GENERAL INFORMATION

Developer Name: PCIS GOLD
Product Name: PCIS GOLD EHR
Version Number: Version 2.5
Certified Health IT:
Product CHPL Listing ID: 15.04.04.2126.PCIS.25.01.1.191228
Developer Real World Testing Page URL: www.pcisgold.com/real-world-testing

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Real World Testing has been defined as a "process by which Health IT Developers demonstrate interoperability and functionality of their Certified Health IT in real world settings and scenarios, rather than in a controlled test environment with an ONC-Authorized Testing Lab (ONC-ATL)." In this document, PCIS outlines our approach to meet the criteria of Real World Testing.

We at PCIS have developed a testing plan to demonstrate the interoperability and functionality of our certified electronic health record (EHR) in the ambulatory setting in the Real World. The following strategy ensures functional transparency and accuracy:

- Our EHR is deployed in a client server-based environment.
- All testing events occur with actual clinical customers in their native environments.
- Users include medical providers, clinical employees, and clerical staff members.

STANDARDS UPDATES

Standard (and version).	2015 Edition CCDS
Updated certification criteria and associated product.	Not applicable
Method used for standard update.	Not applicable
Date of ONC ACB notification.	Not applicable
Date of customer notification (SVAP only).	Not applicable
Conformance measure.	Not applicable
USCDI updated certification criteria (and USCDI version).	Not applicable

MEASURES USED IN OVERALL APPROACH

Description of the Measurement

The following document outlines the measures that best demonstrate conformance to the certification criteria.

Care Coordination

§170.315(b)(1) – Transitions of care

- Users will send and receive the CCDA to and from outside certified EHR systems.
- Users will send and receive transition of care summaries using the Direct protocols.

- Users may limit the data displayed for each CCDA received as required for certification.
- The CCDA will conform to the required standards of MU3 and include all required elements.
- The referring provider contact information is included in the CCDA.
- The reason for the referral is included in the CCDA.
- The CCDA will have pertinent patient identification for appropriate patient matching.
- The transmission logs will be checked for accuracy.

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

- Users incorporate and reconcile the CCDA.
- The CCDA is received and matched to the correct patient.
- Users are able to view the data in the PCIS EHR. This includes the reconciliation of the CCDA, including the medication, allergy and problem lists.
- Users are able to create a CCDA that includes the reconciled data

§170.315(b)(3) – Electronic prescribing

- The PCIS EHR allows the user to create new RX (NEWRX).
- The PCIS EHR allows the user to change prescriptions (RXCHG, CHGRES).
- The system allows the associated diagnosis/reason coded as an ICD-10 code to be sent and received.
- Oral medications are submitted in metric units.
- Leading zeros are present before the decimal. No trailing zeros are present.

§170.315(b)(6) – Data export

- A PCIS EHR user will set the configuration options for a specific export summary, along with a set of export summaries for patients whose information is stored in the EHR.
- Only authorized users can create export summaries.
- The created export summaries are formatted in accordance with the standards outlined in 170.205(a)(4).
- Users may select a time period for data to be used to create the export summaries.
- Users can create export summaries in real time or schedule them for a future time.
- Users can choose where export summaries are saved.

Clinical Quality Measures

§170.315(c)(1) – Record and export

- Users will select CQMs and export the QRDA 1
- For each CQM that providers will attest, the system will have the ability to record all of the data required to calculate results.
- Users can export a data file on demand for one or multiple patients.
- The exported data file is formatted in accordance with the HL7 QRDA Category I specifications.

§170.315(c)(2) – Import and calculate

- Users import the QRDA received from an external system and calculate the measure.
- Users can import a data file formatted in accordance with HL7 QRDA Category I Release 3 for one or multiple patients.

§170.315(c)(3) – Report

- Users will export QRDA 3 files for all measures that undergo reporting.
- Users can create a data file for the transmission of CQM data in QRDA Category 1 and Category 3 formats.
- The Category 1 and Category 3 reports will successfully pass the Cypress test tool validation for CMS submission.

Patient Engagement

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

- CCDAs are available on the PCIS Patient Portal for patients or an authorized representative to view, download, and transmit to a 3rd party.
- Patients and their authorized representatives are able to view the following:
  a) Health Record data as defined by the Common Clinical Data Set.
  b) The provider's name and office contact information.
  c) Laboratory test report(s).
- C-CDA files must successfully validate with the C-CDA message validator.

