The Office of the National Coordinator for Health Information Technology

Test Procedure for §170.314 (e)(1) View, download, and transmit to a 3rd party with edge protocol testing

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 10, 2014. The document[1] is organized by test procedure and derived test requirements with traceability to the normative certification criteria as described in the Overview document located at http://www.healthit.gov/certification (navigation: 2014 Edition Test Method). 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 Section § 170.314(e)(1) for the certification criteria.

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule, the 2014 Edition of this Certification Criterion is classified as new from the 2011 Edition. This certification criterion meets at least one of the factors of new certification criteria: (1) The certification criterion only specifies capabilities that have never been included in previously adopted certification criteria; or, (2) The certification criterion was previously adopted as "mandatory" for a particular setting and subsequently adopted as "mandatory" or "optional" for a different setting.

CHANGES BASED ON 2014 RELEASE 2 EDITION FINAL RULE

This test procedure has been updated to reflect the addition of an alternative approach for demonstrating "transmit" using capabilities that follow the Implementation Guide for Direct Edge Protocols Version 1.1 and to enable a successful transmission with a service that has implemented the primary Direct Project specification. Therefore, this test procedure includes the original steps for viewing, downloading and transmitting data to a third party, as well as, an alternative pathway to accomplish the capabilities of transmitting data using Edge Protocols.

[1] Disclaimer: Certain commercial products may be identified in this document. Such identification does not imply recommendation or endorsement by ONC.

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.

This test procedure evaluates the capabilities of EHR technology to 1) allow patients and their authorized representatives to access their health information through a secure, online channel and to view, download, and transmit their health information to a third party; and 2) record the date and time when health information is viewed, downloaded, and transmitted, as well as the user who performed those actions. Compliance with the specific transmission capability requirement can be demonstrated in one of two ways: 1) The original approach adopted as part of the 2014 Edition Final Rule (certification to the ONC Applicability Statement for Secure Health Transport (Direct)) or 2) The new approach adopted in the 2014 Edition Final Rule Release 2 (certification to the Edge Protocol IG version 1.1). This optionality is supported with regulatory text that states "at least one of the following" to convey that both transmission approaches do not need to be implemented for the purposes of certification. Additionally, this optionality allows EHR vendors to choose which approach to follow.

The test procedure will evaluate that the Vendor's EHR technology provides secure, encrypted online access to health information for patients and authorized representatives to view, download, and transmit in accordance with Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2[i]. Encrypted online access will be verified by confirming that access was obtained using a secure connection (for example, browser access using HTTPS/TLS, inspection of web certificate to verify encryption settings).

EHR technology certified for 170.314(d)(2), Auditable Events and Tamper Resistance, is not required to include a separate capability for a patient accessible log in 170.314(e)(1)(ii)(A), if the EHR is able to provide patients with access to this information (log of the time, date, and users who view, download, and transmit patient health information).

The test procedure will evaluate the capability of the EHR technology to permit patients and their authorized representative(s) to view the provider's name and office contact information and Common MU Data Set using ambulatory EHR technology; and the admission and discharge dates and locations, discharge instructions, and reason(s) for hospitalization, and the Common MU Data Set using inpatient EHR technology, in conformance with the Web Content Accessibility Guidelines (WCAG) 2.0, Level A Conformance standard (http://www.w3.org/TR/2008/REC-WCAG20-20081211/#conformance-reqs). Any capabilities of the EHR technology that permit patients and their authorized representatives to download and transmit health information must also be in conformance with WCAG 2.0 Level A.

This test procedure will evaluate the capability of EHR technology to allow patients and their authorized representatives to electronically download an ambulatory or inpatient summary of the patient health information viewed in human readable format and in a format in conformance with the Consolidated CDA, with the English (that is, non-coded) representation if they associate with a vocabulary/code set. For the inpatient setting only, the EHR technology must also allow patients and authorized representatives to

download a transition of care/referral summary [see (b)(2)] that was created as a result of a transition of care. The EHR technology must make a minimum of two types of documents available for download and transmission in the inpatient setting: an inpatient summary with a minimum of the required elements listed in the 170.314(e)(1) View, download and transmit to a 3rd party certification criterion; and inpatient transition of care/referral summaries that were created as a result of a transition of care with a minimum of the required elements listed in the 170.314(b)(2) Transitions of care - create and transmit summary care records certification criterion.

This test procedure will evaluate the capability of EHR technology to allow patients and authorized representatives to download and transmit the ambulatory summary for ambulatory EHRs, or for inpatient EHRs, the inpatient summary and transition of care/referral summary. EHRs must be able to provide the ambulatory and inpatient summary documents for download and transmit in both human readable format and in conformance with the Consolidated Clinical Document Architecture (C-CDA) standard. Inpatient EHRs must be able to provide the transition of care/referral summary documents for download and transmit in conformance with the Consolidated Clinical Document Architecture (C-CDA) standard. EHRs are not required to provide the transition of care/referral summary in human readable format viewing, download or transmit. The transmission of the C-CDA and human readable document formats may occur as separate transactions or both documents may be transmitted within a single transmission. Accessibility of human readable information must be human readable within a single download and transmission per the ONC definition of human readable: “Human readable format means a format that enables a human to read and easily comprehend the information presented to him or her regardless of the method of presentation (e.g., computer screen, handheld device, electronic document).” For example, a C-CDA conformant document and an associated style sheet must be downloaded or transmitted together in a single transmission. If multiple documents are required for human readable format, these documents must be sent as separate attachments in any order within a single transmission. Vendors may provide additional attachments (e.g. XDM package) in the transmission if desired. These documents must be able to be transmitted to a third-party (by the patient and the patient’s authorized representative(s) in conformance with the ONC Applicability Statement for Secure Health Transport (Direct) specification to a third party or by a service that has implemented the standard specified in the Implementation Guide for Direct Edge Protocols, version 1.1. This test procedure requires that EHR technology demonstrate the capability to transmit a C-CDA document to a third party using either of these approaches.

Using Direct

In evaluating the capability of the EHR technology to transmit information to a third party, this test procedure will test the ability for EHR technology to correctly discover and use address-bound and domain-bound certificates hosted in both DNS and LDAP using the Direct Certificate Discovery Tool (DCDT).

Using the Transport Testing Tool (TTT), this test procedure will verify that the Direct message is encrypted using the recipient’s Public Key and is signed using the sender’s Private Key. In keeping with the Direct specification, CEHRT must maintain an association with a supported address (sender or

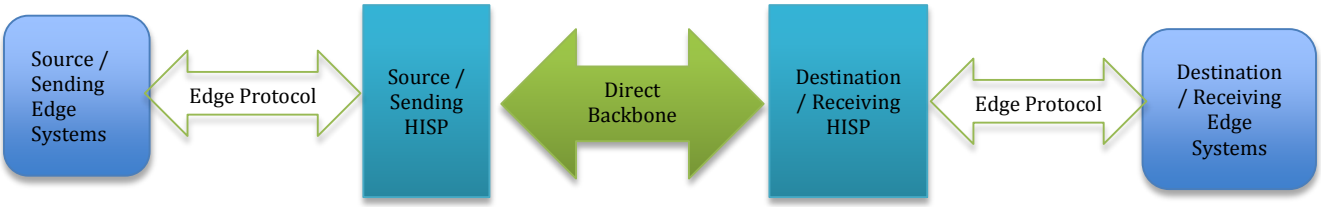
recipient) and a collection of Trusted Anchors[2]. The TTT requires manual upload of Trust Anchors and certificates for testing purposes and is not linked to the DCDT at this time. The Trust Anchor uploaded to the TTT mimics the certificate discovery capability tested using the DCDT to support testing of transport capabilities. This test procedure will evaluate the capability of EHR technology to create a list of individual Direct recipients that can receive documents sent using Direct.

Using Edge Protocols

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 addition of the testing transmission to a third party using edge protocols has been added to this test procedure as an optional test based on the 2014 Release 2 Edition Final Rule. This is the only change to this test procedure. The addition of Direct Edge Protocols to this test procedure would add an alternative pathway for EHR technology developers to demonstrate compliance with the certification criterion. Adding an alternative "decoupled" approach ensures that compliance with the specific transmission capability requirement can be demonstrated in one of two ways. One way is the original approach adopted as part of the 2014 Edition Final Rule certification to the ONC Applicability Statement for Secure health Transport with the Direct Project. The other optional new approach for certification is adopting the Edge Protocol IG, version 1.1.

Edge protocols are used to exchange electronic health information between the Source Edge System and the Source Health Information Service Provider (HISP) as well as the Destination HISP and the Destination Edge System. In Directed exchange, messages are sent from Source Edge systems (i.e. the EHR system or patient portal system) 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.



