80 Pine Street, 21st Floor New York, NY 10005, USA
https://www.curemd.com
support@curemd.com
Phone: (212) 509-6200

Real World Testing Plan – 2025

Condition and Maintenance of Certification

Prepared By: CureMD

Contents

1. Executive Summary

In accordance with the requirements outlined in the 21st Century Cures Act Final Rule and in particular, the ONC's Condition and Maintenance of Certification requirements, CureMD has prepared a comprehensive Real World Testing Plan to test its certified Health IT, CureMD SMART Cloud - Version 10g, in the production environment.

The methodology of the plan is based on Unmoderated Remote Testing, a highly scalable technique where users test real world use cases in their natural environment unaffected by biases caused by moderation. Listed use cases will either test the requirements of a single certification criterion or multiple criteria via measures that will demonstrate ongoing functionality and interoperability. As per ONC's requirements, every use case includes the required elements while details about standards update and the schedule of key milestones is aggregated for the entire plan.

Real World Testing will be conducted throughout the 2025 calendar year for all applicable criteria to collect and report results derived directly from real-world use cases.

2. General Information

Developer Name:	**CureMD.com Inc.**
Product Name(s):	**CureMD SMART Cloud**
Version Number(s):	**10g**
Product List (CHPL) ID(s):	**15.07.04.2706.CURE.10.01.1.230302**
Developer Real World Testing Page URL:	https://www.curemd.com/rwt.asp

3. Justification for Real World Testing Approach

3.1. Employed Methodology – Unmoderated Usability Testing

Unmoderated Remote Testing is used for testing products in their natural environment to verify and evaluate factors such as functionality, usability, reliability, and utilization rates. During its course, users engage with the product without any moderation. At the end of the testing cycle, data collected from user activity is processed to analyze the aforementioned factors; this is accomplished by maintaining logs, which track user actions and corresponding system responses.

In addition to unmoderated remote testing in our production environment, we may at times use synthetic patient data in a simulated environment that mirrors the production environment. This is in accordance with the flexibility provided by ONC and will be only used in special circumstances where low adoption of certified capabilities is observed.

3.2. Justification for Methodology

Unmoderated Remote Testing has the unique advantage of being compatible with Real World Testing due to the absence of external influences that can create bias in collected data, as it will allow users to interact as naturally as possible with the product. For instance, users will perform actions based on their schedules, directly implying a pace, concentration level, and overall workflow in line with real-time usage, as opposed to moderated task-based sessions in which these factors become controlled and unnatural.

Since the data sample size is often a key indicator of its quality, a technique that allows for maximum number of observations within a given timeline was preferred. Unmoderated Remote Testing enables this because it does not rely on resources commonly associated with moderated testing which limit the ability to reach a larger pool of testers.

This methodology is highly scalable as it is independent of factors including size of the organization that production systems support, type of organization and care settings, number of patient records and users, system components and integrations, and volume and types of data exchange in planning for Real World Testing.

3.3. Justification for Care Settings

Testing will be done in five care settings, namely Physician's Office, Urgent Care, House Calls, Public Health and Oncology, as these are the key settings CureMD is marketed in. Since CureMD does not cater to Inpatient settings, all of the tested care settings are Ambulatory.

4. Measures

Measure	**Description**	**Certification Criteria**	**Justification**
Access	Ability of system to successfully process and make required information accessible to the users.	§ 170.315(e)(1) § 170.315(f)(1) § 170.315(f)(5) § 170.315(g)(7) § 170.315(g)(9) § 170.315(g)(10)	Gauges the user's ability to retrieve patients' electronic health information on demand

Compliance with Required Standard	Conformance of certified Health IT to the relevant standard detailed in the Certification Companion Guides (CCG).	§ 170.315(b)(3) § 170.315(h)(1)	Verifies a system's implementation against specifications established in the required standards.
Configurability	Availability of required settings, configurations and customization options for users.	§ 170.315(b)(1) § 170.315(b)(10)	Indicates the user's ability to successfully configure application to customize workflows as per their preference.
Incorporation	Ability of system to successfully incorporate external data into the relevant Health IT module.	§ 170.315(b)(2) § 170.315(c)(2)	Indicates the user's success rate with respect to not just receiving external data, but also its utilization in the system.
Sharing	Ability of system to successfully send and receive patient health information, as per requirements.	§ 170.315(b)(1) § 170.315(b)(3) § 170.315(b)(10) § 170.315(c)(1) § 170.315(c)(3) § 170.315(e)(1) § 170.315(f)(1) § 170.315(f)(2) § 170.315(f)(4) § 170.315(f)(5) § 170.315(f)(7)	Evaluates system's ability to perform required data exchange with external and internal parties.