Public Health

§170.315(f)(1) – Transmission to immunization registries

- Users will send immunization records electronically, as supported, to a state registry.
- The immunization information will be formatted in HL7 2.5.1 standard, using CVX codes for historical vaccines and NDC codes for newly administered vaccines.
- Users will request a patient's immunization history and forecast from the immunization registry.

§170.315(f)(2) – Transmission to public health agencies – syndromic surveillance

- Users will record syndromic surveillance content and generate the HL7 message.
- The message will conform to the HL7 v2.5.1 PHIN Messaging Guide and support ICD-10 and SNOMED CT.

§170.315(f)(4) – Transmission to cancer registries

- A PCIS user will record cancer information and generate a cancer case document.
- The cancer case document will be generated according to the HL7 message specification and support SNOMED CT and LOINC codes for cancer case information.

Application Programming Interfaces

§170.315(g)(7) – Application access – patient selection

- The PCIS EHR API will receive a request with enough information to uniquely identify a patient. This will return an ID that can be used to subsequently execute requests for that patient's data.

§170.315(g)(8) – Application access – data category request

- The PCIS EHR API will return data to requests for patient data for each of the individual data categories specified in the Common Clinical Data Set.
- It will return the full set of data for each category in a computable format for a specified date range.
- API Developer documentation is available at a publicly accessible hyperlink.

§170.315(g)(9) – Application access – all data request

- The PCIS EHR API will respond to requests for all CCDA patient summary records that include all the data categories specified in the Common Clinical Data Set.
- The requests may include a date range.

Associated Certification Criteria

§170.315(b)(1) – Transitions of care
§170.315(b)(2) – Clinical information reconciliation and incorporation
§170.315(b)(3) – Electronic prescribing
§170.315(b)(6) – Data export
§170.315(c)(1) – Record and export
§170.315(c)(2) – Import and calculate
§170.315(c)(3) – Report
§170.315(e)(1) – View, Download, and transmit to 3rd party
§170.315(f)(1) – Transmission to immunization registries
§170.315(f)(2) – Transmission to public health agencies – syndromic surveillance
§170.315(f)(4) – Transmission to cancer registries
§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

Requirements and Test Plan

Care Coordination -

Certification Criteria Measurement	Requirement / Test Plan	Justification
§170.315(b)(1) – Transitions of care	**Send transition of care/referral summaries** 1. Find the patient to send an Outbound TOC CCDA. 2. Open the Health record, and navigate to the TOC section. 3. Select the visit marked as TOC outbound. 4. Send via direct. **Receive transmission of care/referral summaries** 1. User will open the inbound TOC task in eTask. 2. If patient was not automatically matched, then user will search for patient and attach the inbound CCDA to the selected patient.	The PCIS EHR has the ability to send and receive TOC CCDA referral summaries via direct protocols. The goal of this test procedure is to ensure that the expected results are obtained and consistent with the standards set forth in 170.315(b)(1). We will exchange messages with an external system to conduct this test and verify the results. Sent and received messages will be logged

		and counted. All errors will also be recorded.
§170.315(b)(2) – Clinical information reconciliation and incorporation	**Complete the Clinical information reconciliation and incorporate the received TOC CCDA** 1. User will open the inbound TOC task and perform the clinical reconciliation for Medication Lists, Allergy Lists and Problems. 2. User confirms that data is in a single reconciled list.	PCIS EHR has the ability to send and receive TOC CCDA Referral summaries via direct protocols. The goal of this test procedure is to ensure that the expected results are obtained and consistent with the standards set forth in 170.315(b)(2). We will exchange messages with an external system to conduct this test and verify the results. We will select a sample of inbound messages to confirm that they have been incorporated and reconciled.
§170.315(b)(3) – Electronic prescribing	**Electronic Prescription sent by a provider** 1. Find a patient to send an electronic prescription. 2. Click on the <Prescribe Meds> button. 3. Search for the drug to ERx and enter sig and dose information. 4. Select the pharmacy for the ERx and process the eRX.	The PCIS EHR has the ability to send electronic prescriptions. The goal of this test procedure is to ensure that the eRx is successfully sent to external pharmacies and consistent with the standards set forth in 170.315(b)(3). We will confirm that the pharmacy has received the eRX by checking the response status. We will then count the total sent messages and errors.
§170.315(b)(6) – Data export	**Authorized user can create a CCDA export file at any time** 1. Select the <patient queries> function. 2. Create the patient selection query.	The PCIS EHR has the ability to create CCDAs for a single patient, a set of specific patients, or all patients.

