

↳ Real World Testing Plan template

GENERAL INFORMATION

Plan Report ID Number: **20231110pem**

Developer Name: **Physicians EMR, LLC**

Product Name(s): **IPClinical**

Version Number(s): **2.1**

Product List (CHPL) ID(s): **15.05.05.2163.PEMR.01.00.1.200123**

Developer Real World Testing Page URL: https://ipclinical.com/IPClinical_RWT_Plan.html

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

*This is a Real World Testing Plan for following Care Coordination and Patient Engagement certification criteria:
§ 170.315(b)(1) - Transitions of care
§ 170.315(b)(2) - Clinical information reconciliation and incorporation
§ 170.315(e)(1) - View, download, and transmit to 3rd party*

At this time, the Certified Health IT Module is currently marketed to and used by Cardiology specialty care setting and Internal Medicine specialty care settings. This plan will address the certification criteria that includes the implementation and transmission of Consolidated Clinical Document Architecture (C-CDA). All certification criteria listed in this plan are not part of standard workflow in above-mentioned care settings, still, the plan will justify Certified Health IT Module capabilities to Send and Receive CCDA/Referral Note using Edge Protocols (e.g., SMTP, Direct), Incorporate and Reconcile CCDA, Display and download CCDA in human readable format, and Transmit CCDA through encrypted & secure mechanism.

This year, our testing plan approach is to assure the conformance of each requirement of the criterion. The structure of both Continuity of Care Document/Referral Note will be reviewed and any updates found will be addressed. Display requirements and preferences will be verified to ensure that the user is easily able to view and understand the summary of care.

The frequency of reconciling data will be promoted as part of this plan to ensure updated information in patient's summary of care.

Implementation of view summary of care standard will be reviewed and improved as part of this plan to ensure conformance and improve the summary of care records readability experience for all kind of users.

The core objective of our RWT approach is to smoothen and streamline the workflow of deployed certified capabilities in order to promote interoperability and EHI exchange.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI))

| | |
|--|----|
| Standard (and version) | NA |
| Updated certification criteria and associated product | NA |
| Health IT Module CHPL ID | NA |
| Method used for standard update | NA |
| Date of ONC-ACB notification | NA |
| Date of customer notification (SVAP only) | NA |
| Conformance measure | NA |
| USCDI-updated certification criteria (and USCDI version) | NA |

MEASURES USED IN OVERALL APPROACH

DESCRIPTION OF MEASUREMENT/METRIC

| Measurement/Metric | Description |
|--|---|
| <i>View Summary of care</i> | In this metric, we will improve the process and experience of displaying (View) patient summary of care both while importing it in the system and while sending/exporting it. Conformance of WCAG standard will be reviewed and steps will be taken to make Summary of Care interface interactive and easily readable for all kind of users. <i>Relied-upon software: EMR Direct Interoperability Engine (Version 2017).</i> |
| <i>Increase Import & Reconcile</i> | <i>This measurement/metric will assess the frequency of incorporating and reconciling process used for transition of care and new patients. This metric will identify the frequency of patients added in the system through CCDA import and the frequency of reconciliation performed on existing patient's data. After analyzing the frequency, improvement steps will be taken to increase import and reconcile process.</i> <i>Relied-upon software: EMR Direct Interoperability Engine (Version 2017).</i> |

ASSOCIATED CERTIFICATION CRITERIA

| Measurement/Metric | Associated Certification Criteria |
|--|--|
| <i>View Summary of care</i> | § 170.315(b)(1) - Transitions of care § 170.315(e)(1) - View, download, and transmit to 3rd party |
| <i>Increase Import & Reconcile</i> | § 170.315(b)(1) - Transitions of care § 170.315(b)(2) - Clinical information reconciliation and incorporation |

