General Information

Developer Name	T-System, Inc.
Product Name	EV
Version Numbers	6.0, 5.1
Certified Health IT Product List (CHPL) ID	15.04.04.2858.Tsys.06.01.1.191223, 15.04.04.2858.Tsys.51.00.1.180928

Justification for Real World Testing Approach

At this time, the T-System EV product is sold to the emergency department care setting. For this reason, the Real-World Testing plan will apply to this care setting. Since the emergency department information system works with many types of documents and data, there are several certification criteria which will be tested. The product supports C-CDA; Medications, Allergies, and Problems; Data Export, and APIs, so the following certification criteria will be tested: §170.315(b)(1), 170.315(b)(2), §170.315(b)(6), §170.315(f)(2) , §170.315(g)(7), §170.315(g)(8), 170.315(g)(9).

Standards Updates (SVAP and USCDI)

Standard (and version)	All standards versions are those specified in USCDI v1
Date of ONC-ACB Notification (SVAP or USCDI)	Not applicable
Date of customer notification (SVAP only)	Not applicable
USCDI-updated criteria	None

Care Setting

Emergency Department Care Setting: T-System EV supports documentation within the emergency department setting.

Overall Expected Outcomes

- Real World Testing will demonstrate that T-System EV is conformant to the following certification criteria:
    - §170.315(b)(1) Transitions of care
    - §170.315(b)(2) Clinical information reconciliation and incorporation
    - §170.315(b)(6) Data export
    - §170.315(f)(2) Transmission to public health agencies — syndromic surveillance
    - §170.315(g)(7) Application access — patient selection
    - §170.315(g)(8) Application access — data category request
    - §170.315(g)(9) Application access — all data request

Schedule of Key Milestones

Key Milestone	Date/Timeframe
Release of documentation for Real-World Testing to be provided to authorized representatives of the sites at which data will be collected.	January 31, 2022

Collection of data and metrics as specified in Real-World Testing plan	March 1, 2022- November 31, 2022
Analysis and report creation	January 15, 2023
Submit Real World Testing report to Drummond	February 1, 2023

Measures Used

The following outlines the measures that have been identified to best demonstrate conformance to the multiple certification criteria concerning the capabilities of T-System EV.

Measure 1: C-CDA

This measure will catalogue the transport mechanisms used to send C-CDA documents as well as track the usage of those transport mechanisms. Associated certification criteria for C-CDA in the emergency department care setting include:

Certification Criteria	Requirement
§170.315(b)(1) Transitions of care	(iii)(A)-(F) Can create a C-CDA
	(iii)(G) Can create C-CDA with data to assist with patient matching
§170.315(b)(2) Clinical information reconciliation and incorporation	(iv) Can create a C-CDA document with reconciled and incorporated data
§170.315(g)(6) Consolidated CDA creation performance	(i) System can create a C-CDA file which matches gold-standard
	(ii)System can create a C-CDA file for each document template
	(iii) System can create C-CDA which properly implements required vocabulary standards and value sets
	(iv) System can create C-CDA file which includes all the data classes in the USCDI

Justification:

T-System EV supports the creation and transmission of C-CDA documents using HL7, FHIR, SOAP XDS.b, SFTP, or secure email. This metric will provide information on the types of transmissions used and the frequency of usages.

Test Methodology:

The C-CDA transmission logs will be reviewed to determine the frequency and the transport mechanism used for transmission of C-CDA documents. 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 transport mechanisms and input for the calculation of the metric on the specific types of transport mechanisms used. This test methodology will primarily test the conformance of the implementation.

Expected Outcomes:

It is expected that C-CDA documents will be transmitted using the transmission mechanisms provided. Error rates will be tracked and trended over time.

Measure 2: Medications, Allergies, and Problems

This measure will catalogue the transport mechanisms used to receive medications, allergies, and problems as well as track the usage of those transport mechanisms. Additionally, it will track how frequently the medications, allergies, and problems are reconciled and incorporated. Associated certification criteria for medications, allergies, and problems in the emergency department care setting include:

Certification Criteria	Requirement
§170.315(b)(2) Clinical information reconciliation and incorporation	(iii)(A) Display medication list, allergies and intolerances list, and problem list
	(iii)(B)-(D) User can validate and incorporate patient's medications, allergies, and problems

Justification:

T-System EV supports the receipt, reconciliation, and incorporation of medications, allergies, and problems from external systems. This metric will provide information on the types of transmissions used and the frequency of usages, as well as the frequency of reconciliation and incorporation.

