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REAL WORLD TESTING

(b)(10) - Electronic Health Information Export

Thinkhat Software Inc

Contents

1   General Information:

Plan Report ID Number:	[For ONC-Authorized Certification Body use only]
Developer Name:	Thinkhat Software Inc
Product Name(s):	Enliv EHR
Version Number(s):	v1.0
Certified Health IT Product List (CHPL) ID(s):	15.04.04.3191.Enli.01.00.0.240403
Developer Real World Testing Plan Page URL:	https://www.enliv.com/certification

2   Executive Summary:

This document summarises ENLIV's certified EHR solution plan to measure the real-world use of the Electronic Health Information (EHI) Export features for Electronic Case Reporting during the 2025 calendar year. The ONC certification criterion addressed in this plan is § 170.315(d)(10).

It provides real-world test measurements and metrics that align with the intent and objectives of ONC's Condition of Certification and Maintenance of Certification requirements for real-world testing (§ 170.405 Real World Testing). This testing evaluates compliance with certification criteria and the interoperability goals of the 21st Century Cures Act, which prohibits information blocking and mandates the use of standardised APIs for electronic health information (EHI) access and exchange within the care and practice settings for which it is designed.

3   Real World Testing Approach:

The purpose of this Real World Testing (RWT) plan is to outline the process for assessing the real-world performance of the certified (b)(10) Electronic Health Information Export functionality in our Health EHR product.

3.1   Scope of the certification:

Enliv EHR ensures the sharing of healthcare and other necessary records of the patients with patients, and other health units and applications. The conformity of the test criteria in scope of this certification will be provided through the test scenarios. The aim of the test plan approach is to test the data structures through the 170.315 (b)(10): Electronic Health Information Export

3.2   Methodology for Testing:

The Real World Testing methodology will provide test metrics showing the successful EHI Export. Our Electronic Health Record (EHR) application is dedicated to managing and storing EHI following the Fast Healthcare Interoperability Resources (FHIR) standards, which promote right, efficient, and accessible data exchange. Which Includes multiple files holding data in ndjson format, each corresponding to a different FHIR resource type used to store EHI data.

3.3   Test Population:

- Since our product is not yet in use, we will conduct simulated real-world scenarios in collaboration with unit testing test users, including healthcare providers and internal testers. The simulated environments will mimic real-world clinical settings and involve mock patient data to ensure compliance with privacy laws.
- And our measures were designed with this setting in mind. We will test a minimum of three (3) client practice(s). This number covers a sufficient percentage of existing users of our usability testing practices to provide a practical sample of users of the certified EHRs.

3.4   Test User Roles:

- Clinical staff (e.g., physicians, nurses)

- IT administrators

3.5   Test Data:

Patient records will include varying data types, such as demographics, diagnoses, lab results, and treatment histories.

4   Real World Testing Scenarios Overview:

4.1   The testing will evaluate the product's ability to:

- Allow authorised users to export complete patient EHI upon request.
- Ensure the EHI export process is accurate, reliable, and secure.
- Ensure that the exported EHI is accessible and usable for its intended purposes by other health IT systems or end-users.

4.2   Testing will focus on the following performance areas:

- Functionality: How effectively does the export feature work for large and small datasets?
- Usability: How easy is it for authorised users to trigger and manage exports?
- Accuracy: Are all required data elements included in the export?
- Security: Does the export process ensure data security and privacy?

4.3 Key Testing Criteria:

- Success of the export in completing within an acceptable time frame for various data sizes.
- Inclusion of all necessary EHI data fields (as required by law).
- Exported data format is in line with standardised formats (e.g., FHIR).
- End-users' ability to access and use the exported data in other systems.

5 Standards Updates:

Standard (and version)	N/A
Updated certification criteria and associated product	N/A
Health IT Module CHPL ID	15.04.04.3191.Enli.01.00.0.240403
Date of ONC ACB notification	10/30/2024
Date of customer notification	N/A
Conformance method and measurement/metric(s)	Measure 1 Measure 2

6 Measurements(s)/Metrics(S) used in overall approach:

6.1 Metrics for Evaluation

We use the following metrics to prove conformance to requirements of this criterion in real world settings.

- Completion Rate: Percentage of successful exports across scenarios.
- Time to Complete: Average time required to complete the EHI export for both individual and bulk data.
- Data Completeness: Percentage of required data elements accurately exported.
- User Feedback: User satisfaction with the usability of the export feature (collected via surveys).
- Security Compliance: Ensuring the export process meets security protocols (e.g., encrypted transmission).

6.2   Use cases Summary:

Here we are providing the testing plan for a single certification criterion, "Electronic Health Information Export," (§ 170.315(d)(10)).

To cover the entire criterion, two use cases are presented in this plan.

6.2.1   Use Case 1: Demonstrates Single Patient EHI Export:

Upon a patient's request, the patient's EHI is exported by the health information management team. And is available to download through the patient section of Enliv website. The EHI is encrypted with a password that the patient receives when downloading the file. After the patient enters the password to unencrypt the file, they can browse their Records.

Single-patient EHI export enables a user of the Enliv to export whatever selected the EHI for a single patient at any time the user chooses, without the developer's assistance.

