# Medical Information Technology, MEDITECH 21st Century Cures Real World Testing Plan Expanse Release Acute/Ambulatory/Emergency/Oncology Care Settings 2023

#### **GENERAL INFORMATION**

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

Developer Name: Medical Information Technology

Product Name(s): Expanse, 6.x

Version Number(s): 2.2, 2.1, 6.15, 6.1

Certified Health IT:

Product List (CHPL) ID(s) 2015 Edition: inactive as of 12/31/2022

Product	Certificate Number
6.1	
MEDITECH 6.1 Electronic Health Record Core HCIS v6.15	15.04.04.2931.MEDI.HC.00.1.171220
MEDITECH 6.1 Emergency Department Management v6.15	15.04.04.2931.MEDI.15.00.1.171227
MEDITECH 6.1 Ambulatory Electronic Health Record v6.15	15.04.04.2931.MEDI.AM.00.1.171227
MEDITECH Continuity of Care Interface (CCD) v6.1	15.04.04.2931.MEDI.61.00.1.171220
MEDITECH Patient and Consumer Health Portal v2.0	15.04.04.2931.MEDI.02.00.1.171227
MEDITECH Public Health Interface Transmission to Immunization Registries v6.	.1 15.04.04.2931.MEDI.IR.00.1.171227
MEDITECH Public Health Interface for Syndromic Surveillance v6.1	15.04.04.2931.MEDI.PH.00.1.171226
MEDITECH Transmission of Reportable Laboratory Test and Values/Results v6.2	I 15.04.04.2931.MEDI.T6.00.1.171226
MEDITECH Cancer Case Reporting v6.1	15.04.04.2931.MEDI.61.00.1.171226
MEDITECH 6.1 Oncology v6.15	15.04.04.2931.MEDI.ON.00.1.180503
Expanse 2.1	Certificate Number
MEDITECH Expanse (6.16) Core HCIS v2.1	15.04.04.2931.MEDI.CO.00.1.171220
MEDITECH Expanse (6.16) Emergency Department Management v2.1	15.04.04.2931.MEDI.16.01.1.180503
MEDITECH Expanse (6.16) Ambulatory v2.1	15.04.04.2931.MEDI.16.01.1.180606

MEDITECH Continuity of Care Interface (CCD) v6.1	15.04.04.2931.MEDI.61.00.1.171220
MEDITECH Patient and Consumer Health Portal v2.0	15.04.04.2931.MEDI.02.00.1.171227
MEDITECH Public Health Interface Transmission to Immunization Registries v6.1	15.04.04.2931.MEDI.IR.00.1.171227
MEDITECH Public Health Interface for Syndromic Surveillance v6.1	15.04.04.2931.MEDI.PH.00.1.171226
$\label{thm:mediated} \textbf{MEDITECH Transmission of Reportable Laboratory Test and Values/Results v6.1}$	15.04.04.2931.MEDI.T6.00.1.171226
MEDITECH Cancer Case Reporting v6.1	15.04.04.2931.MEDI.61.00.1.171226
MEDITECH Expanse (6.16) Oncology v2.1	15.04.04.2931.MEDI.ON.01.1.190925

Expanse 2.2	Certificate Number
MEDITECH Expanse Core HCIS v2.2	15.04.04.2931.MEDI.CO.01.1.200828
MEDITECH Expanse Emergency Department Management v2.2	15.04.04.2931.MEDI.ED.02.1.200828
MEDITECH Expanse Ambulatory v2.2	15.04.04.2931.2931.02.02.1.200828
MEDITECH Continuity of Care Interface (CCD) v6.1	15.04.04.2931.MEDI.61.00.1.171220
MEDITECH Patient and Consumer Health Portal v2.0	15.04.04.2931.MEDI.02.00.1.171227
MEDITECH Public Health Interface Transmission to Immunization Registries v6.	1 15.04.04.2931.MEDI.IR.00.1.171227
MEDITECH Public Health Interface for Syndromic Surveillance v6.1	15.04.04.2931.MEDI.PH.00.1.171226
MEDITECH Transmission of Reportable Laboratory Test and Values/Results v6.1	15.04.04.2931.MEDI.T6.00.1.171226
MEDITECH Cancer Case Reporting v6.1	15.04.04.2931.MEDI.61.00.1.171226
MEDITECH Expanse Oncology v2.2	15.04.04.2931.MEDI.ON.02.1.200828

# Product List (CHPL) ID(s): Cures Edition

Product and Certificate Number:

Expanse 2.2 - 2015 Cures Update  MEDITECH Expanse Core HCIS v2.2c (6/30//22)	Certificate Number 15.04.04.2931.MEDI.CO.02.1.220630
MEDITECH Expanse Emergency Department Management v2.2c (06/30/22)	15.04.04.2931.MEDI.ED.03.1.220630
MEDITECH Expanse Ambulatory v2.2c (06/30/22)	15.04.04.2931.2931.02.03.1.220630
MEDITECH Continuity of Care Interface (CCD) v6.1c (06/30/22)	15.04.04.2931.MEDI.61.01.1.220630
MEDITECH Patient and Consumer Health Portal v2.0c (09/19/22)	15.04.04.2931.MEDI.02.01.1.220919
MEDITECH Public Health Interface Transmission to Immunization Registries v6.1 (12/27/17)	15.04.04.2931.MEDI.IR.00.1.171227
MEDITECH Public Health Interface for Syndromic Surveillance v6.1 (12/26/17)	15.04.04.2931.MEDI.PH.00.1.171226
MEDITECH Transmission of Reportable Laboratory Test and Values/Results v6.1 (12/26/17)	15.04.04.2931.MEDI.T6.00.1.171226
MEDITECH Cancer Case Reporting v6.1 (12/26/17)	15.04.04.2931.MEDI.61.00.1.171226

