an SMTP-focused edge protocol

VE170.314(b)(8) – 3.02: The Vendor shall create a unique user account with username and password within the Edge Testing Tool in order to log in and authenticate with their SMTP server. This will be entered in the profile section of the Edge TTT.

VE170.314(b)(8) – 3.03: The Vendor shall enable SMTP Authentication Required

VE170.314(b)(8) – 3.04: The Vendor shall identify a username and password for address for PLAIN SASL and DIGEST-MD5 SASL Authentication to be used

VE170.314(b)(8) – 3.05: The Vendor shall enable logging of authentication mechanism used to verify PLAIN SASL usage (Test Case 18 and DIGEST MD5 for Test Case 19)

VE170.314(b)(8) – 3.06: The Vendor shall identify account information (SUT mail address) for the Java client to send messages

VE170.314(b)(8) – 3.07: The Vendor shall identify the SMTP address for the Edge system <TestAddress 2>

VE170.314(b)(8) – 3.08: The Vendor shall identify a non-existent SMTP address for failure testing <TestAddress 3>

VE170.314(b)(8) – 3.09: The Vendor shall identify the C-CDA conformant document(s) created in TE170.314(b)(8) - 1.02

Required Test Procedures

The following steps will test the ability of the Edge system to start a TLS session with the HISP:

TE170.314(b)(8) – 3.01: The Tester shall initiate a TLS session with the Edge Testing Tool (HISP) using email address: wellformed2@hit-testing2.nist.gov (SMTP-14)

TE170.314(b)(8) – 3.02: The Tester shall initiate a TLS session with the Edge Testing Tool SMTP mail server using Address 15 (SMTP-15 is not supported at this time)

The following steps will test the ability of the SUT to authenticate to an SMTP server as an Edge system:

TE170.314(b)(8) – 3.03: The Tester shall authenticate using PLAIN SASL authentication to the Edge Testing Tool SMTP server using email address: wellformed1@hit-testing2.nist.gov and the username and password identified in VE170.314(b)(8)-3.04 (SMTP-18)

TE170.314(b)(8) – 3.04: The Tester shall authenticate using DIGEST-MD5 SASL authentication to the Edge Testing Tool SMTP server using email address: wellformed1@hit-testing2.nist.gov and the username and password identified in VE170.314(b)(8) – 3.04 (SMTP-19)

The following steps will test the Edge system as a Sender to the HISP:

TE170.314(b)(8) – 3.05: The Tester shall cause the Edge system to send the C-CDA document created in DTR170.314(b)(8) – 1.02 in an SMTP mail message to the Edge Testing Tool (HISP) using the email address: wellformed1@hit-testing2.nist.gov (SMTP-1-8)

TE170.314(b)(8) – 3.06: The Tester shall obtain the C-CDA document received by the Edge Testing Tool (HISP) and upload it to the Transport Testing Tool to validate conformance of the Consolidated CDA standard with named vocabulary standards

TE170.314(b)(8) – 3.07: Using the Inspection Test Guide, the Tester shall verify that the Transition of Care/Referral Summary is transmitted according to the Implementation Guide for Direct Edge Protocols v1.1 and formatted according to the Consolidated CDA standard tested and the named vocabulary standards, and is complete and accurate

The following steps will test SMTP Edge system message tracking using processed MDNs:

TE170.314(b)(8) – 3.08: The Tester shall send a series of SMTP mail messages (# TBD) to the Edge Testing Tool with unique message IDs specific to each message to wellformed14@hit-testing2.nist.gov.. The number of messages to be sent shall be determined by the Tester based upon the amount of rigor the testing requires (MU2-17)

TE170.314(b)(8) – 3.08: The Tester shall send the C-CDA document in a single SMTP mail message to processedonly5@hit-testing2.nist.gov and noaddressfailure9@hit-testing2.nist.gov (MU2-18)

The following steps will test SMTP Edge system message tracking using the "Implementation Guide for Delivery Notification" standard:

