Real World Testing Plan

2024

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General Information

Plan Report ID Number:	
Developer Name:	Michelle Geese
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 documentation 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 2024.

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 are 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 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

Regulation	§ 170.315 (b)(2) *Clinical information and reconciliation and incorporation*— i. *General requirements*. Paragraphs (b)(2)(ii) and (iii) of this section must be completed based on the receipt of a transition of care/referral summary formatted in accordance with the standards adopted in § 170.205(a)(3) through (5) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates on and after December 31, 2022. ii. *Correct patient*. Upon receipt of a transition of care/referral summary formatted according to the standards adopted § 170.205(a)(3) through (5), technology must be able to demonstrate that the transition of care/referral summary received can be properly matched to the correct patient. iii. *Reconciliation*. Enable a user to reconcile the data that represent a patient's active medication list, allergies and intolerance list, and problem list as follows. For each list type:

	A. Simultaneously display (i.e., in a single view) the data from at least two sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date. B. Enable a user to create a single reconciled list of each of the following: Medications; Allergies and Intolerances; and problems. C. Enable a user to review and validate the accuracy of a final set of data. D. Upon a user's confirmation, automatically update the list, and incorporate the following data expressed according to the specified standard(s) on and after December 31, 2022: 1. *Medications.* At a minimum, the version of the standard specified in § 170.213; 2. *Allergies and intolerance.* At a minimum, the version of the standard specified in § 170.213; and 3. *Problems.* At a minimum, the version of the standard specified in § 170.213. iv. *System verification.* Based on the data reconciled and incorporated, the technology must be able to create a file formatted according to the standard specified in § 170.205(a)(4) using the Continuity of Care Document template and the standard specified in § 170.205(a)(5) on and after December 31, 2022.
The Office of the National Coordinator for Health Information Technology (ONC) (2022, April 6). Certification Criteria 2015 Edition Cures Update. HealthIT.gov. Retrieved September 11, 2023, from https://www.healthit.gov/test-method/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 identification. 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 medical record. 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 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 will track the reconciliation of problems, medications, and allergies from the CCDs into the patient charts.

Specific measurements will include:

- The number of CCDs correctly matched with patient demographics and imported for reconciliation of medications, allergies, and problems.
- The number of medications received with an indication that clinical reconciliation occurred.
- The number of allergies received with an indication that clinical reconciliation occurred.
- The number of problems received with an indication that clinical reconciliation occurred.

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

Regulation	§ 170.315(b)(3) *Electronic prescribing*. (ii) For technology certified subsequent to June 30, 2020: A. Enable a user to perform the following prescription-related electronic transactions in accordance with the standard specified in § 170.205(b)(1) and, at a minimum, the version of the standard specified in § 170.207(d)(3) as follows: 1. Create new prescriptions (NewRx). 2. Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse). 3. Request and respond to cancel prescriptions (CancelRx, CancelRxResponse). 4. Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse). 5. Receive fill status notifications (RxFill). 6. Request and receive medication history (RxHistoryRequest, RxHistoryResponse). 7. Relay acceptance of a transaction back to the sender (Status). 8. Respond that there was a problem with the transaction (Error). 9. Respond that a transaction requesting a return receipt has been received (Verify). B. Optionally, enable a user to perform the following prescription-related electronic transactions in accordance with the standard specified in § 170.205(b)(1) and, at a minimum, the version of the standard specified in § 170.207(d)(3) as follows:

1. Create and respond to new prescriptions (NewRxRequest, NewRxResponseDenied).
2. Send fill status notifications (RxFillIndicator).
3. Ask the Mailbox if there are any transactions (GetMessage).
4. Request to send an additional supply of medication (Resupply).
5. Communicate drug administration events (DrugAdministration).
6. Request and respond to transfer one or more prescriptions between pharmacies (RxTransferRequest, RxTransferResponse, RxTransferConfirm).
7. Recertify the continued administration of a medication order (Recertification).
8. Complete Risk Evaluation and Mitigation Strategy (REMS) transactions (REMSInitiationRequest, REMSInitiationResponse, REMSRequest, and REMSResponse).
9. Electronic prior authorization (ePA) transactions (PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse and PACancelRequest, and PACancelResponse).

