

Cerner Certified Health IT 2022 Real World Testing Plan

Cerner is proud to offer software that is certified under the Office of the National Coordinator (ONC) for Health Information Technology (HIT) Health IT Certification Program. Contained within is Cerner's calendar year 2022 Real World Testing Plan for all 2015 Edition and 2015 Cures Update Edition certification criteria subject to the Real World Testing Condition & Maintenance of Certification requirements at 45 CFR 170.405 that were certified as of August 31, 2021.

Individual Real World Testing plans are organized by the 2015 Edition or 2015 Cures Update Edition certification criteria with identification of each Certified Health IT Module under which the criteria are certified on the ONC's Certified Health IT Product List (CHPL). In some instances, testing plans have been combined for efficiency to account for multiple Certified Health IT Modules where a criterion is certified under more than one certified Health IT Module. Unless otherwise noted, testing plans account for all active certified versions of the identified Certified Health IT Module.

Please note, several Real World Testing plans involve the use of production activity data from real world use of Cerner's Certified Health IT Modules. This production activity data is aggregated across clients and no protected health information (as defined under HIPAA) or client-specific identifiable information is used or contained in the information provided for Real World Testing results.

Cerner affirms that 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 Cerner's Real World Testing requirements.

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170.315(b)(1) Transitions of Care

Certified Health IT Module(s): *FirstNet (Clinical)*; *PowerChart (Clinical)*

CHPL Product Numbers: 15.04.04.1221.Firs.15.04.1.210308; 15.04.04.1221.Firs.18.05.1.210308;
15.04.04.1221.Powe.15.04.1.210308; 15.04.04.1221.Powe.18.05.1.210308

Real World Testing Methodologies

Real World Testing of the Transitions of Care certified capabilities is best performed by tracking client use for sending a conformant Consolidated Clinical Document Architecture (C-CDA) document upon patient discharge from inpatient or emergency department encounters, or upon referral between ambulatory providers. The C-CDA documents are created per [HL7® CDA C-CDA R2.1 Implementation Guide \(IG\)](#) specifications cited as standard for the Transitions of Care criterion from a combination of clinical data recorded directly by end users in the patient record, reconciled and incorporated from external C-CDA documents received inbound, and/or interfaced through HL7® V2 transactions. The Continuity of Care Document (CCD), Referral Note, and Discharge Summary C-CDA document templates created in *PowerChart (Clinical)* or *FirstNet (Clinical)* are generated locally and exchanged through Direct Messaging and Integrating the Healthcare Enterprise (IHE) query-based document exchange methodologies.

Cerner will track and report on the real world production activity of three distinct components of capabilities supported under the Transitions of Care criterion across our client base. This real world production activity tracking is achieved via the use of a Cerner cross-database analytics tool which provides near real-time activity tracking of active production environment use.

1. The number of C-CDA documents of each required document template (CCD, Referral Note, Discharge Summary) that are created and transmitted outbound in production environments for real world care transitions and referrals using either Direct Messaging or IHE document exchange technologies;
2. The use of the C-CDA viewer capabilities by end-users in production environments, which allow users to view a human-readable rendering of C-CDAs and customize display of the data; and
3. The use of C-CDA document validation capabilities, which provide users with visibility to conformance errors in C-CDA documents they receive and view.

Justification

We chose the methodology of tracking actual production activity for the three identified components across our U.S. client base as this reflects the actual real world use of the certified capabilities in the provision of healthcare for their intended purposes. This is in stark contrast to testing of manufactured care scenarios in production environments or non-production environment activity and aligns closely with the Office of the National Coordinator for Health IT's (ONC) stated intent and purpose of Real World Testing. It also provides a direct view of active use of certified software on a day-to-day basis across all applicable live care settings to avoid exclusion of particular settings or implementations.

For the tracking of C-CDA documents created and transmitted, isolating to the specific certified C-CDA document templates ensures that the testing is exclusively assessing use of standards-conformant C-CDA documents. The methodology also accounts for inclusion of all pertinent patient records in production systems. The production activity being tracked and reported on assesses workflows available to all user roles and assigned by each client based on their workflows and needs. The system does not limit the number of users in these workflows.

Care Settings for Real World Testing

- Acute
- Ambulatory
- Behavioral Health

- Emergency Department
- Pediatrics

Implementation in Acute, Ambulatory, Emergency department, as well as Pediatric and Behavioral health-specific care settings are represented in the aggregate metric reporting.

Standards Version Advancement Process

N/A

Real World Testing Milestones

1. Complete refinement of new C-CDA generation cross-client dashboard: end of Q4 2021
2. Completion of actual Real World Testing activities execution (includes execution of monthly report): end of Q3 2022
3. Complete assessment of Real World Testing data for results and outcomes compilation: end of year 2022

Real World Testing Expected Outcomes

The expected outcomes for C-CDA document creation and exchange tracking will be observance of extremely high volumes of successful document generation and exchange reaching the tens of millions on a monthly basis. This is due to the broad client base actively utilizing these certified capabilities in production environments and reflects the overall success of our certified capabilities in the real world.

The expected outcomes for the C-CDA display component will be consistent usage in month-to-month tracking indicating successful utilization of the certified capabilities without drop-off in volumes.

The expected outcomes for the C-CDA validation component will be very low usage with somewhat scattered numbers on a month-to-month basis. This reflects our experience where the value of the conformance validation error visibility to end-users is very low as their focus is the content of the documents they are viewing and the ability to effectively reconcile data into the local record (a capability that is part of the 170.315(b)(2) Clinical Information Reconciliation and Incorporation criterion).

Real World Testing Metrics

The Real World Testing metrics for creating C-CDA documents will be the following for each component of the methodology:

1. Number of standards-conformant C-CDA documents created per month by C-CDA document template (CCD, Referral Note, Discharge Summary).
2. Number of times per month a C-CDA document was opened and viewed utilizing the certified C-CDA viewer capability.
3. Number of times per month the C-CDA validator capability was leveraged to assess the standards-conformance of a C-CDA being viewed per month.

Justification

Real World Testing metrics selected provide insightful data on actual real world use of the relevant certified capabilities in production environments within the U.S. Tracking across our U.S. client base also ensures representation of all relevant care settings, sizes and types of clients, and relevant workflows for exercising use of the certified capabilities. The metric for number of standards-conformant C-CDA documents created per month is measured and reported only using the certified C-CDA document templates, which provides certainty that the documents tracked conform to required standards.

170.315(b)(1) Transitions of Care

Certified Health IT Module(s): *Soarian Clinicals*

CHPL Product Numbers: 15.04.04.1221.Soar.15.01.1.210331

Real World Testing Methodologies

Real World Testing of the Transitions of Care certified capabilities for *Soarian Clinicals* is best performed by tracking client use for sending a conformant Consolidated Clinical Document Architecture (C-CDA) document upon patient discharge from inpatient or emergency department encounters, or upon referral between ambulatory providers. The C-CDA documents are created per [HL7® CDA C-CDA R2.1 Implementation Guide \(IG\)](#) specifications cited as standard for the Transitions of Care criterion from a combination of clinical data recorded directly by end users in the patient record, reconciled and incorporated from external C-CDA documents received inbound, and/or interfaced through HL7® V2 transactions. The Continuity of Care Document (CCD), Referral Note, and Discharge Summary documents created in *Soarian Clinicals* are transmitted through Cerner's Document Management product.

The method for tracking the sending of C-CDA documents will be counted by two sending workflows: automatic physician-based routing and manual sending. The data will be collected through a file in Document Management per client and sent to Cerner's Healthcare Intelligence analytics product for cross-client production reporting. This file also collects the type of C-CDA documents sent per patient. This reporting approach aligns with needs for Real World Testing as it excludes irrelevant C-CDA workflows such as Automated Document Routing to patient portals (only counting Transition of Care sending to physicians set through automatic workflow or manual sending directly to providers).

The report per client will also contain the number of C-CDA documents received as part of transitioning the patient into a care setting and will be evidence for Transition of Care receive capabilities. Additionally, we capture metrics on invalid C-CDA documents received inbound that we will be used to demonstrate real world counts of C-CDA documents that do not meet the minimum required specifications as defined by the Office of the National Coordinator for Health IT (ONC). Lastly, we will demonstrate real world value of allowing the quantity and order of C-CDA sections displayed via reporting on a system setting that users can apply to establish viewing preferences.

Justification

Cerner selected the methodology of using the Document Management reporting file as this reflects the actual real world use of sending and receiving C-CDA documents as part of patient care transitions. When C-CDA validation is enabled, the reporting provided captures outcomes of validation of C-CDA documents. The validation reports accurately reflect whether the C-CDA document meets conformance specifications. For end-user display of C-CDA documents, the evidence of clients modifying their system settings shows real world use of certified C-CDA viewing capabilities in varying sequences and views. This real world testing and measurement accounts for all *Soarian Clinicals* clients using certified software across relevant care settings and implementations, rather than narrowing to particular settings and implementations.

Importantly, all the metrics that are being reporting on are derived from active client installed and live production environments, which aligns with the intent and purpose of Real World Testing. The methodology also accounts for all patient records in production systems and all relevant workflows for leveraging the certified capabilities.

Care Settings for Real World Testing

- Acute
- Emergency Department

With this criteria, we will be testing Acute (Inpatient setting) and Emergency Department care settings as applicable to the certification of *Soarian Clinicals* as a certified HIT module. *Soarian Clinicals* is not certified or marketed beyond the Acute and Emergency Department care settings.

Standards Version Advancement Process

N/A

Real World Testing Milestones

1. Complete identification of target client participants: end of January 2022
2. Complete readiness for client query execution: end of Q2 2022
3. Completion of actual Real World Testing activities execution (includes execution of monthly report): end of Q3 2022
4. Complete assessment of Real World Testing data to compile results and outcomes: end of year 2022

Real World Testing Expected Outcomes

The Real World Testing outcomes will be measured using a monthly report derived from Cerner's Healthcare Intelligence analytics product for the sending and receiving of C-CDA document, which also includes C-CDA document types, and will provide successful active engagement in client production environments. For the validation criteria, the outcomes will be measured by a unique monthly report that reflects across all clients the count of C-CDAs that are in error. For the display criteria, the outcomes will be measured by a unique monthly report derived from AIS that reflects the instances of clients that have modified their preferences.

Overall, outcomes anticipated are high volumes of utilization of the certified capabilities reflecting successful implementation and use of certified software in the real world.

Real World Testing Metrics

The metrics will consist of the following for each component of the Real World Testing plan:

1. For the sending and receiving of C-CDA documents, number of patient visits for which a C-CDA document was either received or sent (target 50%+).
2. For the validation of C-CDA document, rate of C-CDA documents received inbound with any error (target less than 25%).
3. For the validation capabilities system settings, number of clients who have changed their display settings (target less than 5%).

Justification

For sending, receiving, and creation capabilities, we believe the 50% metric is below what our clients should be achieving for Transitions of Care to support the quality and continuity of care provided to patients. The 50% metric also aligns with the minimum requirement we applied for clinical information reconciliation and incorporation.

For validation capabilities, we believe the real world evidence will prove that there will be a low percentage of C-CDA documents in error, which is due to HIE exchange addressing C-CDA quality through technologies embedded in the HIE. In addition, real world use has shown that clients only use validation in testing, we have chosen to show real world testing in production environments which will show a lower instance of CCD documents in error.

For the display capabilities, clinicians typically want to see all the clinical information on the patient and through our products we provide interactive controls to allow the user to limit or enable the display of clinical information to support usability and readability of the C-CDA document. Low utilization of these settings shows that the capabilities are working as expected and are not disabled or modified.

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

Certified Health IT Module(s): *FirstNet (Clinical)*; *PowerChart (Clinical)*

CHPL Product Numbers: 15.04.04.1221.Firs.15.04.1.210308; 15.04.04.1221.Firs.18.05.1.210308; 15.04.04.1221.Powe.15.04.1.210308; 15.04.04.1221.Powe.18.05.1.210308

Real World Testing Methodologies

Real World Testing for Clinical Information Reconciliation and Incorporation for *PowerChart (Clinical)* and *FirstNet (Clinical)* will utilize reporting derived from a Cerner cross-database analytics tool to provide near real-time activity tracking of active production environment use of the relevant certified capabilities. With these reports, Cerner is able to measure and report real world adoption of these certified capabilities by tracking discrete actions taken on the data extracted from Consolidated Clinical Document Architecture (C-CDA) documents received inbound from external sources.

Specific actions tracked and reported on will be as follows: Problems added, Problems rejected, Allergies added, Allergies rejected, Home Medications added, and Home Medications rejected. These measurements will provide supporting evidence that clinical data reconciliation is being actively utilized by Cerner clients at the point of care. Reconciled data was received from either manually matched C-CDAs that were received inbound from Direct Messaging exchange, or automated patient matching from Integrating the Healthcare Enterprise (IHE) query-based exchange.

