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Real World Test Results

Aura - Sigmund, Medicfusion & Versaform

For Criteria: §170.315 (b)(1), §170.315 (b)(2), 170.315(b)(6), §170.315 (e)(1), §170.315 (g)(7), §170.315 (g)(8), and §170.315 (g)(9)

GENERAL INFORMATION

Plan Report ID Number: VSS Medical RWT November 15 2021

Developer Name: VSS Medical Technologies, LLC

Product Name(s): Aura Sigmund, Aura Medicfusion & Aura Versaform

Version Number(s): 5.0, 5.1

Certified Health IT: 15.04.04.2848.Aura.04.00.0.181001

Product List (CHPL) ID(s): 15.04.04.2848.Aura.04.00.0.181001

Developer Real World Testing Page URL:
https://www.sigmundsoftware.com/privacy-certifications/

SUMMARY OF TESTING METHODS AND KEY FINDINGS (ALIGNS WITH RWT PLAN SECTION: JUSTIFICATION FOR REAL WORLD TESTING APPROACH)

The Certified Health IT module, Aura Sigmund, Aura Medicfusion & Aura Versaform in 2022 were sold by VSS Medical Technologies, LLC as an Ambulatory Care Electronic Health Record (EHR) Software application. It is used in the specialties of Behavioral Health and Healthcare Practices (i.e. Internal Medicine and Chiropractic Medicine)

The applicable 2015 Edition criteria that we will include in our Real World Test Results are:

Table 1

§170.315 (b)(1)	§170.315 (b)(2)
§170.315 (b)(6)	§170.315 (e)(1)

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These criteria were tested individually during the ONC certification process. However, in the real world these certified modules provide one seamless approach to accomplish the clinical and administrative documentation requirements and incorporate the features and functions of all of the criteria mentioned in Table 1. To that end, the Real World Test plan was designed to demonstrate how these combined certified criteria perform in the production environment. The certified product is deployed in multiple settings and specialties within the marketplace, but the majority of them do not utilize the capabilities. In 2021, interest in Cures and interoperability was minimal; in very late 2022 we found that changed. However, we had already scheduled all RWT sessions for the year already and the team was focused in other areas. As a result, we performed two test sessions that will be detailed below with our one customer that had resources dedicated towards cures and could prioritize staff for scheduled tests. We expect that to change in 2023 as there is interest in cures across all our specialties now.

There were no non-conformities found in the testing. We observed the customer was new to these capabilities, and does not use them in their daily workflows. As a result, we had to provide guidance in how to use the capabilities, and explain their purpose(s).

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI))

[X] NO, NONE OF MY PRODUCTS INCLUDE THESE VOLUNTARY STANDARDS.

Standard (and version)	N/A
Updated certification criteria and associated product	N/A
Health IT Module CHPL ID	N/A
Method used for standard update	N/A
Date of ONC-ACB notification	N/A
Date of customer notification (SVAP only)	N/A
Conformance measure	N/A

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USCDI-updated certification criteria (and USCDI version)	N/A

CARE SETTINGS, METRICS AND OUTCOMES

CARE SETTING(S)

Care Setting	Tested Care Settings
Facilities: • Ambulatory Specialties: • Behavioral Health • Internal Medicine • Chiropractic Medicine	Two test sessions were performed with one of our largest Behavioral Health Customers.

MEASURES USED IN OVERALL APPROACH

DESCRIPTION OF MEASUREMENT/METRIC

Describe the measure(s) that will be used to support the overall approach to Real World Testing.

The Measure/Metrics and the Descriptions listed below will apply to the simultaneous and seamless use of the functionality of the applicable certified measures mentioned in Table 1. The RWT will be witnessed via Microsoft Teams session with the participants (current customers) using a mirrored production environment and real patient data. Upon completion we will observe and report the successful conformance of our customers using the certified technology as it was designed, to be able to complete the applicable 2015 Edition Certified criteria listed in Table 1 above.

The Measure/Metrics and Descriptions for Measures 1 - 4 listed below will apply to multiple criteria simultaneously to demonstrate the functionality of these certified measures: § 170.315(b)(1) Transitions of care (Receive), § 170.315(b)(2) Clinical Information Reconciliation and Incorporation, § 170.315(b)(1) Transitions of care (Send), § 170.315 (e) (1)

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View, Download and Transmit to 3rd party.

The Measure/Metrics and Descriptions for Measures 5 - 7 will apply to § 170.315(b)(6) Data export.

