Real World Testing Plan

Contents

Executive Summary

Vericle as a practice management software, caters to the small to medium sized clinics, marketing itself primarily to the Physical Medicine and the Mental Health care setups. We are currently certified with ONC Edition 2015 and the existing certified version is 5.0. This document is a combined real world testing plan- year 2022 for all the applicable criteria Vericle is certified for.

The real-world testing aims towards identifying the interoperability and usability when the system functions within real-world scenarios. This will not only help us establish the continued conformance to the certified criteria but also, identify the practicality of the system features so that the software is implemented for the optimal use at the client site. This document includes test plans for all the 12 criteria and each one is built with the use cases, overall expected outcomes, justification for the approach, subsequent final testing measurements and metrics. System data will be captured and analysed for the measurement reporting at the end of the testing milestone and based on these calculations, we will be able to report the system's continued compliance with the criteria requirements under this RWT Plan.

This RWT plan is defined to establish the interoperability and the usability of the features. functions implemented by Vericle which are certified with ONC. The use cases and the expected outcomes for all the applicable criteria are observed to be the same for both the care settings we market ourselves in, i.e., Physical Medicine and Mental Health care. Hence, the testing plans address both these settings without any significant change to the measures or to the outcomes. As described in the resource guide published by ONC, the participants or the sample of users performing RWT depends upon the usage of a particular functionality by the clients. Considering that we have chosen and mentioned the minimum number of participants under the testing plan for each of the criteria. This sample is defined so as to get a sufficient amount of data to analyse the interoperability and usability of the product. We will try to keep the group heterogenous and involve clients for both the care setups in the real-world testing.

The schedule for the key milestones planned for this project is mentioned as a separate section of the document and the events based on the plan will be timely recorded and reported at the end of testing. For RWT year 2022, we are not planning USCDI or SVAP updates.

Our signed attestation of compliance with the real-world testing requirements is at the end of this documentation.

General Information

Plan Report ID Number: VERP21E22S23

Developer Name: Erez Lirov

Product Name(s): Vericle

Version Number(s): 5.0

Applicable Certified Health IT Criteria:

1. 170.315(b)(1) Transitions of care
2. 170.315(b)(2) Clinical information reconciliation and incorporation
3. 170.315(b)(6) Data export
4. 170.315(c)(1) CQM - record and export
5. 170.315(c)(2) CQM - import and calculate
6. 170.315(c)(3) CQM - report CQM report
7. 170.315(e)(1) View, download and transmit to 3rd party
8. 170.315(g)(7) Application access – patient Selection
9. 170.315(g)(8) Application access – data category request
10. 170.315(g)(9) Application access – all data request
11. 170.315(h)(1) Direct project
12. 170.315(f)(1) Transmission to immunization registries

Product List (CHPL) ID(s): 15.07.04.2500.VERI.05.01.1.210101

Developer Real World Testing Page URL: https://www.vericle.net/real-world-testing

Schedule of Key Milestones

Key Milestone	Date/Time Frame
Communicate with the client and confirm participants in the real-world testing. Release of RWT document which includes specific instructions on what to look for, how to record the issues encountered, and Customer Agreements	January 1, 2021-April 1, 2022
The real-word testing will be performed. Timely follow-up with the client on their findings. Any non-conformities found will be reported to ONC-ACB	April 2, 2022-September 1, 2022
Planned System USCDI updates and work starts on the RWT Plan for 2023	September, 2022
RWT Plan for 2023 will be completed and will be submitted to ONC-ACB as per their due date	October, 2022
End of Real-World Testing period/final collection of all data for analysis	January 1, 2023
Analysis and report creation	January 15, 2023
Submit Real World Testing report to ACB (per their instructions)	February 1, 2023

170.315(b)(1) Transitions of Care, 170.315(h)(1) Direct Project

Use cases

- Vericle has implemented a simple direct point-of-point electronic communications following the transport standards and interoperability standards defined by CMS. Practitioners registered with a direct email address can transmit patient information to another provider who is also registered to the secure health transmission platform.
- Physician user generates the referral summaries, Continuity of Care documents with the minimum required data classes in accordance with the standard templates to share it to another physician via both, the direct messaging and the e-mails based on the edge protocol.
- In addition to the sharing of the documents, users are enabled to receive the referral summaries, continuity of care documents using the same edge protocol. System auto-validate the format before downloading the document.

Justification for Real World Testing Approach

Under this testing plan, we are trying to record the system's ability to send and receive the transition of care/referral summaries via SMTP-based edge protocol. System allows users to generate and share the CCDA document that complies with the standard format specified by the C-CDA templates. The encrypted messages with these documents can be shared with the users of a secure health transaction platform. The measure defined below will provide the quantitative analysis of this functionality. Both, the Physical Medicine and the Mental Health care practitioners, are observed to be following the same workflow for Health information sharing through CCDAs or using the direct messaging, hence this real-world testing plan and the measure can be applied to these settings.

