GENERAL INFORMATION

Plan Report ID Number: 20231212bra

Developer Name: Braintree Health

Product Name: BRAINTREE

Version Number(s) (NEW): 10.5.1.1

Certified Health IT Product List (CHPL) Product Number(s) (CURRENT): 15.02.05.1167.BRNT.01.01.1.211119

Developer Real World Testing Plan Page URL: https://www.braintreehealth.com/braintree-onc-certification-btree/

Developer Real World Testing Results Report Page URL: https://www.braintreehealth.com/braintree-onc-certification-btree/

STANDARD UPDATES

Standard and Version	USCDI v1
Updated Certification criteria and associated product	b1, b2, e1, f5, g9
Health IT Module CHPL ID	15.02.05.1167.BRNT.01.01.1.211119
Conformance Measure	Measure 7 for b1 Measure 8 for b2 Measure 3 for e1 Measure 17 for f5 Measure 20 for g9

SUMMARY OF TESTING METHODS AND KEY FINDINGS

Provide a summary of the Real-World Testing methods deployed to demonstrate real-world interoperability, including any challenges or lessons learned from the chosen approach. Summarize how the results that will be shared in this report demonstrate real-world interoperability.

If any non-conformities were discovered and reported to the ONC-ACB during testing, outline these incidences and how they were addressed.

Note: A single Real World Testing results report may address multiple products and certification criteria for multiple care settings.

The RWT plan included:

§ 170.315(b)(3) Electronic prescribing	• Create new prescriptions (NewRx). • Request and respond to change prescriptions (RxChangeRequest,RxChangeResponse). • Request and respond to cancel prescriptions (CancelRx, CancelRxResponse). • Request and respond to renew prescriptions (RxRenewalRequest,RxRenewalResponse). • Receive fill status notifications (RxFill). • Request and receive medication history (RxHistoryRequest,RxHistoryResponse). • Relay acceptance of a transaction back to the sender (Status). • Respond that there was a problem with the transaction (Error). • Respond that a transaction requesting a return receipt has been received(Veriy)

§§170.315(c)(3) Clinical quality measures (CQMs) — report	• Select certified measures and run the measures. • Export the Cat III XML file generated and validate with visual inspection
§170.315(e)(1) View, download and transmit to 3rd party	• Patients should be able to use internet base technology to view, downloadand transmit CCDA files. • Patient should be able to login into EMR. • Patient should be able to download the CCDA file. • Patient should be able to transmit CCDA file via secured email to providers. • **The system was able to transmit the CCDA file to other providers successfully.**
§170.315(g)(7) Application access — patient selection	• Access verification of token so that API can be tested. • Verification of patient data and ability to notify if sufficient information is provided to uniquely identify the patient data. • Once the patient data is verified return the patient information. • **The api test was successfully completed.**
§170.315(h)(1) Direct Project	• Send • Receive • Message Disposition Notification: Processed • Message Disposition Notification: Failed • Required Enhanced Testing, Send • Required Enhanced Testing, Receive • **The system was tested to send/receive secured emails with different patients and was able to send/ receive the secured emails with/without attachments.**

§170.315(f)(1) Transmission to immunization registries	• Export the immunization information as HL7 message • **The system was successfully able to export the hl7 message for immunization for selected patients.**
§ 170.315 (b)(1) Transitions of Care	• Send Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources • Send Using Edge Protocol for SMTP • Receive Using Edge Protocol for IHE XDR profile for Limited Metadata Document Sources • Receive Using Edge Protocol for SMTP • Receive Using Edge Protocol for IMAP • Receive Using Edge Protocol for POP3 • XDM Processing (Received via Edge Protocol) • **The system was successfully able to complete the above mentioned test cases.**
§ 170.315 (b)(2): Clinical Information Reconciliation and Incorporation	• Correct patient • Reconciliation ○ 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 ○ Enable a user to create a single reconciled list of each of the ○ following: Medications; Allergies and Intolerances; and problems. ○ Enable a user to review and validate the accuracy of a final set of data. ○ Upon a user's confirmation, automatically update the list, and incorporate the medications and allergies. • **The system was able to reconcile the patient medication, allergies and problems.**
170.315 (b)10): Electronic Health Information export	• Export for a single patient at any time the user chooses without developer assistance, and that the export file(s): • Is created in a timely fashion • Is electronic and in a computable format • Includes a publicly accessible hyperlink of the export's format • Grant a set of users the ability to perform the export; or • Grant system administrator(s) the ability to perform the export. • **The system was successfully able to export data successfully.**