*:*TE170.314(b)(8) – 3.09: The Tester shall send a series of SMTP mail messages (# TBD) to the Edge Testing Tool with unique message IDs specific to each message to untrustedhisp11@hit-testing2.nist.gov. The number of messages to be sent shall be determined by the Tester based upon the amount of rigor the testing requires (MU2-45)

TE170.314(b)(8) – 3.10: The Tester shall send an SMTP mail message to the Edge Testing Tool to untrustedhisp11@hit-testing2.nist.gov 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 Implementation Guide for Delivery Notifications (MU2-46)

TE170.314(b)(8) – 3.11: The Tester shall send the C-CDA document in a single SMTP mail message to processedonly5@hit-testing2.nist.gov and noaddressfailure9@hit-testing2.nist.gov (MU2-47)

Inspection Test Guide

IN170.314(b)(8) – 3.01: Using the Edge Testing Tool, the Tester shall verify that a secure session was established and a the STARTTLS command was received (SMTP-14)

IN170.314(b)(8) – 3.02: The Tester shall verify that the secure TLS connection to the Edge Testing Tool is not accepted due to the receipt of an invalid certificate (SMTP-15 is not supported at this time)

IN170.314(b)(8) – 3.03: Using the Edge Testing Tool with a pre-determined username and password, the Tester shall verify successful authentication with PLAIN SASL (SMTP-18)

IN170.314(b)(8) – 3.04: Using the Edge Testing Tool with a pre-determined username and password, the Tester shall verify successful authentication with DIGEST-MD5 SASL (cannot test SMTP-19 for now)

IN170.314(b)(8) – 3.05: Using the Edge Testing Tool, the Tester shall verify that the connection is successful and the transmitted C-CDA conformant document has been sent successfully according to the Implementation Guide for Direct Edge Protocols (SMTP) standard, and the Edge Testing Tool validation report indicates a

successful sequence of commands for SMTP protocols (SMTP-1 through SMTP-8)

IN170.314(b)(8) – 3.06: Using the provided test data and the Log produced by the Edge Testing Tool identified in the Conformance Test Tools section of this test procedure**,** the Tester shall verify that

- The C-CDA Implementation Guide conformance requirements tested are met by the electronically generated (Ambulatory/Inpatient) Transition of Care/Referral Summary
- The standards for the named vocabularies for the Common MU Data Set, Encounter diagnoses, and Immunizations are met by the electronically generated Transition of Care/Referral Summary

IN170.314(b)(8) – 3.07: The Tester shall identify the C-CDA conformant .xml files within the transmitted documents (This may involve reviewing EHR logs to access the transmitted documents, parsing files and inspecting the header to identify the C-CDA conformant document .xml (vs. style sheet, human readable document, etc.))

IN170.314(b)(8) – 3.08: Using the ONC-provided test data, the Tester shall verify that the content of the created C-CDA conformant Ambulatory Summary of Care Record displays completely and accurately, including section headings and at a minimum, the following data elements (Ambulatory Only):

1) Encounter diagnoses
2) Immunizations
3) Cognitive status
4) Functional status
5) Reason for referral
6) Referring or transitioning provider's name
7) Provider name
8) Provider office contact information
9) Common MU Data Set (in their English representation if they associate with a vocabulary/code set)
    1) Patient name
    2) Sex
    3) Date of birth
    4) Race
    5) Ethnicity
    6) Preferred language
    7) Smoking status
    8) Problems
    9) Medications
    10) Medication Allergies
    11) Laboratory test(s)
    12) Laboratory value(s)/result(s)
    13) Vital signs – height, weight, blood pressure, BMI
    14) Care plan field(s), including goals and instructions

15) Procedures
16) Care team member(s)

IN170.314(b)(8) – 3.09: Using the ONC-provided test data, the Tester shall verify that the content of the created C-CDA conformant Inpatient Summary of Care Record displays completely and accurately, including section headings and at a minimum, the following data elements (Inpatient Only):

