

Health IT Certification Program

The Office of the National Coordinator for Health Information Technology

REAL WORLD TESTING PLAN

BACKGROUND & INSTRUCTIONS

Under the ONC Health IT Certification Program (**Program**), Health IT Developers are required to conduct Real World Testing of their Certified Health IT (45 CFR 170.556 and 170.523(i)). The Office of the National Coordinator for Health Information Technology (ONC) issues Real World Testing resources to clarify Health IT Developers' responsibilities for conducting Real World Testing, to identify topics and specific elements of Real World Testing that ONC considers a priority, and to assist Health IT Developers to develop their Real World Testing plans.

Health IT Developers have maximum flexibility to develop innovative plans and measures for Real World Testing. As developers are planning for how they will execute Real World Testing, they should consider the overall complexity of the workflows and use cases within the care settings in which they market their Certified Health IT to determine which approaches they will take. This Real World Testing plan template was created to assist Health IT Developers in organizing the required information that must be submitted for each element in their Real World Testing plan. Health IT Developers must submit one plan for each year of Real World Testing (see resources listed below for specific timelines and due dates). 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, the Health IT Developer should reflect these adjustments in their Real World Testing results report. ONC would expect that the Real World Testing results report will include a description of these types of changes, the reasons for them, and how intended outcomes were more efficiently met as a result. This resource should be read and understood in conjunction with the following companion resources, which describe in detail many of the Program requirements referenced in this resource.

- [Real World Testing—What It Means for Health IT Developers – Fact Sheet](#)
- Real World Testing Resource Guide – Coming Soon
- [Real World Testing Certification Companion Guide](#)

Health IT Developers should also review the following regulatory materials, which establish the core requirements and responsibilities for Real World Testing under the Program.

- 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule, [85 FR 25642](#) (May 1, 2020) (**Century Cures final rule**)
 - ↳ [Section VII.B.5 — “Real World Testing”](#)

GENERAL INFORMATION

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

Developer Name: MedConnect, Inc.

Product Name(s): MedConnectHealth

Version Number(s): 3.0

Health IT Certification Program

The Office of the National Coordinator for Health Information Technology

Certified Health IT Product List (CHPL) ID(s): 15.04.04.1889.MedC.03.00.0.171212

Developer Real World Testing Page URL: <https://www.medconnecthealth.com/realworldtestplan/>

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**", this test plan focuses on capturing and documenting the number of instances that certified capability is successfully utilized in the real world. In instances where no evidence exists due to zero adoption of a certified capability or the inability to capture evidence of successful use for other reasons, we will demonstrate the required certified capability in a semi-controlled setting as close to a "real world" implementation as possible.

It is important to note that Real World Testing is only one component of the Health IT Certification program used to demonstrate compliance with the program requirements. Real World Testing should augment and support testing that was conducted prior to certification being granted. It is not intended to duplicate the methods or results previously demonstrated. Instead, this test plan was developed to demonstrate that the certified capabilities have been successfully deployed for providers to use at their discretion in live settings.

We are using a 3-fold approach to demonstrate successful real-world implementations.

- Adoption Rate
- Summative Testing
- Interactive Testing

Adoption rate will be used to determine if/when certified capability is being used in the real world and to help identify differences in care settings. Evidence of high rates of implementation and usage indicate (but don't by themselves prove) a certified capability's usefulness and practical value. Evidence of low rates of implementation and usage might indicate a potential problem, of which there could be several different causes. Note, it is not the goal of this exercise to identify the individual causes of why a given certified capability may have a high or low adoption rate, but rather to identify the users and care settings for which a given test is relevant.

Summative assessments will be used to measure which certified actions were performed at the conclusion of a given time period. These will be conducted by running reports and examining audit logs from within the certified health IT module to help demonstrate the frequency of actions within the given time frame, and where possible, whether those actions were successful or unsuccessful. High success rates should be an indicator of a successful implementation of a given certified capability in a real-world setting.

Interactive testing will be used to demonstrate conformance to requirements where the adoption rate of a given certified capability is zero and to demonstrate ongoing compliance with updated standards and code sets (SVAP). Interactive tests will require a live test as opposed to examining historical usage statistics. The goal is to allow a user to demonstrate the certified Health IT module being used in a way consistent with their own practice or care setting.

Health IT Certification Program

The Office of the National Coordinator for Health Information Technology

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

MedConnect has not updated MedConnectHealth to any new standards as part of SVAP or the Cures Update criteria as of this date nor plan to prior to the execution of our Real World Test.

CARE SETTINGS

MedConnectHealth is marketed primarily to primary care providers. The overwhelming majority of our users are comprised of family medicine, internal medicine, and pediatrics.

| Care Setting | Justification |
|--------------|---|
| Primary Care | Primary care providers make up close to 90% of our customer base. We do not market to any particular care setting or specialty. |

MEASURES USED IN OVERALL APPROACH

For each measurement/metric, describe the elements below:

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

| Metric | Description |
|--|--|
| Number of licensed installs/users of EHR <ul style="list-style-type: none"> • 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 active installs and/or users of the certified Health IT module, regardless of care setting, participation in incentive programs, or use of certified capabilities. |

Health IT Certification Program

The Office of the National Coordinator for Health Information Technology

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 separately | Identify which certified capabilities are licensed separately from the base EHR 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 active 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 we elected 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 Cures Update version of criteria prior to August 31, 2021. As a result, all testing is scheduled to be conducted against the 2015 Edition version of the criteria.