MEDITECH Expanse Oncology v2.2c (06/30/22)	15.04.04.2931.MEDI.ON.02.1.220630
Expanse 2.1 - 2015 Cures Update	
MEDITECH Expanse 2.1 Core HCIS v2.1c (06/30/22)	15.04.04.2931.MEDI.CO.01.1.220630
MEDITECH Expanse 2.1 Emergency Department Management v2.1c (06/30/22)	15.04.04.2931.MEDI.16.02.1.220630
MEDITECH Expanse 2.1 Ambulatory v2.1c (06/30/22)	15.04.04.2931.2931.16.02.1.220630
MEDITECH Continuity of Care Interface (CCD) v6.1c (06/30/22)	15.04.04.2931.MEDI.61.01.1.220630
MEDITECH Patient and Consumer Health Portal v2.0c (09/19/22)	
MEDITECH Public Health Interface Transmission to Immunization Registries v6.1 (12/27/17)	15.04.04.2931.MEDI.IR.00.1.171227
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MEDITECH Cancer Case Reporting v6.1 (12/26/17)	15.04.04.2931.MEDI.61.00.1.171226
MEDITECH Expanse 2.1 Oncology v2.1c (06/30/22)	15.04.04.2931.MEDI.ON.02.1.220630
6.1 - 2015 Cures Update	
MEDITECH 6.1 Electronic Health Record Core HCIS v6.15c (06/30/22)	15.04.04.2931.MEDI.HC.00.1.171220
MEDITECH 6.1 Emergency Department Management v6.15c (06/30/22)	15.04.04.2931.MEDI.15.00.1.171227
MEDITECH 6.1 Ambulatory Electronic Health Record v6.15c (06/30/22)	15.04.04.2931.MEDI.AM.00.1.171227
MEDITECH Continuity of Care Interface (CCD) v6.1c (06/30/22)	15.04.04.2931.MEDI.61.01.1.220630
MEDITECH Patient and Consumer Health Portal v2.0c (09/19/22)	15.04.04.2931.MEDI.02.01.1.220919
MEDITECH Public Health Interface Transmission to Immunization Registries v6.1 (12/27/17)	
MEDITECH Public Health Interface for Syndromic Surveillance v6.1 (12/26/17)	15.04.04.2931.MEDI.PH.00.1.171226
MEDITECH Transmission of Reportable Laboratory Test and Values/Results v6.1 (12/26/17)	15.04.04.2931.MEDI.T6.00.1.171226
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MEDITECH 6.1 Oncology v6.15c (06/30/22)	15.04.04.2931.MEDI.ON.00.1.180503

Developer Real World Testing Page URL:

https://home.meditech.com/en/d/regulatoryresources/pages/certification.htm

#### JUSTIFICATION FOR REAL WORLD TESTING APPROACH

This document outlines the test plan approach to be followed when Medical Information Technology, MEDITECH, as a health IT vendor successfully tests the real world use of those health IT module(s). They will be tested for interoperability, universally of each care setting certified within the CHPL listings for those criterion included within the Conditions and Maintenance of Certification: Real World Testing (170.405).

# **Care Settings**

Real World Testing is demonstrated following typical physician workflow — providing care in an Acute, Ambulatory, Emergency Department, or Oncology care setting. This scenario incorporates 2015 and Cures Edition Certification criteria for testing purposes within the Care Coordination, Clinical Quality Measures, Patient Engagement, Public Health, and Health IT Design and Performance categories.

#### **CHOSEN MEASURES - SCENARIOS / TESTING ELEMENTS**

## Scenario 1: Sharing of Electronic Health Information

Real World Testing scenario 1 demonstrates that MEDITECH's Health IT module conforms to the following certification criteria: § 170.315(b)(1) Transitions of care, § 170.315(b)(9) Care plan (2015 Edition 6.15 only), §170.315(b)(6) Data Export, and § 170.315(e)(1) View, download, and transmit to 3rd party.

The chart below outlines the measures that have been identified to best demonstrate conformance to multiple certification criteria concerning the sharing of Electronic Health Information across the two use cases demonstrated (single patient and population services).

#### **Certification Criteria Requirement**

Measure 1 – Sharing EHI		
§ 170.315(b)(1) Transitions of care	(i)(A) Send transition of care/referral summaries (i)(B) Receive transition of care/referral summaries	
§ 170.315(e)(1) View, download and transmit	(i)(B)(2) Download ambulatory summary or inpatient summary using CCD Template (i)(B)(3) (Inpatient setting only) Download of transition of care/ referral summaries (i)(C)(1) Transmit to third party (i)(C)(2) (Inpatient setting only) Transmit transition of care/referral summaries	
§ 170.315(b)(9) Care Plan (2015 Edition 6.15 only - inactive as of 12/31/2022)	(i) Record care plan information (ii) Change and access plan information (iii) Create care plan	
Measure 2 - Single Patient Export		
§ 170.315(b)(6) Data Export	(6)(ii) Create export file (6)(iii)(A) real-time export; export based upon a relative date; and export based upon a specific date. (6)(iii)(B) Execute export	

# Sharing of Electronic Health Information Use Case 1 (Single Patient Overview)

MEDITECH's fully web-based solution is an integrated component of MEDITECH's enterprise-wide EHR consisting of advanced patient management; at the center of MEDITECH's EHR is a single electronic patient record. This Certified Health IT Module is utilized when documentation needs to be coordinated between providers and patients both internally and externally within a healthcare organization.