JUSTIFICATION FOR SELECTED MEASUREMENT/METRIC

| Measurement/Metric | Justification |
|--|--|
| <i>View Summary of care</i> | <p><i>The impact of this metric relates to following certified capabilities i.e., Send TOC/Referral Summaries, Receive TOC/Referral Summaries and EHI access through Patient Portal.</i></p> <p><i>The purpose of this metric is to make the EHI exchange process easy and usable for the providers to increase its adoptability</i></p> <p><i>The presentation of summary of care record will be made interactive and easily understandable for the providers so they don't hesitate to send and receive summaries of care.</i></p> <p><i>Summary of care will be displayed with interactive user experience and easily readability mechanism so the providers don't have to indulge in reading summary of care in HTML or XML formats.</i></p> <p><i>This measurement/metric will primarily be applied in Cardiology Specialty Care Setting.</i></p> |
| <i>Increase Import & Reconcile</i> | <p><i>This metric covers two of the certified capabilities i.e., import/incorporate and reconcile. This measure will help us identify number of instances when patients are added into the Certified Health IT Module through CCDAs Import and how frequently reconciliation is performed on existing patients.</i></p> <p><i>Under this metric, steps will be taken to increase the adoption rate of adding patient through import CCDAs and increase reconciliation process on existing to maintain their updated medical record.</i></p> <p><i>This measurement/metric will primarily be applied in Cardiology Specialty Care Setting.</i></p> |

CARE SETTING(S)

| Care Setting | Justification |
|---|---|
| <i>Cardiology Specialty Care Setting</i> | <i>This Certified Health IT is currently marketed to and used by Cardiologists in Cardiology Specialty Care Setting. At this time, there are more than three providers from this setting using our Certified Health IT.</i> |
| <i>Internal Medicine Specialty Care Setting</i> | <i>Another care setting where this Certified Health IT is deployed is the Internal Medicine Specialty Care Setting. The product is also marketed to Internal Medicine Specialty Care Setting.</i> |

EXPECTED OUTCOMES

| Measurement/Metric | Expected Outcomes |
|--|--|
| <i>View Summary of care</i> | <ul style="list-style-type: none"> • <i>User interface of displaying the summary of care records sent and received will be enhanced.</i> • <i>Interactive and easy to understand interface provided for reading summary of care will increase EHI exchange and interoperability adoption rate.</i> • <i>Providers hesitation towards usage of EHI exchange and interoperability process will be reduced.</i> • <i>Electronic exchange of PHI will increase over paperwork and fax process.</i> |
| <i>Increase Import & Reconcile</i> | <ul style="list-style-type: none"> • <i>Real World Testing will show the compliance of Incorporating and Reconciling mechanism with specified standards and vocabulary code sets.</i> • <i>The process of incorporating and reconciling EHI into the system will be evaluated and improved.</i> • <i>The approach chosen will also examine the frequency of Import and Reconcile process and will identify steps to increase adoption rate of this process.</i> • <i>Error rates and validation issues will be faced during the testing will be tracked, analyzed and trended over time.</i> |

SCHEDULE OF KEY MILESTONES

| Key Milestone | Care Setting | Date/Timeframe |
|--|--|---|
| <i>Release of Real World Testing plan documentation shared with office staff and providers using Certified Health IT module.</i> | <i>Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting</i> | <i>Decembe, 2023</i> |
| <i>Start collection of patient data for real-world testing.</i> | <i>Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting</i> | <i>January, 2024</i> |
| <i>Complete enhancements to improve 'View' Summary of Care experience.</i> | <i>Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting</i> | <i>1st Quarter, 2024</i> |
| <i>Get feedback of enhancements and analyze the increase in frequency of EHI exchange</i> | <i>Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting</i> | <i>2nd,3rd and 4th Quarter of 2024</i> |
| <i>Analyze the frequency of CCDA Import & Reconcile for transition of care and new patients</i> | <i>Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting</i> | <i>1st Quarter, 2024</i> |
| <i>Record the increase in frequency of CCDA Import & Reconcile</i> | <i>Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting</i> | <i>2nd,3rd and 4th Quarter of 2024</i> |

| | | |
|--|--|-------------------------|
| <i>Submit Real World Testing report to ACB (per their instructions).</i> | <i>Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting</i> | <i>January 15, 2025</i> |
|--|--|-------------------------|

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.