Test Methodology:

The medications, allergies, and problems interface logs will be reviewed to determine the frequency and the transport mechanism used for transmission of medications, allergies, and problems. Additionally, the application logs for reconciliation and incorporation of medications, allergies, and problems will be reviewed to determine the frequency of reconciliation and incorporation. 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 transport mechanisms and input for the calculation of the metric on the specific types of transport mechanisms used. This test methodology will primarily test the conformance of the implementation.

Expected Outcomes:

It is expected that medications, allergies, and problems will be transmitted using the transmission mechanisms provided, and that providers will reconcile and incorporate the incoming medications, allergies, and problems. Error rates will be tracked and trended over time.

Measure 3: Data Export

This measure will catalogue the transport mechanisms used to export data summaries as well as track the usage of those transport mechanisms. Associated certification criteria for data export in the emergency department care setting include:

Certification Criteria	Requirement
§170.315(b)(6) Data export	(i)(A) User can configure data elements, date and time ranges, and locations when creating an export summary
	(i)(B) The technology limits exports to either a specific set of users or as an administrative function
	(ii) User can configure the technology to create export summaries using the CCD template

	(iii)(A) User can set the date and time period for export summaries
	(iii)(B) User can create export summaries in real time, based on a relative date and time, and based on a specific date and time
	(iv) User can set the storage location for export summaries

Justification:

T-System EV supports the creation and export of data summaries using SFTP or HL7. This metric will provide information on the types of transmissions used and the frequency of usages.

Test Methodology:

The data export logs will be reviewed to determine the frequency and the transport mechanism used for transmission of export summaries. 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 transport mechanisms and input for the calculation of the metric on the specific types of transport mechanisms used. This test methodology will primarily test the conformance of the implementation.

Expected Outcomes:

It is expected that export summaries will be transmitted using the transmission mechanisms provided. Error rates will be tracked and trended over time.

Measure 4: Public Health Surveillance Information

This measure will catalogue the transport mechanisms used to send syndrome-based public health surveillance information as well as track the usage of those transport mechanisms. Associated certification criteria for syndrome—based public health surveillance information in the emergency department care setting include:

Certification Criteria	Requirement
§170.315(f)(2) Transmission to public health agencies — syndromic surveillance	System can create syndrome-based public health surveillance information for electronic transmission to public health agencies

Justification:

T-System EV supports the creation and transmission of syndrome-based public health surveillance information using HL7. This metric will provide information on the types of transmissions used and the frequency of usages.

Test Methodology:

The syndrome-based public health surveillance information transmission logs will be reviewed to determine the frequency and the transport mechanism used for transmission of syndrome-based public health surveillance information. 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 transport mechanisms and input for the calculation of the metric on the specific types of transport mechanisms used. This test methodology will primarily test the conformance of the implementation.

Expected Outcomes:

It is expected that syndrome-based public health surveillance information will be transmitted using the transmission mechanisms provided. Error rates will be tracked and trended over time.

Measure 5: API

This measure will catalogue the transport mechanisms used to receive Application Programming Interface requests as well as track the usage of those transport mechanisms. Associated certification criteria for APIs in the emergency department care setting include:

Certification Criteria	Requirement
§170.315(g)(7) Application access — patient selection	(i) System can receive a request with sufficient information to uniquely identify a patient and return an ID or other token which can be used to request data for that patient
§170.315(g)(8) Application access — data category request	(i)(A) API must be able to respond to requests for patient data for all categories listed in CCDS
	(i)(B) API must respond to requests for patient data associated with a specific date or date range
§170.315(g)(9) Application access — all data request	(i)(A) API must respond to requests for patient data for all data categories specified in USCDI
	(i)(B) API must respond to requests for patient data associated with a specific date or date range

Justification:

T-System EV supports APIs for a variety of functionality, including some of the capabilities tested by other measures in this real-world test plan. This metric will provide information on the types of transmissions used and the frequency of usages.

Test Methodology:

The API call logs will be reviewed to determine the frequency and the transport mechanism used for invocation of APIs. 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 transport mechanisms and input for the calculation of the metric on the specific types of transport mechanisms used. This test methodology will primarily test the conformance of the implementation.

Expected Outcomes:

It is expected that API calls will be received using the transmission mechanisms provided. Error rates will be tracked and trended over time.

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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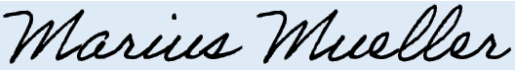
Authorized Representative Signature	
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