MEDITECH demonstrates that both a limited and full set of data, as required in the Common Clinical Data Set (CCDS) 2015 Edition time-limited (inactive as of 12/31/2022) and United States Core Data for Interoperability (USCDIv1) standard, can be sent and received for Transition of Care (TOC) documentation for a single patient. The data can be shared externally using Edge protocol technology (Direct, SMTP email), exported and shared directly with the patient through MEDITECH's Patient Portal. This functionality provides the ability to view, download, and transmit data. TOC summaries provide essential clinical information for the receiving care team and help organize final clinical and administrative activities for the transferring care team. MEDITECH's enterprise-wide EHR ensures the timely availability of patient information within the Inpatient, Ambulatory, Emergency Department, and Oncology care settings.

**Justification:** The Inpatient, Ambulatory, Emergency Department, and Oncology settings include two capabilities for conformance: (1) Sending transition of care/referral summaries and (2) Receiving transition of care referral summaries, including XDM processing. TOC documents are shared using Edge protocols (e.g., SMTP, Direct) while other data may be shared through MEDITECH's Patient Portal using downloads and encrypted or unencrypted transmissions. The Patient and Consumer Health Portal is a fully-integrated component of MEDITECH's IT module. Seamless exchange of information ensures patients and staff alike have timely access to accurate and timely data across care settings. Metrics provide details on the types of transmissions deployed and the frequency of usage.

**Test Methodology:** Management Information System interface logs will be reviewed to determine the frequency and the transport workings used by providers for sending and receiving transitions of care using Edge protocols and downloading or transmitting data by patients using MEDITECH's Patient Portal. Logs obtained during real world testing will be de-identified and used for analysis in several areas to validate the proper operation of the transport system and input for the calculation of the metric on the specific types of transport functionality utilized. The data metrics associated with criteria in the above scenarios confirm the ability to create, receive, and properly consume interoperable documents using a common content and transport standard (e.g., Consolidated Clinical Document Architecture (C-CDA) that includes key health data — accessible and available for exchange).

**Expected Outcome(s)**: A total number of summary of care messages are generated for each transition of care request either receiving or sending information upon receipt of a transition for the Real World Test population of patients. The functionality of incorporating the summary of care information provides a seamless transition into or out of the MEDITECH EHR. It is expected that providers and patients (or their authorized representatives) will be able to share data using the transmission

functionality provided for Medicare Eligible Hospitals (EHs) and Critical Access Hospitals (CAHs) and Medicaid Eligible Professionals to meet or surpass the requirements of Promoting Interoperability programs related to Coordination of Care. Success and error rates will be tracked and trended over time.

#### **Use Case 2 (Patient Population Overview)**

In addition to the sharing of Electronic Health Information on a single patient level, MEDITECH's Certified Health IT module allows for the export of patient information on a population level. The MEDITECH EHR has the ability to send and receive Consolidated Continuity of Care Documents (CCDA) securely to a known, trusted recipient via the internet using Direct Messaging. Our eHealth Exchange Direct provides customers the functionality to meet Transitions of Care and Patient Portal requirements. Processing Direct Messages, MEDITECH's Patient Portal provides patients with the ability to view, download, and transmit hospital admission information. As part of the Real World Testing requirements for § 170.315(b)(6), MEDITECH has incorporated the following testing plan metric for Patient Population Export. This measure will assess the functionality used to export data for a patient population.

# **Certification Criteria Requirement**

§ 170.315(b)(6) Data Export (6)	<ul><li>(ii) Create export file</li><li>(6)(iii)(A) real-time export; export based upon a relative date; and export based upon a specific date.</li><li>(6)(iii)(B) Execute export</li></ul>
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**Justification:** The export of data associated with a patient population is an additional way to share health information with external organizations. The intent is to provide data research to analyze specific trends in the patient population, export of which is only available to authorized users. This will provide a metric on the use of the export of data for a patient population associated with MEDITECH's Health IT Module.

**Test Methodology:** Management Information System logs will be reviewed to ensure the export function is operating properly and to determine the frequency of use. Logs obtained during Real World Testing will be de-identified and utilized for analysis in several areas to validate the proper operation of the export. This test methodology will primarily test the conformance of the implementation.

**Expected Outcome(s):** It is expected that authorized users will be able to share data for a patient population using the export function to share data using the transmission functionality provided for Medicare Eligible Hospitals (EHs), Critical Access Hospitals (CAHs), and Medicaid Eligible Professionals (EPs) to meet or surpass requirements of Promoting Interoperability programs related to Health Information Exchange objectives. Success and errors in transmission will be tracked and analyzed.

