HEALOGICS I-HEAL 2.0 REAL-WORLD TEST PLAN

Executive Summary

This is the real-world test plan for Healogics i-heal 2.0 ONC certified EHR. I-heal 2.0 is certified under the ONC 2015 Edition, certification ID: 15.04.04.1575.ihea.02.00.1.191007.

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

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

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

Developer Attestation

This Real-World Testing plan is complete with all required elements, including measures that address all certification criteria and care settings. All information in this plan is up to date and fully addresses the health IT developer's Real World Testing requirements.

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General Information

Developer Name: Healogics

Product Name(s): i-heal

Version Numbers: 2.0

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

Product List (CHPL) ID and Link:

CHPL Product Number: 15.04.04.1575.ihea.02.00.1.191007

ONC-ACB Certification ID: 15.04.04.1575.ihea.02.00.1.191007

Link to ONC Certification: https://chpl.healthit.gov/#/listing/10140

Real-World Testing Approach

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

Standards Version Assessment Process (2022) Updates

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

| STANDARD (AND VERSION) | None |
|--|------|
| UPDATED CERTIFICATION CRITERIA AND ASSOCIATED PRODUCT | N/A |
| HEALTH IT MODULE CHPL ID | N/A |
| METHOD USED FOR STANDARD UPDATE | N/A |
| DATE OF ONC-ACB NOTIFICATION | N/A |
| DATE OF CUSTOMER NOTIFICATION (SVAP ONLY) | N/A |
| CONFORMANCE MEASURE | N/A |
| USCDI-UPDATED CERTIFICATION CRITERIA (AND USCDI VERSION) | N/A |

Testing Measurements

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

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

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

Testing Methodologies

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

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

Number of Clients Sites

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

Care and Practice Settings Target

Healogics i-heal 2.0 EHR is primarily targeted to ambulatory wound care practices, and our measures were design for this setting in mind. In each measure, we do also address the care settings targeted and note any necessary adjustment or specific factor to consider with this specific measure.

RWT Measure #1 Transition of Care C-CDA

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

Testing Methodology: Reporting/Logging

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

Measurement Justification:

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

Measurement Expected Outcome:

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

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

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

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

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

Care Settings and Number of Clients Site to Test:

We designed this measure to test ambulatory wound care practices that we support and target. We will test a minimum of three (3) client practice(s). This number covers a sufficient percentage of existing practices to provide a viable sample of users of the certified EHRs.

RWT Measure #2 Incorporating Problem List, Medications, Allergies

Associated Criteria: 315(b)(2)

Testing Methodology: Reporting/Logging

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

Measurement Justification:

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

The use of reporting can often provide more information on the impact and value of an interoperability element than a standard software test evaluation without incorporating individual user bias. This reporting measure will reveal if users are using the C-CDA incorporate feature of their EHR to update their patient's record with current or new information from another source. Through this means of testing, we can determine compliance to the associated criteria listed above in real world use.

Measurement Expected Outcome:

This metric can come from different a direct query of the database regarding the number of C-CDA documents have been imported into a patient record. A successful measure increment indicates compliance to the underlying ONC criteria, including successful import of the C-CDA patient summary record and recording the required clinical data elements. In incorporating the C-CDA patient summary record, the EHR will demonstrate ability to confirm successful interoperability of an exchanged patient record with a 3rd party, including support for Direct Edge protocol in connecting to a HISP.

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

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

Care Settings and Number of Clients Site to Test:

We designed this measure to test ambulatory wound care practices that we support and target. We will test a minimum of three (3) client practice(s). This number covers a sufficient percentage of existing practices to provide a viable sample of users of the certified HER.

RWT Measure #3 Electronic Prescriptions

Associated Criteria: 315(b)(3)

Testing Methodology: Reporting/Logging

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

Measurement Justification:

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

Measurement Expected Outcome:

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

Measure #1: Report the number of New Rx electronic prescriptions sent over a three (3) month period. The measurement will produce numeric results over a given interval which can be derived from a direct query of the database. We will utilize various reports and audit logs, including Automated Measure (315.g.2) reports, to determine our measure count.

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

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

Care Settings and Number of Clients Site to Test:

We designed this measure to test ambulatory wound care practices that we support and target. We will test a minimum of three (3) client practice(s). This number covers a sufficient percentage of existing practices to provide a viable sample of users of the certified HER.

RWT Measure #4 Quality Measures

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

Testing Methodology: Reporting/Logging

Measurement Description: This measure is tracking and counting how many Quality Measures (eCQMs) were successfully reported on by the EHR Module to CMS during their submission period for MIPS Quality reporting.

Measurement Justification:

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

Measurement Expected Outcome:

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

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

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

Care Settings and Number of Clients Site to Test:

We designed this measure to test ambulatory wound care practices that we support and target. We will test a minimum of three (3) client practice(s). This number covers a sufficient percentage of existing practices to provide a viable sample of users of the certified EHRs.

RWT Measure #5 Patient Portal Use

Associated Criteria: 315(e)(1)

Testing Methodology: Reporting/Logging

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

Measurement Justification:

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

The use of reporting can often provide more information on the impact and value of the patient portal element than a standard software test evaluation without incorporating individual user bias. The patient portal is intended to support patient engagement with their health records, and the ability to transmit their patient data, as a C-CDA or human readable copy, can be a useful feature.

Measurement Expected Outcome:

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

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

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

Care Settings and Number of Clients Site to Test

We designed this measure to test ambulatory wound care practices that we support and target. We will test a minimum of three (3) client practice(s). This number covers a sufficient percentage of existing practices to provide a viable sample of users of the certified EHRs.

RWT Measure #6 API Access

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

Testing Methodology: Reporting/Logging

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

Measurement Justification:

We do not know how many of our customers are using the API functionality, so we believe the best means to evaluate real world interoperability is to utilize logging/reporting to determine this criteria's use. This measure will verify through reports/logs to determine real world interoperability and usability, specifically how many 3rd party systems or applications are integrated and using the EHR's API interface.

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

Measurement Expected Outcome:

Applications will be able to successfully utilize API's that are developed by Healogics for the consumption of external applications. The measurement will a count and list all applications who have or are connecting to i-heal API's in a given period of time, defined as a 3 month period. The count of distinct applications connecting to i-heal via API will derived from database reporting.

A successful test of this measure indicates compliance to the underlying ONC criteria. It will show that the EHR has external API available to and that they are able to successfully retrieve data. Successfully completing this measure also implies that applications can utilize the API's. A result of no applications connecting to these available API's will not indicate a failure of this measure in a real-world setting, it will simply indicate that no external applications have chosen to utilize these API's despite the availability of these API's.

Care Settings and Number of Clients Site to Test

We designed this measure to test the ability of external applications to connect to i-heal API's. We will test a minimum of three months of database reporting. This number covers a sufficient percentage of existing practices to provide a viable sample of users of the certified EHRs.