REAL WORLD TESTING PLAN

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 170.556 and 170.523(i)). 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 to develop 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 for 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 which 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. 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 would expect 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. 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.

- Real World Testing–What It Means for Health IT Developers – Fact Sheet
- 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, 85 FR 25642 (May 1, 2020) (**Century Cures final rule**)
  - ↳ *Section VII.B.5 — "Real World Testing"*

GENERAL INFORMATION

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

Developer Name: Compugroup Medical US

Product Name(s): CGM Enterprise EHR

Version Number(s): 10.2.0

Certified Health IT

Product List (CHPL) ID(s): 15.04.04.2700.CGME.10.00.1.191230

Developer Real World Testing Page URL: https://www.cgm.com/usa_en/products/electronic-health-records/cgm-enterprise-ehr.html

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

This test plan focuses on capturing and documenting how the certified capabilities of CGM Enterprise EHR are used successfully in the real world. In instances where there is little adoption of a certified capability or metrics of real-world activity cannot be captured, we will demonstrate the required certified capability in a setting as close to a "real world" implementation as possible.

Real World Testing is only one component of the Health IT Certification program used to demonstrate compliance with the program requirements. It is not intended to duplicate the methods or results previously demonstrated. Instead, this test plan was developed to demonstrate that the certified capabilities have been successfully deployed for providers to use in live settings.

We will be using three approaches to demonstrate the real-world capabilities of our certified software:

- Adoption Rate
- Real World Assessment
- Interactive Testing via User Stories

Adoption rate will be used to determine if/when certified capability is being used in the real world and to help identify differences in care settings. Evidence of high rates of implementation and usage indicate (but don't by themselves prove) a certified capability's usefulness and practical value. Evidence of low rates of implementation and usage might indicate a potential problem, of which there could be several different causes. Note, it is not the goal of this exercise to identify the individual causes of why a given certified capability may have a high or low adoption rate, but rather to identify the users and care settings for which a given test is relevant.

Real World assessments will be used to measure which certified actions were performed at the conclusion of a given time period. These will be conducted by running reports and examining audit logs from within the certified health IT module to help demonstrate the frequency of actions within the given time frame, and where possible, whether those actions were successful or unsuccessful. High success rates should be an indicator of a successful implementation of a given certified capability in a real-world setting.

Interactive testing will be used to demonstrate conformance to requirements where the adoption rate of a given certified capability is not sufficient to obtain a significant Real World Assessment. Interactive tests will require a live test as opposed to examining historical usage statistics. The goal is to allow a user to demonstrate the certified Health IT module being used in a way consistent with their own practice or care setting.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS-SVAP AND USCDI)

CGM Enterprise EHR has not updated to any new standards as part of SVAP or the Cures Update criteria as of this date nor plan to prior to the execution of our Real World Test.

CARE SETTINGS

CGM Enterprise EHR is marketed primarily to ambulatory practices. CGM Enterprise EHR does not market differently for different specialties, nor does the certified Health IT function differently in different care settings. However, specialties may include different type of data or use different combinations of certified functionality. As a result, we have organized CGM Enterprise EHR into three different care settings to ensure that our testing includes a broad cross-section of practice types.

Care Setting
Primary Care (e.g., Family Medicine, Pediatrics, OB/GYN, etc.)
General Specialties (e.g., ENT, Neurology, Cardiology)
Behavioral Health

MEASURES USED IN OVERALL APPROACH

For each measurement/metric, describe the elements below:

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

ADOPTION RATES

The following metrics are applicable to all criteria and all care settings. These metrics will primarily be used to aid with the justification for other metrics by providing additional context (i.e. low adoption rates for certain certified capabilities will necessitate a different approach to testing).

Metric	Description
Number of licensed instances/users of EHR	Identify the total number of licensed instances/users of the certified Health IT module, regardless of care setting, participation in incentive programs, or use of certified capabilities.

The following metrics are applicable to all criteria that are licensed separately from the base license and all care settings.

Metric	Description
Certified capabilities that are licensed separately	• DataMotion (Direct email) • Registries (Immunization, Cancer and Syndromic) • CGM eRx
Number of installs/users who licensed a certified capability	Identify the number of licensed installs/users of a given certified capability.

REAL WORLD DATA ASSESSMENT METRICS

The following metrics will be measured by viewing audit logs and reporting systems available to track the behavior of the certified Health IT module during a given time frame. All metrics are designed to reflect the core elements of the criteria, demonstrate interoperability, and demonstrate the success rate of the certified capability being used. In most cases, we elected to record these metrics over a 90-day period to reflect the reporting periods typically required for compliance with the federal incentive programs.

The continued measurable use of certified capabilities will provide implicit evidence of successful implementation of the required certified capability. This is especially meaningful in cases where interoperability with outside systems is demonstrated. In cases where it is not possible to determine “success” via an explicit confirmation by a receiving system, success will be defined as a transmission was made where no error was received from the destination system or its intermediaries. Additionally, we will review internal customer and vendor issue tracking systems for reports of failures or unsatisfactory performance in the field.