#### Scenario 2: Clinical Information Reconciliation and Incorporation

Real World Testing scenario 2 demonstrates that MEDITECH's Health IT module conforms to the

following certification criteria: §170.315(b)(2) Clinical Information Reconciliation and Incorporation.

The chart below outlines the measures that have been identified to best demonstrate conformance to Clinical Information Reconciliation and Incorporation (CIRI) certification criteria concerning the ability to maintain and review accurate medication, allergy, and problem lists for a patient — enabling clinicians to make informed care decisions during office visits.

## **Certification Criteria Requirement**

§170.315(b)(2) Clinical Information Reconciliation and Incorporation	(b)(2)(ii) transition of care summary/referral summary Consolidated-Clinical Document Architecture (C-CDA) document can be properly matched to a patient in the Health IT Module (automatically or manually).  (b)(2)(iii)(B) user creates a single, reconciled list using the data reviewed from the multiple medications, problems, or medication allergies (b)(2)(iii)(D) user accepts the reconciled list
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#### **Clinical Information Reconciliation and Incorporation Use Case**

As part of the Real World Testing requirements for §170.315(b)(2) Clinical Information Reconciliation and Incorporation (CIRI), MEDITECH demonstrates that external medications, allergies, and problems are available for reconciliation in order to confirm all current data. This Certified Health IT module is utilized when providers are required to reconcile patient clinical data using patients' documented medications, reported medications, and any imported external medications to ensure a complete and accurate medication history. Clinical information reconciliation is implemented for the following three clinical information sets:

- 1. Medication Review of the patient's medication, including the name, dosage, frequency, and route of each medication
- 2. Medication allergy Review of the patient's known medication allergies
- 3. Current Problem list Review of the patient's current and active diagnoses.

MEDITECH's enterprise-wide EHR ensures the ongoing capabilities in reconciling patient information within the Inpatient, Ambulatory, Emergency Department, and Oncology care settings.

**Justification:** MEDITECH demonstrates (CIRI) by comparing information from the MEDITECH system with information from external sources, such as discussions with the patient or a CCD to ensure the data on the patient's chart is up-to-date. An inbound CCD will be received for patients and any unmatched CCD medications, allergies, or problems will be displayed. Metrics provide details on the number of reconciliations deployed and the frequency of usage.

**Test Methodology:** Interface reporting logs will be reviewed to capture percentages for the Support Electronic Referral Loops by Receiving and Incorporating Health Information (Receive and Reconcile) measures. Variables capture the reconciliation percentage of imported problems, medications, or allergies. Logs obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation of (CIRI) transactions. The data metrics associated with the criteria in the above scenario confirm the ability of customers to perform accurate clinical information reconciliation.

**Expected Outcome(s):** A total number of transitions or referrals receiving and incorporating Health Information (external medications, allergies, and problems) by performing a clinical information reconciliation are captured over a period for the Real World Test population of patients. This data exchange allows EHs/CAHs and Medicaid EPs to meet or surpass requirements of the Health Information Exchange objective Measure 3 - Clinical Information Reconciliation for threshold-based reporting and the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure for performance-based reporting. Success and error rates will be tracked and trended over time.

#### **Scenario 3: Electronic Prescribing**

Real World Testing scenario 3 demonstrates that MEDITECH's Health IT module conforms to the following certification criteria: § 170.315(b)(3) Electronic Prescribing.

The chart below outlines the measures that have been identified to best demonstrate conformance to Electronic Prescribing (eRX) certification criteria concerning the ability to perform prescription-related transactions. This functionality includes creating new prescriptions, changing prescriptions, transmitting and receiving medication-associated diagnosis, and reasons for each prescription transaction.

#### **Certification Criteria Requirement**

pres trar (b)(	(3)(ii)(A) send and receive specified rescription transactions electronically (all eRX ansaction types) (3)(ii) (C) send and receive the reason for the rescription (all eRX transaction types)
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#### **Electronic Prescribing Use Case**

As part of the Real World Testing requirements for §170.315(b)(3) Electronic Prescribing, MEDITECH demonstrates that an authorized user can be enabled to perform required prescription-related transactions in accordance with the standard. MEDITECH enables Electronic Prescribing and Order Communications from a single, central location. This Certified Health IT module is utilized when clinicians need to enter individual orders or multi-disciplinary order sets for prescription orders. The eRX orders are communicated in real time to the receiving ancillary department's desktop, and clinicians can easily cancel, edit, renew, repeat, or hold orders at any time. MEDITECH's e-RX capabilities are offered in collaboration with DrFirst. Functionality supported includes the ability to electronically submit

prescriptions to outpatient pharmacies, review medication claim histories, electronically query a patient's prescription drug plan to ensure eligibility and check the insurance formulary for covered medications.

**Justification:** The Inpatient, Ambulatory, Emergency Department, and Oncology settings include the following capabilities for conformance: receiving and processing a number of electronic transactions for new prescriptions; requests to change, cancel, or refill prescriptions; and Medication History Information requests. Metrics provide details on the types of transactions deployed and the frequency of usage.

**Test Methodology:** Management Information System interface logs will be reviewed to determine the frequency of transaction transmissions, outbound requests, and inbound responses. Logs obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation of eRX transactions. The data metrics associated with the criteria in the above scenario confirm the ability for customers to generate and transmit permissible prescriptions electronically.