Justification

Measurements reported through this Real World Testing methodology will be derived from actual clinical end-user actions utilizing the certified capabilities in real world patient care scenarios, which directly aligns with the intent and purpose of Real World Testing. *Cerner Millennium*® supports workflows for all defined care settings (listed below). Clinical data reconciliation is a clinical user function and configuration that is independent of care setting, but more dependent on user role. User roles within the defined care settings, based on appropriate configurations, have access to receive and reconcile clinical data that will be reported in this measurement.

This Real World Testing methodology also accounts for the full scope of the Clinical Information and Reconciliation criterion as the metrics selected cover all required clinical concepts and consists only of data from external C-CDA documents that have been successfully matched to a local patient record (either manually or through automation). Once data is incorporated successfully (as measured with this methodology) it is part of the standard patient record which is then able to be exchanged downstream.

Finally, this Real World Testing methodology accounts for all relevant care settings, implementations, and sizes/types of organizations by aggregating production activity tracking data across the U.S. client base live with the certified capabilities.

Care Settings for Real World Testing

- Acute
- Ambulatory
- Behavioral Health
- Emergency Department
- Pediatrics

The Cerner *PowerChart (Clinical)* and *FirstNet (Clinical)* certified HIT modules support workflows for all defined care settings above. Clinical data reconciliation is a clinical end-user function and configuration that is

consistent across care settings and enabled based on user role. Data from all defined care settings is tracked in the Real World Testing metrics for this testing plan.

Standards Version Advancement Process

N/A

Real World Testing Milestones

1. Retrieve client production activity tracking data reports: first week of Q4 2022
2. Complete assessment of production activity tracking data reports: mid-Q4 2022
3. Complete compilation of Real World Testing results from production activity tracking data reports assessment: end of year 2022

Real World Testing Expected Outcomes

Expected outcomes from Real World Testing activities for Clinical Information Reconciliation and Incorporation include:

- General consistency across months throughout the year for overall reconciliation actions (including both add and reject actions). This provides assurances that the certified capabilities are serving our clients' needs on a day-to-day basis without significant issues and/or interruptions.
- Higher volumes of reconciliation actions for Problems and Meds than for Allergies. This is expected as most patients are more likely to have a higher number of Medications and Problems than they would have Allergies, which will naturally result in more actions for those concepts.

Real World Testing Metrics

The Real World Testing metrics for Clinical Information Reconciliation and Incorporation will be the following (all reconciliation actions being tracked are taken on external data parsed from C-CDA documents received inbound):

1. Total number of Problems added and rejected per month
2. Total number of Allergies added and rejected per month
3. Total number of Home Medications added and rejected per month.

Justification

The Real World Testing metrics selected are directly sourced from U.S. client production activity for the workflows and actions enabled by the certified capabilities. These metrics provide the best possible view of real world use of the certified capabilities and ensure representation of all identified care settings in the data.

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

Certified Health IT Module(s): *Soarian Clinicals*

CHPL Product Numbers: 15.04.04.1221.Soar.15.01.1.210331

Real World Testing Methodologies

Real World Testing of Clinical Information Reconciliation and Incorporation certified capabilities is best evidenced by tracking actual client use of the *Soarian Clinicals* workflows in which a C-CDA document that was received was matched to the patient is reconciled into the local record. This shows correct patient matching and incorporation of data provided by the externally sourced C-CDA document.

The data provided by the C-CDA documents are accessed by clinicians through three clinical information reconciliation workflows: Allergy Reconciliation, Problem Reconciliation, and Medication Reconciliation. Cerner's testing methodology will leverage client production environment tracking via our Healthcare Intelligence analytics product with a report which will count only when each of the reconciliation actions occurs with a C-CDA document for the pertinent workflows.

Justification

The Real World Testing methodology described above leverages data from actual client use across a representative sampling of production environments. This demonstrates use of each of the three reconciliation workflows while specifically focusing metrics on reconciling with an imported C-CDA document that was matched to a patient. It also aligns directly with the intent and purpose of Real World Testing, as opposed to relying on manufactured tests and scenarios.

The methodology also accounts for the full scope of the Clinical Information Reconciliation and Incorporation criterion via the focus on reconciling data from a C-CDA document as received from received referrals and care transitions that have been successfully matched to the patient.

Finally, this methodology accounts for all *Soarian Clinicals* client base for the applicable Acute and Emergency Department care settings.

Care Settings for Real World Testing

- Acute
- Emergency Department

With this Real World Testing plan, Cerner will be testing Acute (Inpatient setting) and Emergency Department care settings as applicable to the certification of *Soarian Clinicals* as a certified HIT module. *Soarian Clinicals* is not certified or marketed beyond the Acute and Emergency Department care settings.

Standards Version Advancement Process

N/A

Real World Testing Milestones

1. Complete identification of target client participants: end of January 2022
2. Complete technical readiness for client query execution: end of Q2 2022
3. Completion of actual Real World Testing activities execution (includes monthly report execution): end of Q3 2022

4. Complete assessment of Real World Testing data for results and outcomes compilation: end of year 2022

Real World Testing Expected Outcomes

The overall expected outcome for the Real World Testing plan will be high volumes of reconciliation actions across the sampled client base. This provides indication of active client engagement with and use of Clinical Information Reconciliation and Incorporation capabilities in the real world.

Real World Testing Metrics

The Real World Testing metrics for Clinical Information Reconciliation and Incorporation will be the following

1. Number of patient visits during the measured period with at least one reconciliation workflow performed (target = 50%+)

Justification

This Real World Testing metric views use of the certified capabilities through the lens of patient encounters and provides valuable information on frequency of utilization. The target rate of 50%+ also aligns with former Centers' for Medicare and Medicaid Services (CMS) Promoting Interoperability program measurements for use of these certified capabilities. The Real World Testing plan does not include failures or exceptions as consideration in the evaluation of the outcomes as the data represents the end-user's true experience reconciling data from a C-CDA document.

170.315(b)(3) Electronic Prescribing

Certified Health IT Module(s): *FirstNet (Clinical); PowerChart (Clinical); PowerChart Touch*

CHPL Product Numbers: 15.04.04.1221.Firs.15.04.1.210308; 15.04.04.1221.Firs.18.05.1.210308; 15.04.04.1221.Powe.15.04.1.210308; 15.04.04.1221.Powe.18.05.1.210308; 15.04.04.1221.Powe.03.02.1.210308

Real World Testing Methodologies

In order to demonstrate successful Real World Testing of certified ePrescribing capabilities, the live transactions within client production environments will be queried to show that all services in use are functional across various applicable care settings. Transactions will be reviewed based on the applicable care settings for at least 30 days from the calendar year to demonstrate continued successful use over time while ensuring applicable transaction data is still available for reporting.

Some components of the full ePrescribing criterion will be excluded due to lack of active real world use. As the industry adopts use-cases for those particular components, additional tracking for will be included for future Real World Testing.

Additionally, to account for Real World Testing of the leading/trailing zeros and oral liquid metric dosing requirements under the ePrescribing criterion, implementation testing processes executed when enabling ePrescribing at a client site will include functional requirements for these capabilities.

Justification

By monitoring transactions within actual client production environments, it is possible to show use and the successful processing of transactions by both sending and receiving parties. This guarantees that we test actual real world use of the certified ePrescribing capabilities and not a simulation of use. These queries can also be run in any environment, so selection of organizations to be monitored can account for the variety of care settings that our certified capabilities support.

Standards conformance of the transactions being tracked is also assured as only successful transactions will be processed by the receiving entity. Multiple queries will be used to account for the different components of the ePrescribing criterion and ensure all related transactions are accounted for in tracking as applicable.

Additionally, the Real World Testing methodology accounts for multiple care settings at which the certified capabilities are deployed by identifying the user and encounter associated to the transaction being monitored. This allows Cerner to understand the user's position within the domain as well as the type of encounter that the patient has which will indicate which care setting is related to the specific transaction and ensure that all applicable care settings are represented.

Regarding methodology for the the leading/trailing zeros and oral liquid metric dosing requirements, mandating inclusion of functional requirements as part of implementation testing processes when enabling ePrescribing at client sites will guarantee that we test real world use and not a simulation of use.

Finally, our configuration and process for generating ePrescribing transactions in the required [NCPDP SCRIPT Version 2017071](#) standard are consistent regardless of where the message will be sent or what particular product/application it originated from. This means that our chosen methodology accurately accounts for all identified certified products and all potential variances in implementation in a single Real World Testing plan.

Care Settings for Real World Testing

- Acute
- Ambulatory

- Behavioral Health
- Emergency Department
- Pediatrics

Some of the capabilities covered under the ePrescribing criterion apply to all care settings while others are specifically targeted at a subset of care settings. Those associations are outlined below by specific capability. In addition, the RxFill transaction has no adoption at this time and cannot be tracked as part of the Real World Testing plan. Additional tracking for RxFill will be added when applicable in future Real World Testing plans.

- Create new prescriptions (NewRx): All care settings
- Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse): Ambulatory care setting
- Request and respond to cancel prescriptions (CancelRx, CancelRxResponse): All care settings
- Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse): Ambulatory care setting
- Receive fill status notifications (RxFill): Current adoption too low to track (not industry supported until release on 2017071 and pharmacy adoption has not increased since release)
- Request and receive medication history (RxHistoryRequest, RxHistoryResponse): All care settings
- Relay acceptance of a transaction back to the sender (Status): All care settings
- Respond that there was a problem with the transaction (Error): All care settings

Standards Version Advancement Process

N/A

Real World Testing Milestones

1. Complete identification of target client participants: end of January 2022
2. Complete development of a new report used for tracking real world use of the applicable certified capabilities: end of Q2 2022
3. Completion of actual Real World Testing activities execution: end of Q3 2022
4. Complete assessment of Real World Testing data for results and outcomes compilation: end of year 2022

Real World Testing Expected Outcomes

The expected outcomes for the Real World Testing of ePrescribing certified capabilities would be the ability to show a large volume of each transaction across the supported care settings with a high rate of success. This will demonstrate that all certified capabilities are working as expected in all care settings where they are intended to be used.

Real World Testing Metrics

The Real World Testing metric for ePrescribing will be the success rate across all prescription transactions (including renewal and change requests) routed electronically for the measured testing period (target = 90%+).

Justification

This metric will track the majority of transactions related to this criterion and show that they are overwhelmingly successful in real world use related to actual patient care. Not all prescriptions will be able to be processed for various reasons such as pharmacy or intermediary downtimes, missing information required for standards conformance, or connections issues which is why the target is less than 100%.

This metric tracks all transactions under the criterion with the exception of RxHistory requests and responses. These transactions are more difficult to account for success due to requirements placed on the application by third parties communicating the information back and forth. Often multiple requests will be triggered prior to

receiving a response and cause the success rates to be far more variable. By tracking the success rates of all other transactions, we can validate that they were received whenever possible and conformed to the [NCPDP SCRIPT Version 2017071](#) standard cited for the ePrescribing criterion. If they were not formatted properly then they would be returned as failures.

170.315(b)(3) Electronic Prescribing

Certified Health IT Module(s): *Soarian Clinicals*

CHPL Product Numbers: 15.04.04.1221.Soar.15.01.1.210331

Real World Testing Methodologies

In order to demonstrate successful Real World Testing, the live ePrescribing transactions within client environments will be queried to show that all services in use are functional across various care settings. Transactions will be reviewed based on the applicable care settings for at least 30 days to demonstrate continued successful uses over time while ensuring applicable transaction data is still available. Some components will be exempt as there is no real world use today. Additional tracking for those components will be included as the industry adopts those use cases.

Cerner will leverage client production environment tracking via existing processes which involve retrieval of summarized, non-PHI volume statistics from the system via process monitoring operations. Reports will be compiled using this production activity monitoring data and volumes will be subtotaled by success/failure status (where applicable), and by visit type of Inpatient (IP) and ED (EOP).

Regarding methodology for the the leading/trailing zeros and oral liquid metric dosing requirements, mandating inclusion of functional requirements as part of implementation testing processes when enabling ePrescribing at client sites will guarantee that we test real world use and not a simulation of use.

Justification

By monitoring transactions within actual client production environments, it is possible to show use and the successful processing of transactions by both sending and receiving parties. This guarantees that we test real world use and not a simulation of use. Furthermore, by mandating inclusion of functional requirements for leading/trailing zeros and oral liquid metric dosing requirements in implementation testing processes when enabling ePrescribing at client sites, the methodology guarantees that we test real world use of those capabilities and not a simulation of use.

The selected methodology also accounts for multiple care settings by identifying the encounter associated to the transaction being monitored. This will allow Cerner to understand the type of encounter that the patient has which will indicate which care setting is related to the specific transaction. Each database record created via real-world use is linked to the *Soarian Clinicals* visit type (Inpatient versus Emergency Department) under which patient care was delivered.