Standards Updates

For RWT 2022, we are not planning any SVAP or USCDI updates

Standard (and version)	All standards versions are those specified ● ONC Applicability Statement for Secure Health Transport, V1.2, August 2015 ● ONC Implementation Guide for Direct Edge Protocols, V1.1, June 25, 2014 ● HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012 ● HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1, August 2015 ● International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, September 2015 Release ● SNOMED CT® U.S. Edition, September 2015 Release
Date of ONC-ACB notification (SVAP or USCDI)	Not applicable

Date of customer notification (SVAP only)	Not applicable
USCDI-updated certification criteria (and USCDI version)	Not applicable

Overall Expected Outcome(s)

The overall outcomes of the above use cases are as following:

1. System will allow users to send and receive referral summary documents formatted as per the standards defined by C-CDA using the SMTP supported edge protocol.
2. System will validate the received care documents to check if they comply with the standard C-CDA templates including the check for vocabulary standards, coding standards. System will correctly identify the corresponding sections and reconcile the information as per user selection to the existing document.
3. The received care document will be available to users in human readable format with the sectional view so that they will be able to select the required section out of the available ones or move the sections around.
4. The document will have the required minimum data classes, those are:
    a. Common Clinical Data Set
    b. Encounter diagnosis
    c. Cognitive status
    d. Functional Status
    e. Reason for Referral
    f. Referring or transitioning provider's name and office contact information
    g. Patient demographic data

Care Settings: Physical Medicine and Mental Health

As explained in the summary, this plan addresses RWT in both; the Physical medicine and the Mental Health practices. We are planning to approach and choose a minimum of 3 physician users who use direct messaging communication. This number might change in order to collect enough data for analysing the measure defined below.

Measure used in Overall approach

To test that the system shows real-world interoperability and conformance to § 170.315(b)(1) Transition of Care, the developer has designed the following measure.

Measure 1: Transition of care/referral summaries (C-CDA documents) are successfully sent via direct messaging: This measure will be used for tracking the system's interoperability and compliance with the below criteria requirements:

Certification Criteria	Requirement
§ 170.315(b)(1) Transition of Care	(i) Send and receive via edge protocol— A. Send transition of care/referral summaries through a method that conforms to the standard specified in § 170.202(d) and that leads to such

	summaries being processed by a service that has implemented the standard specified in § 170.202(a); and B. Receive transition of care/referral summaries through a method that conforms to the standard specified in § 170.202(d) from a service that has implemented the standard specified in § 170.202(a)(2).
§ 170.315(h)(1) Direct Project	(i) Applicability Statement for Secure Health Transport. Able to send and receive health information in accordance with the standard specified in §170.202(a)(2), including formatted only as a "wrapped" message

Justification: The above measure is created to analyse the system's ability to send the encrypted and edge protocol supported messages to a 3rd party provider in the real-world setup. The system records log for the sent direct messages. The CCDA documents that are failed to send are also logged and these exceptions will be investigated at the end of testing for the underlying cause and will be reported. The standardized format of the CCDA document as per the template and inclusion of specific data elements will also be verified under this measure as the system does not allow users to generate and send the CCDA which does not follow the standard formatting. These transactions will establish the usability of the function i.e., how frequently this interoperability feature is being used by the clients.

Test Methodology: As users send direct messages, the PHI auditl logs captures the action. These logs will be collected and reviewed to identify the number of C-CDAs that were sent out successfully. The user physician will be creating the tasks if they spot any errors in this transaction which is the existing bug reporting tool in-built in the system. The exceptions in the transaction are also logged under the PHI audit log and will be analysed at the end of the testing and the justification will be submitted under the testing report.

Expected Outcome(s): Users will successfully send the patient CCDAs to another provider via direct messaging. This transaction will be logged under the PHI audit log.

170.315(b)(2) Clinical information reconciliation and incorporation

Use Cases

- Vericle supports standard CCDA document creation and the receipt. Physicians can import the patient's CCDA and select the particular section such as medications, allergies and problems list; they need to be included in the existing PHI. System validates the received document for the standardized template format and opens it in human readable format. Physicians are also able to review and generate the updated documents based on the reconciliation action to generate a standard CCDA file.

Justification for Real World Testing Approach

This plan addresses the clinical information import and reconciliation in the Physical Medicine and the Mental Health care practices. With this plan we will check the interoperability and usability of this feature to our clients. Vericle is supported by Newcrop to maintain patient's medication and allergy records. With Newcrop integration, Vericle supports entries, updates and reconciliation of the patient's medications and allergies. This integration will also be verified under this plan.