1) Encounter diagnoses
2) Immunizations
3) Cognitive status
4) Functional status
5) Discharge instructions
6) Common MU Data Set (in their English representation if they associate with a vocabulary/code set)
    1) Patient name
    2) Sex
    3) Date of birth
    4) Race
    5) Ethnicity
    6) Preferred language
    7) Smoking status
    8) Problems
    9) Medications
    10) Medication Allergies
    11) Laboratory test(s)
    12) Laboratory value(s)/result(s)
    13) Vital signs – height, weight, blood pressure, BMI
    14) Care plan field(s), including goals and instructions
    15) Procedures
    16) Care team member(s)

IN170.314(b)(8) – 3.10: Using the Edge Testing Tool logs, the Tester shall verify that multiple messages are created with a unique message ID specific to each message (MU2-17)

IN170.314(b)(8) – 3.11: Using the System Under Test (SUT) logs, the Tester shall verify that the system has received, processed, and tracked a failure Message (MDN) to noaddressfailure9@hit-testing2.nist.gov and successful MDN to processedonly5@hit-testing2.nist.gov (MU2-18)

IN170.314(b)(8) – 3.12: Using the Edge Testing Tool logs, the Tester shall verify that multiple messages are created with a unique message ID specific to each message (MU2-45)

IN170.314(b)(8) – 3.13: Using the validation report, the Tester shall verify that the Edge Testing Tool will process the Disposition-Notifications-Options header appropriately and include the header in the message to the receiver (MU2-46)

IN170.314(b)(8) – 3.14: Using the System Under Test (SUT) logs, the Tester shall verify that the system has received, processed, and tracked a failure Message (MDN) for Address 9 and successful MDN for Address 5 (MU-47)

IN170.314(b)(8) – 3.15: After the end of the testing cycle, the Tester shall review the Validation Report to validate that all tests have been completed with a status of Success or Fail

DTR170.314(b)(8) – 4: Receive Health Information Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources as the Edge system

Required Vendor Information:

VE170.314(b)(8) – 4.01: The Vendor shall identify the edge protocol to be used to receive health information from the HISP to the Edge system for testing: IHE XDR profile for Limited Metadata Document Sources edge protocol

VE170.314(b)(8) – 4.02: The Vendor shall configure the Edge Testing Tool HISP configuration for:

- Endpoint 5: Provides regular processed Message Disposition Notifications (MDNs) when messages are received (No Dispatched MDN)
- Endpoint 6: Provides both processed and dispatched MDNs when messages are received
- Endpoint 7: Provides processed MDNs when messages are received, dispatched MDNs [60 minutes time] after messages are received. The default time for the Edge Test Tool is 60 minutes but is configurable by the tester/vendor/lab at run time
- Endpoint 8: No MDNs are provided
- Endpoint 9: Non-existent final address (need to send a Failure MDN)
- Endpoint 15: Receiving messages from the Edge system when errors are encountered

VE170.314(b)(8) – 4.03: Additionally, the Vendor shall configure secondary HISP domain Endpoints:

- Endpoints 10-12: Used by the Edge system
- Endpoint 14: Successful/good destination

VE170.314(b)(8) – 4.04: The Vendor shall use the Edge Testing Tool to generate Endpoints for use in XDR testing

Required Test Procedures

The following test steps will test the ability of an Edge system to accept connections from the HISP:

TE170.314(b)(8) – 4.01: The Edge Testing Tool (HISP) shall authenticate with the Edge system (System Under Test) using Mutual TLS correctly (XDR-8)

TE170.314(b)(8) – 4.02: The Edge Testing Tool (HISP) shall authenticate with the Edge system (System Under Test) using bad certificates (incorrect Mutual TLS configuration) (XDR-9)

The following steps will test the Edge system to receive an XDR message from the HISP:

TE170.314(b)(8) – 4.03: The Tester shall receive a properly formatted XDR message with limited metadata from the Edge Testing Tool (HISP) (XDR-3)

TE170.314(b)(8) – 4.04: The Tester shall receive a properly formatted XDR message with Full Metadata from the Edge Testing Tool (HISP) (XDR-5)

The following steps will test the ability of the Edge system to receive an incorrect XDR message from the HISP:

