

Real World Testing - Results Report 2024

Condition and Maintenance of Certification

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1. Executive Summary

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

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

Real World Testing was conducted for the entire calendar year of 2024 for all applicable criteria, with the objective of collecting and reporting results derived directly from the real world use cases and their corresponding measures.

2. General Information

Plan Report ID Number:	[For ONC-Authorized Certification Body use only]
Developer Name:	CureMD Inc.
Product Name(s):	CureMD SMART Cloud
Version Number(s):	10g
Certified Health IT Product List (CHPL) Product Number(s):	15.07.04.2706.CURE.10.01.1.230302
Developer Real World Testing Page URL:	https://www.curemd.com/rwt.asp
Developer Real World Testing Results Report Page URL [if different from above]:	Same as above

3. Summary of Testing Methods and Key Findings

Unmoderated Usability Testing method was used to test product in real world conditions and evaluate its functionality, usability, reliability, and utilization rates. The users interacted with the product without any moderation and the data collected was analyzed through logs that tracked their actions and system responses. This method was preferred due to its compatibility with real-world testing, allowing for a large sample size and scalability.



3.1. Associated Certification Criteria

Certification Criteria	Measure	Description	Justification
§170.315(e)(1) §170.315(f)(1) §170.315(g)(7) §170.315(g)(9)	Access	Ability of system to successfully process and make required information accessible to the users.	Gauges the user's ability to retrieve patients' electronic health information on demand
§170.315(b)(3) §170.315(h)(1)	Compliance with Required Standard	Conformance of certified Health IT to the relevant standard detailed in the Certification Companion Guides (CCG).	Verifies a system's implementation against specifications established in the required standards.
§170.315(b)(1)	Configurability	Availability of required settings, configurations and customization options for users.	Indicates the user's ability to successfully configure application to customize workflows as per their preference.
§170.315(b)(2) §170.315(c)(2)	Incorporation	Ability of system to successfully incorporate external data into the relevant Health IT module.	Indicates the user's success rate with respect to not just receiving external data, but also its utilization in the system.
§170.315(b)(1) §170.315(b)(3) §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)(7)	Sharing	Ability of system to successfully send and receive patient health information, as per requirements.	Evaluates system's ability to perform required data exchange with external and internal parties.



4. Standards Updates (Including Standards Version Advancement Process (SVAP) and United States Core Data for Interoperability (USCDI))

Indicate as to whether optional standards, via SVAP and/or USCDI, are leveraged as part of the certification of your health IT product(s).

☐ Yes, I have products certified with voluntary SVAP or USCDI standards.

☒ No, none of my products include these voluntary standards.

4.1. Care Setting(s)

Testing was carried out in five care settings, namely Physician's Office, Urgent Care, House Call, 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.

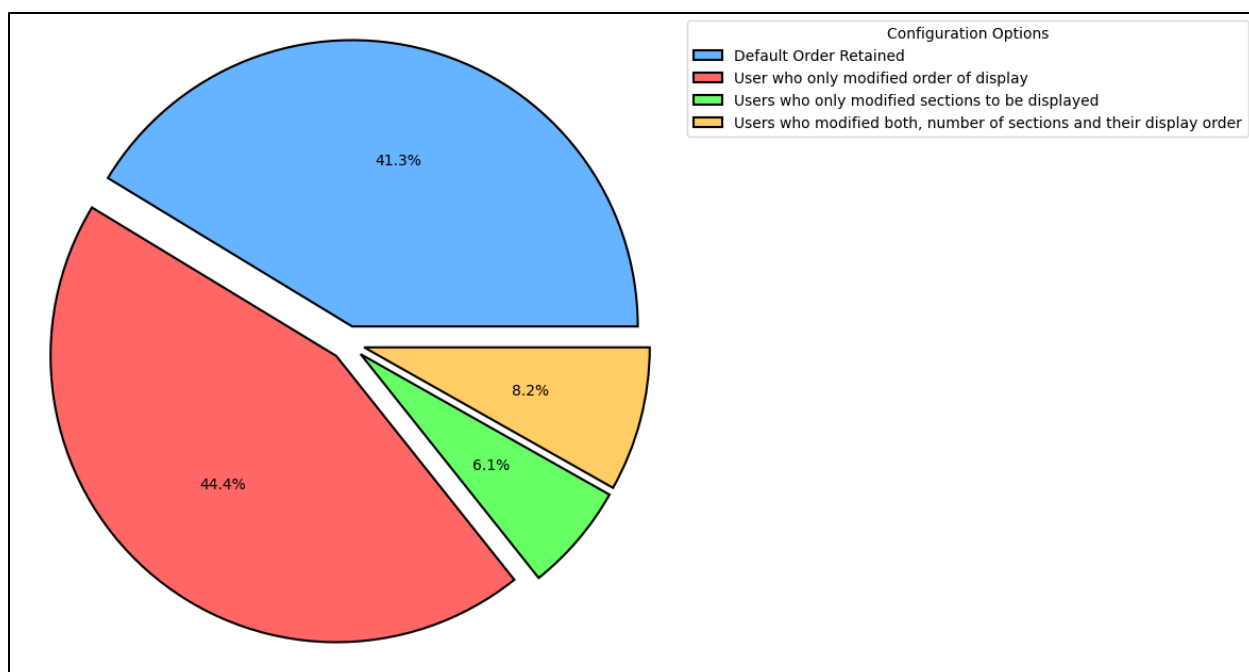
4.2. Metrics and Outcomes

The following section details real world use cases for applicable certification criteria and their corresponding elements. Testing of these use cases demonstrates interoperability and conformance with criteria under CureMD SMART Cloud's certification scope.

4.2.1. Use Case 1

As detailed in the Real World Test Plan, this use case tested the CureMD SMART Cloud – Version 10g’s ability to send and receive Transition of care (TOC) summaries and referral notes which contain key clinical information for continuity of care as patients transfer between different clinicians. Production environment logs of clinician activity were analyzed for all applicable care settings using the ‘Sharing’ measure to reveal ongoing EHI exchange as per requirements. Secondly, the ‘Configurability’ measure was used to demonstrate ongoing functionality of allowing physicians to configure the display of number and order of C-CDA sections.