	3. Select <Scheduled CCDA Export>. 4. Configure export options, including destination and timeframe. 5. Press <OK> to save. 6. Verify the CCDA files are in the destination when the system runs the extract.	The goal of this test procedure is to ensure that the CCDA is successfully exported and saved in the configured destination location and consistent with the standards set forth in 170.315(b)(6). Each scheduled export builds a log to track the number of CCDAs that were created and to check error rates. A sample of these logs will be reviewed.

Clinical Quality Measures -

Certification Criteria Measurement	Requirement	Justification
§170.315(c)(1) – Record and export	**Record and export the CQM QRDA 1 file for measures selected by the end user** 1. Record patient data necessary to calculate quality measures by the PCIS EHR. 2. Select CQM measures under the Tools menu. 3. Select the export QRDA 1. 4. Select one or all patients and export the files to the destination.	The PCIS EHR has the ability to record the data necessary to calculate quality measures through manual entry or import. Also, the PCIS EHR has the ability to export patient level eCQM data formatted to HL7 QRDA 1. The goal of this test procedure is to ensure that the QRDA 1 is successfully exported and saved in the destination location and consistent with the standards set forth in 170.315(c)(1).
§170.315(c)(2) – Import and calculate	**Import the CQM QRDA 1 file and calculate the results for measures selected by the end user** 1. Select CQM measures under the Tools menu. 2. Select the import QRDA 1 option, then select the QRDA 1 file to import.	The PCIS EHR has the ability to import CQM QRDA 1 files and use that data for calculations. The goal of this test procedure is to ensure that

	Note: The system will use the imported data when calculating the CQMs.	the QRDA 1 is successfully imported and included in the calculations and consistent with the standards set forth in 170.315(c)(2). The imported data will be saved in the database so it can be reviewed for completeness.
§170.315(c)(3) – Report	**Create the CQM QRDA 3 results files for the measures selected by the end user** 1. Select <CQM measures> under the Tools menu. 2. Select the provider or the facility tab. 3. Select the checkbox beside each CQM measure to create a QRDA 3 file. 4. Press <Export> button and enter the user information and export location. 5. Press <OK> to create the file.	The PCIS EHR has the ability to create CQM QRDA 3 files for the patients and providers selected. The goal of this test procedure is to ensure that the QRDA 3 file is successfully created and the calculations are consistent with the standards set forth in 170.315(c)(3). The counts in the QRDA 3 file match the report.

Patient Engagement –

Certification Criteria Measurement	Requirement / Test Plan	Justification
§170.315(e)(1) – View, Download, and transmit to 3rd party	**Patient can view the visit summary on the patient web portal** 1. Complete a visit in the EHR to make it available on the Patient Web Portal. 2. Log in as that patient and navigate to the <Medical tab>. 3. Select the <Visit History> menu item. 4. Select <View> under the document's dropdown.	The PCIS EHR has the ability to view, download, and transmit the summary of care CCDA file for selected patients. The goal of this test procedure is to ensure that the CCDA is successfully created and accessible to the patient via the patient web portal. This is consistent with the

	Patient can download the visit summary in the correct CCDA format 1- Complete a visit in the EHR to make it available on the Patient Web Portal. 2- Log in as that patient and navigate to the <Medical tab>. 3- Select the <Visit History> menu item. 4- Select <Download> under the document's dropdown. **Patient can transmit the CCDA to a 3rd party** 1. Complete a visit in the EHR to make it available on the Patient Web Portal. 2. Log in as that patient and navigate to the <Medical tab>. 3. Select the <Visit History> menu item. 4. Select <Transmit> under the document's dropdown. 5. Fill in the required information. 6. Press <Send>.	standards set forth in 170.315(e)(1). The system creates a log each time a patient views, downloads, or transmits the CCDA. The reported errors for these functions will be tracked.

