Secure Exchange Solutions

SES Direct v.2.0

Conditions of Certification

[45 CFR 170.315(h)(2)]

Real World Testing Plan

Version History

Version	Name	Change Date	Description of Changes
1.0	Adam Apatoff	November 2021	Initial Document Creation

1 Overview

Secure Exchange Solutions, Inc. (SES) provides cloud-based SaaS Clinical Data Exchange solutions, including operating as a Health Information Service Provider (HISP) in conformance with the DirectTrust rules, standards, and policies. The SES HISP Platform (SES Direct v.2.0) is certified as a Health IT Module by the Office of the National Coordinator for Health Information Technology (ONC-HIT). SES Direct is subject to ongoing testing to demonstrate compliance with the conditions for certification required by ONC-HIT at 45 CFR 170.315. Changes to those conditions of certification by the 21st Century Cures Act and associated regulations promulgated by ONC-HIT at 45 CFR 170.405 require development of a Real World Testing Plan to demonstrate compliance with applicable ONC-HIT Conditions and Maintenance of Certification.

2 Purpose

SES Real World Testing Plan outlines the testing plan and associated procedures required by 45 CFR 170.405 to enable SES to demonstrate compliance with applicable conditions of certification for SES Direct v.2.0 required to be subject to the ONC-HIT Real World Testing Plan requirements. While SES Direct v.2.0 is certified to the ONC-HIT certification criteria set forth at 170.315(d)(1)-(3), (g)(4, (5), and (h)(2), real-world testing is required only fort compliance with the conditions of certification set forth at 170.315(h)(2). This Real World Testing Plan establishes the plan and procedures for demonstrating compliance with the testing criteria for 170.315(h)(2).

3 Plan and Procedures

General Information

Plan Report ID No. [For ONC-ACB use only] _____

Developer Name: SecureEx Solutions, Inc. dba Secure Exchange Solutions, Inc.

Product Name: SES Direct

Version No.:   2.0

Certified Health IT Product List (CHPL) ID: 15.04.04.2315.SESD.02.00.0.170217

Developer Real World Testing Page URL: https://www.secureexsolutions.com/disclosures-and-communications/

Justification for Real World Testing Approach

SES leverages existing real-world interoperability testing required of DirectTrust accredited Health Information Service Providers (HISPs) for the SES Direct v.2.0 product together with existing SES real-world testing processes in place for routine and ongoing testing of edge protocol connections of SES Direct. This testing process demonstrates the functional interoperability and real-world, real-time exchange of structured clinical data (CDA documents) supporting transitions of care use cases with and among all DirectTrust accredited HISPs. This functionality demonstrates real-world interoperability for 170.315(h)(2) certification criteria.

DirectTrust interoperability testing occurs semi-annually in April and October and requires all accredited HISPs to demonstrate real-world, real-time exchange of CDA documents containing transition of care information on a repeatable, measurable ongoing basis. HISPs exchange Direct S/MIME messages in accordance with the Applicability Statement for Secure Health Transport v.1.2 (the "Direct Protocol") and associated DirectTrust rules and agreements within the DirectTrust trust framework and federated trust exchange community containing CDA documents as encrypted payloads, demonstrating successful transmission, receipt, and acknowledgment of successful interoperable exchange of data. Message Delivery Notifications (MDNs) provided by the receiving HISP to the sending HISP for test messages and associated transitions of care CDA payloads, provide auditable and demonstrable evidence of successful or unsuccessful (non-delivery) real-world exchange of data using modalities consistent with (h)(2) certification requirements.

Testing for aspects of the conditions of certification related to the exchange of data using XDR/XDM occurs on a regular basis throughout the year as standard operating processes for SES customers (both providers and CEHRT vendors). Testing of edge protocol (XDR/XDM) occurring in April and October of each year will be tracked and recorded as a measurement period to leverage this existing real-world testing between CEHRT user customers (both providers and vendors) and SES for exchange of data using edge protocols in existing real-world testing environments provided by SES. This testing generates MDN records for each exchange using the applicable edge protocols and he supports the use of MDNs as the appropriate and accurate data supporting effective and successful real-world interoperability testing to those protocols and standards.

SES Real World Testing to support conditions of certification under the applicable criteria for 170.315(h)(2) through exchange of CDA documents containing transitions of care data between all DirectTrust-accredited HISPs provides for transmission and receipt of Direct messages containing applicable data to demonstrate:

(a) Transmission consistent with the Applicability Statement for Secure Health Transport v.1.2;

(b) compliance with ONC XDR and XDM for Direct Messaging Specification v.1.0, including limited and full XDS metadata profiles; and

(c) support for both protocols set forth in the ONC Implementation Guide for Direct Edge Protocols, v.1.1 such that support for both the XDS Metadata profiles (Limited and Full), as specified in the underlying IHE specifications, ensuring that the transformation between messages packaged using XDR/XDM are done with as much appropriate metadata as possible;

together with the ability to send and receive health information in accordance with the standard specified in §170.202(e)(1).