170.315 (b)(7): Data Segmentation for Privacy – Send	• Ability to select the privacy segment tag from the EMR. • Ability to export the CCD document including the privacy segments. • **The system was successfully able to send the CCDA with privacy notice segment.**

170.315 (b)(8): Data Segmentation for Privacy – Receive	• Receive CCD document including privacy segment. • Display the received privacy segment for the user in the EMR. • **The system was successfully able to import the CCDA with privacy segment enabled.**
170.315 (b)(9): Care Plan	• Ability to export the ccd document including o Patient Name; o Goals o Health Concerns o Health Status Evaluations and Outcomes; and o Interventions • **The system was successfully able to export the CCDA document with above mentioned sections.**
§§170.315(c)(1)Clinical quality measures (CQMs) — - Record and Export	• Select certified measures and run the measures. • Export the Cat III and Cat 1 file generated and validate with visual inspection. • **The system was successfully able to export Cat III and CAT I files with the date range defined.**
170.315 (c)(2): Clinical Quality Measures - Import and Calculate	• Import the Cat I file format into the EMR. • Ability to run certified measures from the EMR with CAT I imported files. • **The system was successfully able to import the CAT 1 file**
170.315 (f)(2): Transmission to Public Health Agencies - Syndromic Surveillance	• Ability to export the HL7 message for syndromic surveillance data. Including o Emergency Department o Urgent Care o Inpatient and ambulatory care o Inpatient settings • **The system was successfully able to run the above mentioned test cases.**

170.315 (f)(3): Transmission to Public Health Agencies - Reportable Laboratory Tests and Values/Results	• Ability to export the HL7 lab results from the EMR. • **The system was successfully able to export the HL7 lab results.**
170.315 (f)(5): Transmission to Public Health Agencies - Electronic Case Reporting	• Ability to export the electronic case reporting through the EMR and export the XML document properly. • **The system was successfully able to export the Electronic case reporting.**

170.315 (f)(6): Transmission to Public Health Agencies - Antimicrobial Use and Resistance Reporting	• Ability to export antimicrobial report to authorized users. • **The system was successfully able to export the antimicrobial report.**
170.315 (f)(7): Transmission to Public Health Agencies - Health Care Surveys	• Ability for the authorized user to export the health care survey. • **The system was successfully able to export the health care survey**
170.315 (g)(9): Application Access – All Data Request	• The API must be able to respond to requests for patient data associated with a specific date as well as with a specific date range. • **The system was successfully able to send the data based on the specific date ranges.**
170.315 (g)(10): Standardized API for patient and population services	• The API must be able to respond to requests for patient data associated including all required validations for FHIR • **The system was able to successfully request the records based on FHIR standards.**

Care Setting(s)

The expectation is that a developer's Real-World Testing is conducted within each type of clinical setting in which their certified health IT is marketed. Health IT developers are not required to test their certified health IT in every setting in which it is marketed for use.

List each care setting that was tested.

Dialysis Access

Change of Plan: None.

Impact: None

Reason: None.

Metrics can be found under this link

Metrics: https://www.braintreehealth.com/wp-content/uploads/2023/12/Metrics.xlsx

Metrics and Outcomes

Health IT developers should detail outcomes from their testing that successfully demonstrate that the certified health IT:

1. is compliant with the certification criteria, including the required technical standards and vocabulary codes sets;
2. is exchanging electronic health information (EHI) in the care and practice settings for which it is marketed for use; and/or,
3. EHI is received by and used in certified health IT.

(from 85 FR 25766)

Health IT developers could also detail outcomes that did not result from their measurement approach if that better describes their efforts.