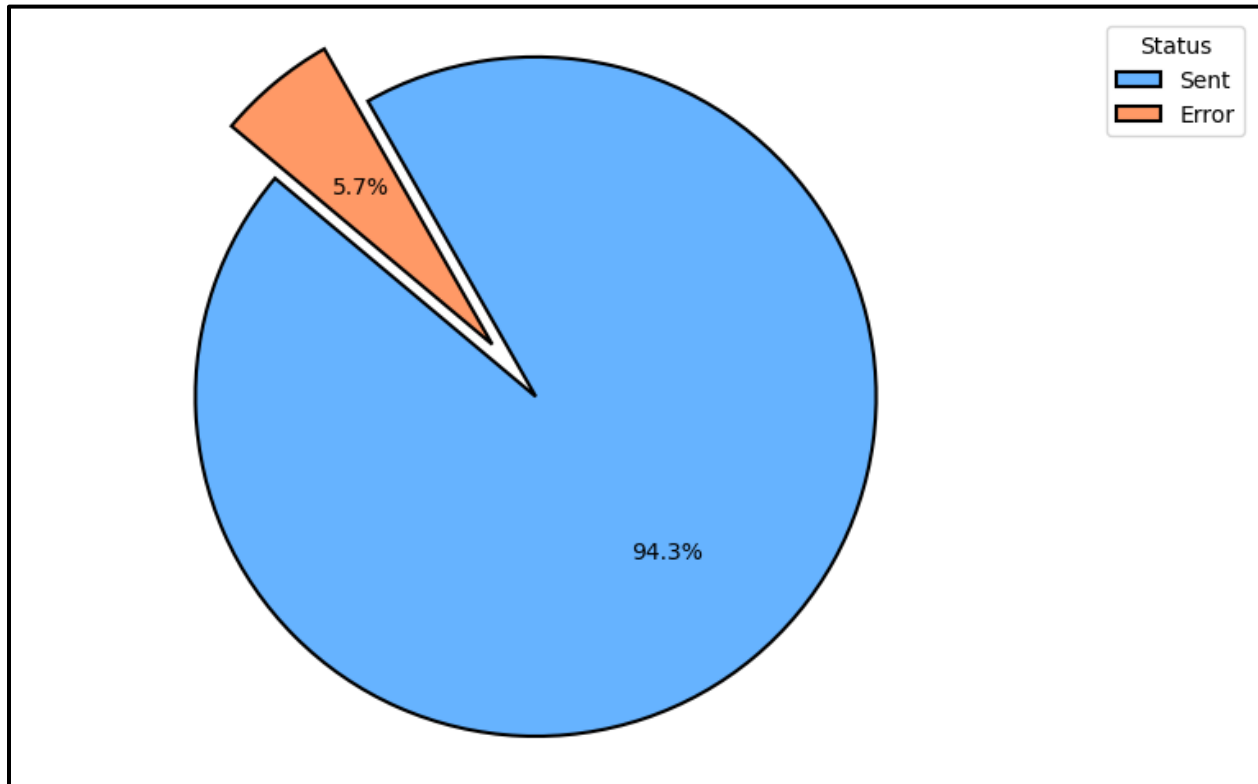
- **Certification Criteria:** § 170.315(b)(1) Transitions of care
- **Relied upon software:** Surescripts Clinical Interoperability (Version Net2Net REST 10.4)
- **Expected Outcomes:** It is expected that the functionalities identified above shall perform as per requirements to demonstrate conformance to 170.315(b)(1), with a significant percentage of users able to successfully exchange TOC documents via Direct Protocol without errors, along with being able to choose the sections and their display order when reviewing these documents.
- **Actual Outcomes:**
 - I. **Measure:** Configurability
 - **Metric:** Utilization Rate of CCD Display Configuration Options



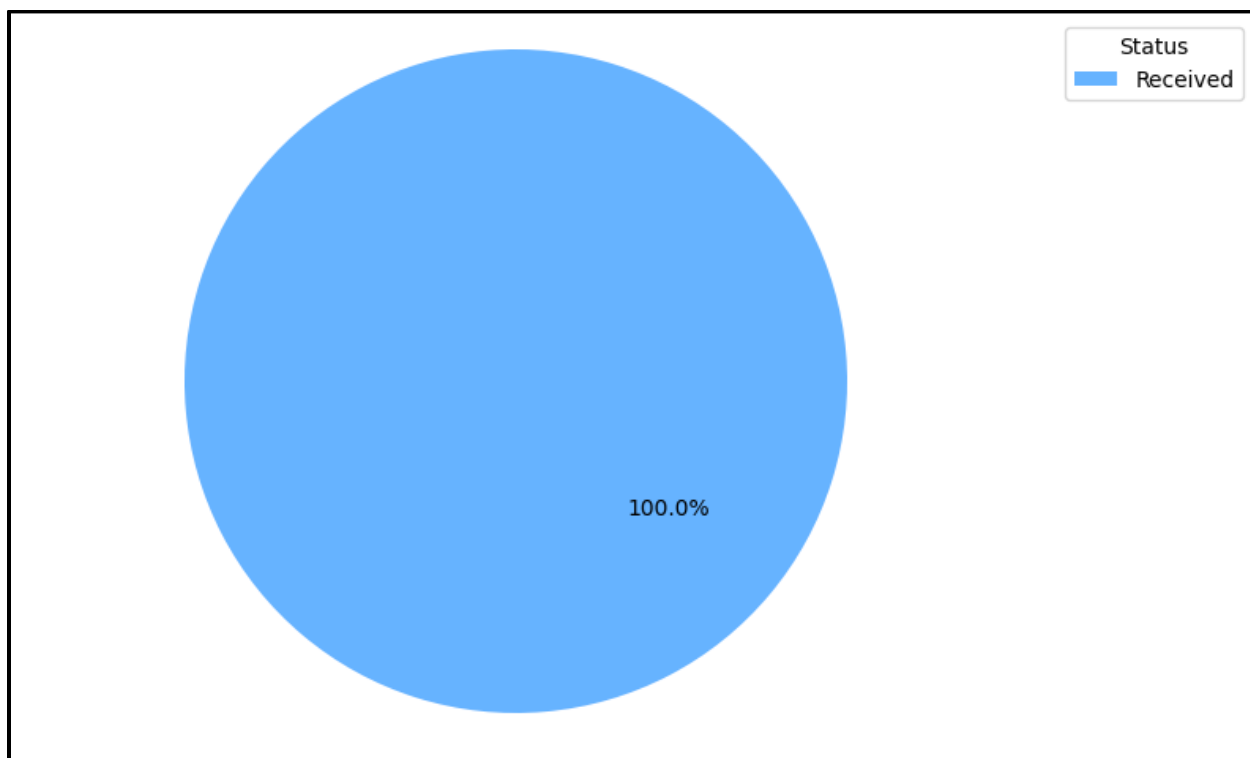
Count of customization i.e. Users who retained the default order, or users who modified count of sections to be displayed, or users who modified Order of display, or users who modified both, number of sections and their display order as percentage of the total number of system users.

