

REAL WORLD TESTING PLAN 2025

GENERAL INFORMATION

Plan Report ID Number: [For ONC-Authorized Certification Body use only]

Developer Name: Clinigence Health

Product Name(s): Clinigence Value Improvement Platform (VIP)

Version Number(s): 4.5

Certified Health IT

Product List (CHPL) ID(s): 15.04.04.2696.Clin.05.00.0.181231

Developer Real World Testing Page URL: <https://clinigencehealth.com/cures-act-real-world-testing/>

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

We have written three measures which we believe will thoroughly test our capabilities to perform the Quality reporting functions we have certified. The testing will collect data from our actual MIPS reporting cycle using client data, calculate measure scores, and submit the report files to CMS.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS-SVAP AND USCDI)

Standard (and version)	§170.315(c)(3) Clinical Quality Measures (CQMs) – Report (Cures)
Updated certification criteria and associated product	Not Applicable
Health IT Module CHPL ID	15.04.04.2696.Clin.05.00.0.181231
Date of ONC ACB notification	Not Applicable
Date of customer notification	Not Applicable
Conformance method and measurement/metric(s)	

MEASURES USED IN OVERALL APPROACH

DESCRIPTION OF MEASUREMENT/METRIC

The following outlines the three measures that have been identified to best demonstrate conformance to multiple certification criteria concerning Clinical Quality Measures (170.315 (c)(1): Record and Export, 170.315 (c)(2): Import and Calculate, 170.315 (c)(3): Report across the use cases demonstrated and § 170.315(b)(10)) across the two use cases demonstrated (single patient and population services).

Measurement/Metric	Description
Measure 1: Data Extraction and Import.	This measure will demonstrate the ability to use our proprietary data extraction tools to consume data from various sources and formats and import that data into our database.
Measure 2: Calculate and Validate.	This measure will demonstrate the ability to use the imported PHI to calculate specific MIPS eCQM and CQM measures for the PY 2024 according to that year's measure specifications. An audit process will be completed to validate the scores prior to submission to CMS. Clinigence will use the following audit Processes for the Quality data submission: <ul style="list-style-type: none"> • Initial Implementation – accuracy of numerator, denominator and exclusion criteria results are verified after an EP's data is initially loaded, mapped and calculated, working with the practice. • Variance Checks – Periodic manual checking for unusual variances in report results and, if found, notify Clinigence support and development teams. • Quality Data Validation Audit Prior to Submission – At least 3% of the TIN/NPIs submitted to CMS (with a minimum of 10 or maximum of 50 TIN/NPIs), with at least 25% of the TIN/NPI's patients (with a minimum 5 patients or maximum sample of 50 patients) for a specific quality measure implemented for 2024. The audit will be performed as soon as all data has been loaded and processed for all 2024 quality measures for each TIN/NPI implemented for 2024 submission. (i.e., Results of the data validation/targeted audits, identifying calculation issues, why they occurred and what was done to remediate.)
Measure 3: Submitting Reports to CMS.	This measure will demonstrate the ability to submit MIPS scores to CMS. We will generate the required QRDA CAT III or JSON files, upload to CMS via the QPP portal, and download the scores and submission ID.
Measure 4: Single Patient Export	This measure will assess functionality used to export EHI for a single patient. The authorized user will be able to create an export file of a single patient's EHI on demand.

Measurement/Metric	Description
Measure 5: Patient Population Export	This measure will assess the functionality used to export EHI for a patient population. Clinigence users will generate an export file that contains all the EHI as defined in § 171.102 in an electronic and computable format.

ASSOCIATED CERTIFICATION CRITERIA

Certification criteria associated with the measures and if updated to 2015 Edition Cures Update criteria.

Certification Criteria	Requirement	Relied Upon Software
§170.315(c)(3) Clinical Quality Measures (CQMs) – Report (Cures)	<p>(c)(3)Generate an aggregate report with calculated summary data for the patient population of the clinical quality measures calculated in the Execute test (§ 170.315(c)(2)), which at a minimum is in accordance with the standard specified in § 170.205(k)(3). CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2020</p> <p>Generate a de-duplicated archive of patient documents in the CMS QRDA Category I IG format of the clinical quality measures calculated in the Execute test (§ 170.315(c)(2)), which at a minimum is in accordance with the standard specified in § 170.205(h)(3). CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2020</p> <p>Submit the quality measurement data file consisting of the data created by the generation of the CMS QRDA Category III IG aggregate report(s) and the de-duplicated CMS QRDA Category I IG report(s) for verification.</p>	None