C. For the following prescription-related transactions, the technology must be able to receive and transmit the reason for the prescription using the diagnosis elements: <Diagnosis><Primary> or <Secondary>:
   1. Required transactions
      i. Create new prescriptions (NewRx).
      ii. Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse).
      iii. Request to cancel prescriptions (CancelRx).
      iv. Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse).
      v. Receive fill status notifications (RxFill).
      vi. Receive medication history (RxHistoryResponse).
   2. Optional transactions:
      i. Request to send an additional supply of medication (Resupply)
      ii. Request and respond to transfer one or more prescriptions between pharmacies (RxTransferRequest, RxTransferResponse)
      iii. Complete Risk Evaluation and Mitigation Strategy (REMS) transactions (REMSInitiationRequest, REMSInitiationResponse, REMSRequest, and REMSResponse).
      iv. Electronic prior authorization (ePA) transactions (PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse and PACancelRequest, PACancelResponse).

	D. *Optional*. For each transaction listed in paragraph (b)(3)(ii)(C) of this section, the technology must be able to receive and transmit reason for prescription using the <IndicationforUse> element in the Sig segment. E. Limit a user's ability to prescribe all oral liquid medications in only metric standard units of mL (i.e., not cc). F. Always insert leading zeroes before the decimal point for amounts less than one and must not allow trailing zeroes after a decimal point when a user prescribes medications.
The Office of the National Coordinator for Health Information Technology (ONC) (2023, May 1). Certification Criteria 2015 Edition Cures Update. HealthIT.gov. Retrieved September 11, 2023, from https://www.healthit.gov/test-method/electronic-prescribing	

Description of Measurement/Metric

This criterion describes the electronic communication between BOLT and a pharmacy regarding the creation, cancelation, renewal, and changing of prescriptions, including the fill status. Additionally, the software will query for and receive a patient's medication history for review by the clinical user.

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))

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 to a Pharmacy using the NCPDP SCRIPT Standard Version 2017071 – NewRx, CancelRx, RxRenewalResponse, RxChangeResponse, NewRxResponseDenied. Outgoing Status, Verify, and Error message acknowledgments 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 acknowledgments 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 number 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 acknowledgment is received.

By counting messages sent and received between the BOLT software and pharmacies, MedOne Systems will validate that the software can perform 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	
Regulation	§ 170.315(c)(1) *Clinical quality measures—record and export—* i. *Record.* For each and every CQM for which the technology is presented for certification, the technology must be able to record all of the data that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of "patient reason," "system reason," or "medical reason."

	ii. *Export.* A user must be able to export a data file at any time the user chooses and without subsequent developer assistance to operate: A. Formatted in accordance with the standard specified in § 170.205(h)(2); B. Ranging from one to multiple patients; and C. That includes all of the data captured for each and every CQM to which technology was certified under paragraph (c)(1)(i) of this section.
The Office of the National Coordinator for Health Information Technology (ONC) (2023, February 23). Certification Criteria 2015 Edition Cures Update. HealthIT.gov. Retrieved September 11, 2023, from https://www.healthit.gov/test-method/clinical-quality-measures-cqms-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 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 settings. 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 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. The following will be tracked and reported:

- Count of exported CQM Data per CMS certification.
- Count of QRDA Category I exports.

Expected Outcomes

This measurement has been selected to verify that organizations are recording CQM data within the health care record and exporting data to measure compliance. This process validates effective real-world use as organizations have ongoing monitoring of recorded CQM data to measure performance over time and export valid QRDA files for submission to CMS based on program deadlines.

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 2023
Data Collection	Inpatient and Ambulatory	Quarterly in 2024
Analysis and Report Creation	Inpatient and Ambulatory	December 2024 – February 2025
Results Submission	Inpatient and Ambulatory	March 2025

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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