Standards Updates

For RWT 2022, we are not planning any SVAP or USCDI updates

Standard (and version)	All standards versions are those specified ● HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012 ● HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1, August 2015 ● RxNorm Sept 8 2015 release ● SNOMED CT® U.S. Edition, September 2015 Release
Date of ONC-ACB notification (SVAP or USCDI)	Not applicable
Date of customer notification (SVAP only)	Not applicable
USCDI-updated certification criteria (and USCDI version)	Not applicable

Overall Expected Outcome(s)

The overall expected outcomes for the above use cases are:

- The system will receive the xml as formatted in accordance with the standards adopted in § 170.205(a) using the Continuity of Care Document.
- The user will be enabled to manually identify the correct patient.

- User will be able to simultaneously view the data from the sources which includes the source and last modification date.
- User will be able to create and review a single reconciled list of each of the following: Medications; Allergies and Intolerances; and problems.
- Upon user confirmation, the document will be updated, and incorporate the following data expressed according to the specified standard(s)
    - Medications. At a minimum, the version of the standard specified in § 170.213; RxNorm Sept 8 2015 release
    - Allergies and intolerance. At a minimum, the version of the standard specified in § 170.213; RxNorm Sept 8 2015 release
    - Problems. At a minimum, the version of the standard specified in § 170.213. SNOMED CT® U.S. Edition, September 2015 Release
- System will be able to create a file formatted according to the standard specified in § 170.205(a)(4) using the Continuity of Care Document template

Care Settings: Physical Medicine and Mental Health

This plan addresses both the Physical Medicine and the Mental Health care setups. Minimum of 3 physician accounts will be used to collect the data for calculating the successful reconciliations and the frequency of use of this feature available to the clients.

Measure used in Overall approach

As part of the Real-World Testing for § 170.315(b)(2), the developer has the following measure created to be applied to the real-world scenarios to establish system's interoperability and conformance to the criteria when used in a practice's actual workflow.

Measure 1: Reconciliation: System successfully reconciles the imported CCDA documents.

This measure is created based on the following requirement of the criterion:

Certification Criteria	Requirement
§ 170.315(b)(2) Clinical information reconciliation	(iii) Reconciliation. Enable a user to reconcile the data that represent a patient's active medication list, medication allergy list, and problem list as follows. For each list type: A. Simultaneously display (i.e., in a single view) the data from at least two sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date. B. Enable a user to create a single reconciled list of each of the following: Medications; medication allergies; and problems.

	C. Enable a user to review and validate the accuracy of a final set of data. D. Upon a user's confirmation, automatically update the list, and incorporate the following data expressed according to the specified standard(s): 1. Medications. At a minimum, the version of the standard specified in §170.207(d)(3); 2. Medication allergies. At a minimum, the version of the standard specified in §170.207(d)(3); and 3. Problems. At a minimum, the version of the standard specified in §170.207(a)(4).

Justification: This measure is created to measure the success of the rate of the reconciliations performed on the system. The system throws validations if the imported document does not support the C-CDA templates, which will also be tested under this measure. The updated CCDAs can be verified to check if it includes the reconciled information. The PHI audit log records the reconciliation. Vericle has an inbuilt bug reporting tool which can be used by the physicians to report any exceptions to the action. These exceptions will also be analysed and reported at the end of RWT.

Test Methodology: As the PHI audit log records the reconciliation action and if it was a successful or a failed transaction, we will be collecting the audit logs of the user participants for the assigned period and these logs will be reviewed to identify the number of the reconciliations happened over the period. The same logs will be used to calculate the success rate of the action and will be reported. The PHI logged exceptions and used reported issues will also be analysed later at the end of RWT and along with the reporting, appropriate action will be taken.

Expected Outcome(s): Imported CCDAs will be successfully reconciled to the existing PHI and the audit log will show the entries for these reconciliation actions.

170.315(b)(6) Data export

Use cases

- Data export capabilities are available to only the selected set of users. Admin can choose the user accounts so as to who will have access to the data export configurations and to create the export summaries. The storage location for the export summaries can be changed through the configurations.
- A physician selects the patient, sets the timeframe for which he/she needs the clinical data for and generates the export summary for the patient. On exporting, this document gets stored to the location defined by the admin user/the practice owner.

Justification for Real World Testing Approach

This testing plan is drafted to establish the system's interoperability through the ability to export patient's data and restricting the set of users who actually has this functionality. Privileged users are allowed access to the time frame and the storage location configurations. The use case above covers all the requirements under the criterion. The export summaries are formatted according to the Continuity of Care Document template to include the minimum required data classes. The generation of export summaries is logged and these logs for the selected users will be studied to calculate the system's performance in interoperability and the actual usability of the feature.