Within this section, health IT developers should also describe how the specific data collected from their Real-World Testing measures demonstrate their results. Where possible, context should be provided to the measures and results to understand the number of sites/users/transactions tested for the specified measures (i.e., the denominator for comparison to the reported results). If applicable, any Relied Upon Software that is used to meet a criterion's requirements should be included in this section.

Measurement /Metric	Associated Criterion(a)	Relied Upon Software(if applicable)	Outcomes	Challenges Encountered(if applicable)
Electronic prescribing	§170.315(b)(3)	DR First	Is compliant with the certification criteria, including the required technical standards and vocabulary codes sets;	None
View, download, and transmit to 3rd party	§170.315(e)(1)	EMR Direct, Net Time	Is exchanging electronic health information (EHI) in the care and practice settings for which it is marketed for use	None
Application access — patient selection	§170.315(g)(7)	None	is compliant with the certification criteria, including the required technical	None
			standards and vocabulary codes sets	

Direct Project	§170.315(h)(1)	EMR Direct	Is exchanging electronic health information (EHI) in the care and practice settings for which it is marketed for use	None
Transmission to immunization registries	§170.315(f)(1)	None	is compliant with the certification criteria	None
Transitions of Care	170.315 (b)(1)	EMR Direct	is exchanging electronic health information (EHI) in the care and practice settings for which it is marketed for use	None
Clinical Information Reconciliation and Incorporation	170.315 (b)(2)	None	EHI is received by and used in certified health IT.	None
Electronic Health Information export	170.315 (b)(10)	None	is compliant with the certification criteria, including the required technical standards and vocabulary codes sets;	None
Data Segmentation for Privacy – Send	170.315 (b)(7)	None	is compliant with the certification criteria, including the required technical standards and	
			vocabulary codes sets;	

Data Segmentation for Privacy – Receive	170.315 (b)(8)	None	EHI is received by and used in certified health IT.	None
Care Plan	170.315 (b)(9)	None	is compliant with the certification criteria, including the required technical standards and vocabulary codes sets;	None
Clinical Quality Measures - Record and Export	170.315 (c)(1)	None	is compliant with the certification criteria, including the required technical standards and vocabulary codes sets;	None
Clinical Quality Measures - Import and Calculate	170.315 (c)(2)	None	is compliant with the certification criteria	None
Clinical quality measures--report	170.315 (c)(3)	None	is compliant with the certification criteria	None
Transmission to Public Health Agencies - Syndromic Surveillance	170.315 (f)(2)	None	is compliant with the certification criteria	None
Transmission to Public Health Agencies - Reportable Laboratory Tests and Values/Results	170.315 (f)(3)	None	is compliant with the certification criteria	None
Transmission to Public Health Agencies - Electronic Case Reporting	170.315 (f)(5)	None	is compliant with the certification criteria	None

Transmission to Public Health Agencies - Antimicrobial Use and Resistance Reporting	170.315 (f)(6)	None	is compliant with the certification criteria	None
Transmission to Public Health Agencies - Health Care Surveys	170.315 (f)(7)	None	is compliant with the certification criteria	None
Application Access - All Data Request	170.315 (g)(9)	None	is compliant with the certification criteria	None
Standardized API for patient and population services	170.315 (g)(10)	None	is compliant with the certification criteria	None

KEY MILESTONES

Include a list of key milestones that were met during the Real-World Testing process. Include details onhow and

when the developer implemented measures and collected data. Key milestones should be relevant and directly related to the outcomes discussed.

For each key milestone, describe when Real World Testing began in specific care settings and the date/timeframe during which data was collected.

