eHealth Exchange

Validation Plan

Version 9 (final)

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1   Purpose and Scope

The *eHealth Exchange Validation Plan* describes the scope, approach and Testing process for verifying that an Applicant or existing Participant in the eHealth Exchange community complies with the Performance and Service Specifications. In addition, this plan outlines the requirements for products to become eHealth Exchange Validated.

The eHealth Exchange Testing program supports the following:

- Applicants who wish to join the eHealth Exchange as Participants;

- Existing eHealth Exchange Participants who wish to test new capabilities or retest as a condition of continued participation in the eHealth Exchange; and

- Vendors who wish to have their product(s) validated as eHealth Exchange compliant.

The eHealth Exchange Testing Program verifies that a System both complies with the eHealth Exchange specifications and has the ability to interoperate with other eHealth Exchange Participant Systems.

1.1   Defined Terms

All capitalized terms in this document have the meaning put forth in the Data Use and Reciprocal Support Agreement (DURSA), unless outlined below.

- **Applicant** shall mean organizations who wish to participate in the eHealth Exchange

- **Breaking Changes** shall mean issues that are identified while Testing an applicant or participant. Issues uncovered real-time during the Testing process.

- **Consolidated CDA (C-CDA)** shall mean implementation guide contains a library of CDA templates, incorporating and harmonizing previous efforts from Health Level Seven (HL7), Integrating the Healthcare Enterprise (IHE), and Health Information Technology Standards Panel (HITSP). It represents harmonization of the HL7 Health Story guides, HITSP C32, related components of IHE Patient Care Coordination (IHE PCC), and Continuity of Care (CCD). It should be used for implementing the following CDA documents and header constraints for clinical notes: Care Plan including Home Health Plan of Care (HHPoC), Consultation Note, Continuity of Care Document (CCD), Diagnostic Imaging Reports (DIR), Discharge Summary, History and Physical (H&P), Operative Note, Procedure Note, Progress Note, Referral Note, Transfer Summary, Unstructured Document, Patient Generated Document (US Realm Header).
- **eHealth Exchange Content Testing Program** shall mean the program of Testing as described in section 1.3 herein, as defined in the DURSA.

- **eHealth Exchange Participant Testing Program** shall mean the program of Testing as described in section 1.3 herein, as defined in the DURSA.

- **eHealth Exchange Product Testing Program** shall mean the overall testing programs required for eHealth Exchange participation which include the following: Participant Testing Program, Product Testing Program, and Content Testing Programs, and is further described in section 1.3 herein.

- **eHealth Exchange Validated** shall mean the designation given to a system technology once it has successfully completed eHealth Exchange Product Testing requirements and has been deemed compliant with the Specifications.

- **Modified System** shall mean changes made to a System that impact compliance with the Performance and Service Specifications.

- **Product Vendor ("Vendor")** shall mean system developers for a system technology.

- **Production Ready** shall mean that development and Testing of the System is complete, and that the System is deployed on a tier that replicates, as closely as possible, the production environment.

- **Qualified Technology Solution (QTS)** shall mean a System implemented by an eHealth Exchange Applicant or Participant, which satisfies the following:

- **Qualified Technology Solution Basic (QTS Basic)** shall mean a System implemented by an eHealth Exchange Applicant or Participant, which satisfies the following:

  o Is an eHealth Exchange Validated System;

  o Has a standardized production-level configuration that complies with the eHealth Exchange Performance and Service Specifications;

  o Has a customer that is exchanging with one or more federal agencies and is recognized as a Federal Fast Track (or equivalent) program partner

  o Has a minimum of four (4) production Participants in the eHealth Exchange network who have successfully completed testing without any failures, and actively exchanging data with other production Participants using a different technology; thus demonstrating a history of reproducible compliance with the Performance and Service Specifications. Those production Participants may not have any outstanding technical issues that impede their ability to exchange information with other eHealth Exchange Participants.