Multiple queries will be used to account for the different components of the ePrescribing criterion and ensure all related transactions are accounted for in tracking as applicable. [NCPDP SCRIPT Version 2017071](#) standards conformance is also proven with the methodology by capturing the status (success or failure) of the transactions as only successful transactions will be processed by the receiving entity.

Finally, the process monitoring operations used for retrieval of real world usage data can be run in any client environment, so selection of specific organizations that are monitored can be done strategically to account for the variety of organizations that our certified capabilities support.

Care Settings for Real World Testing

- Acute
- Emergency Department

Soarian Clinicals is an Acute care solution with an integrated EDIS.

Some of the capabilities covered under the ePrescribing criterion apply to all care settings while others are specifically targeted at a subset of care settings. Those associations are outlined below by specific capability. In addition, the RxFill transaction has no adoption at this time and cannot be tracked as part of the Real World Testing plan. Additional tracking for RxFill will be added when applicable in future Real World Testing plans.

- Create new prescriptions (NewRx): All care settings
- Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse): Not applicable to *Soarian Clinicals's* supported care settings
- Request and respond to cancel prescriptions (CancelRx, CancelRxResponse): All care settings
- Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse). Not applicable to *Soarian Clinicals's* supported care settings
- Receive fill status notifications (RxFill). Current adoption too low to track (not industry supported until release on 2017071 and pharmacy adoption has not increased since release)
- Request and receive medication history (RxHistoryRequest, RxHistoryResponse): All care settings
- Relay acceptance of a transaction back to the sender (Status): All care settings
- Respond that there was a problem with the transaction (Error): All care settings

Standards Version Advancement Process

N/A

Real World Testing Milestones

1. Complete identification of target client participants: end of Q3 2022
2. Completion of actual Real World Testing activities execution: end of Q4 2022
3. Complete assessment of Real World Testing data for results and outcomes compilation: end of year 2022

Real World Testing Expected Outcomes

The expected outcome for the Real World Testing plan is the ability to show a large volume of each transaction across the supported care settings with a high rate of success. This will demonstrate that all certified capabilities are working as expected in all care settings where they are intended to be used.

Real World Testing Metrics

The Real World Testing metric for ePrescribing will be the success rate across all prescription transactions (including renewal and change requests) routed electronically for the measured testing period (target = 90%+).

Justification

This metric will track the majority of transactions related to this criterion and show that they are overwhelmingly successful in real world use related to actual patient care. Not all prescriptions will be able to be processed for various reasons such as pharmacy or intermediary downtimes, missing information required for standards conformance, or connections issues which is why the target is less than 100%.

This metric tracks all transactions under the criterion with the exception of RxHistory requests and responses. These transactions are more difficult to account for success due to requirements placed on the application by third parties communicating the information back and forth. Often multiple requests will be triggered prior to receiving a response and cause the success rates to be far more variable. By tracking the success rates of all other transactions, we can validate that they were received whenever possible and conformed to the [NCPDP SCRIPT Version 2017071](#) standard cited for the ePrescribing criterion. If they were not formatted properly then they would be returned as failures.

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

Certified Health IT Module(s): *HealthLife*

CHPL Product Numbers: 15.04.04.1221.Heal.H9.03.1.200317; 15.04.04.1221.Heal.H9.04.1.210308

Real World Testing Methodologies

To perform Real World Testing for the View, Download, and Transmit to 3rd Party (VDT) criterion, Cerner will track real world use of the *HealthLife* patient portal by consumers credentialed for access to their health information by our clients. This data will be aggregated, de-identified, and shared via a report from the patient portal environments used by our clients.

Reports will be specifically designed to home-in on use of particular capabilities that closely align with the requirements of the VDT criterion, which is reflected by the associated metrics defined for the Real World Testing plan. The description of the data set used in the report will outline the number of *HealthLife* portals based in the U.S. that contributed to the data.

Justification

The report will reflect the activity of *HealthLife* users and interaction with VDT capabilities across our client base, which is the truest form of Real World Testing.

The VDT capabilities in *HealthLife* are the same across all care settings and this methodology will report real world data that is inclusive of all applicable care settings. However, the report will not indicate whether a view, download, or transmit capability was executed within the scope of a specific care setting as *HealthLife* users do not view, download, or transmit health information within the context of a care setting.

The methodology of sharing data from successful VDT events within *HealthLife* by real users will ensure that the metrics reported also reflect conformance to the full scope of the criterion.

Care Settings for Real World Testing

- Acute
- Ambulatory
- Emergency Department

The selected care settings are representative of the primary care settings of the provider organizations which currently utilize *HealthLife* as a patient portal.

Standards Version Advancement Process

N/A

Real World Testing Milestones

1. Completing planning and estimates for the development requirements to carry out the defined Real World Testing plan: end of Q1 2022
2. Complete development required to support capture and aggregation of VDT events defined in the Real World Testing plan (including report for manual compilation of data): end of Q2 2022
3. Establish operational processes allowing retrieval of data for defined metrics needed for submission of Real World Testing results: end of Q3 2022

4. Complete execution of the established operational processes and a draft report of the Real World Testing results: end of November 2022

Real World Testing Expected Outcomes

The outcomes Cerner expects to observe from the *HealthLife* Real World Testing plan include high volume of frequently used VDT capabilities within the product. The volume of unique users will reflect the number of persons that were enabled to interact with the electronic health data for themselves and others within a given timeframe.

Volume for the events of viewing is expected to be greater than the events for downloading and transmitting health records as view actions are considered primary use of *HealthLife* and more user-friendly. Download and transmit features in *HealthLife* are accessed less frequently and thus will have a lower volume of events.

Real World Testing Metrics

Real World Testing metrics for the *HealthLife* Real World Testing plan will include the following and all will be best measured on a monthly basis across a 3-month period during the calendar year:

1. Number of unique *HealthLife* users that viewed an element of the health record
2. Number of total combined viewing events of the health record
3. Number of unique *HealthLife* users that downloaded or transmitted a CCD
4. Number of unique *HealthLife* users that viewed Access Logs
5. Number of total viewing events of Access Logs

Justification

Viewing health information through the *HealthLife* patient portal is the primary purpose of the product. Each view of the health record portion of *HealthLife* will represent a user navigating the portal and accessing their health information. When referenced against the # of unique users that viewed health information, a larger picture can be developed of the effectiveness of *HealthLife* and its real-world capabilities to enable access to health information.

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

Certified Health IT Module(s): *Patient Portal – MMD*

CHPL Product Numbers: 15.07.04.1221.Pati.MM.01.0.180720

Real World Testing Methodologies

Cerner's elected methodology for the Real World Testing of the View, Download, and Transmit to 3rd Party (VDT) criterion for the *Patient Portal – MMD* certified HIT module consists of specialized reports that capture data on both the reportable usage of the VDT capabilities in specific care settings as well as gauging items such as a patient's or proxy's experience accessing their healthcare information. This includes, among other items, accessibility and ease of searching for their information to ensure that the full scope of the certified capabilities are accounted for.

1. A report will be generated from *Patient Portal – MMD* clients' production environments on a quarterly basis that shows the usage of the following VDT capabilities per care setting and selected date range:
 - Discharged patients had access to the Patient Portal on time
 - Discharged patients had access to their C-CDA on time
 - New patients being provisioned to the Patient Portal
 - Patients or their proxies logging in to the Patient Portal
 - Patients or proxies viewed their C-CDA's
 - Patients or proxies downloaded their C-CDA's
 - Patients or proxies transmitted their C-CDA's (both securely and via unsecured email)
 - Patients accessed their audit log
2. An additional *Patient Portal – MMD* user report will be generated from the clients' production environments on a quarterly basis that shows the usage of the following VDT capabilities per de-identified user and selected date range:
 - Number of logins
 - Number of total documents viewed
 - Number of total C-CDA's viewed
 - Number of dashboard (parsed C-CDA aggregated views)
 - Number of Acute visits
 - Number of Ambulatory visits
 - Number of Emergency visits

Activity tracking in these reports will be designed to account for various available methods of access provision, including: manual (a system component), rapid ADT(an integration), Experian (an Integration), and validation code entry (a system component).

Justification

We elected the identified Real World Testing methodology as the use of reporting on real world use of the patient portal provides the best possible validation of successful use of the certified capabilities by our clients and their patients. The combination of the two reports described above validates the clients' utilization of the certified capabilities for the purpose of the patient portal in the real world (i.e., enabling fast, secure, and reliable access to health information electronically). This also conforms with the ultimate intent of Real World Testing by focusing on actual real world activity, as opposed to simulated activity from manufactured test scenarios.

Additionally, the selected methodology allows Cerner to account for all applicable care settings by linking the usage data to the corresponding patient visits from upstream Admission, Discharge, and Transfer (ADT) feeds. This linkage provides the traceability necessary to ensure all applicable care settings are tested and represented.

Finally, the Real World Testing methodology provides Cerner with legitimate assurances that the certified VDT capabilities are being used successfully in the real world across all implementations for the following reasons:

1. The reports are validated against the database and specific test procedures confirm the precise calculations for *Patient Portal – MMD* usage, administrative functions, and system-generated events that make up the VDT criteria.
2. The reports can be executed in any client environment. Therefore, the selection of which organizations to monitor will include clients of varied sizes and type.
3. The tracking of all transactions over a calendar quarter period will accurately reflect the successful use of our certified system over time by all users in the environment across their patient population.

Care Settings for Real World Testing

- Acute
- Ambulatory
- Emergency Department

Patient Portal – MMD is used by healthcare providers in Acute, Emergency Department, and Ambulatory care settings to provide their patients electronic access to their health information.

Standards Version Advancement Process

N/A

Real World Testing Milestones

1. Complete selection of targeted clients whose data will be leveraged for the reports: end of Q1 2022
2. Completion of actual Real World Testing activities execution: mid-Q4 2022
3. Assess data and compile Real World Testing results: end of Q4 2022

Real World Testing Expected Outcomes

The expected outcome of the *Patient Portal – MMD* Real World Testing will be observance of high volume daily use of certified capabilities in production environments across all applicable care settings. We anticipate active participation among all care settings of the VDT criteria and the specific volumes and rates identified for the various metrics will provide a baseline for expected outcomes in future Real World Testing plans.

Real World Testing Metrics

The Real World Testing metrics for *Patient Portal – MMD*, which will be derived from the reports described in the Real World Testing Methodology section of the plan, will be the following:

- Success rate for patients being provided access to their health information (target = 90%)
- Percentage of patients or proxies who have created a username when offered to exercise ability to access their health information on the patient portal (target = 60%)
- Success rate for Consolidated Clinical Document Architecture (C-CDA) documents received on time in the patient portal (target = 98%)

Justification

Measuring the success rate for patients being provided access to their health information and patients (or their proxies) actually creating accounts/usernames to exercise their access addresses the root of the

upstream source of enabling use of the *Patient Portal* – MMD certified HIT module and is a reflection of our clients' confidence in the value of the capabilities for the purpose of enabling patients electronic access to their health information. The 90% and 60% target success rates accounts for the following circumstances:

- Patient does not have an email address (required to be provisioned)
- Patient does not desire access (conscious declination)
- Patient does not have electronic device and/or internet access
- Errors due to incorrect ADT Rapid ADT Provisioning (RAP) segment

Measuring the success rate of C-CDA documents containing patients' structured health information being received on time in the patient portal is critical to ensure that the data patients (and their proxies) are seeking is actually available in a timely manner. The 98% success target accounts for rare occurrences of transmission failures or potential downtimes.

Overall, Cerner feels that the selected metrics are the best options for providing evidence of the certified capabilities being successfully leveraged for their intended purpose (i.e., enabling fast, secure, and reliable access to health information electronically).

170.315(f)(1) Transmission to Immunization Registries

Certified Health IT Module(s): *FirstNet (Immunizations)*;
PowerChart (Immunizations)

CHPL Product Numbers: 15.07.04.1221.Firs.15.01.1.180625; 15.04.04.1221.Firs.18.02.1.200101;
15.04.04.1221.Powe.15.01.1.180728; 15.04.04.1221.Powe.18.02.1.200101

Real World Testing Methodologies

For the Transmission to Immunization Registries criterion as certified under the *PowerChart (Clinical)* and *FirstNet (Clinical)* certified HIT modules, Cerner's Real World Testing methodology will consist of monitoring real world production use of the certified capabilities. The specific system activities tracked will include the following:

- User-initiated queries to Immunization Information Systems (IIS) for patient immunization history
- Reconciliation of immunization history data to update the local patient record and EHR immunization forecast
- Administration of vaccines (whether via automated scanning or manual entry) to initiate submission of the vaccination records to an IIS

Cerner will accomplish this production activity tracking via the use of a Cerner cross-database analytics tool which provides near real-time activity tracking of active production environment use. Additionally, Cerner's new, more advanced certified capability for immunizations reporting under these certified HIT modules enables monitoring of more deeper details for immunization history query and reconciliation, such as failure reasons and discrete data volumes accepted or rejected into the local patient record.

