

Test Procedure for §170.314 (h)(3) Optional – transmit – SOAP transport and security specification and XDR/XDM for direct messaging

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

Questions or concerns regarding the ONC HIT Certification Program should be sent to:

ONC.Certification@hhs.gov

CERTIFICATION CRITERIA

Refer to §170.314(h)(3) for the certification criteria.

<http://www.gpo.gov/fdsys/pkg/FR-2014-09-11>

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

2014 EDITION RELEASE 2 PREAMBLE LANGUAGE

Per Section III.A.2 of the preamble of the 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 where the Transmission certification criteria is discussed. As a result of the proposal to decouple content and transport capabilities from the Transitions of Care (ToC) certification criteria and the View, Download, Transmit (VDT) certification criterion, three separate transmission certification criteria were proposed. The third optional transmission criterion at

§170.314(h)(3) will enable health information to be electronically transmitted in accordance with the standard specified in §170.314(b)(1)(i)(C) and §170.314(b)(2)(ii)(C).

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.

INFORMATIVE TEST DESCRIPTION

This test evaluates the capability for EHR technology to electronically transmit and receive health information (e.g. the transition of care/referral summary document (summary care record) in conformance with the Consolidated Clinical Document Architecture (C-CDA) standard). The vendor may elect to be evaluated for the capability to electronically transmit and receive the transition of care/referral summaries using the Simple Object Access Protocol (SOAP)-Based Secure Transport Requirements Traceability

Matrix (RTM) version 1.0 standard and the XDR and XDM for Direct Messaging Specification
ONC provides the test data for this test procedure.

- Transmit - Evaluates the capability of EHR technology to allow a provider to electronically transmit the health information to another provider or next setting of care or Health Information Service Provider (HISP).
 - The Tester causes the health information in C-CDA format to be transmitted to a third party using the SOAP-Based Secure Transport RTM version 1.0 and XDR, based on ONC supplied test information
- Receive – Evaluates the capability of EHR technology to electronically receive health information from another provider or setting of care or HISP.
 - The Tester causes the health information in C-CDA format to be transmitted from the Edge Testing Tool to the EHR/HISP using the SOAP-Based Secure Transport RTM version 1.0, XDR, and SAML, based on ONC supplied test information

REFERENCED STANDARDS

§170.202 Transport standards	Regulatory Referenced Standard
The Secretary adopts the following transport standards: <u>Standard</u> . ONC Transport and Security Specification (incorporated by reference in § 170.299).	

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.314(h)(3) – 1: Transmit Health Information to a Third Party Using SOAP Protocols

DTR170.314(h)(3) – 2: Receive Health Information from a Third Party Using SOAP Protocols

DTR170.314(h)(3) – 1 Transmit Health Information to a Third Party Using SOAP Protocols

Required Vendor Information

VE170.314(h)(3) – 1.01: The Vendor shall generate a SOAP endpoint for XDR for each C-CDA conformant document that will be sent to the Edge Testing Tool and provide a Name for each Edge Testing Tool connection

Required Test Procedures

TE170.314(h)(3) – 1.01: The Tester shall cause the EHR/HISP to transmit C-CDA document(s) for Referral Summary/Transition of Care using SOAP Protocols with XDR Validation to the SOAP endpoint generated in VE 170.314(h)(3) – 1.01 in the Edge Testing Tool

TE170.314(h)(3) – 1.02: Using the Inspection Test Guide, the Tester shall verify that the Transition of Care/Referral Summary is transmitted using SOAP Protocols with XDR Validation

Inspection Test Guide

IN170.314(h)(3) – 1.01: Using the Edge Testing Tool Message Validators XDR Validator, the Tester shall verify that the transmitted C- CDA document(s) have been transmitted and received successfully according to SOAP Protocols with XDR Validation

DTR170.314(h)(3) – 2: Receive Summary of Care Record Using SOAP Protocols

Required Vendor Information

VE170.314(h)(3) – 2.01: The Vendor shall provide a Site Name, a separate endpoint used by the SUT to receive each XDR message

VE170.314(h)(3) – 2.02 : Vendor shall define and identify an Actor Simulator in the Edge Testing Tool terminology (as described in the Edge Testing Tool User Guide)

