![Lightning Step logo]

General Information

Plan Report ID Number:
Developer Name: Lightning Step Technologies
Product Name(s): Lightning Step
Version Number(s): 1.0
Certified Health IT Product List (CHPL) ID(s): 15.04.04.3183.Ligh.01.00.1.231228
Developer Real World Testing Plan Page URL: https://lightningstep.com/onc-certification

Justification for Real World Testing Approach

Consistent with the ONC's recommendation to "verify that deployed Certified Health IT continues to perform as intended by conducting and measuring observations of interoperability and data exchange," this Real World Testing Plan is designed to document and validate the performance of certified capabilities in active use. This plan emphasizes the collection of real-world evidence, tracking the number of instances in which certified capabilities are utilized successfully within healthcare settings. In cases where adoption is limited or evidence capture is challenging, Lightning Step will conduct controlled demonstrations to simulate real-world deployment as closely as possible.

Real World Testing serves as an essential verification step in the Health IT Certification program, complementing but not duplicating the initial certification testing. Rather than revisiting previously demonstrated compliance, this plan aims to ensure that certified functionalities are effectively integrated and utilized by healthcare providers in actual clinical environments.

- o   170.315 (b)(1): Transitions of Care (Cures Update)
- o   170.315 (b)(2): Clinical Information Reconciliation and Incorporation (Cures Update)
- o   170.315.(b)(10): Electronic Health Information Export
- o   170.315 (c)(1): Clinical Quality Measures - Record and Export
- o   170.315 (c)(2): Clinical Quality Measures - Import and Calculate
- o   170.315 (c)(3): Clinical Quality Measures - Report (Cures Update)
- o   170.315 (e)(1): View, Download, and Transmit to 3rd Party (Cures Update)
- o   170.315 (g)(7): Application Access - Patient Selection
- o   170.315 (g)(9): Application Access - All Data Request (Cures Update)

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Standards Version Advancement Process (SVAP) Standards Updates

Standard (and Version)	All standard versions are as specified in 2015 Cures Update
Updated Certification Criteria and Associated Product	Not Applicable
Health IT Module CHPL ID	15.04.04.3183.Ligh.01.00.1.231228
Date of ONC ACB Notification	Not Applicable
Date of Customer Notification	Not Applicable

Care Settings

Lightning Step targets provider organizations across a range of behavioral health settings, including outpatient clinics, addiction treatment centers, and other specialized care environments where certified EHR capabilities are essential for daily operations. We seek participation from organizations nationwide, representing diverse sizes, patient populations, and missions, to ensure a comprehensive testing of various care settings.

Measurements/Metrics Used in Overall Approach for Each Criterion

(b)(1): Transitions of Care (Cures Update)

Metric 1: Interactive Testing of creation of CCDA and uploaded to the ETT

- o Justification: Transitions of Care is a critical aspect of ensuring seamless communication and continuity of care across providers and care settings. Interactive testing of the creation of a Consolidated Clinical Document Architecture (CCDA) and its upload to the Edge Testing Tool (ETT) validates the system's ability to generate accurate, standardized documents. This metric is essential to demonstrate compliance with ONC requirements and support interoperability in real-world healthcare scenarios.
- o Expected Outcomes: The successful creation and upload of the CCDA to the ETT will confirm that Lightning Step's EMR meets the technical specifications outlined by ONC for transitions of care. This process will ensure that clinical information is accurately formatted and shared in a manner that promotes data exchange and patient safety. Achieving this outcome will validate the software's readiness for nationwide implementation and provider adoption.

Metric 2: Count of CCDAs Sent

- o Justification: Sending Consolidated Clinical Document Architecture (CCDA) files is a key component of meeting the ONC (b)(1) Transitions of Care criterion. Tracking the number of CCDAs sent ensures that the EMR facilitates efficient and consistent data exchange between care providers. This metric highlights the system's ability to support interoperability, improve care coordination, and comply with regulatory requirements.
- o Expected Outcomes: An increase in the number of CCDAs successfully sent will demonstrate that Lightning Step effectively supports transitions of care across various settings. This outcome reflects the software's ability to share standardized clinical information, enhancing communication between providers and improving patient outcomes. Consistent performance will affirm compliance with ONC certification standards.

