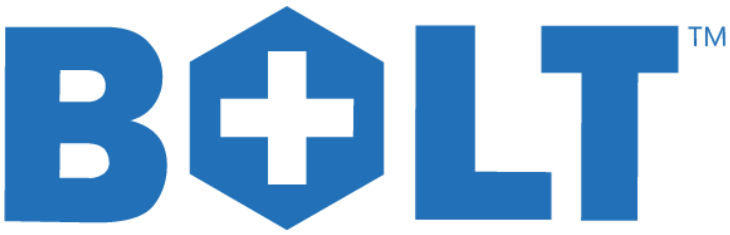

Real World Testing Plan

2023

MedOne Systems, LLC
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MED ONE SYSTEMS

General Information

Plan Report ID Number:	
Developer Name:	Enke-Mari Marx
Product Name:	BOLT
Version Number:	3.5
Certified Health IT Product List (CHPL) Product Number:	15.04.04.1901.BOLT.03.02.1.211122
Developer Real World Testing Plan Page URL:	https://www.medonesystems.com/bolt-certification

Overview

Utilized in both the inpatient and ambulatory setting, BOLT is a software solution that enhances existing enterprise EHR, augmenting its clinical functionality and promoting efficiency, effectiveness, and clinical staff satisfaction. This document describes MedOne Systems' plan to measure the real world use of interoperability features that the BOLT software is certified for, during the calendar year 2023.

Real World Testing Approach

As BOLT is used in two care settings, inpatient and ambulatory, the Real World Testing Plan will incorporate both care settings. The plan intends to incorporate both manual and automated methods to gather metrics at various points in time over the year to ensure the criteria is continuously met.

MedOne Systems will use a random sampling of data at various times throughout the calendar year to confirm compliance, as continuous testing would be overwhelming and impractical for our client. Manual validation is needed to confirm both UI elements of various criteria as well as patient specific data that cannot be validated by any other means. The use of automated validation will be used for complex, non-condition, and maintenance of our certification requirements.

This approach is optimal for the three criteria for which the plan addresses, §170.315(b)(2) Clinical information reconciliation and incorporation, §170.315(b)(3) Electronic Prescribing, and §170.315(c)(1) Clinical quality measures (CQMS) – record and export.

Standards Updates

The certified version of BOLT meets all 2015 Edition and 2015 Cures Update Edition certification criteria as identified on the ONC's Certified Health IT Product List (CHPL) for the certified modules. This includes:

- **USCDI Updates:** BOLT is updated to support the United States Core Data for Interoperability (USCDI) v1 for these specific formerly Common Clinical Data Set (CCDS)-dependent 2015 Edition certification criteria: § 170.315 (b)(2) Clinical information reconciliation and incorporation and § 170.315 (g)(6) Consolidated CDA creation performance.
- **C-CDA Companion Guide Updates:** BOLT supports C-CDA Release 2.1 for the implementation of USCDI v1 for the following criteria: § 170.315(b)(2) Clinical information reconciliation and incorporation and § 170.315 (g)(6) Consolidated CDA creation performance.
- **Electronic Prescribing:** BOLT conforms to the updated certification criterion for § 170.315 (b)(3) Electronic Prescribing and has implemented § 170.205(b)(1): NCPDP SCRIPT Standard, Implementation Guide, Version 2017071 and § 170.207(d)(3): RxNorm, September 8, 2015, Full Release Update.
- **4,90ASTM Updates:** BOLT conforms to the 2015 Edition Cures Update § 170.315(d)(2) Auditable events and tamper-resistance and § 170.315(d)(3) Audit reports criteria, which aligns with the most up to date standard ASTM E1247-18.

Care Coordination

§ 170.315 (b)(2) Clinical Information Reconciliation and Incorporation

Description of Measurement/Metric

This criterion describes the process of electronically receiving a Consolidated Clinical Document (CCD) from an external source. BOLT supports the importing and reconciliation of CCDA Releases 1.1 and 2.1 and automatically associates the most recent CCD to a patient based on demographic information and patient ID. After a BOLT user with the appropriate role and permissions confirms that the patient chart matches the demographic information in the CCD, they import the data to reconcile problems, medications, and allergies from the CCD alongside existing clinical information in the patient's chart. This process ensures that the patient's medical history in terms of problems, medications, and allergies, is up to date, active and accurate, especially when the patient is seen by multiple health systems.

Associated Certification Criteria

- Authentication, access control, and authorization (§ 170.315(d)(1))
- Auditable events and tamper-resistance (§ 170.315(d)(2))
- Audit reports (§ 170.315(d)(3))
- Automatic access time-out (§ 170.315(d)(5))
- Emergency access (§ 170.315(d)(6))
- End-user device encryption (§ 170.315(d)(7))
- Integrity (§ 170.315(d)(8))
- Encrypt authentication credentials (§ 170.315(d)(12))
- Multi-factor authentication (MFA) (§ 170.315(d)(13))
- Automated Numerator / Measure Calculation (§ 170.315(g)(1)/(g)(2))
- Safety-enhanced Design (§ 170.315(g)(3))
- Quality management system (§ 170.315(g)(4))
- Accessibility-centered design (§ 170.315(g)(5))
- Consolidated CDA creation performance (§ 170.315(g)(6))

Justification for Selected Measurement/Metric

MedOne Systems has partnered with Dynamic Health IT (DHIT) and uses their fully certified ConnectEHR product as the relied upon software to generate and to parse received CCDs into BOLT where clinical users reconcile and incorporate clinical data. CCDs are received either from inbound Secure Direct Messaging, or automated query-based patient matching from the Health Information Exchange (HIE). Clinical data reconciliation in the patient chart is implemented in BOLT to be part of the clinician's workflow and is performed at the point of care. This is true for both inpatient and ambulatory care settings.