Justification

Each time a client leverages our certified Transmission to Immunization Registries capabilities, we write out data with our production activity trackers which allow us to monitor volume and usage of our certified capabilities in production across our client base. For example, when a clinician queries an IIS for a patient's immunization history, our system monitors and writes out a record of that activity for analytics and performance indication purposes. Similarly, when a clinician orders/administers a new vaccine for a patient, data is logged for both the end-user activity, as well as the automated outbound submission of the record to external systems, such as IISs the client is connected to. These activity tracking capabilities have long been a standard part of Cerner's technology for the same intended purposes of Real World Testing.

The production activity tracking methodology also allows us to ensure our messages are conformant with the [HL7® 2.5.1 Implementation Guide \(IG\) for Immunization Messaging, Release 1.5](#) specifications by monitoring the failure rate of the Vaccination Update (VXU) (reporting) and Query by Parameter (QBP) messages.

Finally, the production activity tracking methodology provides assurances that all applicable care settings and implementations (e.g., varying sizes and geographical regions of organizations) are appropriately accounted for as the tracking is enabled across all systems where the certified capabilities are in use. The same workflows tracked are also standard across all applicable care settings. This also includes the various available transport techniques for data exchange between the EHR system and IIS. While there are several available techniques – custom point-to-point interfacing, record locator service with Enterprise Master Patient Index (EMPI), or our recommended secure cloud-based centralized registry connection offering – all leverage the same upstream capabilities for initiating and consuming messages to and from the EHR system.

Care Settings for Real World Testing

- Acute
- Ambulatory
- Emergency Department
- Pediatrics

The applicable care settings include any setting where vaccinations may be administered or managed for a patient. This includes Acute venues who often administer pneumococcal and influenza vaccines to deficient patients and the hepatitis B birth doses to newborn babies. This also includes the Emergency Department who often administer Tdap shots for patients who may have come in contact with a rusty object. Of course, Pediatrics and Ambulatory also administer routine vaccines to patients according to Advisory Committee on Immunization Practices (ACIP) recommendations, which is where the majority of vaccine administrations occur.

Standards Version Advancement Process

N/A

Real World Testing Milestones

1. Complete compilation of plan for specific data to measure: end of 2021
2. Execute data reporting of Real World Testing activities for identified timeframe: end of Q3 2022
3. Complete assessment of Real World Testing data for results and outcomes compilation: end of year 2022

Real World Testing Expected Outcomes

Through the identified Real World Testing methodology, we anticipate observing high volume daily use of certified capabilities in production environments by our clients. The close monitoring and reporting for our first Real World Testing activities will allow us to establish baselines for what to expect in future Real World Testing plans.

Real World Testing Metrics

Metrics for the Transmission to Immunization Registries Real World Testing will include:

- Number of production domains live with query and reporting capabilities to any IIS
- Volume of successful queries (QBPs) to an IIS over the measurement period
- Success rate for submissions (VXUs) to an IIS over the measurement period (target = 90%)

Justification

We believe tracking the number of production domains with live connections to at least one IIS will accurately represent our market base and care settings actively using the functionality. A high volume of active connections also provides a reliable indication of the value of our certified capabilities to our client base.

Since query failures are generally out of our system's control (patient match errors, uptime connectivity, etc. are controlled by the IIS), we chose to track query volumes overall instead of a % success or fail. High volumes of successful queries also demonstrates real world interoperability of the certified capabilities in lieu of a success rate metric. Keying on successful queries also ensures conformance to the [HL7® 2.5.1 Implementation Guide \(IG\) for Immunization Messaging, Release 1.5](#) specifications as conformance is a condition of acceptance by the IIS.

Finally, tracking success rates for submissions is the ideal metric for ensuring that certified capabilities are actively and successfully used for interoperability purposes. Further, a successful VXU message provides indication of conformance to the [HL7® 2.5.1 Implementation Guide \(IG\) for Immunization Messaging, Release 1.5](#) specifications the submissions would not otherwise be accepted. We believe a 10% fail rate for submission

(VXUs) across our client base and connected IISs is an appropriate target to account for intermittent failures beyond the system's control, such as:

- Registration staff did not accurately capture patient demographics, or patient was unwilling/unable to provide information necessary to successfully match a patient during query (e.g., mother's maiden name)
- Clinician misdocuments vaccine details during administration (e.g., incorrect lot number)
- Network connectivity issues or failures on the IIS end resulting in inability to accept valid requests

170.315(f)(1) Transmission to Immunization Registries

Certified Health IT Module(s): *Soarian Clinicals*

CHPL Product Numbers: 15.04.04.1221.Soar.15.01.1.210331

Real World Testing Methodologies

The selected Real World Testing methodologies for the *Soarian Clinicals* Transmission to Immunization Registries certified capabilities consists of a combination of production activity tracking via transaction results from connected state Immunization Information Systems (IIS) where available, along with a compilation of internal transaction results compiled from our client base.

Justification

Working with state IISs to produce reports of production activity tracking correlates directly with client's actual use of Transmission to Immunization Registries capabilities as they are the recipient of immunization history requests and submission of immunization records. Interaction and data exchange with these IISs is also the ultimate purpose of the certified capabilities in the real world. However, in working with each state IIS, not all discretely track transmission results or have them available only in raw data transactions. As such, data obtained directly from state IISs is supplemented with data from querying client databases directly for query and submission evidence.

The methodology was also designed to account for all applicable care settings and sizes and types of organizations. The immunization query and submission workflows available in *Soarian Clinicals* are consistent across care settings as a common user interface (UI) service component is shared whether it is called from Acute or Emergency Department care settings.

Care Settings for Real World Testing

- Acute
- Emergency Department

Soarian Clinicals is an Acute care solution with an integrated EDIS. Immunization records will be submitted the same regardless of the patient care settings to the appropriate state IISs upon patient discharge.

Standards Version Advancement Process

N/A

Real World Testing Milestones

1. Complete identification of target *Soarian Clinicals* client participant state IISs providing necessary production activity: end of Q2 2022
2. Completion of actual Real World Testing activities execution: end of Q3 2022
3. Complete assessment of Real World Testing data for results and outcomes compilation: end of year 2022

Real World Testing Expected Outcomes

Expected outcomes from conducting the Real World Testing will be observance of high volumes of daily use of certified immunization query and reporting capabilities in production by clients qualified for the relatively small *Soarian Clinicals* installed client base. Reporting on the discrete data will allow us to establish baselines for volumes and further expectations for future Real World Testing activities.

Real World Testing Metrics

Metrics for the *Soarian Clinicals* Transmission to Immunization Registries Real World Testing will include:

1. Total transactions from state IIS data across the measurement period
2. Number of successful messages from state IIS data across the measurement period
3. Number of failure messages from state IIS data across the measurement period
4. Success rate for submissions and queries with state IISs across the measurement period (target = 90%+)
5. Total transactions from internal client transaction data across the measurement period
6. Number of successful messages from internal client transaction data across the measurement period
7. Number of failure messages from internal client transaction data across the measurement period
8. Success rate for submissions and queries from internal client transaction data across the measurement period (target = 90%+)

Justification

Reporting on production activity tracking data from state IISs as well as querying client's production databases provides a baseline to monitor activity immunization data exchange. Target success rates of 90%+ would indicate an acceptable and productive use of the capabilities as we realize there are some failures outside of normal control, such as timeouts due to network outages, data corruption in payload, etc.

Additionally, by monitoring both overall transaction volumes and success rates we can provide a more complete picture of overall real world interoperability of the certified capabilities while also tracking abnormalities for resolution as a stable network traffic and instance should not deviate from the established threshold.

170.315(f)(2) Transmission to Public Health Agencies — Syndromic Surveillance

Certified Health IT Module(s): *Syndromic Surveillance; HealthSentry*

CHPL Product Numbers: 15.04.04.1221.Synd.20.04.1.210308; 15.04.04.1221.Heal.20.03.1.200303;
15.04.04.1221.Heal.20.04.1.210308

Real World Testing Methodologies

The objective of this Real World Testing plan is to provide evidence of the successful and conformant reporting of syndromic surveillance information to target public health agencies from the Cerner *Syndromic Surveillance* and *HealthSentry* certified HIT modules. The target public health agencies are typically state departments of health (DOH). Many DOHs forward syndromic surveillance data received from their participating hospitals to the National Syndromic Surveillance Program (NSSP) which is affiliated with the Centers for Disease Control and Prevention (CDC). NSSP maintains a database of syndromic surveillance data which provides a greater breadth of data for its intended use in analyzing and following trends in public health.

Two Options are presented as testing methodologies and are reflected as Plan A and Plan B below. As Cerner continues to work with NSSP on details and viability for Plan A, a determination will be made as to whether it can serve as sufficient Real World Testing evidence. If it is determined that Plan A is incomplete or infeasible for Real World Testing, Plan B will be implemented as a fallback.

Plan A

Plan A will leverage a new report which is under consideration from the NSSP of the CDC for a representative sample of clients actively transmitting syndromic surveillance information. The report should capture data for at least 30 days within the reporting year and provide details of data received from the sample clients for Emergency Department (ED) patient encounters. The report should demonstrate information completeness (cases contain the required elements), as well as validity (conformant to [PHIN Messaging Guide for Syndromic Surveillance, Release 2.0](#) specification standards, no errors), and timeliness (received within one day of visit).

Plan B

Plan B will provide evidence of successful creation and transmission of the required [PHIN Messaging Guide for Syndromic Surveillance, Release 2.0](#) specification transactions for ED encounters to target public health agencies. The plan is to engage a representative sample of clients actively transmitting syndromic surveillance information to their respective DOH and capture submission logs and transactions for an appropriate 30-day period to show evidence of ongoing transmission of the following Admission, Discharge, and Transfer (ADT) HL7® transactions:

- A01 – Admissions
- A04 – Emergency Department (ED)
- A03 – Discharge
- A08 – Revise Patient Information

Justification

Cerner's *Syndromic Surveillance* and *HealthSentry* certified HIT modules are designed to provide standardized HL7® transmission of required patient and clinical information to public health agencies. As part of the certification process, Cerner demonstrated *Syndromic Surveillance* and *HealthSentry* generate the appropriate outbound messages as admissions, ED registrations, discharges and patient updates are saved to Cerner *Syndromic Surveillance* and *HealthSentry*. Messages are generated near real-time and submitted to public health authorities per their specified timeliness requirements.

To demonstrate real world implementation/use of these capabilities as expected for Real World Testing, the selected methodology shows successful transmission of the required HL7® transactions to the target public health agency on an ongoing basis (over a 30-day test period) rather than on a scripted occurrence as demonstrated during the certification process. By strategically selecting sample clients for the activities, the methodology also allows for appropriate coverage of applicable care settings.

Care Settings for Real World Testing

- Acute
- Emergency Department

Cerner *Syndromic Surveillance* and *HealthSentry* are standalone applications which processes and formats ED encounter transactions received from *Cerner Millennium*® EHR systems.

Standards Version Advancement Process

N/A

Real World Testing Milestones

1. Determine viability of Plan A for the Real World Testing Plan: mid-Q1 2022
2. Establish target clients for test sample (Plan A or B): end of Q1 2022
3. Gather sample client submission logs (Plan B): end of Q1 2022
4. Prepare summary Real World Testing results report (Plan A or B): end of Q2 2022

Real World Testing Expected Outcomes

The results of the Real World Test will indicate the successful ongoing transmission of the HL7® transactions to the target DOH. It shall demonstrate the test sample clients actively and successfully generate and send information for their ED patients during the test period. This includes admissions (A01), discharges (A03), and ED registrations (A04) as well as any update transactions (A08) specific to data reported for syndromic surveillance for the patients included in the reporting test period. This will show successful “active engagement” with public health registries as required for clients who rely on the certified capabilities as part of measurement under the Centers’ for Medicare and Medicaid Services’ (CMS) Promoting Interoperability programs.

Real World Testing Metrics

The selected metric for the *Syndromic Surveillance* and *HealthSentry* Real World Testing is the percentage of successful daily syndromic surveillance transactions (A01, A04 – ED, A03, A08) for sample clients across the 30-day selected measurement period (target = 85%+).

Justification

Showing the 85% or higher percentage of successful daily submissions provides evidence the required HL7® transactions were successfully created and transmitted from Cerner *Syndromic Surveillance* and *HealthSentry* to the DOH. Using 85% as a target for the metric allows for occasional unanticipated networking errors or interruptions outside of control of the certified *Syndromic Surveillance* and/or *HealthSentry* processing. Furthermore, the chosen metric directly tracks data indicative of sustained successful utilization of the certified capabilities for their real world purpose.