None of the following criteria was updated to the Cures Update version of criteria prior to August 31, 2022. As a result, all testing is scheduled to be conducted against the 2015 Edition version of the criteria.

Criterion	Metric	Care Setting	Justification and Expected Outcome
170.315(b)(1) Transitions of care	Over a 90-day period: 1) Number of CCDAs created 2) Number of CCDAs sent via edge protocols 3) Number of CCDAs received via edge protocols	General Specialties (Cardiology, Pulmonology, etc.)	This criterion requires the ability of a certified Health IT module to create CCDAs according to specified standards and vocabulary code sets, as well as send and receive CCDAs via edge protocols. However, it is not possible to consistently and reliably demonstrate that all required standards and code sets were used because not all CCDAs created in a real-world setting contain all the necessary data elements. Furthermore, it is not feasible to obtain copies of CCDA documents from "outside" developers or providers who have no incentive to participate in this exercise. Therefore, we intend to demonstrate the required certified capabilities by demonstrating how often CCDAs are created and exchanged with other systems to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be moderate utilization by providers with a high success rate.
170.315(b)(2) Clinical information reconciliation and incorporation	Over a 90-day period: 1) Number of times a user reconciled medication list data from a received CCDA 2) Number of times a user reconciled allergies and intolerance list data from a received CCDA 3) Number of times a user reconciled problem list data from a received CCDA	General Specialties (Cardiology, Pulmonology, etc.)	This criterion requires the ability of a certified Health IT module to take a CCDA received via an outside system and match it to the correct patient; reconcile the medication, allergy, and problem lists; and then incorporate the lists into the patient record. The expectation is each of these steps is done electronically within the certified Health IT module. While this certified capability is available to our users, most providers in the real world typically, prefer to perform these steps manually and elect to save any outside received CCDAs as attachments to the patient record. Therefore, we intend to record the frequency that providers are electronically reconciling and incorporating CCDAs that were received from outside providers to demonstrate the certified capability is available and effective, regardless of the frequency, it is used. Our expectation is there will be low utilization by providers with a high success rate.

170.315(b)(3) Electronic prescribing	Over a 90-day period: 1) Number of prescriptions created 2) Number of prescriptions changed 3) Number of prescriptions canceled 4) Number of prescriptions renewed	Primary Care (Internal Medicine, Pediatrics, etc.) General Specialties (Cardiology, Pulmonology, etc.) Behavioral Health	This criterion requires the ability of a certified Health IT module to perform prescription-related electronic transactions (eRx) using required standards. However, it is not possible to demonstrate the correct standards were used because it is not feasible to obtain copies of eRx documents from "outside" companies or pharmacies who have no incentive to participate. Therefore, we intend to demonstrate the required certified capabilities are effective by demonstrating how often eRx transactions are performed by examining reports from our eRx partner. This will demonstrate that not only are the eRx transactions sent from the certified Health IT module, but that the transactions are successfully received by the eRx clearinghouse. Our expectation is there will be high utilization by providers with a high success rate.
170.315(b)(6) Data export	Over a 90-day period: 1) Number of times a data export was performed, whether for a single patient, multiple patients, or all patients in a single transaction	Primary Care (Internal Medicine, Pediatrics, etc.) General Specialties (Cardiology, Pulmonology, etc.)	This criterion requires the ability of a certified Health IT module to export a summary of a patient's record in CCDA format according to specified standards and vocabulary code sets. However, it is not possible to consistently and reliably demonstrate that all required standards and code sets were used because not all CCDAs created in a real-world setting contain all the necessary data elements. Therefore, we intend to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be very low utilization by providers with a high success rate.
170.315(f)(1) Transmission to immunization registries	Over 3 separate unique 10-day periods within a 90-day window: 1) Number (or percentage) of immunization records submitted to the immunization record 2) Number of record requests received by the immunization registry from the Health IT module	Primary Care (Internal Medicine, Pediatrics, etc.) General Specialties (Cardiology, Pulmonology, etc.)	This criterion requires the ability of a certified Health IT module to transmit immunization data to a registry using a specified format. We intend to record the frequency that immunization data is submitted to registries by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate.

170.315(h)(1) Direct Project	1) Number of Direct Messages sent 2) Number of Delivery Notifications received 3) Number of Direct Messages received	General Specialties (Cardiology, Pulmonology, etc.)	This criterion requires the ability of a certified Health IT module to record the frequency that direct messages are sent and received by providers, along with how often MDNs are sent and received. Since not all systems respond with MDNs, we cannot reliably use that metric to define success. Furthermore, it is not feasible to obtain copies of Direct Messages from "outside" developers or providers who have no incentive to participate in this exercise. Therefore, we intend to demonstrate the required certified capabilities by demonstrating how often Direct Messages are exchanged with other systems to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be moderate utilization by providers with a high success rate. This criterion uses the Relied Upon Software: DataMotion Direct. Because this test measures the end user's experience with the certified functionality, it serves as a sufficient test for both CGM EEHR and DataMotion Direct.

