#### **GENERAL INFORMATION**

Developer Name: PCIS GOLD Product Name: PCIS GOLD EHR Version Number: Version 2.6

Certified Health IT:

Product CHPL Listing ID: 15.04.04.2126.PCIS.26.02.1.221222

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).	USCDI Version 1
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).	USCDI Version 1

#### 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)cures – 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 the 2015 Cures Update 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)cures – 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)cures – 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.
- Users can request and receive a patient's medication history.

#### §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**

#### $\S170.315(c)(1)$ – 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.

$$\S170.315(c)(2)$$
 – 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.

$$\S170.315(c)(3)$$
 - 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 3<sup>rd</sup> party

- CCDAs are available on the PCIS Patient Portal for patients or an authorized representative to view, download, and transmit to a 3<sup>rd</sup> 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

 $\S170.315(f)(1)$  – 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.

 $\S170.315(f)(4)$  – 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**

 $\S170.315(g)(7)$  – 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.

 $\S170.315(g)(9)$  – 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.

§170.315(g)(10) – Standardized API for Patient and Population Services

• The PCIS EHR API supports client application registration and uses standardized operations. API

instruction and documentation is available for application developers.

#### Associated Certification Criteria

§170.315(b)(1)cures – Transitions of care

§170.315(b)(2)cures - Clinical information reconciliation and incorporation §170.315(b)(3)cures -Electronic prescribing §170.315(b)(6) - Data export  $\S170.315(c)(1)$  – Record and export  $\S170.315(c)(2)$  – Import and calculate §170.315(c)(3)cures – Report §170.315(e)(1)cures – View, Download, and transmit to 3rd party  $\S170.315(f)(1)$  – Transmission to immunization registries §170.315(f)(2) - Transmission to public health agencies - syndromic surveillance §170.315(f)(4) -

Transmission to cancer registries

 $\S170.315(g)(7)$  – Application access – patient selection

§170.315(g)(9)cures - Application access - all data request §170.315(g)(10)cures - Standardized API for patient and population services

# Requirements and Test Plan

# Care Coordination -

Certifica tionCrite ria  Measure ment	Requirement / Test Plan	Justification
§170.31 5(b)(1) cures – Transitio	Send transition of care/referral s ummaries  1. Find the patient to send an	The PCIS EHR has the ability to send and receive TOCCCDA referral sum
ns of care	Outbound TOC	maries via direct protocols. The PCIS EHR relies upon 3 <sup>rd</sup> party software, Updox to fulfill this
	<ol><li>Open the Health record, and navigate to the TOC</li></ol>	requirement.
	Select the visit marked as T     OC	The goal of this test procedure is to ensure that the expected results are obtained and consistent with
	4. Send via	the standards set forth in
	Receive transmission of care/ref erral summaries	170.315(b)(1). This procedurew ill also verify functionalitywith re lied upon 3 <sup>rd</sup> party
	User will     open the inbound TOC     task in	software partner, Updox. Wewill exchange messages with an ex ternal system to conduct this test and verify the results.
	If patient was not automatically matched, then userwill search for patient and attach the inbound CCDA to the selected patient	Sent and received messages will be logged and counted. All errors will also be recorded.
§170.31 5(b)(2)c ures – Clinical informati	Complete the Clinical information reconciliation and incorporate the received TOC CCDA	PCIS EHR has the ability to send and receive TOC CCDA Referral summaries via direct protocols.

on reconcili ation and incorpor ation
§170.31 5(b)(3)c ures – Electroni c prescribi ng

- User will open the inbound TOC task and perform the clinical reconciliation for Medication Lists, Allergy Lists and
- 2. User confirms that data is in a single reconciled list.

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.

# Electronic Prescription sent by a provider

- 1. Find a patient to send an electronic
- 2. Click on the <Prescribe Meds>
- 3. Search for the drug to eRx and enter sig and dose
- 4. Select the pharmacy for the eRx and process the eRx.

# Users can request and receive a patient's medication history.

- Find a patient to send and electronic
- 2. Within the patient's health record medication section click on <Rx History>.
- User reviews the disclosure, selects the time period and clicks <Req uest Prescription History>.

The PCIS EHR has the ability to send electronic prescriptions and request patient medication hist ory. The PCIS EHR relies upon third party software, New crop to fulfill this requirement.

The goal of this test procedure is to ensure that the eRx is successfully sent to external pharmacies and that

patient medication history can be requested consistent with the standards set forth in 170.315(b)(3). This test procedure verifies successful integration with relied upon third party software.

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.