Measurement/Metric	Description
Measure 1: Clinician logs into Aura and receives a C-CDA from a referring provider via Direct Protocol with no Tech Support and no errors. C-CDA has demographic information adjusted so PHI is not visible. Successful receipt of C-CDA is achieved and observed.	Clinician begins a new patient encounter in the Aura certified software with a patient referred by another clinician. With a preconfigured NewCrop Direct Address the clinician can seamlessly and securely receive a C-CDA from the referring clinician using the Direct Protocol. The Common Clinical Data Set standard will be demonstrated in these transactions through screenshots collected. Log files are also captured. These will all show the successful receipt of the C-CDA with all fields completed and arranged per provider preference. This will meet § 170.315(b)(1) (Receive).
Measure 2: The C-CDA is validated, and Clinical Information Reconciliation is performed. No errors are expected.	After successful receipt of the C-CDA, the clinician validates the C-CDA within Aura. Clinical information reconciliation for medication, medication allergy, and current problem list is performed using Aura software. Common Clinical Data Set standard will be demonstrated in these transactions through screenshots collected. Log files demonstrate the reconciliation. This will meet § 170.315(b)(2).
Measure 3: Updated C-CDA is sent back to referring partner. Successful sending of CCDA is achieved and observed.	Clinician sends updated C-CDA with minimal delay back to referring clinician via Direct Protocol. Updated C-CDA is also sent to the patient portal. Confirmation of sent C-CDA is captured along with log files. This will meet § 170.315(b)(1) (Send).
Measure 4: Access via patient portal - Observation of the View, Download & Transmit functions is performed. This will demonstrate the portal as a key tool for the clinician to share the patient's most current health information with the patient.	Real-time patient data will be adjusted to protect PHI before Measure 5 is completed. A patient will have access to patient portal to view encounter summaries of their choice as human readable C-CDAs and download the C-CDA without assistance. Transmission of patient data will be sent to a provider (Edge Protocol) and a standard email address. This will meet § 170.315 (e)(1).
Measure 5: A selected practice staff member is observed successfully exporting bulk patient data files on demand.	Authorized office practice staff member will perform an export of data from the production server in real-time (on demand) with a specific start & end date immediately. This will be done without delay and sent to a specific file location decided by the staff member. This will be accomplished efficiently and with no error and the file will be inspected when received to ensure it is the file requested. Real world data will be used but demographic information will be changed to protect patient health information. This measure allows the capture of report data selected by and on demand without assistance from development staff. The ability to independently create reports is vital to office practices and integral to a certified EHR. VSS Medical staff will verify the reports have been created

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	successfully with requested data and sent to specific location through screenshots.
Measure 6: a selected practice staff member is successfully exporting a file at a single delayed time - with a specific start and end date in the future.	An authorized office staff member will perform a data export data in the future - 5 minutes from current time - from the production server with a scheduled specific start & end date -such as November 1 - November 2, 2021.This will be accomplished efficiently and with no error and the file will be inspected when received to ensure it is the file requested. This measure allows the staff member to select a time in the future without assistance from development staff. The ability to independently create reports is vital to office practices and integral to a certified EHR. VSS Medical staff will verify the reports have been created successfully and sent to a specific file location with requested data through screenshots.
Measure 7: A selected practice staff member sets an export for a delayed future time during hours after the practice is closed and is able to run successfully. This scheduled event will repeat as scheduled.	An authorized staff member sets up a specific data export to run after the practice is closed. This measure allows the capture of report data selected by and on demand without assistance from development staff. The ability to independently create reports is vital to office practices and integral to a certified EHR. VSS Medical staff will verify the reports have been created successfully with requested data and sent to specific location with screenshots that capture the activity. At the finish of Measure 9 § 170.315(b)(6) Data export will be satisfied.

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ASSOCIATED CERTIFICATION CRITERIA

Measurement/Metric	Associated Certification Criteria
Measures 1 -4 will be completed in one session.	
Measure 1	§ 170.315(b)(1) Transitions of care – Receive
Measure 2	§ 170.315(b)(2) Clinical Information Reconciliation and Incorporation
Measure 3	§ 170.315(b)(1) Transitions of care – Send
Measure 4	§ 170.315 (e)(1) View, Download and Transmit to 3rd party
Measures 5 - 7	§ 170.315(b)(6) Data export

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EXPECTED OUTCOMES

Measurement/Metric	Expected & Actual Outcomes
§ 170.315(b)(1) Transitions of care (Receive)	The Real World Testing will demonstrate that the clinician can receive C-CDA R2.1 C-CDA Document payload type in an the designated setting. Using the Edge Protocol SMTP protocol. Both Referral Notes and Discharge Summaries will be evaluated. The received document will be evaluated for the ability to: • Receive and validate and display any recorded errors if not a valid C-CDA documents. • Parse and present a pre-configured human readable display of all Common Clinical Data Set data from the relevant C-CDA formatted to the CCDS standard. Aura compliant with standards for these criteria and vocabulary code sets in all of these measures. Actual/Outcomes and Results: On 2 separate test dates we had 1 user receiving all expected outcomes.
§ 170.315(b)(2) Clinical Information Reconciliation and Incorporation	The Real World Testing will demonstrate that the receiving clinician will be able to validate the C-CDA, compliant to the Common Clinical Data Set, perform reconciliation successfully for medication, medication allergy and problems at any time without delay and create an updated C-CDA, compliant to the Common Clinical Data Set, as required to demonstrate EHR exchange of information and interoperability. Actual/Outcomes and Results: On 2 separate test dates we had 1 user receiving all expected outcomes.
§ 170.315(b)(1) Transitions of care (Send)	The Real World Testing will demonstrate that the clinician can send R2.1 C-CDA Referral Notes and Discharge Summaries compliant to the Common Clinical Data Set using the SMTP Edge Protocol. We will successfully validate the receipt of the sent documents. Actual/Outcomes and Results: On 2 separate test dates we had 1 user receiving all expected outcomes.