Public Health –

Certification Criteria Measurement	Requirement / Test Plan	Justification
§170.315(f)(1) – Transmission to immunization registries	**Generate HL7 VXU immunization messages to be sent to an immunization registry** Document the immunization details on the patient immunization screen. HL7 VXU message is automatically generated with immunization information and transmitted to immunization partner registry. **Receive and display historical immunization information**	The PCIS EHR has the ability to send and receive immunization details from a partner registry. The goal of this test procedure is to ensure that the immunization information is successfully sent and received. This is consistent with the

	The PCIS system will automatically request immunization history for scheduled patients the morning of their appointment. Immunization details provided from a partner registry will appear on the Patient Immunization screen. **Receive and display immunization forecast information** The PCIS system will automatically request an immunization history for scheduled patients the morning of their appointment. Click <Forecast> to display the forecast details from the partner registry.	standards set forth in 170.315(f)(1). A sample of the VXU sent messages will be compared to the partner registry to calculate a percentage of successful messages.
§170.315(f)(2) – Transmission to public health agencies – syndromic surveillance	**Create syndromic surveillance information for electronic transmission** 1. Open the Patient Visit Charting screen. 2. Select the Urgent Care checkbox in the Transition of Care section. 3. Fill in the appropriate information. Note: The correct HL7 message is generated for electronic transmission.	The PCIS EHR has the ability to generate syndromic surveillance information for submission to a public health agency. The goal of this test procedure is to ensure that the syndromic information is successfully created for submission and consistent with the standards set forth in 170.315(f)(2). The failure rate for the created messages will be tracked.
§170.315(f)(4) – Transmission to cancer registries	**Create cancer case information for electronic submission** 1. Add a cancer diagnosis code to a patient visit. A task for the cancer case is created on the Visit Checkout screen. 2. Fill in the appropriate details on the cancer case task. 3. Press <Send to Registry> to create the HL7 message.	The PCIS EHR has the ability to create cancer case information for submission to a public health agency. The goal of this test procedure is to ensure that the cancer case document is successfully created for submission and consistent with the standards set forth in 170.315(f)(4).

		The failure rate for the number of created messages will be tracked.

Application Programming Interfaces –

Certification Criteria Measurement	Requirement / Test Plan	Justification
§170.315(g)(7) – Application access – patient selection	**Receive a request for information to identify a patient and return an ID that can be used for subsequent requests** 1. A third-party developer follows instructions on the clinic's website for API documentation. 2. The third-party application calls the method on the API with enough information to uniquely identify a patient. The PCIS API returns a unique ID for the patient.	The PCIS EHR has the ability to return a patient id via the API when requested with enough information. The goal of this test procedure is to ensure that the API will find a patient and return the unique Id. This is consistent with the requirements of 170.315(g)(7). The failure rate for the test event will be recorded.

§170.315(g)(8) – Application access – data category request	**The API will return the data for each of the individual data categories defined in the Common Clinical Data Set** 1. A third-party developer follows instructions on the PCIS website for API documentation. 2. The third-party application calls the individual methods for each data category on the API. The PCIS API returns the data.	The PCIS EHR has the ability to return the information from each category in the Common Clinical Data Set via the API when requested with the correct patient identifier. The goal of this test procedure is to ensure that the API will allow a third-party app to retrieve the data. This is consistent with the requirements of 170.315(g)(8). The failure rate for calls that occur during the test event will be recorded.
§170.315(g)(9) – Application access – all data request	**The API will return properly formatted summary CCDAs when requested via the API** 1. A third-party developer follows instructions on the PCIS website for API documentation. 2. The third-party application calls the individual methods to identify and return the CCDA summaries.	The PCIS EHR has the ability to return summary CCDAs via the API when requested with the correct patient identifier. The goal of this test procedure is to ensure that the API will allow a third-party app to retrieve the CCDAs. This is consistent with the requirements of 170.315(g)(9). The failure rate for calls that occur during the test event will be recorded.

