CY 2022 Real World Testing Plan for Prime Clinical Systems

Executive Summary

This is the real world test plan for CY 2022 for Prime Clinical Systems Patient Chart Manager certified EHR solution. We have two versions certified, and we will testing on the most current version, 7.1, which is deployed to our user community.

As ONC has stated in its rule, "The objective of real-world testing is to verify the extent to which certified health IT deployed in operational production settings is demonstrating continued compliance to certification criteria and functioning with the intended use cases as part of the overall maintenance of a health IT's certification." We have worked toward this objective in designing our test plan and its subsequent real world testing measurements and metrics.

This document builds toward the final testing measurements and metrics we will use to evaluate our product interoperability within production settings. Within each use case, we document planned testing methodology, associated ONC criteria, justification for measurement, expected outcomes from the testing, care settings applied for the respective measure, and if applicable the number of clients to use our real world testing approach, including how our test cases were created, our selected methodology, the number of client/practice sites to use, and our general approach and justification for decisions.

We have included our timeline and milestones for completing the real-world testing in CY 2022, and information about compliance with the Standards Version Advancement Process updates.

A table of contents with hyperlinks is provided later in the plan quick access to any document section, including the testing measurements and metrics found at the end of this document. Our signed attestation of compliance with the real-world testing requirements is on the following page.

Developer 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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General Information

Plan Report ID Number: 20210921PRI

Developer Name: Prime Clinical Systems, LLC

Product Name(s): Patient Chart Manager

Version Numbers(s): 7.1 and 7.0

Certified Health IT Criteria: 315(b)(1), (2), (3), (6); (c)(1)-(c)(3); (e)(1); (f)(1), (f)(2), (f)(4); (g)(7)-(9); (h)(1)

Product List (CHPL) ID(s) and Link(s):

- 7.1
 - o 15.02.02.2206.A063.03.02.1.200108
 - o https://chpl.healthit.gov/#/listing/10270
- 7.0
 - $\circ \quad 15.02.02.2206.A063.02.01.1.190531 \\$
 - o https://chpl.healthit.gov/#/listing/10003

Developer Real-World Testing Page URL: <u>http://www.primeclinical.com/wp-</u> content/themes/BLANK-Theme/images/PrimeClinical Real World Test Plan CY2022.pdf

Timeline and Milestones for Real-World Testing CY 2022

- 1Q-2022: Begin communication with clients to ask for their support and participation in real-world testing. The goal is to have a sufficient number of clients committed for real world testing by the end of 1Q-2022.
- 2Q-3Q 2022. During the 2nd and 3rd quarter of CY 2022, the real-world testing with clients will be scheduled and performed. It is expected that a preparatory call will be done with clients to prepare them for testing activities. Results will be documented in the test results section of the test methods and ultimately used to build the test report. If any non-compliances are observed, we will notify the ONC-ACB of the findings and make the necessary changes required.
- 4Q-2022. During the last quarter of the year, the CY 2023 real-world test plan will be completed according to ONC and ONC-ACB requirements and expectations. Test plan will be prepared for submission before the end of the year.
- February 2023. Document our CY 2022 test results into our RWT Test Report and submit to our ONC-ACB.

Standards Version Advancement Process (SVAP) Updates

For CY 2022, we are not planning to make any version updates on approved standards through the SVAP process.

Standard (and version)	None
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

Real World Testing Measurements

The measurements for our real-world testing plan are described below. Each measurement contains:

- Associated ONC criteria
- Testing Methodology used
- Description of the measurement/metric
- Justification for the measurement/metric
- Expected outcomes in testing for the measurement/metric
- Number of client sites to use in testing (if applicable)
- Care settings which are targeted with the measurement/metric

In each measurement evaluate, we elaborate specifically on our justification for choosing this measure and the expected outcomes. All measurements were chosen to best evaluate compliance with the certification criteria and interoperability of exchanging electronic health information (EHI) within the certified EHR.

Testing Methodologies

For each measurement, a testing methodology is used. For our test plan, we use the following methodologies.

Reporting/Logging: This methodology uses the logging or reporting capabilities of the EHR to examine functionality performed in the system. A typical example of this is the measure reporting done for the automate measure calculation required in 315(g)(2), but it can also be aspects of the audit log or customized reports from the EHR. This methodology often provides historical measurement reports which can be accessed at different times of the year and evaluate interoperability of EHR functionality, and it can serve as a benchmark for evaluating real world testing over multiple time intervals.

Survey: This methodology evaluates interoperability and compliance of EHR Module capabilities through feedback from users. This methodology can provide insight into how clinicians employ and use a feature which reveals actual value and impact of interoperability of the EHR Module.

