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GENERAL INFORMATION

Developer Name: CareVue, a Division of Medsphere Systems Corporation

Product Name(s): CareVue

Version Number(s): CareVue v.2.1

Product List (CHPL) ID(s): CareVue - 15.04.04.2806.Open.02.02.1.221222

ONC-ACB Certification ID: CareVue - 15.04.04.2806.Open.02.02.1.221222

Developer Real World Testing Page URL:
https://www.medsphere.com/certifications/RealWorldTesting/CareVue

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

At this time, CareVue is marketed to the small rural inpatient hospital systems. Therefore, the Real World Testing plan will apply to this care setting. We feel it is best to test functionality as a whole workflow rather than by individual measure as this is how it is utilized in the real world. Our Real World Testing approach will consist of five main components, Electronic exchange of information for Care Coordination and Patient Engagement, E-Prescribing, Clinical Quality Measures and Population Health, and Application Programming Interfaces.

Electronic exchange of information for Care Coordination and Patient Engagement

CareVue has developed functionality and created a best practice workflow around sending, receiving, reconciling, and exporting electronic health information. This workflow will allow us to test several certification criteria simultaneously. All criteria involving the Consolidated Clinical Documentation Architecture (C-CDA) documents will be tested, including 170.315(b)(1) Transitions of Care, 170.315(b)(2) Clinical Information Reconciliation and Incorporation, 170.315e(1) View, download, and transmit to 3rd party, Data Export and 170.315(h)(1) Direct Project.

Additionally, CareVue has the ability to export electronic health information for single patients and bulk which is key piece in the interoperability of the data. The methods involved in these exports will be tested to ensure that functionality is working as intended and certified through 170.315 (b)(10) Electronic Health Information Export.

Electronic Prescribing

CareVue has also developed functionality for e-prescribing. It is in our best interest to supply our users with the tools needed to provide fast and efficient mechanisms for patient care. We feel that it is vital to be able to monitor the transmissions of e-prescription activity flowing from the facility to the pharmacy. This plan incorporates the testing of 170.315(b)(3) e-Prescribing.

Clinical Quality Measures

To allow eligible hospitals to submit data related to their Clinical Quality Measures, we have developed functionality that enables users to create and export QRDA files and submit them. We also understand that QRDA files may only be created during 1st quarter of each calendar year due to when clients are submitting the data as part of their attestation, so it is anticipated that our Real World Testing Plans would be most active during Q1. This plan includes testing of 170.315(c)(1) record and export.

Population Health

As the product is targeted for inpatient hospital systems, in which a wide variety of patient ailments are seen and across multiple populations, we find it important to be able to transmit specific data to these external entities. Being able to efficiently transmit certain clinical information to external specialized registries is foundational to population health. This plan will also incorporate the testing of 170.315(f)(1) Transmission to immunization registries, and 170.315(f)(2), Transmission to public health agencies – Syndromic surveillance, 170.315(f)(3) Transmission to public health agencies – reportable laboratory tests and value/results, 170.315(f)(5) Transmission to public health agencies – electronic case reports, and 170.315(f)(7) Transmission to

public health agencies – health care surveys.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP)

This product has no voluntary SVAP standards updates.

MEASURES USED IN OVERALL APPROACH

The following outlines our measures that have been identified to best demonstrate how our product is in and maintains conformance to multiple certification criteria.

Electronic exchange of information for Care Coordination and Patient Engagement

Measure 1 (Care Coordination Exchange Thresholds and Mechanisms)
As part of the Real World Testing requirements for 170.315(b)(1) Transitions of Care, 170.315(b)(2) Clinical Information Reconciliation and Incorporation, 170.315e(1) View, download, and transmit to 3rd party, Data Export and 170.315(h)(1) Direct Project, this measure will assess the sending and receiving of CCD-A documents, reconciling information received through the CCD-A, the methods of transmission for information shared between providers.