Standards Updates

For RWT 2022, we are not planning any SVAP or USCDI updates

Standard (and version)	All standards versions are those specified ● HL7 Implementation Guide for CDA® Release 2 ● SNOMED CT® U.S. Edition, September 2015 Release ● ICD-10-CM
Date of ONC-ACB notification (SVAP or USCDI)	Not applicable
Date of customer notification (SVAP only)	Not applicable
USCDI-updated certification criteria (and USCDI version)	Not applicable

Overall Expected Outcome(s)

- Real-world testing will show how the system allows a user to select specific logins who would be given access for creation, timeframe configuration and location configuration of the export summaries.
- No other user except the privileged once will be able to access the configurations or can create the export summaries.
- System will enable the user to set the start and end date in order to generate export summary for this specific timeframe.

- The export summary will show conformance to the Continuity of Care Document template and will include the required minimal sections, those are:
    - Common Clinical Data Set
    - Encounter diagnosis
    - Cognitive status
    - Functional status
    - Reason for referral
    - Referring or transitioning provider's name and office contact information
- The user will be able to change the location where they want to save these export summaries.

Care Settings: Physical Medicine and Mental Health

The plan can be applied to Physical Medicine as well as Mental Health care practices. We are planning to collect the audit logs to review if the exporting of the data is successfully executed and the frequency of use of this feature with a minimum of 3 physician's accounts..

Measures used in Overall approach

The following measure is defined for this real-world testing plan in order to demonstrate the system's conformance to the §170.315(b)(6) Data export in real-world scenarios.

Measure 1: Export summaries are created successfully: Users, authorized access to the creation of export summary function, successfully generate the export summary for the selected patient.

This measure is created by referring to the below requirement of the criterion:

Certification Criteria	Requirement
§ 170.315(b)(6) Data Export	(ii) Creation. Enable a user to create export summaries formatted in accordance with the standard specified in §170.205(a)(4) using the Continuity of Care Document document template that includes, at a minimum: A. The Common Clinical Data Set. B. Encounter diagnosis. Formatted according to at least one of the following standards: 1. The standard specified in §170.207(i). 2. At a minimum, the version of the standard specified in §170.207(a)(4). C. Cognitive status. D. Functional status. E. Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information. F. Inpatient setting only. Discharge instructions.

Justification: Vericle has specified privileges for the export summary creation, timeframe configuration and location configuration functions. The user who has been assigned these privileges can generate the export summaries. These summaries then get stored in the location specified under the location configuration which is also accessible by the privileged

users. The above measure has been created to calculate the success rate of export summary creation. The frequency of the use of this function will also be checked. Alongside, the system's ability to limit the number of users who can create the export summaries, will be indirectly tested. When a user out of this set tries to access the configuration and to create an export summary, the system will generate an error validation. The export summary generation is logged under the PHI audit log. The flow of the execution of the scenario will also check if the user who has access to the configurations can define the timeframe and location configuration.

Test Methodology: Whenever the export summary is generated by the user, an entry will be made under the PHI audit log with the status as to know if the transaction was successful or failed. These logs for the sample set of users will be collected and analysed to calculate the frequency and the success rate of this action. Any exception to the action will be treated as the failed case. Such exceptions can be reported by the user via the system's bug reporting tool and also are logged under the same audit list. These will be studied for the underlying cause and reported at the end of the testing period.

Expected Outcome(s): User successfully generated the export summary for the selected patient. PHI audit log will keep the entry for the creation of export summaries.

170.315(c)(1) CQMs - record and export, 170.315(c)(2) CQMs – import and calculate, 170.315(c)(3) CQMs – report

Use Cases

- System records all the data components necessary to calculate the six Clinical Quality Measures (CQMs) Vericle is certified with. The data files for selected or all of the CQMs can be exported from the system without any developer assistance for the selected patients.
- Vericle also allows the user to import these data files in a format standardized based on the interoperability guide. These data files are then processed to generate the statistics on the CQM(s).
- Users are enabled to electronically create the data file of the clinical quality measurement reports for transmission as and when required.

Justification for Real World Testing Approach

This testing plan describes the use cases and measurement technique that when executed in real-world scenarios, will help to confirm the system's continued conformance with the above criteria. This testing plan addressed and has measures created for the above three criteria; §170.315(c)(1) CQMs- record and export, §170.315(c)(2) CQMs- import and calculate, §170.315(c)(3) CQMs- report. System's transactions related to the CQMs are logged and we will use those logs to quantitatively analyse the system's ability to create, export and import the cat 1, cat 3 files for the six CQMs we are certified with. The plan defines a measure for each one of these criteria based on the specific requirements. The result for these measures will be used to report Vericle performance in the real-world setup. The practices usually fetch the CQM data files for operational and reporting purposes. However, the usage of this functionality by the client is unclear to us. This will be confirmed as we start approaching and getting clients to participate in RWT.