**Expected Outcome(s):** Transaction types reconcile the corresponding number of new prescriptions; requests to change, cancel or refill prescriptions; and Medication History Information requests. A total number of messages are generated for each eRX request either receiving or sending prescriptions for the Real World Test population of patients. It is expected that authorized users will generate and transmit permissible discharge prescriptions electronically for EHs/CAHs and Medicaid EPs to meet or surpass (eRX) requirements for Promoting Interoperability criteria. Success and error rates will be tracked and trended over time.

# **Scenario 4: Clinical Quality Measurement**

Real World Testing scenario 4 demonstrates that MEDITECH's Health IT Module conforms to the following certification criteria: \$170.315(c)(1) Clinical Quality Measures - Record and Export, \$170.315(c)(2) Clinical Quality Measures - Import and Calculate, and \$170.315(c)(3) Clinical Quality Measures - Report.

The chart below outlines the measures that have been identified to best demonstrate conformance to multiple certification criteria to capture the reporting and execution of QRDA files.

#### **Certification Criteria Requirement**

§170.315(c)(1) Clinical Quality Measures - Record and Export	(c)(1)(i) user demonstrates that they can record the specified data needed for each of the certified CQMs - Record Entry - Record Batch Entry (c)(1)(ii) user can export a file at any time the user chooses and without subsequent developer assistance.
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§170.315(c)(2) Clinical Quality Measures - Import and Calculate	(c)(2)(i) user can execute the import capability described in (c)(2)(i) any time the user chooses and without subsequent developer assistance to operate. (c)(2)(ii) user calculates the aggregate reports for each of the CQMs for which they are seeking certification, based upon the imported and de-duplicated data set. The Health IT Module submits an aggregate report for each of the CQMs to be certified.
§170.315(c)(3) Clinical Quality Measures - Report	(c)(3)(i) (1) user can generate an aggregate report (QRDA Category III) (2) user can generate a de-duplicated archive of patient documents in the QRDA Category I format of the clinical quality measures calculated in the Execute test (§ 170.315(c) (3) The health IT developer submits the quality measurement data file consisting of the data created by the generation of the QRDA Category III aggregate report(s) and the de-duplicated QRDA Category I report(s) for verification.

# **Clinical Quality Measurement Use Case**

MEDITECH reporting is utilized to demonstrate that a user can export a QRDA Category I file(s) for a single patient at any time the user chooses (on-demand) and a list of SQL reports templates are available for customers, corresponding to each required Clinical Quality Measure report specifications and the QRDA Category 1 updates necessary for electronic reporting.

**Justification:** MEDITECH's ARRA Report Manager is a web-based solution for executing MEDITECH's Meaningful Use reports, including variables that capture reporting and execution of QRDA files. The auditing functionality allows for an audit trail of the report execution and results to be saved in audit tables to be used for attestation runs. Metrics provide details on the number of transactions saved for attestation and the frequency of usage.

**Test Methodology:** Reporting logs will be reviewed to capture the number of clinical quality measure percentages over a period of time-based on the specific measure being qualified. Logs obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the proper operation of QRDA transactions. The data metrics associated with the criteria in the above scenario confirm the ability of customers to facilitate accurate Clinical Quality Measure reporting.

**Expected Outcome(s):** It is expected that EHs/CAHs and Medicaid EPs meet or surpass requirements by attesting to measures. A total number of saved attestations are captured for a specific reporting period for the Real World Test population of patients and will be tracked and trended over time.

#### **Scenario 5: Public Health Registries**

Real World Testing scenario 5 demonstrates that MEDITECH's Health IT module conforms to the following certification criteria: §170.315(f)(1) Transmission to Immunization Registries, §170.315(f)(2) Transmission to Public Health Agencies - Syndromic Surveillance, and §170.315(f)(3) Transmission to Public Health Agencies - Reportable Laboratory Tests and Value/Results.

As part of the Real World Testing requirements for § 170.315(f)(1-3), MEDITECH has incorporated the following testing plan metric for Public Health registries. This measure will assess the functionality used to transmit the associated data for a patient population. The chart below outlines the measures that have been identified to best demonstrate conformance to multiple certification criteria concerning the sharing of registry data as demonstrated through the use case for population services.

# **Certification Criteria Requirements**

§170.315(f)(1) Transmission to Immunization Registries	(f)(1)(i) (1) generate the indicated HL7 v2.5.1 Z22 VXU immunization information message, (2) consume the associated acknowledgment message, (3) maintain historical vaccine records (f)(1)(ii) receive HL7 evaluated immunization history and forecast HL7 v2.5.1 Z42 RSP or HL7 v2.5.1 Z33 RSP response messages
§170.315(f)(2) Transmission to Public Health Agencies - Syndromic Surveillance	(f)(2) (2) generate the indicated HL7 v2.5.1 ADT message
§170.315(f)(3) Transmission to Public HealthAgencies - Reportable Laboratory Tests and Value/Results	(f)(3)(i) create Reportable Lab content and generate ELR message

#### **Public Health Registries Use Case**

At the foundation of any effective population management solution is data, and MEDITECH's EHR brings it all together through reporting solutions in capturing public health criteria. Our EHR aggregates data across the continuum of care — from customer hospitals, physician practices, emergency departments, and long-term care facilities. MEDITECH's Certified Health IT module provides functionality to track and store patient immunization information electronically, ensure hospitals possess the ability to report threat and outbreak information to public health agencies with Syndromic Surveillance data, and reportable condition functionality where specific reportable results are defined.

