# athenaPractice v19 2022 Real World Test Plan

# Contents

# General Information

Plan Report ID Number: [For ONC-Authorized Certification Body use only]
Developer Name:  Virence Health Technologies
Product Name(s):  athenaPractice
Version Number(s):  v19
Certified Health IT:  2015 Edition
Product List (CHPL) ID(s): 15.04.04.3039.Cent.19.02.1.181231
Developer Real World Testing Page URL:  https://www.athenahealth.com/terms-and-conditions

# Justification for Real World Testing approach

At this time, athenaPractice v19 is a Certified electronic health record (EHR) that is sold to primary care, specialty and multi-specialty ambulatory groups.  Functionality within the EHR greatly overlaps regardless of care setting, but the Real World Testing plan aims to incorporate data from as diverse a set of these settings as is possible.

As all of the certification criteria apply broadly to the care settings noted above, the Real World Testing plan will incorporate several certification criteria into one plan:

- §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)(6) – Data Export
- §170.315(b)(9) – Care Plan
- §170.315(c)(1) – CQMs – Record and Export
- §170.315(c)(2) – CQMs – Import and Calculate
- §170.315(c)(3) – CQMs – Report
- §170.315(e)(1) – View, Download, and Transmit to 3$^{rd}$ Party
- §170.315(f)(1) – Transmission to Public Health Agencies – Immunization Registry
- §170.315(f)(2) – Transmission to Public Health Agencies – Syndromic Surveillance
- §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
- §170.315(h)(1) – Direct Project

# Standards Updates (SVAP and USCDI)

| | |
|---|---|
| Standard (and version) | All standards versions are as specified in 2015 Edition except for: §170.315(c)(3) – CQMs – Report CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2021 |
| Date of ONC-ACB notification (SVAP or USCDI) | January 2022 (next quarterly attestation) |
| Date of customer notification (SVAP only) | Not applicable |
| USCDI-updated criteria | Not applicable |

# Care Setting(s)

See summary of supported care settings listed in the "Justification for Real World Testing Approach" section.

# Overall Expected Outcomes

- Real World Testing will demonstrate that the EHR is conformant to the criteria listed in the "Justification for Real World Testing" section
- See below for measures and outcomes associated with the use cases associated with the listed certification criteria

# Measure Used

**Use Case 1 – During the course of ambulatory care, providers share patient records (CCDAs) with each other and where appropriate, reconcile key clinical data elements into the chart.**

| Certification Criteria | Requirement |
|---|---|

| § 170.315 (b)(1) Transition of care | (i) Send and receive via edge protocol… |
|---|---|
| | (ii) Validate and display… |
| | (iii) Create… |
| § 170.315 (b)(2) Clinical information reconciliation and incorporation | (i) General requirements… |
| | (iii) Reconciliation… |
| § 170.315 (b)(9) Care plan | Enable a user to record, change, access, create, and receive care plan information in accordance with the Care Plan document template… |
| § 170.315 (g)(6) Consolidated CDA creation performance | (i) Reference C-CDA match.. |
| | (ii) Document-template conformance… |
| | (iii) Vocabulary conformance… |
| | (iv) Completeness verification… |
| § 170.315 (h)(1) Direct project | (i) Applicability Statement for Secure Health Transport… |
| | (ii) Delivery Notification in Direct |

**Measure 1:  Create a valid CCDA** – This measure will demonstrate EHR ability to create and send a CCDA that is conformant to the standards outlined in § 170.315 (b)(1) Transition of care and § 170.315 (g)(6) Consolidated CDA creation performance

- Justification:  Other EHRs will expect to successfully receive a CCDA formatted to Release 2.1 with all required data elements from athenaPractice
- Test Methodology:  A CCDA of each type (Referral Note, CCD, Care Plan) will be created in athenaPractice and sent to another EHR via each certified workflow (if applicable).  athenaPractice and the other EHR will be using a production-grade environment configured in a way typical of the marketed care settings.  System logs will be reviewed to identify possible errors in transport.  A user in the receiving EHR will demonstrate successful display of all required elements
- Expected Outcomes:  Success is when a different EHR receives and recognizes each type of CCDA as conformant

**Measure 2:  Create and send a CCDA:**  This measure will evaluate the creation and sending of required CCDAs (Referral Note, CCD) at scale across many providers using athenaPractice in a live production environment

- Justification:  A statistically significant sample size of CCDAs generated and sent by athenaPractice spanning multiple organizations with expected errors will validate successful use in the real world
- Test Methodology:  System logs will be evaluated for each required type of CCDA that was created and sent
- Expected Outcomes:  Success is defined as CCDAs of each required type successfully being created and sent via Direct with expected errors (e.g. invalid direct address, no response from receiver, etc.)