Testing will assess whether the transmitted C-CDA document and human-readable document arrived at its destination and would validate that a successful transmission has occurred through the Delivery Notification Tracking requirements in Section 1.3 of the Edge Protocol IG, such as the verification of

[2] Section 4.2.3 of the ONC Applicability Statement for Secure Health Transport: "Each implementation MUST maintain an association with a supported address (sender or recipient) and a collection of Trusted Anchors. The address trusts any valid leaf certificate whose certificate chain contains at least one certificate from the address's Anchor list."

Message Disposition Notifications (MDNs). From Section 3 of the Applicability Statement for Secure Health Transport v 1.1, using MDN's would ensure that Destination HISPs send MDN messages to the Source HISP upon successful receipt and trust verification of a message.

In evaluating the capability of the EHR technology to transmit health information to a third party, this test procedure will test the ability for an Edge system to support the various methods selected for edge protocol to transmit information to a HISP for sending to the third party. 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

Record and Display Actions

This test procedure will evaluate the capability of EHR technology to allow patients and authorized representatives to access activity history information about the health information that has been viewed, downloaded, and transmitted.

This test procedure will evaluate the conformance of web pages used to access and conduct view, download, and transmit functions using guidance on how to meet WCAG 2.0 from the World Wide Web Consortium (W3C). As all test tools listed on the W3C site do not adequately test all applicable success criteria, multiple tools, including tools other than those published by W3C, may need to be selected to support all applicable success criteria. This test procedure will evaluate the submitted results of conformance testing tools and evaluate aspects of conformance from Items 1-5 of WCAG2.0 Conformance not verified by testing tools - http://www.w3.org/TR/2008/REC-WCAG20-20081211/#conformance-reqs. WCC provides WCAG 2.0 guidance at:

- WCAG Overview http://www.w3.org/WAI/intro/wcag
- WCAG 2 at a Glance http://www.w3.org/WAI/WCAG20/glance/
- How to Meet WCAG 2.0: A customizable quick reference http://www.w3.org/WAI/WCAG20/quickref/

This test procedure includes a Network Time Protocol (NTP) test to verify synchronization of the EHR and the system clock to the named standards, (RFC 1305) Network Time Protocol, or (RFC 5905) Network Time Protocol Version 4.

ONC provides the test data for this test procedure. This test procedure is organized into five sections:

- View Health Information – evaluates the capability for the EHR to provide patients and authorized representatives a secure, electronic view of the following information:

- For both ambulatory and inpatient settings: the Common MU Data Set data with named standards as appropriate (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 settings only: the provider's name and office contact information
- For inpatient settings only: admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization
- The Vendor creates an existing patient record in the EHR technology with health information based on the ONC-provided test data
- Tester, logs into the online application as a patient (and authorized representative) and electronically views information relevant to inpatient and/or ambulatory settings
- Tester verifies all required information can be viewed
  - Tester verifies the information associated with a vocabulary/code set in human readable format is its in English representation (description)
- The Vendor tells the Tester which authentication method(s) and which encryption and hashing algorithm (identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2) the Vendor is using for this test
- Tester verifies the ability for an authorized patient representative to log into the online application and view the same information viewed by the patient

- Download Health Information – evaluates the capability to electronically download the information that was viewed as part of the "View" step in a human readable format and a format in accordance with the Implementation Guide for CDA® Release 2.0, Consolidated CDA Templates
  - The Tester remains logged into EHR technology's online channel established in the previous "View" step

- Using the Vendor-identified EHR function(s) in the EHR's online technology and the provided test data, the Tester causes the EHR to download the health information viewed in the "View" step as an ambulatory or inpatient summary; and in inpatient settings only, a transition of care/referral summary created as a result of a transition of care
- The Tester validates that the downloaded (ambulatory/inpatient) summary are provided in human readable format.
- The tester validates that the downloaded (ambulatory/inpatient) summary and the downloaded transition of care/referral summary (inpatient only) are provided in C-CDA format
- The Tester imports the downloaded C-CDA clinical summary into the Transport Testing Tool
- Using the Validation Report produced by the C-CDA Transport Testing Tool, the Tester verifies that the Implementation Guide conformance requirements tested are met, and that the named standard vocabularies have been used where applicable in the required test data elements
- Tester verifies the health information is downloaded through a secure channel that ensures all information is encrypted and integrity protected in compliance with Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2 [170.210(f)]

- Transmit via Direct – evaluates the capability of EHR technology to allow a patient and a patient's authorized representative to electronically transmit the health information available for download in the "Download" section of the test procedure to a third party as an ambulatory or inpatient summary (as applicable to the setting for which the EHR technology will be tested); and for inpatient settings only, a transition of care/referral summary using the Direct transport protocol
  - The Tester logs in to the EHR's online technology as the patient who downloaded the information from the "View" step in the "Download" step
  - The Tester verifies that the EHR can discover certificates from other parties in DNS CERT records and LDAP servers[3]
  - Using the Vendor-identified function(s), the Tester verifies that the EHR is able to create and store a listing of Direct recipient address(es) (This may be accomplished as a system administration function and is not required to be an end-user capability.)
  - Using the Vendor-identified function(s), the Tester causes the health information available for download in human readable format and C-CDA format to be transmitted to a third party using the Direct transport standard, based on ONC supplied test information
  - The Tester verifies successful transmission and receipt of the health information, and that the health information can be successfully decrypted
  - The Tester verifies that the information transmitted is in conformance with the C-CDA
    - Using the Vendor-identified EHR function(s), the Tester imports the health information into the NIST Transport Test Tool
    - Using the Validation Report produced by the NIST Transport Test Tool, the Tester verifies that the Implementation Guide conformance requirements tested are met,

[3] Section 2.3 of the ONC Applicability Statement for Secure Health Transport v1.1: "For universal digital certificate distribution, STAs MUST be able to discover certificates using both the DNS as specified in Section 5 of this applicability statement and LDAP as described by the S&I Framework Certificate Discovery for Direct Project Implementation Guide."

and that the named standard vocabularies have been used where applicable for data in the required test data elements

- Using the provided test data, the Tester verifies that the data rendered in the transmitted human readable ambulatory/inpatient summary and C-CDA conformant ambulatory/inpatient summary and transition of care/referral summary (inpatient only) documents are complete and accurate, and that the required data elements are shown in their English representation (description) in the human readable documents if they associate with a vocabulary/code set.

- Transmit via Edge Protocol – evaluates the capability of EHR technology to allow a patient and a patient's authorized representative to electronically transmit the health information available for download in the "Download" section of the test procedure to a third party as an ambulatory or inpatient summary (as applicable to the setting for which the EHR technology will be tested); and for inpatient settings only, a transition of care/referral summary using Edge Protocols
  - The Tester logs in to the EHR's online technology as the provider who created the information in the "View" step in the "Download" step
  - Using the Vendor-identified function(s), the Tester causes the health information available for download in human readable format and C-CDA format to be transmitted to HISP for sending to a third party using one of the edge protocols for IHE XDR or SMTP
  - 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 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 MessageID 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 MessageID 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).
  - 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 (Pl*ease note: Corresponding test case numbers are listed after each test step. Test Cases that are referenced as 'Optional' are not required for certification).*

- Record and Display Actions – evaluates the capability of the EHR technology to capture date, time, and user who views, downloads, and transmits health information and make it accessible to the patient (and their authorized representative)
  - The Vendor creates a test patient record that includes, at a minimum, the health information, based on ONC-supplied test data
  - For each instance of view, download, and transmit of health information conducted previously in this test procedure:
    - Tester verifies that the action of viewed [downloaded/transmitted] information is recorded and conformant with the named security protocols and standards, and that the information was viewed/downloaded/transmitted is complete and accurate (Viewing of at least one item of the Ambulatory/Inpatient Summary should cause an action to be recorded in the activity history log)
    - Tester verifies recorded action, with user information and date/time of the action is accessible to the patient (via access to audit log information or other capability)

- Submit and Verify Summative Testing Results for WCAG Conformance – evaluates Vendor-supplied documentation of referenced practice, testing tools, tool results, and accompanying documentation to ensure the Vendor has achieved conformance with Web Content Accessibility Guidelines (WCAG) 2.0 Level "A" for each EHR technology capability submitted for testing for viewing of health information by a patient and their authorized representative
  - The Tester will verify that for each EHR technology capability submitted for testing for viewing, downloading, and transmitting of health information, the Vendor has defined the scope and use of web pages for testing

- The Tester will verify that each web page associated with a "WCAG2.0-conformant version" of EHR functionality to view, download, and transmit health information is includes submitted documentation for WCAG Level "A" conformance
- The Tester shall examine each Vendor-provided report to ensure the existence and adequacy of test report(s) submitted by the vendor
- The Tester shall inspect the acceptability of the following reporting areas:
  - Web pages associated with "WCAG2.0-conformant version" of related functionality
  - Tool(s) used to test each web page
  - Results/outputs of each tool
  - Description of Pass/Fail scoring for applicable web pages
  - Description of rationale for over-ruling of any tool output
  - Description of aspects of conformance not verified using testing tools
  - Report of evaluation findings

Note: This Test Procedure evaluates conformance to the WCAG 2.0 Level "A" standard. Any additional links or documents referenced in the test procedure that are not normative aspects of the WCAG 2.0 Level "A" standard are provided only as additional resources and will not result in failure of this test if not met by the Vendor.