Number of Clients Sites

Within each measure, we note the minimum number of clients or client sites we plan to use for this measure evaluation. The numbers vary depending on the methodology as well as overall use of the associated EHR Module criteria by our users. For criteria that are not widely used by our customer base, we may test the respective measure in our own production-sandbox environment given lack of customer experience with the criteria functionality.

Care and Practice Settings Targeted

Prime Clinical Systems Patient Chart Manager EHR is primarily targeted to general ambulatory practices, and our measures were design for this setting in mind. In each measure, we do also address the care settings targeted and note any necessary adjustment or specific factor to consider with this specific measure.

RWT Measure #1. Transition of Care C-CDAs Functionality

Associated Criteria: 315(b)(1), (h)(1)

Testing Methodology: Reporting/Survey

Measurement Description

This use case is tracking how many C-CDAs are created and successfully sent from the EHR Module to a 3rd party during a transition of care event using Direct messaging over the course of a given interval.

Measurement Justification

This use case has one measure capture. It will provide a numeric value to indicate both the how often this interoperability feature is being used as well as its compliance to the requirement. An increment to this measure indicates that the EHR can create a C-CDA patient summary record, including ability to record all clinical data elements, and by sending the C-CDA patient summary record, the EHR demonstrates successful interoperability of an exchanged patient record with a 3rd party. This measurement shows support for Direct Edge protocol in connecting to a HISP for successful transmission which reveals compliance to the associated criteria listed above.

Measurement Expected Outcome

We will test a sample of our user base to get reporting values on C-CDAs sent as well as performance of C-CDA error detection.

Measure #1: Report the numbers of C-CDAs sent over a three (3) month period.

This metric can come from different reports, including Automated Measure (315.g.2) reports. A successful measure increment indicates compliance to the underlying ONC criteria, including successful creation of the C-CDA patient summary record and recording the required clinical data elements. In sending the C-CDA patient summary record, the EHR will demonstrate ability to confirm successful interoperability of an exchanged patient record with a 3rd party, including support for Direct Edge protocol in connecting to a HISP.

Successfully completing this measure also implies users have a general understanding of the EHR functional operations for this EHR Module and an overall support for the user experience while not completing this measure may indicate lack of understanding or possibly lack of use or need for this functionality.

We will use the measure count to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts.

Care Settings and Number of Clients Site to Test

RWT Measure #2. Incorporation and Updating of Medication List, Problem List, Allergy List

Associated Criteria: 315(b)(2)

Testing Methodology: Survey

Measurement Description

This is a survey measure to determine how often you are using the C-CDA incorporate and update feature.

Measurement Justification

This measure will survey users to determine real world interoperability and usability, specifically how often are C-CDAs received from 3rd parties incorporated into the patient record and then updating the patient's problem list, medication list, and medication allergy list with the clinical data contained in the C-CDA.

A survey can often provide more information on the impact and value of an interoperability element than a standard software test evaluation. This survey measure will reveal if users are using the C-CDA incorporate feature of their EHR to update their patient's record with current or new information from another source. Through this means of testing, we can determine compliance to the associated criteria listed above in real world use.

Measurement Expected Outcome

The user will be asked the survey question of how often you are using the C-CDA incorporate and update feature and given the survey answer choices below:

- Regularly
- Sporadically
- Rarely
- Never
- Don't Know

The answer will provide insight into how clinicians view both the use and value of this interoperability feature. For example, response may show that additional training is needed to better utilize the feature or that it is not currently utilized as currently designed. It will provide a benchmark for evaluate future surveys as well as to share insight into any new development for improvements or enhancements of the health IT system.

Care Settings and Number of Clients Site to Test

RWT Measure #3. Electronic Prescriptions Functionality

Associated Criteria: 315(b)(3)

Testing Methodology: Reporting/Survey

Measurement Description

This use case is tracking and counting how many NewRx electronic prescriptions were created and successfully sent from the EHR Module to a pharmacy destination over the course of a given interval.

Measurement Justification

This use case measure will provide a numeric value to indicate both the how often this interoperability feature is being used as well as its compliance to the requirement. An increment to this measure indicates that the EHR can create a NewRx SCRIPT electronic prescription message and transmit it to a pharmacy, typically via the Surescripts Network. This use case will also show successful integration with our ePrescribing partner NewCrop and through its completion will reveal compliance to the associated criteria listed above.

Measurement Expected Outcome

We will test a sample of our user base to get reporting values on NewRx electronic prescriptions sent as well as controlled substance usage.

Measure #1: Report the number of NewRx electronic prescriptions sent over a three (3) month period.