TE170.314(b)(8) – 4.05: The Tester shall return an error when an incorrect XDR message containing invalid SOAP envelope details, is received from the Edge Testing Tool (HISP) (XDR-4)

TE170.314(b)(8) – 4.06: The Tester shall return an error when an incorrect XDR message, such as invalid SOAP body details, is received from the Edge Testing Tool (HISP) (XDR-4)

TE170.314(b)(8) – 4.07: The Tester shall return an error when an incorrect XDR message, such as missing metadata elements, is received from the Edge Testing Tool (HISP) (XDR-4)

TE170.314(b)(8) – 4.08: The Tester shall return an error when an incorrect XDR message, such as missing associations between ebRIM constructs, is received from the Edge Testing Tool (HISP) (XDR-4)

TE170.314(b)(8) – 4.09: The Tester shall return an error when an incorrect XDR message, such as missing Direct Address block, is received from the Edge Testing Tool (HISP) (XDR-4)

Inspection Test Guide

IN170.314(b)(8) – 4.01: The Tester shall verify that the Edge System is capable of accepting and validating a Mutual TLS connection when authenticating to the Edge Testing Tool (HISP) (XDR-8)

IN170.314(b)(8) – 4.02: The Tester shall verify that the Edge System shall not accept the connection due to the incorrect Mutual TLS configuration and invalid certificate published by the Edge Testing Tool (HISP) (XDR-9)

IN170.314(b)(8) – 4.03: Using the Validation Report, the Tester shall verify that the Edge system is capable of receiving and processing a valid XDR message with Limited Metadata from the Edge Testing Tool (HISP) (XDR-3)

IN170.314(b)(8) – 4.04: Using the Validation Report, the Tester shall verify that the Edge system is capable of receiving and processing a valid XDR message with Full Metadata from the Edge Testing Tool (HISP) (XDR-5)

IN170.314(b)(8) – 4.05: The Tester shall verify that the System Under Test (Edge system) does not accept various invalid messages sent from the Edge Testing Tool (HISP) containing the following: (XDR-4)

- Bad SOAP Envelope Details in one message
- Bad SOAP Body Details in one message
- Missing Metadata elements
- Missing associations between ebRIM constructs
- Missing Direct Address block

IN170.314(b)(8) – 4.06: After the end of the testing cycle, the Tester shall review the Validation Report to validate that all tests have been completed with a status of Success or Fail

DTR170.314(b)(8) – 5: Receive Health Information Using Edge Protocol for SMTP as the Edge System

Required Vendor Information:

VE170.314(b)(8) – 5.01: The Vendor shall identify the edge protocol to be used to receive health information from the HISP to the Edge system for testing: an SMTP-focused edge protocol

VE170.314(b)(8) – 5.02: The Vendor shall create a unique user account with username and password within the Edge Testing Tool in order to log in and authenticate with their SMTP server. This will be entered in the profile section of the Edge TTT.

VE170.314(b)(8) – 5.03: The Vendor shall enable SMTP Authentication Required

VE170.314(b)(8) – 5.04: The Vendor shall identify a username and password for address for PLAIN SASL Authentication to be used

VE170.314(b)(8) – 5.05: The Vendor shall enable logging of authentication mechanism used to verify PLAIN SASL usage (Test Case 18 and DIGEST MD5 for Test Case 19)

VE170.314(b)(8) – 5.06: The Vendor shall identify account information (SUT mail address) for the Java client to send messages

VE170.314(b)(8) – 5.07: The Vendor shall identify the SMTP address for the Edge system <TestAddress 2>

VE170.314(b)(8) – 5.08: The Vendor shall identify a non-existent SMTP address for failure testing <TestAddress 3>

VE170.314(b)(8) – 5.09: The Vendor shall identify the C-CDA conformant document(s) created in TE170.314(b)(8) - 1.02

Required Test Procedures

The following steps will test the ability of the Edge system to start a TLS session with the HISP:

TE170.314(b)(8) – 5.01: The Tester shall initiate a TLS session with correct syntax from the Edge Testing Tool (HISP) using a C-CDA document contained within the Edge Testing Tool sent from wellformed3@hit-testing2.nist.gov to wellformed1@hit-testing2.nist.gov (SMTP-16)