Key Milestone	Care Setting	Date/Timeframe
Electronic prescribing §170.315(b)(3) - The actual Reporting Metrics were the same as the Planned Reporting Metrics: - Total number of new electronic prescriptions successfully transmitted - Total number of changed electronic prescriptions successfully transmitted - Total number of canceled electronic prescriptions successfully transmitted - Total number of refill prescriptions successfully transmitted - Total number of medication history requests sent electronically - All test cases successfully passed in production environment.	**Dialysis Access**	04/01/2024 – 07/15/2024
Clinical quality measures (CQMs) — report §170.315(c)(3) The actual functional testing demonstrated the ability to generate QRDA 1 and QRDA 3 files which comply with the CMS QRDA Implementation Guide for submission to CMS in production environment.	**Dialysis Access**	04/01/2024 – 07/15/2024
View, download, and transmit to 3rd party §170.315(e)(1) **Demonstration of the following capabilities:** **-** Create and make a valid C-CDA available to the patient in the patient portal - Patient's ability to create a portal count and review their health information, including a C-CDA from their ambulatory visit in production environment.	**Dialysis Access**	04/01/2024 – 07/15/2024
Application access — patient selection §170.315(g)(7) - Evidence of the patients ability to request and retrieve a C-CDA via Braintree API was successfully demonstrated utilizing synthetic data and Postman. During the testing process it was noted for the applicable care settings that clients are not using this functionality.	**Dialysis Access**	04/01/2024 – 07/15/2024
Direct Project §170.315(h)(1) **-** Demonstration of creation of a C-CDA at the end of an ambulatory encounter with transmission to the next provider of care via Direct Messaging with a confirmation of receipt in a client environment that is a replica of production. - Spot check of evidence of successful C-CDA transmissions	**Dialysis Access**	04/01/2024 – 07/15/2024

in the client's environment from the CCDA Queue. - Demonstration of the ability to receive a C-CDA via Direct messaging into the import queue In production environment		

Transmission to immunization registries §170.315(f)(1) - Data Submission & Transmission - Data Elements & Content Validation - Error Handling & Acknowledgment	**Dialysis Access**	04/01/2024 – 07/15/2024
Transitions of Care 170.315 (b)(1) - Total number of successfully transmitted C-CDAs (CCD and Referral Note) via Direct messaging based on receipt of MDN ACK message status. - Total number failed C-CDA (CCD and Referral Note) transmissions based on receipt of MDN NACK message status. - Total number received C-CDAs via inbound Direct messaging.	**Dialysis Access**	04/01/2024 – 07/15/2024
Clinical Information Reconciliation and Incorporation 170.315 (b)(2) - Total number of problem list reconciliations - Total number of medication list reconciliations - Total number of medication allergy list reconciliations	**Dialysis Access**	04/01/2024 – 07/15/2024
Electronic Health Information export 170.315 (b)(10) - Ensure the system exports all required EHI as per ONC's definition. - Validate that structured (C-CDA, FHIR, HL7) and unstructured data (PDF, images) are included. - Confirm that historical and current patient data are exported without loss. - Test patient-specific EHI export (single patient record retrieval). - Validate bulk EHI export for multiple patients in a given date range. - Ensure on-demand and scheduled exports function properly. - Confirm export is available in human-readable and machine-readable formats.	**Dialysis Access**	04/01/2024 – 07/15/2024

Data Segmentation for Privacy – Send 170.315 (b)(7) - Verify that the system can identify and tag sensitive health information. - Validate compliance with HL7 C-CDA R2.1 for structured documents. - Confirm support for FHIR-based security labels when applicable. - Ensure adherence to DS4P Implementation Guides for privacy and consent enforcement. - Test export of segmented data via Direct Secure Messaging (Direct Protocol). - Validate the transmission of C-CDA documents with appropriate data segmentation. - Ensure proper handling of privacy metadata when sending to other systems	**Dialysis Access**	04/01/2024 – 07/15/2024
Data Segmentation for Privacy – Receive 170.315 (b)(8) - Verify that the system correctly receives and identifies segmented data. - Ensure that sensitive information is properly labeled using HL7 security tags. - Confirm support for different levels of segmentation - Validate compliance with HL7 C-CDA R2.1 and FHIR DS4P security labels. - Test adherence to DS4P Implementation Guides for privacy enforcement. - Verify that the system honors security labels and enforces access controls based on user roles and patient consent. - Ensure restricted data is not displayed to unauthorized users. - Test scenarios where a provider requests access to restricted data, requiring patient authorization	**Dialysis Access**	04/01/2024 – 07/15/2024

Care Plan 170.315 (b)(9)
 	
