SECURE EXCHANGE SOLUTIONS, INC.

REAL WORLD TESTING RESULTS REPORT (2022)

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 their Real World Testing plan. To accompany the plan template, ONC has also provided this results report template.

While the use of this template is voluntary, health IT developers may find it useful in preparing their Real World Testing results report(s). Health IT developers must submit one year of results to address the Real World Testing of eligible products as outlined in their previous year's Real World Testing plan(s). If adjustments to approaches are made throughout Real World Testing, the health IT developer should reflect these adjustments in their Real World Testing results report. ONC expects that the results report will include a list of these changes, the reasons for them, and how intended outcomes were more efficiently met as a result.

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

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

Health IT developers should also review the following regulatory materials, which establish the core requirements and responsibilities for Real World Testing under the Certification Program.

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

TEMPLATE INSTRUCTIONS

The following template is organized by elements required to be submitted in the Real World Testing results report. Each section provides a field for submitting responses and/or explanations for how the health IT developer addressed each required element in their Real World Testing approach. These fields serve as a foundation of information required for developing a Real World Testing results report and can be expanded with additional rows or columns to address the specific needs of the Real World Testing results being submitted.

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/

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]
In 2022 during the operating of SES Real World Testing Plan v. 1.0, the SES Real World Testing Plan was modified to include data collection across operational accounts to track identified metrics in the ordinary course of operations in October 2022 independent of DirectTrust interoperability testing processes and exchange of Direct Secure Messages. Testing and data collection in April 2022 occurred as contemplated by the SES Real World Testing Plan v. 1.0	Real World Testing Plan processes changed operationally in 2022 when DirectTrust interoperability testing schedules shifted in frequency from semi-annual (biannual) in April and October of each year to annual only in April of each year starting in 2022.	None.

[OPTIONAL] WITHDRAWN PRODUCTS

If a developer withdrew any products within the past year that were previously included in their Real World Testing plan, please provide the following information.

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

Provide a summary of the Real World Testing methods deployed to demonstrate real-world interoperability, including any challenges or lessons learned from the chosen approach. Summarize how the results that will be shared in this report demonstrate real-world interoperability.

If any non-conformities were discovered and reported to the ONC-ACB during testing, outline these incidences and how they were addressed.

Note: A single 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. Real World Testing plans must include all certified health IT updated to newer versions of standards prior to August 31 of the year in which the updates were made.

Indicate as to whether optional standards, via SVAP and/or USCDI, are leveraged as part of the certification of your health IT product(s).

[ ] Yes, I have products certified with voluntary SVAP or USCDI standards. (If yes, please 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)

The expectation is that a developer's Real World Testing is conducted within each type of clinical setting in which their certified health IT is marketed. Health IT developers are not required to test their certified health IT in every setting in which it is marketed for use.

List each care setting that 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

Health IT developers should detail outcomes from their 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)

Health IT developers could also detail outcomes that did not result from their measurement approach if that better describes their efforts.

Within this section, health IT developers should also describe how the specific data collected from their Real World Testing measures demonstrate their results. Where possible, context should be 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 1-19, 2022 (2,773,704 messages) and October 3-31, 2022 (6,066,623 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 2022 and October 2022 – 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-Delivery; 95%+ return of MDN expected for non-delivery (failed 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 - April 1-19, 2022 (2,773,704 messages) and October 3-31, 2022 (6,066,623 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 (April 2022 and October 2022 – No MDN in 0.83% of messages) generating appropriate "Extended Status" reporting with the associated MDN returned indicating error basis to assure that the product and associated Security/Trusted Agents (STAs) demonstrate error handling capabilities, including handling of XDM packages and message disposition	

KEY MILESTONES

Include a list of key milestones that were met during the Real World Testing process. Include details on how and when the developer implemented measures and collected data. Key milestones should be relevant and directly related to outcomes discussed.

For each key milestone, describe when Real World Testing began in specific care settings and the date/timeframe during which data was collected.

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 1-19, 2022
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 1-19, 2022

Interoperability Testing using DirectTrust community testing protocols and including specified metrics in this Real World Testing Plan – modified to sample selected accounts for monitoring for collection of Real World Testing data	Transitions of Care messages for Acute, Ambulatory, Emergency Department settings	October 3-31, 2022
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 3-31, 2022
Real World Testing Plan – Review and Report Compilation Review of internally collected performance metrics on MDN counts and associated error/outcome reporting; analysis of collected data from biannual reporting periods; preparation of report and associated analytics for Real World Testing Reporting	Transitions of Care messages for Acute, Ambulatory, Emergency Department settings	February 8-27, 2023