170.315(f)(2) Transmission to Public Health Agencies — Syndromic Surveillance

Certified Health IT Module(s): *Soarian Clinicals*

CHPL Product Numbers: 15.04.04.1221.Soar.15.01.1.210331

Real World Testing Methodologies

The objective of this Real World Testing plan is to provide evidence of ongoing (near real-time), successful reporting of syndromic surveillance information to target public health agencies. The Real World Testing methodology consists of two components as summarized below:

1. Collect audit data from the Production database of a representative sample of clients actively transmitting syndromic surveillance information to their respective Department of Health (DOH) jurisdiction. The auditing will show evidence of ongoing (near real-time) events that generate the following ADT HL7® transactions for Syndromic Surveillance reporting of Acute (Inpatient), Emergency Department (ED) and any client designated Urgent Care encounters: A01 – Inpatient Admissions, A04 – Emergency Department (ED)/Urgent Care Registrations, A03 – Discharge (Inpatient/ED/UrgentCare), A08 – Revise Patient Information (Inpatient/ED/Urgent Care). Audit data will be collected for a 2-week testing period within the reporting year and the total (aggregate) number of ADT message events (A01, A04, A03, A08) will be provided for each 2-week sample of audit data. The numbers will show totals for the 2-week test period as well as daily breakdown/averaging to demonstrate ongoing (near real-time) message generation.
2. Monitor *Soarian Clinicals* issue reporting and tracking tools for any issues specific to the syndromic surveillance certified capabilities to support that they are functioning as expected and clients submitting data to their respective DOH jurisdiction are not encountering issues with the successful transmission/receipt of the supported HL7® ADT transactions.

Justification

Soarian Clinicals syndromic surveillance certified capabilities are designed to provide standardized HL7® transmission of required patient demographic and clinical information to public health agencies. *Soarian Clinicals* provides the information on outbound HL7® transactions according to the requirements specified in the [PHIN Messaging Guide for Syndromic Surveillance, Release 2.0](#).

As part of the certification process, Cerner demonstrated that *Soarian Clinicals* generates the appropriate outbound messages as Inpatient Admissions, ED and Urgent Care registrations, Discharges, and Patient Updates are saved in *Soarian Clinicals*. Messages are generated near real-time. Each HL7® message was certified to be conformant to required content and format. Clients who subsequently pursued implementation of these capabilities for “active engagement” with DOH as part of Centers’ for Medicare and Medicaid Services’ (CMS) Promoting Interoperability programs completed an onboarding/verification process with their respective DOH jurisdiction to assure information was being successfully transmitted and received prior to full implementation of their Production data.

To demonstrate Real World use of the feature, the focus of the methodology is to provide evidence that *Soarian Clinicals* is raising the required events for creation of the supported ADT HL7® transactions for syndromic surveillance on a continuous basis (over a 2-week testing period) rather than on a scripted occurrence as demonstrated during the certification process. Focusing on actual submission activity is the best indication of successful real world use for the intended purposes. This will be accomplished by capturing the audit data from a representative sample of clients actively submitting Syndromic Surveillance data from

their production database. The total number of events/transactions by supported ADT HL7® message (A01, A03, A04, A08) and further breakdown/averaging during each day of the test period will provide evidence of ongoing near real-time activity.

The methodology also leverages Cerner's existing mechanism for tracking *Soarian Clinicals* issues related to Office of the National Coordinator for Health IT (ONC) certification requirements. If there are issues with the successful generation and receipt/acceptance of the supported syndromic surveillance ADT HL7® messages, the client would report an issue with Cerner for investigation. Minimal (or no) reported issues will support that the feature is working as expected.

Finally, the Real World Testing methodology will include a representative sample of facilities that are actively submitting syndromic surveillance data for applicable care settings to ensure all are accounted for in the testing data and metrics.

Care Settings for Real World Testing

- Acute
- Emergency Department

Soarian Clinicals is an integrated Acute care solution with an integrated Emergency Department (ED) Information System.

Standards Version Advancement Process

N/A

Real World Testing Milestones

1. Identify clients for representative test sample: end of year 2021
2. Monitor for reported issues: end of Q1 2022
3. Plan for audit data collection: end of Q2 2022
4. Gather audit data from sample clients Production data for test period: end of Q3 2022
5. Prepare summary report: end of year 2022

Real World Testing Expected Outcomes

The results of the Real World Testing will indicate with confidence the ongoing and successful creation of the supported Syndromic Surveillance ADT HL7® transactions. It shall substantiate that the sample clients generate and send information for their acute inpatient, ED and designated Urgent Care patients during the measurement period. This includes A01, A03, A04, and A08 transactions specific to Syndromic Surveillance for qualifying patients/encounters included in the reporting test period. These results coupled with minimal (if any) reported issues specific to syndromic surveillance reporting will further show successful "active engagement" with public health registries (as defined for CMS Promoting Interoperability programs) by *Soarian Clinicals* clients.

Real World Testing Metrics

The metric for *Soarian Clinicals* syndromic surveillance Real World Testing will be aggregate successful submission volume across the selected 2-week measurement period.

Justification

The audit data from a representative sample of clients will demonstrate that *Soarian Clinicals* generates the supported ADT HL7® transactions on a sustained near real-time basis. While specific numbers cannot be set as the timing and type of message generated will depend on patient activity and documentation, the aggregate data will show generation of the supported messages throughout each 24-hour period within the 2-week test period.

Additionally, monitoring for client reported issues affecting syndromic surveillance reporting will further substantiate the conformant transactions are successfully transmitted (and received) on a sustained ongoing basis to target public health agencies where the information is available for the intended use in trending and analysis of public health.

170.315(f)(3) Transmission to Public Health Agencies — Reportable Laboratory Tests and Value/Results

Certified Health IT Module(s): *Electronic Lab Results; HealthSentry*

CHPL Product Numbers: 15.04.04.1221.Elec.20.04.1.210308; 15.04.04.1221.Heal.20.03.1.200303; 15.04.04.1221.Heal.20.04.1.210308

Real World Testing Methodologies

The objective of this Real World Testing plan is to provide evidence of the successful and conformant reporting of reportable laboratory results information to target public health agencies via utilization of the Cerner *Electronic Lab Results* and *HealthSentry* certified HIT modules. The target public health agencies are typically state departments of health (DOH).

The Real World Testing methodology will consist of evidence of successful creation and transmission of the required [HL7® 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1](#) transactions for reportable laboratory results to target public health agencies. The strategy is to engage a representative sample of clients actively transmitting reportable lab information to their respective DOH and capture submission logs and transactions for a 30-day period during the calendar year to show evidence of ongoing successful real world use of the certified capabilities.

Justification

Electronic Lab Results and *HealthSentry* are designed to provide standardized HL7® transmission of required patient and clinical information to public health agencies. These certified HIT modules provide the information on the specified outbound HL7® transactions according to the [HL7® 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1](#) specifications. As part of the certification process, Cerner demonstrated *Electronic Lab Results* and *HealthSentry* generate the appropriate outbound messages containing all required message segments. Messages originating from *Electronic Lab Results* are generated near real-time and submitted to public health authorities per their specified timeliness requirements, while those originating from *HealthSentry* are generated in a batch file and submitted to public health authorities daily.

To demonstrate real world implementation/use of this feature, the plan will show successful transmission of the required HL7® transactions to the target public health agency on an ongoing basis (over a 30-day test period) rather than on a scripted occurrence as demonstrated during the certification process. The testing will gather submission logs for the sample clients who will be strategically selected to ensure coverage of all appropriate care settings served by the certified HIT modules. Since message formatting and submission processing is consistent for all users of the certified HIT modules, the plan also appropriately accounts for any unique implementations or potential variances between different sizes or types of organizations.

Overall, the selected methodology is ideal for Real World Testing as it specifically focuses on proving successful use of the certified capabilities for their ultimate intended purpose of active submission of standards-conformant data to public health agencies.

Care Settings for Real World Testing

- Acute

Electronic Lab Results and *HealthSentry* are both standalone products that perform processing and formatting of reportable laboratory result transactions received from *Cerner Millennium*® EHR systems. These capabilities are exclusively intended for the Acute care venue.

Standards Version Advancement Process

N/A

Real World Testing Milestones

1. Establish target clients for test sample: end of Q1 2022
2. Gather sample client submission logs: end of Q1 2022
3. Prepare summary report: end of Q2 2022

Real World Testing Expected Outcomes

The expected outcomes of the Real World Testing plan will be that the test sample clients generate and transmit information for their reportable laboratory results successfully on a daily-basis during the test period. This will provide proof of “active engagement” with public health registries as required for clients who rely on the certified capabilities as part of measurement under the Centers’ for Medicare and Medicaid Services’ (CMS) Promoting Interoperability programs.

Real World Testing Metrics

The selected metric for the *Electronic Lab Results* and *HealthSentry* Real World Testing is the percentage of successful daily reportable laboratory results transactions for sample clients across the 30-day selected measurement period (target = 85%+).

Justification

Showing the 85% or higher percentage of successful daily submissions provides evidence the required HL7® transactions were successfully created and transmitted from Cerner *Electronic Lab Results* and *HealthSentry* to the DOH. Using 85% as a target for the metric allows for occasional unanticipated networking errors or interruptions outside of control of the certified *Electronic Lab Results* and/or *HealthSentry* processing. Furthermore, the chosen metric directly substantiates sustained successful utilization of the certified capabilities for their real world purpose of serving public health needs.

170.315(f)(3) Transmission to Public Health Agencies — Reportable Laboratory Tests and Value/Results

Certified Health IT Module(s): *NOVIUS Lab*

CHPL Product Numbers: 15.07.04.1221.NOVI.NO.01.0.180720

Real World Testing Methodologies

The Real World Testing methodology for *Novius Lab* Reportable Laboratory Tests and Values/Results certified capabilities will consist of a combination of client production database and outbound transaction queries to identify unique public health transactions that have been generated by our clients to report real world laboratory results to public health departments. The queries will be compiled into a report to demonstrate that transactions are successfully transmitted by *NOVIUS Lab* and received by the client's public health department on an ongoing basis.

Additionally, Cerner will attempt to partner with the client's represented Department of Health (DOH) to obtain a record of the clients' "active engagement" with their public health department as part of Centers' for Medicare and Medicaid Services' (CMS) Promoting Interoperability programs. This additional element of the plan will provide supplemental assurances that the certified capabilities are serving their intended real world purpose for our clients. If partnering with the DOHs proves infeasible for this purpose, we will use our existing internal surveillance report which is generated on a monthly basis to track and respond to any issues identified by clients related to use of the certified capabilities. Having no active issues during the measurement period related to *NOVIUS Lab's* Reportable Laboratory Testing and Values/Results certified capabilities will also provide supplemental assurances that clients are achieving "active engagement" as expected and that submissions are conformant.

Justification

While they all generally align to the [HL7@ 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1](#) specifications, each state DOH has some unique requirements for their reporting. Therefore, *NOVIUS Lab* clients must have the flexibility to configure the system to support their state. Being able to 'trace' an electronic transaction will show evidence that electronic reportable results are generated, transmitted, and ultimately received by these DOHs. This is an ideal methodology for Real World Testing as it provides the best possible indication of successful use of the certified capabilities in the real world.

The second element of the methodology focused on obtaining direct affirmation from the engaged state DOHs of *NOVIUS Lab* clients' "active engagement" requirements for purposes of CMS Promoting Interoperability programs supplements the transactional reporting with additional objective verification. However, ability to actually obtain the necessary engagement from the state DOHs for this purpose is beyond Cerner's control. Therefore, we have accounted for potential challenges by also having the stated backup plan to provide the same types of supplemental assurances.

The transactions that are reported on via the selected methodology will also be obtained from the full scope of applicable care settings for the Real World Testing plan to ensure proper coverage. This is achieved by using a "Patient Class" identifier on the transactions which indicates the source care setting for the results being transmitted. Cerner also determined that due to the small client base of *NOVIUS Lab* and consistency in the implementation model, there is no additional variability to account for that is not already covered inherently with the chosen methodology.

Care Settings for Real World Testing

- Acute
- Emergency Department

NOVIUS Lab is utilized to process laboratory samples that are received for analysis from the Acute, and Emergency Department care settings. The samples are processed within the lab based on sample type and not on individual care setting. Each state DOH determines result values that are required to be sent regardless of the care setting where the sample is collected. *NOVIUS Lab* is marketed exclusively to Acute care hospitals.

Standards Version Advancement Process

N/A

Real World Testing Milestones

1. Complete Identification of target *NOVIUS Lab* clients (those clients who have their systems configured to electronically send results to their public health department) and their reportable result transactions to public health: end of Q1 2022
2. Execute the reports/queries on identified client production databases. We will execute the report/query on a daily basis for a single calendar quarter: end of Q2 2022
3. Attempt to work with an identified state DOHs and obtain a report showing clients are actively sending results and in active engagement. If reaching out to the DOHs is not successful by this time, we will generate and include the surveillance report for the test period as an alternative to the partnership with the DOHs: end of Q2 2022
4. Generate final Real World Testing result report: end of Q3 2022

Real World Testing Expected Outcomes

For targeted clients who have *NOVIUS Lab* configured to send outbound result transactions to their state DOH, it is expected that *NOVIUS Lab* will consistently provide successful submission of the desired data for purposes of lab result reporting. This will specifically be identified by monitoring the status of the transactions providing indication of successful delivery and receipt. Generally, we anticipate that results will show submission frequencies varying from daily to once or twice a week across the individual target clients. This is due to the differing sizes of and ranges of reportable specimens supported by the facilities being measured.