- **Qualified Technology Solution Intermediate (QTS Intermediate)** shall mean a System implemented by an eHealth Exchange Applicant or Participant, which satisfies the following:

  o Has satisfied all requirements for QTS Basic

  o Has successfully submitted test reports under QTS Basic for a **minimum of 6 months** with no issues.

  o Those production Participants may not have any outstanding technical issues that impede their ability to exchange information with other eHealth Exchange Participants as referenced in both the Operating Policies and Procedures and Validation Plan.

  o eHealth Exchange staff, in consultation with the vendor, eHealth Exchange Coordinating Committee and a vendor's customer production partners, will evaluate the QTS vendor to determine if the vendor has demonstrated high degree of consistency and reproducibility with production partners in a significant percentage of the vendor's customer base.

- **Qualified Technology Solution Advanced (QTS Advanced)** shall mean a System implemented by an eHealth Exchange Applicant or Participant, which satisfies the following:
    - Has satisfied all requirements for QTS Basic and Intermediate
    - **ALL** Production Participants utilizing the approved QTS-Intermediate solution have successfully demonstrated Content Testing Validation, with no errors.
    - Those production Participants may not have any outstanding technical issues that impede their ability to exchange information with other eHealth Exchange Participants as referenced in both the Operating Policies and Procedures and Validation Plan.

- **Specification Version** means a set of Testing Program items (Specifications and Test Materials) that are associated with the eHealth Exchange Testing Program, as described in the eHealth Exchange Validation Plan. For example, as of November 2013, the two Specification Versions are the 2010 Version eHealth Exchange Specifications and the 2011 Version eHealth Exchange Specifications.

- **System** shall mean software, portal, platform, or other electronic medium controlled by an applicant through which it conducts its health information exchange (HIE) related activities as part of the eHealth Exchange. This is also the technology submitted by the Applicant to the Coordinating Committee for the purpose of completing the eHealth Exchange Participant and Product Testing programs and demonstrating compliance with the Specifications. For purposes of this definition, it shall not matter whether the applicant controls the software, portal, platform, or medium through ownership, lease, license, or otherwise.

- **System Under Test** ('System') shall mean the underlying System(s) (e.g. an HIE or Electronic Health Record (EHR)) System and/or gateway, to undergo Testing and be used in production by a Participant. This shall include the System components that are relevant to testing, including those components used to create or modify Messages in accordance with the Performance and Service Specifications, as well as the source that generates the clinical content that is exchanged.

- **Test Materials** shall mean the set of Testing requirements that must be successfully demonstrated and validated to comply with the Specifications. This may include, but is not limited to test cases, test scenarios, service sets, conformance checklists, etc.

- **Test Report** shall mean a written report developed by the eHealth Exchange Testing Program that documents the outcomes of the testing process.

- **Testing** shall mean validation of an Applicant, Participant, or Vendor's System used for interoperable health information exchange, to assess conformity with the approved Specifications, Validation Plan and Test Materials.

- **Validation Plan** shall mean the framework for Testing and demonstrations for parties seeking to become eHealth Exchange Participants and for Systems to become eHealth Exchange Validated. The Validation Plan is Attachment 2 in the DURSA, and is amended from time to time in accordance with DURSA Sections 10.02 and 10.03. The Validation Plan is also referenced in the

eHealth Exchange Product Testing Agreement that Vendors sign when seeking to have a System tested and deemed to be eHealth Exchange Validated.

- **Vendor** shall mean a developer of a health IT system which is intended to be used by Applicants or Participants in the eHealth Exchange.

1.2   Scope

The scope of the eHealth Exchange Testing Program is limited to validation of a System's conformance with the Specifications, the Validation Plan and related Test Materials adopted by the Coordinating Committee (collectively called "Performance and Service Specifications").

Testing requirements may vary depending upon Specification version(s), as well as the profiles (i.e. use cases) that an Applicant or Participant wishes to support. For details, see Attachment #1.

Changes to the profiles, Specifications, Validation Plan and Test Materials may be made in accordance with the applicable change processes described in the DURSA.

1.3   Approach

The eHealth Exchange Testing Program is designed to verify that Systems used to share data via the eHealth Exchange comply with the eHealth Exchange Specifications and Test Materials. Systems brought forward for Testing must be Production Ready. The eHealth Exchange currently offers three Testing Programs:

- **eHealth Exchange Participant Testing Program:** This process verifies that Systems used by Applicants and Participants comply with the Specifications and satisfy the requirements established by the DURSA.

