



Medsphere Systems Corporation

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GENERAL INFORMATION

Developer Name: Wellsoft Corporation, a Division of Medsphere Systems Corporation

Plan Report ID Number: 20241031wel

Product Name(s): Wellsoft EDIS

Version Number(s): 11

Product List (CHPL) ID(s): 15.05.05.2538.WLST.01.01.1.180703

ONC-ACB Certification ID: 15.05.05.2538.WLST.01.01.1.180703

Developer Real World Testing Page URL:

<https://www.medsphere.com/certifications/RealWorldTesting/Wellsoft/>

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

At this time, Wellsoft EDIS is marketed as an Emergency Department Solution. Therefore, the Real World Testing plan will apply to this care setting. We feel that having the ability to capture data and transmit data related to communicable diseases to public health agencies as required in 170.315(f)(2) Transmission to public health agencies – syndromic surveillance, is a key piece of interoperability if that information becomes available during an emergency visit. In addition, we also feel that having the ability to export EHI as required in 170.315 (b)(10) is another foundational piece of interoperability. Our Real World Testing approach will help us determine the usability rating and outcomes of these types of transmissions and exports.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP))

This product has no voluntary SVAP standards updates.

MEASURES USED IN OVERALL APPROACH

The following outlines our measures that have been identified to best demonstrate how our product is in and maintains conformance to 170.315(b10) Electronic Health Information Export and 170.315(f)(2) Transmission to Public Health Agencies-Syndromic Surveillance

Measure 1 (EHI Export)

This measure will capture the number of times a data export was performed for individual patients as well as the frequency for bulk export.

Certification Criteria	Associated Criteria	Relied Upon Software
170.315(b)(10) Electronic Health Information export	Individual export of EHI Bulk export	N/A

Rationale: Wellsoft EDIS gives clinicians the ability to export electronic health information in bulk as well as individual patients in the event that they need to export the data for any reason.

Test Approach 1: System logs will be used to extract the frequency in which these action types were performed. Frequency and success rates will be monitored and reported on a quarterly basis to the compliance director for review. Overall results for the year will be compiled and submitted on an annual basis. In addition, we will also review support cases to add those requests to the bulk export numbers in the event clients go through support to obtain their data in bulk.

Expected Outcome(s): It is expected that clients and internal staff will be able to perform these actions without limitations. We anticipate higher numbers for the individual export than bulk however, both numbers will be monitored.

Measure 2 (Message Transmission status to Public Health Agency)

This measure will capture the success/failure rates of HL7 messages being transmitted. Specifically, we will extract ADT messages to analyze error rates for public health agencies. (ADT-04, ADT-08)

Certification Criteria	Associated Criteria	Relied Upon Software
170.315(f)(2) Transmission to Public Health Agencies – Syndromic	Transmit ADT message to public health agency.	N/A

Surveillance		
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Rationale: Wellsoft EDIS gives clinicians the ability to transmit certain information to external entities using HL7 standards. These message types are transmitted through an HL7 engine and logged in the system. When an instance arises around communicable diseases, the data is captured within the system, these data elements



are parsed into an HL7 message and transmitted to the respective external entity. This will provide an analytical view of the success rates of transmission.

Test Approach 1: (in the event that we have clients set up to exchange messages with a public health agency) System logs will be used to extract certain message types related to syndromic surveillance activities. Success rates of ADT messages being delivered to public health agencies will be reviewed and trended over time.

Expected Outcome(s): It is expected that clients will be able to transmit HL7 messages without limitations and in compliance with the certification criteria, including the technical standards and vocabulary code sets. We do anticipate some clients will experience some delay on first attempt due to network connectivity so we anticipate that 90% of messages will be successfully transmitted and the 10% error rate accounts for issues with network.

Test Approach 2: (in the event that we do not have clients set up to exchange messages with a public health agency) System logs from internal test environments that mirror the production release will be used to extract certain message types related to immunization and syndromic surveillance activities. Success rates of ADT messages being delivered to a test entity will be conducted on a quarterly basis.

Expected Outcome(s): It is expected that standard ADT message types will be able to be created within a test environment and transmitted to an external test entity without limitations and in compliance with the certification criteria, including the technical standards and vocabulary code sets. Success/error rates will be captured to determine that the system is functioning as certified.

Care Setting(s)

Wellsoft EDIS is only marketed to emergency department settings, therefore, only emergency departments will be used for Real World Testing.

SCHEDULE OF KEY MILESTONES

Key Milestone	Date/Timeframe
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Begin collection of data laid out by plan	March 2025	
Data Collection and Review	Quarterly	
End of Real World Testing for all measures.	December, 2025	
Final data review and analytics, create results report	January 2026	
Submit Real World Testing Results Report to ACB	January 2026	

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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