Metric 3: Count of CCDAs Received

- o Justification: Receiving Consolidated Clinical Document Architecture (CCDA) files is essential for achieving interoperability and ensuring a seamless flow of information during transitions of care. Measuring the number of CCDAs received validates the system's ability to import and process clinical data from external sources. This metric ensures compliance with ONC standards while supporting improved care coordination and continuity.

- o Expected Outcomes: An increase in the number of CCDAs successfully received will demonstrate Lightning Step's capability to integrate standardized clinical information from other providers or systems. This outcome underscores the EMR's role in enhancing communication across care settings, reducing information silos, and improving patient care. Consistent receipt of CCDAs will confirm compliance with ONC certification requirements for data exchange.

Relied Upon Software

In addition to Lightning Step's software and a web server, (b)(1) Transitions of Care also requires the use of Updox for secure direct messaging.

(b)(2): Clinical Information Reconciliation and Incorporation (Cures Update)

Metric 1: Count of CCDAs Reconciled

- o Justification: The ability to import and reconcile Consolidated Clinical Document Architecture (CCDA) files is vital for ensuring accurate and up-to-date patient information across care settings. Measuring the ratio of CCDAs imported and successfully reconciled demonstrates the EMR's effectiveness in integrating external data into a patient's record. This metric is essential for meeting ONC (b)(2) Clinical Information Reconciliation and Incorporation requirements and enhancing clinical decision-making.
- o Expected Outcome: A high ratio of CCDAs successfully imported and reconciled will confirm Lightning Step's capability to accurately incorporate external clinical data into patient records. This outcome supports the seamless integration of information, reducing errors and improving continuity of care. Meeting this standard demonstrates the software's readiness for real-world use and compliance with ONC certification criteria.

Metric 2: Count of Allergies Reconciled

- o Justification: Reconciliation of allergy information ensures that external allergy data is accurately incorporated into the patient's record, avoiding discrepancies and enhancing patient safety. This metric highlights the system's effectiveness in managing and updating sensitive clinical data.
- o Expected Outcome: A high count of reconciled allergies will confirm that Lightning Step can accurately incorporate and update allergy information, supporting patient care by providing up-to-date and complete data. This outcome ensures compliance with the Cures Update reconciliation requirements for allergy information.

Metric 3: Count of Medications Reconciled

- o Justification: Reconciliation of medications is critical for ensuring that a patient's medication list is accurate and current across all care settings. This metric measures the system's ability to integrate medication data from external sources into the patient record effectively.
- o Expected Outcome: The reconciliation of medications will demonstrate Lightning Step's capacity to accurately update and manage medication records, improving patient safety and care coordination. This outcome aligns with the requirements for medication reconciliation under the Cures Update.

Metric *4: Count of Problems Reconciled*

- o Justification: Reconciliation of problem lists ensures that critical health conditions and diagnoses are consistently updated across systems, supporting accurate clinical decision-making. This metric confirms that the EMR can integrate problem list data from external sources into the patient's record.
- o Expected Outcome: A successful reconciliation of problems will confirm that Lightning Step can accurately manage and update a patient's problem list, promoting comprehensive care and accurate decision-making. This outcome meets the Cures Update's requirements for the reconciliation of health conditions and diagnoses.

(b)(10): Electronic Health Information Export

Metric 1: Count of Single Patient EHI Exports

- o Justification: Tracking the count of single patient Electronic Health Information (EHI) exports is critical for ensuring that patients and providers can efficiently access and share individual health records. This metric validates the system's compliance with ONC (b)(10) Electronic Health Information Export   requirements by demonstrating its capability to support patient-centered data portability. It highlights Lightning Step's commitment to promoting transparency and patient empowerment through accessible health information.
- o Expected Outcomes: A consistent count of successful single patient EHI exports will confirm the EMR's ability to generate and export individual health records in compliance with ONC standards. This outcome supports seamless information sharing and fosters patient engagement in their healthcare journey. Demonstrating this capability ensures readiness for real-world use and regulatory compliance.