- **eHealth Exchange Validated Product:** This process verifies that the Systems developed by Vendors that may be used by Applicants and Participants, comply with the Specifications prior to being implemented in the Applicant's and / or Participant's production environment. The objective is to establish built-in conformance and interoperability into these Systems to minimize variability in System compliance in production.
- **eHealth Exchange Content Testing Program:** documentation, testing methodology, and test data that will be required for interoperability testing to enable the exchange of clinical content between eHealth Exchange Participants.

2 eHealth Exchange Testing Process

2.1 Overview

The eHealth Exchange Testing Program is intended to be a largely automated process augmented by minimal manual review to verify conformance of Systems used in the eHealth Exchange. One of the resources available is an automated Testing environment. The Testing environment facilitates gateway-to-gateway Testing.   The Testing platform automates the tests and enables Applicants, Participants, and Vendors to conduct practice Testing on a self-service basis, with real-time feedback regarding issues of non-compliance.

In addition, there are other mechanisms used to validate that Systems comply with the Specifications for clinical content and other security related requirements.   The following sections describe how the Testing process works, including the steps that Applicants, Participants, and Vendors must follow to complete Testing.

2.2 eHealth Exchange Participant Testing Process

Applicants and Participants who are testing would be eligible to complete the Participant Testing process.   To join the eHealth Exchange, Applicants must follow the process detailed on the eHealth Exchange website and in the Operating Policies and Procedures.   New Applicants must submit a complete Application Package, be approved as Eligible, and pay testing fees, as required, prior to receiving formal test results. The criteria for being accepted as a Participant in the eHealth Exchange are described in Operating Policy and Procedure (OPP) #1: Review and Disposition of Applications for Participation.

Applicants and Participants who are testing, are then expected to work with their Vendor to complete a Testing Readiness Checklist, which outlines the required steps to begin Testing. Testing is self-service and there is no specified timeframe to complete testing. Once testing is completed, the eHealth Exchange testing staff will verify all manual testing requirements to determine the final test results and generate a final test report that will be submitted to the Coordinating Committee. The Coordinating Committee will determine whether the Applicant has satisfied the general and technical requirements for participation in the eHealth Exchange, in accordance with Operating Policy and Procedure #1 and the Applicant will be notified regarding the Coordinating Committee's decision.

2.2.1 Connecting with Federal Partners

Applicants / Participants who complete the Participant Testing process and wish to share data with the Department of Defense (DoD), Social Security Administration (SSA), and Veterans Health Administration (VHA), may be expected to do additional partner testing and / or setup, prior to exchanging data with the federal Participant.

2.2.2 Post-Production Monitoring Period

- eHealth Exchange Participants are subject to a 120-day post-production monitoring period. This is a probationary period during which an eHealth Exchange Participant's compliance with Performance and Service Specifications is assessed.

- o Issues of non-compliance should be reported to administrator@ehealthexchange.com.

- eHealth Exchange staff will triage reported issues to be analyzed and notify the Participant if remediation is required to assure compliance with the Performance and Service Specifications.

- The Coordinating Committee may take action if non-compliance issues are not resolved in a timely manner.

2.3 eHealth Exchange Product Testing Process

The eHealth Exchange Product Testing Program is designed for Vendors who wish to test and verify that their System is eHealth Exchange Validates.to verify that Systems used by Participants in the eHealth Exchange comply with the Specifications. Vendors will take their Systems through a more robust and rigorous set of conformance tests than what is required for the Participant Testing Program. Successful completion of the Product Testing Program should provide Participants with greater assurance that the System complies with the eHealth Exchange Specifications and Tests and has built-in security controls when implemented and used in production. In addition to mitigating risks to production, using eHealth Exchange Validated Systems will off-set the tests that Participants must complete to participate in the eHealth Exchange.

