Real World Test Plan

Developer Name	ZH Healthcare, Inc.
Product Name(s)	blueEHR
Version Number(s)	3.0
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Revision History

Date	Version	Reason for Change
11/17/2021	1.0	Initial draft of the Real World Test Plan

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Introduction

blueEHR is marketed as an integrated care setting supporting physical (general practitioners) and behavioural health practitioners. There are multiple certification criteria involved in the testing. The test plan is defined in such a way to cover all the measures mentioned below. There are dependencies with external application in the case of Direct Messaging. The data needs to be collected from the external application as well, which will be discussed with their team. All other data can be available within blueEHR.

- 170.315 (b)(1): Transitions of Care
- 170.315 (b)(2): Clinical Information Reconciliation and Incorporation
- 170.315 (b)(6): Data Export
- 170.315 (c)(1) Clinical Quality Measures - Record and Export
- 170.315 (e)(1): View, Download, and Transmit to 3rd Party
- 170.315 (f)(2): Transmission to Public Health Agencies - Syndromic Surveillance
- 170.315 (f)(1): Transmission to Immunization Registries
- 170.315 (g)(7): Application Access - Patient Selection
- 170.315 (g)(8): Application Access - Data Category Request
- 170.315 (g)(9): Application Access - All Data Request
- 170.315 (h)(1): Direct Project

Scenario 1 – External Facility Referral

Scenario

Provider conducts visit with the patient where the patient is diagnosed with a cardiac problem that triggers a referral to a specialist. The provider enters a referral in the referral management dashboard and selects the option to send the referral using DIRECT Messaging, the provider will send to another provider using Direct messaging or print and provide to the patient. To complete the external referral process, the Provider will have previously registered for a EMR Direct address. Once this is completed the provider will add their EMR Direct address into the software. This will then allow the provider to share records with other providers via the referral module.

To support the referral process, the Provider Office also provides access to the Patient into the Patient Portal. The Patient logs into the portal where they will locate all medical records from their past visits with the provider. The Patient can download or print this data or choose to share the medical history with other providers.

Justification of Real-World testing approach

The scenario mentioned here is primarily focusing on sending a patient to an external facility. The outcome of this approach will be to demonstrate the ability of the application to send the medical records to an external application.

Description of Measurement/Metric

- Successful transition of data
    - Justification - This measure will help to determine the success rate of transition of data to an external application. The status of the email sent will be notified to the user, whether the emails is delivered successfully or failed because of any specific reason. blueEHR is using a third-party application, EMR Direct, to send and receive Direct emails.
    - Test methodology - The application is logging every email sent to an external entity. The data is logged in the database. From the logs we will be able to determine the failed and successful emails.
    - Expected outcome - The application is expected to achieve 99% success rate.
- Security of the data transferred
    - Justification - This measure will help us to determine all the emails are sent securely. We are using EMR Direct to send emails to external application. All the emails are sent through secure channel. This will satisfy the standard §170.202(a)(2) Direct Project: ONC Applicability Statement for Secure Health Transport, Version 1.2 (incorporated by reference §170.299).
    - Test methodology - This can be done with the help of EMR Direct team. They can get us the log of the emails that has failed because of invalid or expired certificates or that are not secured.
    - Expected outcome - The application is expected to achieve 100% secured mail transfer.
- Data format used for transfer
    - Justification - This measure will help us to the providers are using standardized document format as mentioned in 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) to transfer the patient's medical records.
    - Test methodology – This can be achieved using the logs that we store for each mail sent. We have patient wise records for this. The logs can be viewed from the Care Coordination module in blueEHR. Any user who has access can view the logs.
    - Expected outcome - The providers are expected to use structured data defined in §170.202(d) ONC Implementation Guide for Direct Edge Protocols (incorporated by reference in § 170.299) to transfer patient medical records. We can identify the percentage of data transferred without using structured data.

Associated Certification Criteria

- 170.315 (b)(1): Transitions of Care
- 170.315 (b)(6): Data Export
- 170.315 (h)(1): Direct Project

Care setting addressed

blueEHR markets its Modules in integrated care setting supporting physical (general practitioners) and behavioural health, so this is the care setting in which Real World Testing will occur.

Scenario 2 – Incoming Patient Data from External Facility

Scenario

To support continuity of care of a patient who has been treated and released from a hospital setting, the blueEHR provider needs to receive documentation regarding the services provided to their patient while hospitalized, including any lab results and medications dispensed. Our blueEHR provider can receive a CCDA from the hospital system. Using blueEHR, the provider we will go into Care Coordination module to select Import and upload the CCDA file. Once imported, the system provides options to review and approve, view details or create a new patient if that patient does not appear in the system.