5. Standards Updates

Standard (and version)	Not Applicable
Certification criteria in which product has been updated	Not Applicable
Health IT Module CHPL ID	Not Applicable
Date notification sent to ONC-ACB	Not Applicable
Measure used to demonstrate conformance with updated standard(s)	Not Applicable
Which certification criteria were updated to USCDI and/or to which version of USCDI was the certification criteria updated	Not Applicable

6. Real World Testing Scenarios

The following section details real world use cases for applicable certification criteria and their corresponding elements, namely, associated measures, care settings, justification of choice, test methodology and expected outcomes. Testing of these use cases shall demonstrate interoperability and conformance with criteria under CureMD SMART Cloud's certification scope.

6.1. Use Case 1

Transition of care (TOC) summaries and referral notes contain key clinical information which helps in coordination and continuity of care as patients transfer between different clinicians. CureMD SMART Cloud - Version 10g, therefore, contains provision for securely sending and receiving TOC documents using Direct Edge Protocol. On receipt of TOC and referral summaries, providers can utilize valid ones for assessment of patient's health conditions, and plan their treatment in light of available data. In order to increase their productivity while reviewing these documents, clinicians can configure the initial number of C-CDA sections to be displayed, along with their order, in accordance with their preferences.

- **Certification Criteria:** § 170.315(b)(1) Transitions of care
- **Care Settings:** Physician's Office, Urgent Care, House Calls, Public Health and Oncology
- **Measures:**

  I. Sharing
  II. Configurability

- **Justification:** The measure of Sharing will provide validation for system's ability to support continuity of care by tracking transmission success rates for both, inbound and outbound transition of care documents via Direct Edge protocol. While systems ability to allow customizations according to providers needs when viewing transition of care documents will be evaluated via the Configurability metric.

- **Test Methodology:** System logs will be recorded, de-identified and fed into the above-mentioned measures. Logs for both these measures will be constructed around users' actions that trigger communication with external systems while exchanging transition of care documents, and during their review.
- **Relied upon Software:** CureMD has integrated with Surescripts Clinical Interoperability (Version Net2Net REST 10.4) for its implementation of direct messaging. CureMD Smart Cloud logs all the acknowledgements and delivery receipts from this external software within its database and these database logs are then utilized for evaluating the defined metrics.
- **Expected Outcomes:** It is expected that the functionalities identified above shall perform as per requirements to demonstrate conformance to § 170.315(b)(1) via Direct Edge Protocol.

6.2. Use Case 2

Providers using CureMD SMART Cloud can electronically receive patient's health information in the form of Consolidated Clinical Document Architecture (C-CDA) documents from external sources, and use it to maintain a more accurate and up-to-date patient record. Upon the receipt of these documents, system automatically searches for a match in the available patient profiles which enables providers to reconcile and incorporate data available in the C-CDA files with the data present in the matching patient chart. Once incorporated, system includes the reconciled data in patient's clinical summary every time it is generated for continuity of care.

- **Certification Criteria:** § 170.315(b)(2) Clinical information reconciliation and incorporation
- **Care Settings:** Physician's Office, Urgent Care, Public Health and Oncology
- **Measure:** Incorporation
- **Justification:** The measure of Incorporation will track the providers' ability to successfully update patient's clinical data available in the system with the data coming in from external sources on an ongoing basis.
- **Test Methodology:** System logs will be built by tracking user intent to merge patient data from multiple sources (C-CDA Document and Patient Chart) and comparing it with the instances where they were successful in doing so. These logs will be de-identified and then analyzed to evaluate system's success ratio for the mentioned task.
- **Expected Outcomes:** It is expected that the functionalities identified above shall perform as per requirements to demonstrate conformance to § 170.315(b)(2), with users being able to successfully reconcile and incorporate patient data without errors.