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

§170.204 Functional standards.	Regulatory Referenced Standard
The Secretary adopts the following functional standards:	
(a) Accessibility. Standard. Web Content Accessibility Guidelines (WCAG) 2.0, Level A Conformance (incorporated by reference in § 170.299).	

§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:	
(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)(2) Standard. The code set specified at 45 CFR 162.1002(a)(5).	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)(4).	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.

§170.207 Vocabulary standards for representing electronic health information.	Regulatory Referenced Standard
(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.
(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	

§170.207 Vocabulary standards for representing electronic health information.	Regulatory Referenced Standard
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.

§170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged	Regulatory Referenced Standard
The Secretary adopts the following standard to protect electronic health information created, maintained, and exchanged:	
(f) Encryption and hashing of electronic health information. Any encryption and hashing algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the FIPS Publication 140-2 (incorporated by reference in § 170.299).	
(g) Synchronized clocks. The date and time recorded utilize a system clock that has been synchronized following (RFC 1305) Network Time Protocol, (incorporated by reference in § 170.299) or (RFC 5905) Network Time Protocol Version 4, (incorporated by reference in § 170.299).	

Referenced Certification Criteria

§170.314 2014 Edition electronic health record certification criteria.	Referenced Standards
The Secretary adopts the following certification criteria for Complete EHRs or EHR Modules. Complete EHRs or EHR Modules must include the capability to perform the following functions electronically, unless designated as optional, and in accordance with all applicable standards and implementation specifications adopted in this part:	

§170.314 2014 Edition electronic health record certification criteria.	Referenced Standards
(b)(2) Transitions of care - create and transmit summary care records. (i) Create. Enable a user to electronically create a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(3) that includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s): (A) Encounter diagnoses. The standard specified in § 170.207(i) or, at a minimum, the version of the standard specified § 170.207(a)(3); (B) Immunizations. The standard specified in § 170.207(e)(2); (C) Cognitive status; (D) Functional status; and (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.	See Referenced Standards section for associated standards

§170.314 2014 Edition electronic health record certification criteria.	Referenced Standards
(**d**)(2) Auditable events and tamper-resistance. (i) Record actions. EHR technology must be able to: (A) Record actions related to electronic health information in accordance with the standard specified in § 170.210(e)(1); (B) Record the audit log status (enabled or disabled) in accordance with the standard specified in § 170.210(e)(2) unless it cannot be disabled by any user; and (C) Record the encryption status (enabled or disabled) of electronic health information locally stored on end-user devices by EHR technology in accordance with the standard specified in § 170.210(e)(3) unless the EHR technology prevents electronic health information from being locally stored on end-user devices (see 170.314(d)(7) of this section). (ii) Default setting. EHR technology must be set by default to perform the capabilities specified in paragraph (d)(2)(i)(A) of this section and, where applicable, paragraphs (d)(2)(i)(B) or (d)(2)(i)(C), or both paragraphs (d)(2)(i)(B) and (C). (iii) When disabling the audit log is permitted. For each capability specified in paragraphs (d)(2)(i)(A), (B), and (C) of this section that EHR technology permits to be disabled, the ability to do so must be restricted to a limited set of identified users. (iv) Audit log protection. Actions and statuses recorded in accordance with paragraph (d)(2)(i) must not be capable of being changed, overwritten, or deleted by the EHR technology. (v) Detection. EHR technology must be able to detect whether the audit log has been altered.	§ 170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged. The Secretary adopts the following standards to protect electronic health information created, maintained, and exchanged: (e)(1) Record actions related to electronic health information, audit log status, and encryption of end-user devices. (i) The audit log must record the information specified in sections 7.2 through 7.4, 7.6, and 7.7 of the standard specified at § 170.210(h) when EHR technology is in use. (ii) The date and time must be recorded in accordance with the standard specified at § 170.210(g). (e)(2) (i) The audit log must record the information specified in sections 7.2 and 7.4 of the standard specified at § 170.210(h) when the audit log status is changed. (ii) The date and time each action occurs in accordance with the standard specified at § 170.210(g). (e)(3)The audit log must record the information specified in sections 7.2 and 7.4 of the standard specified at § 170.210(h) when the encryption status of electronic health information locally stored by EHR technology on end-user devices is changed. The date and time each action occurs in accordance with the standard specified at § 170.210(g). (g) Synchronized clocks. The date and time recorded utilize a system clock that has been synchronized following (RFC 1305) Network Time Protocol, (incorporated by reference in § 170.299) or (RFC 5905) Network Time Protocol Version 4, (incorporated by reference in § 170.299). (h) Audit log content. ASTM E2147-01 (Reapproved 2009), (incorporated by reference in § 170.299).

NORMATIVE TEST PROCEDURES

Network Time Protocol (NTP) Test

The test steps below must be performed by the Vendor and the results validated by the Tester prior to beginning the test steps in the Derived Test Requirements. These tests evaluate an EHR technology's ability to meet the standard adopted at 45 CFR 170.210(g), which requires that the date and time recorded by the EHR technology "utilize a system clock that has been synchronized following RFC 1305) Network Time Protocol or (RFC 5905) Network Time Protocol Version 4.

NTP170.314(1)(1) – 1.01: The Vendor shall identify the protocol used to synchronize the system clock on which the EHR technology will base its time.

NTP170.314(e)(1) – 1.02: The Vendor shall choose a time server from the list below, used by the NIST Internet Time Service (ITS), shall add it to their NTP software configuration, and synchronize the system clock that will be used by the EHR technology as the basis for its time.

Note: All users should ensure that their software NEVER queries a server more frequently than once every 4 seconds. Systems that exceed this rate will be refused service. In extreme cases, systems that exceed this limit may be considered as attempting a denial-of-service attack.

Name	IP Address	Location
nist1-ny.ustiming.org	64.90.182.55	New York City, NY
nist1-nj.ustiming.org	96.47.67.105	Bridgewater, NJ
nist1-pa.ustiming.org	206.246.122.250	Hatfield, PA
time-a.nist.gov	129.6.15.28	NIST, Gaithersburg, Maryland
time-b.nist.gov	129.6.15.29	NIST, Gaithersburg, Maryland
nist1.aol-va.symmetricom.com	64.236.96.53	Reston, Virginia
nist1.columbiacountyga.gov	216.119.63.113	Columbia County, Georgia
nist1-atl.ustiming.org	64.250.177.145	Atlanta, Georgia
nist1-chi.ustiming.org	216.171.120.36	Chicago, Illinois
nist-chicago (No DNS)	38.106.177.10	Chicago, Illinois
nist.time.nosc.us	96.226.123.117	Carrollton, Texas
nist.expertsmi.com	50.77.217.185	Monroe, Michigan
nist.netservicesgroup.com	64.113.32.5	Southfield, Michigan
nisttime.carsoncity.k12.mi.us	66.219.116.140	Carson City, Michigan
nist1-lnk.binary.net	216.229.0.179	Lincoln, Nebraska
www.nist.gov	24.56.178.140	WWV, Fort Collins, Colorado
time-a.timefreq.bldrdoc.gov	132.163.4.101	NIST, Boulder, Colorado
time-b.timefreq.bldrdoc.gov	132.163.4.102	NIST, Boulder, Colorado
time-c.timefreq.bldrdoc.gov	132.163.4.103	NIST, Boulder, Colorado
time.nist.gov	global address for all servers	Multiple locations
utcnist.colorado.edu	128.138.140.44	University of Colorado, Boulder

utcnist2.colorado.edu	128.138.141.172	University of Colorado, Boulder
ntp-nist.ldsbc.edu	198.60.73.8	LDSBC, Salt Lake City, Utah
nist1-lv.ustiming.org	64.250.229.100	Las Vegas, Nevada
time-nw.nist.gov	131.107.13.100	Microsoft, Redmond, Washington
nist-time-server.eoni.com	216.228.192.69	La Grande, Oregon
nist1.aol-ca.symmetricom.com	207.200.81.113	Mountain View, California
nist1.symmetricom.com	69.25.96.13	San Jose, California
nist1-sj.ustiming.org	216.171.124.36	San Jose, California
nist1-la.ustiming.org	64.147.116.229	Los Angeles, California

NTP170.314(e)(1) – 1.03: After configuring NTP, the Vendor shall wait the amount of time necessary to ensure synchronization occurs

NTP170.314(e)(1) – 1.04: Using the NTP logs, the Vendor and Tester shall verify that the system clock's time is accurate within five seconds of the NIST time sever chosen in NTP170.314(d)(2) – 1.01. The NIST time servers follow NTPv3 (RFC 1305), thus, the Tester shall consider an accurate synchronization to a NIST time server as evidence of compliance to RFC 1305 or RFC 5905 and does not need to evaluate the polling value/interval.