Standards Updates

For RWT 2022, we are not planning any SVAP or USCDI updates

Standard (and version)	All standards versions are those specified ● HL7 Implementation Guide for CDA® Release 2: QRDA Release 1, DSTU Release 3 ● CMS implementation Guide for QRDA Category III ● Quality Reporting Document Architecture Category III, Implementation Guide for CDA Release 2
Date of ONC-ACB notification (SVAP or USCDI)	Not applicable
Date of customer notification (SVAP only)	Not applicable
USCDI-updated certification criteria (and USCDI version)	Not applicable

Overall Expected Outcome(s)

The overall expected outcomes of the use cases are:

- System will be able to record and generate the data file for the data necessary to calculate all the six CQM the Health IT is certified with.
- Users will be able to export this collected data which is formatted in accordance with the standards specified, ranging from one to multiple patients, as and when required by the user without subsequent developer assistance.
- System will enable users to import the data file based on the selected CQM and the patients. use this data to calculate the CQM.
- Users will be enabled to electronically create a data file as guided by the interoperability and content exchange standards for the transmission of clinical quality measurement data as guided by CMS for the implementation of QRDA, Category III.

Care Settings: Physical Medicine and Mental Health

The use cases written above apply to both the care settings, Physical Medicine and Mental Health care. Hence, a single Real-world testing plan is drafted with the measures that can be captured in both these care settings.

Measures used in Overall approach

Three different measures are drafted to record the systems interoperability and usability based on the certification criteria. The system logs, audit logs will be analysed and reported under the plan result report submission to support the system's conformance with each of these criteria.

Measure 1: Export: The data files with the required information on the selected measure are successfully exported by the user.

This measure is based on the below criterion requirement:

Certification Criteria	Requirement
§ 170.315(c)(1) Clinical Quality Measures– record and export	(ii) Export- A user must be able to export a data file at any time the user chooses and without subsequent developer assistance to operate: 1. Formatted in accordance with the standard specified in §170.205(h)(2); 2. Ranging from one to multiple patients; and 3. That includes all of the data captured for each and every CQM to which technology was certified under paragraph (c)(1)(i) of this section.

Justification: The measure is devised to analyse Health IT's conformance with § 170.315(c)(1) Clinical Quality Measures– record and export. The cat 1 file is generated for the selected CQMs and this action will be logged under the PHI audit list. These measures also will validate that the system records all the required data for all the six CQMs Vericle is certified with. The data files are formatted as per the QRDA guidelines for cat 1 files. These data files can be created and exported for more than one patient at a time.

Test Methodology: Every time a user exports the data files (cat 1 data file), the system records this transaction. The PHI logs for the set of users/participants will be analysed and calculated to understand the usability and the success rate of the above measure. The results will be included in the testing report along with the failed cases with exceptions in performing the export, if there are any. The exceptions will be examined to identify the underlying cause and will be described in the report.

Expected Outcome(s): System logs that the cat 1 data files are exported without or minimal errors.

Measure 2: Import: The data files (cat1) are successfully imported to get the CQM statistics.

This measure is based on the import requirement under the criteria:

Certification Criteria	Requirement
§ 170.315(c)(2) Clinical Quality Measures– import and calculate	(i) Import. Enable a user to import a data file in accordance with the standard specified in §170.205(h)(2) for one or multiple patients and use such data to calculate all the CQM the system is certified for. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.

Justification: This measure will help us to establish that Health IT allows users to import the data files with all the CQM(s) related information even in a real-world setting. The imported cat 1 files enable users to generate the statistics on the selected CQMs. The files can be generated for all the six CQMs for multiple patients at a time. All these functions will be verified under this measure. The PHI log entries for the participant users will be collected and studied for the successful import of the cat 1 data files.

Test Methodology: When a user imports the cat1 data files, the system will create an entry to the PHI audit log for this transaction. The status of the transaction i.e., if the transaction was successful or there was an exception, it will also be recorded with different log messages. These log files for the above use cases will be analysed to identify the frequency of the use of this feature and to calculate the measure report in order to support the system's continued conformance with the above criteria in real-world setup.

Expected Outcome(s): cat 1 files are successfully imported with the selected CQM data to generate the CQM statistics. System records the entries of these imported data files/ cat1 files.

Measure 3: Electronically create a data file: System successfully generates the data files of the CQM report for transmission.

This measure is defined to showcase that a user of the Vericle has been enabled to generate the data file of the clinical quality measurement report in order to transmit the data without any developer assistance. This follows the below criteria requirement:

Certification Criteria	Requirement
§ 170.315(c)(3) Clinical Quality Measures– report	Enable users to electronically create a data file for transmission of clinical quality measurement data as per the interoperability standards and content exchange standards.