Justification: The transmission of Public Health data associated with a patient population using interface functionality provides data research to analyze specific trends in the patient population. With intuitive, web-based interfaces, MEDITECH's Public Health & Clinical Data Exchange functionality within the Inpatient, Ambulatory, and Emergency Department, settings include seamless and active engagement with public health agencies or clinical data registries to submit electronic public health data for conformance to this combined criteria. Interface messages will provide metrics on the use and frequency of transmissions to state agencies for immunizations, syndromic surveillance, reportable laboratory tests and value/results for a patient population associated with MEDITECH's Health IT Module.

**Test Methodology**: Management Information System interface logs will be reviewed to ensure the transmissions are operating properly and to determine the frequency of use. Logs obtained during Real World Testing will be de-identified and utilized for analysis in several areas to validate the proper operation of the Public Health interfaces. This test methodology will primarily test the conformance of the Implementation.

**Expected Outcome(s):** Public Health messages are processed and received via the interfaces used by the healthcare organization. It is expected that eligible hospitals or professionals are in active engagement with a public health agency using functionality provided in order to submit electronic public health data for EHs/CAHs and Medicaid EPs to meet or surpass requirements of Promoting Interoperability programs related to Public Health and Clinical Data Exchange objectives. Success and errors in transmission will be tracked and analyzed over time.

**Scenario 6:** §170.315(f)(4) Transmission to Cancer Registries - Expanse Oncology delivers a full solution for managing the unique care requirements of oncology patients in both ambulatory and inpatient settings. Oncology workflow is integrated with the entire MEDITECH Expanse EHR to enhance communication across care teams and provide patients with the assurance of a safe and comforting care experience.

#### **Cancer Case Reporting Use Case**

Cancer Event Reporting is incorporated into MEDITECH's workflow allowing organizations to use functionality in meeting the MIPS criteria established by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) for Public Health Registry Reporting. MEDITECH's Cancer Registry interface generates outbound messages to meet this measure.

#### **Certification Criteria Requirements**

(f)(4)(i) (2) create cancer case document, Reporting to Public Health Cancer Registries

**Justification:** As part of the Real World Testing requirements for § 170.315(f)(4), MEDITECH demonstrates Reporting to Public Health Cancer Registries via validation reports following standard workflow within dedicated internal platforms for Acute/Oncology and Ambulatory settings.

**Test Methodology:** In order to effectively monitor cancer conditions and meet MIPS requirements, organizations must capture a variety of data elements that the system uses to populate cancer event reports. These data elements include patient demographics, provider and organization information, cancer diagnosis and details, laboratory and pathology results, and medication information. MEDITECH demonstrates the capability by generating a cancer event report when a testing patient is diagnosed with an ICD code recognized by the Centers for Disease Control (CDC) as a cancer condition.

**Expected Outcomes:** Using a dedicated internal platform, it is expected that testing Cancer Case trigger routines respond to and generate a corresponding cancer event report. Visual inspection of success rates with MEDITECH's interface message generator will be captured to demonstrate the capability with outbound messages for Cancer Case reporting.

Scenario 7: Transmission to Public Health Agencies - Antimicrobial Use and Resistance Reporting Real World Testing scenario 7 demonstrates that MEDITECH's Health IT Module conforms to the following certification criteria: §170.315(f)(6) Transmission to Public Health Agencies - Antimicrobial Use and Resistance Reporting. The chart below outlines the measures that have been identified to best demonstrate conformance to the Antimicrobial Use and Resistance (AUR) reporting certification criteria concerning the ability to successfully submit data for each month of the calendar year in order to receive confirmation of compliance from the National Healthcare Safety Network (NHSN).

#### **Certification Criteria Requirement**

§170.315(f)(6) Transmission to Public Health Agencies - Antimicrobial Use and Resistance Reporting	(f)(6) (1) Health IT Module creates Antimicrobial use and resistance reporting information Antimicrobial Resistance Option Report (Numerator) Antimicrobial Resistance Option (ARO) Summary Report (Denominator) Antimicrobial Use (AUP) Summary Report (Numerator and Denominator)
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#### **Antimicrobial Use and Resistance Reporting Use Case**

MEDITECH conforms to the Centers for Disease Control (CDC) specifications for Antimicrobial Use and Resistance Reporting and provides reporting related to generating electronic Microbiology antimicrobial resistance and antibiotic administration reports for transmission to the National Healthcare Safety Network. Measures that have been identified to best demonstrate conformance to the AUR reporting certification criteria include report functionality in success percentages for related Promoting Interoperability(PI) Objective measures.

**Justification:** MEDITECH reporting capabilities provide a web-based solution for executing MEDITECH's meaningful use reports. AUR reporting includes variables that capture Numerator/Denominator values

to assist customers in successfully submitting data in order to receive confirmation of compliance from NHSN. The auditing functionality allows for a history of the report execution and results to be saved in audit tables and used for attestation purposes.

**Test Methodology:** Reporting logs will be reviewed to capture the number of CDA files saved for submission over a period of time. Logs obtained during Real World Testing will be de-identified and used for analysis in several areas to validate the execution of Antimicrobial Use and Resistance data. The metrics associated with the criteria in the above scenario confirm the ability of customers to facilitate export CDA XML files for accurate AUR reporting.