NTP170.314(e)(1) – 1.05: The Vendor shall construct or use an existing display in the EHR system that shows the time from the system clock and the EHR time for comparison (these times should be synchronized to within five seconds). Five seconds was chosen to allow testers to visually verify that there is limited to no time discrepancy between the EHR technology and the synchronized system clock used (in cases where the EHR technology does not implement its own NTP client).

NTP170.314(e)(1) – 1.06: The Tester shall verify, via the NTP logs, that the system time is synchronized to the NIST time server to within five seconds; and then the Tester shall verify, via the EHR display, that the EHR time is synchronized to the system time to within five seconds

The test procedure assumes the operating system synchronizes to the NTP server and the EHR then synchronizes to the operating system; however, the EHR could synchronize directly to the NTP server. The EHR technology may use either method to demonstrate that the synchronization has occurred. Use of internal NTP servers are allowed, but the EHR technology must demonstrate that the internal servers are synced to a NIST timeserver for accuracy.

Derived Test Requirements

DTR170.314(e)(1) – 1: View Health Information

DTR170.314(e)(1) – 2: Download Health Information

DTR170.314(e)(1) – 3: Transmit Health Information to a Third Party Using Direct

DTR170.314(e)(1) – 4: Transmit Health Information to a Third Party Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources as the Edge system

DTR170.314(e)(1) – 5: Transmit Health Information to a Third Party Using Edge Protocol for SMTP as the Edge system

DTR170.314(e)(1) – 6: Record and Display Actions

DTR170.314(e)(1) – 7: Submit and Verify Summative Testing Results for WCAG Conformance

DTR170.314(e)(1) – 1: View Health Information

Required Vendor Information

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

VE170.314(e)(1) – 1.02: Vendor shall identify a patient with the ability to access records online

VE170.314(e)(1) – 1.03: Vendor shall identify an authorized patient representative with access to the patient's health information online (patient identified in VE170.314(e)(1) – 1.02)

VE170.314(e)(1) – 1.04: Vendor shall identify a user who is not an authorized patient representative and does not have access to the patient's health information online (patient identified in VE170.314(e)(1) – 1.02)

VE170.314(e)(1) – 1.05: Vendor shall identify the EHR function(s) that are available for a patient (and their authorized representative) to view health information including the named data elements as well as the Common MU Data Set with associated vocabulary standards

VE170.314(e)(1) – 1.06: The Vendor shall identify the authentication methods and the encryption and hashing algorithm from Annex A of FIPS 140-2 to be used for this test (e.g. Encrypted online access may be verified by confirming that access was obtained using a secure connection (browser access using HTTPS/TLS, inspection of web certificate to verify encryption settings, etc.))

Required Test Procedure

TE170.314(e)(1) – 1.01: Using the Vendor-identified EHR function(s), the Tester shall access the ONC-supplied test patient's record as the patient

TE170.314(e)(1) – 1.02: Using the Vendor-identified EHR function(s), the Tester shall view patient information (and record the user, date, time. and action performed) that includes:

- Ambulatory: Common MU Data Set and the following data elements: provider's name and office contact information (Ambulatory EHR Only)

- Inpatient: Common MU Data Set and the following data elements: admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization (Inpatient EHR Only)

TE170.314(e)(1) – 1.03: Using the Inspection Test Guide, the Tester shall verify that the patient information is complete and accurate and in accordance with TD170.314(e)(1) – Ambulatory (ambulatory only) or TD170.314(e)(1) – Inpatient (inpatient only)

TE170.314(e)(1) – 1.04: Using the Vendor-identified EHR function(s), the Tester shall access the ONC-supplied test patient's record as an authorized patient representative

TE170.314(e)(1) – 1.05: Using the Vendor-identified EHR function(s), the Tester shall be prevented from accessing the ONC-supplied test patient's record as an unauthorized patient representative

TE170.314(e)(1) – 1.06: Using the Vendor-identified EHR function(s), the Tester shall access the patient information viewed in TE170.314(e)(1) – 1.02

TE170.314(e)(1) – 1.07: Using the Inspection Test Guide, the Tester shall verify that the summary information is complete and accurate

Inspection Test Guide

IN170.314(e)(1) – 1.01: Using the ONC-provided test data, the Vendor-identified authentication method, the Vendor-identified encryption and hashing algorithm, and the NIST-identified encryption and hashing algorithms listed as an approved security function in Annex A of the FIPS Publication 140-2, the Tester shall verify that the patient's ambulatory information is viewable including, at a minimum, the following data elements (Ambulatory Only):

1) Provider's name
2) Provider's office contact information
3) 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(e)(1) – 1.02: Using the ONC-provided test data, the Vendor-identified authentication method, the Vendor-identified encryption and hashing algorithm, and the NIST-identified encryption and hashing algorithms listed as an approved security function in Annex A of the FIPS Publication 140-2, the Tester shall verify that the patient's inpatient information is viewable, including, at a minimum, the following data elements (Inpatient Only):

1) Patient admission date
2) Patient discharge date
3) Admission/discharge location
4) Discharge instructions
5) Reason(s) for hospitalization
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(e)(1) – 1.03: The Tester shall verify that only authorized patient representatives are able to access a patient's record, and that unauthorized patient representatives are prevented from accessing a patient's health information

DTR170.314(e)(1) – 2: Download Health Information

Required Vendor Information

VE170.314(e)(1) – 2.01: As defined in DTR170.314(e)(1) – 1, no additional information is required

Required Test Procedure

TE170.314(e)(1) – 2.01: Using the Vendor-identified EHR function(s), the Tester shall access the ONC-supplied test patient's record as the patient

TE170.314(e)(1) – 2.02: Using the Vendor-identified EHR function(s), the Tester shall cause the EHR to download patient information (and record the user, date, time. and action performed) in a human-readable format that includes:

- Ambulatory Summary: Common MU Data Set and the following data elements: provider's name and office contact information (Ambulatory EHR Only)
- Inpatient Summary: Common MU Data Set and the following data elements: admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization (Inpatient EHR Only)

TE170.314(e)(1) – 2.03: Using the Vendor-identified EHR function(s), the Tester shall cause the EHR to download the patient information (and record the user, date, time, and action performed) downloaded in TE1701.314(e)(1)-2.02 according to the Consolidated CDA standard and named vocabulary standards for the data elements indicated in TE170.314(e)(1)-2.02 and

- Inpatient Referral Summary/Transition of Care: Common MU Data Set and the following data elements: Encounter diagnoses, Immunizations, Cognitive status, Functional status and Discharge instructions (Inpatient EHR Only)

TE170.314(e)(1) – 2.04: The Vendor shall provide the Tester with the C-CDA document(s) downloaded in TE170.314(e)(1)-2.03 for the Tester to validate C-CDA conformance using the C-CDA Document Validator within the Transport Testing Tool

TE170.314(e)(1) – 2.05: Using the Inspection Test Guide, the Tester shall verify that the (Ambulatory or Inpatient) summary is downloaded in human readable format, and is complete and accurate

TE170.314(e)(1) – 2.06: Using the Inspection Test Guide, the Tester shall verify that the (Ambulatory or Inpatient) summary and Referral Summary/Transition of Care (Inpatient Only) is downloaded according to the Consolidated CDA standard tested and the named vocabulary standards, and is complete and accurate

Inspection Test Guide

IN170.314(e)(1) – 2.01: Using the ONC-provided test data, the Vendor-identified authentication method, the Vendor-identified encryption and hashing algorithm, and the NIST-identified encryption and hashing algorithms listed as an approved security function in Annex A of the FIPS Publication 140-2, the Tester shall verify that the patient's

ambulatory summary is downloaded in human readable format, including, at a minimum, the following data elements (Ambulatory Only):

1) Provider's name
2) Provider's office contact information
3) 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(e)(1) – 2.02: Using the ONC-provided test data, the Vendor-identified authentication method, the Vendor-identified encryption and hashing algorithm, and the NIST-identified encryption and hashing algorithms listed as an approved security function in Annex A of the FIPS Publication 140-2, the Tester shall verify that the patient's inpatient summary is downloaded in human readable format, including, at a minimum, the following data elements (Inpatient Only):

1) Patient admission date
2) Patient discharge date
3) Admission/discharge location
4) Discharge instructions
5) Reason(s) for hospitalization
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(e)(1) – 2.03: The Tester may need to parse the .xml and use the MIME part to inspect the header to identify the C-CDA documents (vs. style sheet)

