Health IT Certification Program
The Office of the National Coordinator for Health Information Technology

REAL WORLD TESTING PLAN

GENERAL INFORMATION

Plan Report ID Number:

Developer Name: CompuGroup Medical US

Product Name(s): CGM CLINICAL™

Version Number(s): 8.3

Certified Health IT Product List (CHPL) ID(s): 15.04.04.2700.CGMC.08.00.1.191230

Developer Real World Testing Page URL: https://www.cgm.com/usa_en/products/electronic-health-records/other-ehrs/cgm-clinical-pm-and-ehr.html

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

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
- Real-World Use Assessment Testing (Summative)
- 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 use 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)

CompuGroup has not updated CGM CLINICAL to any new standards as part of SVAP as of this date nor plan to prior to the execution of our Real World Test.

CARE SETTINGS

CGM CLINICAL is marketed primarily to ambulatory practices. CompuGroup does not market CGM CLINICAL differently for different specialties, nor does CGM CLINICAL 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 CLINICAL 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)

RELIED UPON SOFTWARE

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

- 170.315(b)(1) Transitions of care
- 170.315(f)(5) Electronic Case Reporting

AIMS Platform is used as relied upon software for the following criteria:

- 170.315(f)(5) Electronic Case Reporting

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 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	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.

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 ▪ Registries (Immunization, Cancer, 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 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. Also, it is not feasible to obtain copies of CCDA documents from non-CGM developers or providers who have no incentive to participate in this exercise. Based on that, 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. Based on that, 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. Based on that, 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.
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 2) Number of record requests received by the immunization registry from the Health IT module	▪ 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.

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.

CompuGroup will leverage interactive testing for the following criteria for CGM CLINICAL:

- §170.315(f)(2) Transmission to public health agencies — syndromic surveillance
- §170.315(f)(4) Transmission to cancer registries
- §170.315(f)(5) Transmission to public health agencies – electronic case reporting
- §170.315(f)(7) Transmission to public health agencies — health care surveys

High Level Interactive Test Plan

- **Test Environment:** All CGM CLINICAL's interactive testing will be performed in a mirrored production environment.
  - o CompuGroup will use Teams to record the test sessions for CGM CLINICAL.
  - o The plan for 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 CompuGroup's CGM CLINICAL software is deployed.
  - o Since CGM CLINICAL'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 CLINICAL has not had enough adoption of our syndromic surveillance interface functionality. Indications are that healthcare providers are waiting for wider adoption and standardization of interfaces among public health agencies 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	CompuGroup 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. CompuGroup 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. CompuGroup will walk through the EHR to generate a Cancer CCDA document for each 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.	Oncology	**Justification:** As of the writing of this plan, CGM CLINICAL 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.
170.315(f)(5) Electronic Case Reporting	CompuGroup will focus on ambulatory specialties for testing electronic case reporting functionality. CompuGroup will walk through the EHR to generate an electronic case report and run the resulting file through the AIMS Validator to validate that the message is received as expected and then use visual inspection to confirm that the expected content is present and uses the applicable value sets.	Ambulatory settings	**Justification:** As of the writing of this plan, CGM CLINICAL has not had any provider adoption of the functionality. 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 to demonstrate the feature is available and functions as expected pending wider adoption.

| §170.315(f)(7) Transmission to public health agencies -- health care surveys | CompuGroup will focus on the Family Practice specialty to demonstrate health care survey interface functionality and conformity to National Health Care Surveys 1.2 XML document.

CompuGroup will configure the EHR to point to the public health agency test suite located at https://cda-validation.nist.gov/cda-validation/muNHCS12.html and use the On-line Validation to validate that the XML document is received as expected, as well as visually inspect that the XML document was correctly formed. | Family Practice | **Justification:**
As of the writing of this plan, CGM CLINICAL has not had enough adoption of our health care survey functionality. Indications are that healthcare providers are waiting for wider adoption and standardization of interfaces among public health agencies of varying jurisdictions before committing to an implementation.

Expected Outcome:
The XML 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.

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