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REAL WORLD TESTING PLAN TEMPLATE

BACKGROUND & INSTRUCTIONS

Under the ONC Health IT Certification Program (**Program**), health IT developers are required to conduct Real World Testing of their certified health IT (45 CFR 170.405). The Office of the National Coordinator for Health Information Technology (ONC) issues Real World Testing resources to clarify health IT developers' responsibilities for conducting Real World Testing, to identify topics and specific elements of Real World Testing that ONC considers a priority, and to assist health IT developers in developing their Real World Testing plans.

Health IT developers have maximum flexibility to develop innovative plans and measures for Real World Testing. As developers are planning how they will execute Real World Testing, they should consider the overall complexity of the workflows and use cases within the care settings in which they market their certified health IT to determine the approaches they will take. This Real World Testing plan template was created to assist health IT developers in organizing the required information that must be submitted for each element in their Real World Testing plan. While the use of this template is voluntary, health IT developers may find it useful in preparing their Real World Testing plans. Health IT developers must submit one plan for each year of Real World Testing (see resources listed below for specific timelines and due dates). ONC does not encourage updating plans outside the submission timeline and will not post updates on the Certified Health IT Product List (CHPL). If adjustments to approaches are made throughout Real World Testing, the health IT developer should reflect these adjustments in their Real World Testing results report. ONC expects that the Real World Testing results report will include a description of these types of changes, the reasons for them, and how intended outcomes were more efficiently met as a result. While every effort has been made to ensure the accuracy of restatements of 45 CFR Part 170, this template is not a legal document. The official program requirements are contained in the relevant laws and regulations. This resource should be read and understood in conjunction with the following companion resources, which describe in detail many of the Program requirements referenced in this resource.

- <u>Real World Testing–What It Means for Health IT Developers Fact Sheet</u>
- Real World Testing Resource Guide Coming Soon
- Real World Testing Certification Companion Guide

Health IT developers should also review the following regulatory materials, which establish the core requirements and responsibilities for Real World Testing under the Program.

- 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule, <u>85 FR 25642</u> (May 1, 2020) (ONC Cures Act Final Rule)
 - o <u>Section VII.B.5</u>— "Real World Testing"

The Office of the National Coordinator for Health Information Technology

TEMPLATE INSTRUCTIONS

The following template is organized by elements required to be submitted in the Real World Testing plan. Each section provides a field for submitting responses and/or explanations for how the health IT developer will address each required element in their Real World Testing approach. These fields serve as a foundation of information required for developing a Real World Testing plan and can be expanded with additional rows or columns to address the specific needs of the Real World Testing plan being submitted.

GENERAL INFORMATION

Plan Report ID Number: [For ONC-Authorized Certification Body use only]

Developer Name: Payoda Technology Inc.

Product Name(s): HealthViewX

Version Number(s): 2.0.85

Certified Health IT Product List (CHPL) ID(s): 15.04.04.3054.Heal.02.00.1.19100

Developer Real World Testing Page URL: https://www.healthviewx.com/certification-disclosure/

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Provide an explanation for the overall approach to Real World Testing, including an outline of the approach and how data will be used to demonstrate successful Real World Testing¹.

All measures should reasonably align with the elements within a Real World Testing plan, the scope of the certification, the types of settings in which the certified health IT is marketed, and other factors relevant to the implementation of the certified Health IT Module(s). The justification should reflect how each element within the plan is relevant to the developer's overall strategy for meeting the Real World Testing Condition and Maintenance of Certification requirements.

Note: A single Real World Testing plan may address multiple products and certification criteria for multiple care settings.

<u>Overview:</u>

HealthViewX Referral Management App provides end-to-end referral life-cycle management with bidirectional EMR integration and also automates insurance prior authorization process. The Platform allows secure online referral communication and coordination between referring and receiving providers with real time referral status tracking and EMR sync. This also enables transfer of CCDA document fetched from EMR and sent via Direct Message to Receiving Provider/Specialist Office in a secure way there by adhering to (b.1) Transition of Care criterion and captures parameters required for MU reporting such as TOC Sent, TOC Sent Electronically and Acknowledgement Received information. The app also calculates and displays the Performance Percentage, Provider wise for MU Credits Reporting Purpose.

The Office of the National Coordinator for Health Information Technology

<u>Scenario 1, Use Case 1 Overview: Transition of Care (TOC Sent Electronically)</u> – In order to test the real world interoperability the HealthViewX application integrates with the EMRs using standard integration protocols such as HL7, FHIR APIs and also with the third party Direct Message vendor and enables the DM component within the system. Whenever a Referral Order is sent to the specialist office, the application also fetches the recent CCDA file from EMR and transfers the consolidated data to the specialist office via Direct Message (if available) through HISP Direct Messaging service. Recipients can view the Referral Order and the CCDA file in their inbox wherever their DM is configured for e.g. in the destination EMR or the DM inbox directly. This also increments the TOC Sent Electronically data within the HealthViewX application.

