FEI Systems

Connecting Every Dimension of Health and Human Services

WITS Requirements Document

2022 Real World Test Plan

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Real World Test Plan

WITS

For Criteria

§170.315 (b)(1), §170.315 (b)(6), §170.315 (c)(1), §170.315 (g)(7), §170.315 (g)(8), and §170.315 (g)(9)

GENERAL INFORMATION

Plan Report ID Number: 2022RWTPlan_Ver1.0

Developer Name: FEI Systems

Product Name(s): Web Infrastructure for Treatment Services (WITS)

Version Number(s): 20

Certified Health IT: 15.04.04.1479.WITS.20.01.1.200603

Product List (CHPL) ID(s): 15.04.04.1479.WITS.20.01.1.200603

Developer Real World Testing Page URL: https://feisystems.com/onc-certified/

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Currently the Certified Health IT module, WITS is sold by FEI Systems as an Ambulatory Care Electronic Health Record (EHR) Software application. Its primary focus in with the Behavioral Health provider specialty. The applicable 2015 Edition criteria that we will include in our Real World Test plan are:

Table 1

§170.315 (b)(1)	§170.315 (b)(6)
§170.315 (c)(1)	§170.315 (g)(7)
§170.315 (g)(8)	§170.315 (g)(9)

These criteria were tested individually during the ONC certification process. However, in the real world these certified modules provide one seamless approach to accomplish the clinical and administrative documentation requirements and incorporate the features and functions of all of the criteria mentioned in Table 1. To that end, the Real World Test plan

will be designed to demonstrate how these combined certified criteria perform in the production environment. Since this certified product is deployed in multiple settings and specialties within the marketplace, we will design our Real World Test plan to reinforce the capabilities that we encounter in these production environments. The WITS application does allow providers to fully satisfy their reporting requirements for the MIPS program.

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

Standard (and version)	N/A
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

MEASURES USED IN OVERALL APPROACH

DESCRIPTION OF MEASUREMENT/METRIC

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

The Measure/Metrics and the Descriptions listed below will apply to the simultaneous and seamless use of the functionality of the applicable certified measures mentioned in Table 1. The RWT will be witnessed via a Microsoft Teams session with the participants (current customers) using a mirrored production environment and real patient data. Upon completion we will observe and report the successful conformance of our customers using the certified technology as it was designed, to be able to complete the applicable 2015 Edition Certified criteria listed in Table 1 above.

The Measure/Metrics and Descriptions for Measures 1 - 4 listed below will apply to multiple criteria simultaneously to demonstrate the functionality of these certified measures: § 170.315(b)(1) Transitions of care (Receive), § 170.315(c)(1) CQM – Record and Export, § 170.315(b)(1) Transitions of care (Send), §170.315(g)(7,8,9) API. The Measure/Metrics and Descriptions for Measures 5 - 7 will apply to § 170.315(b)(6) Data export.

Measurement/Metric	Description

Measure 1: Clinician logs into WITS and receives a C-CDA from a referring provider via Direct Protocol with no Tech Support and no errors. C-CDA has demographic information adjusted so PHI is not visible. Successful receipt of C-CDA is achieved and observed.	Clinician begins a new patient encounter in the WITS certified software with a patient referred by another clinician. With a Direct Address and unique Updox credentials the clinician is able to have a seamless login and secure receipt of C-CDA from the referring clinician using the Direct Protocol. The Common Clinical Data Set standard will be demonstrated in these transactions through screenshots collected. Log files are also captured. These will all show the successful receipt of the C-CDA with all fields completed and arranged per provider preference. This will meet § 170.315(b)(1) (Receive).
Measure 2: Documentation of Medications (CQM68) is done without assistance. No errors are expected.	The clinician easily completes Documentation of Medications (CQM68) within appropriate location in the WITS software to meet 170.315(c)(1) by completing the appropriate fields as they document the patient's medications on the date of the encounter in WITS software. It will be later reflected in the numerator and denominator of this MIPS CQM measure and the generation of a QRDA file format.
Measure 3: Updated C-CDA is sent back to referring partner. Successful sending of CCDA is achieved and observed.	Clinician sends updated C-CDA with minimal delay back to referring clinician via Direct Protocol. Updated C-CDA is also sent to the patient portal. Confirmation of sent C-CDA is captured along with log files. This will meet § 170.315(b)(1) (Send).
Measure 4: The patient will have the ability to access (by authentication) either partial or full encounter summaries by way of an API call from a 3rd-party application running on a patient-owned device to the API of the EHR.	This same patient will be enabled to present their authenticated credentials to use a 3rd-party application running on a patient-owned device to access either partial encounter summary data or a full encounter summary. They will have the ability to view and or transmit their information as they see fit. This will meet § 170.315 (g)(7,8,9).
Measure 5: A selected practice staff member is observed successfully exporting bulk patient data files on demand.	Authorized office practice staff member will perform an export of data from the production server in real-time (on demand) with a specific start & end date immediately. This will be done without delay and sent to a specific file location decided by the staff member. This will be accomplished efficiently and with no error and the file will be inspected when received to ensure it is the file requested. Real world data will be used but demographic information will be changed to protect patient health information. This measure allows the capture of report data selected by and on demand without assistance from development staff. The ability to independently create reports is vital to office practices and integral to a certified EHR. FEI Systems staff will verify the reports have been created successfully with requested data and sent to specific location through screenshots.
Measure 6: a selected practice staff member is successfully exporting a file at a single delayed time - with a specific start and end date in the future.	An authorized office staff member will perform a data export data in the future - 5 minutes from current time - from the production server with a scheduled specific start & end date -such as November 1 - November 2, 2021.This will be accomplished efficiently and with no error and the file will be inspected when received to ensure it is the file requested. This measure allows the staff member to select a time in the future without assistance from development staff. The ability to independently create reports is vital to office practices and integral to a certified EHR. FEI Systems staff will verify the reports have been created successfully and sent to a specific file location with requested data through screenshots.
Measure 7: A selected practice staff member sets an export for a delayed future time during hours after the practice is closed and is able to run	An authorized staff member sets up a specific data export to run after the practice is closed. This measure allows the capture of report data selected by and on demand without assistance from development staff. The ability to independently create reports is vital to office practices and

