Real World Testing Plan

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General Information	
Plan Report ID#:	20221208ast
Developer Name:	Astronaut LLC
Product Name:	Astronaut
Version Number:	1709
Product List (CHPL) ID	15.02.05.3099.ASTR.01.00.1.220201
Certified Health IT:	170.315 (a)(1), 170.315 (a)(2), 170.315 (a)(3), 170.315 (a)(4), 170.315 (a)(5), 170.315 (a)(9), 170.315 (a)(12), 170.315 (a)(14), 170.315 (b)(1), 170.315 (b)(3), 170.315 (b)(6), 170.315 (c)(1), 170.315 (d)(1), 170.315 (d)(2), 170.315 (d)(3), 170.315 (d)(4), 170.315 (d)(5), 170.315 (d)(6), 170.315 (d)(7), 170.315 (d)(8), 170.315 (d)(9), 170.315 (d)(12),

	170.315 (d)(13), 170.315 (e)(3), 170.315 (g)(3), 170.315 (g)(4), 170.315 (g)(5), 170.315 (g)(6), 170.315 (g)(7), 170.315 (g)(8), 170.315 (g)(9), 170.315 (h)(1)
Developer Real World Testing Page URL:	https://astronautehr.com/index.php/real-wo rld-test-plan/
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Real World Testing Approach and Methodology

Astronaut is a browser-based Electronic Health Record system for use in a medical setting with an emphasis on psychiatry. The goal is to demonstrate effective methods of charting patients so that physicians can spend more time with clients and less time bogged down by inefficient technological software. In addition, Astronaut strives to provide reliability, security, and accessibility, so that authorized users can access charts effectively. Methodology and functionality used is consistent with the certified criteria established and certified to the ONC-ACB on Feb 1, 2022. Regarding interoperability, data exportation and direct messaging is exercised using a C-CDA format and is carried out on a patient-by-patient basis. Real world testing is determined by the scenarios in the test plan as well as the software's use in Blue Bonnet Clinic, a psychiatric office that has used Astronaut for years, as well as a few other clinics in the healthcare field. Astronaut continuously utilizes the feedback of its users to add features relevant to real-world use while remaining compliant with government regulations as well as implementing dependable testing methods.

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

Standards Updates (SVAP and USCDI)	
Standard (and version)	N/A
Date of ONC-ACB notification	N/A
Date of customer notification	N/A
USCDI – update criteria	N/A

Measures, Criteria, Relied Software, and Description

Measure Name	Associated Criteria	Relied Upon Software	Description of Metric
Transitions of Care	170.315 (b)(1)	N/A	The software can send and receive transitions of care/referral summaries. The software can also create a C-CDA that includes relevant information.
Electronic Prescribing (Cures Update)	170.315 (b)(3)	NewCropRx	A user can send, receive, and view prescriptions electronically (per the NCPDP SCRIPT Standards). Prescription data is also properly displayed as per the criterion listed.
Data Export	170.315 (b)(6)	Putty	The software can send all required patient data for a specific data range specified. The export function is limited to authorized users. Users can configure export summaries using the CCD template.
Clinical Quality Measures - Record and Export	170.315 (c)(1)	N/A	The software must be able to record all data necessary to calculate CQMs for certification. The exported files can be formatted in accordance with the HL7 QRDA standard.
Application Access - Patient Selection	170.315 (g)(7)	N/A	The technology must be able to receive a request with sufficient information to uniquely identify a patient and return an ID or token.
Application Access - All Data Requests	170.315 (g)(9)	N/A	The system responds to requests for patient data (based on an ID or other token) for all of the data classes expressed in the standards at one time. The system also returns such data in a summary record formatted in accordance with the CCD document template.
Direct Project	170.315 (h)(1)	NewCropRx	Able to send and receive health information in accordance with the standard specified for certification.

Justification for Selected Measures

Associated Criteria - Measure Name	Justification
170.315 (b)(1) - Transitions of Care	Transferral of care and referral summaries are often used when it comes to patient's who are switching their clinic. Having the ability to create a C-CDA of a profile aids this process.
170.315 (b)(3) - Electronic Prescribing (Cures Update)	Having electronic prescriptions (NewCropRx) assists the doctor and allows him/her to have more time to spend with the patient. This results in streamlining the process of prescribing medication.
170.315 (b)(6) - Data Export	Exporting patient data is necessary at times, especially when working with a third-party or when the patient is requesting the data themselves. Being able to export patient data also allows an effective way to send information to providers outside of the Astronaut network.
170.315 (c)(1) - Clinical Quality Measures - Record and Export	Astronaut must be able to record necessary data to calculate CQMs that are required for certification in a format that is understandable for the entities involved (HL7 QRDA).
170.315 (g)(7) - Application Access - Patient Selection	Having a unique ID for each patient is essential as it prevents a provider from mixing up patient files, and also allows the system administrator to extract chosen data using a unique patient ID for criteria "(g)(9)".
170.315 (g)(9) - Application Access - All Data Requests	Using the patient's unique ID, extraction of a lump summary of data structured in CCD format is essential so that all relevant data classes are accessible.