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§ 170.315 (e) (1) View, Download and Transmit to 3rd party	The Real World Testing will demonstrate that the clinician can enable patients (and their authorized representatives) to view, at a minimum, the Common Clinical Data Set; laboratory test report(s); and diagnostic image reports. Enable patient (and their authorized representative) to view for health information filtered by a specific date and date range. Enable patient (and their authorized representatives) to download an ambulatory or inpatient summary (as applicable to setting) in the following formats: • Human readable format • Format C-CDA document summary will include, at a minimum, the Common Clinical Data Set; laboratory test report(s); diagnostic image reports. For all settings, patients (and their authorized representatives) will be able to transmit the C-CDA summary through both: ○ Email transmission to any email address ○ The Edge protocol of electronic transmission • When transmitted, the ambulatory or inpatient summary will be compliant to the Common Clinical Data Set; laboratory test report(s); diagnostic image reports; and: • Enable patient (and their authorized representative) to download for health information filtered by a specific date and date range. For all view, download, and transmit capabilities, the following information will be recorded and made accessible to the patient (and authorized representative): ○ The action that occurred ○ The date and time each action occurred ○ The user who took the action; and the addressee to whom the summary was transmitted Actual/Outcomes and Results: On 2 separate test dates we had 1 user receiving all expected outcomes.
§ 170.315(b)(6) Data export	The Real World Testing will demonstrate that a limited clinician group are enabled to set the configuration options when creating an export summary as well as a set of export summaries for patients whose information is stored in Aura. A clinician within the limited group is able to execute these capabilities at any time the user chooses and without subsequent developer assistance to operate. The limited set of clinicians are enabled to create export summaries formatted in accordance with the standard specified using the C-CDA that is compliant to the Common Clinical Data Set. The limited set of clinicians are enabled to set the date and time period (Start and End Dates) within which data would be used to create the export summaries. They can: ○ Create export summaries in real-time ○ Create export summaries based on a relative date and time (e.g., the first of every month at 1:00am)

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	○ Create export summaries based on a specific date and time (e.g., on 10/24/2015 at 1:00am) The limited set of clinicians are enabled to set the storage location to which the export summary or export summaries are intended to be saved. Actual/Outcomes and Results: On 2 separate test dates we had 1 user receiving all expected outcomes.

KEY MILESTONES

Key Milestone	Care Setting	Date/Timeframe
Prepare the Aura application for use in collecting data to support the RWT plan. Result: Was completed during the planned time frame.	Facilities: • Ambulatory Specialties: • Behavioral Health • Internal Medicine • Chiropractic Medicine	December 2021
Identify the user practices the will participate in the test plan Result: Was completed in November before planned time frame.	Facilities: • Ambulatory Specialties: • Behavioral Health • Internal Medicine • Chiropractic Medicine	January & February 2022
Confirm that the Real World Test Plan participants are able to log into their accounts and are ready to start the RWT plan documentation Result: Was completed during the planned time frame.	Facilities: • Ambulatory Specialties: • Behavioral Health • Internal Medicine • Chiropractic Medicine	March 2022

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Conduct the series of Real World Testing with the participants on a regular basis (minimum, once a quarter) to obtain feedback on their progress and or if there are any issues to address. Result: Was completed during the planned time frame in March and July. Due to unexpected production issues generating heavy Development and IT support demands, and no changes to the technology being tested. As well as two successful test sessions. We decided to defer the last two sessions of the year.	Facilities: • Ambulatory Specialties: • Behavioral Health • Internal Medicine • Chiropractic Medicine	Quarterly 2022
End the Real World Test to coincide with the end of the year. Result: Was completed during the planned time frame.	Facilities: • Ambulatory Specialties: • Behavioral Health • Internal Medicine • Chiropractic Medicine	December 2022
Real World Test analysis and generation of the report Result: Was completed during the planned time frame.	Facilities: • Ambulatory Specialties: • Behavioral Health • Internal Medicine • Chiropractic Medicine	January 2023
Submit Real World Test Report to ACB before established deadline Result: On track to complete during the planned time frame.	Facilities: • Ambulatory Specialties: • Behavioral Health • Internal Medicine • Chiropractic Medicine	February 2023

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CHALLENGES ENCOUNTERED

As a small company the main challenge of this activity is diverting resources from other tasks to work on this occasional activity. Another challenge was finding customers that use the certified technology and/or were interested/willing to assist with testing.