Metric 1 – This metric will determine the thresholds of the types of transport mechanism used to share transitions of care documents and EHI, as well as the success rate of transmission. Associated certification criteria for the electronic exchange of information for Care Coordination and Patient Engagement in the ambulatory care setting include:

Certification Criteria	Associated Criteria	Relied Upon Software
170.315(b)(1) Transitions of Care	Send Transition of care/referral summaries	Surescripts Clinical Direct Messaging
	Receive transition of care/referral summaries	
170.315(b)(2) Clinical Information Reconciliation and incorporation	Reconcile transition of care summary	N/A
170.315(h)(1) Direct Project	Transmit summary using one of the methods of direct exchange	Surescripts Clinical Direct Messaging
170.315(e)(1) View, download and transmit	Download ambulatory summary or inpatient summary using CCD Template	Patient Portal
	Download of transition of care/referral summaries	
	Transmit to third party	

Rationale: The system includes three functionalities of interest transmitting, receiving, and reconciling electronic health information. This metric will provide CareVue with information on the utilization rates of transmissions that are used. We feel that these findings could help us determine utilization rates and help us identify those best practices that we can target those providers with low thresholds in order to reach out to them and provide them logic as to how to increase utilization.

Test Approach 1: De-identifiable data from system logs will be extracted to produce analytic reports that will be reviewed to determine success rates or messages being transmitted and received by Providers.

Expected Outcome(s): It is anticipated that providers will be able to share electronic health information using the methods provided with no limitations and in compliance with the certification criteria, including the technical standards and vocabulary code sets.

Transmission statuses will be tracked and trended over time to determine efficacy utilization rates.

Test Approach 2: Event type actions of download and transmit will be extracted from system logs to determine the frequency rate of patients downloading and transmitting documents.

Expected Outcome: It is expected that patients will be able to view, download and share their information as designed and previously certified. It is also anticipated that patients will be able to transmit using the transmission methods provided with no limitations. The event types within the activity log will be tracked and trended over time ensuring that baseline thresholds are maintained.

Measure 2 (EHI Export)

This measure will capture the number of times a data export was performed for individual patients as well as the frequency for bulk export.

Certification Criteria	Associated Criteria	Relied Upon Software
170.315(b)(10) Electronic Health Information export	Individual export of EHI Bulk export	N/A

Rationale: CareVue gives clinicians and/or internal staff the ability to export electronic health information in bulk as well as individual patients in the event that they need to export the data for any reason.

Test Approach 1: System logs will be used to extract the frequency in which these action types were performed. Frequency and success rates will be monitored and reported on a quarterly basis to the compliance director for review. Overall results for the year will be compiled and submitted on an annual basis. In addition, we will also review support cases to add those requests to the bulk export numbers in the event clients go through support to obtain their data in bulk.

Expected Outcome(s): It is expected that clients and internal staff will be able to perform these actions without limitations. We anticipate higher numbers for the individual export than bulk however, both numbers will be monitored.

Measure 3 (e-Prescribing)

This measure will capture the success rates of electronic prescriptions. We will look at prescription activity logs to determine the number of successful transmissions.

Certification Criteria	Associated Criteria	Relied Upon Software
170.315(b)(3) Electronic Prescribing	Create and transmit prescriptions electronically	NewCrop

Rationale: The transmission of electronic prescriptions is a function within the application that enables providers to send prescriptions to the patient's pharmacy of choice electronically. This allows for a quicker way for prescriptions to reach the pharmacy while alleviating call backs from the pharmacy.

Test Approach: Looking at system logs of prescription activity, we will perform data analytics on the success rate of activity on a quarterly basis.

Expected Outcome: It is anticipated that users will be able to transmit prescriptions electronically without limitations and in compliance with the certification criteria. We do anticipate some failures due to network connectivity issues so we would anticipate a 10% error rate and a 90% success rate.

Measure 4 (Transmission of HL7 messages)
This measure will capture the error rates of HL7 messages being transmitted. Specifically, we will extract the ORU and VXU message types to analyze error rates related to Immunization registries and labs and extract ADT messages to analyze error rates for public health agencies.