INTERACTIVE TESTING

The following test plans will be executed to demonstrate Real World certified capabilities for criteria where metrics are not available because there is no adoption to date.

CGM Enterprise EHR will leverage interactive testing for the following criteria:

- §170.315(b)(9) Care Plan
- §170.315(f)(2) Transmission to public health agencies — syndromic surveillance
- §170.315(f)(4) Transmission to cancer registries

High Level Interactive Test Plan

- **Test Environment:** All interactive testing will be performed in a mirrored production environment.
  - CGM Enterprise EHR will use MS teams to record the interactive test session.
  - The plan for interactive testing the criteria described below in the real world will be to enter information for care setting categories to demonstrate how the certified functionality would work in the Real World in those settings as a representative sample of all the settings in which CGM Enterprise EHR software is deployed.

- **Test Data**: Interactive testing will be performed using test patient data specific to the settings being tested in the mirrored production environment to be as representative as possible of Real-World patients. This precaution will be taken to reduce the risk of exposure to PHI.

Criterion	Interactive Test Plan	Care Setting	Justification and Expected Outcome
§170.315(f)(2) Transmission to public health agencies — syndromic surveillance	CGM Enterprise EHR will select 1 Specialty within the Primary Care setting to demonstrate Syndromic Surveillance. Urgent Care will be the Primary Care setting used to demonstrate the PHIN messaging guide for Urgent Care CGM Enterprise EHR will use the Syndromic Surveillance test suite located at https://hl7v2-ss-r2-testing.nist.gov/ss-r2/#/cb and use the context-free validation to validate that the ADT message, as well as visual inspection of data.	Primary Care (Internal Medicine, Pediatrics, etc.)	**Justification:** As of the writing of this plan, CGM Enterprise has not had sufficient adoption of our syndromic surveillance interface functionality. Indications are that our current healthcare providers base is not required to submit to public health agencies, therefore waiting until required or needed before committing to an implementation. **Expected Outcome:** The Production-Training EHR will send an ADT message that passes the context-free validation of the Syndromic Surveillance test suite and visual inspection will include the correct fields.
§170.315(f)(4) Transmission to cancer registries	CGM Enterprise will focus on the Oncology specialty for testing the Cancer Care Reporting certified functionality since this is the only specialty expected to use this feature. CGM Enterprise will create 2 different Cancer patients and their representative data to be used for this test. Test cases include radiation and no treatment. CGM Enterprise will walk through the EHR to generate a Cancer CCDA document for each test patient and export it and then use visual inspection to confirm that the CCDA document includes all the expected content and uses SNOMED and LOINC value sets.	General Specialties (Cardiology, Pulmonology, etc.)	**Justification:** As of the writing of this plan, CGM Enterprise has not had sufficient adoption of our cancer registry interface functionality. Indications are that our current healthcare providers are not required to submit to the registry, therefore waiting until required or needed before committing to an implementation. **Expected Outcome:** The CCDA documents will be generated for each patient and will include the correct value sets.

§170.315(b)(9) Care Plan	CGM Enterprise EHR will select 1 Specialty within the Primary Care setting to demonstrate Care Plan. CGM Enterprise will create and receive a Care Plan document for 2 patients. CGM Enterprise will walk through the EHR to generate a Care Plan document for test patient, export it, and then use visual inspection to confirm that the CCDA document includes all the expected content and uses SNOMED and LOINC value sets. CGM Enterprise will receive and display care plan document for test patient and then use visual inspection to confirm that the CCDA document includes all the expected content.	Behavioral Health	**Justification:** As of the writing of this plan, CGM Enterprise has very little Indications that our healthcare providers are generating the Care Plan template only, instead of generating a CCDA, in which captures the Care Plan sections as well. **Expected Outcome:** The Care Plan document will be generated and received for each patient and will include only the following sections • **Patient Info;** • **Goals;** • **Health Concerns;** • **Health Status Evaluations and Outcomes;** • **Interventions**

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.

Real World test planning will commence in the first quarter of 2023. Each phase is expected to take 90-days to complete, with report writing to occur end of 2023/early 2024.

Key Milestone	Care Setting	Date/Timeframe
Scheduling and logistics	Primary Care (Internal Medicine, Pediatrics, etc.) General Specialties (Cardiology, Pulmonology, etc.) Behavioral Health	90-days
Data collection	Primary Care (Internal Medicine, Pediatrics, etc.) General Specialties (Cardiology, Pulmonology, etc.) Behavioral Health	90-days
Review and collate data	Primary Care (Internal Medicine, Pediatrics, etc.) General Specialties (Cardiology, Pulmonology, etc.) Behavioral Health	90-days
Writing report	Primary Care (Internal Medicine, Pediatrics, etc.) General Specialties (Cardiology, Pulmonology, etc.) Behavioral Health	90-days

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.

Authorized Representative Name: Neil Simon

Authorized Representative Email: nsimon@emds.com

Authorized Representative Phone: 469-863-8300

Authorized Representative Signature: Neil Simon

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