REAL WORLD TESTING PLAN

GENERAL INFORMATION

Plan Report ID Number: 20211208INP

Developer Name: Inpriva, Inc.

Product Name: hDirect Network Services

Version Number: V2.1

Certified Health IT Product List (CHPL) ID: IG-3497-17-0018

Developer Real World Testing Page URL: https://inpriva.com/resources/RealWorldTesting

REAL WORLD TESTING SCENARIO

ONC established 2015 Edition certification criteria that requires certified health IT to be able to send and receive health information in accordance with specified standards. In order to support this requirement for healthcare provider organizations assembling a system compliant with the CMS EHR Certification requirements ("Provider EHR System"), Inpriva provides hDirect Network Services that meet the §170.315 (h)(2) "Direct Project, Edge Protocol, and XDR/XDM" criteria. A Provider EHR System or other endpoint originating Direct messages to send health information will submit the message to either an hDirect XDR endpoint or to an hDirect SMTP endpoint where the message will be packaged as a Direct Project-compliant message and delivered to the destination Direct Network endpoint. Direct Project-compliant messages inbound are received through the hDirect Network Endpoint, processed and verified for Direct compliance, and delivered to the Provider EHR System or other destination via an XDR, IMAP or POP3 endpoint. Inpriva will test the ability of hDirect Network Services to meet the §170.315 (h)(2) requirements for sending and receiving health information.

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

The hDirect Network Services production message processing logs provide the data necessary to track messages from endpoint submission for outbound message through endpoint delivery for received messages, allowing evaluation of whether the §170.315 (h)(2) criteria are being met. The testing approach will monitor and report on message flow to and from Provider EHR Systems and other endpoints that will be selected so conformance of the hDirect Network Services for each §170.315 (h)(2) criteria can be analyzed. When no production messages have been processed that meet §170.315 (h)(2) negative testing criteria, appropriate test messages will be submitted for production system processing and the resulting logs analyzed to confirm compliance.

STANDARDS UPDATES

Not applicable

CARE SETTING

By providing Direct message transport and delivery at the Provider EHR System edge, hDirect Network Services support any care setting that has requirements to send or receive messages carrying patient-related and/or clinical administration information.

OVERALL EXPECTED OUTCOMES

Real World Testing will:

- Demonstrate that hDirect Network Services conform to the §170.315 (h)(2) "Direct Project, Edge Protocol, and XDR/XDM" certification criteria.
- Demonstrate, in a production environment, that hDirect Network Services can accept messages from XDR and SMTP submitting endpoints and deliver properly formatted Direct messages to the Direct Network that meet the requirements of the standards referenced in the "Direct Project, Edge Protocol, and XDR/XDM" certification criteria.
- Demonstrate that hDirect Network Services enables a wide range of healthcare provider organizations to interoperate with other the conform to the §170.315 (h)(2) certification criteria via the Accredited DirectTrust Network.
- Demonstrate that only a small percentage of Direct messages are not successfully delivered and that most of the messages not delivered were because the required trust criteria had not been met.

SCHEDULE OF KEY MILESTONES

Key Milestone	Date/Timeframe
Initial development of the Real World Testing Plan.	September 1- December 15, 2021
Commence collection of information as laid out by the plan.	January 1, 2022
Data collection and review.	Quarterly, 2022
End of Real World Testing period/final collection of all data for analysis.	January 2023
Analysis and report creation.	January 15, 2023
Submit Real World Testing report to ACB	February 1, 2023

MEASURES USED

The following outlines the measure that has been identified to best demonstrate conformance to the §170.315 (h)(2) "Direct Project, Edge Protocol, and XDR/XDM" certification criterion in accordance with standards referenced in the associated regulations as follows:

- §170.202(a)(2) - "Applicability Statement for Secure Health Transport, Version 1.2"
- §170.202(b) - "XDR and XDM for Direct Messaging Specification, Version 1.0"
- §170.202(d) - "Implementation Guide for Direct Edge Protocols, Version 1.1"
- §170.202(e)(1) - "Implementation Guide for Delivery Notification in Direct, Version 1.0"

The measure provides for message processing to be logged and reports generated that demonstrate conformance to the each required Direct messaging specification, edge connection protocol and delivery notification protocol within an actual production environment. Direct message exchanges will be over the Accredited DirectTrust Network (the "Direct Network") in which all participant HISPs are subject to independent third-party audits to confirm conformance to the standards referenced in the above regulations.

Measure: Interoperability and Conformance Metrics for messages sent to and received from the Direct Network via hDirect Network Services. This measure will test the conformance of the hDirect Network Services when:

- Messages are submitted using XDR protocol and the message metadata and content are packaged into an XDM compliant file that is attached to the Direct message outbound to the Direct Network.
- Messages are submitted using SMTP protocol.
- Received messages are delivered to XDR endpoints with limited metadata.
- Received messages include XDM attachment and are delivered XDR endpoints with full metadata.
- Received messages are delivered to destinations that are accessed by IMAP or POP3 endpoints.

The testing approach will use historical log files that capture detailed information about message flow to and from Provider EHR Systems and other endpoints selected so conformance of the hDirect Network Services for each §170.315 (h)(2) criteria can be analyzed. The associated certification are:

Certification Criteria	Requirement
§170.315 (h)(2) Direct Project, Edge Protocol, and XDR/XDM	(i)(A) Able to send and receive health information in accordance with the standard specified in §170.202(a)(2), including formatted only as a "wrapped" message.
	(i)(B) Able to send and receive health information in accordance with standard specified in §170.202(b), including support for both limited and full XDS metadata profiles.
	(i)(C) Able to send and receive health information in accordance with both edge protocol methods specified by the standard in §170.202(d).
	(ii) *Delivery Notification in Direct*. Able to send and receive health information in accordance with the standard specified in §170.202(e)(1).

- Justification: Since the logs capture data that allows the analysis of message delivery success and failure for multiple Provider EHR Systems and other message endpoints that are delivered to or received from a wide range of recipient Direct addresses managed by large number of HISPs, the measure allows the overall extent of successful interoperable exchange to assessed.
- Test methodology: The log histories captured over each previous quarter for messages outbound from the Provider EHR Systems and other endpoints that send health information together with Direct messages inbound from the Direct Network to endpoints that receive health information will be used for analysis to validate the proper message processing in accordance with "Direct Project, Edge Protocol, and XDR/XDM" as specified in §170.315 (h)(2). The analysis will include at least five sending endpoints that include both XDR/XDM and SMTP protocols and a least five receiving endpoints that include both XDR/XDM and IMAP/POP3 protocos. With respect to the total number of sampled messages, the analysis will determine percentage of messages that were successfully delivered, percentage of messages not delivered and percentages of messages not delivered grouped by the reason that delivery was not successful. When there are message delivery failures that have not been logged which would demonstrate conformance with required negative test criteria, those message events will be simulated in the production environment.
- Expected outcome: Each submitted message will either be successully delivered to the destination endpoint or a message delivery failure reported. It is expected that message delivery failures will be relatively rare with an analysis of the logs providing an indication of the reason for the delivery failure. The percentage of successful messages delivered together with percentages of message failures grouped by reason for failure will be tracked.

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 healthIT developer's Real World Testing requirements.

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