Metric 2: Count of Patient Population EHI Exports

- o Justification: Measuring the count of patient population Electronic Health Information (EHI) exports ensures that Lightning Step can support bulk data transfers for organizational reporting and care coordination. This metric demonstrates the system's ability to manage large-scale data exports effectively, meeting ONC (b)(10) Electronic Health Information Export certification criteria. It also underscores the EMR's scalability and functionality in diverse healthcare settings.
- o Expected Outcomes: An accurate and consistent count of patient population EHI exports will confirm Lightning Step's ability to support data portability for entire patient populations. This outcome facilitates broader interoperability, enabling organizations to share and analyze data at scale for improved healthcare delivery. Meeting this metric affirms the system's compliance and operational readiness.

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

Metric 1: Count of QRDA Category 1 files Exported

- o Justification: Exporting Quality Reporting Document Architecture (QRDA) Category 1 files is essential for meeting regulatory requirements and enabling standardized reporting of clinical quality measures (CQMs). This metric ensures that Lightning Step supports accurate and efficient sharing of patient-level quality data with external reporting entities.
- o Expected Outcomes: A consistent number of QRDA Category 1 files successfully exported will confirm Lightning Step's ability to generate and share quality data in compliance with ONC (c)(1) Clinical Quality Measures - Record and Export requirements. This outcome supports improved healthcare transparency and facilitates effective performance monitoring.

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

Metric 1: Count of QRDA Category 1 files Imported

- o Justification: Importing Quality Reporting Document Architecture (QRDA) Category 1 files is crucial for maintaining accurate clinical quality measure (eCQMs) data within the EMR. This metric demonstrates Lightning Step's ability to support standardized reporting by integrating patient-level quality data from external sources. Ensuring compliance with ONC (c)(2) Clinical Quality Measures - Import and Calculate requirements highlights the system's role in facilitating effective quality measurement and reporting.
- o Expected Outcomes: A consistent number of successfully imported QRDA Category 1 files will confirm Lightning Step's capability to accurately record and incorporate patient-level quality data. This outcome supports improved performance tracking and compliance with regulatory standards, ensuring the system is ready for real-world quality reporting and data exchange.

(c)(3): Clinical Quality Measures - Report (Cures Update)

Metric 1: Count of QRDA Category 3 Aggregate Reports Created

- o Justification: Creating Quality Reporting Document Architecture (QRDA) Category 3 aggregate reports enables users to compile and generate data files for electronic transmission to meet reporting requirements. This metric ensures Lightning Step supports the streamlined aggregation of clinical quality measures (eCQMs) for efficient sharing with external entities.
- o Expected Outcomes: A consistent number of QRDA Category 3 aggregate reports created over the period will confirm Lightning Step's capability to generate accurate, standardized summary data. This outcome supports compliance with ONC (c)(3) Clinical Quality Measures - Report requirements and facilitates effective quality reporting and performance analysis.

(e)(1): View, Download, and Transmit to 3rd Party (Cures Update)

Metric 1: Count of CCDA Previews

- o Justification: Tracking the count of CCDA previews in the patient portal ensures that patients can access their clinical summaries conveniently. This metric validates the system's ability to provide user-friendly, accurate previews of health records for patient review.
- o Expected Outcomes: A high count of successful CCDA previews demonstrates that patients can reliably view their clinical summaries, enhancing engagement and transparency in healthcare decisions in alignment with Cures Update requirements.

Metric 2: Count of CCDA Downloads

- o Justification: Measuring the count of CCDAs downloaded from the patient portal confirms that patients have seamless access to export their health information. This metric highlights the system's support for data portability and patient empowerment.
- o Expected Outcomes: An increased count of CCDA downloads indicates successful patient access to exportable health records, facilitating interoperability and meeting the requirements for patient-directed data sharing under the Cures Update.

