

# ClinNext 10

## 2024 Real World Test Plan

### Sabiamed Corporation

#### **General Product Information:**

**Developer Name:** Sabiamed Corporation

**Product Name:** ClinNext 10

**Version Number:** 1.0

**CHPL Listing ID:** 15.04.04.2297.Clin.01.00.1.181029

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#### **Executive Summary:**

This document outlines the test procedures defined for each one of the fifteen (15) functionalities within the tested product, ClinNext 10, that are currently certified by ONC as part of the Real-World testing requirements that become effective in calendar year 2024. All tests have been designed so that they are as real as possible, using real system users in real facilities on which ClinNext 10 is currently deployed.

All tests measure both functional and standards compliance aspects of each tested criteria and contain all sections that are required to align with ONC guidelines as specified in the ONC Real World test plan template.

All standards validation testing procedures, whenever possible, rely on proven validation tools that were used as part of the certification process with Drummond Group such as ClinNext 10 CDA validator and Cypress test platform for e-CQM Calculations and QRDA I validation. The use of these tools guarantees ongoing standards compliance.

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## Standards Version Advancement Process (SVAP) Updates:

SabiaMed Corp. is not planning to perform any standards upgrade for ClinNext 10 v. 1.0 for calendar year 2024.

|  |      |
|--|------|
| Standard (and version)                                   | None |
| Updated certification criteria and associated product    | N/A  |
| Health IT Module CHPL ID                                 | N/A  |
| Method used for standard update                          | N/A  |
| Date of ONC-ACB notification                             | N/A  |
| Date of customer notification (SVAP only)                | N/A  |
| Conformance measure                                      | N/A  |
| USCDI-updated certification criteria (and USCDI version) | N/A  |

## Testing Methodology Overview:

This document outlines the Real-World test plan for ClinNext 10 v. 1.0 (CHPL: 15.04.04.2297.Clin.01.00.1.181029). The test plan is designed to thoroughly test, and assess functional, ongoing interoperability, and standards compliance in a real-world scenario of the following criteria:

- 170.315 (b)(1): Transition 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 (c)(1): Clinical Quality Measures - Record and Export
- 170.315 (c)(2): Clinical Quality Measures - Import and Calculate
- 170.315 (c)(3): Clinical Quality Measures - Report

- 170.315 (e)(1): View, Download, and Transmit to 3rd Party
- 170.315 (f)(1): Transmission to Immunization Registries
- 170.315 (f)(3): Transmission to Public Health Agencies - Reportable Laboratory Tests and Values/Results
- 170.315 (f)(5): Transmission to Public Health Agencies - Electronic Case Reporting
- 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 Population services
- 170.315 (h)(1): Direct Project

All tests contained within this test plan rely on a non-timed test execution approach, where a real system user will be observed performing a series of tasks covering the functionalities that comprise the tested criteria and observing/documenting whether the user was able to perform those tasks. Successfully performing those tasks and accomplishing all outcomes for each test will give us a clear indication whether the tested functionality is performing as designed or whether certain areas of the product related to the tested criteria would need be optimized to improve usability or user adoption.

All tests contained in this test plan have the following elements in common:

**Selected Facility:** The system under test will be evaluated in a live environment (live database) in a facility whose clinical processes require the use of all the functionalities covered in the test plan in order to execute real clinical workflows aligning with ONC requirements.

**Selected Users:** For all tests, we will use real system users that are currently using the product to perform the functions for which each of the tested functionalities was designed. All selected users will have knowledge of the product functionalities and use them regularly to perform the tasks. Therefore, it is assumed that the user will have knowledge of both the product features as well as the clinical workflows associated with those features. For example, to test criteria 170.315 (b)(1): Transitions of Care, clinical personnel will be selected that is currently responsible for patient transfers within the test facility and handling patient transfer documentation, as opposed to a physician user. Selecting real system users for all tested criteria serves two purposes:

- a. provides the best real-life scenario possible for each tested criterion, and



- b. assures that the test user has the knowledge of the clinical process and the product functionality, thus in the case of unsatisfactory test results or a failed outcome, we can discard user lack of knowledge as the reason of the failure.

**Covered Setting:** All tests will be conducted with real patients in one of three types of patients (the actual combination of patients will be determined per tested criteria):

- Patients registered in the Emergency Room, that were discharged from the ER and were not admitted to the facility.
- Patients that registered to the Emergency Room that ended up being admitted to the Facility, or
- Patients that were directly admitted to the facility directly (Elective admission)

All these patient types comprise the patient population of the domain for which the tested product was certified: In-Patient.

**Testing Methodology:** All tests will be conducted using Observation of real users using the system and validating user experience, functionality, interoperability, and standards compliance. In this section we provide an overview of the strategy that will be used for testing, provide an explanation on why we chose the selected strategy and an explanation on why we chose the selected measurement method for assessing ongoing interoperability.

**Measure(s) to Demonstrate on-going interoperability:** In this section we discuss the approach that will be chosen by on order to measure on-going interoperability and increased functionality user adoption. Two types of measures will be used depending on the tested criteria: (1) SQL queries executed against the database in order to gather data that will allow us to calculate measure performance, draw a trendline and see how is product adoption and use of the specific functionality evolving during the entire calendar year, and (2) surveys to users asking relevant questions that will allow us to identify any interoperability or usability issues within the tested criteria. Within this section we present the specific measurements (**Measurements**) that will be extracted from system stored data that will allow us to assess usage of the tested functionality.

**Test Steps:** A set of steps will be executed that will ensure full coverage of the certified functionality operating in a real world setting in the most representative use case possible for

each tested criteria, which will allow us to detect any functional non-conformances, as well as measure current standards compliance.

**Expected Outcomes:** A series of activities or actions that a real system user will need to be able to accomplish using ClinNext 10 to measure that the functionality is working as designed and demonstrates that the product meets ONC's functional specifications and standards compliance. In order to have a successful test result, the user must be able to successfully execute 100% of outcomes defined for the tested criteria. Any instance where a user is unable to perform an outcome will be thoroughly documented and included in the test results report that will be submitted to Drummond Group by February 28<sup>th</sup>, 2025.

Each test case included in this test plan was designed to ensure that in addition to accomplishing ONC's Real World testing requirements, it accomplishes the following goals:

- Validates that the functionality is working as designed.
- Ensures that the functionality adequately facilitates the activities performed by a real system user performing the tasks that the functionality was intended to facilitate.
- Whenever applicable, validating that the recipient of the transmitted information or file (a file generated in ClinNext 10 and sent to other system) acknowledges having received the file and being able to view it and consume it without any problems.
- Whenever applicable, validating that all data associated with the executed transaction is fully persisted on database and all stored data is accurate and complete.
- Structural validation of all generated C-CDA files will be performed using ClinNext 10 C-CDA validator. In order for the file to be deemed fully compliant, the validation should reflect no errors.

We are confident that by accomplishing those 5 objectives, we will be performing a full and thorough validation of all tested criteria, both from a usability as well as functional and standards compliance standpoint.

The Test Plan is organized so that for each tested criteria, we present the following sections (in that order). Those sections align with ONC's Real World test plan template and ONC Real World testing requirements.

- The testing process that will be used to demonstrate real world interoperability and functional and standards compliance. A justification explaining why the selected testing

process for the criteria was chosen, and why we understand it is the best possible testing approach.

- Care setting that will be used to conduct the test.
- Measures that will be used to demonstrate on-going interoperability and system usage.
- Detailed steps that will be followed to demonstrate functional and standards compliance.
- Scheduled of activities (aligned with the specified Test Steps) that must occur during the calendar year to fully execute the test plan and submit all findings to Drummond Group by February 28th, 2025.
- Execution result for each defined expected outcome; for a test to be declared successful, 100% of the defined outcomes must be met.

