

ASTP/ONC Health Data, Technology, and Interoperability (HTI) Certification §170.405 Real World Testing

2025 Real World Testing Plan

Compulink Healthcare Solutions, Inc CHPL ID 15.04.04.2701.Comp.12.00.1.171106 Product Version 12 Submitted by Karen Perry, OD FAAO



ONC Health IT Certification §170.405 Real World Testing 2025 Real World Testing Plan

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COMPULINK ONC HEALTH IT CERTIFICATION 2025 REAL WORLD TESTING PLAN

REPORT OVERVIEW

The 2025 Real World Testing Plan for Compulink Healthcare Solutions is designed to validate the continued compliance and effectiveness of the Compulink Advantage certified health IT product in real-world healthcare environments. Certified under the ONC Health IT Certification Program, the product undergoes annual testing to ensure it meets interoperability and data exchange standards.

This Real World Test (RWT) Plan will provide a summary of Compulink's strategy to evaluate the Advantage product's interoperability features using live production environments across client organizations during the 2025 calendar year. The ONC certification criteria observed include ASTP/ONC certification measures 170.315(b)(1)-(3), (b)(10), (c)(1)-(3), (e)(1), (g)(7), (g)(9)-(10), and (h)(1).

REAL WORLD TEST PLAN BACKGROUND & INTRODUCTION

In compliance with the 2024 Health Data, Technology, and Interoperability (HTI-1) Rule and the 21st Century Cures Act, certified health IT developers with products certified under the Certification Program must submit a Real World Testing plan (45 CFR 170.405(b)(1)) that describes in detail how the developer will implement all required aspects of Real World Testing. Compulink will conduct Real World Testing annually to demonstrate continued transparency, performance and compliance in real-world healthcare environments.

Compulink will test its certified health IT modules under 45 CFR 170.405(b)(1)(i-iii) and the applicable criteria under 45 CFR 170.405(b), (c)(1-3), (e)(1), (f)(1)-(2), (f)(7), (g)(7)-(9), and (h)(1).

The certification areas for Compulink include:

Care Coordination

- 170.315(b) (1) Transitions of Care
- 170.315(b) (2) Clinical Information Reconciliation and Incorporation
- 170.315(b) (3) Electronic Prescribing
- 170.315(b)(10) Electronic Health Information Export
- 170.315(b)(11) Decision Support Interventions

Clinical Quality Measures

- 170.315(c) (1) Clinical quality measures (CQMs) record and export
- 170.315(c) (2) Clinical quality measures (CQMs) Import and Calculate
- 170.315(c) (3) Clinical quality measures (CQMs) Report

Patient Engagement

- 170.315(e) (1) - View, download, and transmit to 3rd party

Application Programming Interfaces

- 170.315(g) (7) Application Access Patient Selection
- 170.315(g) (9) Application access All Data Requests
- 170.315(g)(10) Standardized API for patient and population services

Electronic Exchange

- 170.315(h) (1) - Direct Project



Real World Testing is a process which ensures that Certified Health IT Developers publicly demonstrate the interoperability and functionality of their Certified Health IT in production settings and scenarios, rather than in a controlled test environment with an ONC-Authorized Testing Lab (ONC-ATL). Real World Testing also shows how Certified Health IT Developers who use newer versions of specific standards approved by ONC demonstrate conformance to these newer standards.

This plan confirms that Compulink will comply with certification criteria outlined in 45 CFR 170.405(a) must have a 2025 Real World Testing Plan approved by their ONC-ACB and made publicly available on the CHPL no later than December 15, 2024. This requirement is intended to validate that certified health IT modules continue to meet the standards for interoperability, security, and usability necessary to support efficient and safe patient care.

The 2025 Real World Testing Plan is designed to authenticate the real-world functionality of the Compulink Advantage product and meet the expectations set forth by the ONC's requirements with a focus on demonstrating the effectiveness of Compulink's Advantage product maintains its interoperability, security, and usability in live healthcare environments.

As a part of this process, Compulink will implement a comprehensive testing strategy that will gather evidence from real-world scenarios to assess the products performance, emphasizing interoperability, data exchange, and care coordination.

The plan outlines the methodology, data collection strategies, and metrics to be used during the testing period to measure the effectiveness of the product's interoperability and overall performance in actual clinical settings.