Vendors must submit an application, which denotes the specific version of their System that they wish to have validated, execute a Testing Agreement, and pay testing fees prior to receiving formal testing results. Testing is self-service and there is no specified timeframe to complete testing. Once testing is completed, the eHealth Exchange testing staff will complete any manual testing required to verify all test results and generate a final test report. Systems which successfully complete the program and pass all testing will be designated an eHealth Exchange Validated System, for the specific version of the System which was validated. Vendors will then have the opportunity to use the eHealth Exchange Validated seal as permitted by the usage guidelines and in accordance with the eHealth Exchange Product Testing Agreement.

2.4 eHealth Exchange Content Testing Process

The eHealth Exchange Content Testing Program is designed for Applicants that are in the process of completing Participant Testing, current eHealth Exchange Participants, and / or Vendors in the process of completing Product Testing or vendors with eHealth Exchange Validated Products. As of July 1, 2013, Applicants, Participants retesting, or Vendors using technology that has been certified for Meaningful Use, were not previously required to complete content testing; however, the Coordinating Committee approved moving forward with an Enhanced Content Testing Program to be launched in 2017, that will utilize more robust test cases. Once the Enhanced Content Testing Program is officially launched, content testing will be required for all eHealth Exchange Participants and / or Vendors.

More specifically, Content Testing will be required for each data source, for example in the case of a Federated HIE model, the HIE must submit a content sample from each data source that will create a C-CDA document to transact through their Gateway.

Participants will be required to run sample C-CDA submission document(s) with appropriate test data against the corresponding eHealth Exchange designated validator and make improvements as appropriate prior to submission to eHealth Exchange staff. eHealth Exchange testing staff will then complete a review, verify test results, and generate a final test report.

All new Participants wishing to onboard to the eHealth Exchange and all current or new Product Validated Vendors will be required to complete the Enhanced Content Testing Program. The timeframes for existing Participants to complete testing as of the date of the Enhanced Content Testing Program launch are as follows:

- All existing Participants as of the date of the Enhanced Content Testing Program launch (February 5, 2018) will be required to submit initial content testing results by May 6, 2019.

- It is expected that multiple organizations will have one or more documents fail the initial testing. Therefore, all existing Participants, as of the date of the Enhanced Content Program launch, will be required to correct errors within 18 months (preferred) from the date of initial test submissions, as identified by the testing report received, or by May 1, 2021 (required) at the latest. Retesting within this time frame is required to establish that conformance issues have been resolved.

- Participants who do not submit completed validation results by October 1, 2019 will have their digital certificates suspended until they submit completed validation results.

- Participants who do not pass content testing but remediate all errors and conformance issues must retest within 18 months from date test results are submitted (preferred), or by May 1, 2021 (required) at the latest to confirm they remediated identified errors and conformance issues.

- Participants who do not remediate conformance issues within 18 months of their initial test results submission must submit a remediation plan and/or a conformance waiver request within two months of the 18-month deadline (preferred), or by March 1, 2021 (required) at the latest for Coordinating Committee approval. The Coordinating Committee can either accept the proposal or request changes.

3 eHealth Exchange Testing Policies

3.1 System Under Test

Applicants, Participants, and / or Vendors shall:

- Bring forth a Production-Ready System noting the specific System version, that will be tested.

- Identify and include the System components that are relevant to testing, including those components used to create or modify eHealth Exchange Messages in accordance with the Performance and Service Specifications in effect for the eHealth Exchange.

- Identify when to bring forward its System for retesting when System changes are made that impact its compliance with the Performance and Service Specifications. The ability to exchange Messages can be affected, or adversely impacted, by modifications to components involved in creating or modifying Exchange Messages. Therefore, Applicants, Participants, and / or Vendors should retest to confirm that System modifications have not introduced non-compliant behaviors. To request guidance, retesting or revalidation, the Applicant, Participant, and / or Vendor should contact the eHealth Exchange testing staff at testing@sequoiaproject.org.