Scenario 1, Use Case 2 Overview: Meaningful Use Stage 3 Report (for Referral MU Credits) - In

addition to the feature of capturing the Transition of Care information, HealthViewXalso captures the Acknowledgement Received status for the TOC Sent Orders and calculates the performance percentage of each Ordering Provider/Practice with the formula and displays the MU Stage 3 report for the selected duration. The MU Stage 3 report is calculated with the below formula automatically which is then presented by the practices to the MU audit team for MU credits.

TOC Sent Electronically (Numerator)

X 100 = Performance %

Total Referral Orders (Denominator)

The Office of the National Coordinator for Health Information Technology

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

Both required and voluntary standards updates must be addressed in the Real World Testing plan. Real World Testing plans must include all certified health IT updated to newer versions of standards prior to August 31 of the year in which the updates were made.

Describe approach (es) for demonstrating conformance to all certification requirements using each standard to which the health IT is certified. List each version of a given standard separately. For each version of a standard submit the following:

- ✓ Identify standard versions
- ✓ Indicate what certification criteria in which product(s) has been updated
- ✓ If reporting for multiple products, identify the certification criteria that were affected by the update for each of the associated products
- ✓ CHPL ID for each Health IT Module
- ✓ Method used for standard update (e.g., SVAP)
- ✓ Date notification sent to ONC-ACB
- ✓ If SVAP, date notification sent to customers
- ✓ Measure used to demonstrate conformance with updated standard(s)
- ✓ Which certification criteria were updated to USCDI and/or to which version of USCDI was the certification criteria updated?

Standard (and version)	All standard versions are those specified in USCDI v1.		
Updated certification criteria and associated product	170.315 (b)(1): Transitions of Care, HealthViewX Referral Management V2.0.85		
Health IT Module CHPL ID	15.04.04.3054.Heal.02.00.1.191002		
Method used for standard update	Health Level Seven (HL7®), Fast Healthcare Interoperable Resources (FHIR®) and Consolidated Clinical Document Architecture (C-CDA)		
Date of ONC ACB notification	April 2022		
Date of customer notification (SVAP only)	Not Applicable		
Conformance measure	Not Applicable		
USCDI updated certification criteria (and USCDI version)	USCDI v1		

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MEASURES USED IN OVERALL APPROACH

Each plan must include at least one measurement/metric that addresses each applicable certification criterion in the Health IT Module's scope of certification. Describe the method for measuring how the approach (es) chosen meet the intent and purpose of Real World Testing.

For each measurement/metric, describe the elements below:

- ✓ Description of the measurement/metric
- ✓ Associated certification criteria
- ✓ Justification for selected measurement/metric
- ✓ Care setting(s) that is addressed
- ✓ Expected outcomes

Description of Measurement/Metric

Describe the measure(s) that will be used to support the overall approach to Real World Testing.

Measurement/Metric	Description		
	Total Number of Referral Orders or Transactions that are performed for the selected reporting durations		
	To capture the Transition of Care Document Sent or Not Sent along with		
	the Patient Record/Referral Order		
	To capture the mode by which the Transition of Care Document Sent (Electronically or by any other Means)		
	To capture the acknowledgement for the TOC Sent Electronically from the recipient and record it in the system either automatically/manually		
	To automatically calculate the performance percentage of each		
	facility/ordering provider and present the data in MU Stage 3 Report		

Associated Certification Criteria

List certification criteria associated with the measure and if updated to the 2015 Edition Cures Update criteria.

Measurement/Metric	Associated Certification Criteria		
	Send transition of care/referral summaries via HISP Certified Direct Message		

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Justification for Selected Measurement/Metric

Provide an explanation for the measurement/metric selected to conduct Real World Testing.

Measurement/Metric	Justification			
170.315(b)(1) Transitions of	HealthViewXReferral Management System includes two functionalities			
care	conformance with the Transition of Care criteria.			
	(A) Send transition of care/referral summaries and (B) Calculator			
	Performance Percentage for MU Report.			
	(A) Transitions of care documents are shared using Edge			
	protocols (Direct Message) and also while sharing additional			
	information such as TOC Sent, TOC Sent Electronically and			
	Acknowledgement Received are captured within the application.			
	(B) Using the data captured above, MU report is generated for the			
	specified duration and provider wise performance percentage is			
	calculated. This is submitted by the practices during MU audit in			
	order to claim the credits.			