TE170.314(b)(8) – 5.02: The Tester shall initiate a TLS session using invalid TLS commands from the Edge Testing Tool (HISP) when the C-CDA is sent from badcommands4@hit-testing2.nist.gov to wellformed1@hit-testing2.nist.gov (SMTP-17)

The following steps will test the ability of the Edge system to authenticate the HISP:

TE170.314(b)(8) – 5.03: The Tester shall authenticate the Edge Testing Tool (HISP) using PLAIN SASL as an SMTP server from wellformed3@hit-testing2.nist.gov to wellformed1@hit-testing2.nist.gov (SMTP-20)

TE170.314(b)(8) – 5.04: The Tester shall authenticate the Edge Testing Tool (HISP) using DIGEST-MD5 as an SMTP server from wellformed3@hit-testing2.nist.gov to wellformed1@hit-testing2.nist.gov (SMTP-21 – cannot be tested for now)

TE170.314(b)(8) – 5.05: The Tester shall authenticate the Edge Testing Tool (HISP) using an invalid PLAIN SASL username/password as an SMTP server from wellformed3@hit-testing2.nist.gov to wellformed1@hit-testing2.nist.gov (SMTP-22)

TE170.314(b)(8) – 5.06: The Tester shall authenticate the Edge Testing Tool (HISP) using an invalid DIGEST-MD5 as an SMTP server from wellformed3@hit-testing2.nist.gov to wellformed1@hit-testing2.nist.gov (SMTP-23 – cannot be tested for now)

The following steps will test the ability of the Edge system to receive messages from the HISP:

TE170.314(b)(8) – 5.07: The Tester shall receive the C-CDA document from the Edge Testing Tool (HISP) utilizing valid SMTP commands from wellformed3@hit-testing2.nist.gov to wellformed1@hit-testing2.nist.gov and verify that connection was established (SMTP-9)

TE170.314(b)(8) – 5.08: The Tester shall receive the HITSP/C32 document from the Edge Testing Tool (HISP) utilizing valid SMTP commands from wellformed3@hit-testing2.nist.gov to wellformed1@hit-testing2.nist.gov and verify that connection was established (SMTP-9)

TE170.314(b)(8) – 5.09: The Tester shall receive the ASTM CCR document from the Edge Testing Tool (HISP) utilizing valid SMTP commands from wellformed3@hit-testing2.nist.gov to wellformed1@hit-testing2.nist.gov and verify that connection was established (SMTP-9)

TE170.314(b)(8) – 5.10: The Tester or System Under Test shall utilize the Edge Testing Tool (HISP) to receive the C-CDA which sends invalid data as part of the DATA command from badcommands4@hit-testing2.nist.gov to wellformed1@hit-testing2.nist.gov (SMTP-10)

TE170.314(b)(8) – 5.11: The Tester or System Under Test shall utilize the Edge Testing Tool (HISP) to receive the C-CDA which sends invalid SMTP commands data as part of the DATA command from badcommands4@hit-testing2.nist.gov to wellformed1@hit-testing2.nist.gov (SMTP-11)

TE170.314(b)(8) – 5.12: The Tester or System Under Test shall utilize the Edge Testing Tool (HISP) to receive the C-CDA which sends data beyond the allowable size limits from badcommands4@hit-testing2.nist.gov to wellformed1@hit-testing2.nist.gov (SMTP-12 - cannot be tested because these are not invalid per the specification as RFC 2821 does not mandate any failure on large sizes)

TE170.314(b)(8) – 5.13: The Tester shall receive the C-CDA from the Edge Testing Tool (HISP) from badcommands4@hit-testing2.nist.gov to wellformed1@hit-testing2.nist.gov beyond the allowable time period (SMTP-13)

Inspection Test Guide

IN170.314(b)(8) – 5.01: Using the Edge Testing Tool, the Tester shall verify that a secure session was established based on TLS initiation using correct syntax (SMTP-16)