Authorized Representative Name: **Rana Fahad Arshad**

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Authorized Representative Phone: **(407) 605-3666**

Authorized Representative Signature:



Date: **10/23/2023**

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GENERAL INFORMATION

Plan Report ID Number: **20231110pem**

Developer Name: **Physicians EMR, LLC**

Product Name(s): **IPClinical**

Version Number(s): **2.1**

Product List (CHPL) ID(s): **15.05.05.2163.PEMR.01.00.1.200123**

Developer Real World Testing Page URL: https://ipclinical.com/IPClinical_RWT_Plan.html

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

This Real World Testing Plan contains two certification criteria:

§ 170.315(b)(9) - Care plan

§ 170.315(h)(1) – Direct Project

The Certified Health IT Module is currently used by and marketed to Cardiology specialty care setting and Internal Medicine specialty care settings. Care Plan module is used quite rarely by both settings in real world but the Certified Health IT is completely capable to record all the elements of Care Plan and transmit it according to standards. The real world test plan will demonstrate data collection under each component of Care Plan and the association of all components with each other. System’s ability to import and export Care Plan as per standards will also be evaluated. All these actions will be performed using real patient data.

Regarding § 170.315(h)(1) – Direct Project, the Cardiology specialty care setting has real-world scenario of receiving patient CCDAs from hospitals through Direct protocols. The Real World Testing Plan will demonstrate that the messages are received in wrapped format using given Applicability Statement standards and accurate delivery notification is sent back by Security/Trust Agents (STAs). Currently, the Certified Health IT does not send electronic health information through Direct protocols in real-world but the standards are implemented for sending through Direct and this plan would evaluate the system’s ability to send Direct Message and receive Message Delivery Notification (MDN). Different aspects will be verified such as associated certificates, encryption, trust verification, delivery notifications etc.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI)

| | |
|---|----|
| Standard (and version) | NA |
| Updated certification criteria and associated product | NA |
| Health IT Module CHPL ID | NA |

| | |
|--|----|
| Method used for standard update | NA |
| Date of ONC-ACB notification | NA |
| Date of customer notification (SVAP only) | NA |
| Conformance measure | NA |
| USCDI-updated certification criteria (and USCDI version) | NA |

MEASURES USED IN OVERALL APPROACH

DESCRIPTION OF MEASUREMENT/METRIC

| Measurement/Metric | Description |
|---|---|
| <i>Care plan Components Relationship</i> | <i>This measure has been chosen to explain the relationship between components of Care plan and how important it is to effectively associate the information added under each component with other component. This measure will also identify mechanisms to improve process of recording data in each component. Relied-upon software: None</i> |
| <i>Secure and Successful Transmission</i> | <i>This measure will classify the processes involved in receiving health information through Direct and evaluate them in terms of security and compliance. Relied-upon software: EMR Direct Interoperability Engine (Version 2017).</i> |

ASSOCIATED CERTIFICATION CRITERIA

| Measurement/Metric | Associated Certification Criteria |
|---|---|
| <i>Care plan Components Relationship</i> | <i>§ 170.315(b)(9) - Care plan</i> |
| <i>Secure and Successful Transmission</i> | <i>§ 170.315(h)(1) - Direct Project</i> |

JUSTIFICATION FOR SELECTED MEASUREMENT/METRIC

| Measurement/Metric | Justification |
|---|---|
| <i>Care plan Components Relationship</i> | <p><i>This measure will make evident the effective association between Care plan components such as Health Concerns relation with Observation, Intervention relation with goals evaluated outcome relation with goal.</i></p> <p><i>The relationship between components will be evaluated both in the system and in the CCD A file format exported for transmission.</i></p> <p><i>Another reason for selecting this measure is because it will help us evaluate the efficiency of data collection in each care plan component.</i></p> <p><i>This measurement/metric will primarily be applied in Cardiology Specialty Care Setting.</i></p> |
| <i>Secure and Successful Transmission</i> | <p><i>The reason for selecting this measure is because this criterion evolves around secure and encrypted transmission of patient health information and this measure will identify the security and compliance of process in real world data exchange.</i></p> <p><i>This measure will identify that security measures are applied to the code and to critical aspects of the data associated with the Security/Trust Agent (STA), including private keys, trust anchors, and other configurations. Certificate verification process will also be evaluated.</i></p> <p><i>The metric chosen will demonstrate successful transmission in terms of delivery notification process. Interaction between sending and receiving STA will be evaluated to examine the process.</i></p> <p><i>This measurement/metric will primarily be applied in Cardiology Specialty Care Setting.</i></p> |

CARE SETTING(S)

| Care Setting | Justification |
|---|---|
| <i>Cardiology Specialty Care Setting</i> | <i>This Certified Health IT is currently marketed to and used by Cardiologists in Cardiology Specialty Care Setting. At this time, there are more than three providers from this setting using our Certified Health IT.</i> |
| <i>Internal Medicine Specialty Care Setting</i> | <i>Another care setting where this Certified Health IT is deployed is the Internal Medicine Specialty Care Setting. The product is also marketed to Internal Medicine Specialty Care Setting.</i> |