Certification Criteria	Requirement	Relied Upon Software
§ 170.315(b)(10) EHI export – Patient population EHI export	Single patient EHI export: (i)(A) Create an export file (i)(B) Execute at any time (i)(C) Limit ability of users who can create export (i)(D) Electronic and computable format Patient population EHI export: (ii)(A) Create an export file	None

JUSTIFICATION FOR SELECTED MEASUREMENT/METRIC

Measurement/Metric	Justification
Measure 1	Health IT needs to be able to record all data necessary to successfully calculate selected clinical quality measures (CQMs). Clinigence’s proprietary methodology allows us to extract and/or import data from many different EMRs and import several different file formats, including CCDs, and QRDA CAT I.
Measure 2	Certain CMS programs require or provide the option for electronic Clinical Quality Measures (eCQM/CQM) reporting. Each year, CMS issues annual updates to eCQMs and CQMs (herein referred to as the “CMS annual measure update(s)”) which are published on the Electronic Clinical Quality Improvement (eCQI) Resource Center. The audit process described ensures that Clinigence is meeting the measure specifications and has validated the scores prior to submission to CMS.
Measure 3	A user can export a data file formatted in accordance with HL7 QRDA Category I Release 3 or the corresponding version of the QRDA standard for the CMS annual measure update being certified for one or multiple patients that includes all the data captured in (c)(1)(i) of this criterion.
Measure 4	The export of EHI associated with a patient is another way to share information with an external organization. Export is typically used when there is a need for a full patient record. This metric will provide information on the type of data exported for a single patient.
Measure 5	The export of the health information associated with a patient population is another way to share health information with an external organization. Export of a patient population is an administrative function only available to credentialed users. This export will be run as one of the audit functions of MIPS reporting.

CARE SETTING(S)

Care Setting	Justification
Group	Clinigence generates and submits one file for all NPIs in The TIN (group). Scores are aggregated in the CAT III or JSON file for the entire group.
Individual	Clinigence generates and submits one file for each provider. This can be for a single provider practice or multiple providers under the same TIN. One CAT III or JSON file is generated per NPI.

EXPECTED OUTCOMES

Measurement/Metric	Expected Outcomes
Measure 1	Real World Testing will show that Health IT will be able to record all data necessary to successfully calculate selected clinical quality measures (CQMs). Clinigence’s proprietary methodology will allow us to extract and/or import data from many different EMRs and import several different file formats, including CCDs, and QRDA CAT I.
Measure 2	Real World Testing will show that the audit process ensures that Clinigence is meeting the PY2024 measure specifications and validated the scores prior to submission to CMS.
Measure 3	Real World Testing will demonstrate that an authorized user can export a data file formatted in accordance with HL7 QRDA Category I Release 3 or the corresponding version of the QRDA standard for the CMS annual measure update being certified for one or multiple patients that includes all the data captured in (c)(1)(i) of this criterion. We will generate the required QRDA Cat III files, successfully upload them to CMS via the QPP portal, and download the scores and submission ID. Any errors will be tracked, analyzed, and corrected, so that 100% of the MIPS submissions will be accepted by CMS.
Measure 4	It is expected that authorized users will be able to share EHI using the export function. Error rates will be tracked and trended over time.
Measure 5	It is expected that authorized users will be able to share EHI for a patient population using the export function. The export produces a file for each patient in the IPP for each measure selected for the practice. That file has the evidence (the clinical data) for each measure that the patient qualifies for. Errors in transmission will be tracked and analyzed.

SCHEDULE OF KEY MILESTONES

Key Milestone	Care Setting	Date/Timeframe
Confirm data extraction and import for all EPs who have purchased the MIPS reporting service	All	Jan. 1, 2025 – Mar. 31, 2025
Calculate measure scores for Groups and EPs selected to participate in the RWT	All	Jan. 1, 2025 – Mar. 31, 2025
Validate the measure scores	All	Jan. 1, 2025 – Mar. 31, 2025
Generate the QRDA CAT III or JSON files	All	Jan. 1, 2025 – Mar. 31, 2025
Upload QDRA CAT III files to QPP portal (eCQMs) and download submission reports	All	Jan. 1, 2025 – Mar. 31, 2025
Upload QDRA JSON files via QPP portal (CQMs) and download submission reports	All	Jan. 1, 2025 – Mar. 31, 2025
Generate the V5 Export of the Entire Patient Population	All	Jan. 1, 2025 – Mar. 31, 2025
Generate the Export of the Single Patient	All	Jan. 1, 2025 – Mar. 31, 2025
Create RWT results report	All	July 31, 2025
Submit RWT results report	All	October 15, 2025

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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Date: Dec. 2, 2024