## Detailed Test plan:

### 170.315 (b)(1): Transition of Care

#### a. Testing Process & Approach Justification:

- This functionality will be evaluated in a real-world scenario by coordinating a date/time with a system user in a facility of one of our customers. SabiaMed personnel will visit the facility and observe the user transmitting a C-CDA file for a patient that has been transferred to an external facility, then contacting the receiving facility to validate that the C-CDA was received, and the recipient was able to download and open it without any problems. We will then locate the generated C-CDA file within the system database and validate it using ClinNext 10 CDA Validation tool to reassess standards compliance.
- *Justification:* We believe that the best way to test this functionality is by observing an actual system user performing the actions required to transfer a real patient to another facility, having the user send a C-CDA file to the receiving facility, validating that the receiving facility confirms having received the file and being able to open it, and validating that the generated C-CDA file is fully compliant with the standard by using ClinNext 10 CDA Validation tool.

The measure chosen to evaluate for ongoing usage, increased feature adoption, and ongoing interoperability is executing SQL queries against



the transactional tables on a quarterly basis. The query output will allow us to calculate how the documentation performance rate for the measure is evolving during the year. This trendline will give us a clear indication of the feature adoption trend. An up-trending performance trendline will be evidence of increased interoperability.

b. Care Setting:

The tested product, ClinNext 10, is only currently certified in the In-Patient domain. All patients that will be selected to conduct the test will be receiving services under that clinical setting.

c. Measures to demonstrate on-going interoperability:

- SQL queries will be executed against the transactional tables that stored the data/activity associated with this measure every quarter. This will allow us to calculate the performance rate where the Denominator is the number of patient encounters that meet the conditions necessary to be included in the patient population based on ONC functional specifications and the Numerator will be the number of patients within the Denominator where the required user action pertinent to this criteria (sending a C-CDA to the receiving facility for outgoing patient referrals) was performed in a timely manner at least once, based on ONC functional requirements. We will perform these measurements on a quarterly basis, calculate the performance rate, and plot a trendline of the incremental quarterly performance rate to assess increased user adoption and interoperability.
- Measurements:
  1. Number of patients that were transferred to other institutions for care continuity during the tested period.
  2. Number of C-CDAs that were generated for patient visits on which the patient ended up being transferred to another facility.
  3. % of patient transfers on which at least one C-CDA was generated and sent to the receiving facility.

d. Test Steps:



- A facility will be selected that currently use ClinNext 10 v.1.0
- A date and time will be coordinated with a system user at the selected facility that currently uses the “Send C-CDA” functionality that allows them to send C-CDA documents when referring patients to an external facility.
- In the coordinated date/time, a resource from Sabiamed’s team will visit the facility and observe the user sending a Referral Summary C-CDA of a patient that requires to be transferred to another facility. The C-CDA will be transferred to the receiving facility via SMTP protocol.
- The receiving facility will be contacted to validate that they received the C-CDA file and were able to Download it and open it without complications.
- The record associated with the C-CDA generation event will be located within our system database, and the generated C-CDA will be validated using ClinNext 10 validation tool to test for standards compliance.

e. Expected outcomes:

- The user can generate and send the C-CDA file to the receiving facility.
- The receiving facility acknowledges having received the C-CDA file.
- The receiving user can download the C-CDA file.
- The receiving user can open and view the file in the human readable version (.html) of the C-CDA.
- The inspected file shows no visual malformations.
- The generated C-CDA file is stored in the system database.
- The generated file passes compliance validation using ClinNext 10 CDA Validation tool.

f. Scheduled Activities:

- Identify facility to be used to perform the test and a system user that will be assisting with the test by January 15, 2025.
- Perform test and document test results by February 15, 2025.
- Send a test result report to Drummond Group by February 28<sup>th</sup>, 2025. specifying which of the outcomes were achieved. For outcomes that were not achieved, detail will be provided as to why the outcome was not met.

## 170.315 (b)(2): Clinical Information Reconciliation and Incorporation

### a. Testing Process & Approach Justification:

- This functionality will be evaluated in a real-world scenario by coordinating a date/time with a real system user. SabiaMed personnel will visit the facility and observe a user receiving a C-CDA file for a real patient that has been transferred into their facility. We will observe the process used to receive the C-CDA file, select a patient record to reconcile the C-CDA into, import the C-CDA file into the system for the selected patient, and reconciling Diagnosis, Medication, and Allergy data into the patient's clinical record. We will then locate the imported C-CDA file within the database and validate it using ClinNext 10 CDA Validation tool. We will then open the patient record to validate that the imported data is present. Finally, we will generate a new C-CDA file after the export has been completed to ensure that the newly imported data is included in the C-CDA file and that the file successfully validates in ClinNext 10 CDA validation tool.
- Justification: We believe that the best way to test this functionality and verify that it works as designed is by observing an actual system user receiving a C-CDA file from a facility that transferred a patient into their facility, observing that the user is able to perform the data reconciliation process, validating that all reconciled data is correctly committed to database, validating that newly reconciled data is included in future C-CDA files, and validating that those files are compliant with the standards by using ClinNext 10 C-CDA Validator.

The measure chosen to assess for ongoing usage, increased feature adoption, and ongoing interoperability is executing SQL queries against the transactional tables on a quarterly basis. The query output will allow us to calculate how is the documentation performance rate for the measure is evolving during the year. This trendline will give us a clear indication on feature adoption. An up-trending performance trendline will be evidence of increased interoperability and usage.

b. Care Setting:

The tested product, ClinNext 10, is only currently certified in the In-Patient domain. Patients that will be selected to conduct the test will be receiving services under that clinical setting.

c. Measures to demonstrate on-going interoperability:

SQL queries will be executed against the transactional tables that store the data/activity associated with this measure every quarter. This will allow us to calculate the performance rate; where the Denominator is the number of patient encounters that meet the conditions necessary to be included in the patient population based on ONC functional specifications, and the Numerator will be the number of patients within the Denominator where the required user action (performing a C-CDA reconciliation for incoming patient referrals) was performed in a timely manner at least once, based on ONC requirements. We will perform these measurements on a quarterly basis, calculate the performance rate, and plot a trendline of the incremental quarterly performance rate to assess increased user adoption and interoperability.

- Measurements:

1. Number of patients that were received from other institutions as incoming referrals during the tested period.
2. Number of C-CDAs that were attached and reconciled to Incoming referral encounters.
3. % of Incoming referrals with an attached and reconciled C-CDA file during the tested period.

d. Test Steps:

- A facility will be selected that currently use ClinNext 10 v.1.0

- A date/time will be coordinated with a system user at the selected facility that currently uses the C-CDA Reconciliation process for incoming referrals.
  - At the coordinated date/time, a resource from SabiaMed's team will visit the facility and observe the user receiving a C-CDA file for a real patient that was transferred into their facility and observe how was the data reconciliation process performed.
  - The user will receive the C-CDA file and perform a full C-CDA reconciliation of the received clinical data, including all allergies, diagnoses, and medications.
  - After reconciliation, it will be validated that the reconciled file is accessible and viewable in the patient's record, and that all reconciled data was correctly stored into the system.
  - A new C-CDA file will be generated after data reconciliation is performed.
  - The new C-CDA file will be visually inspected to ensure that it contains all newly reconciled data and contains no cosmetic malformations.
  - The newly generated C-CDA file will be validated using ClinNext 10 CDA validation tool to evaluate for compliance with the applicable standards.
- e. Expected outcomes:
- The user can import the received C-CDA file to the patient record.
  - The user can perform a full data reconciliation, including medications, diagnoses, and allergies of the received C-CDA file into the patient record.
  - Both the C-CDA file and all reconciled data are correctly reconciled to the patient record
  - The reconciled C-CDA file is accessible and viewable from within the patient record.
  - All reconciled data is correctly and fully persisted to the database (this will be validated by executing SQL queries against transactional tables for allergies, medications, and problems).