successfully. This scheduled event will repeat as scheduled.	integral to a certified EHR. FEI Systems staff will verify the reports have been created successfully with requested data and sent to specific location with screenshots that capture the activity. At the finish of Measure 8 § 170.315(b)(6) Data export will be satisfied.

ASSOCIATED CERTIFICATION CRITERIA

Measurement/Metric	Associated Certification Criteria
Measures 1 - 4 will be completed in one session.	
Measure 1	§ 170.315(b)(1) Transitions of care - Receive
Measure 2	§ 170.315(c)(1) CQM – Record and Export
Measure 3	§ 170.315(b)(1) Transitions of care - Send
Measure 4	§ 170.315 (g)(7, 8, 9) API
Measures 5 - 7	§ 170.315(b)(6) Data export

JUSTIFICATION FOR SELECTED MEASUREMENT/METRIC

Measurement/Metric	Justification
Measure 1: Clinician logs into WITS and receives a C-CDA from a referring provider via Direct Protocol with no Tech Support and no errors. Successful receipt of C-CDA is achieved and observed.	The ability to electronically receive a C-CDA, without developer assistance, from another provider and or point of service by using the Edge Protocol is integral to the exchange of data and interoperability and inherent in a certified EHR. The C-CDA will use the Common Clinical Data Set standard.
Measure 2: The clinician will document the patient's current medication status and a routine part of every encounter.	A clinician must be able to perform medication reconciliation and enter proper documentation into the record without developer assistance. The clinician's actions will be captures and logged to indicate that the requirement for a given eCQM (CMS068) has been satisfied. Additionally, the WITS EHR will be able to generate a QRDA format of the eCQM for export purposes. The ability to do this as part of the test plan will show how clinicians can complete this task efficiently and without error.
Measure 3: Updated C-CDA is sent back to referring provider. Successful sending of the C-CDA is achieved and observed.	To complete the ability to bi-directionally participate in the interoperability of patient information the certified EHR technology must be able to allow providers to send a C-CDA using the Edge Protocol, and the Common Clinical Data Set standard.
Measure 4: Additionally, the patient will have the ability to access (by authentication) either partial or full encounter summaries by way of an API call from a 3rd-party application running on a patient-owned device to the API of the EHR.	The certified EHR technology must provide the patient with an additional ability to obtain their medical information via a request from an application of their own, outside of the domain of an EHR. This functionality will supplement the capabilities that are achieved with a patient portal.

Measure 5: Authorized staff member is observed successfully exporting data files on demand.	Exporting data on demand is an essential requirement for a clinical practice with a certified EHR. A selective member of the office staff needs the capability of doing this immediately and successfully without developer assistance.
Measure 6: Authorized staff member is successfully exporting a file at a delayed time - with a specific start and end date.	Exporting data at a relative time is a requirement for a clinical practice with a certified EHR. A selective member of the office staff needs the capability of doing this successfully without developer assistance.
Measure 7: Authorized staff member sets an export for a delayed time during hours after the practice is closed and is able to run successfully.	Exporting a specific report with large amount of data after hours is an essential requirement for a clinical practice with a certified EHR. A selective member of the office staff needs the capability of doing this successfully without developer assistance. The certified EHR requires this capability to avoid placing undue load on the technology during regular business hours and allows the staff member to place the files in a location of their choice.

