Health IT Certification Program

The Office of the National Coordinator for Health Information Technology

REAL WORLD TESTING PLAN

GENERAL INFORMATION

Plan Report ID Number: 20211130hea

Developer Name: **Healthfully Inc.**

Product Name(s): **Flagler Health + Anywhere**

Version Number(s): **17**

Certified Health IT Product List (CHPL) ID(s): **15.05.05.3081.HEFY.01.00.0.201222, 15.05.05.3081.HEAL.01.00.0.201222**

Developer Real World Testing Page URL: https://www.healthfully.io/about/certification-and-additional-costs

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Our overall approach to real world testing is to synthesize, expand and operationalize key testing performed during our system, integration, and production gates.

In our case, real world testing applies to Patient Engagement, certification criterion 170.315(e)(1) View, download, and transmit to 3rd party. Our testing focus will include:

1) Quality Assurance - using a known data set with expected outcomes

2) Patterning - capture statistics of data to pattern what is standard vs. non-conforming

For Real World Testing, we plan to build out these tests in production to be applied for our continuous integration.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS-SVAP AND 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
Known Dataset	We will use a known dataset with predictable outcomes for verification and validation
Statistic Capture	We will capture statistics as data flows through and trend this data to ensure conformity

ASSOCIATED CERTIFICATION CRITERIA

Measurement/Metric	Associated Certification Criteria
Known Dataset	170.315(e)(1) View, download, and transmit to 3rd party
Statistic Capture	170.315(e)(1) View, download, and transmit to 3rd party

JUSTIFICATION FOR SELECTED MEASUREMENT/METRIC

Measurement/Metric	Associated Certification Criteria
Known Dataset	170.315(e) requires content as specified https://www.healthit.gov/test-method/view-download-and-transmit-3rd-party. In order to prove that this content is supported, we will create datasets specific to ensure completeness of the content
Statistic Capture	For our real world testing, we need to monitor production data flowing through and trend this data to ensure that it conforms to expectations and alert on any potential non conformities to allow for investigation and reporting when applicable.

CARE SETTING(S)

Care Setting	Justification
Ambulatory	For the ambulatory setting, we will use both 1) a known dataset to continuously confirm application conformance with requirements are met per https://www.healthit.gov/test-method/view-download-and-transmit-3rd-party 2) statistical data capture, trending, monitoring, and alerting to ensure that real patient data as it flows through a patient's journey conforms to the anticipated trend. The Ambulatory Care Setting was chosen as the applicable care setting for real world testing as it represents the marketed care setting as well as the majority of the business.

EXPECTED OUTCOMES

Measurement/Metric	Associated Certification Criteria
Known Dataset	Using a known dataset allows you to have completely predictable outcome. This is how we test that the application is functional and meets quality assurance tests. Success is measured when there is 100% the same outcome time over time.

Statistic Capture	For a given population, the expectation is that over time there will be established trends in the data along with acceptable margins. Once the trends and acceptable margins are defined, the expectation is that all data fall within these measures.

SCHEDULE OF KEY MILESTONES

The below timeline is focused on a Quality Assurance & Patterning approach.

Key Milestone	Care Setting	Date/Timeframe
Define known dataset, build known dataset	Ambulatory	Due 4/10/2022
Define statistics for capture and process by which to capture statistics, develop and deploy	Ambulatory	Due 3/1/2022
Review data capture for given population and trend overtime, define acceptable margins	Ambulatory	Due 6/1/2022
Develop and deploy monitoring, reporting, and alerting mechanism based on defined trends and acceptable margins	Ambulatory	Due 7/1/2022
Build repeatable process to consume, analyze, and report on known dataset in production (note: this repeatable process will facilitate the ongoing compliance & adherence to the patient engagement criteria)	Ambulatory	Due 8/1/2022
SLI Real World Testing Results	Ambulatory	Due 1/15/2023

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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