- All newly reconciled data is accessible from within the patient medical record.
- A C-CDA file generated after reconciliation is performed includes all reconciled data.
- A C-CDA file generated after reconciliation was performed passes validation using ClinNext 10 CDA Validation tool.

f. Scheduled Activities:

- Identify a facility to be used to perform the test and system user that will be assisting with the test by January 15, 2025
- Perform test and document all test results by February 15th, 2025.
- Send a test result report to Drummond Group by February 28th, 2025, specifying which of the outcomes were achieved. For outcomes that were not achieved, detail will be provided as to why the outcome was not met.

### 170.315 (b)(3): Electronic Prescribing

a. Testing Process & Approach Justification:

- This functionality will be tested in a real-world scenario by coordinating a date/time with a system user. On the scheduled date/time a resource from SabiaMed's team will visit the facility and observe the process of a physician using the e-Prescription functionality to send prescriptions for real patients. We will observe the process used to launch the e-Prescribing module, selecting the medications to be e-prescribed, observing the documentation process, and validating that the prescription is correctly persisted into the database with all prescription information including route, medication, instructions, and dosage. We will then contact the pharmacy to which the prescription was transmitted to validate that they received it and were able to fill it.
- Justification: We believe that the most realistic approach to evaluate this functionality and verify that it works as designed it by observing an actual system user documenting a real prescription for a patient, validating that

the prescription was correctly received at the pharmacy, and that they were able to fill it.

The measure chosen to evaluate for ongoing usage, increased feature adoption, and ongoing interoperability is executing SQL queries against the transactional tables on a quarterly basis. The query output will allow us to calculate how is the documentation performance rate for the measure evolving during the year. This trendline will give us a clear indication on feature adoption. An up-trending performance trendline will be evidence of increased interoperability and usage.

b. Care Setting:

The tested product, ClinNext 10, is only currently certified in the In-Patient domain. Patients that will be selected to conduct the test will be receiving services under that clinical setting.

c. Measures to demonstrate on-going interoperability:

SQL queries will be executed against the transactional tables that store the data/activity associated with this measure every quarter. This will allow us to calculate the performance rate where the Denominator is the number of patient encounters that meet the conditions necessary to be included in the patient population based on ONC functional specifications and the Numerator will be the number of patients within the Denominator where the required user action (placing the prescriptions electronically) was performed, based on ONC requirements. We will perform these measurements on a quarterly basis, calculate the performance rate and plot a trendline with the four samples.

• Measurements:

1. Number of prescriptions that were generated though the system, both electronically though ClinNext 10 prescription module and prescriptions sent to a pharmacy through e-Prescribing during the tested period.

2. Number of prescriptions generated and transmitted through e-Prescribing during the tested period.
3. % of total prescriptions generated through e-Prescribing during the tested period.

d. Test Steps:

- A facility will be selected that currently use ClinNext 10 v.1.0
- A date/time will be coordinated with a system user that currently uses the e-Prescription functionality.
- At the coordinated date/time, a resource from Sabiamed's team will visit the facility and observe the process of a physician documenting and transmitting an electronic prescription for a real patient to their preferred pharmacy.
- The selected pharmacy will be contacted to validate that they received the prescription and that it contains all the required information to be able to fill it.
- We will validate that all prescription data is completely and correctly persisted into the database by executing SQL queries against the corresponding transactional tables.

e. Expected outcomes:

- The physician can launch the e-Prescribing module.
- The physician can document and transmit an electronic prescription for a real patient.
- The pharmacy validates that they received the prescription.
- The pharmacy validates that they were able to fill the prescription.
- We validate that all prescription data is completely and correctly committed to database.

f. Scheduled Activities:

- Identify facility to be used to perform the test and system user that will be assisting with the test by January 15, 2025
- Perform test and document all test results by February 15, 2025

- Send a test result report to Drummond Group by February 28<sup>th</sup>, 2025, specifying which of the outcomes were achieved. For outcomes that were not achieved, detail will be provided as to why the outcome was not met.

b. Relied upon software: DoseSpot

#### 170.315 (b)(6): Data Export

a. Testing Process & Approach Justification:

- This functionality will be tested in a real-world scenario by coordinating a date with a system user where SabiaMed personnel can visit the facility and observe a user performing a Data Export for a group of patients of their choosing. A minimum of ten patients must be selected for this test. We will observe the process used to generate the C-CDA files on batch of the selected patients. A random sample of 3 out of the 10 generated files will be inspected by the user and SabiaMed's personnel to validate that they are properly formatted. Finally, a random sample of 3 out of the 10 generated C-CDA files in XML format will be validated using ClinNext 10 CDA Validator.
- Justification: We believe that the best way to test this functionality and verify that it works as designed it by observing an actual system user generating a set of C-CDA in batch for a group of patients, which is the function that the functionality is intended to provide; validating that all human readable files are properly formatted and that the XML files pass a validation test using ClinNext 10 CDA validator to ensure standards compliance.  
This is a functionality that is not commonly used within the system, and we proposed a survey approach to assess usage and interoperability of this feature. We will ask a group of users whether they have used the functionality, whether they experienced any issues with it, and other relevant questions that will allow us to assess how frequently they are performing patient data export.



b. Care Setting:

The tested product, ClinNext 10, is only currently certified in the In-Patient domain. Patients that will be selected to conduct the test will be receiving services under that clinical setting.

c. Measures to demonstrate on-going interoperability:

We will perform a brief questionnaire on a quarterly basis to a selected group of users that are likely to use this feature asking relevant questions that will allow us to assess how frequently they are performing Patient Exports and whether they had experienced any problems performing the process.

- Measurements:

1. Total number of C-CDA file generated on the system during the tested period.

d. Test Steps:

- A facility will be selected that currently use ClinNext 10 v.1.0
- A date/time will be coordinated with a system user that currently uses the functionality to be evaluated.
- At the coordinated date/time, a resource from Sabiamed's team will visit the facility and observe the process of the user performing a data export for a set of patients, of no less than 10 patients.
- The exported human readable version of 3 of the generated C-CDA files will be visually inspected to detect any cosmetic malformations.
- 3 of the exported C-CDA files in XML format will be tested using ClinNext 10 CDA Validator to test compliance.

- Expected outcomes:

- The user can perform the data export for a user-selected group of 10 patients.

- The human readable version of the C-CDA files is correctly formatted, readable, and shows no cosmetic malformations.
- XML version of the generated C-CDA files pass a validation test using ClinNext 10 CDA Validation tool.
- Scheduled Activities:
  - Identify facility to be used to perform the test and system user that will be assisting with the test by January 15, 2025
  - Perform test and document all test results by February 15, 2025
  - Send a test result report to Drummond Group by February 28<sup>th</sup>, 2025. specifying which of the outcomes were achieved. For outcomes that were not achieved, detail will be provided as to why the outcome was not met.