**Measure 3:  Receive and display a CCDA** – This measure will demonstrate EHR ability to receive and display a CCDA of each required type (Referral Note, CCD, Care Plan) in a live production environment

- Justification:  Two sub-measures will be evaluated: 1) A manual evaluation of several production examples of each required type of CCDA (Referral Note, CCD and Care Plan) will show that athenaPractice can successfully receive and display CCDAs.  2) An evaluation of a statistically significant number of CCDAs received and displayed by providers using athenaPractice spanning multiple organizations will validate successful use in the real world
- Test Methodology:  1) Examples of CCDAs of each type will be randomly selected for manual review spanning various care settings in the athenaPractice network.  2) System logs will be evaluated to identify the proportion of each type of CCDA that were successfully received.
- Expected Outcomes:  Success is defined as:

1) Chosen examples are successfully received and displayed

2) CCDAs successfully received via Direct with expected errors (e.g. incorrect CCDA format)

**Measure 4:  Receive and reconcile a CCDA** – This measure will demonstrate EHR ability to receive and reconcile a CCDA of each required type (Referral Note, CCD) in a live production environment

- Justification:  An evaluation of reconciliation use spanning a statistically significant number of active users spanning multiple organizations will validate successful use in the real world
- Test Methodology:  System logs will be evaluated to determine the number of users that successfully reconcile at least one CCDA using CEHRT
- Expected Outcomes:  A high number of users successfully use CEHRT to receive and reconcile data into patient charts

**Use Case 2 – During the course of ambulatory care, patients access a copy of their record (CCDs) for viewing, downloading and/or transmitting.**

| Certification Criteria | Requirement |
|---|---|
| § 170.315 (e)(1) View, download, and transmit to 3rd party | (i) (A) View… |
|  | (i)(B) Download… |
|  | (i)(C) Transmit to third party… |
| § 170.315 (h)(1) Direct project | (i) Applicability Statement for Secure Health Transport… |
|  | (ii) Delivery Notification in Direct |

**Measure 1:  Validate user behavior around view actions** – This measure will demonstrate the ability for a patient to preview a CCD document template in a live production environment of their patient portal

- Justification:  The CCD document template contains all required data elements in § 170.315 (e)(1)(i)(A)
- Test Methodology:  System logs will be evaluated to identify patients with a successful CCD document view in the patient portal
- Expected Outcomes:  Success is defined by the number of patients with successful CCD document previews

**Measure 2:  Validate user behavior around download actions** – This measure will demonstrate the ability for a patient to download a CCD document template in a live production environment of their patient portal

- Justification:  An evaluation of a statistically significant number of CCD document downloads spanning multiple organizations will demonstrate the successful real world use of the download feature
- Test Methodology:  System logs will be evaluated to identify patients with a successful CCD document download in the patient portal
- Expected Outcomes:  Success is defined by the number of patients that can successfully download CCD documents

**Measure 3:  Validate user behavior around transmit actions** – This measure will demonstrate the ability for a patient to transmit a CCD document template to a third party in a live production environment of their patient portal

- Justification:  An evaluation of a statistically significant number of CCD document transmissions spanning multiple organizations will demonstrate the successful real world use of the transmit feature

- Test Methodology: System logs will be evaluated to identify the volume of successful CCD document transmits in the portal. The analysis will break out use of transmission via either Direct or email
- Expected Outcomes: Success is defined as:
    - CCD documents successfully sent via Direct with expected errors (e.g. invalid Direct address, lack of response, etc.)
    - CCD documents successfully sent via email with expected errors (e.g. invalid email address, etc.)