Justification: The system has a feature to generate the statistics for the selected CQM(s) based on the data files fed into the system. This is done by using the cat 1 data files with all the data components. These cat 1 files are processed to generate the statistics on the CQM(s), the cat 3 files. The above measure is devised to establish that Health IT is able to create the data file/ cat 3 in compliance with the QRDA format with the ability to transmit it without or with minimum errors. The generation of the CQM report will be logged and will later be reviewed for the calculation of the measurement metric. The defined measure also tests if the file generated is guided by the interoperability and content exchange standards.

Test Methodology: Under the measure, we verify if the cat 3 file is successfully generated by the system. Also, the usability of this feature will be verified as that is something not vivid to us. PHI audit logs for the defined set of users which records the importing, exporting of the cat 1 and cat 3 files will be verified and analysed further to calculate the success rate of this transaction. If there would be any exception reported, it will be treated as a failed case and will be reviewed to identify the underlying cause and the same included in the result report.

Expected Outcome(s): The data files are successfully created electronically for the transmission without or with less than 1% errors. The action is logged under the PHI audit log.

170.315(e)(1) View, download and transmit to 3rd party

Use Cases

- Vericle enables providers to share with patients the access to his/her care documents via the patient portal. Patients or the authorized representative can log in anytime, anywhere to view the care documents and summary with the access link shared by the provider. The summary document includes the minimum required sections defined under the criteria. The documents can be viewed in human readable format.
- Patients can download their ambulatory care summary CCDA. This downloaded document is formatted according to the standard Continuity of care template and it includes the data for the time frame selected by the patient.
- Vericle allows patients to securely share the care summary documents to another providers/contact via both, the direct messaging and the e-mail. All these transactions on the patient account are recorded with the date, time of transmission, action performed and the user who took the action.

Justification for Real World Testing Approach

Vericle has its own patient portal which when given access to, allows patients to access their care data at any given time and place. This access is guided by the interoperability standards in compliance with the above criteria. Patients/ authorized representatives with credentials can view, download and share their care summary to the provider of choice via direct messaging or via e-mails. The above use cases cover all the functions to reiterate the system's continued conformance, interoperability. As per the RWT requirement, a measure has been defined aiming to the establish this conformance quantitatively when Vericle is put into real-world scenario.

Standards Updates

For RWT 2022, we are not planning any SVAP or USCDI updates

Standard (and version)	All standards versions are those specified ● HL7 Implementation Guide for CDA® Release 2 ● SNOMED CT® U.S. Edition, September 2015 Release ● ICD-10 CM ● Web Content Accessibility Guidelines (WCAG) 2.0, Level A Conformance
Date of ONC-ACB notification (SVAP or USCDI)	Not applicable
Date of customer notification (SVAP only)	Not applicable
USCDI-updated certification criteria (and USCDI version)	Not applicable

Overall Expected Outcome(s)

The overall expected outcomes for the above use cases are:

1. Vericle will enable patients/authorized representatives to use internet-based technology to access their health information guided by the Interoperability standards.
2. Patient/authorized representative will be able to view the summary document which will have, at the minimum, the following data:
    a. Common Clinical Data set
    b. Provider name and office contact information
    c. Lab test reports
    d. Diagnostic image report(s)
3. Patient/authorized representative will be able to download the ambulatory summary for a specific time frame in human readable format and the standard format defined by the CCD document template.
4. The downloaded document will have all the sections from the minimum required list.
5. System will allow patients to transmit their summary document for the selective timeframe via both, the email and the direct messaging.
6. Patients/authorized representatives will be able to look at the audit log on their account with the information such as; action performed, user who took the action, date and time of each action and if applicable, the addressee to whom the summary is sent.

Care Settings: Physical Medicine and Mental Health

This testing plan applies to both; Physical medicine and Mental health care setups. A minimum of 3 physician accounts will be used to collect the data on patient's activity on their care documents via the portal.

Measure used in Overall approach

As part of the Real-World Testing requirements for § 170.315(e)(1), the developer has the following measure created to be applied to the real-world scenarios.

Measure 1: Patients successfully download their care summaries using the patient portal: Vericle allows patients or authorized representatives to access the patient portal and download their care summaries without any subsequent assistance.

This measure is based on the below requirement of the certification criterion:

Certification Criteria	Requirement
§ 170.315(e)(1) View, download and transmit to 3rd party	(i) Patients (and their authorized representatives) must be able to use internet-based technology to view, download, and transmit their health information to a 3rd party in the manner specified below. Such access must be consistent and in accordance with the standard adopted in § 170.204(a)(1) and may alternatively be demonstrated in accordance with the standard specified in § 170.204(a)(2) A. View B. Download C. Transmit to third party

	D. Time Frame selection

Justification: The above measure will be used to perform a quantitative analysis of Vericle patient portal functions; especially to download patient's care summary. The measure indirectly verifies that the patients can access the portal for their care data and the CCDAs are displayed in human readable format. All the actions on patient care summary such as view, download and transfer are getting logged under the audit log history; on both the portal itself and under the PHI audit log of the physician who had or has an appointment with the patient. System's usability and interoperability will be tested under the use case as patient accesses and downloads the clinical data summary via the internet-based technology. Along with it is reported the system's capability of patient engagement by allowing them to access their real-time care information for the selected timeframe. Audit log that keeps the trail of all the actions performed on the care summary is accessible to the patient or his/her authorized representative, who has access to the portal.