IN170.314(b)(8) – 5.02: Using the Edge Testing Tool, the Tester shall verify the Edge system does not accept the TLS session based on the incorrect syntax used (SMTP-17)

IN170.314(b)(8) – 5.03: Using the Edge Testing Tool with a pre-determined username and password, the Tester shall verify successful authentication with PLAIN SASL (SMTP-20)

IE170.314(b)(8) – 5.04: Using the Edge Testing Tool, the Tester shall verify successful authentication with DIGEST-MD5 (SMTP-21 – cannot be tested for now)

IN170.314(b)(8) – 5.05: Using the Edge Testing Tool, the Tester shall verify that the Edge system dose not accept the authentication request due to an invalid PLAIN SASL username and password (SMTP-22)

IN170.314(b)(8) – 5.06: Using the Edge Testing Tool, the Tester shall verify that the Edge system does not accept the authentication request due an invalid DIGEST-MD5 value (SMTP-23 – cannot be tested for now)

IN170.314(b)(8) – 5.07: The Tester shall verify that the transmitted C-CDA conformant document has been received successfully according to the Implementation Guide for Direct Edge Protocols (SMTP) standard, and the Edge Testing Tool validation report indicates the successful sequence of commands for SMTP protocols (SMTP-9)

IN170.314(b)(8) – 5.08: The Tester shall verify that the transmitted HISTP/C32 document has been received successfully according to the Implementation Guide for Direct Edge Protocols (SMTP) standard, and the Edge Testing Tool validation report indicates the successful sequence of commands for SMTP protocols (SMTP-9)

IN170.314(b)(8) – 5.09: The Tester shall verify that the transmitted ASTM CCR document has been received successfully according to the Implementation Guide for Direct Edge Protocols (SMTP) standard, and the Edge Testing Tool validation report indicates the successful sequence of commands for SMTP protocols (SMTP-9)

IN170.314(b)(8) – 5.10: Using the Log provided by the Edge Testing Tool, the Tester shall verify that a secure session cannot be established based on the following invalid data provided and does not accept the data by using appropriate responses:

- Invalid Data command (SMTP-10)
- Invalid SMTP commands (SMTP-11)
- Invalid size limits of SMTP commands (SMTP-12 – cannot be tested because these are not invalid per the specification)

IN170.314(b)(8) – 5.11: Using the Log provided by the Edge Testing Tool, the Tester shall verify that the Test Tool has kept the transaction open for beyond the specified time limits and therefore cannot accept the incoming message (SMTP-13)

IN170.314(b)(8) – 5.12: After the end of the testing cycle, the Tester shall review the Validation Report to validate that all tests have been completed with a status of Success or Fail

DTR170.314(b)(8) – 6 Display Summary of Care Record

Required Vendor Information

VE170.314(b)(8) – 6.01: Vendor shall identify the EHR function(s) that are available for a provider to display Summary Care Records received electronically by third parties

Required Test Procedures

TE170.314(b)(8) – 6.01: Using the Vendor-identified EHR function(s), the Tester shall access a test patient's record as the provider

TE170.314(b)(8) – 6.02: Using the Vendor-identified EHR function(s), the Tester shall display an Ambulatory Summary Care Record received from a third party. (If the EHR technology requires additional users that are not the provider to receive the message, view message header information, and match the summary care record to the patient prior to being available for the provider, this is permitted)

TE170.314(b)(8) – 6.03: Using the Inspection Test Guide, the Tester shall verify that the information displayed for the Ambulatory Summary of Care record is complete and accurate and all sections are displayed individually

TE170.314(b)(8) – 6.04: Using the Vendor-identified EHR function(s), the Tester shall display an Inpatient Summary Care Record received from a third party. (If the EHR technology requires additional users that are not the provider to receive the message, view message header information, and match the summary care record to the patient prior to being available for the provider, this is permitted)

TE170.314(b)(8) – 6.05: Using the Inspection Test Guide, the Tester shall verify that the information displayed for the Inpatient Summary of Care record is complete and accurate and all sections are displayed individually