- Verify that the system creates, updates, and stores care plans using structured data.
- Ensure that care plans include all required elements:
  ○ Health concerns (problems, diagnoses)
  ○ Goals (short-term and long-term health goals)
  ○ Interventions (planned treatments, therapies, and follow-ups)
  ○ Care team members (providers, caregivers, specialists)
- Confirm support for patient-specific customization of care plans.
- Validate that care plans conform to HL7 C-CDA R2.1 Care Plan document structure.
- Ensure correct use of LOINC, SNOMED-CT, ICD-10, and CPT codes for structured data.
- Confirm support for FHIR-based care plan exchange where applicable.
- Test the ability to export and transmit care plans to external providers and HIEs.
- Verify that the system can receive and integrate care plans from other certified EHRs.
- Ensure that data remains intact and properly formatted during transmission and import**.**
	Dialysis Access	04/01/2024 – 07/15/2024

Clinical Quality Measures - Record and Export 170.315 (c)(1) - Verify compliance with QRDA Category I and Category III standards for CQM data export. - Test the ability to export CQM data for individual patients (QRDA I) and aggregate reports (QRDA III). - Ensure exported files are formatted correctly and readable by receiving systems.	**Dialysis Access**	04/01/2024 – 07/15/2024
Clinical Quality Measures - Import and Calculate 170.315 (c)(2) - Verify that the system can import CQM data from external sources - Ensure the system supports QRDA Category I (individual patient-level data) and QRDA Category III (aggregate data) formats. - Validate correct mapping of imported data to appropriate patient records and CQM fields. - Confirm that all required clinical elements (e.g., diagnoses, medications, procedures, labs) are	**Dialysis Access**	04/01/2024 – 07/15/2024

successfully ingested.		
Transmission to Public Health Agencies - Syndromic Surveillance 170.315 (f)(2) - Data Identification: Confirm the system captures emergency department (ED) and urgent care visit data for surveillance. - Standardized Reporting: Validate compliance with HL7 v2.5.1 ADT messages for syndromic surveillance. - Transmission & Acknowledgment: Ensure successful data submission	**Dialysis Access**	04/01/2024 – 07/15/2024
Transmission to Public Health Agencies - Reportable Laboratory Tests and Values/Results 170.315 (f)(3) - Data Capture: Verify recording of reportable lab results. - Standardized Messaging: Ensure data transmission in HL7 v2.5.1.	**Dialysis Access**	04/01/2024 – 07/15/2024
Transmission to Public Health Agencies - Electronic Case Reporting 170.315 (f)(5) - Data Extraction: Confirm automatic detection and reporting of reportable conditions based on diagnosis codes. - Interoperability: Ensure data is structured in HL7 eICR (Electronic Initial Case Report) format. - Transmission & Acknowledgment: Validate secure transmission and receipt of acknowledgment (ACK).	**Dialysis Access**	04/01/2024 – 07/15/2024
Transmission to Public Health Agencies - Antimicrobial Use and Resistance Reporting 170.315 (f)(6) - Data Collection: Verify the system captures antimicrobial use (AU) and resistance (AR) data from clinical and lab systems. - Standards Compliance: Ensure compliance with CDC's NHSN AUR reporting requirements and HL7 CDA format. - Transmission: Validate submission to NHSN via Direct Messaging or secure API.	**Dialysis Access**	04/01/2024 – 07/15/2024

Transmission to Public Health Agencies - Health Care Surveys 170.315 (f)(7) - Verify that the system can collect and package health care survey data required by public health agencies. - Ensure structured data elements (e.g., patient demographics, encounter details, provider data) are correctly captured. - Validate compliance with survey format requirements.	**Dialysis Access**	04/01/2024 – 07/15/2024
Application Access - All Data Request 170.315 (g)(9) - Evidence of the patients ability to request and retrieve a C-CDA via Braintree API was successfully demonstrated utilizing synthetic data and Postman. During the testing process it was noted for the applicable care settings that clients are not using this functionality**.**	**Dialysis Access**	04/01/2024 – 07/15/2024
Standardized API for patient and population services 170.315 (g)(10) Evidence of the patient's ability to make a data category request for one or more data elements in the USCDI v1 using the Braintree FHIR API was successfully demonstrated.	**Dialysis Access**	04/01/2024 – 07/15/2024