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2024 Real World Test Results

Aura – Sigmund and MedicFusion Erx

For Criteria: §170.315 (b)(1), §170.315 (b)(2), §170.315 (b)(3), 170.315(b)(6), §170.315 (e)(1), §170.315 (f)(1), §170.315 (f)(2), §170.315 (f)(5)

GENERAL INFORMATION

Plan Report ID Number: VSS Medical RWT November 15,2023

Developer Name: VSS Medical Technologies, LLC

Product Name(s): Aura Sigmund, MedicFusion Erx

Version Number(s): 5.04, 5.05, 5.06

Certified Health IT: 15.04.04.2848.Aura.05.03.1.230731

Product List (CHPL) ID(s): 15.04.04.2848.Aura.05.03.1.230731

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

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Currently the Certified Health IT module Aura Sigmund & MedicFusion Erx are 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 plan are:

Table 1

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§170.315 (b)(1) Cure Update	§170.315 (b)(2) Cures Update
§170.315 (b)(3) Cures Update	§170.315 (b)(6)
§170.315 (e)(1) Cures Update	§170.315 (f)(1) Transmission to immunization registries
§170.315 (f)(2) Transmission to public health agencies — syndromic surveillance	§170.315 (f)(5) Transmission to public health agencies — electronic case reporting

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 will be 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 C-CDA capabilities and no one uses direct messaging, additionally no customers use any of the newly added (f)(x) criteria in 2024. In 2024, customer interest/inquiries in using Cures and interoperability was rare; with only a few exceptions via sales inquiries.. As a result we prioritized internal testing for the capabilities not used by any customers. Two internal testing session were performed 2024(October and December). One exception is (b)(3) where we have production data that can be mined to show usage and performance of that module.

There were no non-conformities found in the C-CDA generation and (f)(1,2,5) criteria. In our October test session we identified direct email was not working. This issue was resolved by reregistration of our test accounts; no code change required. Direct email is unused by customers, and they were not effected. ERx (b)(3) Results were nearly identical to 2023; we had one out of scope exemption with a larger than expected CancelRx error rate in just 1 of the 3 Customer DBs sampled in the 4th quarter only. We have opened an investigation of the CancelRx anomaly, and will escalate it if that rate continues in 2025.

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

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
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	Erx data was mined from 3 of our Erx higher volume Behavioral Health Customers. Criteria unused by customers was tested internally.

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.

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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 was preformed using a mirrored production environment with deidentified 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 - 5 listed below will apply to multiple criteria simultaneously to demonstrate the functionality of these certified measures: § 170.315(b)(1) Transitions of care (Cures Update) (Receive), § 170.315(b)(2) Clinical Information Reconciliation and Incorporation (Cures Update), § 170.315(b)(3) Electronic Prescribing (Cures Update), § 170.315(b)(1) Transitions of care (Cures Update) - (Send), § 170.315 (e) (1) View, Download and Transmit to 3rd party (Cures Update).

The Measure/Metrics and Descriptions for Measures 6 - 8 will apply to § 170.315(b)(6) Data export. The Measure/Metrics and Descriptions for Measures 9 will apply to § 170.315(f)(1) Transmission to immunization registries. The Measure/Metrics and Descriptions for Measures 10 will apply to § 170.315(f)(2) Transmission to public health agencies — syndromic surveillance. The Measure/Metrics and Descriptions for Measures 11 will apply to § 170.315(f)(5) Transmission to public health agencies — electronic case reporting. *Note for Measures other than 3: These technologies are unused or not currently deployed to any customers in 2024. Therefore, the plan was be executed with in internal testing only for these measure.

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) (Cures Update) (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

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	these transactions through screenshots collected. Log files demonstrate the reconciliation. This will meet § 170.315(b)(2) Cures Update) .
Measure 3: The ability to review and approve a prescription refill requests and to create and transmit a new e-Prescriptions. No errors are expected.	The clinician easily completes the review and renewal of a refill request and to create and transmit a new prescription electronically within appropriate location in the EHR software to meet 170.315(b)(3) Cures Update) by completing the appropriate fields in the EHR.
Measure 4: 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) (Cures Update) (Send).
Measure 5: 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) (Cures Update).
Measure 6: 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 successfully with requested data and sent to specific location through screenshots.
Measure 7: 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, 2024.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 8: 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 8 § 170.315(b)(6) Data export will be satisfied.

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Measure 9: a selected practice staff member is successfully able to create and submit an Immunization record for a patient.	The staff member can easily complete the review of an immunization record and then successfully submit the Immunization Record to a registry in the EHR software to meet 170.315(f)(1) Transmission to immunization registries by following the documented workflow.
Measure 10: a selected practice staff member is successfully able to create and submit a syndrome-based public health surveillance information record for a patient.	The staff member can easily create syndrome-based public health surveillance information record and then successfully submit the record to a public health agency in the EHR software to meet 170.315(f)(2) Transmission to public health agencies — syndromic surveillance.
Measure 11: a selected practice staff member is successfully able to review patients that have triggered electronic case reporting criteria and create and submit a case report for a patient.	The staff member can easily complete the review patients that have triggered electronic case reporting criteria and then successfully create and submit the Case Report in the EHR software to meet 170.315(f)(5) Transmission to public health agencies — electronic case reporting.