#### 170.315 (c)(1): Clinical Quality Measures - Record and Export

##### a. Testing Process & Approach Justification:

- This functionality will be tested in a real-world scenario by coordinating a date with a system user where SabiaMed personnel can visit the facility and observe a user executing an eCQM report for 2 measures that they currently report to CMS whose IPP contains 2 real patients (2 patients by measure) that have been treated in the facility in the 4 weeks preceding the visit. The system user will perform all functions including identifying the patients to be used for the test and evaluating whether the patients should fall within the DEN/NUM/NOT MET/or EXCL populations of the selected measures. Then an eCQM report will be executed for the time period containing those visits to ensure that the calculated values match the expected values based on the documented clinical data. Then the QRDA I files for those patients will be exported and the generated files will be tested using Cypress test tool. Both standards compliance and calculations will be validated.
- Justification: We believe that the best way to test this functionality and verify that it works as designed is by having a user that is currently

involved in the facility compliance team select patients that they know meet certain clinical criteria that makes them fall within 2 measures that they currently submit to CMS and comparing the calculated values for those measures to ensure that the patients are included in the correct measure populations. The most effective way to evaluate for conformance of the exported QRDA files and calculations is by importing the generated QRDA I files into cypress to analyze. To assess ongoing use of this functionality we propose a survey approach to test usage of this feature. We will ask users that normally use the e-CQM module whether they have used the functionality, whether they experienced any issues with it, and other relevant questions that will allow us to assess how frequently they are generating eCQM reports and whether there are any functional deficiencies or defects.

b. Care Setting:

The tested product, ClinNext 10, is only currently certified in the In-Patient domain. Patients that will be selected to conduct the test will be receiving services under that clinical setting.

c. Measures to demonstrate on-going interoperability:

We will perform a brief questionnaire on a quarterly basis to a selected group of users that are likely to use this feature asking relevant questions that will allow us to assess how frequently they are executing e-CQM reports and whether they had experienced any problems performing the process.

• Measurements:

1. Number of patient visits and all underlying clinical data that was stored in the database after being captured by the end user that is available for eCQM measure calculations and QRDA I file generation.

d. Test Steps:

- A facility will be selected that currently use ClinNext 10 v.1.0
- A date/time will be coordinated with a system user that currently uses ClinNext 10 e-CQM module.
- The user will identify two patients that are contained within 2 e-CQM measures that the facility currently reports to CMS prior to the visit.
- At the coordinated date/time, a resource from SabiaMed's team will visit the facility and observe the process of the user generating the report for the selected two measures for the period that contains those 4 visits.
- Both the calculated values for those measures and the detailed patient list within the generated report will be inspected to ensure that all selected patients fall in the correct populations within the two tested measures, when compared against the documented clinical data.
- The generated QRDA I files will be imported into Cypress to validate standards compliance, calculate on which measures and populations those four patients reside, and compare that with the calculations performed by ClinNext 10 e-CQM module. The results must match.

e. Expected outcomes:

- The user can execute an e-CQM report for the selected 2 measures.
- The two patients identified for each of the 2 measures are listed in the correct measure populations.
- The user is able to perform an export containing QRDA I files for the 4 patients.
- SabiaMed's resource is able to import the 4 QRDA I files into Cypress validation tool without errors.
- Cypress validation tool returns no conformance errors in any of the four files.
- Cypress calculations match the calculations performed by the system eCQM module, for both measures.



f. Scheduled Activities:

- Identify a facility to be used to perform the test and system user that will be assisting with the test by January 15, 2025
- The selected facility will need to identify the four patients and two measures to be used for the test by January 22<sup>nd</sup>, 2025.
- Perform test and document all test results by February 15, 2025
- Send a test result report to Drummond Group by February 28<sup>th</sup>, 2025. specifying which of the outcomes were achieved. For outcomes that were not achieved, detail will be provided as to why the outcome was not met.

170.315 (c)(2): Clinical Quality Measures - Import and Calculate

a. Testing Process & Approach Justification:

- This functionality will be evaluated in a real-world scenario by coordinating a date/time with a system user where SabiaMed personnel can visit the facility and observe a user performing a QRDA I data import of a Cypress Generated data set containing patients for two user selected measures that the facility currently reports to CMS. The user will perform the Data Import and inspect where the patients fall within the two selected measure populations. The user will then generate the report and perform an export that will contain the QRDA I files for the imported patients. The QRDA I files will be uploaded into Cypress for validation. Cypress generated data and the exported data set will be compared to ensure that there is a full match.
- Justification: We believe that the best way to test this functionality and verify that it works as designed it by having a user performing a real import of patients into the system for 2 measures that they currently submit to CMS, performing an export from the system that will contain those patients and load the exported data into Cypress for calculation

validation. The Cypress tool will validate both standards compliance as well as calculations.

Bulk QRDA I import is a feature not commonly used within the system. To assess ongoing use of this functionality we propose a survey approach to evaluate usage of this particular QRDA I import feature. We will ask users that normally use the e-CQM module whether they have used the QRDA1 Import functionality, whether they experienced any issues with it, and other relevant questions that will allow us to assess how frequently they are importing data and executing e-CQM reports against the imported data.

b. Care Setting:

- The tested product, ClinNext 10, is only currently certified in the In-Patient domain. Patients that will be selected to conduct the test will be receiving services under that clinical setting.

c. Measures to demonstrate on-going interoperability:

Bulk QRDA I import is a feature not commonly used within the system. To measure ongoing use of this functionality will perform a brief questionnaire on a quarterly basis to a selected group of users that are potential users of the Import feature asking relevant that will allow us to assess how frequently they are importing QRDA I files and generating e-CQM reports and whether they had experienced any problems performing the process.

- Measurements:

1. Number of QRDA III files generated during the test period.

d. Test Steps:

- A facility will be selected that currently use ClinNext 10 v.1.0
- A date/time will be coordinated with a system user that currently uses ClinNext 10 e-CQM module.

- The user will identify 2 e-CQM measures that the facility reports to CMS prior to the visit.
- SabiaMed resource will produce a Cypress data set for the two selected measures prior to the test.
- At the coordinated date/time, a resource from SabiaMed’s team will visit the facility and observe the process of the user importing the Cypress data set into the system.
- The user will perform a data export for the time range that contains those patients.
- The QRDA I files corresponding to the patients in the imported data will be isolated (this is necessary since this is a live system and real patients will be included in the exported data set).
- The QRDA I files for the patients matching the Cypress data set will be imported back into Cypress for calculations validation.
- Cypress results will be analyzed and documented. The result should be a 100% success rate for all measures tested within Cypress.
- The imported test data is deleted from the system to restore the system to the pre-test state.

e. Expected outcomes:

- The user is able to import the Cypress generated data set for the two identified measures without errors.
- The user is able to run a report for the date range that contains the imported data set and observe where those 2 patients fall within the measure populations of each of the 2 selected measures.
- The user is able to perform an export containing the QRDA I files for the 4 imported patients within the 2 selected measures.
- SabiaMed’s resource can import the exported data set into Cypress without errors.
- Cypress validation tool returns no standards compliance errors in any of the 4 imported QRDA I files.

- Cypress compares the calculations with the imported data set with the calculations on the Cypress generated data set and reports no mismatches in any of the two tested measures (pass result).

f. Scheduled Activities:

- Identify facility to be used to perform the test and system user that will be assisting with the test by January 15, 2025
- Sabiamed's resource will need to generate a Cypress data set for all the selected two measures by January 22<sup>nd</sup>, 2025.
- Perform test and document all test results by February 15th, 2025.
- Send a test result report to Drummond Group by February 28<sup>th</sup>, 2025, specifying which of the outcomes were achieved. For outcomes that were not achieved, detail will be provided as to why the outcome was not met.