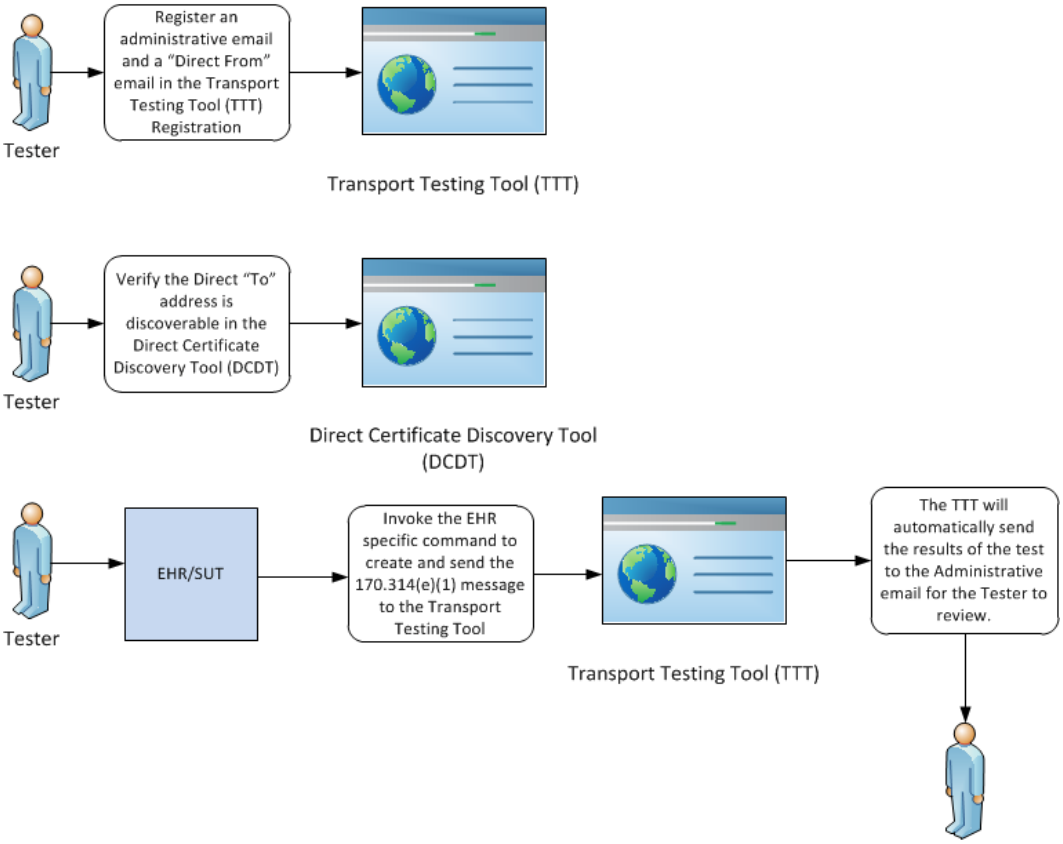
IN170.314(e)(1) – 2.04: Using the provided test data, the Vendor-identified authentication method, the Vendor-identified encryption and hashing algorithm, and the NIST-identified encryption and hashing algorithms listed as an approved security function in Annex A of the FIPS Publication 140-2, and the results of the C-CDA Document Validator within 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) summary and Transition of Care/Referral Summary: Common MU Data Set and the following data elements: Encounter diagnoses, Immunizations, Cognitive status, Functional status and Discharge instructions (Inpatient Only)
- The standards for the named vocabularies for the Common MU Data Set are met by the electronically generated summary (Ambulatory/Inpatient) and Transition of Care/Referral Summary (Inpatient Only)

IN170.314(e)(1) – 2.05: Using the ONC-provided test data, the Tester shall visually inspect the C-CDA .xml to verify that the content of the C-CDAs is complete and accurate

DTR170.314(e)(1)–3: Transmit Health Information to a Third Party Using Direct

Figure 1



Required Vendor Information

VE170.314(e)(1) – 3.01: The Vendor shall identify a Direct address and a registered domain for sending of Direct messages for certificate discovery testing for enabling of testing using the Direct Certificate Discovery Tool

VE170.314(e)(1) – 3.02: The Vendor shall identify a non-Direct email address to be used for delivery of results of certificate discovery testing for enabling of testing using the Direct Certificate Discovery Tool

VE170.314(e)(1) – 3.03: The Vendor shall identify a Contact Email address to be used for receipt of the validation report generated by the Transport Testing Tool

VE170.314(e)(1) – 3.04: The Vendor shall identify the Direct address for registering within the Transport Testing Tool

VE170.314(e)(1) – 3.05: The Vendor shall obtain the Transport Testing Tool's Public Key and Trust Anchor from the Transport Testing Tool and store it within EHR technology for encrypting Direct message(s) to be sent to the 3rd party[4]

[4] When the test procedure refers to the Transport Testing Tool's trust anchor and certificates, this refers to NIST hosted version on transport-testing.nist.gov. If your organization is hosting its own version of Transport Testing Tool

VE170.314(e)(1) – 3.06: The Vendor shall identify its signing certificate to sign message content with its Private Key and include the Public Key in messages sent to the Transport Testing Tool

Required Test Procedures

TE170.314(e)(1) – 3.01: The Tester shall download the Direct Certificate Discovery Tool's Trust Anchor and import it into the EHR technology's trust store

TE170.314(e)(1) – 3.02: The Tester shall use the Direct (From) address provided in VE170.314(e)(1)-3.01 to execute the test using the Direct Certificate Discovery Tool

TE170.314(e)(1) – 3.03: The Tester shall use the non-Direct email address provided in VE170.314(e)(1)-3.02 for receipt and validation of results of certificate discovery testing

TE170.314(e)(1) – 3.04: The Tester shall execute all test cases within the Direct Certificate Discovery Tool

TE170.314(e)(1) – 3.05: Using the Inspection Test Guide, the Tester shall verify that the EHR technology is able to correctly discover and use address-bound and domain-bound certificates hosted in both DNS and LDAP

TE170.314(e)(1) – 3.06: The Tester shall cause the EHR to register the Direct (To) addresses specified in the Transport Testing Tool (to be available as a recipient for sending of Direct messages within the EHR)

TE170.314(e)(1) – 3.07: The Tester shall cause the EHR to transmit human readable document(s) using ONC Applicability Statement for Secure Health Transport (Direct) standard (and record the user, date, time. and action performed) to the Direct (To) address(es) specified in the Transport Testing Tool that are available within the EHR following TE170(e)(1) – 3.06. The Direct message shall be encrypted using the recipient's (Transport Testing Tool) Public Key obtained in VE170.314(e)(1) – 3.05 and signed using the sender's (Vendor) Private Key:

- Ambulatory: Ambulatory Summary available for download or downloaded in TE170.314(e)(1) – 2.02
- Inpatient: Inpatient Summary available for download or downloaded in TE170.314(e)(1) – 2.02

TE170.314(e)(1) – 3.08: The Tester shall cause the EHR to transmit Consolidated CDA document(s) using ONC Applicability Statement for Secure Health Transport (Direct) standard to the Direct (To) address(es) specified in the Transport Testing Tool (and record the user, date, time. and action performed). The Direct message shall be encrypted using the recipient's (Transport Testing Tool) Public Key obtained in VE170.314(e)(1) – 3.05 and signed using the sender's (Vendor) Private Key:

- Ambulatory: Ambulatory Summary available for download or downloaded in TE170.314(e)(1) – 2.03

(TTT), then you will need to create your own trust anchor certificates and use these instead. For example, the trust anchor for "hit-testing.nist.gov", may change to "ttt.yourdomain.com".

- Inpatient: Inpatient Summary and Referral Summary/Transition of Care document available for download or downloaded in TE170.314(e)(1) – 2.03

TE170.314(e)(1) – 3.09: Using the Inspection Test Guide, the Tester shall verify that the (Ambulatory or Inpatient) summary is transmitted in human readable format, and is complete and accurate

TE170.314(e)(1) – 3.10: Using the Inspection Test Guide, the Tester shall verify that the (Ambulatory or Inpatient) summary and Referral Summary/Transition of Care (Inpatient Only) is transmitted according to the Consolidated CDA standard tested and the named vocabulary standards, and is complete and accurate

Inspection Test Guide

IN170.314(e)(1) – 3.01: Using the Direct Certificate Discovery Tool, the Tester shall inspect the results received via email to verify that all test cases were successful

IN170.314(e)(1) – 3.02: The Tester shall verify the appropriate Direct (To) address(es) (provided within the Transport Testing Tool) have been registered within the EHR technology and are visible Direct addresses for transmitting of health information to the Transport Testing Tool according to the ONC Applicability Statement for Secure Health Transport (Direct) standard

IN170.314(e)(1) – 3.03: Using the Transport Testing Tool, the Tester shall verify that the transmitted human readable document(s) and C-CDA document(s) have been transmitted and received successfully according to the ONC Applicability Statement for Secure Health Transport (Direct) standard, including successful decryption validation (Note: the human readable and C-CDA documents may be transmitted using the Direct standard in a single transmission or separate transmissions. If multiple documents are required for human readable format, all documents must be sent as separate attachments within a single transmission).