Authorized user can create a	The PCIS EHR has the ability to
CCDA export file at any time	create CCDAs for a single
	patient, a set of specific
1.Select the <patient queries=""> function.</patient>	patients, or all patients.
	The goal of this test
2. Create the patient selection qu	procedure is to ensure that
ery.	the CCDA is successfully
	exported and saved in the
	configured destination
<5cheduled CCDA Export>.	location and consistent with the
4 Configure export options	standards set forth
	in 170.315(b)(6).
timeframe.	Each scheduled export builds
	a log to track the number of
5. Press <ok> to save.</ok>	CCDAs that were created and to
	check error rates. A sample of
-	these logs will be reviewed.
-	
теехтаст.	
	<ol> <li>Select the <patient queries=""> function.</patient></li> <li>Create the patient selection query.</li> <li>Select <scheduled ccda="" export="">.</scheduled></li> <li>Configure export options, including destination and timeframe.</li> </ol>

# Clinical Quality Measures -

Certificatio n Criteria	Requirement	Justification
Measureme nt		
§170.315(c )(1) -	Record and export the CQM QRDA 1 file for measures selectedby the end user	The PCIS EHR ha s the ability to record the
Record and export	Record patient data necessary to calculate quality measures by the PCIS EHR.	data necessary to calculate quality measures through manual

	<ol> <li>Select CQM measures under the Tools</li> <li>Select the export QRDA</li> <li>Select one or all patients and export the files to the destination.</li> </ol>	entry or import. Also, the PCIS EHR has the ability to export patient level eCQ M 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. Place the QRDA 1 files in the folder designated for imports.	The PCIS EHR has the ability to import CQMQRDA 1 files and use that data for calculations.
	<ul><li>2. Start a CQM run (manual/automated).</li><li>3. Verify the quality measure results include the data from the imported QRDA file.</li></ul>	The goal of this test procedure is to ensure that 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)cures – Report	Create the CQM QRDA 3 results files for the measures selected by the end user  1. Select <quality measures=""> under the Tools menu.  2. Select the provider or the facility tab.</quality>	The PCIS EHR has the ability to create CQMQRDA 3 files for the patients and providers selected.
	<ol> <li>Select the checkbox beside each CQM measure to create a QRDA 3 file.</li> <li>Press <export> button and enter the user information and export location.</export></li> <li>Press <ok> to create the file.</ok></li> </ol>	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 in170.315(c)(3).  The counts in the QRDA 3 file match the report.

Certification Criteria Measurement	Requirement / Test Plan	Justification
§170.315(e)(1)cures – View, Download, and transmit to 3 <sup>rd</sup> 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.  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 3<sup>rd</sup> party  5. Complete a visit in the EHR to make it available on the Patient Web Portal.</download></visit></medical></view></visit></medical>	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 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.

10. Press <send>.</send>		<ul> <li>6. Log in as that patient and navigate to the <medical tab="">.</medical></li> <li>7. Select the <visit history=""> menu item.</visit></li> <li>8. Select <transmit> under the document's dropdown.</transmit></li> <li>9. Fill in the required information.</li> <li>10. Press <send>.</send></li> </ul>
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# Public Health -

Certification Criteria Measurement	Requirement / Test Plan	Justification
	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.	The PCIS EHR has the ability to send and receive immunization details from a partner registry.
	Receive and display historical immunization information	The goal of this test procedure is to ensure that the immunization
§170.315(f)(1) – Transmission to immunization registries	request immunization history for	information is successfully sent and received. This is consistent with the standards set forth in 170.315(f)(1).
	partner registry will appear on the Patient Immunization screen.	A sample of the VXU sent messages will be compared to the partner registry to calculate a percentage of successful
	Receive and display immunization forecast information	messages.
	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.</forecast>	
	Create syndromic surveillance information for electronic transmission	The PCIS EHR has the ability to generate syndromic surveillance information for submission to a public health agency.
§170.315(f)(2) – Transmission to public health agencies – syndromic surveillance	<ol> <li>Open the Patient Visit Charting screen.</li> <li>Select the Urgent Care checkbox in the Transition of Care section.</li> <li>Fill in the appropriate information.</li> </ol>	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).
	Note: The correct HL7 message is generated for electronic transmission.	The failure rate for the created messages will be tracked.
	Create cancer case information for electronic submission  1. Add a cancer diagnosis code to a patient visit.	The PCIS EHR has the ability to create cancer case information for submission to a public health agency.
§170.315(f)(4) – Transmission to cancer registries	A task for the cancer case is created on the Visit Checkout screen.	The goal of this test procedure is to ensure that the cancer case document is successfully created for submission and consistent
	<ol> <li>Fill in the appropriate details on the cancer case task.</li> <li>Press <send registry="" to=""> to create the HL7 message.</send></li> </ol>	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	subsequent requests  1. An application developer registers their application with the API by following the API documentation instructions.  2. The application performs standalone patient launch using user credentials that are associated with a 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