EXPECTED OUTCOMES

| Measurement/Metric | Expected Outcomes |
|--|---|
| <i>Care plan Components Relationship</i> | <ul style="list-style-type: none"> <i>The Real World Testing approach will measure that the Certified Health IT module of Care Plan comply with certification criteria, specified standards and Implementation Guides.</i> |

| | |
|---|---|
| | <ul style="list-style-type: none"> • <i>This approach will make us evaluate Certified Health IT’s capability of recording and exchanging a Care plan for any care settings including the ones implemented and marketed.</i> • <i>Real patient data will be recorded and exchanged as part of care plan between both care settings to ensure successful exchange and use of EHI.</i> • <i>Issues faced during the process will be addressed and steps will be taken to streamline the process, where required.</i> |
| <i>Secure and Successful Transmission</i> | <ul style="list-style-type: none"> • <i>It is expected that the Real World Testing approach will measure that the Certified Health IT module comply with certification criteria, specified standards and Implementation Guides.</i> • <i>This measure will illustrate the exchange of electronic health information (EHI) in selected Cardiology care settings.</i> • <i>Security protocols will be explained that result in secure transmission.</i> • <i>Successful exchange will be demonstrated by incorporating and using electronic health information (EHI) received.</i> • <i>Errors confronted during the process will be tracked and fixed to assure secure and successful transmission.</i> |

SCHEDULE OF KEY MILESTONES

| Key Milestone | Care Setting | Date/Timeframe |
|--|--|-------------------------|
| <i>Release of Real World Testing plan documentation shared with office staff and providers using Certified Health IT module.</i> | <i>Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting</i> | <i>December, 2023</i> |
| <i>Send and receive process evaluation in terms of security and successful transmission for Direct Project.</i> | <i>Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting</i> | <i>Quarterly, 2024</i> |
| <i>Record and exchange Care plan to evaluate the process and streamline, if required.</i> | <i>Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting</i> | <i>Quarterly, 2024</i> |
| <i>End of Real-World Testing period/final collection of all data for analysis.</i> | <i>Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting</i> | <i>December, 2024</i> |
| <i>Submit Real World Testing report to ACB (per their instructions).</i> | <i>Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting</i> | <i>January 15, 2025</i> |



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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Developer Name: **Physicians EMR, LLC**

Product Name(s): **IPClinical**

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Developer Real World Testing Page URL: https://ipclinical.com/IPClinical_RWT_Plan.html

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

*This is a Real-World Testing Plan for the following certification criteria:
 §170.315(c)(1) Clinical quality measures (CQMs) — record and export
 §170.315(c)(2) Clinical quality measures (CQMs) — import and calculate
 §170.315(c)(3) Clinical quality measures (CQMs) — report*

The Certified Health IT is currently marketed to and used by providers from Cardiology Care settings and Internal Medicine settings. At this moment, providers from both care settings are using these Certified Health IT modules to report CMS programs like MIPS and APM. The Real-World Testing approach will explain how the functionalities of import, export, calculate and report comply with certification criteria and technical standards. It will demonstrate the data recorded in patient record in real world, calculation performed for each eCQM, export of patient data in QRDA I format for data exchange or migration and export of QRDA III format to reporting programs. Real-World Testing approach will also demonstrate our Certified Health IT capability of performing all these steps without subsequent developer assistance.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI)

| | |
|---|----|
| Standard (and version) | NA |
| Updated certification criteria and associated product | NA |
| Health IT Module CHPL ID | NA |
| Method used for standard update | NA |
| Date of ONC-ACB notification | NA |

Health IT Certification Program



The Office of the National Coordinator for Health Information Technology

| | |
|--|----|
| Date of customer notification (SVAP only) | NA |
| Conformance measure | NA |
| USCDI-updated certification criteria (and USCDI version) | NA |

MEASURES USED IN OVERALL APPROACH

DESCRIPTION OF MEASUREMENT/METRIC

| Measurement/Metric | Description |
|----------------------------------|--|
| <i>Record, Export and Report</i> | <i>This measure will demonstrate how the data is recorded throughout the year and the export process performed without subsequent developer assistance. This metric will help understand yearly data collection and it's aggregate reporting. Relied-upon software: None</i> |
| <i>Import & Calculate</i> | <i>This measurement/metric will show Certified Health IT capability to import single or multiple patients' data into the system and place it in related clinical components with yearly updated codes and value sets. Relied-upon software: None</i> |