Required Test Procedures

TE170.314(h)(3) – 2.01: The Tester shall cause the Edge Testing Tool Message Validators XDR Validator to transmit a C-CDA document using SOAP Protocols with XDR Validation with both NHIN SAML and TLS selected to the EHR's/HISP's SOAP endpoint provided in VE170.314(h)(3) – 2.01

TE170.314(h)(3) – 2.02: Using the Inspection Test Guide, the Tester shall verify that the C-CDA documents transmitted in TE170.314(h)(3) – 2.01 was successful

Inspection Test Guide

IN170.314(h)(3) – 2.01 Using the Edge Testing Tool Validation Report, the Tester shall verify that the transmitted documents were received successfully by the EHR according to SOAP Protocols with XDR Validation with no errors reported by the Edge Testing Tool

TEST DATA

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

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

- The Tester determines that the Vendor product is sufficiently specialized that the provided test data needs to be modified in order to conduct an adequate test. Having made the determination that some modification to the provided test data is necessary, the Tester shall record the modifications made as part of the test documentation.
- The Tester determines that changes to the test data will improve the efficiency of the testing process; primarily through using consistent demographic data throughout the testing workflow. The Tester shall ensure that the applicable requirements identified in the criterion can be adequately evaluated for conformance and that the test data provides a comparable level of robustness. Having made the determination that some modification to the provided test data is necessary, the Tester shall record the modifications made as part of the test documentation.

Test Data for §170.314(h)(3) Optional – SOAP Transport and Security Specification and XDR/XDM for Direct Messaging is available at <http://www.healthit.gov/certification> (navigation: 2014 Edition Test Method)

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

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

CONFORMANCE TEST TOOLS

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

- Edge Testing Tool (ETT) - The Edge Testing Tool is designed to support this test procedure.
 - The Edge Testing Tool Direct Testing (Sections: Register Direct, Send Direct Message and Message Validator) includes the capability to verify the ability to exchange Consolidated CDA (C-CDA) conformant documents using Direct transport standards (e.g., Direct and Direct + XDM).
 - The Edge Testing Tool Message Validators (Section: XDR Validator) includes the capability to verify the ability to exchange Consolidated CDA (C-CDA) conformant documents using ONC XDR and XDM for Direct Messaging.
 - The Edge Testing Tool Message Validators (Section: CCDAR1.1 Validator) includes the capability to verify the conformance of the CDA (C-CDA R1.1) documents.
 - The Edge Testing Tool Edge Testing (Sections: Homepage, SMTP Test Cases, IMAP Test Cases, POP3 Test Cases, XDR Test Cases) includes the capability to verify the ability to exchange Consolidated CDA (C-CDA) conformant documents using transport standards (e.g. SOAP).
 - The Edge Testing Tool HISP Testing and Delivery Notification (Section: Message Tracking) includes the capability to verify the receipt of messages.
 - This application can be installed and deployed locally.
 - The Edge Testing Tool (ETT) is available at: healthit.gov/ett

Multiple browsers may be used to access this tool. As the tool has been tested using both Chrome and Firefox browsers, these are the recommended browsers. The Edge 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 Edge Testing Tool (ETT):

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

Document History

Version Number	Description of Change	Date Published
1.0	Released for public comment	October 8, 2014
1.1	Delivered for National Coordinator Approval	December 23, 2014
1.1	Posted Approved Test Procedure	December 24, 2014
1.2	<p>Changed references to the Transport Testing Tool (TTT) to Edge Testing Tool due to the retirement of the TTT Tool. The following tests were impacted:</p> <ul style="list-style-type: none"> • Informative Test Description • DTR170.314(h)(3) – 1 Transmit Health Information to a Third Party Using SOAP Protocols: VE170.314(h)(3) – 1.01, TE170.314(h)(3) – 1.01 • DTR170.314(h)(3) – 2: Receive Summary of Care Record Using SOAP Protocols: VE170.314(h)(3) – 2.02, TE170.314(h)(3) – 2.01, IN170.314(h)(3) – 2.01, • Conformance Tools updated the description of the validation tools used within the Test Procedure; removed the tool support information (this is available within the tools). <p>DTR170.314(h)(3) – 1 Transmit Health Information to a Third Party Using SOAP Protocols – removed Figure 1 which provided TTT workflow. DTR170.314(h)(3) – 2: Receive Summary of Care Record Using SOAP Protocols removed Figure 2 which provided TTT workflow.</p>	January 27, 2017