TE170.314(b)(8) – 6.06: Using the Vendor-identified EHR function(s), the Tester shall cause the EHR to select individual sections (not all) for display for either the Inpatient or Ambulatory received C-CDA conformant Summary Care record

TE170.314(b)(8) – 6.07: Using the Vendor-identified EHR function(s), the Tester shall display the HITSP/C32 document received

TE170.314(b)(8) – 6.08: Using the Inspection Test Guide, the Tester shall verify that the HITSP/C32 document can be successfully displayed

TE170.314(b)(8) – 6.09: Using the Vendor-identified EHR function(s), the Tester shall display the ASTM CCR document received

TE170.314(b)(8) – 6.10: Using the Inspection Test Guide, the Tester shall verify that the ASTM CCR document can be successfully displayed

Inspection Test Guide

IN170.314(b)(8) – 6.01: Using the ONC-provided test data, the Tester shall verify that the content of the received C-CDA conformant Ambulatory Summary of Care Record displays completely and accurately, including section headings and at a minimum, the following data elements (in their English representation if they associate with a vocabulary/code set):

1) Encounter diagnoses
2) Immunizations
3) Cognitive status
4) Functional status
5) Reason for referral
6) Referring or transitioning provider's name

7) Provider name
8) Provider office contact information
9) Common MU Data Set
    1) Patient name
    2) Sex
    3) Date of birth
    4) Race
    5) Ethnicity
    6) Preferred language
    7) Smoking status
    8) Problems
    9) Medications
    10) Medication Allergies
    11) Laboratory test(s)
    12) Laboratory value(s)/result(s)
    13) Vital signs – height, weight, blood pressure, BMI
    14) Care plan field(s), including goals and instructions
    15) Procedures
    16) Care team member(s)

IN170.314(b)(8) – 6.02: Using the ONC-provided test data, the Tester shall verify that the content of the received C-CDA conformant Inpatient Summary of Care Record displays completely and accurately, including section headings and at a minimum, the following data elements (in their English representation if they associate with a vocabulary/code set):

1) Encounter diagnoses
2) Immunizations
3) Cognitive status
4) Functional status
5) Discharge instructions
6) Common MU Data Set
    1) Patient name
    2) Sex
    3) Date of birth
    4) Race
    5) Ethnicity
    6) Preferred language
    7) Smoking status
    8) Problems
    9) Medications
    10) Medication Allergies
    11) Laboratory test(s)
    12) Laboratory value(s)/result(s)
    13) Vital signs – height, weight, blood pressure, BMI

14) Care plan field(s), including goals and instructions
15) Procedures
16) Care team member(s)

IN170.314(b)(8) – 6.03: Using the ONC-provided test data, the Tester shall verify the EHR provides the individual section information contained within the Summary Care Record C-CDA conformant documents

IN170.314(b)(8) – 6.04: Using the ONC-provided test data, the Tester shall verify the EHR accurately displays header information and only the selected sections in TE170.314(b)(8) – 4.05 without having to view or navigate the entire document

IN170.314(b)(8) – 6.05: Using the ONC-provided test data, the Tester shall verify that the content of the received HITSP/C32 document displays completely and accurately and coded information displays in its English representation if associated with a vocabulary/code set

IN170.314(b)(8) – 6.06: Using the ONC-provided test data, the Tester shall verify that the content of the received ASTM CCR document displays completely and accurately and coded information displays in its English representation if associated with a vocabulary/code set

DTR170.314(b)(8) – 7: Receive Health Information from a Third Party Using Edge Protocol for IMAP4 as an Edge System/HISP (Optional)

DTR170.314(b)(8) – 8: Receive Health Information from a Third Party Using Edge Protocol for POP3 as an Edge System/HISP (Optional)

TEST DATA

ONC-supplied test data are provided with the test procedure to ensure that the applicable requirements identified in the criteria can be adequately evaluated for conformance, as well as to provide consistency in the testing process across multiple National Voluntary Laboratory Accreditation Program (NVLAP) Accredited Testing Labs (ATLs). The provided test data focus on evaluating the basic capabilities of required EHR technology, rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support. The test data are formatted for readability of use within the testing process. The format is not prescribing a particular end-user view or rendering. No additional requirements should be drawn from the format.

