REAL WORLD TESTING PLAN

GENERAL INFORMATION

Plan Report ID Number:

Developer Name: CliniComp, Intl.

Product Name: CliniComp|EHR

Version Number: 213.03

Certified Health IT Product List (CHPL) ID(s):15.05.05.2695.CLIN.02.00.1.221013

Developer Real World Testing Page URL: https://www.clinicomp.com/cehrt.html

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Clinicomp has designed four real world testing measures that will address the applicable 15 real world testing criteria of which they are certified.

Clinicomp is actively marketing its product's capabilities in an acute care hospital setting. Each of the 15 real world testing certification criteria will be tested in a way that produces measurable evidence of the product's ability to function successfully and demonstrate interoperability in the inpatient environment.

The entirety of the 15 real world testing certification criteria for CliniComp's certified product is not yet deployed or used by customers. Because of this, Clinicomp cannot test the features that are certified to real world testing criteria in a production environment with real patient data. Instead, to demonstrate Clinicomp's compliance with meeting the Real World Testing Condition and Maintenance of Certification Requirements, Clinicomp will test the 15 measures on an internal server. Clinicomp engages clinical consultants that are familiar with Clinicomp's non-CEHRT products. These consultants will perform the Real World Tests on a bi-annual basis.

Testing will occur in June and November of 2023. Four measures encompass the certified real world testing criteria. The measures will use de-identified patient data from one of Clinicomp's non-certified products for testing.

Each of the four measures will consist of measurable criteria to demonstrate successful real world testing. The results will depict consistency of the user experience, as well as usability trending.

The testing results for 2023 will be submitted to SLI by January 12, 2024.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI))

Standard (and version)	n/a
Updated certification criteria and associated product	n/a
Health IT Module CHPL ID	n/a
Method used for standard update	n/a
Date of ONC ACB notification	n/a
Date of customer notification (SVAP only)	n/a
Conformance measure	n/a
USCDI updated certification criteria (and USCDI version)	n/a

Measure/Workflow USED IN OVERALL APPROACH

Meausre/Workflow	Description
CQM	1) User electronically creates a data file for transmission of clinical quality measurement data of all patients admitted during the testing period. a) Report percentage of successful file creation for all patients in the denominator of each Clinicomp certified CQM. §170.315(c)(3) 2) Report percentage of a user successfully exporting a single data file of a patient (admitted during the testing period) that meets criteria to be included in the denominator of each certified CQM. § 170.315(c)(1) 3) Report percentage of a user successfully importing a single file for each certified CQM. §170.315 (c)(2)
Care Coordinator	1) User selects 10 patients from the appropriate testing pool and reports percentage of successfully accomplishing the following tasks: a. Send a SOC document. §170.315 (b)(1) b. Viewing a received SOC document. §170.315 (b)(1) c. Viewing the reconciled list (1 allergy, 1 medication, 1 problem). §170.315 (b)(2) d. Creating an export summary on one patient, tagged as private, in real time. §170.315 (b)(6)(7) e. Creating an export summary on one patient for last 2 months. §170.315 (b)(6) f. Viewing a received SOC document, tagged as secure. §170.315 (b)(8) 2) For the same 10 test patients, user documents success rate of accomplishing the following Care Plan activities: §170.315 (b)(9) a. accessed and created; recorded; changed. b. Received. 3) For the same 10 test patients, user documents success rate of creating an immunization record for submission to a registry. §170.315 (f)(1) 4) For the same 10 test patients, user documents success rate of requesting and viewing imported immunization history and forecast from a registry. §170.315 (f)(1) 5) For the same 10 test patients, user documents success rate of creating a syndromic-based public health

	surveillance document for transmittal to a public health agency. §170.315 (f)(2) 6) For the same 10 test patients, user documents success rate of sending patient's health information to a recipient via direct address. §170.315 (h)(1)
Patient	1) User enacts the patient role from the appropriate testing pool of patients and documents success rate of viewing and sending the downloaded inpatient summary via the Patient Portal to a third party. The user will do this for 10 patients. §170.315 (e)(1)
API	1) User selects 10 patients from the appropriate testing pool and documents success rate of using a third party application to access specific patient data for the desired patient for a given time frame. §170.315 (g)(7;9)