3.2 Peer to Peer Testing for Applicants or Participants Who Support 2010 Specifications

Applicants or Participants who have successfully completed testing for the 2011 eHealth Exchange specifications and wish to validate compliance with the 2010 eHealth Exchange specifications for the same version of their System, are eligible to test via peer to peer testing.   This simplifies the validation process and reduces the testing cost and burden. To be eligible for this testing methodology, the Applicant or Participant who is retesting must first successfully complete testing for the 2011 version of the eHealth Exchange Specifications. The peer to peer Testing process requires an Applicant or Participant to capture and send sample messages directly to the eHealth Exchange testing staff via e-mail at testing@sequoiaproject.org. The eHealth Exchange testing staff run internal tools to validate the messages and conduct a delta analysis against the 2011 test results. Once testing is completed, the eHealth Exchange testing staff will verify all test results and generate a final test report that will be submitted to the Coordinating Committee for approval.

3.3 Qualified Technology Solutions (QTS)

Applicants or Participants who use a QTS are still required to maintain compliance with the Performance and Service Specifications; however, the validation requirements vary according to the level of maturity of the product as follows:

3.3.1 QTS Basic (Transport and Content Testing Required)

Applicants or Participants who use a product that meets the QTS Basic requirements as defined in Section 1.1, may validate their ability to comply and interoperate with the Performance and Service Specifications via peer to peer testing in either the eHealth Exchange validation or production environments in lieu of the Testing Process described in Section 2.2. Peer to peer testing is coordinated by the eHealth Exchange testing staff and is subject to the following additional conditions:

- Only Applicants or Participants who use a QTS may utilize the QTS Process.

- Peer to peer testing must adequately demonstrate the use cases which will be supported by the Applicant or Participant who uses a QTS in production.

- Peer to peer testing must be supported by a documented test plan (e.g. obtaining all messages as both an initiator and responder for each trading partner), to support the testing process that adequately demonstrates the use case(s) supported by Participants in production.

- Any Applicant or Participant who comes forward for testing must use the "Approved Configuration" of a QTS.

- Applicants or Participants must agree to post-production monitoring for 180 days, where such Applicant or Participant promptly addresses issues of non-compliance with the Performance and Service Specifications as determined by the Coordinating Committee.

- QTS peer to peer Testing process requires an Applicant or Participant to send sample messages directly to the eHealth Exchange testing staff via e-mail at testing@sequoiaproject.org.

- Once Testing is completed, the eHealth Exchange testing staff will verify all test results and generate a final test report.
- Test results will be provided to the Coordinating Committee for approval, in accordance with Operating Policies and Procedures.

Applicants or Participants who use a QTS Basic product must complete Content Testing as detailed in Section 2.4.

3.3.2   QTS Intermediate (Content Testing Required, Transport Testing Waived)

Applicants or Participants who use a product that successfully meets the QTS Intermediate criteria as defined in Section 1.1, must complete Content Testing as detailed in Section 2.4. Transport Testing is waived.

3.3.3   QTS Advanced (Transport and Content Testing Waived)

Applicants or Participants who use a product that meets the QTS Advanced requirements as defined in Section 1.1. Transport and Content Testing are waived.

3.4   Retesting Due to System Changes

eHealth Exchange Participants are required, as a condition of continued participation in the eHealth Exchange, to comply with the DURSA and assure that its Systems comply with the Specifications.

Similarly, eHealth Exchange Validated products must also remain compliant with the Specifications to retain eHealth Exchange Validated status as noted in the Product Testing Agreement.

It is acknowledged that Participant Systems and eHealth Exchange Validated Systems may be changed over time to assure appropriate maintenance and functionality of the System. Retesting for every change would be burdensome and costly to Participants and to Vendors, particularly when changes do not impact the HIE functionality related to the eHealth Exchange. That said, ongoing compliance with the Specifications is necessary to have reasonable assurances that Participant Systems can interoperate in production. In lieu of having Participants and Vendors retest with each release of a System, the following policy shall apply:

3.4.1   Ongoing Monitoring for Compliance

The Sequoia Project shall have the right to monitor, audit and inspect Vendor Systems which have been validated for the eHealth Exchange to verify that the System remains in compliance with the Specifications in accordance with Testing Agreements . Such monitoring, auditing and inspections may be undertaken by The Sequoia Project at any time including, but not limited to, in response to a complaint submitted to The Sequoia Project alleging that the Participant or eHealth Exchange Validated System are non-compliant with the Specifications. Any such audits or inspections of the System, facilities, data and records shall be conducted during business hours and performed so as to not unreasonably disrupt the Participant's or Vendor's business operations. The Sequoia Project shall provide reasonable advance notice to the Participant or Vendor prior to any such inspection or audit, unless such advance notice, in The Sequoia Project's opinion, would prejudice The Sequoia Project's ability to ascertain the information desired from the inspection or audit.

