REAL WORLD TESTING PLAN: CGM EMDS

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:

Developer Name: CompuGroup Medical US (CGM)

Product Name(s): CGM eMDs

Version Number(s): 10

Certified Health IT Product List (CHPL) ID(s): 15.04.04.2700.eMDs.10.02.1.221227

Developer Real World Testing Page URL: https://emds.com/certifications/

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

This test plan focuses on capturing and documenting how the certified capabilities CGM eMDs 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 two approaches to demonstrate the real-world capabilities of our certified software:

- Adoption Rate
- Real World Assessment

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. 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.

STANDARDS UPDATES

CGM has not upgraded CGM eMDs to any new standards as part of SVAP or the Cures Update criteria as of this date, and we do not plan to before our Real World Test.

CARE SETTINGS

CGM eMDs is marketed to ambulatory practices. CGM does not market differently for different specialties, and the certified Health IT does not function differently in different care settings. However, specialties may include different types of data or use different combinations of certified functionality. As a result, we have organized practices into five 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)
Orthopedic Specialties (e.g., Physical Therapy, Orthopedics, Podiatry, etc.)
Surgical Specialties (e.g., General Surgery, Plastic Surgery, Hand Surgery, etc.)
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	• Immunization Interface
Number of installs/users who licensed a certified capability	Identify the number of licensed installs/users of a given certified capability.

REAL WORLD 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 and demonstrate interoperability. We chose 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.

All testing is scheduled to be conducted against the 2015 Cures Update 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 Data source: reports from a representative sample of our customer base, with each care setting included	• Primary Care • General Specialties • Orthopedic Specialties • Surgical Specialties • Behavioral Health	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. This criterion uses the Relied Upon Software: Updox Direct. Because this test measures the end user's experience with the certified functionality, it serves as a sufficient test for both CGM eMDs and Updox Direct.

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 Data source: reports from a representative sample of our customer base, with each care setting included	• Primary Care • General Specialties • Orthopedic Specialties • Surgical Specialties • Behavioral Health	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, but many providers still prefer a manual workflow. Therefore, we intend to record the successful instances in which 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 Data source: report from prescribing network for entire customer base	• Primary Care • General Specialties • Orthopedic Specialties • Surgical Specialties • 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. This criterion uses the Relied Upon Software: First Databank. Because this test measures the end user’s experience with the certified functionality, it serves as a sufficient test for both CGM eMDs and First Databank.

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 Data source: reports from a representative sample of our customer base, with each care setting included	• Primary Care • General Specialties • Orthopedic Specialties • Surgical Specialties • Behavioral Health	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 low utilization by providers with a high success rate.
170.315(b)(9) Care Plan	Over a 90-day period: 1) Number of times a Care Plan CCDA was produced Data source: reports from a representative sample of our customer base, with each care setting included	• Primary Care • General Specialties • Orthopedic Specialties • Surgical Specialties • Behavioral Health	This criterion requires the ability of a certified Health IT module to export a patient's care plan 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 low utilization by providers with a high success rate. This criterion uses the Relied Upon Software: Updox Direct. Because this test measures the end user's experience with the certified functionality, it serves as a sufficient test for both CGM eMDs and Updox Direct.
170.315(f)(1) Transmission to immunization registries	Over a 90-day period: 1) Number of immunization records submitted to the immunization registry 2) Number of record requests received by the immunization registry from the Health IT module Data source: reports from separate immunization registries on a representative sample of our customer base that is currently utilizing this separately licensed functionality	• Primary Care	This criterion requires the ability of a certified Health IT module to transmit immunization data to a registry using a specified format as well as receive and reconcile data from the immunization registry. Both of these metrics can be retrieved from the immunization registries themselves, allowing CGM eMDs to demonstrate the real-world use of these functions.

(g)(7): Application Access - Patient Selection (g)(9): Application Access - All Data Request (g)(10) Standardized API for patient and population services	1) Number of FHIR API responses from the CEHRT that include a patient's Clinical Summary CCDA document. 2) Total number of FHIR API responses made by the CEHRT. Data source: reports from CGM's Metrics server which will tabulate traffic through the production FHIR API.	• Primary Care • General Specialties • Orthopedic Specialties • Surgical Specialties • Behavioral Health	These criteria require the certified Health IT module to provide a standard FHIR API and supporting documentation that enable external applications to request a unique patient identifier that can be used to request additional patient data (g7), respond to data requests with Summary Record that includes all stored USCDI patient data (g9), and/or respond to a request with standard FHIR API resources (g10). To demonstrate the certified capability is available and effective, we will record the number of valid responses both with and without Summary Records that are sent from the CEHRT, which will demonstrate that the full workflow is functioning as intended. This criterion uses the Relied Upon Software: Cloverleaf. Because this test measures successful API traffic, it serves as a sufficient test for both CGM eMDs and Cloverleaf.

SCHEDULE OF KEY MILESTONES

Real World test planning will commence in first quarter of 2024, with report writing to occur end of 2024/early 2025.

Key Milestone	Date/Timeframe	Care Setting
Scheduling and logistics	• 30-days	• Primary Care • General Specialties • Orthopedic Specialties • Surgical Specialties • Behavioral Health
Data collection	• 90-days	
Review and collate data	• 30-days	
Writing report	• 30-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

Date: 11/30/2023