Justification of Real-World testing approach

The scenario mentioned here is primarily focusing on receiving a patient from an external facility. The outcome of this approach will be to demonstrate the ability of the application to receive the medical records from an external application and incorporate the data into blueEHR system.

Description of Measurement/Metric

- Successful transition of data
    - Justification - This measure will help to determine the success rate of receiving data from an external application. We are using a third-party application, EMR Direct, to achieve Direct emailing. EMR Direct manages the error codes for failed emails and will be sent to the sender.
    - Test methodology - The application is logging every email received from an external entity. The data is logged in the database. From the logs we will be able to determine the successful emails received. We can also use the logs from EMR Direct to determine the failed emails.
    - Expected outcome - The application is expected to achieve 99% success rate.
- Security of the data transferred
    - Justification - This measure will help us to determine all the emails received from secure source. We are using EMR Direct to send/receive emails from external application. All the emails are sent through secure channel. This will satisfy the standard §170.202(a)(2) Direct Project: ONC Applicability Statement for Secure Health Transport, Version 1.2 (incorporated by reference §170.299).
    - Test methodology - This can be done with the help of EMR Direct team. They can get us the log of the emails that has failed because of invalid or expired certificates or that are not secure.

- o Expected outcome - The application is expected to achieve 100% secured mail transfer and reject all the emails with invalid/expired certificates.
- Importing of data received
  - o Justification - This measure will help us to identify how many referrals has structured data. We can identify the number of invalid documents received from another facility. We can also make sure how many documents were imported successfully.
  - o Test methodology - The import of CCDA can be done from our Care Coordination module. All the messages received from external source will be listed in this module. User can review and import the required data. We keep log of all the data that are received and that are imported.
  - o Expected outcome - We will need external entities to share us the patient data in structured format. We will be able to identify whether this is being followed. We also need the providers to import all the data that they received in structured format. We can make sure that providers are doing the same.

Associated Certification Criteria
- 170.315 (b)(1): Transitions of Care
- 170.315 (b)(2): Clinical Information Reconciliation and Incorporation
- 170.315 (h)(1): Direct Project

Care setting addressed
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Scenario 3 – CQM Reporting

Scenario
As part of required reporting, the Provider must submit the CQM report to the applicable registry. Within blueEHR, the Provider will first set up the Clinical Decision Rule Engine (CDR) with the CQMs the provider is reporting upon, such as Controlling High Blood Pressure. Once the CDR is set, when the provider conducts a visit with the patient, the provider enters the blood pressure or vitals during the visit/encounter. The provider can then go to the CQM report within the system and enter the specific details that will provide a report of all patients that have met the measure or need to complete the measure.

Justification of Real-World testing approach
The scenario mentioned here will be focusing on submission of Clinical Quality Measure data to registry. The outcome of this approach will be to demonstrate blueEHR will be able to generate the data required to submit to the registry as mentioned in the standard

§170.205(h)(2) – HL7 CDA® Release 2 Implementation Guide for: Quality Reporting Document Architecture – Category I(QRDA I), DTSU Release 3 (US Realm).

Description of Measurement/Metric

- Recording data
    - Justification - This measure will help us to identify that the measures are recorded correctly.
    - Test methodology - This can be achieved by manually adding data to blueEHR. Providers who have access to add medical records can make sure that the data added is reflected in the CQM report. CQM report will list all the supported Clinical Quality Measures supported by the system and will list down the count of each measure recorded. User can manually verify this from the interface.
    - Expected outcome – We can make sure that providers/authorized users are able to record and view the data related to each CQM measure.
- Export Report
    - Justification - The providers can export the QRDA data from blueEHR and upload them to the registry or any other application accepting the data. This measure will help us to identify whether the providers are exporting the CQM data in structured format.
    - Test methodology – Providers can achieve this from the Report in blueEHR. Report support export of both Cat I and Cat III according to the standards specified in §170.205(h)(2) - HL7 CDA® Release 2 Implementation Guide for: Quality Reporting Document Architecture – Category I(QRDA I), DTSU Release 3 (US Realm). The data exported is logged in the system. We can check the logs from the backend and determine whether the data is exported or not.
    - Expected outcome - We can make sure the providers are exporting the data according to the standards required.

Associated Certification Criteria

- 170.315(c)(1) Clinical Quality Measures - Record and Export

Care setting addressed

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Scenario 4 – Transmitting Immunization Information

Scenario

During a patient visit at a provider's office, a vaccination is ordered. The provider, from within the patient's chart, will select on the Immunization tab to enter vaccination. Once completed the provider will go into the Care Coordination module, select the Immunization tab, search for a date range, CVX code, or specific patient to locate the data to share. The provider can print and/or send the vaccine information to the immunization registry.

Use Case 1:

Transmitting existing and new Immunization details to Immunet.