Associated Certification Criteria

Measurement/Metric	Associated Certification Criteria
CQM	(c)(1-3)
Care Coordinator	(b)(1-2); (b)(6-9); (f)(1- 2); (h)(1)
Patient	(e)(1)
API	(g)(7;9)

Justification for Selected Measurement/Metric

Measurement/Metric	Justification
CQM	To demonstrate successful Real World Testing, the results for each CQM criterion are measured as a percentage of successful transmission. The data can easily be compared on a bi-annual basis to ensure interoperability and verify the consistency of the user experience. It will also provide visibility on usability trending.
Care Coordinator	To demonstrate successful Real World Testing, the results of the Care Coordinator criterion are measured as a percentage of success. The results will be viewed as trending data for the two testing periods in the year. EMR Direct Data Exchange Protocol API is the relied upon software for the (h)(1) measure.
Patient	To demonstrate successful Real World Testing, the results of the Patient criterion are measured as a percentage of successful transmission. The results will be viewed as trending data for the two testing periods in the year.
API	To demonstrate successful Real World Testing, the results of the API criterion are measured as a percentage of successful access. The results will be viewed as trending data for the two

	testing periods in the year.

Care Setting(s)

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Measurement/ Metric	Care Setting	Justification
CQM	Inpatient Acute	Clinicomp is certified to several inpatient CQMs. Clinicomp is actively marketing its inpatient product. Inpatient acute is the appropriate care setting to demonstrate compliance and adherence to the Real World Testing criteria.
Care Coordinator	Inpatient Acute	Clinicomp is actively marketing its inpatient product. Inpatient acute is the appropriate care setting to demonstrate compliance and adherence to the Real World Testing criteria.
Patient	Inpatient Acute	Clinicomp is actively marketing its inpatient product. Inpatient acute is the appropriate care setting to demonstrate compliance and adherence to the Real World Testing criteria.
API	Inpatient Acute	Clinicomp is actively marketing its inpatient product. Inpatient acute is the appropriate care setting to demonstrate compliance and adherence to the Real World Testing criteria.

Expected Outcomes

Measurement/Metric	Expected Outcomes
CQM	The expected percentage of success for each criterion is 85%. Over the year, the expectation is that the rate of success will not decrease.
Care Coordinator	The expected percentage of success for each criterion is greater than 85% and to remain consistent with each testing phase. The usability of the tester is expected to be positive. Clinicomp also expects suggestions for ways to improve the user's experience.
Patient	The expected percentage of success for each criterion is greater than 85% and to remain consistent with each testing phase. Clinicomp will consider all suggestions made to improve workflow and the user experience.
API	The expected percentage of success for each criterion is greater than 85% and to remain consistent with each testing phase. Clinicomp will consider all suggestions made to improve workflow and the user experience.

SCHEDULE OF KEY MILESTONES

Key Milestone	Care Setting	Date/Timeframe
Collect patient data	Inpatient Acute	1/1/23 – 5/31/23
Test de-identified patient data	Inpatient Acute	6/1/22 – 6/30/22
Collect patient data	Inpatient Acute	6/1/23 – 10/31/23
Test de-identified patient data	Inpatient Acute	11/1/23 – 11/30/23
Report Real World Test Results to SLI	Inpatient Acute	01/12/24

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: 10/26/2022

[i] Certified health IT continues to be compliant with the certification criteria, including the required technical standards and vocabulary codes sets; certified health IT is exchanging EHI in the care and practice settings for which it is marketed for use; and EHI is received by and used in the certified health IT. (85 FR 25766)

[ii] https://www.federalregister.gov/d/2020-07419/p-3582

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2023 Real World Testing Results

ONC HealthIT Certification Program

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Contents

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General Information

Plan Report ID Number: 20221129cli

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CHPL Product Number: 15.05.05.2695.CLIN.02.01.1.221013 (current)

15.05.05.2695.CLIN.02.00.1.221013 (previous)

Developer RWT Plan Page URL: https://www.clinicomp.com/cehrt.html

Developer RWT Results Page URL: https://www.clinicomp.com/cehrt.html

Initial Plan Modification

In 2020, CliniComp software underwent certification using Office of the National Coordinator (ONC) data and testing tools. However, developers are cautioned against only using open-source testing platforms, as doing so may diverge from the main goal of Real-World Testing, which is to replicate the intended usage scenarios and settings for certified health IT. Consequently, some of the incomplete tests are due to the absence of software deployment at a customer's location. In 2023, CliniComp had none of their certified software components deployed at any customer site.