#### 170.315 (c)(3): Clinical Quality Measures – Report

a. Testing Process & Approach Justification:

- This functionality will be tested in a real-world scenario by coordinating a date/time with a system user where Sabiamed personnel can visit the facility and observe a user executing an e-CQM report for 2 user selected measures and exporting the resulting QRDA I files.
- Justification: We believe that the best way to evaluate this functionality and verify that it works as designed, is by having a user executing a report on 2 measures that they are familiar with, ideally measures that they report to CMS and performing an export of the corresponding QRDA I files.

b. Care Setting:

The tested product, ClinNext 10 v1.0, is only currently certified in the Inpatient domain. Patients that will be selected to conduct the test will be receiving services under that clinical setting.

c. Measures to demonstrate on-going interoperability:



Bulk QRDA I import is a feature not commonly used within the system. To measure ongoing use of this functionality will perform a brief questionnaire on a quarterly basis to a selected group of users that are potential users of the Import feature asking relevant that will allow us to assess how frequently they are importing QRDA I files and generating e-CQM reports and whether they had experienced any problems performing the process.

- Measurements:

1. Number of QRDA I files generated during the tested period.

d. Test Steps:

- A facility will be selected that currently use ClinNext 10 v.1.0
- A date/time will be coordinated with a system user that currently uses ClinNext 10 e-CQM module.
- The user will identify 2 e-CQM measures that the facility reports to CMS prior to the visit.
- SabiaMed resource will produce a Cypress data set for the two selected measures prior to the test.
- In the coordinated date/time, a resource from SabiaMed's team will visit the facility and observe the process of the user importing the Cypress data set into the system.
- The user will perform a data export for the time range that contains those patients.
- The QRDA Category I files corresponding to the patients in the imported data will be isolated (this is necessary since this is a live system and real patients will be included in the exported data set).
- The QRDA Category I files for the patients matching the Cypress data set will be imported into Cypress for calculations validation.
- Cypress results will be analyzed and documented. The result should be a 100% success rate for all measures tested within Cypress.
- The imported test data is deleted from the system.

d. Expected outcomes:

- The user can import the Cypress generated data set for the 2 identified measures without errors and without developer assistance.
- The user is able to run a report for the date range that contains the imported data set and observe where that the imported patients fall within the populations of each of the 2 selected measures.
- The user can perform an export containing the QRDA Category I files for the imported patients within the 2 selected measures.
- SabiaMed's resource can import the exported data set into Cypress without errors.
- Cypress validation tool returns no standards compliance errors in any of the imported QRDA Category I files.
- Cypress compares the calculations with the imported data set with the calculations on the Cypress generated data set and reports no mismatches in any of the two tested measures.

e. Scheduled Activities:

- Identify facility to be used to perform the test and system user that will be assisting with the test by January 15, 2025
- SabiaMed's resource will need to generate a Cypress data set for all the selected two measures by January 22, 2025.
- Perform test and document all test results by February 15, 2025
- Send a test result report to Drummond Group by February 28, 2025, specifying which of the outcomes were achieved. For outcomes that were not achieved, detail will be provided as to why the outcome was not met.

**170.315 (e)(1): View, Download, and Transmit to 3rd Party**

a. Testing Process & Approach Justification:

- This functionality will be evaluated in a real-world scenario by coordinating a date/time with a real system user in a facility that will perform the test. At the scheduled date/time, a resource from SabiaMed's team will visit the facility and observe the user registering a test patient within the system, granting Portal access to the patient,

documenting the following clinical sections for the test patient: Allergies, Medications, Diagnoses, Family History, and Vital Signs, and generating a Discharge Summary C-CDA for the patient. The user will then complete the Registration into the patient portal, access the portal profile and inspect each of the selected clinical sections (Allergies, Medications, Diagnoses, Family History, and Vital Signs) to verify that all information matches the one documented. Finally, the user will visit the audit log to verify that there are audit events registered for the login event, for every section that was viewed, as well as for the C-CDA generation event.

- Justification: We believe that the most realistic way to test this functionality and verify that it works as designed it by having a user acting as all clerk, nurse and patient (for privacy reasons, a real patient was not selected for this test), granting portal access to the test patient, documenting a set of clinical data for the patient, generating a C-CDA file, and then observing that what is reflected within the patient's portal account is 100% accurate.

To assess ongoing use of this functionality we will perform a set of SQL queries against the PatientPortalAuditLog table within the system. This table contains all the activities generated by all users of the patient portal. This activity will be performed on a quarterly basis to be able to draw trendlines of the measured transactions (e.g., Logins, CDA exports, View Clinical Data, etc.) and assess ongoing usage.

b. Care Setting:

The tested product, ClinNext 10, is only currently certified in the In-Patient domain. Patients that will be selected to conduct the test will be receiving services under that clinical setting.

c. Measures to demonstrate on-going interoperability:

SQL queries will be executed against the Patient Portal Audit Log, a transactional table that stores all data/activity associated with the use of the patient portal. This will allow us to calculate patient login volume, view clinical

info. volume, C-CDA transmission volume, and other representative measures to access on-going patient portal usage. We will perform these measurements on a quarterly basis, to establish the annual usage trendline that will allow us to conclude whether usage and interoperability are improving over time.

- Measurements:

1. Total number of new patient visits during the tested period
2. Total number new patients for which portal access was granted.
3. Total number of patients with granted access to logged into the Portal and performed at least one View, Download, or Transmit transaction.
4. % of new patients for which access to the patient portal was granted during the tested period.
5. % of patients granted access who logged-in and used the patient portal during the tested period.

d. Test Steps:

- A facility will be selected that currently use ClinNext 10 v.1.0
- A date/time will be coordinated with a real system user that has knowledge of the following functionalities: registration, granting access to the patient portal, medical record documentation, and C-CDA generation.
- At the coordinated date/time, a resource from Sabiamed's team will visit the facility and observe the process of the user performing these actions:
  - Registering a test patient
  - Granting portal access to the test patient
  - Reading the system generated "Welcome to the Patient Portal" email and completing the registration and 2-step authentication process.
  - Documenting the following information into the patient's medical record: Allergies, Medications, Diagnoses, Family History, and Vital Signs



- Generating a Discharge Summary C-CDA for the patient
- Login into the Patient Portal account as the test patient
- Validating that all patient demographic information is accurate.
- Validating that all clinical information is accurate.
- Validating that an audit log entry was captured for the login event.
- Validating that an audit log entry was captured for each clinical section viewed by the user.
- Validating that an audit log entry was captured for the C-CDA generation event.
- Validating that the generated C-CDA file is viewable from within the patient portal.

e. Expected outcomes:

- The user can successfully grant a patient access to the Patient Portal
- The patient receives a patient portal registration welcome e-mail.
- The patient is able to complete the registration process by clicking on the registration link contained in the welcome e-mail.
- Once registration is completed, the patient is able to perform the 2-step authentication process and login into the Patient Portal account.
- The patient is able to view all clinical information that was captured.
- The patient is able to view audit events for all sections visited as well as for C-CDA generation requests performed by the facility against his clinical profile.
- The patient is able to View C-CDA files generated against his clinical profile.
- All inspected files are fully readable and contain no mal formations.

f. Scheduled Activities:

- Identify facility to be used to perform the test and system user that will be assisting with the test by January 15, 2025

- Perform test and document all test results by February 15th, 2025.
- Send a test result report to Drummond Group by February 28<sup>th</sup>, 2025, specifying which of the outcomes were achieved. For outcomes that were not achieved, detail will be provided as to why the outcome was not met.