ASSOCIATED CERTIFICATION CRITERIA

| Measurement/Metric | Associated Certification Criteria |
|----------------------------------|---|
| <i>Record, Export and Report</i> | <i>§ 170.315(c)(1) Clinical quality measures (CQMs) – record and export § 170.315(c)(3) Clinical quality measures (CQMs) – report</i> |
| <i>Import & Calculate</i> | <i>§ 170.315(c)(2) Clinical quality measures (CQMs) – import and calculate</i> |

JUSTIFICATION FOR SELECTED MEASUREMENT/METRIC

| Measurement/Metric | Justification |
|----------------------------------|---|
| <i>Record, Export and Report</i> | <i>This metric includes three functionalities: Record patient data, Export single and batch patients and report aggregated data. This measure will evaluate patient data recorded throughout the year in real world environment and exported in case of data exchange or migration to another system.</i> |

| | |
|--------------------|---|
| | <p>The aggregated report is generated for data submission to CMS. This metric will explain how the data needs to be recorded in relative modules, exported with updated value sets and aggregated with accurate information.</p> <p>This measurement/metric will primarily be applied in Cardiology Specialty Care Setting.</p> |
| Import & Calculate | <p>This metric includes two functionalities named Import and Calculate. Data is imported for single or multiple patients into Certified Health IT and calculation takes place after import. This metric will identify that QRDA I file received for import contains clinical information as per latest eCQM Specifications.</p> <p>Secondly, it will evaluate system's capability to calculate imported data and display accordingly in population criteria.</p> <p>This metric will also define system's ability of running such workflows place without subsequent developer assistance.</p> <p>This measurement/metric will primarily be applied in Cardiology Specialty Care Setting.</p> |

CARE SETTING(S)

| Care Setting | Justification |
|--|--|
| Cardiology Specialty Care Setting | This Certified Health IT is currently marketed to and used by Cardiologists in Cardiology Specialty Care Setting. At this time, there are more than three providers from this setting using our Certified Health IT. |
| Internal Medicine Specialty Care Setting | Another care setting where this Certified Health IT is deployed is the Internal Medicine Specialty Care Setting. The product is also marketed to Internal Medicine Specialty Care Setting. |

EXPECTED OUTCOMES

| Measurement/Metric | Expected Outcomes |
|---------------------------|--|
| Record, Export and Report | <ul style="list-style-type: none"> Real World Testing will demonstrate that the Health IT Module is conformant to the following certification criteria: §170.315(c)(1) Clinical quality measures (CQMs) — record and export and §170.315(c)(3) Clinical quality measures (CQMs). Real World Testing will demonstrate the ability of Certified Health IT to export EHI in QRDA I format for single/multiple patients to be used by external organization. Real World Testing will also demonstrate Certified Health IT compliance with QRDA III standards to transmit aggregate patient population and CQMs data to CMS. |

| | |
|--------------------|--|
| | <ul style="list-style-type: none"> Issues occurred during QRDA I export will be evaluated and addressed to comply. Validation issues arising during QRDA III file submission to CMS will also be fixed as part of this approach. |
| Import & Calculate | <ul style="list-style-type: none"> Real World Testing will demonstrate that the Health IT Module is conformant to the following certification criteria: §170.315(c)(2) Clinical quality measures (CQMs) — import and calculate. Real World Testing will demonstrate capability of Health IT Module to receive patient’s EHI from external organization through successful import of QRDA I file. Validation errors that will occur during import mechanism will be evaluated and fixed under this real world testing approach. The calculation methodology will also be reviewed to assure accurate results. |

SCHEDULE OF KEY MILESTONES

| Key Milestone | Care Setting | Date/Timeframe |
|---|--|------------------|
| Release of Real-World Testing plan documentation to office staff and providers using Certified Health IT module. | Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting | December, 2023 |
| Follow-up with providers and clinical staff on quarterly basis to discuss any issues arising with recording data. | Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting | Quarterly, 2024 |
| Analysis on import/export of QRDA I from/to external organization. | Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting | December, 2024 |
| Generate aggregate QRDA III report with calculated summary data for the patient population of CQMs selected for reporting to CMS. | Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting | January, 2025 |
| Submit Real World Testing report to ACB (per their instructions). | Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting | January 15, 2025 |