Our strategy is to perform testing with actual patient data on a production server as soon as we have a customer using any or all our certified software. However, we were unable to secure a customer in 2023. We are actively promoting our services to acute inpatient hospitals and anticipate acquiring a customer in 2024. Until that time, our testing is confined to employing Use Cases and conducting tests on an internal, certified software server.

Summary of Change: The purpose and procedure of Real-World Testing entail vendors utilizing their deployed software to assess production data and actions, and then publicly disclosing the outcomes to showcase compliance. Given this objective and the fact that CliniComp's certified software wasn't operational at customer locations in 2023, it was decided that the most effective way for CliniComp to adhere to this certification requirement would be to conduct testing for each measure using a User Story on an internal server featuring the certified software.

Rationale: The extraction of patient data from production servers and the semi-annual testing of each measure were excluded from the test plan because they were found to be technically unfeasible. The intricacy of the test plan did not contribute any value or provide additional clarification regarding compliance with the measures, given that the software is not operational in a production setting at this time.

Limitation: Performing real-world testing on production servers using certified software that hasn't been deployed in actual production environments poses significant challenges. Several of the measures can only be partially duplicated without the presence of the certified software on a production server.

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Summary of Testing Methods

In the initial year of RWT results collection and monitoring in 2023, CliniComp did not have their certified software actively running in production. Although the primary goal of Real-World Testing as a certification requirement was linked to deployed software, CliniComp is currently showcasing interoperability and data exchange capabilities on internal servers using certified software and user stories.

In 2020, CliniComp software obtained certification through ONC data and testing tools. However, developers are advised against utilizing open-source testing platforms because this may deviate from the primary objective of Real-World Testing, which is to emulate the intended usage scenarios and settings for certified health IT. Some of the tests are incomplete due to lack of production data.

The Metrics and Outcomes section outlines all 15 certified criteria, summarizing their original testing method, the specific modifications made to the test plan along with the rationale, interoperability results, and any associated risks.

Metrics and Outcomes

In this section, we outline the compliance of the data gathered from our Real-World Testing with the certification criteria and the exchange of Electronic Health Information (EHI) in an acute setting. We cannot showcase the receipt and utilization of the EHI in the certified health IT due to the non-deployment of the certified software.

Refer to the Expected Outcomes and Limitations sections for a detailed listing of the 15 criteria.

Clinical Quality Measure (CQM) – Record and Export: §170.315(c)(1)

Test Method: Record percentage of successful user attempts to export a single data entry of a patient for all certified CQMs.

Modified Test Plan: On the internal server, documentation was completed in the supporting fields of the CMS9v11CQM. A user generated a Quality Reporting Document Architecture (QRDA) file for a patient included in the denominator of the CMS9v11CQM.

Rationale: Since the software hasn't been deployed, repeating this User Story for all eight CQMs was redundant and didn't enhance the fulfillment of the ONC certification purpose.

Expected Outcomes: User can document on CQM measures in CliniComp|EHR and generate a QRDA file for submission to the Centers for Medicare & Medicaid Services (CMS).

Results Demonstrating RW Interoperability: QRDA file has been successfully created to facilitate data exchange/interoperability, ensuring that the reports can be submitted electronically to CMS.

Success rate: Document on CQM & Generate Export File in QRDA Format: 1/1 = 100%

Risk: When the software is deployed, minor defect corrections may be requested by the customer. Successfully generating a QRDA file renders the risk low.

Limitation: Practical testing on production servers with certified software not yet deployed in production presents considerable limitations.