6.3. Use Case 3

CureMD SMART Cloud offers a prescription module which enables its users to electronically communicate with pharmacies to efficiently manage their patients' medication needs. This certified Health IT module allows providers to request and review medication history for their patients, create new prescriptions and receive fill status notifications against them. Providers can also respond to change and renewal requests from the pharmacies, and request prescription cancellations when needed.

- **Certification Criteria:** § 170.315(b)(3) Electronic prescribing
- **Care Settings:** Physician's Office, Urgent Care, House Calls, Public Health and Oncology
- **Measures:**

  I. Compliance with Required Standard *(NCPDP SCRIPT 2017071)*
  II. Sharing

- **Justification:** Compliance measure will provide insights on the system's ability to successfully generate and process prescription messages that are in conformance to the NCPDP SCRIPT 2017071 standard. Whereas, the Sharing metric will evaluate robustness of the transmission mechanism deployed to electronically send and receive prescription messages, along with tracking their frequencies.

- **Test Methodology:** Logs generated by clinicians' prescription activities during the real world testing will be used to analyze, the structural validity of the messages created for interoperability between CureMD SMART Cloud and the pharmacies, the reliability of established transportation mechanisms, and utilization rates of implemented transaction types.

- **Relied upon Software:** CureMD relies upon Medi-Span Drug Database (Version 5) for up to date drug details. NDC codes populated in the messages formatted according to NCPDP Script Standard are pulled from Medi-Span Drug Database. Hence, the outcome of metric ***Compliance with Required Standard*** is impacted by this relied upon software.

- **Expected Outcomes:** It is expected that providers will be able to successfully communicate with the pharmacies using prescription-related electronic transactions which are in conformance to the standard referred in §170.315(b)(3).

6.4. Use Case 4

To facilitate accessibility and exchange of clinical data with other Health IT systems, CureMD SMART Cloud supports export of patient data as a system administrative function. Depending on the context of exchange, these users can export data for a single patient or an entire population.

- **Certification Criteria:** § 170.315(b)(10) Electronic Health Information export
- **Care Settings:** Physician's Office, Urgent Care, House Calls, Public Health and Oncology
- **Measures:**

  I. Configurability
  II. Sharing

- **Justification:** The Sharing measure will track users' ability to export clinical data files by monitoring success and error rates in relation to export attempts. Similarly, the Configurability metric will evaluate users' ability to choose the data elements to be included in the export while generating these files.
- **Test Methodology:** Data obtained from system logs will be used for analysis and as an input for the calculation of metric on specific types of configurations used while generating and exchanging patients' clinical data.
- **Expected Outcomes:** It is expected that the functionalities identified above shall perform as per requirements to demonstrate conformance to § 170.315(b)(10), with users being able to successfully exchange EHI without errors.

6.5. Use Case 5

CureMD SMART Cloud enables its users to electronically record all required data to accurately calculate Clinical Quality Measure (CQM) performance reports, and export all data to relevant organizations and programs in a standardized format e.g. QRDA I and III. Moreover, by leveraging this Certified Health IT module, clinicians can electronically import CQM data for either a patient or a set of patients, reducing the need for manual data entry while calculating and aggregating eCQM results for evaluation and reporting.

- **Certification Criteria:**

  I. § 170.315(c)(1) CQMs - Record and export,
  II. § 170.315(c)(2) CQMs - Import and calculate
  III. § 170.315(c)(3) CQMs - Report.

- **Care Settings:** Physician's Office, Urgent Care, House Calls, Public Health and Oncology
- **Measures:**

  I. Incorporation
  II. Sharing

- **Justification:** The measure of Sharing will track clinicians' ability to successfully export CQM data which they have recorded in CureMD SMART Cloud, while Incorporation metric will assess system's capability to successfully incorporate CQM data imported from external sources, and run calculations on it for supported CQMs.

- **Test Methodology:** Logs generated during the real world testing will be fed into the abovementioned measures for determining the conformance of the implementation. These measures will be constructed around front and backend triggers to track both, clinicians' click actions and system's responses when recording, importing, calculating and exporting CQM data.

- **Expected Outcomes:** It is expected that the functionalities identified above shall perform as per requirements to demonstrate conformance to §170.315(c)(1) Clinical quality measures—record and export, §170.315 (c)(2) Clinical quality measures—import and calculate, and §170.315(c)(3) Clinical quality measures—report, with a significant percentage of clinicians able to successfully exchange CQM data in a standardized format.