CARE SETTING(S)

Care Setting	Justification
Facilities: • Ambulatory Specialties: • Behavioral Health	The WITS is currently used by providers in the Behavioral Health specialty. This test plan will demonstrate that the overall functionality is the same regardless of the number of providers that are using it at a given time. We will get feedback from multiple clinician roles within the Behavioral Health scope of practice. Additionally, we will document that the EHR performs the same in under those multiple clinician conditions of use. The overall process will be the same in all levels of demand. However, we will confirm that the EHR accommodates the specific workflow under each condition with multiple simultaneous users of the EHR. We will be conducted the Real World Testing with clinicians from the listed care setting with between 1-5 clinicians. These are the FEI Systems target audience. Real patient data will be deidentified and the testing will be using a mirrored production environment. The ability to complete all measures successfully with these practices will be documented through observation of the completed tasks. Deviations from the designed process, if any, will be noted and addressed.

EXPECTED OUTCOMES

Measurement/Metric	Expected Outcomes
§ 170.315(b)(1) Transitions of care (Receive)	The Real World Testing will demonstrate that the clinician can receive C-CDA R2.1 C-CDA Document payload type in an the designated setting. Using the Edge Protocol SMTP protocol. Both Referral Notes and Discharge Summaries will be evaluated.

	The received document will be evaluated for the ability to: • Receive and validate and display any recorded errors if not a valid C-CDA documents. • Parse and present a pre-configured human readable display of all Common Clinical Data Set data from the relevant C-CDA formatted to the CCDS standard. WITS is compliant with standards for these criteria and vocabulary code sets in all of these measures.
§ 170.315(c)(1) CQM – Record and Export	The Real World Testing will demonstrate that the clinician will be able to record all of the data that would be necessary to calculate the certified eCQMs (CMS68). Data required for CQM exclusions or exceptions will be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of "patient reason," "system reason," or "medical reason." A clinician will be able to export a data file at any time the user chooses and without subsequent developer assistance to operate. It will be formatted in accordance with the standard specified in § 170.205(h)(2), ranging from one to multiple patients; and that includes all of the data captured for the CQM that is certified (CMS68).
§ 170.315(b)(1) Transitions of care (Send)	The Real World Testing will demonstrate that the clinician can send R2.1 C-CDA Referral Notes and Discharge Summaries compliant to the Common Clinical Data Set using the SMTP Edge Protocol. We will successfully validate the receipt of the sent documents.
§ 170.315(g)(7,8,9) API	The Real World Testing will demonstrate that the clinician has the functionality within WITS to receive a request with sufficient information to uniquely identify a patient and return an ID or other token that can be used by an application to subsequently execute requests for that patient's data. The EHR will demonstrate the functionality to respond to requests for patient data for partial or all of the data categories specified in the Common Clinical Data Set at one time and return such data (according to the specified standards, where applicable) in a summary record formatted according to the standard adopted C-CDS standard. The requests will respond to requests for patient data associated with a specific date as well as requests for patient data within a specified date range.
§ 170.315(b)(6) Data export	The Real World Testing will demonstrate that a limited clinician group are enabled to set the configuration options when creating an export summary as well as a set of export summaries for patients whose information is stored in WITS. A clinician within the limited group is able to execute these capabilities at any time the user chooses and without subsequent developer assistance to operate. The limited set of clinicians are enabled to create export summaries formatted in accordance with the standard specified using the C-CDA that is compliant to the Common Clinical Data Set. The limited set of clinicians are enabled to set the date and time period (Start and End Dates) within which data would be used to create the export summaries. They can: ○ Create export summaries in real-time ○ Create export summaries based on a relative date and time (e.g., the first of every month at 1:00am) ○ Create export summaries based on a specific date and time (e.g., on 10/24/2015 at 1:00am) The limited set of clinicians are enabled to set the storage location to which the export summary or export summaries are intended to be saved.

SCHEDULE OF KEY MILESTONES

Key Milestone	Care Setting	Date/Timeframe
Prepare the WITS application for use in collecting data to support the RWT plan.	Facilities: • Ambulatory Specialties: • Behavioral Health	December 2021
Identify the user practices the will participate in the test plan	Facilities: • Ambulatory Specialties: • Behavioral Health	December 2021 & January 2022
Confirm that the Real World Test Plan participants are able to log into their accounts and are ready to start the RWT plan documentation	Facilities: • Ambulatory Specialties: • Behavioral Health	January 2022
Conduct the series of Real World Testing with the participants on a regular basis (minimum, once a quarter) to obtain feedback on their progress and or if there are any issues to address.	Facilities: • Ambulatory Specialties: • Behavioral Health	Quarterly 2022
End the Real World Test to coincide with the end of the Year.	Facilities: • Ambulatory Specialties: • Behavioral Health	December 2022

Real World Test analysis and generation of the report	Facilities: • Ambulatory Specialties: Behavioral Health	January 2023
Submit Real World Test Report to ACB before established deadline	Facilities: • Ambulatory Specialties: • Behavioral Health	February 2023

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.[i]

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: Deeksha Garg

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Authorized Representative Phone: 443-270-5146

Authorized Representative Signature:

Date: 11/9/2021

Deeksha Garg