IN170.314(e)(1) – 3.04: Using the ONC-provided test data, the Tester shall verify that the patient's ambulatory summary is transmitted in human readable format, including, at a minimum, the following data elements (Ambulatory Only):

1) Provider's name
2) Provider's office contact information
3) Common MU Data Set (in their English representation (description) 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)

Note: The tester may need to place the C-CDA XML and style sheet XML, acquired from the validation report, in separate files and save them in the same directory on the test computer in order to view the human readable document

IN170.314(e)(1) – 3.05: Using the ONC-provided test data, the Tester shall verify that the patient's inpatient summary is transmitted in human readable format, including, at a minimum, the following data elements (Inpatient Only):

1) Patient admission date
2) Patient discharge date
3) Admission/discharge location
4) Discharge instructions
5) Reason(s) for hospitalization
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)

Note: The tester may need to place the C-CDA XML and style sheet XML, acquired from the validation report, in separate files and save them in the same directory on the test computer in order to view the human readable document

IN170.314(e)(1) – 3.06: The Tester shall identify the C-CDA .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 document .xml (vs. style sheet, human readable document, etc.))

IN170.314(e)(1) – 3.07: 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) summary and Transition of Care/Referral Summary (Inpatient Only)
- The standards for the named vocabularies for the Common MU Data Set are met by the electronically generated summary (Ambulatory/Inpatient) and Transition of Care/Referral Summary (Inpatient Only)

IN170.314(e)(1) – 3.08: Using the ONC-provided test data, the Tester shall visually inspect the content of the C-CDA documents available within the .xml output (available within the Validation Report produced by the Transport Testing Tool) by visually inspecting that the .xml output is complete and accurate.

DTR170.314(e)(1) – 4: Transmit Health Information to a Third Party 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(e)(1) – 4.01: The Vendor shall identify the edge protocol to be used to send health information: IHE XDR profile for Limited Metadata Document Sources

VE170.314(e)(1) – 4.02: 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 Testing 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(e)(1) – 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(e)(1) – 4.04: The Vendor shall use the Edge Testing Tool to generate Endpoints for use in XDR testing

VE170.314(e)(1) – 4.05: 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(e)(1) – 4.01: The Tester shall establish a Mutual TLS session to authenticate to the Edge Testing Tool (HISP) (XDR-6)

TE170.314(e)(1) – 4.02: 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(e)(1) – 4.03: The Tester shall send the summary record from the patient selected in VE170.314(e)(1) as a C-CDA document downloaded in TE170.314(e)(1) - 2.03 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(e)(1) – 4.04: The Tester shall send the human readable document downloaded in TE170.314(e)(1) - 2.02 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(e)(1) – 4.05: The Tester shall send the C-CDA document in an XDR message to the Edge Testing Tool (HISP) with full metadata using the standard edge protocol (optional XDR-2)

TE170.314(e)(1) – 4.06: 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(e)(1) – 4.07: Using the Inspection Test Guide, the Tester shall verify that the C-CDA document 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(e)(1) – 4.07: 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(e)(1) – 4.08: 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(e)(1) – 4.09: 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(e)(1) – 4.10: 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(e)(1) – 4.11: 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(e)(1) – 4.01: The Tester shall verify that a mutual TLS session is established between the Edge system (sender) and the Edge Testing Tool (receiver) prior to transmitting any data (XDR-6)

IN170.314(e)(1) – 4.02: 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(e)(1) – 4.03: 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(e)(1) – 4.04: 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(e)(1) – 4.05: 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(e)(1) – 4.06: 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(e)(1) – 4.07: 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(e)(1) – 4.08: 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(e)(1) – 4.09: 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(e)(1) – 4.10: 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(e)(1) – 4.11: 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(e)(1) – 4.12: 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(e)(1) – 4.13: 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(e)(1) – 4.14: 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(e)(1) – 5: Transmit Health Information to a Third Party Using Edge Protocol for SMTP as the Edge system

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

VE170.314(e)(1) – 5.01: 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(e)(1) – 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 Testing Tool.

VE170.314(e)(1) – 5.03: The Vendor shall enable SMTP Authentication Required

VE170.314(e)(1) – 5.04: The Vendor shall identify a username and password for address for PLAIN SASL and DIGEST-MD5 SASL Authentication to be used

VE170.314(e)(1) – 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(e)(1) – 5.06: The Vendor shall identify account information (SUT mail address) for the Java client to send messages

VE170.314(e)(1) – 5.07: The Vendor shall identify the SMTP address for the Edge system <TestAddress 2>

VE170.314(e)(1) – 5.08: The Vendor shall identify a non-existent SMTP address for failure testing <TestAddress 3>

VE170.314(e)(1) – 5.09: The Vendor shall identify the C-CDA conformant document(s) created in TE170.314(e)(1) - 2.03

Required Test Procedures

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

TE170.314(e)(1) – 5.01: The Tester shall initiate a TLS session with the Edge Testing Tool (HISP) using email address: wellformed2@hit-dev.nist.gov (SMTP-14)

TE170.314(e)(1) – 5.02: 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(e)(1) – 5.03: The Tester shall authenticate using PLAIN SASL authentication to the Edge Testing Tool SMTP server using email address: wellformed1@hit-dev.nist.gov and the username and password identified in VE170.314(e)(1)-5.04 (SMTP-18)

TE170.314(e)(1) – 5.04: The Tester shall authenticate using DIGEST-MD5 SASL authentication to the Edge Testing Tool SMTP server using email address: wellformed1@hit-dev.nist.gov and the username and password identified in VE170.314(e)(1) – 5.04 (SMTP-19 is not supported at this time)

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

TE170.314(e)(1) – 5.05: The Tester shall cause the Edge system to send the C-CDA document created in TE170.314(e)(1) – 2.03

in an SMTP mail message to the Edge Testing Tool (HISP) using the email address: wellformed1@hit-dev.nist.gov (SMTP-1-8)

TE170.314(e)(1) – 5.06: 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(e)(1) – 5.07: 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(e)(1) – 5.08: 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(e)(1) – 5.09: 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(e)(1) – 5.10: 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 (MU2-45)

TE170.314(e)(1) – 5.11: The Tester shall send an SMTP mail message to the Edge Testing Tool to wellformed14@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(e)(1) – 5.12: 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(e)(1) – 5.01: 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(e)(1) – 5.02: 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(e)(1) – 5.03: 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(e)(1) – 5.04: Using the Edge Testing Tool with a pre-determined username and password, the Tester shall verify successful authentication with DIGEST-MD5 SASL (SMTP-19 is not supported at this time)

IN170.314(e)(1) – 5.05: 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(e)(1) – 5.06: Using the provided test data and the Logs 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(e)(1) – 5.07: 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(e)(1) – 5.08: 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(e)(1) – 5.09: 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(e)(1) – 5.10: 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(e)(1) – 5.11: 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(e)(1) – 5.12: 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(e)(1) – 5.13: Using the Edge Testing Tool logs, 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(e)(1) – 5.14: 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(e)(1) – 5.15: At 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(e)(1)-6 Record and Display Actions

Required Vendor Information

VE170.314(e)(1) – 6.01: Vendor shall identify if capabilities certified in § 170.314(d)(2) are accessible to the patient or whether a separate action log capability is utilized for the activity history log

Required Test Procedures

TE170.314(e)(1) – 6.01: The Tester shall execute DTR170.314(e)(1) – 1, DTR170.314(e)(1) – 2, and DTR170.314(e)(1) – 3 or DTR170.314(e)(1) - 4.

TE170.314(e)(1) – 6.02: The Tester logs into the online system as the patient

TE170.314(e)(1) – 6.03: The Tester causes the online system to display user, date, and time for information viewed in TE170.314(e)(1) – 1.02 and TE170.314(e)(1) – 1.04 and verifies that the action log information is accurate and complete

TE170.314(e)(1) – 6.04: The Tester causes the online system to display user, date, and time information for information downloaded in TE170.314(e)(1) – 2.02 and verifies that the action log information is accurate and complete

TE170.314(e)(1) – 6.05: The Tester causes the online system to display user, date, and time information for information downloaded in TE170.314(e)(1) – 2.03 and verifies that the action log information is accurate and complete

TE170.314(e)(1) – 6.06: The Tester causes the online system to display user, date, and time information for information transmitted in TE170.314(e)(1) – 3.07 or both TE170.314(e)(1) - 4.03 and TE170.314(e)(1) – 5.05 and verifies that the action log information is accurate and complete.