Justification of Real-World testing approach

We are using a third-party application to test the ability to transmit to immunization registries in production. blueEHR has the ability to generate immunization information in the format mentioned in § 170.207(e)(4) for administered vaccines. User will be able to upload the data to the registry.

Description of Measurement/Metric

- Generate Immunization information of a patient
  - Justification – This measure will help us to identify whether the immunization data created has all the required information as specified in the standards §170.205(e)(4) HL7 2.5.1 Implementation Guide for Immunization Messaging.
  - Test Methodology – Users who has access to immunization module can add/edit immunization data. The information required to be transmitted to registries can be generated from the immunization widget and can be uploaded to the registry.
  - Expected Outcome – All the information exported is stored in logs. We can retrieve the logs and verify the structure of the immunization information manually. Using this measure, we can confirm that the user can generate the immunization information according to the standards mentioned in §170.205(e)(4).

Use Case 2:

Pull immunization history information from Immunet.

Justification of Real-World testing approach

Immunet has the ability to share patient's immunization history data. User can use blueEHR to pull the immunization history information of a patient. BlueEHR will be able to pull the information using the standards mentioned in § 170.207(e)(3) for historical vaccines.

Description of Measurement/Metric

- Generate message to pull Immunization history

- o Justifications - This measure will help us to verify whether the message generated for pulling Immunization history from the registry has all the required information as specified in the standards § 170.207(e)(3).
- o Test Methodology - Users who has access to Immunization module and patient Demographics module has the ability to pull the patient's immunization history. This can be done from the immunization widget in patient demographics.
- o Expected Outcome - The request sent from blueEHR to Immunet and the response received from Immunet is logged in blueEHR. We can manually verify that the request sent from blueEHR to pull the patient's Immunization history is generated according to the standards mentioned in § 170.207(e)(3).

Associated Certification Criteria
- 170.315 (f)(1): Transmission to Immunization Registries

Care setting addressed
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Scenario 5 – Using APIs to Access Data

Scenario
Using APIs to access patient data in blueEHR, to send data from blueEHR to another system and to support data migration from a legacy system to blueEHR.

Use Case 1:

When a provider is using another software as an endpoint, such as a care management program, the blueEHR APIs can search for a specific patient, based on several criteria such as name, DOB, and address. When a provider creates an API key most commonly the provider will search for a patient using a PID, and DOB in conjunction and return data requested within the parameters of that API's function.

Use Case 2:

When a provider using another software such as a care management program, sends an API to pull back a patient chart, or part of the chart with select patient data within a date range the system will log, who requested the information (user name) when (date and time), and what was requested. The system receiving the information will be able to parse the data that was returned for analytical, financial, or care purposes as required.

<u>Use Case 3:</u>

When a provider is transferring between EHRs often they will use an all-data request to request information that should be sent and mapped to the new system or to drop in data received from the old system to the new. The APIs allow for the pulling of a complete patient record, as well as the mapping of a complete patient demographics, and insurance from one system to another if configured appropriately.

Justification of Real-World testing approach

blueEHR is integrated with a client's Care Management (CM) solution. The CM solution is an external application which is used by one of our clients to pull data from blueEHR. blueEHR uses all the capabilities mentioned in the standards to provide data to the CM solution.

Description of Measurement/Metric

- Connecting securely with blueEHR
    - Justification - External applications can connect to blueEHR using an authentication mechanism. Oauth 2.0 and in-house token generation are the two methods used. All our recent APIs are using Oauth 2.0. This measure will help us to identify whether all the external connections are properly authenticated.
    - Test Methodology - We are maintaining logs for all the incoming connections. From the logs we will be able to identify successful and failed connections. For failed connections we will be able to identify the reason for failure, we will be able to identify the failures due to invalid authentication data.
    - Expected Outcome - All the invalid connections should be rejected by blueEHR application.
- Completeness of the data exported
    - Justification – The CM solution can connect to blueEHR and export data from blueEHR to the CM solution. This measure will help us to identify the data that is being exported to the CM solution and make sure that all the patient data as expected in the standards mentioned in 170.315 (g)(8) is accessible.
    - Test Methodology - We are maintaining logs of all the API transactions. The data exported to the CM solution will be stored in the logs. We can retrieve the logs of couple of patients and make sure that all the expected data are included in the response.
    - Expected Outcome - All the data elements and vocabularies applicable to the Common Clinical Data Set (CCDS) should be available in the response.
- Format of the CCDA exported
    - Justification – The CM solution can connect to blueEHR and pull the CCDA of a particular patient. This measure will help us to confirm the CCDA pulled is generated according to the standards specified in § 170.205(a)(4): HL7 CDA R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1.
    - Test Methodology – This can be achieved using the logs in blueEHR. We are maintaining the log of all the CCDAs that are exported from the system by

any means, API or Direct mail or manual download. We can get the CCDA that is fetched by the CM solution and using tools we can verify that the structure is a valid.

