BOLT Real World Test Plan 2022

MedOne Systems, LLC
401 Matthew Street
Marietta, OH 45750
740.242.7987
Product Name: BOLT
Version: 3.5
CHPL ID: 15.04.04.1901.BOLT.03.01.1.191220

General Information

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.

Justification for Real World Testing Approach

As BOLT is used in 2 care settings, Inpatient and Ambulatory, the Real World Test 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 always being met.

We have chosen to use 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-patient or non-UI specific aspects of the criteria, specifically file formats and general content. The combined use of these validations will demonstrate that our overall strategy meets the Real World Testing condition and maintenance of our certification requirements. We believe that this approach is optimal for the two criteria for which the plan addresses, §170.315(b)(2) Clinical information reconciliation and incorporation and §170.315(c)(1) - Clinical quality measures (CQMs) — record and export.

Criteria

Included in plan
§ 170.315(b)(2) Clinical information reconciliation and incorporation
§ 170.315(c)(1)—record and export

To be removed from BOLT certified criteria in December, 2021 – certified 3rd party product provides criteria
§ 170.315(b)(1) Transitions of care
§ 170.315(b)(6) Data export
§ 170.315(c)(2)—import and calculate
§ 170.315(c)(3)—report
§ 170.315(e)(1) View, download, and transmit to 3rd party
§ 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

Key Milestones Summary

Criteria	Setting	Measurement Period	Date	Key Milestones
Care Coordination				
§ 170.315(b)(2) Clinical information reconciliation and incorporation	Inpatient	7/1/2022 - 12/31/2022	Third Quarter	Patients matched with C-CDA document Items reconciled Documents validated
			Fourth Quarter	Patients matched with C-CDA document Items reconciled Documents validated
	Ambulatory	7/1/2022 - 12/31/2022	Third Quarter	Patients matched with C-CDA document Items reconciled Documents validated
			Fourth Quarter	Patients matched with C-CDA document Items reconciled Documents validated
Clinical Quality Measures				
§ 170.315(c)(1)—record and export	Inpatient	1/3/2022 - 10/3/2022	1/3/2022	Manual validation of QRDA 1 file contents Electronic validation of QRDA 1 files
			4/4/2022	Manual validation of QRDA 1 file contents Electronic validation of QRDA 1 files
			7/5/2022	Manual validation of QRDA 1 file contents Electronic validation of QRDA 1 files
			10/3/2022	Manual validation of QRDA 1 file contents Electronic validation of QRDA 1 files
	Ambulatory	1/3/2022 - 10/3/2022	1/3/2022	Manual validation of QRDA 1 file contents Electronic validation of QRDA 1 files
			4/4/2022	Manual validation of QRDA 1 file contents Electronic validation of QRDA 1 files
			7/5/2022	Manual validation of QRDA 1 file contents Electronic validation of QRDA 1 files
			10/3/2022	Manual validation of QRDA 1 file contents Electronic validation of QRDA 1 files

§ 170.315(b)(2) Clinical information reconciliation and incorporation

Measure Description:
Reconcile and incorporate specific information from C-CDAs formatted to both C-CDA Releases 1.1 and 2.1.
- Demographics for patient matching
- Problems
- Medication
- Allergies

Justification:
We chose to concentrate on the aspects of this criterion that would closely follow the actual activities of BOLT users with respect to C-CDA reconciliation and incorporation. With a significant portion of the criteria being UI based, we felt the best testing approach would be to monitor and report on actual uses of the feature in the production environment to ensure all criteria elements are addressed.

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))

Metric Description:
1) 100 percent patient matched with correct C-CDA document
- Minimum of 10% C-CDA Release 1.1 format
- Minimum of 10% C-CDA Release 2.1 format

2) 80 percent had at least 1 reconciled data item
- Minimum of 1 Problem
- Minimum of 1 Medication
- Minimum of 1 Allergy

3) 100 percent post reconciliation C-CDA document passes validation with appropriate tool

Standards Implemented:
HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012.
HL7 Implementation Guide for CDA Release 2 Consolidation CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1 C-CDA 2.1 with Errata, August 2015, May 2018 (with Errata)

Developer Info:
MedOne Systems, LLC
401 Matthew Street
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Care Setting:
BOLT is used in both ambulatory and inpatient environments, thus this test plan accounts for both care settings.

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Methods Used to Demonstrate Interoperability:
- Shadow production clinical user to observe usage and compliance
- Document results of observations
- Validate pre and post C-CDA document with validation tool