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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JUSTIFICATION FOR REAL WORLD TESTING APPROACH

*This is a Real World Testing Plan for the following two certification criteria:
 § 170.315(f)(1) - Transmission to immunization registries
 § 170.315(f)(2) - Transmission to public health agencies - syndromic surveillance*

The Certified Health IT Module is currently used by and marketed to Cardiology specialty care setting and Internal Medicine specialty care settings. Though the Certified Health IT has not integrated with any Public Health and Clinical Data Registry for any of the care settings but it is compliant to content exchange and vocabulary standards. This Certified Health IT Module has not been utilized in real-world since the care settings do not have a great frequency of immunizations information and syndromic surveillance data sharing. Therefore, the approach chosen for Real World Testing Plan will test system’s capability to record complete immunization information, generate appropriate HL7 messages for both Immunization and syndromic surveillance, receive & process acknowledgement messages and cover all applicable scenarios of certification criteria. The Real World Testing Plan will also analyze the frequency of immunization and syndromic surveillance data exchange in case of integration with Public Health and Clinical Data Registry and what measure can be taken to streamline the process.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI)

| | |
|---|----|
| Standard (and version) | NA |
| Updated certification criteria and associated product | NA |
| Health IT Module CHPL ID | NA |
| Method used for standard update | NA |

| | |
|--|----|
| Date of ONC-ACB notification | NA |
| Date of customer notification (SVAP only) | NA |
| Conformance measure | NA |
| USCDI-updated certification criteria (and USCDI version) | NA |

MEASURES USED IN OVERALL APPROACH

DESCRIPTION OF MEASUREMENT/METRIC

| Measurement/Metric | Description |
|-----------------------------------|--|
| <i>Send and Receive Mechanism</i> | <i>This measure will examine the format and authenticity of HL7 messages generated by Health IT module. This measure will also evaluate the transmission and processing of both Immunization and Syndromic Surveillance information. Message and Profile Pairs will be verified to confirm accuracy of information sent and received. Relied-upon software: None</i> |
| <i>Applicable Scenarios</i> | <i>This measure will verify that the Health IT module is capable of handling all possible scenario of sending and receiving Immunization and Syndromic Surveillance information. The measure would evaluate that the system is able to effectively record, update and send both immunization and syndromic surveillance information. Relied-upon software: None</i> |

ASSOCIATED CERTIFICATION CRITERIA

| Measurement/Metric | Associated Certification Criteria |
|-----------------------------------|--|
| <i>Send and Receive Mechanism</i> | <i>§ 170.315(f)(1) - Transmission to immunization registries § 170.315(f)(2) - Transmission to public health agencies - syndromic surveillance</i> |
| <i>Applicable Scenarios</i> | <i>§ 170.315(f)(1) - Transmission to immunization registries § 170.315(f)(2) - Transmission to public health agencies - syndromic surveillance</i> |

JUSTIFICATION FOR SELECTED MEASUREMENT/METRIC

| Measurement/Metric | Justification |
|--------------------|---------------|
|--------------------|---------------|

| | |
|-----------------------------------|---|
| <i>Send and Receive Mechanism</i> | <p><i>This measure mainly involves two functionalities i.e., generate and send HL7 messages and receive HL7 response against the message/request sent. Purpose of this measure is to verify the HL7 message infrastructure that it includes all segments defined by HL7 messaging specifications such as MSH, PID, OBX, RXA etc. and that each segment contains all the required information. The HL7 message infrastructure will be verified using real patient data. Moreover, this measure will help evaluate system’s capability of using correct Message Type, Profile and Acknowledgement code. Response to query of Z42 and Z33 messages will also be examined with this metric. This measurement/metric will primarily be applied in Cardiology Specialty Care Setting.</i></p> |
| <i>Applicable Scenarios</i> | <p><i>This measure will specify that the Health IT module is able to record and send complete Demographic information, Registry Information, Observations and mostly importantly, Vaccine Administration Information. The main purpose of this measure is to make sure that Health IT module sends complete and accurate information in the message and receives appropriate response. Another purpose of this measure is to examine that the system accurately processes all the information received in response to a query of Evaluated History and Forecast and all the information received is accurately displayed in the system. This measurement/metric will primarily be applied in Cardiology Specialty Care Setting.</i></p> |