#### 170.315 (f)(1): Transmission to Immunization Registries

##### a. Testing Process & Approach Justification:

- This functionality will be evaluated in a real-world scenario by coordinating a date with a system user where SabiaMed personnel can visit the facility and observe a user successfully transmitting Immunization HL7 records to the Puerto Rico Electronic Immunization System (PREIS). The user will select a patient for which Immunization records have been documented and use the Export functionality within the immunization documentation module to generate and transmit the Immunization HL7 records to the PREIS.
- Justification: We understand that the most realistic way to evaluate this functionality and verify that it works as designed it by having a user transmitting Immunization records of real patients to an ONC compliant IIS and validating that the IIS was able to successfully receive and process the HL7 files with no errors. For this test, the PREIS, which is the IIS implemented by the Puerto Rico Health Department to exchange electronic Immunization records will be used.

The measure chosen to assess for ongoing usage, increased feature adoption, and ongoing interoperability is executing SQL queries against the transactional tables on a quarterly basis. The query output will allow us to calculate the cumulative immunization transmission rate and establish a transmission rate trendline. This trendline will give us a clear indication of feature adoption and transmission rates. An up trending trendline will be evidence of increased interoperability and usage.

b. Care Setting:

The tested product, ClinNext 10, is only currently certified in the In-Patient domain. Patients that will be selected to conduct the test will be receiving services under that clinical setting.

c. Measures to demonstrate on-going interoperability:

SQL queries will be executed against the transactional tables that stored the data/activity associated with transmission of Immunization HL7 files to other systems. Measurements will be taken every quarter. This will allow us to calculate the cumulative transmission rate, establish a trendline, and determine whether interoperability rate and usage are improving.

• Measurements:

1. Total number of patients for which at least one vaccination was documented during the tested period.
2. Total number of patients for which vaccination information was transmitted to Puerto Rico electronic Immunization System (PREIS).
3. % of patients with vaccination information documented for which information was actually electronically transmitted to PREIS.

d. Test Steps:

- A facility will be selected that currently use ClinNext 10 v.1.0
- A date/time will be coordinated with a system user that currently uses ClinNext 10 Immunization module.
- The user will identify two patients for which Immunization information was documented not more than 2 weeks prior to the test.
- In the coordinated date/time, a resource from SabiaMed's team will visit the facility and observe the documented immunizations for the 2 selected patients.
- The user will transmit the immunization records to the PREIS, and the PREIS returns no errors when processing the files.
- The user will perform an Import for those two patients in order to validate that the immunization information persisted in PREIS

matches the immunization information that was documented for the patients in ClinNext 10.

e. Expected outcomes:

- The user can successfully generate an export the patient Immunization record for the 2 selected patients to the IIS/PREIS
- The user is able to Import the immunization record for those 2 patients in order to view the immunization information that was stored in the PREIS (IIS) for each of the patients.
- The imported immunization information matches the immunization record that was transmitted.

f. Scheduled Activities:

- Identify facility to be used to perform the test and system user that will be assisting with the test by January 15, 2025
- User will need to identify two patients, each containing immunization information captured not more than 2 weeks prior to the test.
- Perform test and document all test results by February 15th, 2025.
- Send a test result report to Drummond Group by February 28<sup>th</sup>, 2025, specifying which of the outcomes where achieved. For outcomes that were not achieved, detail will be provided as to why the outcome was not met.

### 170.315 (f)(3): Transmission to Public Health Agencies - Reportable Laboratory Tests and Values/Results

a. Testing Process & Approach Justification:

- For this test will need the participation of Health Gorilla, the entity designated by the Puerto Rico Department of Health to receive Laboratory Results in HL7 v. 2.5.1 format. All of our customers are currently connected to the Health Gorilla platform and Lab. Results information is currently being exchanged. Health Gorilla processes and



reconciles these files into a central repository. The most realistic test we can perform involves placing Lab. Results for real patients and validating that the corresponding HL7 files are being generated and successfully transmitted to Health Gorilla. The validation will consist of 2 steps: (1) having Health Gorilla confirm that they received the file and were able to process it.

- Justification: We believe that the most realistic test that we can perform to validate this functionality is by observing the Lab. Results HL7 generation process generating and transmitting Lab. Results file to the only entity in Puerto Rico that is authorized by the Department of Health as a Health Information Exchange, Health Gorilla, and having them confirm that they received the file and were able to process it.

The measure chosen to test for ongoing usage, increased feature adoption, and ongoing interoperability is executing SQL queries against the transactional tables on a quarterly basis. The query output will allow us to calculate the cumulative Laboratory Result HL7 transmission rate and establish a transmission rate trendline. This trendline will give us a clear indication on feature adoption and transmission rates. An up trending trendline will be evidence of increased interoperability.

b. Care Setting:

The tested product, ClinNext 10, is only currently certified in the In-Patient domain. Patients that will be selected to conduct the test will be receiving services under that clinical setting.

c. Measures to demonstrate on-going interoperability:

SQL queries will be executed against the transactional tables that stored the data/activity associated with transmission of Reportable Lab. HL7 files to other systems. Measurements will be taken every quarter. This will allow us to calculate the cumulative transmission rate, establish a

trendline, and determine whether reportable lab. HL7 transmission rate is improving over time.

• Measurements:

1. Total number of patients with lab. Results documented to the visit record during the tested period.
2. Out of the number of patients with documented results, how many of them have a transaction of an Lab. HL7 generated in the system.
3. % of patients with laboratory results for which at least one reportable HL7 lab. Results file was generated.

d. Test Steps:

- A facility will be selected that currently use ClinNext 10 v.1.0
- A date/time will be coordinated with a laboratory at the selected facility and a technical resource at PRDoH Health Gorilla
- In the coordinated date/time, a resource from SabiaMed's team will visit the facility and observe the process of the laboratory user documenting lab. results for 2 real patients and transmitting the Information to PRDoH Health Gorilla
- PRDoH Health Gorilla will review the received files for content and structure.
- The information in both HL7 files will be compared with the Lab results that were documented for each patient to validate there are no data inconsistencies.

e. Expected outcomes:

- The user is able to fully document the lab. test results for the 2 selected patients
- The user is able to transmit the HL7 files to PRDoH Health Gorilla
- PRDoH Health Gorilla is able to receive and process the files
- The information in both files match the documented lab. test results

f. Scheduled Activities:

- Identify facility to be used to perform the test and system user that will be assisting with the test as well as a technical resource from PRDoH Health Gorilla by January 15, 2025
- Perform test and document all test results by February 15<sup>th</sup>, 2025
- Send a test result report to Drummond Group by February 28<sup>th</sup>, 2025, specifying which the of the outcomes where achieved. For outcomes that were not achieved, detail will be provided as to why the outcome was not met.

170.315 (f)(5): Transmission to Public Health Agencies - Electronic Case Reporting

a. Testing Process & Approach Justification:

- This functionality will be tested in a real-world scenario by coordinating a date/time with a system user where SabiaMed personnel can visit the facility and observe a user creating a trigger (selection criteria) for a diagnosis of their preference, executing that trigger within the Case Reporting module in order to generate a patient list for the trigger, and generating the resulting set of C-CDA files for the generated patient list. A SQL query will be executed against the facility database for patients that have the selected diagnosis coded, to ensure that the results are a perfect match.
- Justification: We believe that the ideal way to test this functionality and verify that it works as designed it by having a user creating a meaningful trigger for a diagnosis of their choosing, executing the report against the trigger, and validating using SQL queries that there are no patients missing or extra patients not belonging to the population (based on the tested trigger). Interoperability will be tested by validating all generated C-CDA files using ClinNext 10 CDA validation tool, to ensure that they are fully compliant with the standard and can therefore be properly processed by a receiving system.

b. Care Setting:

The tested product, ClinNext 10, is only currently certified in the In-Patient domain. Patients that will be selected to conduct the test will be receiving services under that clinical setting.

c. Measures to demonstrate on-going interoperability:

The user will create a patient list using the Care Reporting module based on a trigger diagnosis of their choosing and will proceed to generate the patient list based in the selected trigger. The tester will provide SabiaMed the configured set of diagnosis and we will validate that the set of returned patients for the report is correct for the specified trigger, by running SQL queries against the database and comparing the demographic information in each C-CDA matches the patient data retrieved by the query. All generated C-CDA files will be visually inspected and validated using ClinNext 10 C-CDA validation tool to validate the structural compliance of all files. A successful validation (0 errors) will be required to ensure interoperability compliance (i.e., ensure that an ONC certified receiving system will be able to properly process the received C-CDA files).