Care Settings

Care Setting	Care Setting Justification
Ambulatory Clinics	The target market of the PCIS GOLD EHR Version 2.5 is in the outpatient ambulatory setting. The software is used in both single and multi-specialty ambulatory clinics. The following criteria will serve as the primary care setting for all Real World testing events:

	§170.315(b)(1) – Transitions of care §170.315(b)(2) – Clinical information reconciliation and incorporation §170.315(b)(3) – Electronic prescribing §170.315(b)(6) – Data export §170.315(c)(1) – Record and export §170.315(c)(2) – Import and calculate §170.315(c)(3) – Report §170.315(e)(1) – View, download, and transmit to 3rd party §170.315(f)(1) – Transmission to immunization registries §170.315(f)(2) – Transmission to public health agencies – syndromic surveillance §170.315(f)(4) – Transmission to cancer registries §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 All test procedures outlined in this document are applicable to the ambulatory care setting.

Expected Outcomes / Metric

Certification Criteria	Expected Outcomes / Metric
§170.315(b)(1) – Transitions of care	Transition of care/referral summaries are sent and received to and from external sources with an error rate of less than five percent.

§170.315(b)(2) – Clinical information reconciliation and incorporation	Clinical information reconciliation is completed and the CCDA is incorporated for more than 90 percent of the received messages.
§170.315(b)(3) – Electronic prescribing	Providers can successfully send electronic prescriptions with a failure rate of less than one percent.
§170.315(b)(6) – Data export	Authorized users can create CCDA export files at any time. These files will be exported with a success rate of more than 95 percent.
§170.315(c)(1) – Record and export	The information necessary to calculate quality measures can be manually recorded and exported in QRDA 1 format. The number of files in the destination will match the number of selected files.
§170.315(c)(2) – Import and calculate	The CQM QRDA 1 file is imported and the results are calculated for measures selected by the end user. A sample of the imported patients will be selected and error rates will be tracked.
§170.315(c)(3) – Report	The CQM QRDA 3 results files are created for measures selected by the end user. The calculated counts in the QRDA 3 will match those in the report.
§170.315(e)(1) – View, Download, and transmit to 3rd party	Patients can do the following: 1. view the visit summary on the patient web portal, 2. download the visit summary in the correct CCDA format, and 3. transmit the CCDA to a 3rd party. The reported error rate will be less than 5 percent.
§170.315(f)(1) – Transmission to immunization registries	The PCIS GOLD EHR completes the following tasks: 1. sends immunization information to the partner registry, 2. receives and displays historical immunization information, and 3. receives and displays immunization forecast information. More than 95 percent of the sample VXU messages will be successfully received by the partner registry.
§170.315(f)(2) – Transmission to public health agencies – syndromic surveillance	Users can create syndromic surveillance information for electronic transmission. This will be done with more than a 99 percent success rate.
§170.315(f)(4) – Transmission to cancer registries	Users can create cancer case information for electronic submission with a success rate of more than 99 percent.
§170.315(g)(7) – Application access – patient selection	The API can receive a request for information to identify a patient. It can also return an ID that can be used for subsequent requests with a success rate of more than 95 percent.

§170.315(g)(8) – Application access – data category request	The API will return the data for each of the individual data categories as defined in the Common Clinical Data Set. This will be done with a success rate of more than 95 percent.
§170.315(g)(9) – Application access – all data request	The API will return properly formatted summary CCDAs when requested via the API. This will be done with a success rate of more than 95 percent.

Schedule of Key Milestones

Key Milestone	Date/Timeframe
Design and develop the PCIS Real World Testing plans.	August - November 2021
Submit Real World Testing Scripts to the Drummond Group	November 2021
Release of documentation for the Real World Testing to be provided to authorized representatives and providers running the PCIS EHR	December 2021
Begin collection of data as laid out by the PCIS Real World Testing Plan.	January 1st, 2022
Meet with previously identified providers and representatives to validate Real World Testing methods are effective.	Quarterly 2022
Follow-up with providers/representatives to review any issues that were discovered with the data collection.	Quarterly 2022
Data collection and review	Quarterly 2022
End of Real World Testing period collection of all data for analysis.	End of 2022
Data analysis and report generation.	January 2023
Submit Real World Testing Report	February 2023

This Real World Testing plan is complete with all required elements, including measures that addresses 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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