Ideally, we can also observe outcomes of engaged state DOHs providing positive affirmation of “active engagement” (as defined for CMS Promoting Interoperability program purposes) from the *NOVIUS Lab* clients. However, if that is not achievable we expect that the internal surveillance report will show no open public health communication issues during the measurement period.

Real World Testing Metrics

The selected metric for the *NOVIUS Lab* Real World Testing is the volume of Reportable Laboratory Tests and Values/Results successfully generated and transmitted to the appropriate state DOH per client for the single calendar quarter testing period (target = at least 10).

Justification

Measuring successful submissions of data to state DOHs is the best approach for providing a metric that assures successful real world use of the certified capabilities. Due to the small client base for *NOVIUS Lab*, the expected volumes will be relatively low. Therefore, showing successful transactions from at least one client should be attainable. However, we will attempt to show the successful transactions from as many clients as possible (the number being dependent on how many clients are actively using *NOVIUS lab* reporting during the testing period). The targets for the metric also take into account any possible issues beyond the control of the certified capabilities (e.g., networking, client configuration, etc.).

170.315(f)(6) Transmission to Public Health Agencies — Antimicrobial Use and Resistance Reporting

Certified Health IT Module(s): *Antimicrobial Usage and Resistance Reporting*

CHPL Product Numbers: 15.04.04.1221.Anti.20.04.1.200324; 15.04.04.1221.Anti.20.05.1.210601

Real World Testing Methodologies

The Real World Testing methodology for the *Antimicrobial Usage and Resistance Reporting* certified HIT module will involve observing production use of the certified capabilities through activity trackers embedded in the software. These trackers can be used to determine when clients are generating the Antimicrobial Use and Resistance (AUR) reports for subsequent submission to the National Health Safety Network (NHSN). This data can be used to reliably determine which clients are actively utilizing the reports and how often, but it will not provide proof that clients were able to successfully upload the data to the NHSN, which is important to understand as an assurance that the ultimate purpose of these certified capabilities in the real world (i.e., submission to the NHSN's AUR Module) is being served for the users of the certified HIT module.

To account for this final element of the full successful use of the certified capabilities, Cerner engaged with the NHSN requesting information confirming rates of successful submission by participating organizations utilizing Cerner software. However, NHSN is unfortunately not able to provide such information at this time. Accordingly, Cerner will leverage a backup option of requesting direct confirmation from clients who have been identified as actively utilizing the *Antimicrobial Usage and Resistance Reporting* certified HIT module of their successful submission. Clients will be able to confirm this based on the immediate response received within the NHSN upload application affirming success or failure of a submission.

Justification

The Real World Testing methodology selected involves tracking actual real world use in production instead of developing mock testing activities that may fail to properly represent real world use of the certified capabilities. Individual clients tracked will be strategically selected to ensure all applicable care settings are accounted for, and since the same capabilities are deployed to all care settings and organizations for AUR reporting without variance this methodology also appropriately accounts for any potential uniqueness in implementation. Furthermore, because there is only one integration option with the *Cerner Millennium®* EHR system, we determined there are not multiple approaches to account for.

Submission to the associated NHSN AUR reporting module requires adherence to the same [HL7 Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection Reports, Release 1](#) specification that is required for certification to the Antimicrobial Use and Resistance criterion. Therefore, by completing additional testing activity to track the actual successful submission of AUR reporting by our identified clients the methodology will also ensure that the real world use of the certified capabilities is appropriately conforming to the standards for the criterion.

Care Settings for Real World Testing

- Acute
- Emergency Department

AUR Reporting is specific to Inpatient and Emergency Department locations based on the NHSN protocols.

Standards Version Advancement Process N/A
Real World Testing Milestones <ol style="list-style-type: none">1. Identificaiton of clients currently using AUR Reporting in production: end of Q3 20222. Complete execution of reports for production activity tracking data and retrieval of NHSN submission evidence from partner clients: end of Q3 20223. Compile data for Real World Testing results submission: end of Q4 2022
Real World Testing Expected Outcomes <p>The expected outcomes of the <i>Antimicrobial Usage and Resistance Reporting</i> Real World Testing will consist of observing successful generation of AUR reports across installed clients, along with positive affirmation of successful submission to the NHSN for the vast majority of our identified clients.</p>
Real World Testing Metrics <p>The selected metrics for the <i>Antimicrobial Usage and Resistance Reporting</i> Real World Testing plan are:</p> <ol style="list-style-type: none">1. Total number of successfully generated Antimicrobial Use (AU) reports over tested time period.2. Total number of successfully generated Antimicrobial Resistance (AR) reports over tested time period. <p>Justification</p> <p>The selected Real World Testing metrics will display that the AUR reports are providing the means to submit the data to the required data to the NHSN, which is the ultimate purpose of the certified capabilities in the real world. Since the NHSN does not allow this data to be manually entered into their website, the only way the data can be successfully submitted is through file generation and upload.</p> <p>The NHSN has specific protocols for how the data should be generated and submitted. Cerner followed NHSN protocols during development of AUR reports and has been through the NHSN SDS validation for Antimicrobial Use. Therefore, reports successfully generated from our certified software have a reasonable certainty of conforming to standards for the criterion and associated NHSN protocols. Any evidence of conformance failures would also be identified through our additional testing methodology of obtaining confirmation of subsequent successful submission.</p>

170.315(f)(6) Transmission to Public Health Agencies — Antimicrobial Use and Resistance Reporting

Certified Health IT Module(s): *Soarian Clinicals*

CHPL Product Numbers: 15.04.04.1221.Soar.15.01.1.210331

Real World Testing Methodologies

The methodology employed for the *Soarian Clinicals* Antimicrobial Use and Resistance (AUR) Reporting certified capabilities will involve production activity tracking for use of the capabilities in the real world. Cerner will specifically be tracking client transactional data to determine our clients AUR reporting activity to the NHSN. To execute the methodology, each month our support teams will upload client transactional file generation activity to correlate with clients submitting the reports to the National Health Safety Network (NHSN).

To account for the actual successful submission of the generated reports as part of the Real World Testing plan, Cerner engaged with the NHSN requesting information confirming rates of successful submission by participating organizations utilizing Cerner software. However, NHSN is unfortunately not able to provide such information at this time. Accordingly, Cerner will leverage a backup option of requesting direct confirmation from clients who have been identified as actively utilizing the AUR Reporting capabilities of the *Soarian Clinicals* certified HIT module of their successful submission. Clients will be able to confirm this based on the immediate response received within the NHSN upload application affirming success or failure of a submission.

Justification

Utilizing tracking of actual client file generation activity provides the most direct evidence that the certified capabilities are being successfully used in the real world for their intended purpose. This is in contrast to mock testing which may not appropriately represent client use, even if conducted in production environments. By also testing success rates of clients' reporting submissions to the NHSN the methodology ensures that the full scope of the AUR Reporting criterion and associated [HL7 Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection Reports, Release 1](#) specification conformance are accounted for.

AUR Reporting in *Soarian Clinicals* is consistent across all organizations regardless of size, type, or care setting and does not deviate from client-to-client. Therefore, the methodology is also suitable for all possible users and system variations as the tracking takes into account activity from all sources.

Care Settings for Real World Testing

- Acute
- Emergency Department

Soarian Clinicals is an Acute care solution with an integrated EDIS. AUR Reporting is applicable to Acute and Emergency Department care settings based on the NHSN protocols.

Standards Version Advancement Process

N/A

Real World Testing Milestones

1. Completion of actual monthly files generated by our client base: end of Q3 2022

2. Complete assessment of Real World Testing data for results and outcomes compilation: end of year 2022

Real World Testing Expected Outcomes

Real World Testing outcomes for *Soarian Clinicals* AUR Reporting are expected to be comprised of successful ongoing generation of AUR reports in production environments, along with successful subsequent submission of those reports to the NHSN.

Real World Testing Metrics

The selected metrics for the *Soarian Clinicals* AUR Reporting Real World Testing plan are:

1. Total number of successfully generated Antimicrobial Use (AU) reports over tested time period.
2. Total number of successfully generated Antimicrobial Resistance (AR) reports over tested time period.

Justification

The selected Real World Testing metrics will display that the AUR reports are providing the means to submit the data to the required data to the NHSN, which is the ultimate purpose of the certified capabilities in the real world. Since the NHSN does not allow this data to be manually entered into their website, the only way the data can be successfully submitted is through file generation and upload.

The NHSN has specific protocols for how the data should be generated and submitted. Cerner followed NHSN protocols during development of AUR reports and has been through the NHSN SDS validation for Antimicrobial Use. Therefore, reports successfully generated from our certified software have a reasonable certainty of conforming to standards for the criterion and associated NHSN protocols. Any evidence of conformance failures would also be identified through our additional testing methodology of obtaining confirmation of subsequent successful submission.

170.315(f)(7) Transmission to Public Health Agencies — Health Care Surveys

Certified Health IT Module(s): *PowerChart (Health Care Surveys)*

CHPL Product Numbers: 15.04.04.1221.Powe.HC.00.1.180801; 15.04.04.1221.Powe.HC.02.1.200101

Real World Testing Methodologies

National Health Care Surveys (NHCS) is a sample-based public health registry with providers/facilities being selected by the Office of National Statistics, a division of the Centers for Disease Control and Prevention (CDC). Providers/facilities sign up to participate in the NHCS registry and are notified throughout the year if they have been sampled and are required to submit data. The CDC and their contractor communicate a project plan and engage with the provider/facility (and their developer, if requested) to review procedures and specifications for data submission, including the applicable date ranges for their survey.

This sampling of providers/facilities changes every 5 years. Currently, facilities that are onboarded to submit to the National Health Care Survey (NHCS) will submit Inpatient (Acute), Outpatient, and Emergency Department encounter data for an entire year; for the National Ambulatory Medical Care Survey (NAMCS), providers are asked to submit all of their outpatient encounters for a randomly assigned 1-week reporting period during the year; and for the National Hospital Ambulatory Medical Care Survey (NHAMCS), providers/facilities are asked to submit Outpatient (Ambulatory) and Emergency Department encounters for a randomly assigned 4-week reporting period during the year.

Cerner and other developers are not provided access to the list of participating providers/facilities, which limits the ability to positively identify the clients surveyed for the registry to those that engage for assistance with implementation of the certified capabilities after having been contacted by NHCS. Accordingly, Cerner's Real World Testing methodology for the *PowerChart (Health Care Surveys)* certified capabilities will consist of two approaches:

1. Cerner will work with the CDC directly to obtain an annual report of sampled Cerner clients to obtain statistics on the rate of successful submission.
2. As a fallback option if the first element of the methodology does not prove feasible, Cerner will identify a representative sample of partner clients that have been selected by CDC for the surveys and engaged with Cerner for assistance with submission. will be run through the [NHCS IG Validator](#) to demonstrate data compliance. As part of the NHCS submission process, these providers/facilities will receive documentation from the CDC confirming their compliance with requirements of the registry, including that their implemented HL7 Consolidated Document Architecture (CDA®) templates conform with the [HL7 Implementation Guide for CDA Release 2: National Health Care Surveys \(NHCS\), R1 DSTU 2 Release 1.2](#) specifications. We will confirm with these clients that they have received this compliance affirmation as direct evidence of successful real world use of the certified capabilities.

Justification

Since the sole purpose of the Health Care Surveys certification criterion is for supporting submission to the CDC's NHCS registry, this Real World Testing plan methodology is ultimately focused on the most direct source of evidence for successful use of the certified capabilities. The methodology will also ensure that all applicable care settings are accounted for by selecting a representative sample of clients who have been surveyed for each of the NHCS survey options (NHCS, NAMCS, NHAMCS) which directly correlate back to particular care settings as explained above.

Furthermore, the methodology ensures that the certified capabilities are conforming to the full scope of the criterion and associated standard specifications because the NHCS will not consider providers/facilities compliant if data is not submitted according to their specifications.

Care Settings for Real World Testing

- Acute
- Ambulatory
- Emergency Department

The care settings supported by the PowerChart (Health Care Surveys) directly correlate to those involved in the various NHCS survey types as described in the Methodology section above.

Standards Version Advancement Process

N/A

Real World Testing Milestones

1. Identifying partner clients (that are sampled by CDC and engage with Cerner for submission assistance) to perform the testing and validation with: end of Q2 2022
2. Completing the testing validation activities with partner clients: end of Q3 2022
3. Obtain Reporting data from CDC: end of Q4 2022
4. Compile data for Real World Testing results: end of Q4 2022

Real World Testing Expected Outcomes

The expected outcomes for the *PowerChart (Health Care Surveys)* Real World Testing plan will be positive affirmation from the CDC that all sampled providers/facilities utilizing Cerner's certified HIT module have submitted successfully. We also expect to see a successful validation of data for each of the NHCS' survey options when we engage with clients who have been sampled by the CDC.