Metric 3: Count of CCDA Transmissions via Direct or Email

- o Justification: Tracking the count of CCDAs transmitted via Direct Messaging or email ensures the system facilitates secure sharing of patient health data with third parties. This metric confirms interoperability and secure exchange capabilities.
- o Expected Outcomes: A high count of successful CCDAs transmitted validates the EMR's ability to securely share clinical data, improving care coordination and compliance with data exchange standards in the Cures Update.

Relied Upon Software

In addition to Lightning Step's software and a web server, (e)(1) View, Download, and Transmit to 3rd Party also requires the use of Updox for secure direct messaging.

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

Metric 1: Count of API Calls for a Single Patient ID

- o Justification: Tracking API calls for a single patient ID ensures that third-party applications can efficiently retrieve specific patient data from the system. This metric demonstrates the EMR's ability to support granular, patient-centered data access.
- o Expected Outcomes: Successful API calls for individual patient data confirm that the system supports seamless and accurate retrieval of patient-specific information, aligning with interoperability and patient access requirements.

(g)(9): Application Access - All Data Request (Cures Update)

Metric 1: Count of API Calls for CCDA for a Single Patient

- o Justification: Monitoring API calls for requesting CCDAs ensures that external applications can retrieve comprehensive clinical information for a specific patient. This metric validates the EMR's ability to facilitate all-data access requests effectively.
- o Expected Outcomes: A high count of successful API calls for CCDAs demonstrates that the system can accurately process and deliver complete patient data to third-party applications, meeting the requirements for data sharing under the Cures Update.

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Schedule of Key Milestones

Adoption Rate Baseline Establishment

- o   Care Setting: Outpatient behavioral health clinics and addiction treatment centers
- o   Date/Timeframe: Q3 2025
- o   Details: Begin tracking the adoption rate of certified capabilities within initial test sites. This baseline data will capture early usage patterns and provide a reference point to compare changes in adoption over the testing period.
- o   Data Collection: Monthly reports from usage logs, focusing on the frequency of capability utilization within the setting.

Summative Testing for Usage Frequency and Success Rates

- o   Care Setting: Outpatient clinics, addiction recovery facilities, and mental health centers
- o   Date/Timeframe: Mid-Q3 2025
- o   Details: Conduct summative testing to gather data on the total number of successful and unsuccessful actions for certified functionalities. This milestone will also verify initial adoption rates and success rates after six months of testing.
- o   Data Collection: Summative reports generated quarterly from audit logs, capturing action frequency and completion status.

Interactive Testing for Low-Adoption Capabilities

- o   Care Setting: Facilities with low adoption or where usage data is sparse (e.g., smaller or specialized behavioral health centers)
- o   Date/Timeframe: Mid-Q3 2025
- o   Details: Conduct interactive, live testing for certified capabilities with low or zero adoption rates in select settings. This milestone will confirm Real World Testing Plan October 2024 functionality and compliance for features underrepresented in real-world usage data.
- o   Data Collection: Real-time interactive testing sessions, documented in reports with evidence of feature performance.

Mid-Point Review and Adjustment

- o Care Setting: All participating behavioral health facilities
- o Date/Timeframe: End of Q3 2025
- o Details: Review data collected from adoption rates, summative testing, and interactive testing to assess progress and make adjustments to the testing plan as necessary. This checkpoint ensures the testing plan aligns with expected outcomes and identifies any emerging issues.
- o Data Collection: Summary report of all data collected thus far, with actionable insights and adjustments to be implemented in Q4 if needed.

Final Summative Testing and Outcome Analysis

- o Care Setting: Comprehensive analysis across all participating care settings
- o Date/Timeframe: End of Q4 2025
- o Details: Conduct final summative testing across all sites to measure the cumulative adoption and success rates of certified capabilities over the full testing period. This milestone will confirm compliance, interoperability, and effectiveness of the certified functionalities.
- o Data Collection: Final report summarizing adoption, success rates, and interactive testing outcomes to verify real-world performance and overall impact.

Attestation

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

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