Test Methodology: Patients access their care documents via the patient portal which fetch the clinical information from PHI. The actions such as view, download, transmit, performed by the patient will be recorded under the PHI logs of the physician who had or has an appointment with the patient. The actions are also logged under the patient's account on the portal. These logs will be reviewed to calculate the rate of the successful downloads of the care summaries and the frequency of use of this function by the patients. The result will help to establish that Vericle backs up patient engagement and interoperability on its patient portal. The exceptions in the transactions will be treated as failures and will also be reviewed and reported with the underlying cause. We will identify a way for patient's to report the exceptions. However, physicians can use bug reporting tool.

Expected Outcome(s): Patient successfully downloads the care summary from their patient portal account. This action gets logged on the portal as well as on the PHI audit log records of the physician who has or had an appointment with the patient.

170.315(g)(7) *Application access – patient selection,* §170.315 (g)(8) *Application access – data category request,* §170.315 (g)(9) *Application access – all data request*

Use Case

- 3rd party applications complying with the API standards get access to Vericle and request for a patient data with sufficient information to identify the patient. In response, the system returns an ID that can be used by this external application to subsequently execute requests for this patient's data. System further responds to these requests with data of individual data categories as specified in the common data set with full set of data for that data category.
- Vericle responds to the requests for patient data for all the data categories at a time and returns this data in the form of summary formatted as per the standard CCD document template.

Justification for Real World Testing Approach

Vericle system follows the API standards for third party application access for patient selection, individual data category requests and all data requests. System provides the responses to the above stated requests with a patient ID, set of data for the requested data category and data summary for all the selected data categories in the standard CCD document template format, respectively. The same is covered under the above use cases which describes Vericle's conformance to the requirements under the criteria; 170.315(g)(7) Application access – patient selection, §170.315 (g)(8) Application access – data category request and §170.315 (g)(9) Application access – all data request certification criteria. This testing plan aims to establish interoperability when the system is put in the real-world. A measure is defined to address these criteria in order to measure the system's performance while receiving and responding to the external app requests. In order to calculate the system's performance, we are planning to collect a viable sample of data. However, we do not know the frequency of this function used by the clients yet. This will be clear when the identify participants in RWT.

Standards Updates

For RWT 2022, we are not planning any SVAP or USCDI updates

Standard (and version)	All standards versions are those specified ● HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1, August 2015
Date of ONC-ACB notification (SVAP or USCDI)	Not applicable
Date of ONC-ACB notification (SVAP or USCDI)	Not applicable
USCDI-updated certification criteria (and USCDI version)	Not applicable

Overall Expected Outcome(s)

The expected outcomes for system's use cases for the 3rd party app requests are:

1. Vericle will be able to receive external app requests with sufficient information to uniquely identify a patient and will return an ID which will be used by the application to subsequently execute requests for that patient's data.
2. System will respond to requests for patient data (based on an ID) for each of the individual data categories specified in the Common Clinical Data Set and return the full set of data for that data category.
3. System responds to requests for patient data associated with a specific date as well as requests for patient data within a specified date range.
4. System will respond to requests for patient data for all of the data categories specified in the Common Clinical Data Set at one time and will return such data in a summary record formatted according to the standard specified in §170.205(a)(4) following the CCD document template.
5. System will respond to requests for patient data associated with a specific date as well as requests for patient data within a specified date range.

Care Settings: Physical Medicine and Mental Health

The plan addressed Physical medicine and Mental health care practices. We will identify a minimum of 3 users to track the activity related to the below measure.

Measure used in Overall approach

As part of the Real-World Testing requirements for §170.315(g)(7) Application access – patient selection, §170.315 (g)(8) Application access – data category request and §170.315 (g)(9) Application access – all data request certification criteria, we have developed a measure to verify system's response the API requests.

Measure 1: API requests are responded successfully: Vericle successfully receives and responds to the external application requests with sufficient information to identify the patient.

This measure is based on the below requirement of the criterion:

Certification Criteria	Requirement
§ 170.315(g)(7) Application access – patient selection	(i) Functional requirement- The technology must be able to receive a request with sufficient information to uniquely identify a patient and return an ID or other token that can be used by an application to subsequently execute requests for that patient's data.
§170.315 (g)(8) Application access – data category request	(i) Functional requirements: Respond to requests for patient data (based on an ID or other token) for each of the individual data categories specified in the Common Clinical Data Set and return the full set of data for that

	data category (according to the specified standards, where applicable) in a computable format.
§170.315 (g)(9) Application access – all data request	(i)Functional requirements: Respond to requests for patient data (based on an ID or other token) for all of the data categories specified in the Common Clinical Data Set at one time and return such data (according to the specified standards, where applicable) in a summary record formatted according to the standard specified in §170.205(a)(4) following the CCD document template.