Real World Testing Metrics

The metric for the Real World Testing plan will be the success rate of compliance with NHCS reporting submission for sampled Cerner clients (target = 100%)

Justification

The selected metric is the most critical measurement that can be used for Real World Testing as it indicates that the certified capabilities are able to be successfully used in all cases for their sole intended purpose. We fully anticipate that any sampled client who chooses to respond and participate in the NHCS submission will do so successfully and this will be identifiable through either our direct engagement with CDC for submission data, or via direct engagement with our partner clients.

170.315(h)(1) Direct Project

Certified Health IT Module(s): *FirstNet (Clinical)*; *PowerChart (Clinical)*; *Soarian Clinicals*

CHPL Product Numbers: 15.04.04.1221.Firs.15.04.1.210308; 15.04.04.1221.Firs.18.05.1.210308; 15.04.04.1221.Powe.15.04.1.210308; 15.04.04.1221.Powe.18.05.1.210308; 15.04.04.1221.Soar.15.01.1.210331

Real World Testing Methodologies

The Real World Testing methodology for Cerner's Direct Project certified capabilities, which are shared across the *FirstNet (Clinical)*, *PowerChart (Clinical)*, and *Soarian Clinicals* certified HIT modules, will consist of collecting data on Direct messages that have been sent and received through the Cerner Direct Health Information Service Provider (HISP). This data will be obtained via existing message volume reporting which is provided to DirectTrust on a quarterly basis as part of being recognized as a DirectTrust accredited HISP.

This reporting includes counts of Direct message transactions inbound and outbound through the Cerner Direct HISP, broken down by month. Through this reporting, we are able to track data on all *Soarian Clinicals* and Cerner Millennium (*FirstNet (Clinical)* and *PowerChart (Clinical)*) clients live with the Cerner Direct HISP in production environments. This also allows us to success and failure rates of real world transactions through our Direct HISP.

Justification

By monitoring message transactions from live production client environments, it is possible to show use and the successful processing of message transactions inbound and outbound. This ultimately provides the best possible approach to Real World Testing as the data is a true representation of real world utilization of the certified capabilities. It also ensures we are equally accounting for all clients using certified software across the applicable certified HIT modules, which inherently accommodates all applicable care settings as the same HISP is leveraged by all venues and all endpoints are hosted by Cerner with consistent configuration for the messaging exchange.

Additionally, this methodology includes validation of conformance to applicable [ONC Applicability Statement for Secure Health Transport, Version 1.2](#) and [Implementation Guide for Delivery of Notification in Direct v1.0](#) as criteria for message success includes specifications conformance and receipt of Message Delivery Notifications (MDNs).

Care Settings for Real World Testing

- Acute
- Ambulatory
- Behavioral Health
- Emergency Department
- Pediatrics

The above identified care settings have been determined as the full scope of those applicable to users of the *Soarian Clinicals*, *FirstNet (Clinical)*, and *PowerChart (Clinical)* certified HIT modules.

Standards Version Advancement Process

N/A

Real World Testing Milestones

1. Complete retrieval of data from the Cerner Direct HISP Message Volume by Transaction report: first week of Q4 2022

2. Complete retrieval of *Cerner Millennium*® client asset list: first week of Q4 2022
3. Complete assessment of Real World Testing data for results and outcomes compilation: end of year 2022

Real World Testing Expected Outcomes

Expected outcomes for the Direct Project Real World Testing will be the following:

1. Higher monthly volumes of outbound message transactions than inbound transactions. We believe our reporting will demonstrate this as a result of Emergency Department workflows using document query from an HIE for transitions of care. Additionally, we believe there will be higher volumes outbound due to our standardized deployment and use of Direct messaging across the Cerner client base.
2. Consistency in the transaction volumes across months, which indicates some level of user retention/satisfaction (i.e., continuing to use the capabilities instead of abandoning them).
3. Low rates of errors as the ultimate indication of successful real world use (see "Metrics" section for more details).

Real World Testing Metrics

The metric for the Direct Project Real World Testing plan will be the success rate for all message transactions (inbound and outbound) over the Q1-Q3 2022 measurement period (target = 80%+).

Justification

Measuring successful delivery of Direct Messages establishes by nature that our clients are using the technology successfully. While our % of successful message transactions may not be 100%, it is evidence that the technology is in use and validates that 100% of Direct Messages are accounted for. The 80% target for the metric was baselined on from previous years' success rates and continues to demonstrate real world use is occurring through live production data at each of our client sites.

Failures can occur for numerous reasons, many of which are out of our control. Failure reasons can generally be accounted for in one of the following categories:

- System downtime (planned or unplanned)
- System performance issues with 3rd party vendor (delayed confirmation of successful deliveries)
- Configuration issues at endpoints
- Build issues at the endpoint
- Networking/DNS issues
- Trust and/or User Error
- Typo of Direct Address
- Non-Direct email address used
- Not DirectTrust network address.

Application Access – 170.315(g)(7)-(9)

Certified Health IT Module(s): *FirstNet (Clinical)*; *PowerChart (Clinical)*

CHPL Product Numbers: 15.04.04.1221.Firs.15.04.1.210308; 15.04.04.1221.Firs.18.05.1.210308;
15.04.04.1221.Powe.15.04.1.210308; 15.04.04.1221.Powe.18.05.1.210308

Real World Testing Methodologies

The Real World Testing methodology for the *FirstNet (Clinical)* and *PowerChart (Clinical)* Application Access certified capabilities will consist of tracking live production API requests and responses from registered applications. This tracking is accomplished via utilization of a Cerner cross-database analytics tool which provides near real-time activity tracking of active production environment use, including a dedicated dashboard of tracking specific to Cerner's certified APIs.

This dedicated API dashboard provides real world utilization data that can provide the insights necessary to ensure that the certified APIs are reliably serving their intended purpose for our clients after achieving certified status. The data provided includes daily activity data across all connected client systems by requesting application type (consumer vs. provider) and operation type, along with granularity to the specific *Fast Healthcare Interoperability Resources (FHIR)* resource requested and success/vs. failure status of each API response.

Justification

Because the reporting dashboard for the APIs is based exclusively on production activity, it represents direct visibility of real world use of the certified APIs. This represents a direct alignment of the selected methodology to the intent of Real World Testing. Filtering by the requesting application type also allows direct alignment to the scope of the current Application Access criteria to consumer (patient) access requests.

The production activity tracking also tracks across all clients actively utilizing the APIs meaning that all care settings for which the capabilities are marketed and supported are represented equally, instead of picking and choosing only certain care setting implementations. Similarly, the full scope of the criterion is accounted for in the methodology given that all FHIR resources accommodating the required Common Clinical Data Set (CCDS) are tracked – this includes use of the Binary resource to retrieve conformant HL7® Consolidated Clinical Document Architecture (C-CDA) documents as required for the All Data Requests Application Access criterion. Any requests would also have been appropriately authenticated and authorized as a pre-requisite, which accounts for the Patient Identification Application Access criterion.

Finally, discretely tracking the success and failure of the API responses in the real world via HTTP response codes shows the real world use is resulting in successful API calls (not just high volumes with high failure rates).

Care Settings for Real World Testing

- Acute
- Ambulatory
- Behavioral Health
- Emergency Department
- Pediatrics

The above care settings have been determined as those applicable to the client base leveraging the certified APIs under the *PowerChart (Clinical)* and *FirstNet (Clinical)* certified HIT modules in the real world.

Standards Version Advancement Process

N/A

Real World Testing Milestones

1. Compile a comprehensive list of all client API implementation to be included in the API dashboard tracking: Q1 2022
2. Review current production activity tracking dashboard in-depth to identify any data gaps or issues to be addressed: Q1 2022
3. Begin data retrieval from dashboard for Real World Testing and follow-up on any “loose ends” discovered in prep activities: Q3 2022
4. Complete all Real World Testing and d completed Real World Testing results for 2022: Q4 2022

Real World Testing Expected Outcomes

Expected outcomes for the *PowerChart (Clinical)* and *FirstNet (Clinical)* certified APIs Real World Testing will include high volumes of successful API transactions across all of the live production endpoints. This would be observed on a daily basis showing application usage for the certified APIs. Additionally, we anticipate that volumes of transacitons will vary widely across individual FHIR resources based on the types of CCDS data that is more commonly requested by popular apps today. For example, volumes for the Observation resource will be significantly higher than any other resource.

Real World Testing Metrics

The metric for the *PowerChart (Clinical)* and *FirstNet (Clinical)* certified APIs Real World Testing will be the success rate of transactions observed across client production activity for the calendar year (target = 98%+).

Justification

The selected metric is a simple but powerful one. It shows that the API is performing at a high rate of success delivering the data to users consistently and effectively. The 98% success rate target accounts for intermittent failures due to occurrences such as bad requests, networking failures, and other expected complexities in the real world.

Application Access – 170.315(g)(7)-(9)

Certified Health IT Module(s): *Soarian Clinicals*

CHPL Product Numbers: 15.04.04.1221.Soar.15.01.1.210331

Real World Testing Methodologies

There are two methodologies presented for the Soarian Clinicals Application Access Real World Testing plan.

The primary methodology and preferred method for Real World Testing involves the collection of API usage statistics from clients' production environments. Each time a resource is retrieved by an app, the *Soarian Clinicals* EHR inserts a record in an API activity log that includes the type of resource (Patient, AllergyIntolerance, etc.), patient, and success/failure indicator. Our methodology is to query this log to ensure a positive count of successful retrievals across all resources required for the Application Access criteria.

Soarian Clinicals EHR clients are in the process of migrating to other EHR solutions. Because of this, the number of clients using the *Soarian Clinicals* EHR is steadily declining. The app developer community is aware of this and as a result has shown less interest in investing in API integration with the *Soarian Clinicals* EHR than it has with other EHRs. Consumer enthusiasm has also yet to materialize. For these reasons, we define a secondary, fall back method to be used if there is insufficient usage of apps connected to the *Soarian Clinicals* EHR API among consumers.

This secondary method involves an app exercising the same *Soarian Clinicals* API software on a simulated client production environment. This environment would be configured to use the same EHR software version, authorization server, and network connectivity as our production hospital clients use to provide as close to a real world production scenario as possible.

Justification

Patient Identification

The primary and fallback test methods exercise the complete consumer access workflow, which includes the consumer's identity being verified by the facility's chosen Identity Provider (e.g., patient portal login), linked to those patients that the consumer is authorized to access, presented with a patient selection screen, and an authorization token returned to the app corresponding to that patient.

Data Category Request

The primary and fallback test methods leverage counts from the activity log for each of the resources that comprise the Common Clinical Data Set (CCDS). A positive count for each demonstrates that each resource has been accessed via the API.

All Data Request

The primary and fallback test methods leverage a count from the activity log for the DocumentReference resource associated with HL7® Consolidated Clinical Document Architecture (C-CDA) document retrieval. A positive count demonstrates that the DocumentReference resource, and in turn the C-CDA document, has been accessed via the API. The C-CDA documents returned in the DocumentReference resource in response to All Data Requests are created by the same code referenced in the *Soarian Clinicals* Real World Test for 170.315(b)(1), and hence validated using the methodology documented for that Real World Test.

The *Soarian Clinicals* EHR does not segregate data available via the API based on the care setting. The same API workflow and data sources are utilized for Acute care and Emergency Department patients. Thus, regardless of the care setting in which the patient was seen, identical code is exercised to retrieve resources via the API and accounted for with this methodology. This is also true regardless of the organization size and type.

Care Settings for Real World Testing

- Acute
- Emergency Department

Soarian Clinicals is used in Acute and Emergency Department care settings.

Standards Version Advancement Process

N/A

Real World Testing Milestones

1. Identify production client environments for which API usage statistics will be gathered: Q1 2022
2. Assess need for fallback test method, based on client API usage. If necessary, set up EHR environment that mirrors real world to implement fallback test method: Q2 2022
3. Execute Real World Testing activities (primary or secondary methodology): Q3 2022
4. Complete assessment of Real World Testing data for results and outcomes compilation (primary or secondary methodology): Q4 2022

Real World Testing Expected Outcomes

Milestones for the *Soarian Clinicals* Application Access Real World Testing plan will consist of the following for each identified methodology:

- Primary Methodology – It is expected that the API activity log will reflect relatively low levels of app usage by patients of hospitals that use the *Soarian Clinicals* API in production. As explained earlier in this test plan, the *Soarian Clinicals* client base is relatively small and neither Cerner nor its *Soarian Clinicals* clients can force app developers to support the *Soarian Clinicals* API in their products, much less force patients to use those apps that are available. If no usage is indicated by the API activity log, the secondary methodology will be used.
- Secondary Methodology – It is expected that the API activity log will reflect the usage of a test client app successfully exercising all of the required API functions in an environment that mirrors a hospital client's production environment in EHR software and network configuration.

