

# Health IT Certification Program

The Office of the National Coordinator for Health Information Technology

## 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*”

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## 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/cgm-clinical.html](https://www.cgm.com/usa_en/products/electronic-health-records/cgm-clinical.html)

## 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
- 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,

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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 or the Cures Update criteria 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 CLINICAL differently for different specialties, nor does 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 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)  |

## 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

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## 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          | <ul style="list-style-type: none"><li>▪ DataMotion</li><li>▪ Registries (Immunization, Cancer, Syndromic)</li><li>▪ CGM eRx</li></ul> |
| Number of installs/users who licensed a certified capability | Identify the number of licensed installs/users of a given certified capability.   |

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## 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.

None of the following criteria were updated to the Cures Update version of criteria prior to August 31, 2021. 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)<br>Transitions of care | Over a 90-day period:<br>1) Number of CCDAs created<br>2) Number of CCDAs sent via edge protocols<br>3) Number of CCDAs received via edge protocols | <ul style="list-style-type: none"> <li>▪ Primary Care</li> <li>▪ General Specialties</li> <li>▪ Orthopedic Specialties</li> <li>▪ Surgical Specialties</li> <li>▪ Behavioral Health</li> </ul> | <p>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.</p> <p>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 CCDAs 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.</p> |

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| <p>170.315(b)(2)<br/>Clinical information reconciliation and incorporation</p> | <p>Over a 90-day period:</p> <ol style="list-style-type: none"> <li>1) Number of times a user reconciled medication list data from a received CCDA</li> <li>2) Number of times a user reconciled allergies and intolerance list data from a received CCDA</li> <li>3) Number of times a user reconciled problem list data from a received CCDA</li> </ol> | <ul style="list-style-type: none"> <li>▪ Primary Care</li> <li>▪ General Specialties</li> <li>▪ Orthopedic Specialties</li> <li>▪ Surgical Specialties</li> <li>▪ Behavioral Health</li> </ul> | <p>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.</p> |
| <p>170.315(b)(3)<br/>Electronic prescribing</p>                                | <p>Over a 90-day period:</p> <ol style="list-style-type: none"> <li>1) Number of prescriptions created</li> <li>2) Number of prescriptions changed</li> <li>3) Number of prescriptions canceled</li> <li>4) Number of prescriptions renewed</li> </ol>  | <ul style="list-style-type: none"> <li>▪ Primary Care</li> <li>▪ General Specialties</li> <li>▪ Orthopedic Specialties</li> <li>▪ Surgical Specialties</li> <li>▪ Behavioral Health</li> </ul> | <p>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.</p>  |

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| <p>170.315(b)(6)<br/>Data export</p>                             | <p>Over a 90-day period:<br/>1) Number of times a data export was performed, whether for a single patient, multiple patients, or all patients in a single transaction</p>  | <ul style="list-style-type: none"> <li>▪ Primary Care</li> <li>▪ General Specialties</li> <li>▪ Orthopedic Specialties</li> <li>▪ Surgical Specialties</li> <li>▪ Behavioral Health</li> </ul> | <p>This criterion requires the ability of a certified Health IT module to export a summary of a patient's record in CCD 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 CCDs created in a real-world setting contain all the necessary data elements. Based on that, 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.</p> |
| <p>170.315(f)(1)<br/>Transmission to immunization registries</p> | <p>Over 3 separate unique 10-day periods within a 90-day window:<br/>1) Number (or percentage) of immunization records submitted to the immunization registry<br/>2) Number of record requests received by the immunization registry from the Health IT module</p> | <ul style="list-style-type: none"> <li>▪ Primary Care</li> </ul>   | <p>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.</p>  |

## 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)(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.
  - CompuGroup will use Zoom to record the test sessions for CGM CLINICAL.
  - 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 CompuGroup's CGM CLINICAL software is deployed.
  - 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.



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| Criterion   | Interactive Test Plan  | Care Setting  | Justification and Expected Outcome  |
|---|--|---|---|
| <p>§170.315(f)(2)<br/>Transmission to public health agencies — syndromic surveillance</p> | <p>CompuGroup will select 3 Specialties within the Primary Care setting to demonstrate Syndromic Surveillance.</p> <p>Urgent Care will be one of the Primary Care settings used in order to demonstrate the PHIN messaging guide for Urgent Care</p> <p>CompuGroup will utilize the Syndromic Surveillance test suite located at <a href="https://hl7v2-ss-r2-testing.nist.gov/ss-r2/#/cb">https://hl7v2-ss-r2-testing.nist.gov/ss-r2/#/cb</a> and use the context-free validation to validated that the ADT message is received as expected, as well as visually inspect that the ADT was correctly formed.</p>   | <p>3 Specialties within the Primary Care setting including Urgent Care and 2 others</p> | <p><b>Justification:</b><br/>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.</p> <p><b>Expected Outcome:</b><br/>The Production-Training EHR will send an ADT message that pass the context-free validation of the Syndromic Surveillance test suite and visual inspection will include the correct fields.</p> |
| <p>§170.315(f)(4)<br/>Transmission to cancer registries</p>                               | <p>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.</p> <p>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.</p> <p>CompuGroup 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.</p> | <p>Oncology</p>   | <p><b>Justification:</b><br/>As of the writing of this plan, 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.</p> <p><b>Expected Outcome:</b><br/>The CCDA documents will be generated for each patient and will include the correct value sets.</p>  |

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| <p>§170.315(f)(7)<br/>Transmission to public health agencies -- health care surveys</p> | <p>CompuGroup will select 3 Specialties within the Primary Care setting to demonstrate health care survey interface functionality.</p> <p>Family Practice will be one of the Primary Care settings used in order to demonstrate conformity to National Health Care Surveys 1.2 XML document</p> <p>CompuGroup will configure the EHR to point to the public health agency test suite located at <a href="https://cda-validation.nist.gov/cda-validation/muNHCS12.html">https://cda-validation.nist.gov/cda-validation/muNHCS12.html</a> 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.</p> | <p>3 Specialties within the Primary Care setting</p> | <p><b>Justification:</b><br/>As of the writing of this plan, 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.</p> <p><b>Expected Outcome:</b><br/>The XML documents will be generated for each patient and will include the correct value sets.</p> |
|---|---|--|---|

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## SCHEDULE OF KEY MILESTONES

Real World test planning will commence in first quarter of 2022. Each phase is expected to take 90-days to complete, with report writing to occur end of 2022/early 2023.

| Key Milestone            | Care Setting   | Date/Timeframe |
|--------------------------|--|----------------|
| Scheduling and logistics | <ul style="list-style-type: none"><li>Primary Care</li><li>General Specialties</li><li>Orthopedic Specialties</li><li>Surgical Specialties</li><li>Behavioral Health</li></ul> | 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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Authorized Representative Signature:



Date: *11/8/21*