Health IT Certification Program

The Office of the National Coordinator for Health Information Technology

| Criterion | Metric | Care Setting | Justification and Expected Outcome |
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| 170.315(b)(1) Transitions of care | Over a 90-day period: 1) Number of CCDAs created 2) Number of CCDAs sent via HISP 3) Number of CCDAs received via HISP | Primary Care | 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 CCDAs 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. In our case, we connect to our HISP via API and not Edge protocols and will track that usage instead. Our expectation is there will be moderate utilization by providers with a high success rate. |
| 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 CCDAs 2) Number of times a user reconciled allergies and intolerance list data from a received CCDAs 3) Number of times a user reconciled problem list data from a received CCDAs | Primary Care | This criterion requires the ability of a certified Health IT module to take a CCDAs 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. |

Health IT Certification Program

The Office of the National Coordinator for Health Information Technology

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| <p>170.315(b)(3) Electronic prescribing</p> | <p>Over a 90-day period:</p> <ol style="list-style-type: none"> 1) Number of prescriptions created 2) Number of prescriptions changed 3) Number of prescriptions canceled 4) Number of prescriptions renewed | <p>Primary Care</p> | <p>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 our eRx partner. This will demonstrate 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.</p> |
| <p>170.315(c)(1-3) Clinical quality measures (CQMs)</p> | <p>Over a 90-day period:</p> <ol style="list-style-type: none"> 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 | <p>Primary Care</p> | <p>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. We intend 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. Our expectation is there will be moderate utilization by providers with a high success rate.</p> |

Health IT Certification Program

The Office of the National Coordinator for Health Information Technology

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| 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, whether via encrypted or unencrypted method | Primary Care | 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 CCD 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. |
| 170.315(f)(1) Transmission to immunization registries | Over 3 separate unique 10-day periods within a 90-day window: 1) Number (or percentage) of immunization records submitted to the immunization record | Primary Care | This criterion requires the ability of a certified Health IT module to transmit immunization data to a registry using a specified format. We intend to record the frequency that immunization data is submitted to registries by 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. |
| 170.315(h)(1) Direct Project | 1) Number of Direct Messages sent 2) Number of Delivery Notifications received 3) Number of Direct Messages received 4) Number of Delivery Notifications sent | Primary Care | 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

The following test plans will be executed to demonstrate Real World certified capabilities for criteria where metrics are not available because there is no adoption to date of these criteria in Real World deployments. The justifications for why each criterion has had low adoption are outlined in the table below.

Health IT Certification Program

The Office of the National Coordinator for Health Information Technology

MedConnect will leverage interactive testing for the following criteria:

- §170.315(b)(6) Data export
- §170.315 (f)(2) Transmission to public health agencies – syndromic surveillance
- §170.315(f)(4) Transmission to cancer registries
- § 170.315(g)(7) Application access—patient selection
- § 170.315(g)(8) Application access—data category request
- § 170.315(g)(9) Application access—all data request

High Level Interactive Test Plan

- **Care Settings:** All interactive testing will be performed to represent the Real World context of Primary Care practices in the ambulatory space.
- **Test Environment:** All interactive testing will be performed in a live, production environment unless otherwise specified in the table below.
 - Developer will use a recorded teleconference session to capture the results of the interactive test.
 - The plan for interactive testing the criteria described below in the real world will be to engage with a Clinician in 2 different Primary Care practices where the certified Health IT module is deployed as a representative sample to show that this certified capability is deployed in the real world and that it works the same way in all Primary Care practices.
- **Test Data:** Interactive testing will be performed using specially developed test patient data in the live production environment. Test patients will be created using the data that is typically used by MedConnect providers in their day-to-day practice in order to be as representative as possible of real-world patients. MedConnect will ensure that the test data entered for each patient includes the minimum necessary to meet the data requirements for each criterion being tested using the interactive testing method.