II. Measure: Sharing

- **Metric:** Success Rate of Outbound TOC/Referral Summaries



- **Metric:** Success Rate of Inbound TOC/Referral Summaries



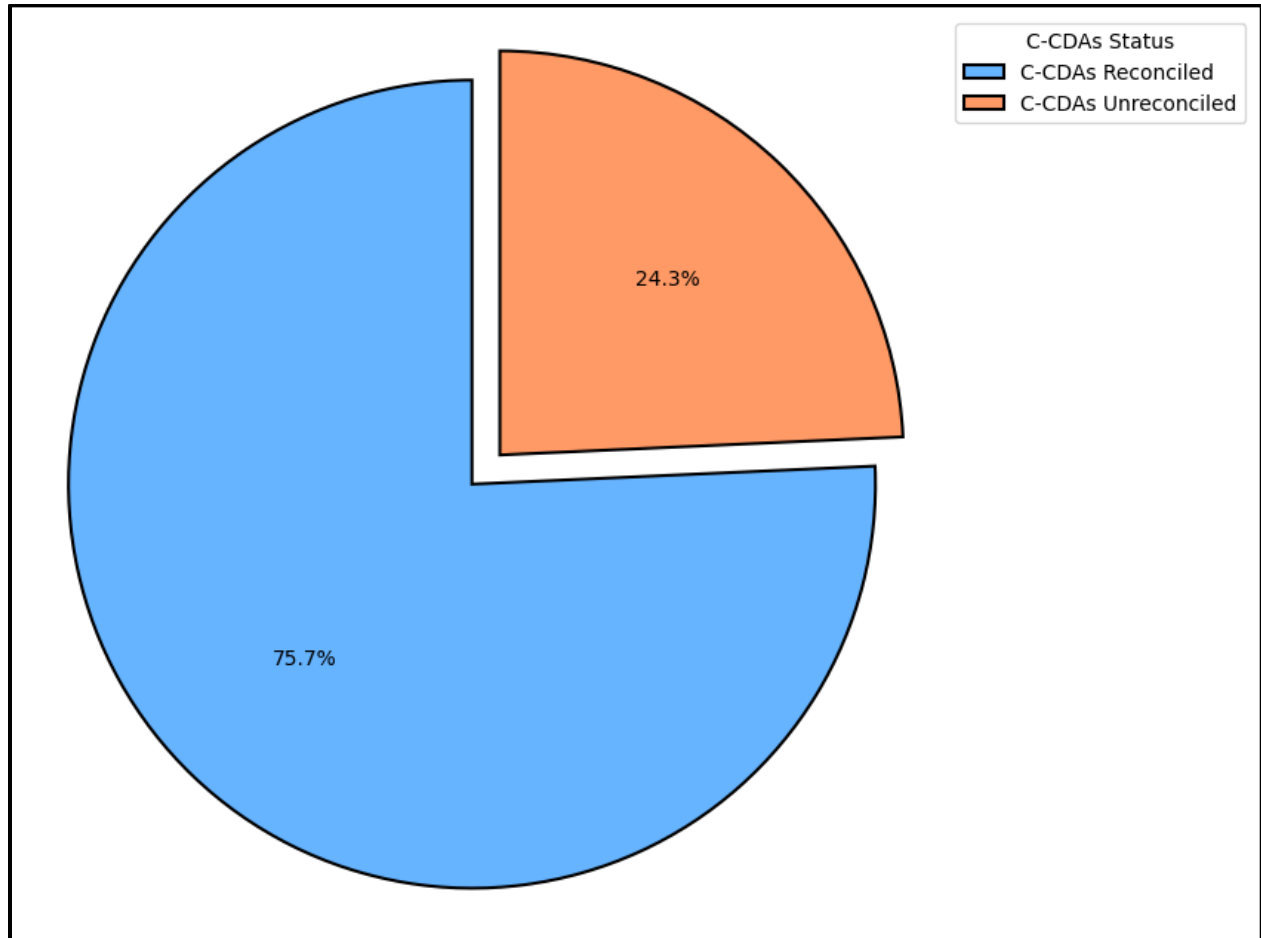
4.2.2. Use Case 2

This use case tested the CureMD SMART Cloud – Version 10g’s ability to electronically receive patient’s health information in the form of Consolidated Clinical Document Architecture (C-CDA) documents from external sources, and automatically search for a match from available patient profiles; allowing patients to reconcile and incorporate data available in the C-CDA files with the data present in the matching patient chart. Production environment logs of clinician activity were extracted from all applicable care settings and analyzed using the ‘Incorporation’ measure which indicated 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.

- **Certification Criteria:** § 170.315(b)(2) Clinical information reconciliation and incorporation
- **Expected Outcomes:** It is expected that the functionalities identified above shall perform as per requirements to demonstrate conformance to § 170.315(b)(2), with a significant percentage of users able to successfully reconcile and incorporate patient data without errors.
- **Actual Outcomes:**

I. Measure: Incorporation

Metric: Utilization Rate of Reconciliation

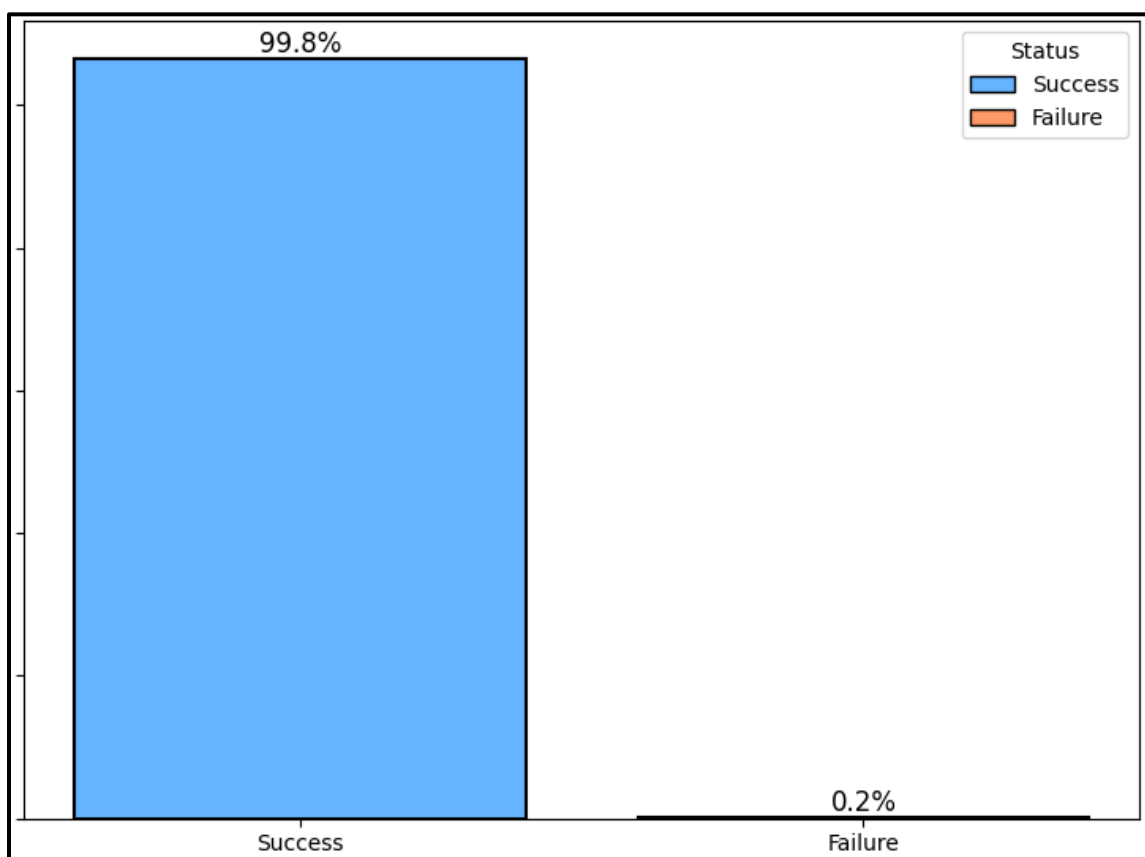


Percentage of reconciliations attempted by users against total C-CDAs received in the system

Metric: Success Rate of Reconciliation and Incorporation

Numerator: Count of CCDs incorporated successfully

Denominator: Total count of attempts to incorporate data from CCDs after reconciliation



4.2.3. Use Case 3

As detailed in the Real World Test Plan, this use case tested the ability of the CureMD SMART Cloud's prescription module to enable its users to electronically communicate with pharmacies for efficiently managing their patients' medication needs. Production environment logs of clinician activity were extracted from all applicable care settings and analyzed based on two measures: ongoing 'Sharing' of e-prescription information and the extent of 'Compliance with the Required Standard i.e. NCPDP SCRIPT 2017071'.