CQM – Import and Calculate: §170.315(c)(2)

Test Method: Report percentage of a user successfully importing a single file for each certified CQM.

Modified Test Plan: Testing the criteria was removed from the test plan due to a lack of technical feasibility.

Rationale: Successfully demonstrating importing a single file for each certified CQM was done in 2020 using the ONC test data and testing tools. It is not feasible to perform this test on customer data until the software is deployed a customer site.

Expected Outcomes: The QRDA submission file generated by CliniComp|EHR and uploaded to CMS is an exact match in measure calculations with CMS.

Results Demonstrating RW Interoperability: none

Success Rate: Criterion Removed

Risk: When a customer uses this certified software, there might be some minor defect corrections requested.

Limitation: Conducting real world testing on production servers with certified software that is not yet deployed in production is challenging. This measure could not be tested without having the certified software on a production server.

CQM – Report: §170.315(c)(3)

Test Method: User creates a data file for all patients in the denominator for all certified CQMs. Report percentage of successful file creation for all patients in the denominator of each CliniComp certified CQM.

Modified Test Plan: On internal server, generated a file with patients in denominator for CMS9v11.

Rationale: Demonstrating compliance with 1 CQM, rather than all. There is no value added to duplicate proven compliance with every certified clinical quality measures.

Expected Outcomes: User successfully creates a data file for appropriate patient group.

Results Demonstrating RW Interoperability: QRDA file successfully generated to support data exchange/interoperability and ensure the reports can be electronically submitted to CMS.

Success rate: QRDA file generated with multiple pts from denominator of single measure: 1/1 = 100%

Risk: When the software is deployed, minor defect corrections may be requested by the customer. The risk is minimal with the successful generation of a QRDA file.

Limitation: Conducting real world testing on production servers with certified software that is not yet deployed in production is challenging.

Care Coordinator – Transitions of Care: §170.315 (b)(1)

Test Method: For ten test patients: Send a SOC document; View a received SOC document.

Modified Test Plan: User story for one patient, to demonstrate user can create a SOC and take action to send the document. Testing the criteria of viewing a received SOC was removed.

Rationale: Receiving/viewing a SOC document was demonstrated successfully using the test tool but is not feasible using customer data until the software is deployed at a customer site.

Expected Outcomes: RWT will demonstrate interoperability through CliniComp|EHR's conformance to §170.315 (b)(1). SOC documents can be viewed, sent, and received.

Results Demonstrating RW Interoperability: User can create an SOC and there are actions available to send the SOC – the steps for receiving and viewing are not actionable until the software is deployed. Additionally, the test tools were not to be used in RWT certification. **Success Rate:**

- creating and take action to send SOC: 1/1 = 100%
- viewing a received SOC: Criterion Removed

Risk: A customer may request defect corrections when the software is deployed but the risk is minimal with the successful demonstration of receiving and viewing a SOC document using the test tool.

Limitation: Conducting real world testing on production servers with certified software that is not deployed in production is challenging. One component of this measure could not be testing without having the certified software on a production server.

Care Coordinator – Clinical Info Rec & Incorp: §170.315 (b)(2)

Test Method: For ten test patients: Viewing the reconciled list (1 allergy, 1 medication, 1 problem) and incorporating CDA data.

Modified Test Plan: User story for one patient, rather than ten, to demonstrate user can view a reconciled list of allergies, medications, and problems. Testing the criteria of incorporating CDA removed.

Rationale: There is no value added to duplicate user stories for the same measure. One User Story sufficiently demonstrates compliance. Incorporating CCD into clinical reconciliation was demonstrated successfully using the test tool but is not feasible using customer data until the software is deployed at a customer site.

Expected Outcomes: CliniComp|EHR allows users to incorporate CDA and reconcile clinical information.

Results Demonstrating RW Interoperability: User can view pre-post reconciliation of meds, allergies, and problems.

Success Rate:

- viewing a reconciled list of meds, allergies, & problems: 1/1 = 100%
- incorporating CDA data: Criterion Removed

Risk: None

Limitation: Conducting real world testing on production servers with certified software that is not yet deployed in production is challenging. One component of this measure could not be testing without having the certified software on a production server.