The Participant or Vendor shall cooperate with and provide such assistance as The Sequoia Project shall reasonably require in connection with any such inspections and audits, including making personnel available to The Sequoia Project for interviews. Based on its monitoring, auditing or inspection findings, The Sequoia Project may require the Participant or Vendor to submit the System for additional Testing.

3.4.2   Retesting Upon a Finding of Non-Compliance

If, after reasonable monitoring, auditing or inspection, eHealth Exchange staff determine that the System is likely to be non-compliant with the Specifications, the Participant or Vendor shall retest. Retesting must begin within thirty (30) days of being provided with notice of non-compliance, as well as payment of applicable Testing fees.

3.4.3   Validation Period

Once a System has successfully completed Testing by eHealth Exchange staff, the validation of that System shall be in effect for a period of up to three (3) years from either of the following approval dates ("Approval Dates"):

- For eHealth Exchange Participants: The date that the Coordinating Committee approves the Applicant as an eHealth Exchange Participant.
- For Vendors of eHealth Exchange Validated Products: The date that the Vendor is provided official notice that the System has been approved as an eHealth Exchange Validated System.

3.4.4   Retesting after Validation Period

In order to remain an eHealth Exchange Participant or to retain eHealth Exchange Validated status, a System must be retested prior to the end of the Validation Period. Please note that retesting fees may apply. If Participant or Vendor's System fails to successfully complete or pass retesting prior to the end of the Validation Period, the following may occur:

- For eHealth Exchange Participants: The Coordinating Committee may terminate participation in the eHealth Exchange or suspend participation until Participant remediates the non-compliance and successfully completes and passes retesting.

- For Vendors of eHealth Exchange Validated Products: The eHealth Exchange Validated status may be revoked for a non-compliant System; or require that the Vendor implement a remediation plan acceptable to eHealth Exchange staff and successfully complete and pass retesting in a timeframe to be determined by eHealth Exchange staff.

3.5   Retesting When Specifications and Test Materials Change or are Added

Ongoing compliance with the Specifications is required as a condition of continued participation in the eHealth Exchange and for Systems to retain eHealth Exchange Validated status.

In the event, there are changes in the eHealth Exchange Specifications, the Coordinating Committee shall, with Participant and Vendor input, assess the impact of the changes to eHealth Exchange Participants and establish a rationale should retesting be warranted. In the future, the Coordinating Committee may require more rigorous testing such as continuous testing as a condition of exchange. In addition, new Specifications may be adopted that require new testing requirements to be required for all Participants.

3.6   Breaking Changes

Background: Testing often uncovers Breaking Changes that are identified while an Applicant, Participant, or Vendor is undergoing testing. Issues uncovered real-time during the Testing process should be handled as described below:

- Testing for the eHealth Exchange should be objective and repeatable, with consistent results based upon conformance with the Specifications, Validation Plan and test cases in effect at the time the System is tested. The Testing process should not be subjective or discretionary to avoid introducing inconsistencies and potential for bias in the outcomes.

- If errors are discovered due to ambiguity / errors in the Specifications, then the issue should be addressed through the Specification change management process. Systems must conform to the Specifications in effect at the time they test until Specifications are corrected through the change management process.

- If there is an error in the Test Materials or test tools, but the System conforms to the Specifications:

    o The System should be found conformant. An error in the test tools or Test Materials should not prevent a System from proceeding through the Testing process or going into production if the System otherwise complies with the Specifications.

    o The Testing Process is not intended to de-bug issues in Systems. Systems brought forward for Testing are expected to be Production-Ready.