## Use Case 3 – EHR users export CCDAs for one or many patients for the purpose of sharing with providers, patients or other third-parties under the purview of HIPAA

| Certification Criteria | Requirement |
|---|---|
| § 170.315 (b)(6) Data export | (i) General requirements for export summary configuration… |
| | (ii) Creation… |
| | (iii) Timeframe configuration… |
| | (iv) Location configuration… |

**Measure 1: Single/Multi patient export** – This measure will assess functionality used to export EHI for a single patient and multiple patients in a production environment.

- Justification: The evaluation of statistically significant number of exports by users spanning multiple organizations using athenaPractice will demonstrate the real world utility of the data export
- Test Methodology: System logs will be reviewed to determine the volume of exports generated in various configurations (e.g. single-patient, multi-patient, etc.) and only by authorized users
- Expected Outcomes: Only authorized users will be able to successfully create export summaries and there will be evidence of successful exports using various configurations (e.g. single-patient, multi-patient, etc.)

## Use Case 4 – Clinicians electronically prescribe medications

| Certification Criteria | Requirement |
|---|---|
| § 170.315 (b)(3) Electronic prescribing | (i)(A) Enable a user to perform the following prescription-related electronic transactions… |
| | (i)(C) For the following transactions, the technology must be able to receive and transmit the reason for the prescription… |

**Measure 1: Transaction success rates** – This measure will evaluate successful use of required eRx transaction types in a production environment

- Justification: A statistically significant sample size of electronic prescriptions spanning multiple organizations using athenaPractice will demonstrate the real world utility of the feature
- Test Methodology: System logs will be reviewed to determine frequency of errors for each transaction type
- Expected Outcomes: Transactions are successfully delivered with expected errors (e.g. pharmacy does not support electronic transactions). Data validation errors are prevented, or end user is notified of errors when appropriate:
    - NewRx

- o RxChange
- o CancelRx
- o RxRenewal
- o RxFill
- o Medication History

**Use Case 5 – EHR users generate QRDA files that comply with the latest specifications for submission to CMS and other quality reporting needs**

| Certification Criteria | Requirement |
|---|---|
| § 170.315 (c)(1) CQMs – record and export | (i) Record… |
| | (ii) Export… |
| § 170.315 (c)(2) CQMs – import and calculate | (i) Import… |
| | (ii) Calculate each and every clinical quality measure… |
| § 170.315 (c)(3) – report | Enable a user to electronically create a data file for transmission… |

**Measure 1:  eCQM calculation success rates** – This measure will validate the correct calculation of implemented eCQMs relative to measure specifications

- Justification:  Using live customer data to validate the accurate calculation of eCQMs is difficult due to the variability of data inputs.  A better approach is to have a controlled production-grade environment with known eCQM data inputs that can be regularly run to evaluate the accurate calculation of the eCQMs over time
- Test Methodology:  A comprehensive test tool previously developed by the EHR vendor for the same purpose will be leveraged to assure the accurate calculation of eCQMs.  We will leverage the end to end testing framework for eCQMs using production test cases for each scenario (namely IPP, Denominator, Numerator, Exclusions and Exceptions) and the various workflows which satisfy in EHR
- Expected Outcomes:   Test cases pass with expected errors (e.g. due to known specification gap, etc.)

**Measure 2:  QRDA file export conformance** – This measure will validate 1) that a QRDA I file generated by athenaPractice can be successfully imported by a different EHR and 2) that a QRDA III file generated by athenaPractice visually conforms to the standard

- Justification:  1) The ability for a different EHR to recognize and successfully import a QRDA I file generated by athenaPractice will demonstrate file conformance.  2) A visual inspection of a file generated in production will validate conformance to what is implemented in the real world
- Test Methodology:  1) A QRDA I file using synthetic test data will be generated by athenaPractice and imported into a different EHR.  Manual review of system logs and eCQM reports in the other EHR will validate conformance to specifications.  2) Visual inspection of a sample QRDA III files generated in production using currently implemented QRDA III standard
- Expected Outcomes:   1) Files conform to required specifications and all data for the eCQMs in the file are present in the other EHR.  2) File samples conform to currently implemented QRDA III standard

**Measure 3:  QRDA file import conformance** – This measure will assess the use of the athenaPractice QRDA I import feature using a QRDA I file created in a different EHR