Justification: This measure has been drafted by the developer to quantitatively measure the system's ability to receive and respond to the external app requests with sufficient information. Successful data responses from the system are recorded (response code 200). The audit logs under the user who has or has an appointment with the patient, gets the entry for the request and response. We will be getting the data from these logs to calculate the success rate of the above measure. Any exceptions will be treated as failures and we will review them at the end of the testing. The numerical value of this measure will confirm the system's compliance with the interoperability requirement and conformance with the above criteria.

Test Methodology: The measure will be applied to the scenarios where external applications request to access the PHI with sufficient information to identify the patient and the system responds to that request successfully. System transactions for third party applications are logged under the PHI logs for the user who has or has an appointment with the patient and will be reviewed to get the success rate in execution of the requests. The failed responses (response code 400) will also be reviewed for the underlying causes. The usability of the feature will be evaluated under this measure.

However, we need to identify the frequency of this function being used by our existing partners.

Expected Outcome(s): Third party app requests with sufficient information are responded successfully (with the response code 200).

170.315(f)(1) Transmission to immunization registries

Use Cases

- System allows users to record the immunization information using the standard set of codes and the format. This information can then be shared with the immunization registries directly via the system.
- Physicians, as and when required, request and access the patient's immunization history and the forecasts using the system.

Justification for Real World Testing Approach

Vericle has inbuilt ability to communicate patient's immunization information with the immunization registries. This information is transmitted as per the HL7 guidelines, supporting interoperability with an immunization registry. Users are enabled to record the immunization information with the NDC Directory and HL7 standard code set CVX, all the clinical data elements, and immunization messages. Users also are able to access the immunization history of the patient from the registry.

Standards Updates

For RWT 2022, we are not planning any SVAP or USCDI updates

Standard (and version)	All standards versions are those specified ● HL7 2.5.1 Immunization guide for Immunization messaging, release 1.5 ● HL7 standard code set CVX ● NDC Directory
Date of ONC-ACB notification (SVAP or USCDI)	Not applicable
Date of customer notification (SVAP only)	Not applicable
USCDI-updated certification criteria (and USCDI version)	Not applicable

Overall Expected Outcome(s)

The expected outcomes of this function are:

- The User records the patient immunization details with all the required data elements and using the NDC directory and standard code set CVX.
- Vericle allows users to send this information to the immunization registry via HL7 messaging.
- Users will also be able to request and access a patient's immunization history and the forecasts available on the registry via the system.

Care Settings: Physical Medicine and Mental Health

This plan addressed both; the Physical Medicine and Mental Health practices. We are planning to collect the transaction logs from a minimum of 3 physician accounts to check for

the frequency of use of this feature as well as the successful transmission of the information to the registry.

Measure used in Overall approach

As part of the Real-World Testing requirements for § 170.315(f)(1), the developer has the following measure created to be applied to the real-world scenarios.

Measure 1: The immunization information created is successfully transmitted to the immunization registry: The number of successful transmissions of the immunization information to the immunization registries will be recorded.

This measure is based on the below requirement of the certification criterion:

Certification Criteria	Requirement
§ 170.315(f)(1) Transmission to immunization registries	(i) Create immunization information for electronic transmission in accordance with: A. The standard and applicable implementation specifications specified in §170.205(e)(4). B. At a minimum, the version of the standard specified in §170.207(e)(3) for historical vaccines. C. At a minimum, the version of the standard specified in §170.207(e)(4) for administered vaccines.

Justification: The above measure is created in order to check for the usability of this feature and if the system establishes interoperability with the immunization registry. In addition, the standard data classes recorded under the immunization record and the usage of standard codes will also be verified as we will be tracking the successful transmission of the information. We will calculate the success rate of the transmission alongside the number of times this frequency is being used by the set of providers selected for the RWT.

Test Methodology: PHI audit log records the action of sending the immunization information outside to the registry. These logs for the users will be collected and that data will be used for the quantitative analysis. Along with the bug reporting tool that we have; these PHI logs will be used to identify the exception in sharing this information and those will also be analysed and reported to our ACB.

Expected Outcome(s): User successfully sends the created immunization record for the patient to the registry. PHI log creates the entry for the successful and the failed transmission of this information.

Attestation

This Real-world testing plan is complete with all the mandatory elements, including a measure defined per applicable criteria addressing the Physical Medicine and Mental Health care setup. All the information in the plan is up to date and completely addresses the real-world testing requirements.

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