Care Setting(s)

The expectation is that a developer's Real World Testing plan will address each type of clinical setting in which their certified health IT is mark eted. Health IT developers are not required to test their certified health IT in every setting in which it is marketed for use. Developers should address their choice of care and/or practice settings to test and provide a justification for the chosen approach.

Note: Health IT developers may bundle products by care setting, criteria, etc. and design one plan to address each, or they may submit any combination of multiple plans that collectively address their products and the care settings in which they are marketed

List each care setting which is covered by the measure and an explanation for why it is included.

Care Setting	Justification	
	Community Hospitals can place clinical referrals within the HealthViewX application and transfer CCDA documents to specialist offices via Direct Message which will be counted for <i>Transition of Care criteria</i> (b(1)).	
Specialty Clinics	Specialty Clinics can receive CCDA documents/Referral Orders directly in their Direct Message source and incorporate it within their EMR/HIS systems. Specialist Office can also process the referrals and send back the consult notes back to care settings.	
CMS Programs/Services	FQHCs/Practices that are eligible to provide CMS programs such as Chronic Care Management (CCM), Remote Patient Monitoring (RPM), Annual Wellness Visit (AWV), etc., can also subscribe for add-on modules within HVX, provide appropriate service and send monthly summary and billing reports along with updated CCDAs to specialist office or PCPs for them to have updated data of their patients always.	

The Office of the National Coordinator for Health Information Technology

Expected Outcomes

Health IT developers should detail how the approaches chosen will successfully demonstrate that the certified health IT:

- 1) is compliant with the certification criteria, including the required technical standards and vocabulary codes sets;
- 2) is exchanging electronic health information (EHI) in the care and practice settings for which it is marketed for use; and/or,
- 3) EHI is received by and used in the certified health IT.

(from 85 FR 25766)

Not all of the expected outcomes listed above will be applicable to every certified Health IT Module, and health IT developers may add an additional description of how their measurement approach best addresses the ongoing interoperability functionality of their product(s). Health IT developers could also detail outcomes that should <u>not</u> result from their measurement approach if that better describes their efforts.

Within this section, health IT developers should also describe how the specific data collected from their Real World Testing measures demonstrate expected results. Expected outcomes and specific measures do not necessarily have to include performance targets or benchmarks, but health IT developers should provide context for why specific measures were selected and how the metrics demonstrate individual criterion functionality, EHI exchange, and/or use of EHI within certified health IT, as appropriate.

Measurement/Metric	Expected Outcomes	
Transition of Care Data Capture (TOC Sent Electronically	Real World Testing of TOC Sent Electronically will demonstrate the transfer of CCDA documents in real time electronically to the recipient and view it within their DM inbox. Also this is conformant to the measure (b.1) Transition of Care Criterion in order to promote interoperability in a Healthcare setting.	
MU Stage 3 Report	Real World Testing of MU 3 Report will demonstrate the data against each Ordering Provider/Practice on their performance with respect to Transition of Care electronically thereby providing an opportunity for the practices to increase their performance percentage by onboarding more specialist offices to electronic mode from traditional fax mode.	

The Office of the National Coordinator for Health Information Technology

SCHEDULE OF KEY MILESTONES

Include steps within the Real World Testing plan that establish milestones within the process. Include details on how and when the developer will implement measures and collect data. Key milestones should be relevant and directly related to expected outcomes discussed in the next section.

For each key milestone, describe when Real World Testing will begin in specific care settings and the date/timeframe during which data will be collected.

Key Milestone	Care Setting	Date/Timeframe
Capture the required parameters such as Total Referral Orders,	FQHCs	
TOC Sent, TOC Sent Electronically and Acknowledgement		Jan 2023 to March
Received for each Referral Order Transaction		2023
Calculate the Performance Percentage and display the data for	FQHCs	April 2023
the chosen duration and Ordering Provider/Practice		

The Office of the National Coordinator for Health Information Technology

ATTESTATION

The Real World Testing plan must include the following attestation signed by the health IT developer authorized representative.

Note: The plan must be approved by a health IT developer authorized representative capable of binding the health IT developer for execution of the plan and include the representative's contact information.

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: Mr. Subbiah Viswanathan, Chief Executive Officer & Co-Founder

Authorized Representative Email: subbiah.v@healthviewx.com

Authorized Representative Phone: 91-9566147474

Authorized Representative Signature: TVSubbid

Date: 11/18/2022

Certified health IT continues to be compliant with the certification criteria, including the required technical standards and vo cabulary codes sets; certified health IT is exchanging EHI in the care and practice settings for which it is marketed for use; and EHI is received by and used in the certified health IT. (85 FR 25766)

https://www.federalregister.gov/d/2020-07419/p-3582