- <u>Justification:</u>  The ability for athenaPractice to successfully import a QRDA I file generated by a different EHR that is also certified to the CQM criteria will demonstrate the real world utility of the QRDA I import feature
- <u>Test Methodology:</u>  A QRDA I file will be generated in a different EHR using synthetic test data and then imported into athenaPractice.  Manual review of system logs and eCQM reports will validate the successful import and calculation of eCQMs based on imported data
- <u>Expected Outcomes:</u>   Files import, with any import errors (file or formatting related) flagged to users, and imported data is used to calculate eCQMs results correctly

## Use Case 6 – Data is appropriately triggered and submitted to relevant public health agencies

| Certification Criteria | Requirement |
|---|---|
| § 170.315 (f)(1) Transmission to immunization registries | (i) Create immunization information for electronic transmission… |
| | (ii) Enable a user to request, access, and display… |
| § 170.315 (f)(2) Transmission to public health agencies – syndromic surveillance | Create syndrome-based public health surveillance information… |

**Measure 1:  Immunization message success** – This measure will evaluate the ability for athenaPractice to submit conformant immunization messages

- <u>Justification:</u>  The evaluation of a statistically significant number of immunization messages spanning multiple organizations using athenaPractice will demonstrate the real world utility of the capability
- <u>Test Methodology:</u>  System logs will be evaluated for different message types including administered, historical and forecast query
- <u>Expected Outcomes:</u>   Success is defined as (with expected errors including no response from registry, formatting error beyond the scope of CEHRT specification requirements, etc.):
    - Administered vaccines successfully sent to immunization registry
    - Historical vaccines recorded are successfully sent to immunizations registry
    - Forecast query requests successfully sent with historical immunizations and forecast returned

**Measure 2:  Syndromic surveillance message success** – This measure will evaluate the ability for athenaPractice to submit conformant syndromic surveillance messages in the urgent care setting

- <u>Justification:</u>  The evaluation of a statistically significant number of syndromic surveillance messages spanning multiple organizations using athenaPractice will demonstrate the real world utility of the capability.  Although these messages apply to urgent care, emergency department and inpatient settings, athenaPractice only serves the urgent care setting
- <u>Test Methodology:</u>  System logs will be evaluated for all applicable messages sent to registries
- <u>Expected Outcomes:</u>   Success is defined as the successful message submission to and receipt by all actively engaged registries, with expected errors (e.g. no response from registry, formatting error beyond scope of CEHRT specification requirement, etc.)

**Use Case 7 – Independent vendors, as well as athenahealth customers use certified APIs for both patient and provider-oriented use cases**

| Certification Criteria | Requirement |
|---|---|
| § 170.315 (g)(7) Application access – patient selection | (i) Functional requirement… |
| § 170.315 (g)(8) Application access – data category request | (i) Functional requirements… |
| § 170.315 (g)(9) Application access – all data request | (i) Functional requirements… |

**Measure 1:  Request success rate for certified APIs** – This measure will evaluate the successful use of all certified APIs (https://mydata.athenahealth.com/fhirapidoc) through the lens of individual transaction requests by request, API Information Source and API Users

- Justification:  The evaluation of a statistically significant sample size of API requests spanning a broad spectrum of API Information Sources will demonstrate the real world utility of the APIs
- Test Methodology:  System logs will be reviewed to determine the success rates for the following:
  - Requests Served
    - Denominator:  Total requests of certified API(s)
    - Numerator:  # of successful responses
  - API Information Sources with at least one successful response – Validates successful API use spanning current API Information Sources
    - Denominator:  Total API Information Sources with at least one request
    - Numerator:  Total API Information Sources with at least one successful response
  - API Users with at least one successful response – Validates successful API use spanning current API Users
    - Denominator:  Total API Users with at least one request
    - Numerator:  Total API Users with at least one successful response

Expected Outcomes:  We expect to see a high rate of success in the above sub-measures, with expected errors included (e.g. failure in authorization/authentication, incorrectly formatted requests, etc.)

# Schedule of key milestones

| Key Milestones | Date/Timeframe |
|---|---|
| Recruitment of organizations that will participate in de-identified data collection | January 2022 |
| Start of collection of necessary data as laid out by plan (will vary by measure) | January 2022 |
| End of collection of necessary data as laid out by plan (will vary by measure) | January 2023 |
| Analysis of data (will vary by measure) | On-going 2022 |
| Submit Real World Testing report to ACB | February 2023 |

# 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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