- o Expected Outcome - The CCDA generated from blueEHR should be valid according to the standards specified in § 170.205(a)(4): HL7 CDA R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1.

Associated Certification Criteria

- 170.315 (g)(7): Application Access - Patient Selection
- 170.315 (g)(8): Application Access - Data Category Request
- 170.315 (g)(9): Application Access - All Data Request

Care setting addressed

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Scenario 6 – Patient Portal

Scenario

Using the patient portal, blueEHR can share the medical records to patients. The provider's office provides the patient access to the patient portal. The patient logs into the portal where they will locate all medical records shared from the provider. The Patient can download or print their data or choose to share it electronically with other providers.

Justification of Real-World testing approach

blueEHR has its own patient portal, MyDocsPortal. MyDocsPortal is connected to blueEHR through APIs. MyDocsPortal can sync the medical records with blueEHR. This is done real time. Patients can gain access to to blueEHR by any authorized user at the providers facility. The login credentials are generated in blueEHR and sent to the patient. The patient can use the same to login to MyDocsPortal and view their medical records.

Description of Measurement/Metric

- Securely connectivity
    - o Justification - MyDocsPortal is an in-house application used to share the medical records with patients. MyDocsPortal uses API to connect to blueEHR and retrieve data. So, the connectivity has to be secured.
    - o Test Methodology - Any authorized user in blueEHR has the ability to enable patient portal for a patient. Once enabled, patient will receive the login credentials and they can login and see the medical records. From the report

in blueEHR we can make sure that no patient without login has access to MyDocsPortal.

- o Expected Outcome - The connectivity between blueEHR and MyDocsPortal is safe and secure.
- Sharing information
    - o Justification - MyDocsPortal will pull the CCDA from blueEHR. Patients will be able to View the records in human readable format and Download/Transmit the CCDA in the format specified in § 170.205(a)(4).
    - o Test Methodology – Any authorized user in blueEHR has to share the credentials to the patient. This is a one-time process. Once the patient receives the credentials, they can log in to MyDocsPortal and access their information. Patient can send the information to an external entity or they can download the information. All the actions are logged. From the logs we can identify whether patient has viewed the information or transmitted to a third party to downloaded the information.
    - o Expected Outcome - We can make sure that the patients are engaged in the portal program and they are getting updates on their medical records immediately after the visit.

Associated Certification Criteria

- 170.315 (e)(1): View, Download, and Transmit to 3rd Party

Care setting addressed

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Scenario 7 – Syndromic Surveillance Registry

Scenario

Transmitting data to Syndromic Surveillance registry. The provider marks specific diagnosis codes in the code type set up to be reportable. Once this code is used to diagnosis a patient during a visit the provider will go to the Care Coordination module, select on Syndromic Surveillance. Enter the date range, diagnosis, and provider to locate the data. The provider can print or download the HL7 file to upload into the public health registry.

Justification of Real-World testing approach

In this scenario we are going to measure the ability of blueEHR to generate information required to be transmitted to Syndromic Surveillance registries. We will also make sure that the information is generated in accordance with the standards mentioned in §170.205(d)(4) HL7 2.5.1 (incorporated by reference in §170.299).

Description of Measurement/Metric

- Generate Syndromic Surveillance information for a patient
  - Justification - This measure can be used to verify whether the information created has all the required information as specified in the standards §170.205(d)(4) HL7 2.5.1 (incorporated by reference in §170.299).
  - Test Methodology - User can generate the required information from the widget Syndromic Surveillance in patient demographics. The information generated in this module is stored in the logs. From the logs we will be able to retrieve the data and verify it manually.
  - Expected Outcome - Using this measure, we can confirm that the user can generate the immunization information according to the standards mentioned in §170.205(d)(4) HL7 2.5.1 (incorporated by reference in §170.299).

Associated Certification Criteria

- 170.315 (f)(2): Transmission to Public Health Agencies - Syndromic Surveillance

Care setting addressed

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Schedule of key milestones

Key Milestones	Date/Time
Meet with provider/authorized representatives to discuss the test plan	Dec 27th 2021
Meet with EMR Direct team to discuss about data collection	Jan 10th 2022
First follow up meet with provider/authorized representatives to identify any issues/risk	Jan 10th 2022
First phase of data collection for analysis	Jan 10th 2022
Review the data collected	Jan 17th 2022
Second follow up meet with provider/authorized representatives to identify any issues/risk	April 4th 2022
Second phase of data collection for analysis	April 11th 2022
Review the data collected	April 25th 2022
Final data collection for analysis	Aug 29th 2022
Analysing the final data and result report creation	Sep 12th 2022
Submit the test report to test lab	Sep 26th 2022

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	11/22/2021