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:

Developer Name: CompuGroup Medical US (CGM)

Product Name(s): CGM APRIMA

Version Number(s): 19

Certified Health IT Product List (CHPL) ID(s): 15.04.04.2700.Apri.19.01.1.221228

Developer Real World Testing Page URL: CGM APRIMA EHR and Practice Management - cgm.com

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Consistent with the ONC's recommendation that "Real World Testing verify that deployed Certified Health IT continues to ***perform as intended by conducting and measuring observations of interoperability and data exchange***", this test plan focuses on capturing and documenting the number of instances that certified capability is successfully utilized in the real world. In instances where no evidence exists due to zero adoption of a certified capability or the inability to capture evidence of successful use for other reasons, we will demonstrate the required certified capability in a semi-controlled setting as close to a "real world" implementation as possible.

It is important to note that Real World Testing is only one component of the Health IT Certification program used to demonstrate compliance with the program requirements. Real World Testing should augment and support testing that was conducted prior to certification being granted. 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 at their discretion in live settings.

We are using a 3-fold approach to demonstrate successful real-world implementations.

- Adoption Rate
- Summative Testing
- 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.

Summative 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 zero and to demonstrate ongoing compliance with updated standards and code sets (SVAP). 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 has not updated CGM APRIMA 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 APRIMA is marketed primarily to ambulatory practices. CGM does not market CGM APRIMA differently for different specialties, nor does CGM APRIMA 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 CGM APRIMA 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, Internal Medicine, OB/GYN, Pediatrics, Urgent Care, etc.)
General Specialties (e.g., ENT, Neurology, Cardiology, Gastroenterology, etc.)
Orthopedic Specialties (e.g., Physical Therapy, Podiatry, etc.)
Surgical Specialties (e.g., General Surgery, Cardiac Surgery, Hand Surgery, Neurosurgery, Orthopedic Surgery, etc.)
Behavioral Health (e.g., Addiction Medicine)

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

RELIED UPON SOFTWARE

SurescriptsHISP is used as relied upon software for the following criteria:

- 170.315(b)(1) Transitions of care
- 170.315(e)(1) View, download, and transmit to 3rd party

First Databank is used as relied upon software for the following criteria:

- 170.315(b)(3) Electronic Prescribing

Cloverleaf is used as relied upon software for the following criteria:

- 170.315(g)(10) Standardized API for Patient and Population Services

Surescripts Clinical Direct Messaging is used as relied upon software for the following criteria:

- 170.315(h)(1) Direct Project

ADOPTION RATES

The following metrics are applicable to all criteria and all care settings. These metrics will not be used directly to demonstrate interoperability or conformance to certification criteria. Instead, they will primarily be used to help determine the participants that will be in scope for this evaluation. They can also aid with the justification for other metrics by providing additional context (i.e., extremely low adoption rates for certain certified capabilities will necessitate a different approach to testing).

Metric	Description
Number of licensed installs/users of EHR • The definition of a "license" is dependent upon the model used (e.g., total number of systems, total number of seats per license, etc.)	Identify the total number of licensed installs/users of the certified Health IT module, regardless of care setting, participation in incentive programs, or use of certified capabilities.
Number of active installs/users of EHR	Identify the total number of ***active*** installs and/or 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	Identify which certified capabilities are licensed separately from the base EHR license. Examples may include eRx, CQMs, public health, etc.
Number of installs/users who licensed a certified capability	Identify the number of licensed installs/users of a given certified capability.
Number of installs/users that have used the certified capability in the preceding 365 days	Where applicable, identify the number of ***active*** installs/users of a given certified capability.

SUMMATIVE 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.

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	▪ 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.

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	▪ 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. 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 ▪ 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.
170.315(b)(10) EHI Export	Over a 90-day period: 1) Number of times an EHI export was performed, whether for a single patient or all patients in a single transaction	▪ Primary Care ▪ General Specialties ▪ Orthopedic Specialties ▪ Surgical Specialties ▪ Behavioral Health	This criterion requires the ability of a certified Health IT module to perform an EHI export for a single patient or for all patients. 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.