The scope of this Real World Testing plan covers several key certification criteria, including §170.315(b)(1) Transitions of Care, §170.315(b)(2) Clinical Information Reconciliation and Incorporation, and §170.315(g)(10) Standardized API for Patient and Population Services, among others.

In alignment with the ASTP/ONC's expectations, the 2025 Real World Testing plan is structured to test critical workflows across various healthcare environments marketed by Compulink, ranging from small private practices to large healthcare organizations.

The focus will be on data exchange capabilities, ensuring that the health IT product facilitates smooth transitions of care, efficient information reconciliation, and compliance with patient access to their health information through standardized APIs.

Through this Real World Testing, we aim to verify that our health IT solution remains robust, adaptable, and interoperable, ultimately supporting the goals of the 21st Century Cures Act by improving care coordination, enhancing the patient experience, and contributing to better health outcomes.

The Office of the National Coordinator for Health Information Technology (ONC) issues Real World Testing resources and certification criteria clarifications to conduct Real World Testing. Compulink's Real World Testing Plan establishes a roadmap for demonstrating conformance to these certification criteria, using test procedures, with associated test tools and/or test data, approved by the National Coordinator; and guidance on topics and specific elements of Real World Testing that ONC considers a priority. Compulink has reviewed and incorporated the following regulatory materials, which establish the core requirements and responsibilities for Real World Testing under the Program.

- 1. Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Final Rule, <u>89 FR 1192</u> (January 9, 2024) (HTI-1 Final Rule) | Section III.E "Real World Testing—Inherited Certified Status"
- 2. 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule, 85 FR 25642 (May 1, 2020) (ONC Cures Act Final Rule) | Section VII.B.5 — "Real World Testing"
- Interim Final Rule with Comment Period, Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency, <u>85 FR 70064</u> (November 4, 2021) (IFC)



Additionally, the following resources have been utilized by Compulink Healthcare Solutions to fully assess and integrate the requirements of the Real World Testing Condition and Maintenance of Certification:

- 1. Real World Testing–What It Means for Health IT Developers Fact Sheet
- 2. <u>Real World Testing Certification Companion Guide</u>
- 3. Real World Testing Resource Guide
- 4. <u>Real World Testing Plan Template</u>
- 5. <u>Real World Testing Results Report Template</u>

Health IT Developers have maximum flexibility in developing innovative Real World Testing plans. Compulink has considered the complexity of workflows and use cases in the care settings where its certified health IT product is marketed. Additional factors considered for in the RWT method(s)/methodology(ies) include:

- 1. Size of the organizations that production systems support
- 2. Type(s) of organizations and setting(s)
- 3. Number of patient records and users
- 4. System components and integrations
- 5. Volume and types of data exchange
- 6. Certification criteria measured, either individually or concurrently
- 7. Health IT Modules addressed, either individually or concurrently
- 8. Use of Inherited Certified Status Flexibility

This Real World Testing plan is structured based on the ONC Real World Testing Plan Template created to assist Health IT Developers in organizing the required information that must be submitted for each element in the Real World Testing plan. Health IT Developers must submit one plan for each year of Real World Testing based on specific timelines and due dates as indicated by ONC. ONC does not encourage updating plans outside the submission timeline and will not post updates on the Certified Health IT Product List (CHPL). If adjustments to approaches are made throughout Real World Testing, Compulink will reflect these adjustments, in their Real World Testing results report, including a description of the types of changes, the reasons for changes and how intended outcomes were affected as a result.

Should any adjustments be made during the Real World Testing process, they will be reflected in the final Real World Testing Results Report, along with the reasons for the changes and their impact on intended outcomes.



PRODUCT INFORMATION

Plan Report ID Number	[For ONC-Authorized Certification Body use only]
Developer Name	Compulink Healthcare Solutions
Product Name(s)	Compulink Advantage
Version Number(s)	Version 12
Certified Health IT Product List (CHPL) ID(s)	15.04.04.2701.Comp.12.00.1.171106
Developer Real World Testing Page URL	https://www.compulinkadvantage.com/cures-certification-rwt/

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Consistent with the ONC's recommendation that "Real World Testing verify that deployed Certified Health IT continues to perform as intended by conducting and measuring observations of interoperability and data exchange", Compulink has developed this test plan that to capture and document the number of instances that certified capabilities are successfully utilized in real-world environments. When evidence is unavailable due to zero adoption rates or when capturing successful use is not feasible for other reasons, we will conduct semi-controlled tests that closely mirror real-world scenarios to demonstrate the certified capabilities.