Certification Criteria	Associated Criteria	Relied Upon Software

170.315(f)(1) Transmission to Immunization Registries	Transmit VXU message to external entity	Mirth
170.315(f)(2) Transmission to Public Health Agencies – Syndromic Surveillance	Transmit ADT message to public health agency.	Mirth
170.315(f)(3) Transmission to Public Health Agencies – reportable laboratory tests and value/results	Transmit ORU message to external entity	Mirth
170.315(f)(5) Transmission to Public Health Agencies – Electronic Case Reports	Number of electronic case reports generated	N/A
170.315(f)(7) Transmission to Public Health Agencies – health care surveys	Transmit CDA for survey purposes	Mirth

Rationale: CareVue allows clinicians the ability to transmit certain information to external entities using HL7 standards. These message types are transmitted through an HL7 engine and logged in the system. When immunization data, lab tests and results, surveys, or communicable disease data is captured within the system, these data elements are parsed into an HL7 message and transmitted to the respective external entity. This will provide an analytical view of the success rates of transmission.

Test Approach 1: For testing of 170.315(f)(1) Transmission to immunization registries, and 170.315(f)(2), Transmission to public health agencies – Syndromic surveillance, 170.315(f)(3) Transmission to public health agencies – reportable laboratory tests and value/results. System logs will be used to extract certain message types related to immunization and syndromic surveillance activities. Success rates of VXU message types being delivered to immunization registries, ORU message types for lab tests and results as well as ADT messages being delivered to public health agencies will be reviewed and trended.

Expected Outcome(s): It is expected that clients will be able to transmit HL7 messages without limitations and in compliance with the certification criteria, including the technical standards and vocabulary code sets. We do anticipate some clients will experience some delay on first attempt due to network connectivity so we anticipate that 90% of messages will be successfully transmitted and the 10% error rate accounts for issues with network.

For testing of 170.315(f)(5) Transmission to public health agencies – electronic case reports, we have two approaches.

Approach 1: In the event we have clients using this functionality, systems logs will be reviewed to determine numeric representation of the usage. Statuses of failure to send will be reviewed to determine adjustments.

Approach 2: in the event we do not have clients using this functionality, a quarterly test will be done using test environments to ensure the product is functioning as designed and

previously certified. These quarterly tests will be logged, and errors will be researched and corrected.

For testing and 170.315(f)(7) Transmission to public health agencies – health care surveys, we have two approaches.

Approach 1: In the event we have clients using this functionality, systems logs will be reviewed to determine numeric representation of the usage. Success rates and return rates will be evaluated.

Approach 2: in the event we do not have clients using this functionality, a quarterly test will be done using test environments to ensure the product is functioning as designed and previously certified. These quarterly tests will be logged, and errors will be researched and corrected.

Expected Outcome(s): It is expected with either approach that either external or internal test systems will be able to transmit surveys without limitations and in compliance with the certification criteria, including the technical standards and vocabulary code sets.

Measure 5(Export Data File)

This measure will capture the number of successful and unsuccessful events of exporting QRDA Cat 1 files.

Certification Criteria	Associated Criteria	Relied Upon Software
170.315(c)(1) – record and export	Export a QRDA Cat 1 file	N/A

Rationale: CareVue gives clinicians the ability to create a QRDA Cat 1 file to submit to CMS for attestation given a particular reporting period. We feel that extracting the successful and unsuccessful events will give us a numeric representation as to what is happening in the real world.

Test Approach 1: (in the event we have an active client using the functionality) System logs will be used to extract data related to QRDA exports. Success rates of these types of exports will be trended over time. We do anticipate that most of these exports will occur during Q1 as this is when the clients will report to CMS.

Test Approach 2: (in the event we do not have an active client using this functionality, Internal test systems will be used to create and export a QRDA Cat 1 file. Internal system logs will be reviewed to analyze success rates of the export function.

Expected Outcome(s): It is expected in either case that both internal and external clients will be able to export QRDA Cat 1 files without limitations and in compliance with the certification criteria, including the technical standards and vocabulary code sets. We do anticipate that most of these exports will occur during Q1 as this is when the clients will report to CMS.

Care Setting(s)

CareVue is marketed to inpatient hospitals, therefore, only the inpatient setting will be used for Real World Testing.

SCHEDULE OF KEY MILESTONES

Key Milestone	Date/Timeframe
Begin collection of data	March 2025
Data Collection and Review	Quarterly
End of Real World Testing for all measures.	December, 2025
Final data review and analytics, create results report	January 2026
Submit Real World Testing Results Report to ACB	February 2026

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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