Testing will include processing of invalid test cases to demonstrate that the product and associated Security/Trusted Agents (STAs) can demonstrate error handling capabilities, including handling of XDM packages and message disposition, as well as demonstrate the capability of providing MDNs to any sending HISP as matter of standard functionality in addition to base certification requirements to provide MDNs upon request, consistent with the standard set forth at 170.202(e)(1) to provide a high level of assurance to senders that a message has arrived at its destination, a necessary component to interoperability.

Aspects of testing involving MDN processing and delivery will additionally demonstrate compliance with certain exception flows that result in compromised message delivery and the mitigation actions taken by STAs for the product to provide success and failure notifications to the sending system. Testing is consistent with the requirement to send and receive messages in only "wrapped" format even though the specification (IG) allows use of "unwrapped" messages to further improve interoperability among STAs while minimizing development impact on health IT developers.

Testing will additionally demonstrate that when the product converts an SMTP message into XDR (with limited metadata), UUIDURNs formatted as OIDs should be used for DocumentEntry.uniqueId, SubmissionSet.sourceId, and SubmissionSet.uniqueId.

Standards Updates

Standard and Version	170.315(h)(2) 2015 edition
Updated Certification Criteria and Associated Product	170.315(h)(2) SES Direct v.2.0
Health IT Module CHPL ID	15.04.04.2315.SESD.02.00.0.170217
Method Used for Standard Update	Not Applicable
Date of ONC-ACB Notification	11/15/2021
Date of Customer Notification (DVAP only)	Not Applicable
Conformance Measure	Not Applicable
USCDI Updated Certification Criteria and USCDI Version	Not Applicable

Measures Used in Overall Approach

Real World Testing Plans must include at least one measurement/metric that addresses each applicable certification criterion in the Health IT Module's scope of certification.

Description of Measurement/Metric

MEASUREMENT/METRIC	DESCRIPTION
MDN for Successful Delivery	Each Direct message transmitted to a corresponding receiving HISP within the DirectTrust community returns a MDN indicating successful receipt of the sent message consistent with the standard set forth at 170.202(e)(1) to provide a high level of assurance to senders that a message has arrived at its destination, a necessary component to interoperability. Receipt/Return of an MDN demonstrates both successful processing of the Direct message in accordance with the Direct

	Protocol and associated modalities subject to (h)(2) criteria, as well as the message delivery notification requirements
MDN for Non-Delivery	Specified messages transmitted result in message failure notice to demonstrate compliance with certain exception flows that result in compromised message delivery and the mitigation actions taken by STAs for the product to provide success and failure notifications to the sending system. Message failure notifications (MDN for Non-Delivery) support criteria subject to the certification conditions identified for (h)(2) certification.

Associated Certification Criteria

MEASUREMENT/METRIC	ASSOCIATED CERTIFICATION CRITERIA
MDN for Successful Delivery	45 CFR 170.315(h)(2)
MDN for Non-Delivery	45 CFR 170.315(h)(2)

Justification for Selected Measurement/Metric

MEASUREMENT/METRIC	JUSTIFICATION
MDN for Successful Delivery	MDN for Successful Delivery demonstrates successful transmittal and receipt of messages with associated CDA payloads to receiving HISPs consistent with the standards identified in the (h)(2) conditions of certification
MDN for Non-Delivery	MDN for Non-Delivery indicates effective processing of invalid test cases showing that the product and associated Security/Trusted Agents (STAs) can demonstrate error handling capabilities, including handling of XDM packages and message disposition, as well as demonstrate the capability of providing MDNs to any sending HISP as matter of standard functionality in addition to base certification requirements to provide MDNs upon request, consistent with the standard set forth at 170.202(e)(1) to provide a high level of assurance to senders that a message has arrived at its destination, a necessary component to interoperability.

Care Settings

SES Direct utilizes the Direct Protocol and associated Direct messaging modalities subject to the certification requirements of 170.315(h)(2) to deliver secure communications containing encrypted

CDA document payload concerning transitions of care, the primary use case of SES Direct and associated DirectTrust accredited HISPs in the following care settings.

CARE SETTING	JUSTIFICATION
Acute	Transitions of care for communications between providers are the primary application and use case for Direct Secure Messaging enabled by certified Health IT Module subject to 170.315(h)(2) criteria.
Ambulatory	Transitions of care for communications between providers are the primary application and use case for Direct Secure Messaging enabled by certified Health IT Module subject to 170.315(h)(2) criteria.
Emergency Department	Transitions of care for communications between providers are the primary application and use case for Direct Secure Messaging enabled by certified Health IT Module subject to 170.315(h)(2) criteria.