- Measurements:

1. Total number of triggers created on the system during the tested period.

d. Test Steps:

- The user will create a patient list using a diagnosis based trigger of their choosing.
- The user will execute the report for the selected trigger
- All generated C-CDA files will be visually inspected
- A SQL query will be executed against the DB for the same trigger criteria.



- The results of the SQL query will be compared with the list of generated C-CDA files, specifically the demographic information in the C-CDA files. The results must match.
- All generated C-CDA files will be visually inspected to ensure there are no visual malformations or readability issues.
- All generated C-CDA files will be validated using the ClinNext 10 C-CDA validation tool to ensure full compliance with the standard and therefore ensure interoperability with receiving systems.

e. Expected outcomes:

- The user is able to create/configure a patient a list for a diagnosis based trigger of their choosing using the Case Reporting module
- The user is able to successfully generate the list for the selected trigger criteria and is able to access the generated C-CDA files.
- The demographic information in the generated C-CDAs matches the list of patients obtained by executing a SQL query against the DB for the same trigger criteria, to ensure functional compliance.
- All generated C-CDA files will be validated using ClinNext 10 CDA Validation tool, to ensure interoperability compliance.

g. Scheduled Activities:

- Identify facility to be used to perform the test and system user that will be assisting with the test as well as a technical resource from Health Gorilla by January 15, 2025
- Perform test and document all test results by February 15<sup>th</sup>, 2025
- Send a test result report to Drummond Group by February 28<sup>th</sup>, 2025, specifying which the of the outcomes where achieved. For outcomes that were not achieved, detail will be provided as to why the outcome was not met.

## 170.315 (g)(7): Application Access - Patient Selection

### a. Testing Process & Approach Justification:

- The way this functionality will be tested is by coordinating a date/time with a facility to perform the test. The test will consist in performing several SQL queries for various combinations on patient demographic information and using Postman in order to place requests with matching demographic information and validating that the patient list returned by the service matches the query output for each set of parameters. A matching set of patients for each test indicates that the service is working correctly.
- Justification: Currently none of our customers has the API open to third party applications. Given that fact, the most realistic test we can perform is to provision a test app. within in the test facility's database and using Postman to simulate a 3<sup>rd</sup> party application placing secured service API calls.

On-going usage of this measure cannot be assessed since none of our customers have opened the API to other parties. However, we will perform a brief quarterly inquiry to determine if or when they are planning to open the API to third party developers.

### b. Care Setting:

The tested product, ClinNext 10, is only currently certified in the In-Patient domain. Patients that will be selected to conduct the test will be receiving services under that clinical setting.

### c. Measures to demonstrate on-going interoperability:

Measurements:

Number of calls received though the API for Patient Search.

### d. Test Steps:

- A test date/time will be coordinated with the selected facility
- At the scheduled date/time, we will perform 3 queries against the facility database: one for patient last name, another for patient first

name and last name, and another one for patient first name, last name and date of birth. The results of each query will be saved as a reference data set.

- We will provision a test application that will emulate a third-party application placing Restful calls to the API
- Service calls will be setup in postman, one for each of set of parameters for which each SQL query was executed: patient last name, patient first name and last name, and patient first name, last name and date of birth
- The data returned for each service call will be compared with the reference result set of the corresponding SQL query. There should be a matching data set for each service call.

e. Expected outcomes:

- The tester is able to provision a test application within the facility's database (emulating a real third-party application).
- Using Postman, the tester is able to place Restful calls coming from the 3<sup>rd</sup> party app, for each set of selected set of parameters using a valid security token.
- Using Postman, the tester is unable to place restful calls to the API with an expired security token.
- Using Postman, the tester is unable to place restful calls to the API with an invalid security token.

f. Scheduled Activities:

- Identify facility to be used to perform the test and system user that will be assisting with the test as well as a technical resource from Health Gorilla by January 15, 2025
- Perform test and document all test results by February 15th, 2025
- Send a test result report to Drummond Group by February 28<sup>th</sup>, 2025, specifying which the of the outcomes where achieved. For outcomes

that were not achieved, detail will be provided as to why the outcome was not met.

#### 170.315 (g)(9): Application Access - All Data Request

##### a. Testing Process & Approach Justification:

- The way this functionality will be tested is by coordinating a date and time with a facility to perform the test. The test will consist in performing SQL queries for a real Patient ID and all the transactional tables that store the clinical data for all data categories within the tested criteria. We will then use Postman to place restful calls to the API for the selected Patient ID and all the data categories. A 100% match for each of the data categories will indicate correct functionality of the tested Restful service (All Categories Request) within the ClinNext 10 API.
- Justification: Currently none of our customers has the API open to third party applications. Given that fact, the most realistic test we can perform is to provision a simulated test application in the test facility's database and using Postman to emulate the actual application placing secured Restful service calls to the API for the selected Patient ID and All Data Categories.

On-going usage of this measure cannot be assessed since none of our customers have opened the API to other parties. However, we will perform a brief quarterly inquiry to determine if or when they are planning to open the API to third party developers.

##### b. Care Setting:

The tested product, ClinNext 10, is only currently certified in the In-Patient domain. Patients that will be selected to conduct the test will be receiving services under that clinical setting.

##### c. Measures to demonstrate on-going interoperability:

Measurements:



Number of API calls received for a complete patient record (All data request).

d. Test Steps:

- A test date/time will be coordinated with the selected facility
- At the scheduled date/time, we will perform queries against the facility database for the selected Patient ID and the transactional tables for all data categories that comprise the Common Clinical Data Set (USCDI V1). The result of each query will be saved as a reference data set.
- We will provision a test application that will simulate a third-party app. placing Restful calls to the facility API.
- A call will be setup in postman for the selected Patient ID and all the data elements within the USCDI V1 (All Data Categories)
- The data returned by the service will be compared with the result of the SQL queries. Both data sets should match.

e. Expected outcomes:

- The tester is able to provision a test application within the database (simulating a real third-party application connected to the API).
- Using Postman, the tester is able to successfully place a restful call for the selected patient and the full USCDI V1 (All Data Categories)
- Using Postman, the tester is unable to place Restful calls to the API with an expired security token.
- Using Postman, the tester is unable to place Restful calls to the API with an invalid security token.

f. Scheduled Activities:

- Identify the facility to be used to perform the test and a system user that will be assisting with the test by January 15, 2025
- Perform test and document all test results by February 15, 2025
- Send a test result report to Drummond Group by February 28th, 2025, specifying which of the outcomes were achieved. For outcomes that

were not achieved, detail will be provided as to why the outcome was not met.