The Results from Compulink's real world testing will be leveraged to provide valuable insights to ensure that healthcare providers and organizations have access to interoperable and high-quality data, supporting the delivery of efficient, cost-effective, and patient-centered care.

It is important to note that Real World Testing is a complement to, not a replacement for, the testing conducted prior to certification. Real World Testing only one component of the Health IT Certification program used to demonstrate compliance with the program requirements. This test plan is not intended to replicate previously demonstrated methods or results. Instead, it is designed to demonstrate that certified capabilities have been successfully deployed and used in live settings at the discretion of providers.

Compulink will employ a three-fold approach to measure and evaluate real-world implementations and measure utilization and interoperability with the Advantage product tools and resources:

- 1. Adoption Rate
- 2. Summative Testing
- 3. Interactive Testing

Adoption Rate:

The adoption rate will be used to help determine how frequently certified capabilities are being utilized in real-world settings and will also help identify differences across care environments. High usage rates can indicate (but don't by themselves prove) practical value, while evidence of low usage rates may highlight potential barriers or areas for improvement. However, the primary goal is not to identify the specific causes of adoption rates, but rather to understand the relevance of the tests across various user groups and care settings.

Summative Testing:

Summative assessments will measure certified actions performed over a designated time frame by querying data, generating reports, and reviewing audit logs within the certified health IT system. These evaluations will track the frequency of actions and, where possible, assess their success or failure. High success rates will serve as indicators of effective real-world implementation.

Interactive Testing

Interactive will be conducted to demonstrate conformance to requirements where the adoption rate of a given certified capability is low or nonexistent. This method ensures continued compliance with updated standards and code sets (e.g., SVAP) by requiring live tests rather than historical data reviews. The goal is for users to demonstrate that the certified health IT module is functioning as expected within their practice or care setting.



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

Compulink Advantage product has been updated to comply with the 2024 CMS-required standards. As of August 31, 2024, no additional Standards Version Advancement Process (SVAP) updates have been programmed into the Advantage product for any of the ASTP/ONC certification criteria. All 2025 Real World Testing (RWT) will be conducted based on the criteria set forth in the ASTP/ the 21st Century Cures Act and The Health Data, Technology, and Interoperability (HTI-1, HTI-2) Certification Program Updates Edition.

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

This Real World Testing plan addresses both required and voluntary standards updates. It includes all certified health IT systems updated to newer versions of standards by August 31 of the corresponding year in which updates were made.

Compulink's conformance with all certification requirements is demonstrated through adherence to each applicable standard to which the health IT is certified. Although each version of a given standard is listed separately, no SVAP updates were programmed into the Advantage V12 product as of August 31, 2024.

Therefore, the information below regarding SVAP updates is not applicable for the 2024 RWT Plan. For documentation purposes, Compulink provides the following information as a reference.

Developer Name	Compulink Healthcare Solutions
Product Name(s)	Compulink Advantage
Version Number(s)	Version 12
Certified Health IT Module Product (CHPL) ID	15.04.04.2701.Comp.12.00.1.171106
Method used for Standard Update	Cypress Testing will be utilized for testing updated
	functionality and certification of eCQMs with the ONC-ACB.
Updated Certification Criteria	N/A
Planned Certification/SVAP	2024 Q4 for client attestation availability 2025 Q1
Standard (and version)	QRDA 1 Release 1, STU Release 4.3, Supports QDM 5.6
Date of ONC ACB notification	N/A
Date of customer notification (SVAP only)	N/A
Conformance method and measurement/metric(s)	N/A
USCDI updated certification criteria	USCDI v1

Standard Versions Identified.

RELIED UPON THIRD-PARTY SOFTWARE

The following software programs will be involved and/or relied upon to demonstrate real world testing and interoperability with specific criteria and functionality:

Product Measure/Metric		Relied Upon Software Explanation	
Updox	170.315(b)(1) Transitions of care 170.315(h)(1) Direct Project 170.315(e)(1) View, download, and transmit to 3rd party.	The Updox Communication Platform provides the user interface for sending direct messages to the Advantage program.	
Surescripts	170.315(b)(3) Electronic prescribing	The Surescripts integrated e prescribing platform provides a portal for providers to manage prescriptions safely and efficiently in real time through an integrated, technology- platform.	