MedOne Systems will validate that the functionality for clinical information reconciliation and incorporation is used in the real world by analyzing the number of times BOLT users matched patient demographics with that from CCDs received from external sources. Subsequently, MedOne Systems can track the reconciliation of problems, medications, and allergies from the CCDs into the patient charts.

Specific measurements will include:

- Number of CCDs correctly matched with patient demographics and imported for reconciliation
- Number of Problems added/rejected
- Number of Medications added/rejected
- Number of Allergies added/rejected

Expected Outcomes

It is possible that CCDs will be received by the system but not incorporated because that action is dependent on whether a user chooses to perform the specific actions in BOLT resulting in the incorporation and reconciliation of clinical data from the CCD. Those CCDs will not count towards the metric as no action would have been taken. The metrics will only include cases where the CCD was matched with the patient's demographics. Any statistics reported on problem, medication and/or allergy incorporation and reconciliation will be for CCDs that were matched to the patient.

MedOne Systems expects general consistency across the measurement period in terms of CCDs that are matched to patient demographics and selected for incorporation and reconciliation by the BOLT users, and those who are not included. It is, however, likely that for CCDs that are matched with patient demographics, more problems and medications might be incorporated and reconciled since patients are less likely to have high numbers of allergies. Therefore, it is expected that the number of actions performed in relation to problems and medications will outweigh the number of actions performed on allergies from CCDs that are matched with patient demographics.

§ 170.315(b)(3) Electronic Prescribing

Description of Measurement/Metric

This criterion describes the electronic communication between BOLT and pharmacies about creating, cancelling, renewing, and changing prescriptions. The software is also required to query for and receive a patient's medication history for review by the clinical user.

Associated Certification Criteria

- § 170.315(b)(3) Electronic Prescribing
- § 170.315(d)(1-3)
- § 170.315(d)(5-8)
- § 170.315(d)(12-13)
- § 170.315(g)(3-5)

Justification for Selected Measurement/Metric

BOLT software tracks all messages sent and received. Therefore, MedOne Systems chose to automatically collect statistics of electronic prescription communication between BOLT and pharmacies for inpatient and ambulatory settings. Additionally, the software tracks when a patient's Medication History was queried and received for review by a clinical user in the inpatient setting. The following will be tracked and reported:

- Count of prescription messages sent from BOLT using the NCPDP SCRIPT Standard Version 2017071, and successfully received by the pharmacy – NewRx, CancelRx, RxRenewalResponse, RxChangeResponse, NewRxResponseDenied. Outgoing Status, Verify and Error message acknowledgements will not be counted.
- Count of messages using the NCPDP SCRIPT Standard Version 2017071, containing prescription information received from pharmacies – RxFill, RxChangeRequest, RxRenewalRequest, CancelRxResponse, NewRxRequest. Incoming Status, Verify and Error message acknowledgements will not be counted.
- Count of encounters where a patient's medication history was queried (RxHistoryRequest) and received (RxHistoryResponse) using the NCPDP SCRIPT Standard Version 2017071 and contained information about at least one medication.

Expected Outcomes

It is expected that the count of messages sent from BOLT to pharmacies will outweigh the number of messages received from pharmacies. Almost every incoming/received message will have a corresponding outgoing/send message with the most likely exception being the RxFill message received from pharmacies. Conversely, not all messages that are sent will trigger corresponding messages received. For example, the NewRx message type for which the Status or Verify acknowledgement is received.

By counting messages sent and received between the BOLT software and pharmacies, MedOne Systems will validate that the software is able to perform certified actions it is certified for under the criterion description.

The results for certain message types are dependent upon the participation of the pharmacy. Therefore, it is expected that there will be circumstances in which BOLT will not receive messages from a non-participating pharmacy.

Clinical Quality Measures (CQMs)

§ 170.315 (c)(1) Record and Export

Description of Measurement/Metric

This criterion describes electronically recording relevant data for Clinical Quality Measures (CQMs) and exporting a data file according to the format described by the HL7 Quality Reporting Document Architecture Category I (QRDA I) for submission of the CQM data as required for participation in CMS programs.

Justification for Selected Measurement/Metric

As part of their normal clinical workflow, users discretely record data points in BOLT related to relevant CQMs in the inpatient and ambulatory setting. MedOne Systems has chosen to focus testing on ensuring BOLT is recording patient and clinical data over time for multiple patients in a manner that is consistent with the requirements of the CQM standards.

MedOne Systems has partnered with Dynamic Health IT (DHIT) and will be using their fully certified CQM Solution product to export the recorded clinical data into the specified QRDA I file format for validation using appropriate tools. The successful generation of a valid QRDA I files at certain intervals will, over time, be used to produce percentages for CQMs for both eligible clinicians/providers and hospitals proving real world use of the functionality.

Expected Outcomes

A visual inspection and matching of QRDA I data to EHR data as well as validating the QRDA I data file structure using appropriate tools. 100% success on execution and validation of the QRDA I file generation validates effective real world use.

It is expected that customers will be able to track performance and report to CMS and test systems without errors. This will demonstrate real world compliance with recording and exporting according to the certification criteria.

Schedule of Key Milestones

Key Milestone	*Care Setting*	*Date/Timeframe*
Testing Plan Submission	Inpatient and Ambulatory	November 2022
Data Collection	Inpatient and Ambulatory	First week of each quarter in the year 2023
Analysis and Report Creation	Inpatient and Ambulatory	December 2023 – February 2024
Results submission	Inpatient and Ambulatory	March 2024

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 Real World Testing requirements.

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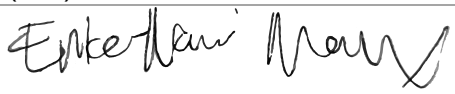
Authorized Representative Signature	
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