SES Direct is configured and used in the same manner in each of these care settings for the transitions of care use case for the secure point-to-point transmission and delivery of CDA documents between providers.

Expected Outcomes

Data collected from the functional Real World Testing under this Real World Testing Plan demonstrates the expected results and outcomes of use and operation of the SES Direct product in accordance with the applicable conditions of certification. Periodic interoperability testing is a basic tenet of interoperable exchange by an among DirectTrust accredited HISPs participating in the DirectTrust federated exchange trust community. Additionally, interoperability testing for edge protocol integrations occurs on a constant basis between SES and our CEHRT vendor customers and SES and provider users/customers integrating to a separate CEHRT system, with measurement periods in April and October (concurrent with the DirectTrust testing process) occurring to monitor and record ongoing use of existing SES testing environments. Message Delivery Notifications (MDNs) are the medium of data generate to indicate success/failure of transmission of data using the Direct Protocol and associated modalities consistent with the conditions for certification identified at 170.315(h)(2).

MEASUREMENT/METRIC	EXPECTED OUTCOMES
MDN for Successful Delivery; 95%+ return of MDN for successful delivery expected as reviewed during the biannual testing periods	All messages directed at a valid endpoint at a corresponding HISP are delivered and messages received from the corresponding HISP are received with MDNs returns/received in that exchange. All messages sent to valid endpoints return the applicable MDN. The MDN represents the auditable, identifiable record which confirms successful

	transmission/receipt of the secure message, demonstrating compliance with the (h)(2) conditions of certification.
	Each Direct message sent/received by a corresponding HISP generates an MDN, indicating successful delivery (or alternatively, indicating a failed delivery). MDN transmission occurs regardless of success or failure. A target metric of 95%+ return of MDN showing successful delivery demonstrates a target service level commitment to users of the certified health information technology module based upon historical analysis of actual counts of receipt of MDNs for success/failure of the message transmission reflected in the total volume of messages exchanged on any periodic basis as analyzed against the volume of message transmissions during the biannual testing periods.
MDN for Non-Delivery; 95%+ return of MDN expected for non-delivery (failed delivery) expected as reviewed during the biannual testing periods	Specific messages which include process flow exceptions and errors are not successfully received by the specified corresponding recipient HISP triggering return of an MDN for Non-Delivery. Receipt and processing of such MDNs notifying the product and user of the error in each instance provides an auditable, identifiable data record of failed delivery (non-delivery) allowing for product users and developers to respond to the non-delivery consistent with the applicable (h)(2) conditions of certification requiring the ability to receive, react, and respond to non-delivery of a message.
	Each Direct message sent/received by a corresponding HISP generates an MDN, indicating delivery status – whether failed (non-delivery) or successful delivery. MDN transmission occurs regardless of success or failure. A target metric of 95%+ return of MDN showing failed delivery (non-delivery) demonstrates compliance with certification criteria that the certified health information technology module measurably demonstrates the ability of the systems to receive, react, and respond to non-delivery of a message. Metric of 95+ is based on historical analysis of receipt of MDNs for success/failure of the message transmission reflected in the total volume of messages exchanged on any periodic basis as analyzed against the volume of message transmissions during the biannual testing periods

Schedule of Key Milestones

Key Milestone	Care Setting	Date/Timeframe
Interoperability Testing using DirectTrust community testing protocols and including specified metrics in this Real World Testing Plan	Transitions of Care messages for Acute, Ambulatory, Emergency Department settings	April 2022 (testing occurs within the DirectTrust community during the monthly period and is complete by end of month)
Measurement period for recording MDN records generated by ongoing use of in SES real-world testing environment by SES customers/users for edge protocol exchange integrations	Transitions of Care messages for Acute, Ambulatory, Emergency Department settings	April 2022 (use of testing environments is ongoing, April designated as measurement period to record MDN records for use in accordance with this Real World Testing Plan)
Interoperability Testing using DirectTrust community testing protocols and including specified metrics in this Real World Testing Plan	Transitions of Care messages for Acute, Ambulatory, Emergency Department settings	October 2022 (testing occurs within the DirectTrust community during the monthly period and is complete by end of month)
Measurement period for recording MDN records generated by ongoing use of in SES real-world testing environment by SES customers/users for edge protocol exchange integrations	Transitions of Care messages for Acute, Ambulatory, Emergency Department settings	October 2022 (use of testing environments is ongoing, October designated as measurement period to record MDN records for use in accordance with this Real World Testing Plan)

4   Attestation

This Real World Testing Plan is complete with all required elements, including measures that address all certification criteria and care settings. All information in this plan is up to date and fully addresses the health IT developer's Real World Testing requirements.

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Date: November 15, 2021