CARE SETTINGS

Historically, Compulink Advantage was primarily deployed in ophthalmic practices and is currently expanding the Advantage product into other Healthcare specialty markets with the intent to diversify product offerings. The table below indicates Compulink's current care settings and justification.

Care Setting	Justification
Behavioral Health	This care setting comprises the third largest care setting among Compulink's user base. It includes behavioral health specialties including Psychology, Psychiatry, Addiction, and Pain Management. Behavioral health practices have stricter privacy rules than other specialties, which alters how providers implement certified Health IT modules.
Ophthalmic	This care setting comprises nearly 80% of our user base. It includes specialties comprising of, Ophthalmology, Ophthalmic Ambulatory Surgery Centers (ASC), and Optometry. This care setting was distinguished because it comprises such a large percentage of our user base.
Orthopedic	This care setting comprises the second largest care setting among our user base. It includes specialties encompassing Chiropractic, Orthopedics, Physical Therapy, and Podiatry. Several of the providers in this care setting are not permitted to issue prescriptions, so they oftentimes use fewer features than other care settings but differ from Otolaryngology in that they focus on different systems.
Otolaryngology	This care setting includes specialties comprising Audiology and Otolaryngology (ENTs). Several of the providers in this care setting are not permitted to issue prescriptions, so they oftentimes use fewer features than other care settings but differ from Orthopedics in that they focus on different systems.
Other Specialties	This care setting is comprised of all other specialties in our user base, including Dermatology, Gastroenterology, Primary Care, and Urology.

MEASUREMENT(S)/METRIC(S) USED IN OVERALL APPROACH

For each measurement/metric, the elements are described below:

- ✓ Description of the measurement/metric
- \checkmark Associated certification criteria
- ✓ Justification for selected measurement/metric
- ✓ Care setting(s) that are addressed
- ✓ Expected Outcomes



ADOPTION RATES

The following metrics are applicable to all criteria and all care settings. These metrics will not be used directly to demonstrate interoperability or conformance to certification criteria. Instead, they will primarily be used to help determine the participants that will be in scope for this evaluation. They can also aid with the justification for other metrics by providing additional context (i.e., extremely low adoption rates for certain certified capabilities will necessitate a different approach to testing).

Description of Measure/Metric:

Metric	Description
 Number of licensed installs/users of EHR The definition of a "license" is dependent upon the model used (e.g., total number of systems, total number of seats per license, etc.) 	Identify the total number of licensed installs/users of the certified Health IT module, regardless of care setting, participation in incentive programs, or use of certified capabilities.
Number of active installs/users of EHR	Identify the total number of <i>active</i> installs and/or users of the certified Health IT module, regardless of care setting, participation in incentive programs, or use of certified capabilities.

The following metrics are applicable to all criteria that are licensed separately from the base license and all care settings.

Metric	Description
Certified capabilities that are licensed	Identify which certified capabilities are licensed separately from the base EHR
separately	license. Examples may include eRx, CQMs, public health, etc.
Number of installs/users who licensed a certified capability	Where applicable, identify the number of licensed installs/users of a given certified capability.
Number of installs/users that have used the certified capability in the preceding 365 days	Where applicable, identify the number of <i>active</i> installs/users of a given certified capability.

SUMMATIVE ASSESSMENT METRICS

The following metrics will be measured by viewing audit logs and reporting systems available to track the behavior of the certified Health IT module during a given time frame. All metrics are designed to reflect the core elements of the criteria, demonstrate interoperability, and demonstrate the success rate of the certified capability being used. In most cases Compulink elects to record these metrics over a 90-day period to reflect the reporting periods typically required for compliance with the federal incentive programs.

The continued measurable use of certified capabilities will provide implicit evidence of successful implementation of the required certified capability. This is especially meaningful in cases where interoperability with outside systems is demonstrated. In cases where it is not possible to determine "success" via an explicit confirmation by a receiving system, success will be defined as a transmission was made where no error was received from the destination system or its intermediaries. Additionally, we will review internal customer and vendor issue tracking systems for reports of failures or unsatisfactory performance in the field.

None of the following criteria were updated to the version of criteria prior to August 31, 2022. As a result, all testing is scheduled to be conducted against the 2015 Edition version of the criteria.