170.315 (h)(1) - Direct Project	Being able to send and receive health data in accordance with the standards for the relevant criterion is necessary as there are criteria that are dependent on the ability for health data extraction.
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Care Settings

Care settings for Astronaut are as follows: **Inpatient and Outpatient Clinics/Hospitals.** These care settings can be justified because Astronaut has been developed with the ability to cater to the needs of both inpatient and outpatient facilities. The features of Astronaut allow these types of facilities to conduct their day-to-day operations in an effective manner. In addition, the system also carries certain features that will help streamline the process of entering/extracting patient health data and prescribing medications.

Expected Outcomes

Clinicians, such as therapists and psychiatrists, as well as authorized office staff will utilize the effectiveness of the software and will ensure the expected outcomes are met.

Associated Criteria - Measure Name	Expected Outcomes
170.315 (b)(1) - Transitions of Care	These features are present in the system and follow the relevant certification protocols. Summaries are consistently produced with a <1% error rate.
170.315 (b)(3) - Electronic Prescribing (Cures Update)	Prescriptions are sent through Newcrop and are pulled back into Astronaut for easy viewing. Prescriptions display accurately and update properly when changes are made in Newcrop's E-Prescribing system with a <1% error rate.
170.315 (b)(6) - Data Export	Export functionality is present and contains the data specified in the criterion. The file is configured for interoperability and is accessible based on the authorized user's needs. The exporting functionality is aimed to have an error rate of <1%.

170.315 (c)(1) - Clinical Quality Measures - Record and Export	Astronaut can export relevant data reliably in a format that fits with the criterion for certification. Exporting the data should be reliable and will have an error rate of <1%.
170.315 (g)(7) - Application Access - Patient Selection	Every patient created has a unique ID that can be identified in their demographics file. Because of the way the system is configured, the error rate for this should be less than or extremely close to 0.00001%. Any anomalies will be immediately identified and corrected by IT staff.
170.315 (g)(9) - Application Access - All Data Requests	The API responds to requests for patient data for all of the data categories specified in the USCDI at one time in a summary record formatted according to the C-CDA template. Patient data requests should have an error rate of <1%.
170.315 (h)(1) - Direct Project	The health IT can electronically transmit (send and receive) health information to a 3rd party in the proper format and following the criteria required for certification. Transmitting this data is aimed to have an error rate of <1%.

To analyze the proper outcomes, we will commence with both white-box and black-box testing when applicable. In addition, we use dynamic testing methods such as creating fictional profiles to demonstrate some of the Health IT software's abilities that are relevant for certification. Printed XMLs will provide us a properly formatted exportation of a patient's information that matches the gold standard set by the certification entities.

Analysis of security is done by ensuring the system is using proper tokens when accessing patient data. Auditing user activity is an important feature to prevent misuse of the system, and these audits can be displayed intuitively when needed. Administrators will also be able to review the data sent, received, and transmitted. Providers are trained for proper use of the system and are held accountable for their actions and their use of the system.

Any other analysis that uses accuracy metrics is undergone by analyzing the data and ensuring the error rate is as close to 0% as possible. Any bugs that are discovered will be immediately addressed by the team of programmers and system administrators. Physicians and staff that use the software also provide valuable feedback regarding manual testing/day-to-day use of the software for the activities that are relevant to their clinical duties.

Key Milestones

Milestone	Timeframe
Real World Test Plan Submission	December - 2022
Submit call to action for prospected providers for testing	January - 2023
Start phased approach implementing testing and analysis	April – June 2023
Review and analyze data based on testing results	July - September 2023
Report findings of Real World Testing to ACB	October 1, 2023
Submit Real World Testing Plan Module 2	October - 2023

Milestones will be conducted within an inpatient/outpatient care setting. Users include authorized staff, physicians, therapists, and IT/System Administrators.

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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Date: 12/6/2022