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ASSOCIATED CERTIFICATION CRITERIA

Measurement/Metric	Associated Certification Criteria	Relied Upon Software
Measures 1 -5 will be completed in one session.		
Measure 1	§ 170.315(b)(1) Transitions of care (Cures Update) - Receive	NewCrop – Edge Protocol
Measure 2	§ 170.315(b)(2) Clinical Information Reconciliation and Incorporation	NewCrop – Edge Protocol
Measure 3	§ 170.315(b)(3) Electronic Prescribing	N/A
Measure 4	§ 170.315(b)(1) Transitions of care (Cures Update) - Send	NewCrop – Edge Protocol
Measure 5	§ 170.315 (e)(1) View, Download and Transmit to 3rd party (Cures Update)	NewCrop – Edge Protocol
Measures 6 - 8	§ 170.315(b)(6) Data export	N/A
Measure 9	§ 170.315(f)(1) Transmission to immunization registries	N/A
Measure 10	§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance	N/A
Measure 11	§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting (Cures Update)	N/A

EXPECTED OUTCOMES

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Measurement/Metric	Expected Outcomes
§ 170.315(b)(1) Transitions of care (Cures Update) (Receive)	The Real World Testing will demonstrate that the clinician can receive C-CDA R2.1 C-CDA Document payload type in 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 test date user received all expected outcomes. With 0% error rate.
§ 170.315(b)(2) Clinical Information Reconciliation and Incorporation (Cures Update)	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 test date user received all expected outcomes. With 0% error rate.
§ 170.315(b)(1) Transitions of care (Cures Update (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 test date user received all expected outcomes. With 0% error rate.
§ 170.315(b)(3) Electronic Prescribing	The Real World Testing will demonstrate that the clinician can perform the following prescription-related transactions in accordance with established required standard as follows: • Create new prescription with full sig • Change prescriptions Transmit to pharmacy of choice and receive notification of success. A 0% error rate is expected. Expected outcomes will include the following data points: total number of events tested, number of passed (i.e. successful) events, number of failed events, and a success rate expressed in

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_____ _____	percentage (successes / total number of events). A 95% completion success rate is expected within the established normal time (usually under 30 seconds) to complete each function. As detailed in this plan under the "Schedule of Key Milestones" section, each measure/metric will be tested at least once a quarter with our clinician RWT groups to ensure the expected outcomes are reliably attained Actual/Outcomes and Results: 3 Customer DBs were analyzed for ERx performance results from 1/1/2024 to 12/31/2024. NewRx volume across DBs 20050, 36251, 13124 and the corresponding error rate percentage was 0.33%, 0.42%, 0.87%. ChangeRx volume across DBs 24, 600, 125 and the corresponding error rate percentage was 0%, 0%, 0%. Therefore the results are well within expected outcome metrics. We did document and are tracking an out of scope potential issue with CancelRx in one of the Customer DBs.

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§ 170.315 (e) (1) View, Download and Transmit to 3rd party (Cures Update)	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 test date user received all expected outcomes. With 0% error rate.
§ 170.315(f)(1) Transmission to immunization registries	The Real World Testing will demonstrate that the clinician can create and submit an Immunization record for a patient. A 0% error rate is expected. Expected outcomes will include the following data points: total number of events tested, number of passed (i.e. successful) events, number of failed events, and a success rate expressed in percentage (successes / total number of events). A 95% completion success rate is expected. As detailed in this plan under the "Schedule of Key Milestones" section, each measure/metric will be tested at least once a year with our clinician RWT groups to ensure the expected outcomes are reliably attained. Actual/Outcomes and Results: On test dates user received all expected outcomes. With 0% error rate.

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§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance	The Real World Testing will demonstrate that the clinician can create and submit a syndrome-based public health surveillance information record for a patient. A 0% error rate is expected. Expected outcomes will include the following data points: total number of events tested, number of passed (i.e. successful) events, number of failed events, and a success rate expressed in percentage (successes / total number of events). A 95% completion success rate is expected. As detailed in this plan under the "Schedule of Key Milestones" section, each measure/metric will be tested at least once a year with our clinician RWT groups to ensure the expected outcomes are reliably attained. Actual/Outcomes and Results: On test dates user received all expected outcomes. With 0% error rate.
§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting	The Real World Testing will demonstrate that the clinician is successfully able to review patients that have triggered electronic case reporting criteria and create and submit a case report for a patient. A 0% error rate is expected. Expected outcomes will include the following data points: total number of events tested, number of passed (i.e. successful) events, number of failed events, and a success rate expressed in percentage (successes / total number of events). A 95% completion success rate is expected. As detailed in this plan under the "Schedule of Key Milestones" section, each measure/metric will be tested at least once a year with our clinician RWT groups to ensure the expected outcomes are reliably attained. Actual/Outcomes and Results: On test dates user received all expected outcomes. With 0% error rate.
§ 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) ○ 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 test dates user received all expected outcomes. With 0% error rate.

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CHALLENGES ENCOUNTERED

Diverting resources from other tasks to work on these RWT criteria remains challenging. Another challenge is finding customers who use the certified technology and are willing to assist with testing these unused criteria.