APPLICABLE CRITERIA: MEASURES, JUSTIFICATION AND EXPECTED OUTCOMES

Criterion	Metric	Care Setting	Justification and Expected Outcome
170.315(b)(1)	Over a 90-day period:	Behavioral Health	Compulink requires the use of Updox as a relied
Transitions of	1) Number of CCDAs	Ophthalmic	upon third party software. This criterion requires the
care	 Number of CCDAs created Number of CCDAs sent via edge protocols Number of CCDAs received via edge protocols 	 Ophthalmic Orthopedic Otolaryngology Other Specialties 	upon third party software. This criterion requires the ability of a certified Health IT module to create CCDAs according to specified standards and vocabulary code sets, as well as send and receive CCDAs via edge protocols. However, it is not possible to consistently and reliably demonstrate that all required standards and code sets were used because not all CCDAs created in a real-world setting contain all the necessary data elements. Furthermore, it is not feasible to obtain copies of CCDA documents from "outside" developers or providers who have no incentive to participate in this exercise. Therefore, we intend to demonstrate the required certified capabilities by demonstrating how often CCDAs are created and exchanged with other systems to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be moderate utilization by providers with a high success rate. This standard is available on HealthIT.gov and
			includes standards referenced (https://www.healthit.gov/test-method/transitions- care).
170.315(b)(2) Clinical information reconciliation and incorporation	 Over a 90-day period: 1) Number of times a user reconciled medication list data from a received CCDA 2) Number of times a user reconciled allergies and intolerance list data from a received CCDA 3) Number of times a user reconciled problem list data from a received CCDA 3) Number of times a user reconciled problem list data from a received CCDA 	 Behavioral Health Ophthalmic Orthopedic Otolaryngology Other Specialties 	This criterion requires the ability of a certified Health IT module to take a CCDA received via an outside system and match it to the correct patient; reconcile the medication, allergy, and problem lists; and then incorporate the lists into the patient record. The expectation is each of these steps is done electronically within the certified Health IT module. While this certified capability is available to our users, most providers in the real world typically prefer to perform these steps manually and elect to save any outside received CCDAs as attachments to the patient record. Therefore, we intend to record the frequency that providers are electronically reconciling and incorporating CCDAs that were received from outside providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization by providers with a high success rate. This standard is available on HealthIT.gov and includes standards referenced (https://www.healthit.gov/test-method/clinical- information-reconciliation-and-incorporation).



		1	
170.315(b)(3) Electronic prescribing	 Over a 90-day period: 1) Number of prescriptions created 2) Number of prescriptions changed 3) Number of prescriptions canceled 4) Number of prescriptions renewed 	 Behavioral Health Ophthalmic Orthopedic (not Physical Therapy) Otolaryngology (Not Audiology) Other Specialties 	Compulink requires the use of Surescripts as a relied upon third party software. This criterion requires the ability of a certified Health IT module to perform prescription-related electronic transactions (eRx) using required standards. However, it is not possible to demonstrate the correct standards were used because it is not feasible to obtain copies of eRx documents from "outside" companies or pharmacies who have no incentive to participate. Therefore, we intend to demonstrate the required certified capabilities are effective by demonstrating how often eRx transactions are performed by examining reports from Compulink's eRx partner. This demonstrates that not only are the eRx transactions sent from the certified Health IT module, but that the transactions are successfully received by the eRx clearinghouse. Our expectation is there will be high utilization by providers with a high success rate. This standard is available on HealthIT.gov and includes standards referenced (https://www.healthit.gov/test-method/electronic- prescribing).
170.315(b)(10) Electronic Health Information Export	 Over a 90-day period: Two separate metrics will be considered for EHI Export: 1) Count of Single patient electronic health information export. a. Count of single Patient EHI Exports b. Ratio of Single Patient EHI Exports to All Visits 2) Count of EHI Exports for a Patient Population 3) Average number of patients per patient population EHI Export 	 Behavioral Health Ophthalmic Orthopedic (not Physical Therapy) Otolaryngology (Not Audiology) Other Specialties 	 This criterion establishes the requirements for healthcare IT systems to enable standardized access to health data for both individual patient services and broader population-level data. Thus, healthcare organizations are able to export computable electronic health information (EHI) for a single patient and for a patient population. Workflow 1: Single Patient EHI Export Goal: Validate the system's ability to export a single patient's electronic health information using standardized APIs, ensuring compliance with the "Standardized API for Patient Services" certification criterion. Test Procedure: Patient-initiated Access: The test simulates a patient requesting their health data through a third-party application using the standardized API. Authentication (OAuth 2.0): Patients will authenticate using OAuth 2.0 for secure token exchange. The system will verify that only authorized users can access the requested health data. Data Sharing & Consent: The test will evaluate how patients manage consent to share data with third-party applications, ensuring compliance with privacy laws (e.g., HIPAA).