Care Coordinator – Data Export: §170.315 (b)(6) & Security Tags: §170.315 (b)(7)

Test Method: Creating an export summary for ten patients, tagged as private, in real-time.

Modified Test Plan: User Story to create an export summary for one private patient.

Rationale: Duplicating user stories for the same measure would be redundant. One User Story sufficiently demonstrates compliance.

Expected Outcomes: CliniComp|EHR allowed user to create an SOC file for the selected patient.

Results Demonstrating RW Interoperability: Export summary successfully created.

Success Rate: Export Summary: 1/1 = 100%

Risk: Receiver of exported summary may not be able to read the summary. The risk is low since we successfully demonstrated the summary was readable by the receiver when we validated the test using the test tool.

Limitation: Conducting real world testing on production servers with certified software that is not deployed in production is challenging.

Care Coordinator – Security Tags – SOC – Receive: §170.315 (b)(8)

Test Method: Viewing a received SOC document, tagged as secure.

Modified Test Plan: Testing the criteria was removed from the test plan due to a

lack of technical feasibility

Rationale: The test plan was successfully demonstrated in 2020 using the ONC test data and testing tools. However, the software is not deployed in production and therefore this test can only be done using the testing tools.

Expected Outcomes: User can receive and view a SOC

Results Demonstrating RW Interoperability: none

Success Rate: Criterion Removed

Risk: When a customer uses this certified software, there might be some minor defect corrections requested. The risk is low with the successful demonstration of viewing a received SOC document using the ONC test data and testing tools.

Limitation: Conducting real world testing on production servers with certified software that is not deployed in production is challenging. This measure cannot be replicated without having the certified software on a production server.

Care Coordinator – Care Plan: §170.315 (b)(9)

Test Method: User documents success rate of accomplishing Care Plan activities (accessed & created, recorded, changed, and received) for ten patients.

Modified Test Plan: User Story to demonstrate accessing, creating, recording, and changing care plans for 1 patient. Testing the receipt of a care plan was removed from the test plan due to a lack of technical feasibility.

Rationale: One User Story sufficiently demonstrates compliance. Duplicating user stories will have the same result. Receiving a care plan was successfully demonstrated in 2020 using the testing tools. Since the software is not deployed in production, it is not feasible to demonstrate receipt of a care plan without using the tools.

Expected Outcomes: User demonstrates, via CliniComp|EHR, interoperability and EHI received and used in deployed certified software.

Results Demonstrating RW Interoperability: Creation and manipulation of Care Plans was demonstrated. Receiving a care plan is not a technically feasible without using testing tools since there is not a production server with the certified software.

Success Rate:

- Compliant with criterion to create and manipulate Care Plan: 1/1 = 100%
- Interoperability – receiving EHI: Criterion Removed

Risks: Receiving Care Plan documents may not be able ingestible by CliniComp. The risk is low since we demonstrated successfully received and viewed a care plan document using the ONC data and testing tools.

Limitation: Conducting real world testing on production servers with certified software that is not yet deployed in production is challenging. Many of the measures can only be partially replicated without having the certified software on a production server.

Care Coordinator – Transmission to Immunization Registries: §170.315 (f)(1)

Test Method: For ten test patients, user documents success rate of creating and submitting an immunization record to a registry; requesting and viewing imported immunization history and forecast from a registry.

Modified Test Plan: Testing the criteria was removed from the test plan due to a lack of technical feasibility.

Rationale: The test plan was successfully demonstrated in 2020 using the ONC test data and testing tools.

The steps for transmitting, importing, and viewing an immunization record to/from a registry are not actionable until the software is deployed or using the ONC test data and test tools.

Expected Outcomes:

Results Demonstrating RW Interoperability: none

Success Rate: Criterion Removed

Risk: When a customer uses this certified software, there might be some minor defect corrections requested. The risk is low since the test was successfully performed in 2020 using ONC test data and testing tools.

Limitation: Conducting real world testing on production servers with certified software that is not yet deployed in production is challenging. This measure cannot be replicated without having the certified software on a production server.