### 170.315 (g)(10): Standardized API for Patient and Population Services

#### a. Testing Process & Approach Justification:

- The way this functionality will be tested is by coordinating a date and time with a facility to perform the test. The test will consist in creating various types of applications using ClinNext 10 API identity server. This is the module within ClinNext 10 that allows the facility to provision applications and scopes within the system in order to grant API access to the E H R to all supported application types. One of each of the types of applications included in the ONC Test Script will be tested to ensure full test coverage; specifically, one Standalone patient App, one E H R Practitioner Application, a Public Client Application, and a Single Patient Application, and a Bulk application. For each application, full access (all scopes) and a limited number of scopes will be tested to ensure access is granted only to the set of provisioned scopes. Also, token revocation and expiration tests will be performed for each tested application to ensure none of them can connect to the API with an expired, revoked or invalid token. Finally, a Bulk Client application will be provisioned, and a patient will be selected to perform the Bulk Data export for the selected patient in order to complete the tests. The ClinNext 10 Identity Server will be used to provision all applications and Scopes that will be used for the test. The ONC inferno test tool will be used to validate the correct level of access and scopes is granted for each tested scenario.
- Justification: It was determined the more realistic approach to test the full functionality covered in this criteria is to setup an application of each of the types of apps in the ONC test script that were certified, including a bulk data export application, and testing various combinations of scopes to ensure only the provisioned number of scopes are granted and accessible for each type of application. Also, we include test cases for token revocation and expiration for each tested application to validate no

provisioned application can access the ClinNext 10 API with an invalid or expired token.

g. Care Setting:

The tested product, ClinNext 10, is only currently certified in the In-Patient domain. Patients that will be selected to conduct the test will be receiving services under that clinical setting.

h. Measures to demonstrate on-going interoperability:

Measurements:

- Number of application registrations using ClinNext 10 Identity Server during the tested period.
- Number of API calls placed by FHIR profile (e.g., Encounter, MedicationRequest, Patient, AllergyIntolerance, etc.).

i. Test Steps:

- Setup a Standalone patient Application with full scope access in ClinNext 10 API Identity Server. Use the ONC inferno test tool to validate access to all scopes is available.
- Remove a number of Scopes from the Standalone patient Application. Use the ONC Inferno test tool to validate that the removed scopes are no longer accessible to the app.
- Let token expire and place an API call with the expired token to validate access is not granted.
- Attempt to place a request to the API with an invalid token to validate access is not granted.
- Setup an E H R Practitioner Application with full scope access in ClinNext 10 API Identity Server. Use the ONC inferno test tool to validate access to all scopes is available.
- Remove a number of Scopes from the E H R Practitioner Application. Use the ONC Inferno test tool to validate that the removed scopes are no longer accessible to the app.

- Let token expire and place an API call with the expired token to validate access is not granted.
  - Attempt to place a request to the API with an invalid token to validate access is not granted.
  - Setup a Public Client Application with full scope access in ClinNext 10 API Identity Server. Use the ONC inferno test tool to validate access to all scopes is available.
  - Remove a number of Scopes from the Public Client Application. Use the ONC Inferno test tool to validate that the removed scopes are no longer available to the app.
  - Let token expire and attempt to place an API call to validate access is not granted.
  - Attempt to place a request to the API with an invalid token to validate access is not granted.
  - Setup a Single Patient Application with full scope access in ClinNext 10 API Identity Server. Use the ONC inferno test tool to validate access to all scopes is available.
  - Remove a number of Scopes from the Single Patient Application. Use the ONC Inferno test tool to validate that the removed scopes are no longer accessible to the app.
  - Let token expire and place an API call with the expired token to validate access is not granted.
  - Attempt to place a request to the API with an invalid token to validate access is not granted.
  - Setup a Bulk client and place bulk client request to the API for a selected patient.
  - Let token expire and place an API call with the expired token to validate access is not granted.
  - Attempt to place a request to the API with an invalid token to validate access is not granted to the app.
- j. Expected outcomes:



- All applications provisioned with full scope access are able to access all provisioned scopes.
- All applications provisioned with a limited set of scopes are only able to access the set of scopes granted.
- None of the tested applications, including the Bulk client app, is able to access the API with a revoked, invalid, or expired token.
- A Bulk client app. is able to place a request to the API and perform a bulk data download for a selected patient.

k. Scheduled Activities:

- Identify the facility to be used to perform the test and a system user that will be assisting with the test by January 15, 2025
- Perform test and document all test results by February 15, 2025
- Send a test result report to Drummond Group by February 28th, 2025, specifying which of the outcomes were achieved. For outcomes that were not achieved, detail will be provided as to why the outcome was not met.

c. Relied upon Software: Firely Server (Version v.4.10.0)

### 170.315 (h)(1): Direct Project

i. Testing Process & Approach Justification:

- The process that we propose to live test this functionality is similar to the approach proposed to test 170.315 (b)(1): Transition of Care, except that the transmission of the C-CDA document will take place over Direct protocol and not over SMPT and we will test both inbound and outbound direct messages. Similar to other tests, a date/time will be coordinated with a system user where Sabiamed personnel can visit the facility and observe the user receiving a C-CDA over Direct for a patient that has been transferred into their facility (an incoming referral). The user will also send a C-CDA file over Direct (outgoing referral) for a patient that is being transferred to another facility. The received C-CDA will be saved and validated using ClinNext 10 CDA Validation tool.

- Justification: We believe that the best way to test this functionality is by observing an actual system user sending and receiving a C-CDA for a real patient over Direct protocol.

The measure chosen to test for ongoing usage, increased feature adoption, and ongoing interoperability is executing SQL queries against the transactional table that stores C-CDA transmitted files that were sent over Direct standard, on a quarterly basis. The query output will allow us to calculate how often are users sending a C-CDA files for patients transferred to other facilities over Direct and establish an annual trendline. This trendline will give us a clear indication on feature adoption. An up trending trendline will be evidence of increased interoperability and usage rates.

b. Care Setting:

The tested product, ClinNext 10, is only currently certified in the In-Patient domain. Patients that will be selected to conduct the test will be receiving services under that clinical setting.

c. Measures to demonstrate on-going interoperability:

SQL queries will be executed against the transactional tables that stored the data/activity associated with transmission of C-CDA files over Direct protocol to other facilities. Measurements will be taken every quarter. This will allow us to calculate a quarterly cumulative transmission rate, establish a trendline, and determine whether transmission rate over Direct is improving over time.

Measurements:

- Number of messages transmitted through Direct protocol over the tested period.

d. Test Steps:

- A facility will be selected that currently use ClinNext 10 v.1.0
- A date will be coordinated with a system user at the selected facility that currently uses the “Updox direct inbox” a third-party web

application that is integrated into ClinNext 10 and allow system users to send/receive C-CDA documents using the Direct standard.

- At the coordinated date/time, a resource from SabiaMed's team will visit the facility and observe the user sending and receiving a C-CDA file for a patient that was transferred into and out of their facility, over Direct protocol.

e. Expected outcomes:

- The receiving facility receives the C-CDA file into the system user's Updox Direct inbox and can access and view it.
- The receiving user can open and view the file C-CDA in Human Readable format and it shows no cosmetic malformations.
- The user is able to send a C-CDA file over Direct to a receiving facility.

f. Scheduled Activities:

- Identify the facility to be used to perform the test and a system user that will be assisting with the test by January 15, 2025
- Perform test and document all test results by February 15<sup>th</sup>, 2025.
- Send a test result report to Drummond Group by February 28<sup>th</sup>, 2025, specifying which of the outcomes were achieved. For outcomes that were not achieved, detail will be provided as to why the outcome was not met.

## 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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Date: 12/1/2023