	 EHI Export Process: The patient's EHI will be exported and made available for download through the patient portal, with password protection to secure the exported file. Once the patient unencrypts the file, they can browse their records. Expected Outcomes: Secure, timely, and accurate data export for individual patients. No more than 1% error rate in fulfilling patient data requests. Metrics: Count of single patient EHI exports. Ratio of single patient EHI exports to all patient visits.
	Workflow 2: Patient Population EHI Export Goal: Validate the system's ability to export population- level data using standardized APIs, ensuring
	compliance with the "Standardized API for Population Services" certification criterion. Test Procedure:
	 Population Data Export: An administrative user selects specific criteria from patient records to define a population. The system will export the EHI for all patients meeting the selected criteria. Third-Party Application Integration: The test will simulate third-party research entities or healthcare organizations accessing the population data through the certified API.
	 Expected Outcomes: Accurate and timely bulk data exports for a population of patients. Scalability and performance of the system under high data volumes, with less than 1%
	error in bulk data exports. Testing will ensure the certified Health IT module meets interoperability standards using FHIR® APIs to relay USCDI data elements for both individual and population data exports. This includes testing FHIR Bulk Data Access (Group Export) to retrieve subsets of USCDI data classes or elements.
	The system's conformance to the § 170.315(g)(10) certification criterion will be verified by demonstrating accurate data export capabilities in both individual and population workflows. Real World Testing Justification



	Real-world testing is essential to validate the
	performance, scalability, and security of APIs in a live
	healthcare environment, particularly for these
	reasons:
	Secure Data Access:
	Ensures authorized patients can access their health data securely, improving patient
	engagement.
	Seamless Integration: Confirms that third-party applications and providers can efficiently retrieve and use population-level data for public health reporting and research
	Scalability:
	 Scalability: Demonstrates that the system can handle large data volumes, particularly in population-level exports, without compromising performance. This Real World Test Plan demonstrates that the certified API technology, using FHIR standards, effectively supports secure and accurate data exports for both individual patients and populations, meeting ONC's interoperability requirements under § 170.315(b)(10). The system's ability to manage multiple patient services and population services applications concurrently will be validated, ensuring compliance with real-world healthcare scenarios.
	This standard is available on HealthIT gov and
	includes standards referenced
	(https://www.healthit.gov/test-method/electronic- health-information-export).



170.315(c)(1) Clinical quality measures (CQMs)- Record and Export 170.315(c)(2) Clinical quality measures (CQMs)-Import and Calculate 170.315(c)(3) Clinical quality measures (CQMs)-Report	 Over a 90-day period: 1) Number of measures recorded during the period 2) Number of QRDA Category 1 files exported 3) Number of QRDA Category 1 files imported (if applicable) 4) Number of QRDA Category 3 aggregate report(s) created over the period 	• Ophthalmic	These criteria will be tested together. C1 requires a certified Health IT module to record required data, calculate CQMs from the recorded data, and export the data in QRDA Category 1 format. C2 requires a certified Health IT module must be able to import data from a QRDA Category 1 formatted file and calculate the CQMs based on that data. C3 requires a certified Health IT module must be able to create a QRDA Category 1 formatted file and a QRDA Category 3 aggregate report to be used for transmitting CQM data to CMS. Compulink intends to record the frequency that CQM files are imported and/or exported by providers to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Metrics for CQMs will be focused on the Ophthalmic care setting. Usage of these features is predominantly leveraged by Ophthalmic providers in the Advantage program. Our expectation is there will be moderate utilization by providers with a high success rate
170.315(e)(1) View, download, and transmit to 3rd party	 Over a 90-day period: 1) Number of views of health information by a patient or authorized representative 2) Number of downloads of health information by a patient or authorized representative 3) Number of transmissions of health information by a patient or authorized representative using unencrypted email 4) Number of transmissions of health information by a patient or authorized representative using unencrypted email 	 Behavioral Health Ophthalmic Orthopedic Otolaryngology Other Specialties 	Compulink requires the use of Updox as a relied upon third party software. This criterion requires the ability of a certified Health IT module to provide patients access to a patient portal with the ability to view, download, and send their health care records to other providers via encrypted or unencrypted transmission methods in CCDA format. We intend to record the frequency that patients are viewing, downloading, and transmitting their records from the portal using the certified capabilities to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be moderate utilization by patients for view and lower utilization for download and transmit with a high success rate for all certified capabilities.