The measurement will produce numeric results over a given interval. We will utilize various reports and audit logs, including Automated Measure (315.g.2) reports, to determine our measure count.

A successful measure increment indicates compliance to the underlying ONC criteria. It will show that the EHR can create the NewRx message and send over a production network, like the Surescripts Network, to a pharmacy. Successfully completing this measure also implies users have a general understanding of the EHR functional operations for this EHR Module and an overall support for the user experience while not completing this measure may indicate lack of understanding or possibly lack of use or need for this functionality.

We will use the measure count to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts.

Care Settings and Number of Clients Site to Test

RWT Measure #4. Batch Patient Data Export

Associated Criteria: 315(b)(6)

Testing Methodology: Survey/Self-Test

Measurement Description

This is a survey measure to determine how often you are using the batch patient data export feature.

Measurement Justification

We do not know how many of our customers are actually using the batch patient exporting so we believe the best means to evaluate real world interoperability is to survey them on this criteria use. This measure will survey users to determine real-world interoperability and usability, specifically how often do clinicians use the batch patient export feature.

A survey or self-testing can often provide more information on the impact and value of an interoperability element than a standard software test evaluation. Batch patient export can be used for various use cases, including supporting working a local HIE or registry as well as quality and population health metrics.

Measurement Expected Outcome

The user will be asked the survey question of how often do you perform the batch patient export during the average month and given the survey answer choices below:

- Regularly
- Sporadically
- Rarely
- Never
- Don't Know

The answer will provide insight into how clinicians view both the use and value of this interoperability feature. For example, response may show that additional training is needed to better utilize the feature or that it is not currently utilized as currently designed. It will provide a benchmark for evaluate future surveys as well as to share insight into any new development for improvements or enhancements of the health IT system.

Care Settings and Number of Clients Site to Test

RWT Measure #5. Number of Quality Measures Successfully Reported on to CMS

Associated Criteria: 315(c)(1)-(c)(3)

Testing Methodology: Reporting/Survey

Measurement Description

This measure is tracking and counting how many eCQM quality measures were successfully reported on by the EHR Module to CMS during their submission period for MIPS Quality reporting.

Measurement Justification

This measure will provide a count and list of electronic clinical quality measures (eCQMs) which are calculated and submitted to CMS for a given program, like MIPS. Clinical quality measures are only used for the respective CMS programs and any production measures should utilize submission to CMS. Because CQM criteria, 315(c)(1)-(c)(3), all work collectively together in the eCQM functionality of the EHR Module, this measurement is used for all three.

Measurement Expected Outcome

The measurement will a count and list of eCQMs submitted to CMS over a given interval. We will ask our customer users to report on the number eCQMs they successfully reported on to CMS which reveals compliance to the associated criteria listed above.

A successful measure submission indicates compliance to the underlying ONC criteria. It will show that the EHR can do calculations on the eCQM and that they are accepted by CMS. Successfully completing this measure also implies users have a general understanding of the EHR functional operations for this EHR Module and an overall support for the user experience while not completing this measure may indicate lack of understanding or possibly lack of use or need for this functionality.

We will use the measure result to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts.

Care Settings and Number of Clients Site to Test

RWT Measure #6. Patient Portal Use

Associated Criteria: 315(e)(1)

Testing Methodology: Reporting/Survey

Measurement Description

This use case is tracking and counting how patients are given access to their portal account over the course of a given interval.

Measurement Justification

This use case measure will provide a numeric value to indicate both the how often this interoperability feature is being used as well as its compliance to the requirement. An increment to this measure indicates that the EHR can create a new patient portal account and give the patient access to it.

A survey can often provide more information on the impact and value of an interoperability element than a standard software test evaluation. The patient portal is intended to support patient engagement with their health records, and the ability to transmit their patient data, as a C-CDA or human readable copy, can be a useful feature.

Measurement Expected Outcome

We will contact a sample of our user base to get reporting values on patient portal access as well as patients use of the portal's interoperability features.

Measure #1: Report the number of new patient accounts created over a three (3) month period.

The measurement will produce numeric results over a given interval. We will utilize various reports and audit logs, including Automated Measure (315.g.2) reports, to determine our measure count.

A successful measure increment indicates compliance to the underlying ONC criteria list above.

Number of Clients Site to Test

RWT Measure #7. IIS/Immunization Registries Use

Associated Criteria: 315(f)(1)

Testing Methodology: Reporting

Measurement Description

This is a reporting measure to determine the number of immunization messages sent to public health registries.

Measurement Justification

This measure will be used to determine real world interoperability and usability, specifically how many immunization messages were sent to an immunization information system (IIS) or public health immunization registries by the provider.