(c)(1-3) Clinical quality measures (CQMs)	Over a 90-day period: 1) Number of measures recorded during the period 2) Number of QRDA Category 1 files exported 3) Number of QRDA Category 1 files imported (if applicable) 4) Number of QRDA Category 3 aggregate report(s) created over the period	▪ Primary Care ▪ General Specialties ▪ Orthopedic Specialties ▪ Surgical Specialties ▪ Behavioral Health	These criteria will be tested together. C1 requires a certified Health IT module to record required data, calculate CQMs from the recorded data, and export the data in QRDA Category 1 format. C2 requires a certified Health IT module must be able to import data from a QRDA Category 1 formatted file and calculate the CQMs based on that data. C3 requires a certified Health IT module must be able to create a QRDA Category 1 formatted file and a QRDA Category 3 aggregate report to be used for transmitting CQM data to CMS. We intend to record the frequency that CQM files are imported and/or exported by providers 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.
(e)(1) View, download, and transmit to 3rd party	Over a 90-day period: 1) Number of views of health information by a patient or authorized representative 2) Number of downloads of health information by a patient or authorized representative 3) Number of transmissions of health information by a patient or authorized representative, whether encrypted or unencrypted	▪ Primary Care ▪ General Specialties ▪ Orthopedic Specialties ▪ Surgical Specialties ▪ Behavioral Health	This criterion requires the ability of a certified Health IT module to provide patients access to a patient portal with the ability to view, download, and send their health care records to other providers via encrypted or unencrypted transmission methods in CCDA format. We intend to record the frequency that patients are viewing, downloading, and transmitting their records from the portal using the certified capabilities 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 patients for view and lower utilization for download and transmit with a high success rate for all certified capabilities.
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 registry	▪ Primary Care	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(f)(2) Transmission to public health agencies — syndromic surveillance	Over 3 separate unique 10-day periods within a 90-day window: 1) Total number of syndromic surveillance events created and submitted	▪ Primary Care ▪ General Specialties	This criterion requires the ability of a certified Health IT module to transmit syndrome-based public health surveillance data to a registry using a specified format. We intend to record the frequency that syndromic surveillance 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 that, at the time of testing, there will not be sufficient adoption of this certified capability by our users to perform a satisfactory test, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected pending wider adoption.
170.315(f)(4) Transmission to cancer registries	Over 3 separate unique 10-day periods within a 90-day window: 1) Total number of cancer registry data records created and submitted	▪ Primary Care ▪ General Specialties ▪ Orthopedic Specialties ▪ Surgical Specialties	This criterion requires the ability of a certified Health IT module to transmit cancer case information to a registry using a specified format. We intend to record the frequency that cancer case information 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 that, at the time of testing, there will not be sufficient adoption of this certified capability by our users to perform a satisfactory test, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected pending wider adoption.
170.315(f)(5) Electronic Case Reporting	Over a 90-day period: 1) Total number of Electronic Case Reports generated. 2) Total number of Reportability Responses received from Public Health Agencies.	▪ Primary Care ▪ General Specialties ▪ Orthopedic Specialties ▪ Surgical Specialties ▪ Behavioral Health	This criterion requires the ability of a certified Health IT module to transmit electronic case reports automatically to a practice's jurisdictional public health agency when certain trigger conditions are met. Since all case reports (eICRs) route through a single source (AIMS) we are uniquely positioned to calculate actual, real-world traffic.
(g)(7): Application Access - Patient Selection	Over a 90-day period: 1) Number of FHIR API responses from the CEHRT that include a patient's Clinical Summary CCDA document.	▪ Primary Care ▪ General Specialties ▪ Orthopedic Specialties ▪ Surgical Specialties	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

(g)(9): Application Access - All Data Request (g)(10) Standardized API for patient and population services	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.		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.
(h)(1) Direct Project	Over a 90-day period: 1) Number of Direct Messages sent 2) Number of Delivery Notifications received 3) Number of Direct Messages received 4) Number of Delivery Notifications sent	▪ Primary Care ▪ General Specialties ▪ Orthopedic Specialties ▪ Surgical Specialties ▪ Behavioral Health	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.

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 will leverage interactive testing for the following criteria for CGM APRIMA:

- §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 will use Microsoft Teams to record the test sessions for CGM APRIMA.
  - The plan for testing the criteria described below in the real world will be to enter information for 3 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 APRIMA software is deployed.
  - Since CGM APRIMA's production environment is hosted in a centralized server, it is not necessary to engage with Clinician customers to perform this testing.

- **Test Data**: 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 of PHI.

Criterion	Interactive Test Plan	Care Setting	Justification and Expected Outcome
§170.315(f)(2) Transmission to public health agencies — syndromic surveillance	CompuGroup will focus on Urgent Care specialty to demonstrate Syndromic Surveillance. CompuGroup will utilize 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 is received as expected, as well as visually inspect that the ADT was correctly formed.	▪ Urgent Care	**Justification:** As of the writing of this plan, CGM APRIMA has not had enough adoption of our syndromic surveillance interface functionality. Indications are that healthcare providers planning to rely on electronic case reporting to fulfill these functions. **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 will focus on the Oncology specialty for testing of the Cancer Care Reporting certified functionality since this is the only specialty expected to use this feature. CGM will create 3 different cancer patients and their representative data to be used for this test. These test patients will include a test patient with a cancer diagnosis with no treatment, as well as 2 patients with different prescribed treatments. CGM will generate a Cancer CCDA document for each test patient, export it, and use visual inspection to confirm that the CCDA document includes all the expected content and uses SNOMED and LOINC value sets.	▪ Oncology	**Justification:** As of the writing of this plan, CGM APRIMA has not had enough adoption of our cancer registry interface functionality. Indications are that healthcare providers are waiting for wider adoption and standardization of interfaces among cancer registries of varying jurisdictions before committing to an implementation. **Expected Outcome:** The CCDA documents will be generated for each patient and will include the correct value sets.

SCHEDULE OF KEY MILESTONES

Real World test planning will commence in first quarter of 2025. Each phase is expected to take 90-days to complete, with report writing to occur end of 2025/early 2026.

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

Date: 12/12/2024