- **Certification Criteria:** § 170.315(b)(3) Electronic prescribing
- **Relied upon software:** Medi-Span Drug Database (Version 5)

- **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).

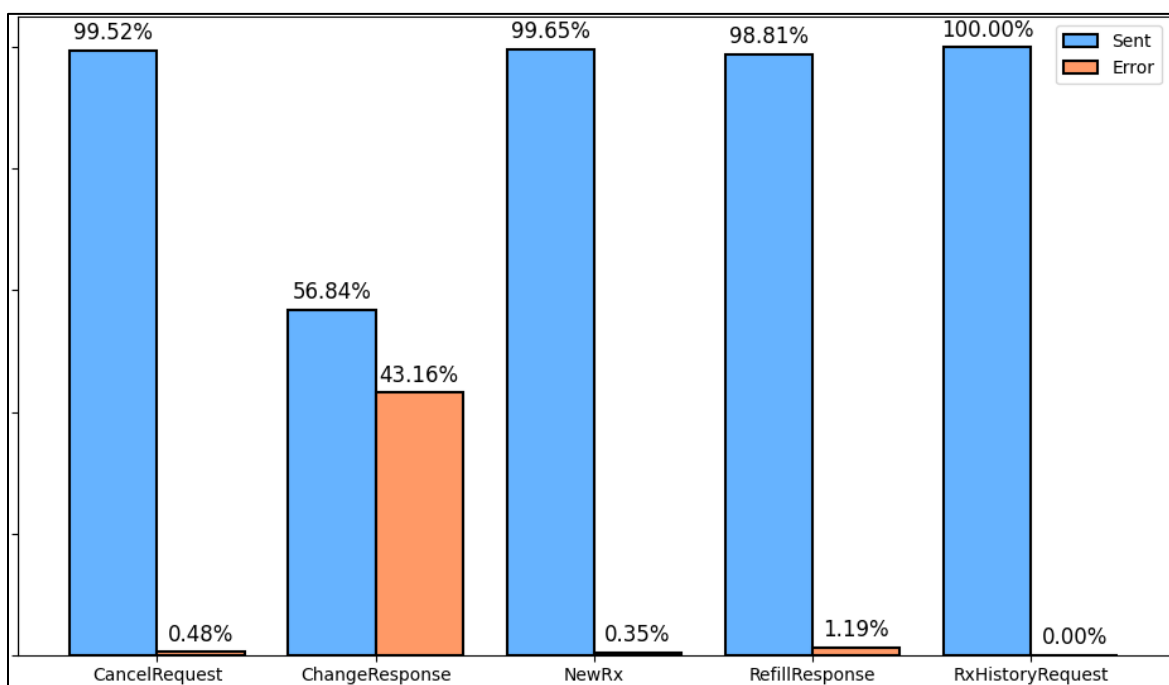
- **Actual Outcomes:**

I. Measure: Sharing

Metric: Success Rate of Outbound e-Prescription Messages

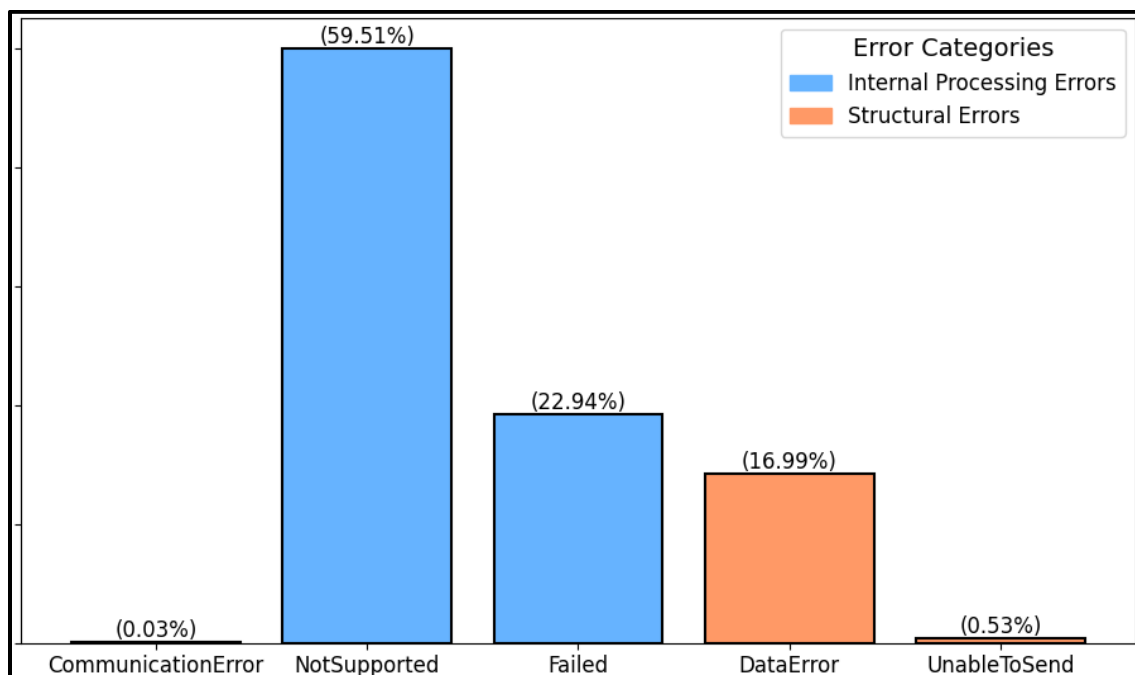
Numerator: Count of Outbound messages successfully sent (Cancel Request/Change Response/New Rx/Refill Response/Rx History Request)

Denominator: Total count of outbound messages sent (Cancel Request/Change Response/New Rx/Refill Response/Rx History Request)



II. Measure: Compliance with Required Standard (NCPDP SCRIPT 2017071)

- **Metric:** Distribution of Errors by Types



4.2.4. Use Case 4

As of December 31, 2023, the Certification Criterion **§ 170.315(b)(6) Data Export** has been sunset under the ONC Cures Act Final Rule and replaced by **§ 170.315(b)(10) Electronic Health Information Export**, therefore we are not including it in our RWT Results Report for 2024.

In accordance with CureMD's Real World Test Plan – 2025, the Certification Criterion § 170.315(b)(10) Electronic Health Information Export will be included in our upcoming Real World Test Results Report for 2025.

4.2.5. Use Case 5

This use case tested the ability of CureMD SMART Cloud to enable users to electronically record all required data for accurate calculation of Clinical Quality Measure (CQM) performance reports, and export that data to relevant organizations and programs in a standardized format e.g. QRDA I and III. Moreover, it tested the system's ability to allow electronic importing of CQM data for either a patient or a set of patients. The metrics of 'Sharing' and 'Incorporation' were chosen to demonstrate ongoing interoperability and the CureMD SMART Cloud's ability to consume the incorporated data, respectively.

- **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.

- **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, without errors.