**Expected Outcome(s):** It is expected that authorized users will generate electronic Microbiology antimicrobial resistance and antibiotic administration reports for transmission to the National Healthcare Safety Network for EHs/CAHs and Medicaid EPs to meet or surpass requirements related to Public Health and Clinical Data Exchange objectives. A total number of saved CDA XML files are captured for a specific reporting period for the Real World Test population of patients and will be tracked and trended over time.

#### **Scenario 8: Application Access**

Real World Testing scenario 8 demonstrates that MEDITECH's Health IT module conforms to the following certification criteria: §170.315(g)(7) Application Access - Patient Selection, §170.315(g)(8) Application Access - Data Category Request (inactive as of 12/31/2022), §170.315(g)(9) Application Access - All Data Request, and §170.315(g)(10) Application Access - Standardized API for Patient and Population Services.

The chart below outlines the measures that have been identified to best demonstrate conformance to multiple certification criteria to validate Application Programming Interface (API) interoperability-specific application requests and responses.

#### **Certification Criteria Requirement**

§170.315(g)(7) Application Access - Patient Selection	The health IT developer submits their self-declaration to the ONC-ATL.
§170.315(g)(8) Application Access - Data Category Request (inactive as of 12/31/2022)	(g)(8)(i)(A) user demonstrates that one or more API routines respond to and return the full set of data for each data category from the CCDS for the unique patient identified by the ID or token. (g)(8)(i)(B) API functions return data to the developer-identified requesting application for a specific date the requesting application identifies. (Previous process, replaced with g10 criteria, demonstrating Single and Multi-Patient Authorization.)

§170.315(g)(9) Application Access - All Data Request	(g)(9)(i)(A) (2) user demonstrates that the API responds to and returns all data from the Common Clinical Data Set (g)(9)(i)(B) API functions return data to the developer-identified requesting application for a specific date that the requesting application identifies.
§170.315(g)(10) Application Access - Standardized API for Patient and Population Services	170.315(g)(10)(i), (ii) Demonstrate Single Patient API 170.315(g)(10)(i), (ii), (iv) Demonstrate Multi-Patient Authorization and API

#### **Application Access Use Case**

Interoperability Services (IOPS), an Application Programming Interface (API) platform installed alongside the RESTful API Infrastructure, provides the MEDITECH EHR with next-generation interoperability capabilities. The platform runs interoperability-specific applications (collections of APIs) — enabling the MEDITECH EHR to take advantage of more advanced features and integrations. The MEDITECH API platform is an extension of the MEDITECH Health Care Information System (HCIS) which enables client applications to interact with MEDITECH's databases. An authorized user acting as the Health Care Organization's System Administrator will register the API User client application with the MEDITECH API platform in order to demonstrate the facilitation of Application Access requests for Patient Selection, Data Category Requests, and Application Access - All Data Requests.

**Justification:** MEDITECH remains at the forefront of the interoperability movement. As a contributing member of the CommonWell Health Alliance and a collaborator in Argonaut's FHIR Project, we are committed to increasing our customers' data exchange avenues. Where Application Access criteria requirements include health IT developers submitting ongoing certification via self-declaration, supplemental testing of patient request, data category, and all data requests by an authorized MEDITECH user over a period of time best demonstrate conformance to Application Programming Interface (API) interoperability-specific application requests and responses for Real World Testing.

**Test Methodology:** An authorized user acting as the Health Care Organization's System Administrator will register the API User client application with the MEDITECH API platform over a period of time in order to demonstrate the facilitation of Application Access requests for Patient Selection, Data Category Requests, and Application Access - All Data Requests. This test methodology will primarily test the conformance of the implementation.

**Expected outcome(s):** Using a developer-supplied API test client, it is expected that testing API routines respond to and return full sets of data for each data category from the CCDS for the unique patient identified by the ID or token. Additionally, API functions are expected to return data to the MEDITECH requesting application for a specific date the requesting application identifies. Visual inspection of successful test data will be tracked and analyzed.

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

Standard (and version)	NCPDP 2017071	
Updated certification criteria and associated product	§170.315(b)(3) Electronic Prescribing Expanse 2.2, 2.1, 6.15	
Health IT Module CHPL ID	MEDITECH Expanse 2.2 Core HCIS v2.2c 15.04.04.2931.MEDI.CO.02.1.220630 MEDITECH Expanse 2.2 Ambulatory v2.2c 15.04.04.2931.MEDI.ED.03.1.220630 MEDITECH Expanse 2.2 Emergency Department Management v2.2c 15.04.04.2931.MEDI.ED.03.1.220630 MEDITECH Expanse Emergency Department Management v2.1c 15.04.04.2931.MEDI.16.02.1.220630 MEDITECH Expanse 2.1 Core HCIS v2.1c 15.04.04.2931.MEDI.CO.01.1.220630 MEDITECH Expanse 2.1 Ambulatory v2.1c 15.04.04.2931.MEDI.CO.01.1.220630 MEDITECH 6.1 Emergency Department Management v6.15c 15.04.04.2931.MEDI.15.01.1.220630 MEDITECH 6.1 Electronic Health Record Core HCIS v6.15c 15.04.04.2931.MEDI.HC.01.1.220630 MEDITECH 6.1 Ambulatory Electronic Health Record v6.15c 15.04.04.2931.MEDI.AM.01.1.220630	
Method used for standard update	Certification Attestation	
Date of ONC -ACB notification	N/A	
Date of customer notification (SVAP only)	N/A	
Conformance measure	N/A	
USCDI -updated certification criteria (and USCDI version)	USCDIv1 §170.315(b)(1) Transitions of Care §170.315(b)(2) Clinical Information Reconciliation	