6.2.2   Use Case 2: Demonstrates Patient Population Export:

This functionality allows providers (when a provider is leaving an organisation and needs to take their patient records with them to another practice) to export entire EHI records for a patient, as required by the ONC Health IT Certification Program. Patient population EHI export enables Enliv to create an export of all the EHI for a patient population upon request.

7   Technical Specifications:

The files in the EHI export package are packed into a single, encrypted ZIP file. The export package could include folders with selected format files. Each included folder contains a file that provides a unique identifier followed by the name of the FHIR resource.

a.   Single Patient Export:

Extract folder contains a single file named patient.ndjson will be present inside the archive (zip), with all related documents stored in a documents folder.

b.   Bulk Export (All Patient Export):

For Bulk Exports, our EHR application generates files for each FHIR resource type involved in storing Electronic Health Information (EHI). The file naming convention for these exports incorporates a unique identifier followed by the name of the FHIR resource, ensuring easy identification and organisation of the data.

8 Measures Used:

The following outlines the measures that have been identified to best demonstrate conformance to single certification criteria concerning the sharing of EHI (§ 170.315(b)(10)) across the two use cases demonstrated (single patient and population services).

8.1 Use Case1: (Single Patient) Metrics:

As part of the Real World Testing requirements for § 170.315(b)(10), we have developed the following metrics the testing plan:

Measure 1: Single Patient Export. This measure will assess functionality used to export EHI for a single patient. The associated certification criterion is:

Certification Criteria	Requirement
§ 170.315(b)(10) EHI export – Single patient EHI export	(i)(A) Create an export file
	(i)(B) Execute at any time
	(i)(C) Limit ability of users who can create export
	(i)(D) Electronic and computable format

8.1.1 Justification:

- Since we do expect that there will be some actual real world usage of the single patient export capabilities, tracking such real world usage is the most authentic approach to the RWT activities.
- This export of EHI associated with a patient is a way to share information with an external organisation.
- When there is a need for a full patient record this functionality allows providers to export entire EHI records for a patient, as required by the ONC Health IT Certification Program.
- This metric will provide information on the type of data exported for a single patient and the frequency of usage.

8.1.2 Test Methodology:

- Single patient export statistics will be tracked via audit reports specific to EHI Export functions.
- Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to confirm the proper operation of the export.
- This test methodology will primarily test the conformance of the implementation.

8.1.3 Expected outcome(s):

- It is expected that authorised users will be able to share EHI using the export function.
- Single-patient EHI export enables a user of the Enliv to export whatever selected the EHI for a single patient at any time the user chooses, without the developer's assistance.
- Error rates will be tracked and trended over time.
- We expect that the number of EHI exports for a single patient will be greater than the number of EHI exports for a patient population because gathering information on a single patient might be more common than an entire population.

8.2 Use Case 2 (Population Services) Metrics:

As part of the Real World Testing requirements for § 170.315(b)(10), we have developed the following metrics the testing plan:

Measure 1: Patient Population Export. This measure will assess the functionality used to export EHI for a patient population. The associated certification criterion is:

Certification Criteria	Requirement
§ 170.315(b)(10) EHI export – Patient population EHI export	(ii)(A) Create an export file: The export created must be electronic and in a computable format.

8.2.1 Justification:

- To date, Provider Portal has not received any requests for a patient population EHI Export. Therefore, we are pursuing a strategy involving a mock export that would closely mirror real world conditions to ensure we have an appropriately representative data set for the RWT results.
- This export is used for research or quality purposes to look for specific trends in the patient population and also another way to share health information with an external organisation.
- This functionality is an administrative function, only available to credentialed users.
- Since this function has a significant impact on the Health IT module performance, this function will be run as a scheduled activity.

8.2.2   Test methodology:

- Patient population EHI Export statistics will be gathered by reviewing recorded logs and system logs to ensure the export function is operating properly and to determine their successful delivery dates.
- Log files obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation of the export.
- This test methodology will primarily test the conformance of the implementation.

8.2.3   Expected outcome(s):

- It is expected that authorised users will be able to share EHI for a patient population using the export function upon request. Errors in transmission will be tracked and analysed.
- We expect that the number of EHI exports for a single patient will be greater than the number of EHI exports for a patient population because gathering information on a single patient might be more common than an entire population.

9   Data Collection and Reporting

- During the testing period, data will be collected and analysed based on the outlined metrics. Issues identified during testing will be documented and addressed, and the results will be used to improve the product. A final Real World Testing report will be submitted to the ONC by the required deadline.
- Upon obtaining customers, real-world data from actual clinical settings will be incorporated into future iterations of the Real World Testing process. Until then, our simulated environments will serve as a proxy for evaluating the performance of the (b)(10) functionality.

10   Care and Practice Settings

- The single patient export is operated the same in all applicable care settings and implementations, therefore the methodology allows for results applicable to all care settings and implementations.
- Additionally, since the EHI Export capability is equivalent for all care settings and implementations, this will provide evidence applicable across any setting or implementation.

11 Schedule of Key Milestones:

Key Milestone	Date/Time Frame
Test Plan Submission to ONC-ACB	October 31, 2024
Data Collection & Test Execution	January 1, 2025-December 31, 2025
Validation of Expected Outcomes	Quarterly
Analysis and Report Creation	January 1, 2026-January 31, 2026
Results Submission to ONC-ACB	January 31, 2026

12 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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