

Real World Testing Results Report Plan



HeliosMD

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General Information	
Plan Report ID#:	20211201AME
Developer Name:	American Medical Solutions, Inc.
Product Name:	Helios
Version #:	2.0
Product List (CHPL) ID#:	15.02.05.1086.AMEM.01.01.1.220217 (current), 15.02.02.1086.A112.01.00.1.200331 (previous)
Certified Health ID:	170.315(b)(1), 170.315(b)(2), 170.315(b)(6), 170.315(c)(1), 170.315(c)(2), 170.315(c)(3), 170.315(e)(1), 170.315(f)(1), 170.315(f)(5), 170.315(g)(7), 170.315(g)(8), 170.315(g)(9), 170.315(g)(10), and 170.315(h)(1)
Developer Real World testing Page URL:	https://amsemr.com/services/
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[Justification for Real World Testing Approach](#)

Helios is a web-based Practice management Software (PPMS, EHR) system for use in an ambulatory care setting. The goal is to demonstrate interoperability through data transfer with respect to clinical data and documents. Methodology and functionality used is consistent with the certified criteria established and certified to the ONC-ACB on March 31, 2020. Interoperability is achieved through C-CDA format utilizing direct messaging processes in a patient-by-patient basis. Additionally other parts of interoperability are achieved through patient access. Real world testing will be performed on specific scenarios included in this test plan, as demonstrated by the use of this application with outcomes logged, reported and analyzed.

Justification for using an analytics approach is based on the best way to demonstrate the interoperability and functionality of the system.

Changes To Original Plan

There were 2 changes to the original test plan. The inclusion of criteria 170.315(b)(6) and 170.315(g)(10). Changes were made to the original test plan in an effort to include all aspects of the EHR use and to promote interoperability. These 2 changes were added and resulted. The impact on our original test plan was minimal and resulted in a more detailed analysis and longer test plan duration.

170.315(b)(6) – Data Export	Summary data file to be created and exported	Review using the data analytics approach indicating the information was exported and available to the targeted audience with a > 1% error rate
170.315 (g)(10) – Standardized API for patient and population services	Allow access to standardized API for facilitating data transfer	Review if applicable parties can gain access with a > 1% error rate

Withdrawn Products

There were no withdrawn products from the original test plan.

Summary Of Testing Methods and Key Findings

The real-world test plan conducted consisted of sending data, analyzing data and the verification of conformity depending on the measure. During our testing, we reviewed the requirement, established the workflow appropriate, conducted the test and documented the outcome. For any criteria associated with exporting, importing data to or from a target, each test was successfully accomplished. Instances when there were a lag or disruption in data transfer reaching the target was due to network traffic on the side of the target entity however after delay the data was processed. It made us aware that we will need to have a contingency plan to alert users of a network disruption.

The methods chosen were done so with the idea that these methods would be readily available to the clinic users and the information tested were based in industry standards to promote interoperability. Meaning, elements of the interoperability standard were reviewed, and testing procedures and methods were chosen to help test, analyze, correct and provide feedback to development teams of changes of necessary actions.

Based on our selected criteria. The analysis was performed by taking note of the number of data packets sent vs. the number of data packets received if applicable. Additionally, where there is quantitative data available, the number of tangible data elements such as appointments, encounters or patients sent vs. received was factored in to determine the

success or failure of the test.

For criteria based on patient portal and patient access, the results were documented based on the number of patients granted access vs. the number who are able to access the system.

As an analysis for expected outcomes. Administrators reviewed the total number of data sets sent, received, transmitted or reported depending on the measure. Only expected measures with controllable outcomes were reviewed and reported. Patient access is a measure where granting access and not gaining access was the determining factor.

Other analysis was conducted based on total number of information data set points attributed to the applicable measure with starting values prior to import, reporting, export or transmission and an ending value of data set points. Error rates were reviewed to determine processed data between entities or expected outcomes in reporting or access controls.

[Standards Updates \(Including Standards Version Advancement Process \(SVAP\) and United States Core Data For Interoperability \(UCSDI\)\)](#)

This product does not include these voluntary standards.

[Care Settings](#)

The care setting was representative of an ambulatory clinic focusing on primary care.