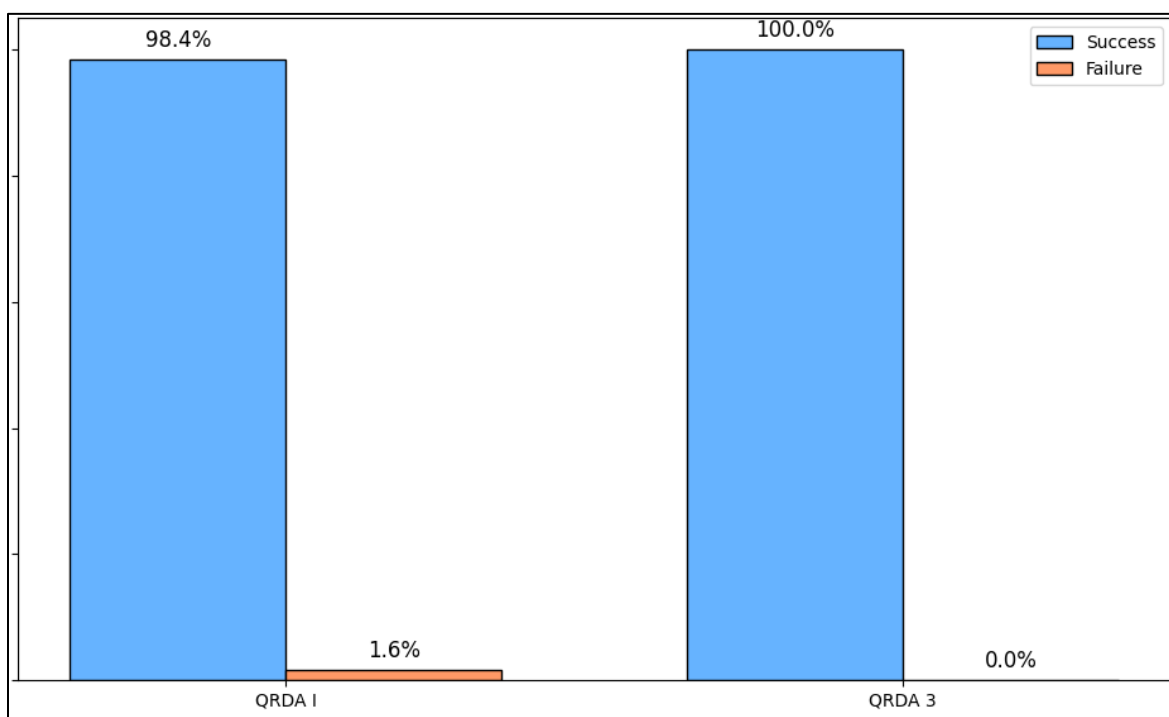
- **Actual Outcomes:**

I. Measure: Sharing

- **Metric:** Success Rate of QRDA I and III file exports

Numerator: Number of times files generated successfully [QRDA I and III file exports]

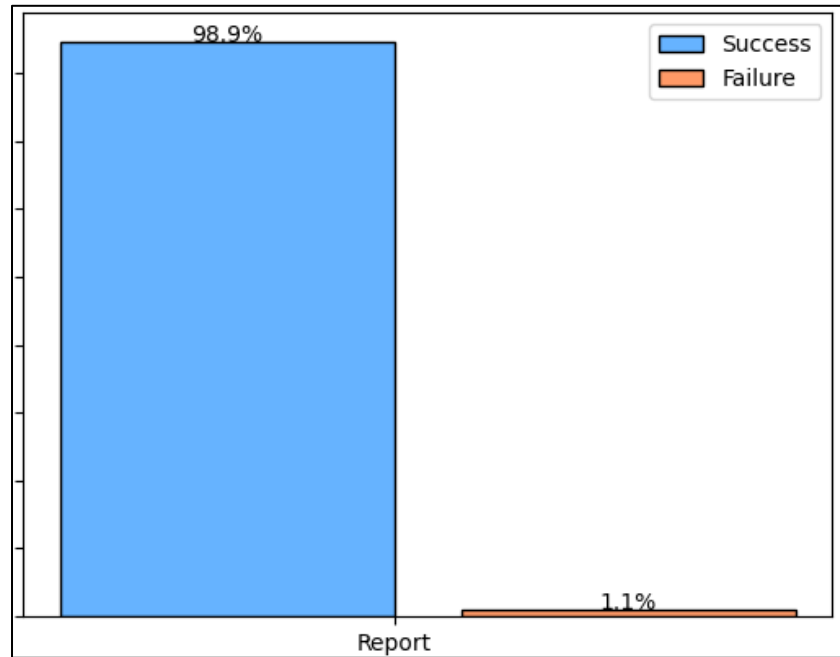
Denominator: Total count of export requests [QRDA I and III file exports]



- **Metric:** Success Rate of Clinical Quality Measures Report

Numerator: Count of successful report generation [Reports]

Denominator: Total count of report requests [Reports]

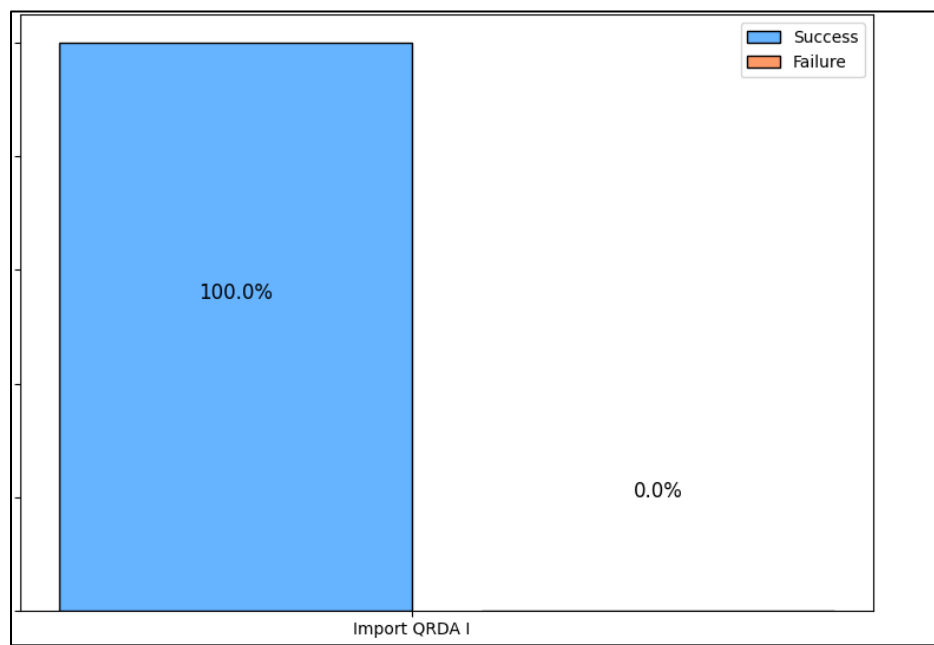


II. Measure: Incorporation

- **Metric:** Success Rate of QRDA I File Imports

Numerator: Count of successful action [QRDA I file imports]

