Real World Testing Plan

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General Information	
Plan Report ID#	20231208amm
Developer Name:	American Medical Solutions, Inc.
Product Name:	Helios
Version Number:	2.0
Product List (CHPL) ID	15.02.05.1086.AMEM.01.01.1.220217
Certified Health IT:	170.315(b)(1), 170.315(b)(2), 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)(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 or the system.

Standards Updates (Including Standards Version Advancement Process (SVAP) and United States Core Data for Interoperability (USCDI))

Standards Updates (SVAP and USCDI)	
Standard (and version)	USCDI V1
Date of ONC-ACB notification	12/27/2022
Date of customer notification (SVAP only)	N/A
USCDI – update criteria	b1, b2, e1, f5, g9
Health IT Moduel CHPL ID	15.02.05.1086.AMEM.01.01.1.220217
Method used for standard update	Cures Update
Conformance measure	Transition of Care - for b1 Clinical Information Reconciliation and Incorporation - for b2 View download transmit 3rd party - for e1 Transmission to Public Health Agencies - Electronic Case Reporting - for f5 Application access all data - for g9
USCDI updated certification criteria (USCDI version)	b1, b2, e1, f5, g9 - USCDI V1

Measures and Approach

All measures conducted in an ambulatory clinical setting specifically our typical clinicians range from Neurosurgical, Family Practice, Integrative Medicine, and Naturopathic Clinicians.

Associated Criteria	Approach	Expected Outcomes	Additional Relied Upon Software	Justification
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	EMR Direct	To gage the ability and verify if information is sent and received to determine information is available to health professionals when needed.
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	N/A	To measure the accuracy and completeness of the most recent information is available to health professionals when needed.

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.	N/A	To measure clinical quality measures being documented and available to external users.
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	N/A	To measure clinical quality measures being available to internal users.
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	N/A	To measure clinical quality measures being reported and available.
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	N/A	To measure the accuracy and availability of data being available for viewing, downloading and transmission to 3rd parties.
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	N/A	To measure the availability of immunization data being transmitted to appropriate registries.

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	N/A	To measure the availability of health data being transmitted to appropriate health agencies electronically
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	EMR Direct	To measure and assure patient access to data
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	EMR Direct	To measure health data being available to appropriate applications without specific criteria making all data available
170.315 (g)(10) – Standardized API for patient and population services	Allow access to standardized API facilitating data transfer	Review if applicable parties are able to gain access with a > 1% error rate.	EMR Direct	To measure health data being available to API applications
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	EMR Direct	To measure health data being available to appropriate users using direct messaging functionality

Based on our selected criteria. The analysis will be 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 will be the determining factor of success or failure of the test.

For criteria based on patient portal and patient access, the analysis will be conducted 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 will review the total number of data sets sent, received, transmitted or reported depending on the measure. Only expected measures with controllable outcomes will be reviewed and reported. Patient access is a measure where granting access and not gaining access will be the determining factor. Other factors could inhibit gaining access to the EHR outside the boundaries of the system. (i.e., Internet access, lost passwords etc.)
Other analysis will be 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 should be reviewed to determine processed data between entities or expected outcomes in reporting or access controls.

Key Milestones

Milestone	Date/Timeframe
Real World Test Plan Submission	November 14, 2023
Submit call to action for prospected providers for testing	January 2024
Submit test results for testing	January 15, 2024
Start phased approach implementing testing and analysis	April – June 2024
Review and analyze data based on testing results	July - September 2024
Report findings of Real World Testing to ACB	October 1, 2024
Submit Real World Testing Plan	November – 2024
Submit test results for testing	January 15, 2025

All milestones, testing and analysis will be conducted within an ambulatory/ clinic care setting. Helios is only provided to these types of clinicians and illustrates our only customer base. All certified measures are also only provided to these types or providers in this type of care setting.

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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