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170.315(g)(7) Application access - patient selection	1) 2) 3)	Number of requests for a patient ID or token Number of requests that provided sufficient information to provide a valid response Number of follow-up requests made using the provided patient ID or token	 Behavioral Health Ophthalmic Orthopedic Otolaryngology Other Specialties 	This criterion requires the certified Health IT module to provide an API and supporting documentation that enable external applications to request a unique patient identifier from the certified Health IT module that can be used to request additional patient data. We intend to record the frequency that patient ID requests are received by providers via API to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be zero adoption of this certified capability by our users, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature.
170.315(g)(9) Application access — all data request	1) 2)	Number of requests for a patient's Summary Record made by an application via an all- data category request using a valid patient ID or token Number of requests for a patient's Summary Record made by an application via an all- data category request using a valid patient ID or token for a specific date range	 Behavioral Health Ophthalmic Orthopedic Otolaryngology Other Specialties 	This criterion requires the certified Health IT module to provide an API and supporting documentation that enable external applications to request all categories of patient data defined in the CCDS from the certified Health IT module. We intend to record the frequency that patient data requests for all categories are received by providers and fulfilled via API to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be zero adoption of this certified capability by our users, so we have added interactive testing methodology for these capabilities to the test plan below to demonstrate the feature is available and functions as expected should any users elect to begin using this feature.
170.315(g)(10) Standardized API for patient and population services	1) 2) 3) 4)	Number of authorized Patient Applications Number of authorized Provider Applications Number of authorized Bulk Applications Number of patient data requests	• Ophthalmic	This criterion requires the ability of a certified Health IT module to respond to requests for patient data thru FHIR standards from authorized/registered applications. We intend to record the frequency that data is requested thru FHIR applications to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be low utilization with a high success rate.



170.315(h)(1) Direct Project	1) 2) 3) 4)	Number of Direct Messages sent Number of Delivery Notifications received Number of Direct Messages received Number of Delivery Notifications sent	 Behavioral Health Ophthalmic Orthopedic Otolaryngology Other Specialties 	Compulink requires the use of Updox as a relied upon third party software. This criterion requires the ability of a certified Health IT module to record the frequency that direct messages are sent and received by providers, along with how often MDNs are sent and received. Since not all systems respond with MDNs, we cannot reliably use that metric to define success. Furthermore, it is not feasible to obtain copies of Direct Messages from "outside" developers or providers who have no incentive to participate in this exercise. Therefore, we intend to demonstrate the required certified capabilities by demonstrating how often Direct Messages are exchanged with other systems to demonstrate the certified capability is available and effective, regardless of the frequency it is used. Our expectation is there will be moderate utilization by providers with a high success rate.

INTERACTIVE TESTING

In order to demonstrate Real World functionality for API Criteria, Compulink will use live, interactive testing to show that this functionality is available in the real world.

Compulink will leverage interactive testing for the following criteria:

- § 170.315(g)(7) Application access—patient selection
- § 170.315(g)(9) Application access—all data request
- § 170.315(g)(10) Standardized API for Patient and Population Services

JUSTIFICATION FOR THIS APPROACH

Compulink maintains two Application Programming Interfaces (APIs), however only one is certified to the API criteria. With the intent of providing advanced functionality, Compulink API functionality was initially developed per ONC requirements with the expectation of augmenting the View, Download, Transmit functionality and with the intention of providing similar functionality.