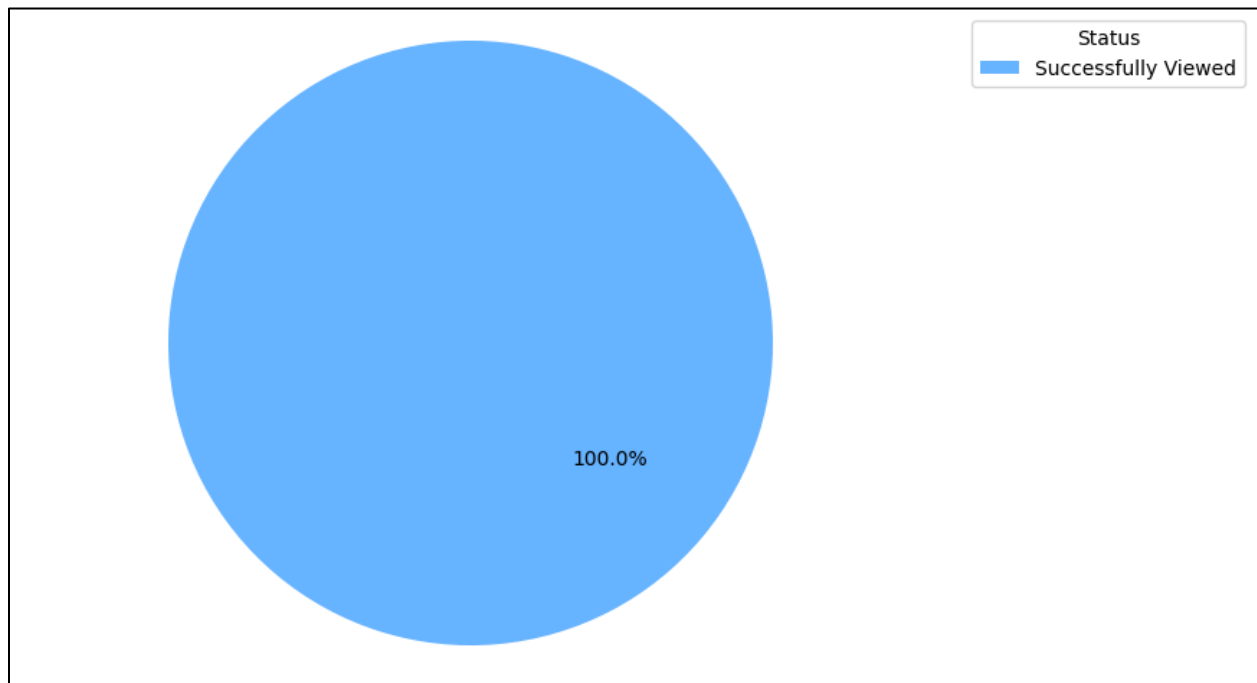
Denominator: Total count of action [QRDA I file imports]



4.2.6. Use Case 6

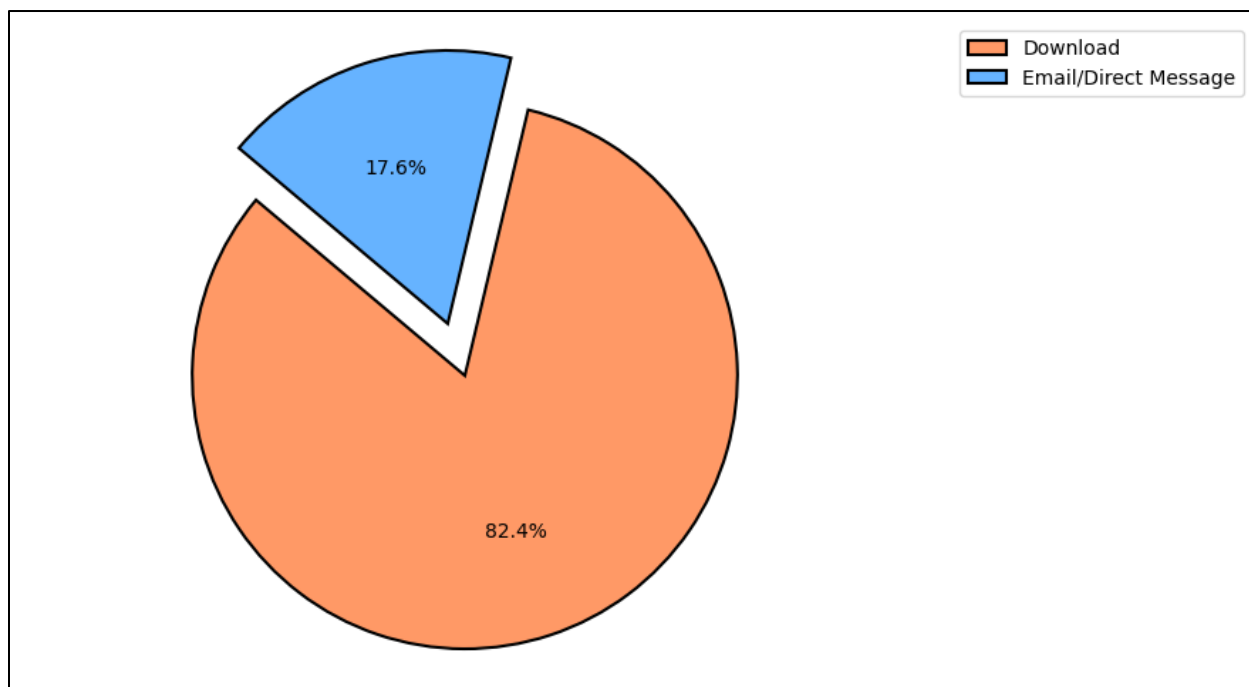
As detailed in the Real World Test Plan, this use case tested the ability of CureMD SMART Cloud's Patient Portal to allow registered patients (and their authorized representatives) to view their EHI and share it with chosen third parties. Production environment logs of activity were analyzed for patient portal users of all applicable care settings using the 'Access' and 'Sharing' measures to reveal their ability to view and exchange EHI through different methods, respectively.

- **Certification Criteria:** § 170.315(e)(1) View, Download, and Transmit to 3rd party
- **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 able to successfully view and transmit EHI in the form of CCD files without errors.
- **Actual Outcomes:**
 - I. **Measure:** Access
 - **Metric:** Success Rate of Viewing EHI



II. **Measure:** Sharing

- **Metric:** Utilization Rates of Different Transmission Methods



4.2.7. Use Case 7

This use case tested the ability of the CureMD SMART Cloud to enable successful engagement with public health agencies (PHAs). This includes the ability to record historical and administered vaccines, and access a patient's immunization history from a registry. The measure of 'Sharing' tracked CureMD SMART Cloud's transmission capabilities in required formats. Additionally, the 'Access' measure tracked the 170.315(f)(1) requirement of requesting and displaying Immunization history and forecast data received from the registries.

I. **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)(7) Transmission to public health agencies - health care surveys
- **Expected Outcomes:** It is expected that the functionalities identified above shall perform as per requirements to demonstrate conformance to the tested criteria, with a significant percentage of

users able to successfully exchange EHI formatted in accordance with the referenced HL7 standards for each criterion, without significant percentage of errors.

- **Actual Outcomes:**

Out of the four criteria clubbed in this use case, utilization was only reported for *170.315(f)(1) Transmission to immunization registries*, and is reflected in the metrics below. Since there was no utilization for the other 3 criteria on any of our production clients throughout 2024, testing against these criteria was completed using synthetic data that simulated real world scenarios. This testing was executed in environment that mirrored production environment. Following are the details regarding test scenarios that were executed for each of them:

(f)(2) Transmission to public health agencies - syndromic surveillance

- **Test Scenario:** an infant is seen at an urgent care center for fever, cough, and earache. Diagnostic tests show that he has influenza and stenosis of the external ear canal. He is discharged to home with treatment instructions and a prescription. This test case involves 2 steps: a registration message, followed by a discharge message.
- **Count of Report Generated using Synthetic Data:** 2
- **Result:** No errors in the generation of these messages were encountered.