	and Incorporation §170.315(e)(1) View, Download, and Transmit to 3rd Party §170.315(g)(9) Application Access - All Data Request §170.315(g)(10) Application Access
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Care Setting(s)	Justification
Acute	MEDITECH's fully web-based Inpatient solution is an integrated component of MEDITECH's enterprise-wide EHR consisting of advanced patient management via Registration capturing details for public health interfaces and data export. Clinical workflows incorporate medication reconciliation and list medications, problems, and allergies. Inpatient Data Export Exchange routines export single patient and/or bulk patient data files for Continuity of Care documents, Discharge Summaries, Referral Notes, and Care Plans.
Ambulatory	MEDITECH's Ambulatory solution is device- and browser-agnostic, specifically designed for use with touch screen devices to provide more efficient patient care. Clinical functionality within MEDITECH's Ambulatory solution is optimized with over 40 tailorable specialty-specific workflows, including: anesthesiology, behavioral health, general surgery, obstetrics, and gynecology, orthopedics, pediatrics. In the Ambulatory system, users can review and reconcile a patient's enterprise-wide allergy list via the Allergy/Adverse Reaction screen. The patient's active problem list can be reviewed in the Problems widget within the patient's chart, highlighted via a visual indicator. The External Data Available flag displays in order to reconcile the data for this patient. The patient's existing Problems, Medications, and Allergies are easily compared with those available from another source and entries reconciled.
Emergency Department	MEDITECH's Emergency Department Management solution assists ED staff with the critical task of treating patients quickly and efficiently. As an integrated component of MEDITECH's EHR, Emergency Department Management supports the seamless exchange of patient information between the acute care, ambulatory, and ED settings, expediting care and providing all clinicians with the complete information they need to make safer, more informed decisions.
	Specialty-driven workflows — along with modern tablet conventions like tap and swipe — increase provider productivity while streamlining transitions of care.

Oncology	MEDITECH's Oncology delivers a full solution for managing the unique care requirements of oncology patients in ambulatory and inpatient settings. Oncology workflow is integrated with the entire MEDITECH EHR to enhance communication across care teams and provide patients with the assurance of a safe and comforting care experience.
	Oncology incorporates queuing of new orders while reviewing or documenting in the patient's chart, simplifying health and disease management through integrated flowsheets and a shared problem list, and closed-loop medication management by integrating Oncology with Pharmacy, Order Management, and Patient Care.

#### **SCHEDULE OF KEY MILESTONES**

#### **Testing Milestones – All Scenarios**

MEDITECH, following change control approval procedures, will connect to a number of predetermined customer directories or dedicated internal environments gathering data for a specific period each quarter beginning in January 2023 in order to capture metrics for each criterion. These statistics substantiate the demonstration of interoperability and functionality of our Certified Health IT in the care settings and scenarios for the 2023 test plan as described in the above scenarios. Once all of the use case criteria tests have been conducted, authorized MEDITECH representatives will analyze the result outcomes. Upon completion of the Real World Testing results review, the Certification group will draft a final summary report for self-preparation and submission to the Drummond Group.

The execution of the testing process, capturing data on a quarterly basis, will be completed by year-end 2023 for an analysis of success rates over a period of time for submission of reporting results by March 2024.

Key Milestone	Care Setting	Date/Timeframe
Initial development of the Real World Testing plans designed by platform combination.	Acute Ambulatory Emergency Oncology	June – September 2022
Development submission of reporting utilities to gather data for analysis.	Acute Ambulatory Emergency Oncology	September 30, 2022
Submit final Real World Test plans to Drummond Group.	Acute Ambulatory Emergency Oncology	November 1, 2022

Post approved Real World Test Plan to external url.		December 15, 2022
Initiate collection of metrics for each group of criteria based on the reporting tools and utilities noted.	Acute Ambulatory	Quarterly – March, June, September, December 2023
Meet with designated testers and Certification group review for analysis of data collected.	Acute Ambulatory	Quarterly – March, June, September, December 2023
Design Real World Testing Results report	Acute Ambulatory	December 31, 2023
Complete metric analysis and Real World Testing report completion.	Acute Ambulatory	January 1 – March 1, 2024
Submit Real World Testing report to Drummond Group.	Acute Ambulatory	Date TBD by Drummond Group prior to March 15, 2024

# **ATTESTATION**

Authorized Representative Name: Geoff Smith

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Authorized Representative Phone: 781-774-4660

Authorized Representative Signature:

Date: October 24, 2022

i Certified health IT continues to be compliant with the certification criteria, including the required technical standards and vocabulary codes sets; certified health IT is exchanging EHI in the care and practice settings for which it is marketed for use; and EHI is received by and used in the certified health IT. (85 FR 25766)

ii https://www.federalregister.gov/d/2020-07419/p-3582