6.6. Use Case 6

To facilitate care coordination and engagement, patients registered on CureMD SMART Cloud are provided with access to a patient portal. Using this portal, patients and their authorized representatives can view their electronic health information and share it with third parties of their choosing. This can be done by either downloading the EHI, or by transmitting it using encrypted (Direct) or unencrypted (email) methods available in the Certified Health IT module. The portal also enables its users to control the timeframe within which the clinical data can be filtered for viewing, downloading and transmission. Lastly, all of these activities are logged to track how the patient's health information is being utilized.

- **Certification Criteria:** § 170.315(e)(1) View, Download, and Transmit to 3rd party
- **Care Settings:** Physician's Office, Urgent Care, House Calls, Public Health and Oncology
- **Measures:**

  I. Access
  II. Sharing

- **Justification:** To gauge system's ability of successfully presenting patients' EHI for their choice of timeframe (e.g. a specific date, or a date range), we will rely on results of the Access metric. Whereas the measure of Sharing will provide information on the types of transmission methods deployed, along with their frequency of usage.

- **Test Methodology:** User actions performed towards viewing, downloading and transmitting EHI via the patient portal will be logged by the system; these logs will then be reviewed to determine the success rates of these actions. Moreover, these logs will also aid in highlighting the utilization rates of the different transmission mechanisms available at user's disposal, e.g. downloads and unencrypted vs. encrypted transmission.

- **Expected Outcomes:** It is expected that the functionalities identified above shall perform as per requirements to demonstrate conformance to § 170.315(e)(1), with a significant percentage of users being able to successfully view and transmit EHI in the form of CCD files without errors.

6.7. Use Case 7

In accordance with the care settings and state/jurisdictional requirements, CureMD SMART Cloud enables its users to actively engage with public health agencies (PHAs) e.g. public health departments and the Centers for Disease Control and Prevention (CDC). The Certified Health IT module enables this by transmitting health data to these PHAs in a standardized format. For instance, clinicians can leverage immunization registries managed by a state's public health department to access consolidated information about a patient's vaccinations via HL7 messages, which otherwise may not be available in the system. Moreover, by reporting data regarding administered and historical vaccines to an immunization registry, clinicians assist in the compilation of public health information on vaccine coverage in their communities. Similarly, providers operating in urgent care clinics can report data to their state's syndromic surveillance system, which can be leveraged for providing indicators on infectious diseases and tracking their progression in a population. Furthermore, clinicians associated with Oncology care setting can create cancer case information and report it to their state's cancer registry, which can be utilized for research and development of improved treatment plans. Lastly, CureMD SMART Cloud can also be used to create and transmit National Health Care Survey information as these surveys assists in answering key questions of interest to healthcare policymakers, public health professionals, and researchers.

- **Certification Criteria:**

  I. § 170.315(f)(1) Transmission to immunization registries
  II. § 170.315(f)(2) Transmission to public health agencies - syndromic surveillance
  III. § 170.315(f)(4) Transmission to cancer registries
  IV. § 170.315(f)(5) Transmission to public health agencies - electronic case reporting
  V. § 170.315(f)(7) Transmission to public health agencies - health care surveys

- **Care Settings:** Physician's Office, Urgent Care, House Calls, Public Health and Oncology.

- **Measures:**

  I. Access
  II. Sharing

- **Justification:** The measure of Sharing will track the system's ability to transmit the relevant health information to a public agency in required formats. Insights will be derived from both system and user analytics by evaluating success and error rates of the transmission attempts. Additionally, for the 170.315(f)(1) and § 170.315(f)(5) requirements of requesting and displaying Immunization history and forecast data, and Reportability Responses received from the registries, respectively, will be covered by the Access measure to determine intended usage.

- **Test Methodology:** CureMD SMART Cloud keeps track of all the outbound and inbound electronic transactions. These transactions are segmented based on their statuses, for example, whether

the EHI message was successfully generated and transmitted or not. Hence, both measures will be calculated by leveraging and processing these status logs.

In case of low utilization of any of the above-referenced certified criteria, our system's conformance will be verified using synthetic data and ONC-approved testing tools.