(f)(4) Transmission to cancer registries

- **Test Scenario:** An adult female patient with a history of Type 2 Diabetes Mellitus and Breast Cancer visited to the office for her scheduled cycle of chemotherapy. The patient previously underwent biopsy and was diagnosed with breast cancer, which was treated with surgery. During this visit, the patient reported fatigue, insomnia, and back pain, for which she was prescribed medicine. The patient was also administered chemotherapy during the visit and an MRI of the spine was ordered to evaluate potential metastatic spread.
- **Count of Report Generated using Synthetic Data:** 1
- **Result:** No errors in the generation of this message were encountered.

(f)(7) Transmission to public health agencies - health care surveys

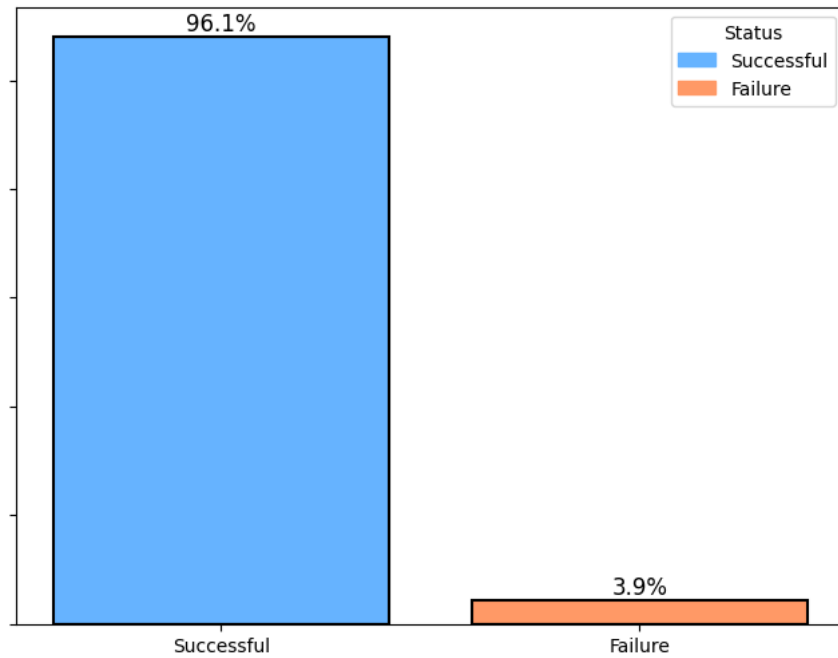
- **Test Scenario:** An adult male patient with hypertension and other chronic conditions visits the clinic. The patient reports headache, and feeling anxious. The provider conducts an examination during which he records vitals, review results, prescribes medication to manage reported conditions, provides dietary education and refers the patient to another physician for further assessment.
- **Count of Report Generated using Synthetic Data:** 1
- **Result:** No errors in the generation of this message were encountered.

I. Measure: Sharing

- **Metric:** Success Rate of Electronic Transmission to PHAs

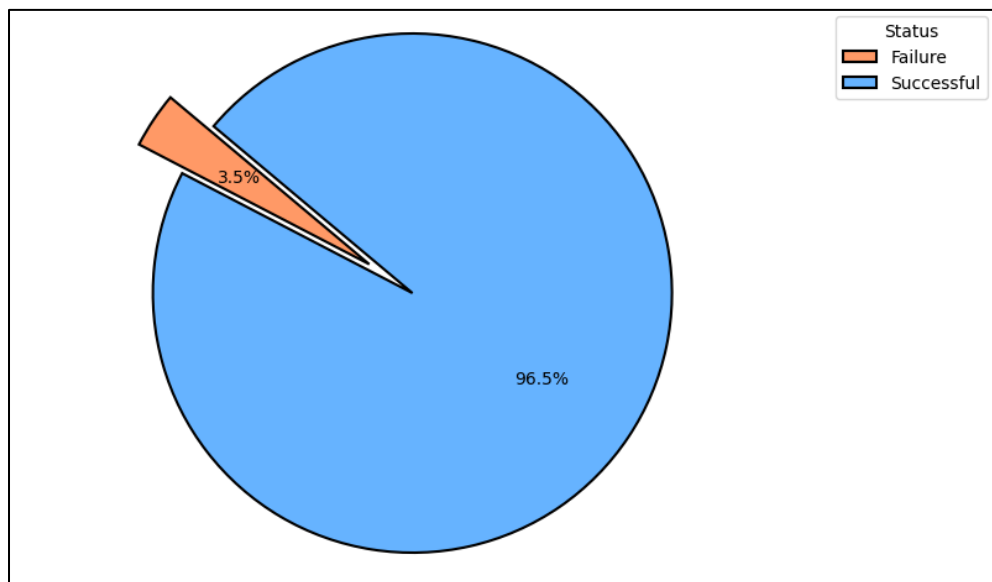
Numerator: Count of successful transmission attempts to Immunization Registries

Denominator: Total count of transmission attempts to Immunization Registries



II. Measure: Access

- **Metric:** Task Completion Rate of Receiving Immunization History and Forecast



4.2.8. Use Case 8

As detailed in the Real World Test Plan, this use case tested the ability of third-party developers to access patient data for utilization in their applications using CureMD SMART Cloud's certified API technology. The metric of 'Access' was chosen to demonstrate authorized access to EHI of patients for patient selection and data access.

- **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

- **Relied upon software:** HAPI FHIR (Version 7.6.0) AND Keycloak (Version v 24.0.5)