This measure will provide a numeric value to indicate both the how often this interoperability feature is being used as well as its compliance to the requirement. An increment to this measure indicates that the EHR can create an immunization message, including ability to record all clinical data elements, and by sending the message, the EHR demonstrates successful interoperability with an IIS/immunization registry.

Measurement Expected Outcome

As the clinician user submits immunization messages in their normal workflow and clinical activities, we will obtain their messaging metrics to evaluate real world interoperability. To capture this information, we will either use a special report to gather this information from our system or have the clinician user obtain the usage report from the registry.

A successful measure increment indicates compliance to the underlying ONC criteria. It will show that the EHR can create the HL7 immunization record, including ability to record the required clinical data elements. In sending the immunization message, the EHR will demonstrate ability to confirm successful interoperability of patient's immunization data to an IIS/immunization registry. Successfully completing this measure also implies users have a general understanding of the EHR functional operations for this EHR Module and an overall support for the user experience while not completing this measure may indicate lack of understanding or possibly lack of use or need for this functionality.

We will use the measure count to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts.

Care Settings and Number of Clients Site to Test

RWT Measure #8. Syndromic Surveillance Registries Use

Associated Criteria: 315(f)(2)

Testing Methodology: Reporting

Measurement Description

This is a survey measure to determine the number of syndromic surveillance registries in use.

Measurement Justification

This measure will provide a numeric value to indicate both the how often this interoperability feature is being used as well as its compliance to the requirement. An increment to this measure indicates that the EHR can create a syndromic surveillance message, including ability to record all clinical data elements, and by sending the message, the EHR demonstrates successful interoperability with a public health registry.

Measurement Expected Outcome

The measurement will produce numeric results over a given interval. We will utilize various reports and audit logs, to determine our measure count.

A successful measure increment indicates compliance to the underlying ONC criteria. It will show that the EHR can create the HL7 syndromic surveillance message, including ability to record the required clinical data elements. In sending the syndromic surveillance message, the EHR will demonstrate ability to confirm successful interoperability of patient's immunization data to public health registry. Successfully completing this measure also implies users have a general understanding of the EHR functional operations for this EHR Module and an overall support for the user experience while not completing this measure may indicate lack of understanding or possibly lack of use or need for this functionality.

We will use the measure count to establish a historic baseline of expected interoperability use so it can be used in subsequent real world testing efforts.

Care Settings and Number of Clients Site to Test

RWT Measure #9. Cancer Registries Use

Associated Criteria: 315(f)(4)

Testing Methodology: Survey

Measurement Description

This is a survey measure to determine the number of cancer public health registries in use.

Measurement Justification

We do not know how many of our customers are actually using the cancer case transmission functionality so we believe the best means to evaluate real world interoperability is to survey them on this criteria use. This measure will survey users to determine real world interoperability and usability, specifically many different cancer registries are used by the provider.

A survey can often provide more information on the impact and value of an interoperability element than a standard software test evaluation. This survey measure will the number and names of cancer registries which are integrated with the EHR.

Measurement Expected Outcome

The user will be asked the survey question and given the survey answer choices below:

• How many cancer registries do you connect with? (numeric answer to the question, and if willing, the names of the systems)

The answer will provide insight into how clinicians view both the use and value of this interoperability feature. For example, response may show that additional training is needed to better utilize the feature or that it is not currently utilized as currently designed. It will provide a benchmark for evaluate future surveys as well as to share insight into any new development for improvements or enhancements of the health IT system.

Care Settings and Number of Clients Site to Test

RWT Measure #10. API Access

Associated Criteria: 315(g)(7)-(g)(9)

Testing Methodology: Survey

Measurement Description

This is a survey measure to determine how many different systems or applications are connecting to your EHR via the API.

Measurement Justification

We do not know how many of our customers are actually using the API functionality so we believe the best means to evaluate real world interoperability is to survey them on this criteria use. This measure will survey users to determine real world interoperability and usability, specifically many 3rd party systems or applications are integrated and using the EHR's API interface.

A survey can often provide more information on the impact and value of an interoperability element than a standard software test evaluation. API capabilities are an important component of the modern health IT system, and utilization of API resources will help improve patient care and care coordination.

Measurement Expected Outcome

The user will be asked the survey question and given the survey answer choices below:

• How many clients or software systems are connected to your EHR via the API? (numeric answer to the question, and if willing, the names of the other systems.

The answer will provide insight into how clinicians view both the use and value of this interoperability feature. For example, response may show that additional training is needed to better utilize the feature or that it is not currently utilized as currently designed. It will provide a benchmark for evaluate future surveys as well as to share insight into any new development for improvements or enhancements of the health IT system.

Care Settings and Number of Clients Site to Test