

SECURE EXCHANGE SOLUTIONS, INC. REALWORLD TESTING RESULTS REPORT (2023)



BACKGROUND & INSTRUCTIONS

Under the ONC Health IT Certification Program (Certification Program), health IT developers are required to conduct Real World Testing of their certified health IT (45 CFR 170.405). The Office of the National Coordinator for Health Information Technology (ONC) issues Real World Testing resources to clarify health IT developers' responsibilities for conducting Real World Testing, to identify topics and specific elements of Real World Testing that ONC considers a priority, and to assist health IT developers in developing their Real World Testing plans and results reports.

A Real World Testing plan template was created to assist health IT developers in organizing the required information that must be submitted for each element in a Real World Testing plan. To accompany the plan template, ONC has also provided this results report template which Secure Exchange Solutions has adopted as the format of our Real World Testing Plan results report.

While the use of this template is voluntary, as a health IT developer, Secure Exchange Solutions found it useful in preparing our Real World Testing results report(s). As required of all Health IT developers, we are submitting one year of results to address the Real World Testing of eligible products as outlined in our previous year's Real World Testing Plan. If adjustments to approaches are made throughout Real World Testing, As a health IT developer, we will disclose those adjustments in this Real World Testing results report. The applicable sections of this Real World Testing Plan results report includes a list of these changes, the reasons for them, and how intended outcomes were more efficiently met as a result in accordance with ONC expectations.

While every effort has been made to ensure the accuracy of restatements of 45 CFR Part 170, the template on which our Real World Testing Plan results report is not a legal document. The official program requirements are contained in the relevant laws and regulations. This report should be read and understood in conjunction with the following companion resources, which describe in detail many of the ONC Certification Program requirements referenced in the template and included in this report.

- Real World Testing

 What It Means for Health IT Developers Fact Sheet
- Real World Testing Resource Guide
- Real World Testing Certification Companion Guide

Our presentation of our Real World Testing Plan results report includes consideration of the following regulatory materials, which establish the core requirements and responsibilities for Real World Testing under the ONC Certification Program.

- 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule, <u>85 FR 25642</u> (May 1, 2020) (ONC Cures Act Final Rule)
 - Section VII.B.5 "Real World Testing"



OVERVIEW

This report sets forth the elements required to be submitted in the Real World Testing results reporting accordance with guidance and standards established by ONC. Each section sets forth applicable responses and/or explanations for how Secure Exchange Solutions, Inc. as a health IT developer addresses each required element in our Real World Testing approach set forth in the Secure Exchange Solutions Real World Testing Plan v. 1.1, as established by SES and published as required by applicable regulations. These fields provide the foundation of information required for this Real World Testing results report setting forth the Real World Testing results being submitted.

GENERAL INFORMATION

Plan Report ID No. [For ONC-ACB use onl	v1
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Developer Name: Secure Ex 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/

CHANGES TO ORIGINAL PLAN

If a developer has made any changes to their approach for Real World Testing that differs from what was outlined in their plan, note these changes here.

Summary of Change [Summarize each element that changed between the plan and actual execution of Real World Testing]	Reason [Describe the reason this change occurred]	Impact [Describe what impact this change had on the execution of your Real World Testing activities]
modified to include data collection	Real World Testing Plan processes changed operationally for 2023 when DirectTrust interoperability testing processes ended the required exchange of data for DirectTrust interoperability testing which was used previously by SES for the April measurement period under RWT Plan v.1.0 and intended for 2023 under RWT Plan v.1.1 to infrastructure/ standards testing only. This additional change followed a shift in 2022 from bi-annual to annual testing only within DirectTrust.	



WITHDRAWN PRODUCTS

Secure Exchange Solutions, as a Health IT developer, confirms it did not withdraw any products within the past year that were previously included our Real World Testing Plan. In the event that any products are withdrawn, the following fields will be used to disclose such occurrence.

Product Name(s):	
Version Number(s):	
CHPL Product Number(s):	
Date(s) Withdrawn:	
Inclusion of Data in Results Report:	
[Provide a statement as to whether any data was captured on the withdrawn products. If so, this data should be identified in the results report.]	

SUMMARY OF TESTING METHODS AND KEY FINDINGS

The following is a summary of the Real World Testing methods deployed to demonstrate real-world interoperability, including any challenges or lessons learned from the chosen approach. This information summarizes how the results shared in this report demonstrate real-world interoperability.

Any non-conformities discovered and reported to the ONC-ACB during testing will be identified in this section, detailing such incidences and how they were addressed.

Note: Our Real World Testing results report may address multiple products and certification criteria for multiple care settings.

Testing included analysis of Direct Secure Messages between identified accounts containing encrypted payloads to demonstrate successful transmission, receipt, and acknowledgment of successful interoperable exchange of data.

Testing included review of Message Delivery Notifications (MDNs) provided by the receiving HISP to the sending HISP for identified messages and accounts and associated transitions of care CDA payloads as evidence of successful or unsuccessful (non-delivery) real-world exchange of data using modalities consistent with (h)(2) certification requirements.

Testing of edge protocol (XDR/XDM) included analysis of Direct Secure Messages and associated MDNs for edge protocol use cases and deployments within the indicated measurement periods.