The Tester shall use and apply the provided test data during the test, without exception, unless one of the following conditions exists:

- The Tester determines that the Vendor product is sufficiently specialized that the provided test data needs to be modified in order to conduct an adequate test. Having made the determination that some modification to the provided test data is necessary, the Tester shall record the modifications made as part of the test documentation.
- The Tester determines that changes to the test data will improve the efficiency of the testing process; primarily through using consistent demographic data throughout the testing

workflow. The Tester shall ensure that the applicable requirements identified in the criterion can be adequately evaluated for conformance and that the test data provides a comparable level of robustness. Having made the determination that some modification to the provided test data is necessary, the Tester shall record the modifications made as part of the test documentation.

Test Data for §170.314(b)(8) Transitions of care - create and transmit summary care records is available at http://www.healthit.gov/certification (navigation: 2014 Edition Test Method)

Any departure from the provided test data shall strictly focus on meeting the basic capabilities required of EHR technology relative to the certification criterion rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support.

The test procedures require that the Tester enter the applicable test data into the EHR technology being evaluated for conformance. The intent is that the Tester fully controls the process of entering the test data in order to ensure that the data are correctly entered as specified in the test procedure. If a situation arises where it is impractical for a Tester to directly enter the test data, the Tester, at the Tester's discretion, may instruct the Vendor to enter the test data, so long as the Tester remains in full control of the testing process, directly observes the test data being entered by the Vendor, and validates that the test data are entered correctly as specified in the test procedure.

CONFORMANCE TEST TOOLS

The following testing tools are available to evaluate conformance to the standards referenced in this test procedure:

- Edge Testing Tool (ETT) - The Edge Testing Tool is designed to support this test procedure. The Edge Testing Tool includes the capability to verify the ability to conform to the Implementation Guide for Direct Edge Protocols v1.1.
    - **Note: TTT functionality to support Edge Protocol testing for this test procedure is not yet available**
- Transport Testing Tool (TTT) – The Transport Testing Tool includes the capability to verify the ability to exchange Consolidated CDA (C-CDA) conformant documents using transport standards (e.g., Direct, Direct + XDM, SOAP). C-CDA conformance testing within the Transport Testing Tool relies on Model Driven Health Tools (MDHT) for Consolidated CDA validation developed by ONC.
    - The Transport Testing Tool (TTT) is available at: http://transport-testing.nist.gov

    Support for the Transport Testing Tool is available by submitting questions to the Transport Testing Tool user group at: https://groups.google.com/d/forum/transport-testing-tool. Inquiries may also be sent to this user group via email: transport-testing-tool@googlegroups.com

Multiple browsers may be used to access this tool; if the tool does not load completely using the current version of Internet Explorer, alternative browsers such as Firefox, Google Chrome, or Safari are recommended. The Transport Testing Tool uses non-standard ports. If your firewall blocks HTTP traffic on non-standard ports, this tool may not be accessible. Please retry access from a location without a firewall that blocks non-standard ports. Alternatively users may download and run a local version of the tool.

The following information is provided to assist the Tester in interpreting the conformance reports generated by the Transport Testing Tool (TTT):

The Transport Testing Tool (TTT), via MDHT, evaluates individual conformance statements which have been derived from the standards and the "HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012" identified in the Final Rule and the test data provided in this test procedure. The validation tools evaluate the submitted HL7 message instance for each conformance statement, and then produce a conformance report. The Tester should consider that a report containing only Affirmative and Warning messages indicates general conformance to the standard and test data expectations. If reported, errors should be considered as significant departures from the standard or test data requirements which need to be corrected in order to claim conformance. ATLs will need to further analyze each error to determine if, in the context of meeting the criterion and overall meaningful use objective, the error results in a failure of the test procedure by the EHR technology. The Tester may need to inspect test data values derived from required vocabularies and code sets.

Document History

Version Number	Description of Change	Date Published
1.0	Released for public comment	October 8, 2014