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

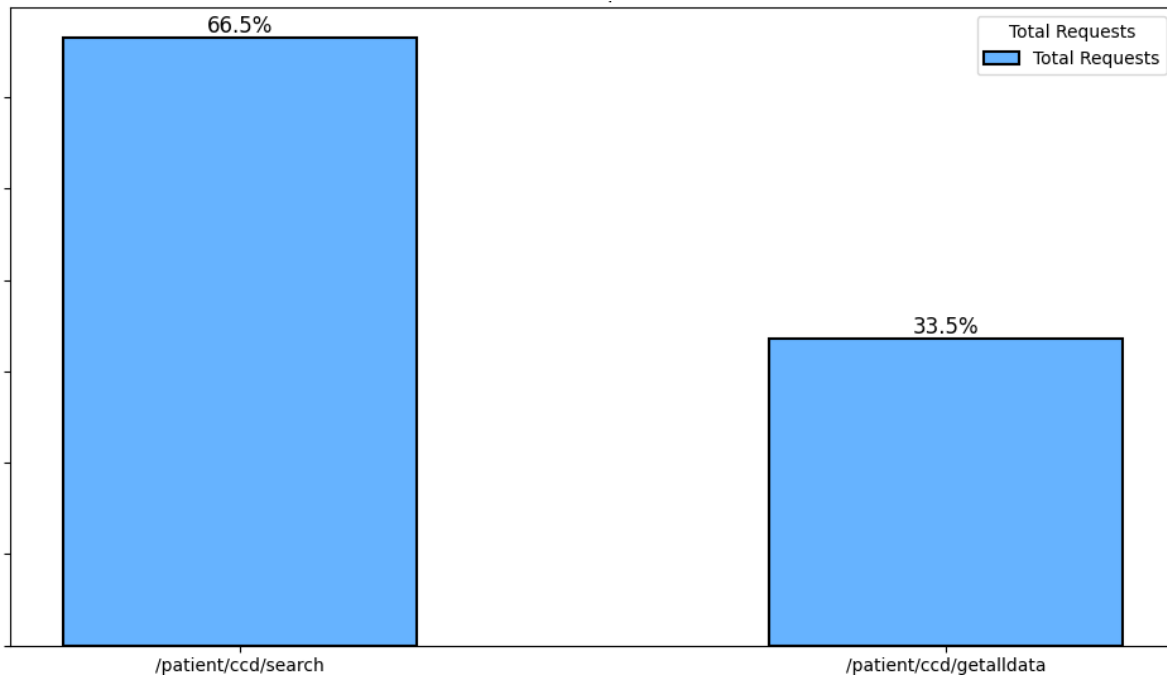
- **Actual Outcomes:**

Out of the three criteria clubbed in this use case, utilization was reported for 170.315(g)(7) Application access — patient selection and 170.315(g)(9) Application access — all data request and is reflected in the metric below. Since there was no utilization of **§ 170.315(g)(10) Standardized API for Patient and Population Services** across any of our production clients throughout 2024, testing against this criterion was conducted using synthetic data. Validations were performed using the Inferno Test Kit in an environment that mirrored the production environment. Following are the details regarding scenarios that were tested:

1. Verified that patients can authenticate and access their individual health records via FHIR API.
2. Confirmed that the EHR system supports OAuth 2.0 authentication and issues access tokens.
3. Validate that the FHIR server exposes all USCDI v1 required resources (e.g., Patient, Condition, Observation, etc.).
4. Tested that the FHIR API supports search queries, ensuring correct handling of filtering parameters.
5. Validated that the API returns appropriate error codes for invalid, unauthorized, or malformed requests
6. Verified that an authorized client can request bulk patient data exports using the \$export operation and retrieve NDJSON files via pre-signed URLs.
7. Confirmed that the API implements SMART on FHIR scopes for controlled data access.
8. Verified that the system supports token refresh using OAuth 2.0 refresh tokens.

I. Measure: Access

- **Metric:** Utilization Rate of Patient Data Requests Endpoints



4.2.9. Use Case 9

As detailed in the Real World Test Plan, this use case tested the users' ability to securely share patient health information with other trusted providers or parties using Direct Messaging protocol. The metric of 'Compliance with Required Standard' was chosen to demonstrate ongoing conformance of CureMD SMART Cloud's DIRECT Protocol implementation with the Applicability Statement for Secure Health Transport standard in all applicable care settings.

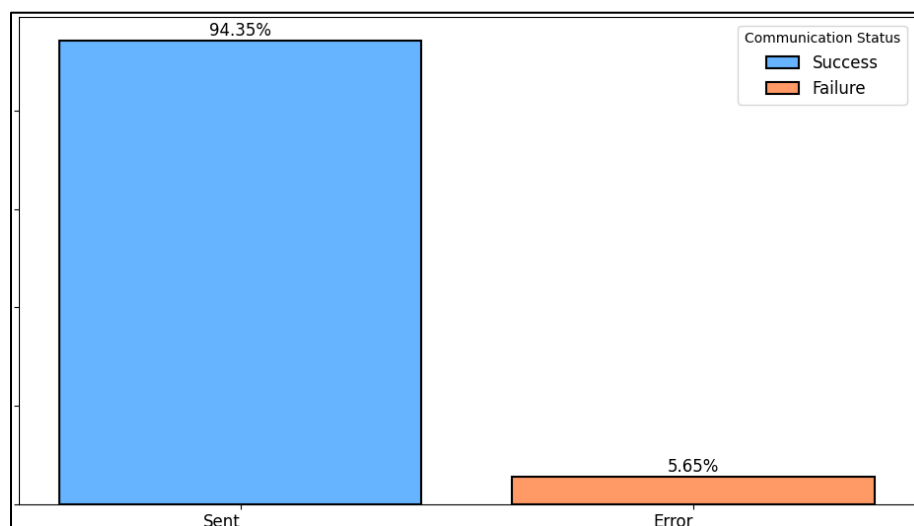
- **Certification Criteria:** § 170.315(h)(1) Direct project
- **Relied upon software:** Surescripts Clinical Interoperability (Version Net2Net REST 10.4)
- **Expected Outcomes:** It is expected that the functionalities identified above shall perform as per requirements to demonstrate conformance to § 170.315(h)(1), with a significant percentage of users able to securely exchange EHI with other trusted providers and parties.
- **Actual Outcomes:**

I. Measure: Compliance with Required Standard

- **Metric:** Conformance Rate of Outgoing Direct Messages

Numerator: Count of outgoing messages successfully sent

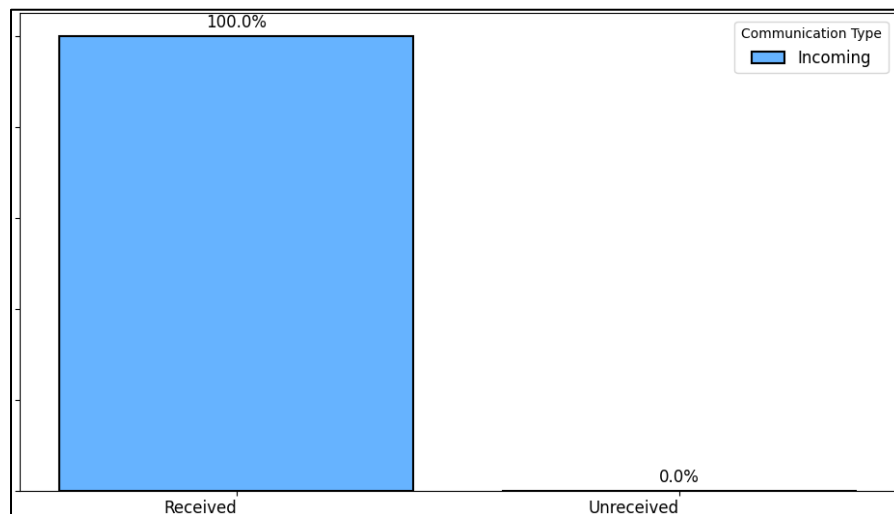
Denominator: Total count of outgoing messages attempted



- **Metric:** Success Rate of Incoming Direct Messages

Numerator: Count of incoming messages processed successfully

Denominator: Total count of incoming messages received



5. Key Milestone

The present RWT Results Report for the year 2024 has been prepared subsequent to the collection of data for all four quarters. The data was gathered and analyzed with the objective of meeting the key milestones as specified in the RWT Plan 2024.

Key Milestones	Care Setting	Date/Timeframe
Begin collection of information as laid out by the plan.	Physician's Office, Urgent Care, House Call, Public Health and Oncology (Ambulatory Settings)	January 1, 2024
Data collection and review.		Quarterly
End of Real World Testing period/final collection of all data for analysis.		December 31, 2024
Analysis and report creation		January 23, 2025
Submission of Real World Testing report to ACB, as per their instructions		January 25, 2025
Submission with Amendments suggested by ACB		February 27, 2025

6. Attestation

This Real World Testing Results Report 2024, is complete with all required elements, including measures that address all certification criteria and care settings. All information in this report is up to date and fully addresses the health IT developer's Real World Testing and Results Report requirements.

Authorized Representative Name: Matt Anderson

Authorized Representative Email: matt.anderson@curemd.com

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

Authorized Representative Signature:

Matt Anderson

Date: 02/27/2025