Care Coordinator – Transmission to Public Health Agencies: §170.315 (f)(2)

Test Method: User documents success rate of creating a syndromic-based public health surveillance document for transmittal to a public health agency for ten patients.

Modified Test Plan: Testing the criteria was removed from the test plan due to a lack of technical feasibility.

Rationale: The test plan was successfully demonstrated in 2020 using the ONC test data and testing tools. Performing this test requires deployed software or utilizing ONC test data and testing tools.

Expected Outcomes: CliniComp|EHR accommodates creating and sending syndromic surveillance data to the appropriate registry.

Results Demonstrating RW Interoperability: none

Success Rate: Criterion Removed

Risk: When a customer uses this certified software, there might be some minor defect corrections requested.

Limitation: Conducting real world testing on production servers with certified software that is not yet deployed in production is challenging. This measure cannot be replicated without having the certified software on a production server.

Care Coordinator – Direct Project: §170.315 (h)(1)

Test Method: For ten patients, user documents success rate of sending patient's health information to a recipient via direct address.

Relied Upon Software: EMR Direct Data Exchange Protocol API (Version 1.3.2)

Modified Test Plan: Testing the criteria was removed from the test plan due to a lack of technical feasibility.

Rationale: The test plan was successfully demonstrated in 2020 using the ONC test data and testing tools. The software is not deployed production and the technical requirements are not eligible for testing without a production server.

Expected Outcomes: Ability to electronically send and receive EHI to a third party.

Results Demonstrating RW Interoperability: none

Success Rate: Criterion Removed

Risk: When a customer uses this certified software, there might be some minor defect corrections requested.

Limitation: Conducting real world testing on production servers with certified software that is not deployed in production is challenging. This measure cannot be replicated without having the certified software on a production server.

Patient – View, download & Transmit (VDT): §170.315 (e)(1)

Test Plan: User enacts the patient role, for ten patients, from the appropriate testing pool of patients and documents success rate of viewing and sending the downloaded inpatient summary via the Patient Portal to a third party.

Modified Test Plan: User story – view and email SOC from patient portal.

Reason: Duplicating user stories for the same measure would be redundant. One User Story sufficiently demonstrates compliance.

Expected Outcomes: User can perform VDT without assistance from the patient portal.

Results Demonstrating RW Interoperability: SOC sent successfully.

Success Rate: SOC VDT: 1/1 = 100%

Risk: none

Limitation: Conducting real world testing on production servers with certified software that is not yet deployed in production is challenging.

API – Application Access: Patient Selection & Data Request: §170.315 (g)(7)(9)

Test Plan: User selects 10 patients from the appropriate testing pool and documents success rate of using a third-party application to access specific patient data for the desired patient for a given time frame.

Modified Test Plan: Testing the criteria was removed from the test plan due to a lack of technical feasibility.

Reason: The test plan was successfully demonstrated in 2020 using the ONC test data and testing tools. The software is not deployed and therefore this test can only be done using the testing tools. The technical requirements are not feasible without a production server.

Expected Outcomes: An API is used to access patient data.

Results Demonstrating RW Interoperability: none

Success Rate: Criterion Removed

Risk: When a customer uses this certified software, there might be some minor defect corrections requested.

Limitation: Conducting real world testing on production servers with certified software that is not yet deployed in production is challenging. This measure cannot be replicated without having the certified software on a production server.

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Standards Updates

☐	Yes, I have products certified with voluntary SVAP or USCDI standards.
☒	No, none of my products include these voluntary standards.

Care Setting

- **Inpatient Acute*:*** CliniComp is proactively promoting its inpatient EMR solutions. The acute inpatient setting is the appropriate setting for demonstrating compliance and adherence to the Real-World Testing criteria.

Key Milestones

Key Milestone	Care Setting	Date/Timeframe
Revised Test Plan	Inpatient Acute	Q1, 2023
Gathered Data	Inpatient Acute	Q2-4, 2023
Analyze Data	Inpatient Acute	Q4 2023
Create Report	Inpatient Acute	Q1 2024