Real World Testing Metrics

The selected metric for the *Soarian Clinicals* Application Access Real World Testing plan will be the number of successful API reads by resource type across the testing year. The target for this metric will be at least one successful access event via API is recorded in the EHR's API activity log for each of the following resource types for the CCDS data scope: Condition; DiagnosticReport; AllergyIntolerance; Patient; DocumentReference; Immunization; Observation; Procedure; Assessment; CarePlan; Device; MedicationStatement; Conformance

Justification

The counts derived from the activity log apply only to successful API accesses through the entire pathway from consumer app through networking to the EHR and out. As the counts are broken down by resource type, a positive count for each resource type demonstrates that the API has successfully returned the full CCDS. We set the minimum bar of 1 successful read of all covered data resources in a "real world" environment, again bearing in mind our limited adoption by patients and clients across a client base that is migrating away from the *Soarian Clinicals* EHR.

As mentioned immediately above, the nature of the activity log also tests the full depth and breadth of the API in a real world context.

Clinical Quality Measures (CQMs) – 170.315(c)(1)-(3)

Certified Health IT Module(s): *FirstNet (CQMs); PowerChart (CQMs)*

CHPL Product Numbers: 15.07.04.1221.Firs.15.02.1.190514; 15.04.04.1221.Firs.18.03.1.200101;
15.04.04.1221.Powe.C5.02.1.190514; 15.04.04.1221.Powe.C8.03.1.200101

Real World Testing Methodologies

The following is an overview of the methodologies and approaches that will be employed for the Real World Testing of the Clinical Quality Measures (CQM) criteria.

The CQM – record and export criterion at 170.315(c)(1) enables the client/user to record all of the data that would be required to calculate CQMs and allows the client/user to export a data file conforming to the [HL7® CDA® Release 2 Implementation Guide for: Quality Reporting Document Architecture – Category 1 \(QRDA I\); Release 1, DSTU Release 3](#) specifications at any time. The CQM – import and calculate criterion at 170.315(c)(2) enables the client to import and calculate every CQM used for reporting purposes utilizing the same HL7® CDA® QRDA I specification. The CQM – report criterion at 170.315(c)(3) enables a user to electronically create a data file conformant with the Category I and Category III CMS Implementation Guides for Quality Reporting Document Architecture for transmission of clinical quality measurement data.

In order to demonstrate successful real world testing for the CQM – record and export and CQM – report criteria, we will track data submissions to Centers for Medicare and Medicaid Services (CMS) and Joint Commission (TJC) for a sample of *Cerner Millennium®* clients that have used *Cerner's FirstNet (CQMs)* and *PowerChart (CQMs)* certified capabilities to record and process the CQM data through the Cerner Quality Clearinghouse portal. The following EH measures will be used during the testing: ED-2, VTE-1, VTE-2. These are applicable to Acute and Emergency Department care settings. Additionally, CMS-165 and CMS-122 will be included as these are applicable to the Ambulatory Care setting.

For the CQM – import and calculate criterion, we will demonstrate successful real world use by coordinating with a client that requires the import of QRDA data files from an external third-party source system to *Cerner Millennium®* system and observe the successful use of our certified capabilities to import the data.

Justification

A client's ability to successfully submit eCQM data to CMS/TJC for the Hospital Inpatient Quality Reporting (IQR), Joint Commission Accreditation, Merit-based Incentive Payment System (MIPS) Quality Measurement Category, Primary Care First, and Promoting Interoperability Programs directly correlates to the client's actual real world use of the CQM – record and export and CQM - report criteria certified capabilities. Likewise, ability to import and submit QRDA data files for a client that has transitioned from a third-party EHR to *Cerner Millennium®* correlates with client's use of CQM – import and calculate criterion. Our methodologies will include the validation reports provided by the regulatory agencies once files are successfully submitted to ensure direct alignment with reporting requirements of these real world programs which represent the ultimate purpose for which these criteria exist in the program.

The workflows utilized for the eCQMs remain the same for all of the care settings applicable for the CQM certified capabilities, thus the testing methodology appropriately accounts for all care settings. Traceability of tracked data to all care settings is verifiable via the output file (QRDA) which includes data identifying the source care setting. Similarly, Cerner eCQM Reporting is consistent across all organizations regardless of size or type and Cerner's Quality Clearinghouse can cater to numerous providers for different quarters and/or for a full year evaluation. This is irrespective of the large volumes of patients which can be sourced from the *Cerner Millennium®* EHR. Accordingly, the selected methodologies also appropriately account for potential variances in implementations at different sizes and types of organizations.

Care Settings for Real World Testing

- Acute
- Ambulatory
- Emergency Department

Cerner has identified the above care settings as those supported by our certified CQM capabilities. These applicable care settings are derived directly from the care settings which the actual CQMs the *FirstNet (CQMs)* and *PowerChart (CQMs)* certified HIT modules are certified for. All of the measures under the Eligible Hospital (EH)/Critical Access Hospital (CAH) eCQMs can be mapped to Acute or Emergency Department care settings, while all of the measures under the Eligible Clinician (EC) eCQMs can be mapped to Ambulatory Care setting.

Standards Version Advancement Process

N/A

Real World Testing Milestones

1. Complete identification of target clients (EH and EC): end of January 2022
2. Complete actual Real World Testing activities execution: end of Q3 2022
3. Complete assessment of Real World Testing data for results and outcomes compilation: end of year 2022

Real World Testing Expected Outcomes

Real World Testing outcomes for the *FirstNet (CQMs)* and *PowerChart (CQMs)* CQM certified capabilities will comprise the metrics of the client's successful QRDA file submission and the metric which compares the outcomes in the submission report and *Cerner Millennium®* reports.

For Eligible Hospitals, Cerner reports display the measure outcomes for each qualifying encounter and the aggregated outcome count for the quarter. The encounter could have an outcome assigned of Initial Population, Denominator, Denominator Exclusion, Numerator, or Exception. The aggregated count will include a total for each of the outcomes. These counts should match CMS/TJC submission reports. For Eligible Clinician measures, the QRDA III Cerner audit report matches the submission detail report generated by the Cerner Quality Clearinghouse. The following outcomes are evaluated: Patient population, Denominator, Denominator Exclusion, Numerator, Exception, Performance rate, Medicare Population (Denominator), and Tax Identification Number (TIN) counts. The validation of the expected outcome correlates to successful real world use of the certified capabilities.

Real World Testing Metrics

Metrics for the *FirstNet (CQMs)* and *PowerChart (CQMs)* CQM Real World Testing will be the following:

1. CQM – record and export criterion: percentage of selected patients for whom QRDA files are successfully generated (target = 100%)
2. CQM – import and calculate: percentage of patient data successfully imported (target = 90%)
3. CQM – report criterion: percentage of successful QRDA file submissions to CMS/TJC with less than 10% outcome mismatches against Cerner reporting (target = 95%)

Justification

The selected metrics are the best options to align closely to evidence of successful use of the certified capabilities in the real world.

For the CQM – record and export metric, 100% success on execution of QRDA file generation provides clear evidence of effective real world use. For the CQM – report criterion, 95% of QRDA files with less than 10% outcome mismatches between CMS/TJC and Cerner reports was selected to account for issues outside the control of the certified capabilities that will inherently impact some tested samples. Examples of such issues

include QRDA file size exceeding (10) MB maximums for submission, files with discharge dates falling outside the reporting period, Eligible Clinicians no longer active on the practice roster during the reporting period, or failure to satisfy pre-requisite implementation steps. For the CQM – import and calculate criterion, 90% success rate target was selected to account for the dependency on the data provided by a 3rd party system. Some potential issues with data include missing required data elements (e.g., physical practice location addresses, date/time, etc.) and files generated from third party vendors using obsolete versions of specifications.

Clinical Quality Measures (CQMs) – 170.315(c)(1)-(3)

Certified Health IT Module(s): *Soarian Clinicals*

CHPL Product Numbers: 15.04.04.1221.Soar.15.01.1.210331

Real World Testing Methodologies

The methodology for Real World Testing of the *Soarian Clinicals* CQM certified capabilities under the CQM – record and export (170.315(c)(1)) and CQM – report (170.315(c)(3)) criteria will make use of the real-world generation of certified Quality Reporting Document Architecture (QRDA) files by clients and their subsequent successful submission of that data to the Centers for Medicare and Medicaid Services (CMS) and The Joint Commission (TJC) for CQM reporting programs. We will utilize a client pool that represents an appropriate sampling of different hospital settings, workflows, and processes that are used in the real world for the certified capabilities. As part of the methodology reports will be validated in a systematic way by utilizing various queries and *Soarian Clinicals* eCQM reports. These reports will be compared with the reports provided by the regulatory agencies (CMS/TJC) after submission to determine the success rate of these criteria. The following Eligible Hospital measures will be used during the testing: eED-2, eVTE-2, STK-2

For the CQM – import and calculate criterion (170.315(c)(2)), the methodology will make use of test scripts and the actual mock testing scenario execution will be performed on the testing EHR environment that appropriately mirrors real world use and conditions. A set of mock data will be imported into Cerner's Healthcare Intelligence eMeasure application and will be used to generate the QRDA files.

Justification

The Real World Testing methodologies for CQM – record and export and CQM – report criteria correlate to the actual use of the certified capabilities in the real world through the tracking of actual client data submissions to CMS or TJC that are performed using our certified capabilities. This aligns well with the intent of Real World Testing and will provide reliable evidence of the certified capabilities' real world usability post-certification.

For the CQM – import and calculate criterion, the current *Soarian Clinicals* client base does not have an identifiable real-world use case for import functionality. Thus, tracking of real world use will be infeasible and the functionalities pertaining to the criterion can only be tested in an internal mock testing environment that will closely mirror a client production environment.

Our Real World Testing methodologies appropriately account for all applicable care settings for the certified capabilities, which is traceable via data in the output file (QRDA) which identifies the care setting from which the encounter originated. Tracing of the appropriate care settings can also be attained by dissecting the data in the client database for the data elements which is traversed from *Soarian Clinicals* to the eMeasure application. Furthermore, *Soarian Clinicals* eCQM reporting is consistent for all hospitals, regardless of their size or type.

Care Settings for Real World Testing

- Acute
- Emergency Department

We have identified the above care settings as those supported by the *Soarian Clinicals* CQM certified capabilities and the same workflows are utilized across both. All of the measures under the Eligible Hospitals (EH)/Critical Access Hospital (CAH) eCQMs which *Soarian Clinicals* is certified for can be mapped to Acute or Emergency Department care settings.

Standards Version Advancement Process

N/A

Real World Testing Milestones

1. Complete identification of target clients (EH) for CQM – record and export and CQM – report criteria: end of Q1 2022
2. Complete set up of testing EHR environment that replicates CQM – import and calculate criterion usage in the real world: end of Q1 2022
3. Complete actual Real World Testing activities for CQM – record and export and CQM – report criteria: end of Q1 2022
4. Complete actual Real World Testing activities for CQM – import and calculate criterion: end of Q2 2022
5. Complete assessment of Real World Testing data for results and outcomes compilation: end of year 2022

Real World Testing Expected Outcomes

The expected outcomes for the *Soarian Clinicals* CQM Real World Testing will consist primarily of the observations outlined in the Real World Testing metrics.

For Eligible Hospitals, *Soarian Clinicals* eCQM reports display the measure outcomes for each qualifying encounter and the aggregated outcome count for the quarter. These counts should match with the relevant population in CMS/TJC submission reports. The various population counts for the selected measures and calendar quarter will be compared with values in *Soarian Clinicals* eCQM reports and justified with the results returned using Database queries.

Real World Testing Metrics

Metrics for the *Soarian Clinicals* CQM Real World Testing will be the following:

1. CQM – record and export: Percentage of successful QRDA file generation for export for patients qualified according to the measure logic (target = 100%)
2. CQM – report: percentage of successful QRDA file submissions to CMS/TJC with less than 10% outcome mismatches against Cerner reporting (target = 95%)
3. CQM – import and calculate: Percentage of successfully imported QRDA files from the testing (target = 100%)

Justification

The identified metrics were selected as they each provide the best possible reflection of successful utilization of the certified CQM capabilities in the real world. For starters, 100% success on execution of QRDA file generation for export provides clear evidence of effective real world use. The same is true for 100% success on execution of import and calculate functionality in the testing EHR environment that mirrors real world conditions.

The 95% target for percentage of successful QRDA file submissions to CMS/TJC with less than 10% outcome mismatches against Cerner reporting accounts for issues outside of the control of the certified software. These include examples such as QRDA files exceeding (10) MB size limits for submission, files missing discharge dates within the reporting period, failure to meet pre-requisites for submission, or issues related to specification discrepancies and sync issues between regulatory bodies.