TE170.314(e)(1) – 6.07: The Tester causes the online system to display user, date, and time information for information transmitted in TE170.314(e)(1) – 3.08 or both TE170.314(e)(1) –

4.04 and TE 170.314(e)(1) – 5.06 and verifies that the action log information is accurate and complete

Inspection Test Guide

IN170.314(e)(1) – 6.01: Using the Vendor-identified patient ID and the dates, times, and users noted in TE170.314(e)(1) – 1.02 and TE170.314(e)(1) – 1.04, and viewing the test patient's health information, the Tester shall

- Verify that the actions of viewing health information by both the patient and patient's authorized representative in DTR170.314(e)(1) – 1: View Health Information test is accurate compared to the correct patient's record
- Verify that, for those actions, the correct date and time (utilizing a system clock that has been synchronized following the (RFC 1305) Network Time Protocol, or (RFC 5905) Network Time Protocol Version 4), and user are stored accurately and without omission in the correct patient's record

IN170.314(e)(1) – 6.02: Using the Vendor-identified patient and the dates, times, and users noted in TE170.314(e)(1) – 2.02 and TE170.324.e.1 – 2.03, downloading the test patient's health information, the Tester shall

- Verify that the actions of downloading health information in DTR170.314(e)(1) – 2: Download Health Information test is accurate compared to the correct patient's record
- Verify that, for those actions, the correct date and time (utilizing a system clock that has been synchronized following the (RFC 1305) Network Time Protocol, or (RFC 5905) Network Time Protocol Version 4), and user identification are stored accurately and without omission in the correct patient's record

IN170.314(e)(1) – 6.03: Using the Vendor-identified patient and the dates, times, and users noted in TE170.314(e)(1) – 3.07 and TE170.324(e)(1) – 3.08, transmitting the test patient's health information, the Tester shall

- Verify that the action of transmitting health information to a third party in DTR170.314(e)(1) – 3: Transmit Health Information Using Direct test is accurate compared to the correct patient's record OR Verify that the action of transmitting health information to a third party in DTR170.314(e)(1) – 4 Transmit Health Information Using IHE XDR Edge Protocols and DTR170.314(e)(1) – 5: Transmit Health Information Using SMTP Edge Protocols test is accurate compared to the correct patient's record
- Verify that, for those actions, the correct date and time (utilizing a system clock that has been synchronized following the (RFC 1305) Network Time Protocol, or (RFC 5905) Network Time Protocol Version 4), and user identification are stored accurately and without omission in the correct patient's record

DTR170.314(e)(1)-7 Submit and Verify Summative Testing Results for WCAG Conformance

Required Vendor Information

VE170.314(e)(1) – 7.01: The Vendor shall identify each web page associated with an "accessible version" of view, download, and transmit functions (and accessing them)

VE170.314(e)(1) – 7.02: The Vendor shall identify "pure decoration" and third-party content on accessible web pages associated with view, download, and transmit functions (and accessing them)

VE170.314(e)(1) – 7.03: The Vendor shall identify supported browsers associated with view, download, and transmit functions (and accessing them) (For supplemental guidance, reference: http://www.w3.org/TR/UNDERSTANDING-WCAG20/conformance.html#uc-accessibility-support-head)

VE170.314(e)(1) – 7.04: The Vendor shall provide documentation describing the techniques and methods used in development to support WCAG2.0

VE170.314(e)(1) – 7.05: The Vendor shall provide documentation of the applicable success criteria for level A conformance (see "How to Meet WCAG 2.0" (customized for only Level A success criteria and excluding advisory techniques) for supplemental guidance) and document any success criteria that are not applicable (and rationale for non-applicability) (see http://www.w3.org/WAI/WCAG20/quickref/ for supplemental guidance)

VE170.314(e)(1) – 7.06: The Vendor shall provide documentation of testing tools applied to each web page identified in VE170.314(e)(1) – 5.01

VE170.314(e)(1) – 7.07: The Vendor shall provide documentation of aspects of conformance not verified by testing tools from Items 1-5 of WCAG2.0 Conformance - http://www.w3.org/TR/2008/REC-WCAG20-20081211/#conformance-reqs

VE170.314(e)(1) – 7.08: The Vendor shall provide documentation of explanation of any conformance failures or rationale for over-ruling of tool output

VE170.314(e)(1) – 7.09: The Vendor shall record and report all WCAG2.0 conformance results (e.g. as indicated in http://www.w3.org/WAI/ER/conformance/ED-methodology-20120915#step5)

Required Test Procedures

TE170.314(e)(1) – 7.01: Using the Inspection Test Guide, the Tester shall examine the Vendor-provided documentation identified in VE170314(e)1 – 5.01 through VE170314(e)1 – 5.08

TE170.314(e)(1) – 7.02: Using the Inspection Test Guide, the Tester shall examine the Vendor-provided conformance testing results submitted in VE170314(e)1 – 5.09

Inspection Test Guide

IN170.314(e)(1) – 7.01: The Tester shall evaluate that the Vendor-provided documentation for WCAG2.0 conformance testing and use of conformance tools for each web page submitted for testing are complete, and meet the conformance

requirements for WCAG 2.0 Level A (Vendors may choose to report these results with the content and completion requirement guidance listed athttp://www.w3.org/WAI/ER/conformance/ED-methodology-20120915#step5)

IN170.314(e)(1) – 7.02: The Tester shall evaluate the Vendor-provided documentation of tool failures or over-ruling of tool outputs (Accessibility evaluation guidance available at: http://www.w3.org/WAI/eval/Overview.html)

IN170.314(e)(1) – 7.03: The Tester shall evaluate the Vendor-provided documentation of conformance not verified by testing tools (For supplemental guidance, reference http://www.w3.org/WAI/eval/selectingtools.html)

IN170.314(e)(1) – 7.04: The Tester shall evaluate that the results in conformance testing of web page(s) selected by the tester is comparable to Vendor-provided documentation and Vendor-provided conformance testing results

TEST DATA

ONC-supplied test data is 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-Accredited Testing Laboratories (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 is 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 functional and interoperable 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(e)(1) VDT 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 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:

- Direct Certificate Discovery Tool (DCDT) – ONC provides a web application certificate discovery testing tool to support this test procedure. This tool was created to support automated testing of systems that plan to enact the Certificate Discovery and Provider Directory Implementation Guide, approved as normative specification by the Direct community, as of July 9, 2012. It is based on the written test package and requirement traceability matrix created by the Modular Specifications project.
    - This application can be installed and deployed locally.
    - The Direct Certificate Discovery Tool, User's Guide, configuration instructions, and other documentation are available at: http://code.google.com/p/direct-certificate-discovery-tool/

- Transport Testing Tool (TTT) -- the Transport Testing Tool is designed to support this test procedure. 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

- 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.
    - The Edge Testing Tool (ETT) is available at: http://edge.nist.gov/

Support for the Edge Testing Tool is available by submitting questions to the Edge Testing Tool user group at: https://groups.google.com/forum/#!forum/edge-test-tool. Inquiries may also be sent to this user group via email: edge-test-tool@googlegroups.com

Multiple browsers may be used to access this tool; if the tool does not load completely using Internet Explorer 8 or Internet Explorer 9, 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 inspection 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	November 19, 2012
1.1	Delivered for National Coordinator Approval	December 3, 2012
1.2	Posted Approved Test Procedure	December 14, 2012
1.3	Posted Updated Approved Test Procedure Updates: • Removed Normative Test Procedure steps to upload trust anchor to TTT and validate the trust anchor, and removed references to these steps in the Informative Test Description • Inserted references to visually inspect .xml to verify content/values are acceptable • Added footnote in Normative Test Procedure clarifying Transport Testing Tool Trust Anchor and Certificates for local installation • Inserted new VE – 3.06 • Updated step numbers in Normative Test Procedure to be consecutive • Modified Record and Display Normative Test Procedure references to correctly reference steps in previous sections of the Normative Test Procedure	February 1, 2013
1.4	Posted Updated Approved Test Procedure Updates: • In Informative Test Description, added statement “The transmission of the C-CDA and human readable document formats may occur as separate transactions or both documents may be transmitted within a single transmission.” • In Normative Test Procedure, added step TE170.314(e)(1) – 2.04 for the Tester to validate C-CDA conformance using the C-CDA Document Validator within the Transport Testing Tool • In Inspection Test Guide, modified IN170.314(e)(1) – 2.05 to replace “Validation Report” with “results of the C-CDA Document Validator” • In Inspection Test Guide, modified IN170.314(e)(1) – 2.06 to clarify instructions for a visual inspection of the C-CDA.xml • In Inspection Test Guide, added “Note: the human readable and C-CDA documents may be transmitted using the Direct standard in a single transmission or separate transmissions” in IN170.314(e)(1) – 3.03 • In Inspection Test Guide, added strikethrough to IN170.314(e)(1) – 3.07 • In Inspection Test Guide, modified IN170.314(e)(1) – 3.09 to clarify instructions for a visual inspection of the C-CDA documents available within the .xml output, and add strikethrough to “(by inspecting .xml)”	February 22, 2013

1.5	Posted Updated Approved Test Procedure Updates: • In VE170.314(e)(1) – 1.04 changed “and authorized ” to “an authorized” • In DTR170.314(e)(1) – 4 inspection test guide changed “patient ID” to “patient” and “user ID” to “user” • Clarification provided in informative test description outlining the requirement for EHR technology to make available two documents for download and transmission in the inpatient setting (page 5) • Added clarification in informative test description that information in human readable format must be human readable in a single download and transmission (for example C-CDA conformant document and associated style sheet must be available in a single download and a single transmission) (page 5)	May 8, 2013