CARE SETTING(S)

| Care Setting | Justification |
|---|--|
| <i>Cardiology Specialty Care Setting</i> | <p><i>This Certified Health IT is currently marketed to and used by Cardiologists in Cardiology Specialty Care Setting. At this time, there are more than three providers from this setting using our Certified Health IT.</i></p> |
| <i>Internal Medicine Specialty Care Setting</i> | <p><i>Another care setting where this Certified Health IT is deployed is the Internal Medicine Specialty Care Setting. The product is also marketed to Internal Medicine Specialty Care Setting.</i></p> |

EXPECTED OUTCOMES

| Measurement/Metric | Expected Outcomes |
|-----------------------------------|--|
| <i>Send and Receive Mechanism</i> | <ul style="list-style-type: none"> <i>It is expected that the Real World Testing approach will measure that the Certified Health IT module comply with certification criteria, required technical standards and vocabulary code sets.</i> |

| | |
|----------------------|--|
| | <ul style="list-style-type: none"> • The metric chosen will identify any issue with structure of file formats and transmission mechanism to address them. • Though the Health IT has not integrated with a Public Health and Clinical Data Registry, but the Real-World Testing will test Health IT conformance with standards required to integrate. • Real-World testing will evaluate the processing of incoming messages to confirm appropriate response for meeting interoperability. • Most importantly, this approach will track the issues occurred during transmission process to address them accordingly. |
| Applicable Scenarios | <ul style="list-style-type: none"> • The Real World Testing approach will measure that the Certified Health IT module is conformant and capable to record and send all the information required for generating an HL7 message. • The approach chosen will specify that the Health IT module supports all possible scenarios of sharing Immunization and Syndromic Surveillance information. • This approach will evaluate the efficiency of Health IT module to record all required information for transmission. The issues confronted during the process will be analyzed and addressed to make sure the transmission is smooth when integrating with a Public Health and Clinical Data Registry. |

SCHEDULE OF KEY MILESTONES

| Key Milestone | Care Setting | Date/Timeframe |
|---|--|------------------|
| Release of Real World Testing plan documentation shared with office staff and providers using Certified Health IT module. | Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting | December, 2023 |
| Collection of real-world patient data for testing. | Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting | January, 2024 |
| System and transmission process evaluation as per Real-World Testing approach. | Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting | Quarterly, 2024 |
| End of Real-World Testing period/final collection of all data for analysis. | Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting | December, 2024 |
| Submit Real World Testing report to ACB (per their instructions). | Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting | January 15, 2025 |



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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Authorized Representative Signature:

Date: **10/23/2023**

↳ Real World Testing Plan template

GENERAL INFORMATION

Plan Report ID Number: **20231110pem**

Developer Name: **Physicians EMR, LLC**

Product Name(s): **IPClinical**

Version Number(s): **2.1**

Product List (CHPL) ID(s): **15.05.05.2163.PEMR.01.00.1.200123**

Developer Real World Testing Page URL: https://ipclinical.com/IPClinical_RWT_Plan.html

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

This is a Real World Testing Plan for following certification criteria:

§ 170.315(g)(7) - Application access — patient selection

§ 170.315(g)(9) - Application access — all data request

§ 170.315(g)(10) – Standardized API for patient and population services

At this time, the Certified Health IT Module is only marketed to and used by the Cardiology specialty care setting and Internal Medicine specialty care settings. The Certified Health IT has implemented Patient access API for conformance to (g)(7), (g)(9) and FHIR API for conformance to (g)(10). Both API are capable to integrate with platforms (EHR Systems, Applications) for Electronic Health Information exchange. Currently, the Certified Health IT has not integrated its API with any platform to share electronic health information but it is still conformant to all above-mentioned certification criteria.

For (g)(7), (g)(9), the Real-World testing approach will review implementation of both Patient API and FHIR API. The RWT plan will verify the authentication protocol OAuth 2.0 implemented to authenticate connection requests. Specified parameters will be used to send requests to Patient API and verify appropriate response received. The CCDA received in response will also be validated as part of the plan to verify conformance.

