SCC SoftComputer
2022 Real World Testing Final Report

Plan Report ID Number: [For ONC-Authorized Certification Body use only] _____

Developer Name: SCC SoftComputer _____

Product Name(s): SoftLab_____

Version Number(s): 4.0.7, 4.0.8, 4.0.9, 4.5.4, 4.5.5 _____

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

Product List (CHPL) ID(s): 15.07.07.2287.SO03.01.00.1.170515, 15.07.07.2287.SO03.02.01.1.170706, 15.07.07.2287.SO03.03.02.1.210325, 15.07.07.2287.SO03.04.02.1.180909, 15.07.07.2287.SO03.03.03.1.181116 _____

Developer Real World Testing Page URL: https://www.softcomputer.com/regulatory-affairs/_____

CHANGES TO ORIGINAL PLAN

No changes have been made to the original plan.

WITHDRAWN PRODUCTS

No products have been withdrawn from the original plan.

SUMMARY OF TESTING METHODS AND KEY FINDINGS

Measure 170.315(f)(3) of 2015 CEHRT/Cares Act is satisfied through implementation of an ELR interface that transmits reportable lab results to a receiving system such as a state DOH. SCC SoftComputer's stock ELR interface has been designed, tested, and demonstrated to be capable of transmitting messages in accordance with the standards referenced in the criterion. Although the Implementation Guide upon which the criterion is dependent includes references to many vocabulary items, the criterion specifically calls out and focuses on the use of LOINC and SNOMED CT codes. Conformance is established not only by the mechanics of the interface, but also by data input to the system by users and by other systems. Users of SoftLab must define and maintain data dictionaries and must utilize the system appropriately while ordering and resulting in order to capture the necessary data. External HIS, EMR, and CIS systems must transmit the necessary data to SoftLab to be captured and re-sent through the ELR interface.

During each interface implementation at a client site, the ELR interface is validated with the client and with the state DOH to meet the particular needs of the state for interoperability and function. Typically, each reportable test is validated between the client and the state before the interface is used for live data transmission. In addition, each installed ELR interface is validated during implementation to

conform to the Implementation Guide. Sample messages are captured and input to the same NIST testing tool that is used for certification testing. The interface as implemented at each client is thus verified to be conformant at the time of installation and is expected to remain so throughout its use.

The goal of this Real World Test is to measure observations of interoperability and data exchange. SCC has gathered statistical data via a non-intrusive method of regularly querying client systems for information about the history of reporting by ELR interface. Such queries provide meaningful, quantitative statistical data regarding use of the ELR interface in the field in the form of number of tests qualified for reporting vs. number of tests reported with a focus on inclusion of LOINC and SNOMED CT codes.

Queries have been installed at a majority of SoftLab/SoftMic clients using an ELR interface throughout the United States. A high degree of capture and transmission of reportable results with LOINC codes as required by standards and for certification is deemed a good indication of maintenance of functionality of the Certified Health IT in real world settings. An observation of inclusion of SNOMED CT codes is included as well. In addition, a tally of complaints regarding conformance to certification requirements over the same period of time supplements conclusions regarding maintenance of interoperability and functionality.

STANDARDS UPDATES (INCLUDING STANDARDS VERSION ADVANCEMENT PROCESS (SVAP) AND UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI))

No standards updates have been made that affect measure *170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results.*

SVAP references as standards *170.205(g) HL7 v2.5.1 IG: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 Errata and Clarifications, September, 29, 2011* and *170.205(g) ELR 2.5.1 Clarification Document for EHR Technology Certification, July 16, 2012.* Currently, neither of these standards has new versions.

USCDI is not currently applicable to *170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results.*

CARE SETTING(S)

Care Setting	Justification
All settings	Testing is agnostic of facility size or setting. SCC SoftComputer does not market or install ELR capability differently per care setting. The system is expected to function equally in all care settings, at facilities of all sizes. Results from all care settings have been combined and reported in total.

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METRICS AND OUTCOMES

All metrics below are associated with criterion 170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results.

Measurement/Metric	Outcome	Challenges
Number of clients sampled	12	none
Number of tests qualified to report	1,622,725	none
Number of tests actually reported	1,620,539	none
Number of tests reported with LOINC codes	1,608,066	none
Number of tests reported without LOINC codes	12,473	none
Number of tests qualified to report as Coded results	1,127,110	none
Number of tests reported with SNOMED codes	1,125,903	none
Average number of results reported per month per client	12,005	none
Ratio of Reported / Qualified	99.9%	none
Ratio of Reported with LOINC / Reported	99.2%	none
Ratio of Reported with SNOMED / Qualified Coded	99.9%	none
Number of complaints registered regarding conformance	0	none

KEY MILESTONES

Key Milestone	Care Setting	Date/Timeframe
Validate approach to collect data for Real World Testing Plan.	All settings	November, 2021
Activation of queries on client systems.	All settings	December, 2021
Publication of Real World Testing plan.	All settings	December 15, 2021
Begin collection of information as laid out by the plan.	All settings	January 1, 2022
Evaluate data collection to understand and address any concerns.	All settings	Monthly, 2022
Data collection and review.	All settings	Monthly, 2022
End of Real World Testing period/final collection of all data for analysis.	All settings	January 2023
Analysis and report creation.	All settings	January 15, 2023
Submit Real World Testing report to ACB (per their instructions)	All settings	March 1, 2023

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SUMMARY

OBSERVATIONS

On initial review of individual client data the following points were observed:

- LOINC codes were not properly defined by the clients for some reportable tests. In most cases, these were observed to be for COVID tests.
- Some test results were not sent because of incorrect test dictionary setup.

Clients were informed of the reasons for failure to comply. Some clients corrected their setup errors. Thus, conformance has improved over the course of the year.

To summarize, statistically:

- 99.9% of tests that should have reported were actually reported.
- 99.2% of tests were properly reported with a LOINC code.
- 99.9% of results that were expected to report with a SNOMED CT code were reported properly.
- No clients or departments of health have registered complaints regarding compliance.

CONCLUSIONS

With regard to *Transmission of Reportable Laboratory Tests to Public Health Agencies*, the SoftLab product has been demonstrated to be at least 99.2% conformant with measure 170.315(f)(3) at all sampled sites during the year 2022. Final statistics reflect adherence to requirements to send ELR results with LOINC codes when qualified. Roughly 2/3 of reportable results were qualified to be sent as coded results, and were sent with SNOMED CT codes. A small amount of failures have been observed, primarily due to client failure to properly link LOINC or SNOMED codes in setup dictionaries. The overall failure rate is significantly less than 1% and is found to be acceptable.