1.6	Updated Approved Test Procedure Updates: • Removed v1.4 note explaining strikethrough text in informative test description • Added clarification in the informative test description that EHR vendors must make a minimum of two "types" of documents available rather than two individual documents (page 5) • Specified in the informative test description that the inpatient summary must contain the elements listed in the 170.314(e)(1) certification criterion (page 5) • Replaced "a transition of care/referral summary that may be created" with "transition of care/referral summaries that were created" in the informative test description to better align with the certification criterion language (page 5) • Added clarification to the informative test description: "If multiple documents are required for human readable format, these documents must be sent as separate attachments in any order within a single transmission. Vendors may provide additional attachments (e.g. XDM package) in the transmission if desired." (page 5) • Added note to informative test description clarifying that resources provided that are not normative parts of the WCAG 2.0 level "A" standard are provided as supplemental guidance only (page 9) • Removed strikethrough of text in normative test procedure • Added note to IN170.314(e)(1) – 3.03 "If multiple documents are required for human readable format, all documents must be sent as separate attachments within a single transmission)." • Added note to IN170.314(e)(1) – 3.04 and IN170.314(e)(1) – 3.05 "Note: The tester may need to place the C-CDA XML and style sheet XML, acquired from the validation report, in separate files and save them in the same directory on the test computer in order to view the human readable document" • Removed "IN170.314(e)(1) – 5.04: The Tester shall evaluate that the Vendor-provided conformance testing results conform(s) to the content and completion requirements specified at http://www.w3.org/WAI/ER/conformance/ED-methodology-20120915#step5" • Updated VE170.314(e)(1) – 5.03, VE170.314(e)(1) – 5.05, and IN170.314(e)(1) – 5.03 to indicate that links provided are supplemental guidance • Added note to IN170.314(e)(1) – 5.01 "(Vendors may choose to report these results with the content and completion requirement guidance listed athttp://www.w3.org/WAI/ER/conformance/ED-methodology-20120915#step5)" • Updated Test Procedure steps to maintain correct numerical order	June 10, 2013

1.7	Updated Approved Test Procedure Updates: • Updated the NTP protocol to allow for synching to occur within 5 seconds • Updated the Document History of Version 1.6 to clarify which step was removed when referring to IN170.314(e)(1) – 5.04 • Updated the Document History of Version 1.6 to indicate that test procedure steps were renumbered to maintain numerical order after modifications	July 11, 2013
1.8	Updated Approved Test Procedure Updates: • Removed reference to inpatient and ambulatory summary in 'View' section of Informative Test Description and Normative Test Procedure • Removed requirement to download and transmit summary of care/referral summary in human readable format in Normative Test Description and Normative Test Procedure	March 21, 2014
1.9	Released for public comment Updates: The Test Procedure has been updated to reflect the 2014 Edition Release 2 Rule for §170.314(e)(1) View, download, and transmit to a 3rd party with edge protocol testing. • Updated introductory, Informative Test Description, and Standards sections to include optional Edge Protocol Testing • Inserted new Derived Test Requirement: DTR170.314(e)(1) – 4: Transmit Health Information to a Third Party Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources as the Edge system • Inserted new Derived Test Requirement: DTR170.314(e)(1) – 5: Transmit Health Information to a Third Party Using Edge Protocol for SMTP as the Edge system • Renumbered former DTRs due to insertion of above DTRs: DTR170.314(e)(1) – 4 and DTR170.314(e)(1) – 5 are updated to DTR170.314(e)(1) – 6 and DTR170.314(e)(1) – 7, respectively • Inserted reference information for the Edge Testing Tool (ETT) within the Conformance Tools section	October 8, 2014
1.10	Delivered for National Coordinator Approval Updates: • Updated DTR170.314(e)(1) – 4 and DTR170.314(e)(1) – 5 to incorporate public comment feedback and align test steps with Edge Testing Tool (ETT) functionality • Updated ETT support contact information	March 23, 2015
1.11	Posted Approved Test Procedure	March 27, 2015

[i] **ANNEX A: APPROVED SECURITY FUNCTIONS**

Annex A provides a list of the Approved security functions applicable to FIPS PUB 140-2. The categories include transitions, symmetric key, asymmetric key, message authentication and hashing. An excerpt is provided below.

Transitions

National Institute of Standards and Technology, *Recommendation for Transitioning the Use of Cryptographic Algorithms and Key Lengths*, Special Publication 800-131A, January 2011. Sections relevant to this Annex: 1, 2, 3, 9 and 10.

Symmetric Key (AES, TDEA and EES)

1. **Advanced Encryption Standard (AES)**

National Institute of Standards and Technology, *Advanced Encryption Standard (AES)*, Federal Information Processing Standards Publication 197, November 26, 2001.

National Institute of Standards and Technology, *Recommendation for Block Cipher Modes of Operation, Methods and Techniques*, Special Publication 800-38A, December 2001.

National Institute of Standards and Technology, *Recommendation for Block Cipher Modes of Operation: Three Variants of Ciphertext Stealing for CBC Mode*, Addendum to Special Publication 800-38A, October 2010.

National Institute of Standards and Technology, *Recommendation for Block Cipher Modes of Operation: The CCM Mode for Authentication and Confidentiality*, Special Publication 800-38C, May 2004.

National Institute of Standards and Technology, *Recommendation for Block Cipher Modes of Operation: Galois/Counter Mode (GCM) and GMAC*, Special Publication 800-38D, November 2007.

National Institute of Standards and Technology, *Recommendation for Block Cipher Modes of Operation: The XTS-AES Mode for Confidentiality on Storage Devices*, Special Publication 800-38E, January 2010.

2. **Triple-DES Encryption Algorithm (TDEA)**

National Institute of Standards and Technology, *Recommendation for the Triple Data Encryption Algorithm (TDEA) Block Cipher*, Special Publication 800-67, May 2004.

National Institute of Standards and Technology, *Recommendation for Block Cipher Modes of Operation, Methods and Techniques*, Special Publication 800-38A, December 2001. Appendix E references Modes of Triple-DES.

American Bankers Association, *Triple Data Encryption Algorithm Modes of Operation,* ANSI X9.52-1998. Copies of X9.52-1998 may be obtained from X9, a standards committee for the financial services industry.

3. **Escrowed Encryption Standard (EES)**

National Institute of Standards and Technology, *Escrowed Encryption Standard (EES)*, Federal Information Processing Standards Publication 185, February 9, 1984.

Asymmetric Key (DSS – DSA, RSA and ECDSA)

1. **Digital Signature Standard (DSS)**
    a. National Institute of Standards and Technology, *Digital Signature Standard (DSS)*, Federal Information Processing Standards Publication 186-3, June, 2009. (DSA2, RSA2 and ECDSA2)
    b. National Institute of Standards and Technology, *Digital Signature Standard (DSS)*, Federal Information Processing Standards Publication 186-2, January, 2000 with Change Notice 1. (DSA, RSA and ECDSA)
    c. RSA Laboratories, *PKCS#1 v2.1: RSA Cryptography Standard*, June 14, 2002. Only the versions of the algorithms RSASSA-PKCS1-v1_5 and RSASSA-PSS contained within this document shall be used.

Secure Hash Standard (SHS)

1. **Secure Hash Standard (SHS) (SHA-1, SHA-224, SHA-256, SHA-384, SHA-512, SHA-512/224 and SHA-512/256)**

    National Institute of Standards and Technology, *Secure Hash Standard*, Federal Information Processing Standards Publication 180-4, March, 2012.

Random Number Generators (RNG and DRBG)

1. **Annex C: *Approved Random Number Generators*** National Institute of Standards and Technology, *Annex C: Approved Random Number Generators for FIPS 140-2, Security Requirements for Cryptographic Modules*.

Message Authentication (Triple-DES, AES and SHS)

1. **Triple-DES**
   National Institute of Standards and Technology, *Computer Data Authentication*, Federal Information Processing Standards Publication 113, 30 May 1985.
2. **AES**
   National Institute of Standards and Technology, *Recommendation for Block Cipher Modes of Operation: The CMAC Mode for Authentication*, Special Publication 800-38B, May 2005.
   National Institute of Standards and Technology, *Recommendation for Block Cipher Modes of Operation: The CCM Mode for Authentication and Confidentiality*, Special Publication 800-38C, May 2004.
   National Institute of Standards and Technology, *Recommendation for Block Cipher Modes of Operation: Galois/Counter Mode (GCM) and GMAC*, Special Publication 800-38D, November 2007.

3. **SHS**

National Institute of Standards and Technology, *The Keyed-Hash Message Authentication Code (HMAC)*, Federal Information Processing Standards Publication 198-1, July, 2008.