Testing included identification of specified messages containing invalid test cases to review and process MDNs indicating failed messages or failed delivery of received messages within the measurement periods to demonstrate that the product and associated Security/Trusted Agents (STAs) 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.

Testing included collection of operational results demonstrating 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 (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI))

Both required and voluntary standards updates must be addressed in the Real World Testing Plan. Our Real World Testing Plan includes all certified health IT products we offer updated to newer versions of standards prior to August 31 of the year in which the updates were made.

As required by applicable rules, we hereby disclose whether optional standards, via SVAP and/or USCDI, are leveraged as part of the certification of our health IT product(s) covered by our Real World Testing Plan and this results report.

[] Yes, I have products certified with voluntary SVAP or USCDI standards. (If yes
р	lease complete the table below.

[\(\)] No, none of my products include these voluntary standards.

Standard (and version)
Updated certification criteria and associated product
CHPL Product Number
Conformance measure

Care Setting(s)

As a Health IT developer, our Real World Testing is conducted within each type of clinical setting in which our certified health IT is marketed. Consistent with applicable rules, as a Health IT developer, we are not required to test our certified health IT in every setting in which it is marketed for use.

Care settings where the certified Health IT was tested: Acute, Ambulatory, Emergency Department for testing with EHR application vendor customers which use SES Direct v.2.0 for transitions of care for communications between providers are the primary use case for Direct Secure Messaging enabled by certified Health IT Module subject to 170.315(h)(2) criteria

Metrics and Outcomes

As a Health IT developer, this report details outcomes from our testing that successfully demonstrate that the certified health IT:

- 1. is compliant with the certification criteria, including the required technical standards and vocabulary codes sets;
- 2. is exchanging electronic health information (EHI) in the care and practice settings for which it is marketed for use; and/or,
- 3. EHI is received by and used in the certified health IT.(from 85 FR 25766)



As a Health IT developer, we also detail outcomes that did <u>not</u> result from their measurement approach to the extent applicable.

The following section describes how the specific data collected from our Real World Testing measures demonstrate our results. Where possible, context is provided to the measures and results to understand the number of sites/users/transactions tested for the specified measures (i.e., the denominator for comparison to the reported results). If applicable, any Relied Upon Software that is used to meet a criterion's requirements should be included in this section.

Measurement /Metric	Associated Criterion(a)	Relied Upon Software (if applicable)	Outcomes	Challenges Encountered (if applicable)
MDN for Successful Delivery; 95%+ return of MDN for successful delivery expected as reviewed during the biannual testing periods	45 CFR 170.315(h)(2)		Real World Testing data successfully collected for biannual testing periods - between April 1-30, 2023 (6,644,765 messages) and October 1-31, 2023 (9,440,742 messages). Data collected indicated that all accounts identified for testing processed messages successfully with receipt by HISP (MDN = Received) and delivery to recipient (MDN = Dispatched) in excess of 95% metric during both measurement periods (April 2023 and October 2023 – successful MDN reported 100% of messages) indicating a high level of assurance to senders that a message has arrived at its destination, a necessary component to interoperability	



MDN for Non-	45 CFR	Real World Testing
Delivery; 95%+	170.315(h)(2)	data successfully
return of MDN		collected for biannual
expected for non-		testing periods -
delivery (failed		between April 1-30,
		2023 (6,644,765
delivery) expected as		messages) and
reviewed during the		October 1-31, 2023
biannual testing		(9,440,742
periods		messages).
		Data collected
		indicated that all
		accounts identified for
		testing that included
		errors in designated
		recipient or which
		contained defects in
		payload configuration
		or intended endpoint
		receipt processed
		messages with the
		expected failure
		notification (MDN =
		failed) in excess of 95%
		metric during both measurement periods
		(No MDN in 1.3% (April
		2023) and 0.788%
		(October 2023) of
		messages) generating
		appropriate "Extended
		Status" reporting with
		the associated MDN
		returned indicating
		error basis to assure
		that the product and
		associated
		Security/Trusted Security/Trusted
		Agents (STAs)
		demonstrate error
		handling capabilities,
		including handling of
		XDM packages and
		message disposition

KEY MILESTONES

The following identifies key milestones met during the Real World Testing process with details on how and when we implemented measures and collected data as a Health IT developer. All key milestones are relevant and directly related to outcomes discussed.

Each key milestone describes when Real World Testing began in specific care settings and the date/timeframe during which data was collected.

Key Milestone	Care Setting	Date/Timeframe
identified Direct messaging domains (directaddress.net or direct-address.net) and selected accounts for the specified time period within the applicable	Transitions of Care messages for Acute, Ambulatory, Emergency Department settings	April 1-30, 2023
in SES real-world testing environment by SES customers/users for edge	Transitions of Care messages for Acute, Ambulatory, Emergency Department settings	April 1-30, 2023



i	and selected accounts for the specified time period within the applicable	Transitions of Care messages for Acute, Ambulatory, Emergency Department settings	October 1-31, 2023
	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 1-31, 2023
	Review of internally collected performance metrics on MDN counts and	Transitions of Care messages for Acute, Ambulatory, Emergency Department settings	January 22 - 31,2023