For (g)(10), the plan will review application registration and authentication process for connection with FHIR API. Revoke access will be verified to assure conformance to criteria and maintain security protocols. During data sharing process through FHIR API, each clinical resource data will be reviewed to confirm FHIR US Core implementation standard conformance.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI)

| | |
|---|----|
| Standard (and version) | NA |
| Updated certification criteria and associated product | NA |

| | |
|--|----|
| Health IT Module CHPL ID | NA |
| Method used for standard update | NA |
| Date of ONC-ACB notification | NA |
| Date of customer notification (SVAP only) | NA |
| Conformance measure | NA |
| USCDI-updated certification criteria (and USCDI version) | NA |

MEASURES USED IN OVERALL APPROACH

DESCRIPTION OF MEASUREMENT/METRIC

| Measurement/Metric | Description |
|------------------------------|---|
| <i>Standards Conformance</i> | <i>Since these certified capabilities are not used in real-world, therefore, the metric chosen will verify implemented standards and review conformance to certification criteria. Standard requirements including API connection, authentication protocols, requests/responses, data shared and structure all will be reviewed and verified as part of this measurement/metric. Relied-upon software: None</i> |

ASSOCIATED CERTIFICATION CRITERIA

| Measurement/Metric | Associated Certification Criteria |
|------------------------------|---|
| <i>Standards Conformance</i> | <i>§ 170.315(g)(7) - Application access — patient selection § 170.315(g)(9) - Application access — all data request § 170.315(g)(10) – Standardized API for patient and population services</i> |

JUSTIFICATION FOR SELECTED MEASUREMENT/METRIC

| Measurement/Metric | Justification |
|------------------------------|--|
| <i>Standards Conformance</i> | <i>The purpose of selecting is to review standards implemented and verify Health IT module's conformance to these API criteria. As part of this measurement/metric, both Patient API and FHIR API connection, authentication processes will be reviewed as per implemented</i> |

| | |
|--|--|
| | <p><i>standard workflows. Requests and responses for data sharing will be reviewed and any errors/issues occurred during the process will be addressed. Structure of clinical resources data shared through API will be reviewed and validated and any errors/issues confronted will be addressed.</i></p> |
|--|--|

CARE SETTING(S)

| Care Setting | Justification |
|---|---|
| <i>Cardiology Specialty Care Setting</i> | <i>This Certified Health IT is currently marketed to and used by Cardiologists in Cardiology Specialty Care Setting. At this time, there are more than three providers from this setting using our Certified Health IT.</i> |
| <i>Internal Medicine Specialty Care Setting</i> | <i>Another care setting where this Certified Health IT is deployed is the Internal Medicine Specialty Care Setting. The product is also marketed to Internal Medicine Specialty Care Setting.</i> |

EXPECTED OUTCOMES

| Measurement/Metric | Expected Outcomes |
|------------------------------|---|
| <i>Standards Conformance</i> | <ul style="list-style-type: none"> <i>Process of connecting with Certified Health IT's Patient and FHIR APIs will get improved.</i> <i>Authentication process implementation as per standard will get reviewed.</i> <i>Based on request/response verification, data sharing process will get streamlined.</i> <i>Clinical component/resources structure conformance to standard will get reviewed.</i> <i>Issues faced during the review process will be tracked and addressed.</i> <i>Health IT's capability to integrate with any system through API will get streamlined and improved.</i> |

SCHEDULE OF KEY MILESTONES

| Key Milestone | Care Setting | Date/Timeframe |
|--|--|-----------------------|
| <i>Release of Real World Testing plan documentation shared with office staff and providers using Certified Health IT module.</i> | <i>Cardiology Specialty Care Setting/ Internal</i> | <i>December, 2023</i> |

| | | |
|--|--|-------------------------|
| | <i>Medicine Specialty Care Setting</i> | |
| <i>Collection of real-world patient data for testing.</i> | <i>Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting</i> | <i>January, 2024</i> |
| <i>Evaluation of API connection and authentication process</i> | <i>Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting</i> | <i>Quarterly, 2024</i> |
| <i>Analysis and improvement of clinical components/resources structure</i> | <i>Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting</i> | <i>Quarterly, 2024</i> |
| <i>Submit Real World Testing report to ACB (per their instructions).</i> | <i>Cardiology Specialty Care Setting/ Internal Medicine Specialty Care Setting</i> | <i>January 15, 2025</i> |

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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Date: **10/23/2023**