- In addition to the ONC required API, Compulink developed a second API to enable digital connectivity between the Advantage Software and patient engagement enterprises per the client needs. This proprietary API facilitates billing and payor technology, clinical diagnostic technology and other third-party solutions which fuel digital networks and eCommerce in a transforming digital economy. Compulink clients have readily adapted to this second API feature.
- Compulink acknowledges that APIs are the cornerstone of digital transformation in healthcare, but overall, the healthcare industry continues to face challenges with API adoption over interoperability, patient data exchange and infrastructure. API adoption has been predominately driven by regulatory compliance rather than improving clinical outcomes, patient care experiences and business processes. The Compulink Advantage user base is mainstream in these considerations. While Compulink healthcare providers aspire to adopt digital transformation, their focus is directed toward immediate patient care operations through traditional workflows. Adoption rates for Compulink API technology have not yet aligned with the priorities of Compulink providers.
- As of this writing, while there continues to be demonstrated adoption of the Compulink portal, there has been no adoption of the API functionality and metrics are not available to demonstrate certified functionality in the Real World.



HIGH LEVEL INTERACTIVE TEST PLAN

- **Care Settings**: Compulink Advantage software is utilized in typical ambulatory care settings and outpatient facilities which include healthcare Primary Care physicians, Specialty Clinicians, Surgeons, Behavioral Health Specialists, Physicians Assistants, Nurse Practitioners, Clinical Psychologists, Physical or Occupational Therapists, Speech-Language Pathologists, Audiologists and other qualified Healthcare providers and support staff.
- **Test Environment:** All interactive testing will be performed in a live, production environment. Compulink Advantage software offers flexible solutions including a cloud-based environment or server based (on-premises) hosting options. Real World Testing for API criteria will be performed utilizing a sampling of data from both platforms' representative of Real World deployments.
 - o Compulink will use a recorded videoconferencing solution to capture the results of this testing.
 - Compulink will perform real world testing on a representative number of deployments in order to demonstrate that this functionality exists and functions in an identical manner in all cloud based as well as on-premises deployments.
- **Test Data**: Interactive testing will be performed using live patient data in the live production environment in order to represent characteristics of real-world deployments. Precautions will be taken to reduce the risk of exposure of PHI.

EXPECTED OUTCOMES

Compulink will demonstrate that its certified capabilities function as previously demonstrated and are available to users upon request. Specifically, the expected outcomes of the Real World Testing for Compulink's API technology are as follows:

- Patient Selection:
 - The Compulink API will receive requests to uniquely identify a patient and return an ID or token. This ID or token will enable applications to subsequently execute requests for that patient's data.
- Data Category Request:
 - o The Compulink API will respond to requests for patient data based on an ID or token for individual data categories specified in the Common Clinical Data Set (CCDS). It will return the full set of data for the requested category in a computable format, in accordance with applicable standards.
 - The API will also be able to respond to requests for patient data associated with specific dates or data within a specified date range.
- All Data Request:
 - o The Compulink API will respond to requests for all data classes expressed in the CCD document template, based on an ID or token.
 - o It will also support requests for patient data associated with a specific date or within a specified date range.



SCHEDULE OF KEY MILESTONES

Real World test planning will commence in first quarter of 2025. Each phase is expected to require 90-days to complete, with report writing to occur end of 2025/early 2026.

Key Milestone	Care Setting	Date/Timeframe
Initial development of the Real World Testing plan	 Behavioral Health Ophthalmic Orthopedic Otolaryngology Other Specialties 	October 31, 2024
Participant Outreach	 Behavioral Health Ophthalmic Orthopedic Otolaryngology Other Specialties 	90-days
Scheduling and logistics	 Behavioral Health Ophthalmic Orthopedic Otolaryngology Other Specialties 	90-days
Data collection and validation	 Behavioral Health Ophthalmic Orthopedic Otolaryngology Other Specialties 	90-days
Review and collate data	 Behavioral Health Ophthalmic Orthopedic Otolaryngology Other Specialties 	90-days
Analysis and report development	 Behavioral Health Ophthalmic Orthopedic Otolaryngology Other Specialties 	90-days
RWT Results Report Submission	 Behavioral Health Ophthalmic Orthopedic Otolaryngology Other Specialties 	January 31, 2026



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 requirementsⁱⁱⁱ.

Authorized Representative Name: Karen Perry, OD FAAO

Authorized Representative Title: Director Professional Relations

Authorized Representative Email: kfp@compulinkadvantage.com

Authorized Representative Phone: 805-716-8677 ext. 348

Authorized Representative Signature:

Original Submission Date: 10/21/2024

Updated Submission Date: N/A

Updated: N/A

ⁱ <u>https://www.federalregister.gov/d/2020-07419/p-3582</u>

ⁱⁱ <u>https://www.federalregister.gov/d/2023-28857/p-30</u>