Test Step:	Testing Procedure:	Expected Outcomes:	Key Milestones/Dates:	Outcomes:	Comment(s)
	*** Inpatient Setting**				
1i	Work with client to identify a clinical user to shadow	Client will best know which clinical user would be the best candidate for shadowing, including factors such as patient volume, level of experience, willingness to assist with testing, and a clinical setting that routinely benefits from C-CDA reconciliation.	Start test plan execution: July, 2022		
2i	Shadow user once a quarter for two consecutive quarters	Identify date(s) to shadow the clinical user			
3i	Identify 5 patients that would provide good reconciliation results	List of patients to perform reconciliation on			
4i	Observe and complete C-CDA Reconciliation Event Form during the C-CDA document reconciliation process • Demographics for patient matching • Problems • Medication • Allergies	Complete C-CDA Reconciliation Event Form for each event, documenting the results			
5i	Generate post-reconciliation C-CDA 2.1 document for each patient and validate, along with the C-CDA document used during the reconciliation event	Demonstrate that the data files generated by the Health IT module are formatted in accordance with the standard version of the C-CDA during the reconciliation event	December, 2022		
	*** Ambulatory Setting**				
1a	Work with client to identify a clinical user to shadow	Client will best know which clinical user would be the best candidate for shadowing, including factors such as patient volume, level of experience, willingness to assist with testing, and a clinical setting that routinely benefits from C-CDA reconciliation.	Start test plan execution: July, 2022		
2a	Shadow user once a quarter for two consecutive quarters	Identify date(s) to shadow the clinical user			
3a	Identify 5 patients that would provide good reconciliation results	List of patients to perform reconciliation on			

4a	Observe and complete C-CDA Reconciliation Event Form during the C-CDA document reconciliation process • Demographics for patient matching • Problems • Medication • Allergies	Complete C-CDA Reconciliation Event Form for each event, documenting the results	
5a	Generate post-reconciliation C-CDA 2.1 document for each patient and validate, along with the C-CDA document used during the reconciliation event	Demonstrate that the data files generated by the Health IT module are formatted in accordance with the standard version of the C-CDA during the reconciliation event	December, 2022

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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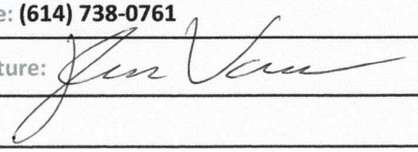
Authorized Representative Signature: 	
Date: **11/30/2021**	

§ 170.315(c)(1) - Clinical quality measures (CQMs) — record and export

	Measure Description: • Capture and record electronic clinical quality measure (eCQM) data in EHR for calculating eCQMs. • Electronically create a data file for transmission of CQM data.	**Justification:** With criteria (c)(1) dealing specifically with recording and exporting clinical data in a specific format, we chose to focus our testing to ensure BOLT is performing this aspect CQM reporting. We have partnered with Dynamic Health IT and their fully certified CQMsolution product to complete the remaining CQM criteria, so we will focus our plan on the only aspect in which BOLT plays a role. Ensuring BOLT reports patient and clinical data over time for multiple patients that is consistent with the required standards ensures the remaining CQM criteria will succeed.			
	Metric Description: 1) 100 percent matching data elements in QRDA I vs EHR. This will be confirmed by visual validation of the following data: • Demographics • Problems • Medications • Allergies 2) 0 percent of files uploaded to submission environment result in errors		**Standards Implemented:** • HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 1 - Introductory Material, June 2015 • HL7 CDA R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 2 - Templates and Supporting Material, June 2015		
	Developer Info: MedOne Systems, LLC 401 Matthew Street Marietta, OH 45750 740.242.7987 Care Setting: BOLT is used for eCQM submission in both ambulatory and inpatient environments, thus this test plan accounts for both care settings.	**Product Info:** Product Name: BOLT Product Version: 3.5 CHPL ID: 15.04.04.1901.BOLT.03.01.1.191220	**Methods Used to Demonstrate Interoperability:** • Visual inspection and matching of QRDA I data to EHR data • Validate QRDA 1 data file structure using appropriate tools		
Test Step:	**Testing Procedure:**	**Expected Outcomes:**	**Key Milestones/Dates:**	**Outcome:**	**Comment(s)**
	*** Inpatient Setting**				
1i	Identify four (4) EH (Eligible Hospital) eCQMs for RWT.	Based on historical data, select the most popular eCQMs	Start test plan execution: January, 2022		
2i	Generate QRDA 1 files on the first business day of every quarter and randomly select five (5) files for validation.	Selection of documents to be used during testing phase			
3i	Compare the contents of each QRDA 1 file with the information in BOLT and confirm all data elements match.	Manual validation between the information stored in the EHR to that of the content of the generated QRDA documents			
4i	Validate each QRDA 1 file with the appropriate tool	Demonstrate that the data files generated by the Health IT module are formatted in accordance with the standard version of the CMS QRDA Category I for inpatient measures for the period being reported			
	*** Ambulatory Setting**				

1a	Identify four (4) EP (Eligible Professional) eCQMs for RWT.	Based on historical data, select the most popular eCQMs	Start test plan execution: January, 2022
2a	Generate QRDA 1 files on the first business day of every quarter and randomly select five (5) files for validation.	Selection of documents to be used during testing phase	
3a	Compare the contents of each QRDA 1 file with the information in BOLT and confirm all data elements match.	Manual validation between the information stored in the EHR to that of the content of the generated QRDA documents	
4a	Validate each QRDA 1 file with the appropriate tool	Demonstrate that the data files generated by the Health IT module are formatted in accordance with the standard version of the CMS QRDA Category I for outpatient measures for the period being reported	
5	Compile the results of each validation pass from both the Inpatient and Ambulatory settings.	Completion of the RWT results	October, 2022

Attestation:

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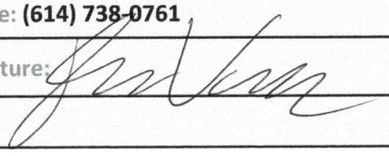
Authorized Representative Signature: 
Date: **11/30/2021**