	3. The OAuth token exchange response body contains the patient identifier.	requirements of 170.315(g)(7). The failure rate for
		the test event will be recorded.
	The API will return properly formatted summary CCDAs when requested via the API	The PCIS EHR has the ability to return summary CCDAs via the API when requested with the correct patient identifier.
§170.315(g)(9) – Application access – all data request	<ol> <li>A third-party developer follows instructions on the PCIS website for API documentation.</li> <li>The third-party application calls the individual methods to identify and return the CCDA summaries.</li> </ol>	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.
	The API supports client application registration	The PCIS EHR API supports
§170.315(g)(10)cur es	Application developer follows documentation instructions to register their client application.	Application registration and uses standardized operations. Documentation is available for
- Standardized API for Patient and Population Services	2. The client application uses stand alone patient launch application flow to authorize with the API.	application developers.
	to authorize with the AFI.	The goal of this test is to ensure that client
	3. The client application makes several calls to obtain patient data.	applications can register and use the API to access patient data, and

The API uses standardized operations  1. The API endpoint is identified from the endpoint service directory section of the API documentation.	that documentati on is available.  Any errors encountered by the client application during the test event are recorded.
2. Navigating to the API end point metadata address produces data that is reviewed for conformance to standards.	
API Documentation is available for application developers  1. Application developer navigates to the API documentation URL.	
2. Application developer clicks the links to access instructions and documentation.	

# Care Settings

Care Setting	Care Setting Justification
	The target market of the PCIS GOLD EHR 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:
Clinics	§170.315(b)(1)cures – Transitions of care §170.315(b)(2)cures – Clinical information reconciliation and incorporation §170.315(b)(3)cures – 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)cures – Report

§170.315(e)(1) cures – 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)(9) cures – Application access – all data request §170.315(g)(10) cures – Standardized API for patient and populations services

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) cures	Transition of care/referral summaries are sent
<ul> <li>Transitions of care</li> </ul>	and received to and from external sources with
	an error rate of less than five percent.
§170.315(b)(2) cures	Clinical information reconciliation is completed
<ul> <li>Clinical information</li> </ul>	and the CCDA is incorporated for more than 90
reconciliation and	percent of the received messages.
incorporation	
§170.315(b)(3)cures -	Providers can successfully send electronic
Electronic prescribing	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) -	The information necessary to calculate quality
	measures can be manually recorded and
Record and export	exported in QRDA 1 format. The number of files
	in the destination will match the number of
0470.045(.)(0)	selected files.
§170.315(c)(2) -	The CQM QRDA 1 file is imported and the
Import and calculate	results are calculated for
Import and calculate	magauras salasted by the and user A sample
	measures selected by the end user. A sample of the imported patients will be selected and
	error rates will be tracked.
	enorrates will be tracked.
§170.315(c)(3)cures	The CQM QRDA 3 results files are created for
- Report	measures selected by the end user. The
	calculated counts in the QRDA 3 will match
	those in the report.

§170.315(e)(1)cures - View,	Patients can do the following:	
Download, and transmit to 3 <sup>rd</sup> party	1. View the visit summary on the patient web portal, download the visit summary in the corre ct CCDA format, and transmit the CCDA to a 3 <sup>rd</sup> party	
	The reported error rate will be less than 5 perce nt.	
§170.315(f)(1) -	The PCIS GOLD EHR completes the following ta sks:	
Transmission to immunization registries	Sends immunization information to the partner registry, receives and displays historical immunization information, and 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) -	The API can receive a request for information to identify a patient. It can also return an ID that	

Application access – patient selection	can be used for subsequent requests with a success rate of more than 95 percent.
§170.315(g)(9)cures – Applic ation 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.
§170.315(g)(10)cures  – Standardized API for patient and	The API documentation website is available and returns the documentation and instructions for application developers. The API returns patient data to the client application with a
Populations services	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 2022
Submit Real World Testing Scripts to the Drummond Group	November 2022
Release of documentation for the Real World Testing to be provided	December 2022
to authorized representatives and providers running	
the PCIS EHR	
Begin collection of data as laid out by the PCIS Real World	January 1st, 2023
Testing Plan.	
Meet with previously identified providers and	Quarterly 2023
representatives to validate Real World Testing methods	Quarterly 2020
are effective.	
Follow-up with providers/representatives to review any	Quarterly 2023
issues that were discovered with the data collection.	, , , , , , , , , , , , , , , , , , , ,
Data collection and review	Quarterly 2023
End of Real World Testing period collection of all dataforan	End of 2023
alysis.	

Data analysis and report generation.	January 2024
Submit Real World Testing Report	February 2024

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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