Health IT Certification Program

The Office of the National Coordinator for Health Information Technology

| Criterion | Interactive Test Plan | Justification and Expected Outcome |
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| <p>§170.315(b)(6) Data export</p> | <p>MedConnect will pair with 2 providers to demonstrate that the data export certified capability is available in the same way for all providers, in the production environment.</p> <p>MedConnect will create 5 test patients with various encounters and CCDA documents.</p> <p>MedConnect will work with the providers to walk them through the following functions:</p> <ol style="list-style-type: none"> 1. Exporting a subset of the test patients based on the date of their encounter, or location 2. Exporting users by name | <p>Justification: Clients have not made use of the data export feature since 2020. While MedConnect clients do export CCDA documents either one at a time or in batches, providers find it too onerous to do these exports manually. MedConnect clients typically engage MedConnect to do the configuration work to set up a secure connection with their intended recipients to push CCDA documents.</p> <p>While data export functionality was developed in order to empower providers to set up their own batch transmissions without developer intervention, most of the primary care providers in MedConnect network prefer to have the developer take on this task since the providers typically do not have IT teams dedicated to these functions.</p> <p>Expected Outcome: Both providers will be able to export individual and batch test patient CCDAs based on timeframe, location, and patient identifiers.</p> |
| <p>§170.315.(f)(2) Transmission to public health agencies – syndromic surveillance</p> | <p>MedConnect will pair with 2 Providers within the Primary Care setting to demonstrate Syndromic Surveillance.</p> <p>MedConnect will create 3 patients with data that qualifies for syndromic reporting and then send the reports but catch them on the backend before they go to the registry and use visual inspection to validate that the ADT message is correctly formed.</p> <p>Urgent Care will be one of the Primary Care settings used in order to demonstrate the PHIN messaging guide for Urgent Care sent to Alabama Department of Public Health.</p> | <p>Justification: The providers who were expecting to use the Syndromic surveillance reporting certified capability were not being eligible for this program because their taxonomy was not emergency care focused enough to qualify for claims for their Department of Health. As a result, usage metrics are not available for this certified capability because messages are not currently being sent out.</p> <p>If a MedConnect client does qualify for Syndromic Surveillance, the messages would be able to be sent out.</p> <p>Expected Outcome: Both Provider systems will send an ADT message that is well formed for each patient.</p> |

Health IT Certification Program

The Office of the National Coordinator for Health Information Technology

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| <p>§170.315(f)(4) Transmission to cancer registries</p> | <p>MedConnect will create 3 different patients with Cancer diagnoses and their representative data in the MedConnect production system.</p> <p>These test patients will include a test patient with a Cancer diagnosis with no treatment, as well as 2 patients with Cancer diagnoses with different prescribed treatments.</p> <p>MedConnect will walk through the EHR, mimicking the intended workflow of a Primary Care Clinician following up after an Oncology referral and use the manual generation feature to generate 3 Cancer CCDA documents, then use visual inspection to confirm that the documents include all the expected content for each patient and uses SNOMED and LOINC value sets per the required standard.</p> | <p>Justification: There are very few customers currently using this certified capability in the field. MedConnect providers who were expecting to use the Cancer reporting ended up not being eligible in their state and as a result did not use the certified capability for Cancer reporting.</p> <p>MedConnect providers typically refer out the diagnoses that are reportable to Cancer Registries.</p> <p>If a provider were to perform a diagnosis that qualifies, this capability is available in their EHR and would be able to send the report to the registry per the expectations of the Criterion</p> <p>Expected Outcome: The CCDA documents will be generated for each patient and will include the correct value sets.</p> |
| <p>170.315 (g)(7): Application Access - Patient Selection meets170.315</p> | <p>MedConnect will work with 2 Primary Care Provider clinics to run through the following high-level steps using MedConnect patients in the provider's deployment of the MedConnect API.</p> | <p>Justification: MedConnect will use interactive testing to demonstrate that API capabilities are present and available for use in Real-World customer deployments.</p> |
| <p>(g)(8): Application Access - Data Category Request meets170.315</p> | <p>Test patients will be used, they will be set up in each provider's EHR in advance.</p> <p>MedConnect test user will log into the Health Records app on an iPhone</p> | <p>The main blocker for adoption of the API criteria is that there are not a lot of developers pulling together apps to query the API.</p> <p>Since the implementation of these API criteria has varied so much from developer</p> |

Health IT Certification Program

The Office of the National Coordinator for Health Information Technology

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| <p>(g)(9): Application Access - All Data Request</p> | <p>as the MedConnect patient that has been created in the Provider's EHR.</p> <p>Test patient will use the Health Records app to query the API for:</p> <ul style="list-style-type: none"> • A patient token to be used to query for additional data • Their test results and prescriptions • Their CCDS data as a CCDA | <p>to developer, the ROI for app developers to connect to each individual primary care EHR is not enough for app developers to use these features.</p> <p>Most patients and providers just use the portal features to get their data since it is available, and it works and there are no apps out there.</p> <p>Expected outcomes:</p> <ul style="list-style-type: none"> • Patient ID is accepted, and token is returned • Patient CCDS data is retrieved by the Health Record app as either discreet data fields or as a CCDA |
|--|--|---|

SCHEDULE OF KEY MILESTONES

Real World test planning will commence in first quarter of 2022. Each phase is expected to take 90-days to complete, with report writing to occur end of 2022/early 2023.

| Key Milestone | Care Setting | Date/Timeframe |
|--------------------------|--------------|----------------|
| Scheduling and logistics | Primary Care | 90-days |
| Data collection | Primary Care | 90-days |
| Review and collate data | Primary Care | 90-days |
| Writing report | Primary Care | 90-days |

ATTESTATION

This Real World Testing plan is complete with all required elements, including measures that address all certification criteria and care settings. All information in this plan is up to date and fully addresses the Health IT Developer's Real World Testing requirements.

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Authorized Representative Signature: *[Signature]*

Date: *11/15/21*

Health IT Certification Program

The Office of the National Coordinator for Health Information Technology