- **Relied upon Software:** CureMD relies upon eCR Now FHIR App (Version 3.1.4) for generating Electronic Initial Case Reports (eICRs) and receiving the corresponding Reportability Responses (RRs) from the AIMS platform. The eCR Now FHIR App formats the eICRs to meet the various reporting requirements of jurisdictional public health authorities (PHAs). Consequently, the performance and outcome of both the metrics are impacted by this relied upon software.

- **Expected Outcomes:** It is expected that the functionalities identified above shall perform as per requirements to demonstrate conformance to the tested criteria, with users being able to successfully exchange EHI formatted in accordance with the referenced HL7 standards for each criterion, without significant percentage of errors.

6.8. Use Case 8

Third-party developers can use CureMD SMART Cloud's certified API technology to provide patients access to their data in other applications or platforms. The goal of these APIs is to provide patients access to their clinical data for a time period of their choice.

- **Certification Criteria:**

  I. § 170.315(g)(7) Application access — patient selection
  II. § 170.315(g)(9) Application access — all data request
  III. § 170.315(g)(10) Standardized API for patient and population services

- **Care Settings:** Physician's Office, Urgent Care, House Calls, Public Health and Oncology

- **Measure**: Access

- **Justification:** Since third party developers will access EHI of individual patients through CureMD's API after acquiring their consent, Access measure will be used to track authorized use of these APIs for patient selection and their data access.

- **Test Methodology:** CureMD SMART Cloud will log all inbound API requests for patient data access and their corresponding responses. These logs will then be de-identified and used for analysis in several areas (i.e. authentication of requesters, utilization rates of available API endpoints and accuracy of their responses), to validate the proper operation of the APIs.

  If low adoption of any of the above-referenced certified criteria is observed, the system's conformance will be verified using synthetic data and ONC-approved testing tools in conjunction with the real world utilization logs.

- **Expected Outcomes:** It is expected that data access issues are rare and that the functionalities identified in the above criteria perform without errors.

6.9. Use Case 9

Direct Messaging serves as a secure mechanism for electronically exchanging health information instead of relying on slow, inconvenient, expensive methods of exchange such as paper and faxes. Therefore, CureMD SMART Cloud enables its users to securely share patient health information with other trusted providers or parties using Direct protocol.

- **Certification Criteria:** § 170.315(h)(1) Direct project
- **Care Settings:** Physician's Office, Urgent Care, House Calls, Public Health and Oncology
- **Measure:** Compliance with Required Standard
- **Justification:** This measure will test conformance of CureMD SMART Cloud's implementation of DIRECT Protocol with the *Applicability Statement for Secure Health Transport* standard.
- **Test Methodology:** System logs will be constructed to track validation and delivery statuses of both inbound and outbound Direct messages. These logs will then be reviewed to evaluate success rate of communication via Direct Protocol, and for instances where errors occurred due to non-conformity with the referenced standard, these logs will help us identify the specific reason.
- **Expected Outcomes:** It is expected that the functionalities identified above shall perform as per requirements to demonstrate conformance to § 170.315(h)(1), with users being able to securely exchange EHI with other trusted providers and parties.

7. Key Milestone

This Real World Testing Plan is structured in a way that key milestones are aggregated for all applicable certification criteria. In other words, prior to each of the following dates/timeframes, key milestone requirements will be met for all relevant criteria. This approach has been chosen for its efficiency, suitability and overall ease for tested users. For example, significant overlap is expected between chosen providers per criterion so releasing unified documentation on a distinct date will ensure a smoother testing cycle.

Key Milestones	**Date/Timeframe**
Initial development of the Real World Testing plan	October 1, 2024
Finalization of the Real World Testing plan, and submission to ONC-ACB	October 28, 2024
Begin collection of data as laid out by the plan.	January 1, 2025
Data collection and review.	Quarterly, 2025
End of Real World Testing period/final collection of all data for analysis.	December 31, 2025
Analysis and report creation	February, 2026
Submission of Real World Testing report to ACB, as per their instructions	February, 2026

8. 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: **Matt Anderson**

Authorized Representative Email: **matt.anderson@curemd.com**

Authorized Representative Phone: **(212) 852-0279 Ext. 320**

Authorized Representative Signature:

Date: 10/28/2024