Metrics and Outcomes

Associated Criteria	Approach	Expected Outcomes	Resulted Outcomes and Challenges Encountered	Relied Upon Software
170.315 (b)(1) – Transition of Care	Clinical information sent and received using established appropriate protocols	Review using the data analytics approach indicating the information sent and received should reach target with a > 1% error rate	Information was sent and received target with 0% error rate. No challenges were encountered	EMR Direct
170.315 (b)(2) – Clinical Information Reconciliation and Incorporation	Clinical information reconciled and incorporated within the patient account	Review using the data analytics approach indicating the information was incorporated within the targeted data set with a > 1% error rate	Information was incorporated within the target data with 0% error rate. No challenges were encountered	None
170.315 (b)(6) – Data Export	Patient Data Export	Review using the data analytics approach indicating the information was exported and available to the targeted audience with a > 1% error rate	Information was exported and was available to the target audience with 0% error rate. No challenges were encountered	None
170.315 (c)(1) – Clinical Quality Measures - Record and Export	CQM information to be recorded and exported using appropriate functionality and protocols	Review using the data analytics approach indicating the data recorded and exported with a 1% error rate	CQM information was exported with 0% error rate. No challenges were encountered	None
170.315 (c)(2) – Clinical Quality Measures - Import and Calculate	CQM information to be imported and calculated in the appropriate section	Review using the data analytics approach indicating the data was imported and calculated with a > 1% error rate	CQM data was imported and calculated correctly with a 0% error rate. No challenges were encountered	None

170.315 (c)(3) – Clinical Quality Measures – Report	CQM data to be reported using appropriate tools or functionality	Review using the data analytics approach indicating the data reported with a > 1% error rate	Data was reported with 0% error rate. No challenges were encountered	None
170.315 (e)(1) – View, Download, and Transmit to 3rd Party	Data to be displayed/viewed, exported and available for download and transmitted to a 3rd party using appropriate protocol and or tools	Review using the data analytics approach indicating the data processed with a > 1% error rate	Data was processed with 0% error rate. No challenges were encountered	None
170.315 (f)(1) – Transmission to Immunization Registries	Appropriate data set to be transmitted to approved immunization registries	Review using the data analytics approach indicating the data transmitted with a > 1% error rate	Data was transmitted with 0% error rate. No challenges were encountered	None
170.315 (f)(5) – Transmission to Public Health Agencies - Electronic Case Reporting	Appropriate data set to be transmitted to approved public health agencies in electronic format	Review using the data analytics approach indicating the information data transmitted with a > 1% error rate	Data was transmitted with 0% error rate. No challenges were encountered	None
170.315 (g)(7) – Application Access - Patient Selection	Grant patient access to appropriate data set in the system	Review using the observational testing approach indicating the patients gain access with a > 1% error rate	Patients were able to gain access to the appropriate data set with a 0% error rate. No challenges were encountered	EMR Direct
170.315 (g)(8) – Application Access - Data Category Request	Grant access to specific data sets in the system	Review using the observational testing approach indicating the patients gain access to specific data categories with a > 1% error rate	Patients were able to gain access to specific categories with a 0% error rate. No challenges were encountered	EMR Direct

170.315 (g)(9) – Application Access - All Data Request	Grant access without specific data set criteria allowing for an all data request	Review using the observational testing approach indicating the patients gain access to all data with a > 1% error rate	Patients were able to gain access to all data with a 0% error rate. No challenges were encountered	EMR Direct
170.315 (g)(10) – Standardized API for patient and population services	Allow access to standardized API for facilitating data transfer	Review if applicable parties are able to gain access with a > 1% error rate	Applicable parties were able to gain access with a 0% error rate. No challenges were encountered	EMR Direct
170.315 (h)(1) – Direct Project	Create a file using direct messaging functionality to send information to another entity	Review using the data analytics approach to assure the creation and that the file was sent with respective data with a > 1% error rate	A direct messaging compatible file was created and sent with respective data with a 0% error rate. No challenges were encountered	EMR Direct

Key Milestones

Milestone	Care Setting	Date/Timeframe
Real World Test Plan Submission	Ambulatory – Primary Care	November 12, 2021
Submit call to action for prospected providers for testing	Ambulatory – Primary Care	January - 2022
Conducted analysis of prospects and decision on providers of testing	Ambulatory – Primary Care	April 2022
Testing	Ambulatory – Primary Care	May 2022
Review and analyze data based on testing approach	Ambulatory – Primary Care	September 2022
Report testing results	Ambulatory – Primary Care	February 2023

Attestation

This report of Real-World testing results is an accurate attestation of the results discovered.

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Date:

02/01/2023

Signature:

A handwritten signature in black ink, appearing to read 'Anthony Puglisi', with a horizontal line underneath.