Examples of Breaking Changes:

- Changes in which tests are required for a given candidate (e.g. based upon functions supported)
- Make a critical fix to the Validation Plan or Test Materials used during Testing.
- Changes in content to the Testing Materials or test tools, such as:

    o Add coverage within a given feature (e.g. more Testing of negative paths)

- o Changes to Testing methods that also include substantive changes (e.g. Automate a previously manual test)

- o Update a test case

- o Add Testing for a new feature (e.g. asynch, or Query for Docs (FindAssociations))

- o Add Testing for a new spec (e.g. new clinical content spec)

- o Add Testing for a new version of a spec

- o Sunset Testing for an old version of a spec

- The following types of changes to Test Materials should NOT be subject to the change management process in the DURSA.

  - o Changes to test data

  - o Fixes to testing tools or the test lab that do not otherwise change the test requirements and expected outcomes.

  - o Editorial changes (e.g. to Test Materials should not be subject to the change management process.)

4 eHealth Exchange Use Cases

The eHealth Exchange has adopted a use case-based approach, which enables Participants to determine which use cases and related Specifications / content requirements they wish to support in production. eHealth Exchange use cases define how a community of eHealth Exchange Participants wishes to exchange data using transport, service and content specifications to support their business needs. The Coordinating Committee may only enforce compliance with particular technical Specifications if those Specifications are adopted through the eHealth Exchange formal change management process as detailed in OPP #4 – Change Process – Performance and Service Specifications. As a result, if Participants wish to have Coordinating Committee oversight of compliance with the technical requirements, then a new use case/ Specification must be submitted for approval. The new use case / Specification process is described below.

This approach enables the eHealth Exchange to support a myriad of use cases, based upon a common set of standards and Specifications.

4.1 Use Case Definition

- Use cases shall identify and describe business purpose and Specifications required as well as specify how to constrain or implement those specifications.

- Use cases may also specify the following:
    - Whether optional Specifications are used, including version(s) supported;
    - Data content requirements, including the version(s) of content supported; and
    - Other requirements, agreed upon by the community for that profile.

- Use cases may be updated to reflect new versions of Specifications adopted for the eHealth Exchange.

4.2 New Use Case / Specification Request Process

eHealth Exchange Participants and other stakeholders are encouraged to contribute to future innovations of the eHealth Exchange network. While the network has leveraged a specific set of technical specifications, new use cases can propose the adoption of other Specifications, Content Requirements, and transport protocols. The following describes the process for submitting requests for new use cases or Specifications:

- Participants or other stakeholders should submit requests for new use cases or Specifications to administrator@ehealthexchange.com, including:

    - Requestor name(s) and organization(s)

    - Use Case / Specification Title

    - Brief description of the use case, identifying the applicable specifications

    - Testing Approach: Identify suggested testing approach, if any (e.g. no eHealth Exchange Network testing, partner testing only, reference other authoritative testing process, etc.)

- The CC will consider requests for new use cases at any time throughout the year.

4.3   Transport and Service Specifications

The below transport and service Specifications are not intended to be linked to any particular use case, but are available for implementation across a myriad of use cases.

The below Specifications have been approved by the eHealth Exchange Coordinating Committee:

- Web Services Registry Web Service Interface Specification v 3.1
- Messaging Platform v3.0
- Patient Discovery v2.0
- Query for Documents v3.0
- Retrieve Documents v3.0
- Authorization Framework v3.0
- Web Services Registry v3.0
- Publish / Subscribe
- CAQH CORE X12 Document Submission Service Interface Specification v1.0
- Electronic Submission of Medical Documentation (esMD) X12 Profile v1.0
- Electronic Submission of Medical Documentation (esMD) XDR Production Specification Profile v1.0Documment Submission v2.0
- Administrative Distribution v2.0
- Direct Secure Messaging – Direct Project Applicability Statement for Secure Transport v1.2
- Fast Healthcare Interoperability Resources (HL7® FHIR®) Standard for Trial Use (STU3)
- End Stage Renal Disease Implementation Guide Package [June 30, 2016]

The Direct and FHIR® protocols may be implemented for a variety of use cases which fall within the defined set of Permitted Purposes.

The below standards have been approved by the eHealth Exchange Coordinating Committee in support of specific use cases:

- Encounter Alerts
    - o   VPN (transport)-DRAFT
    - o   Direct Secure Transport v 2.1
- PDMP (Treatment sub-use case)
    - o   Standards: NCPDP, PMIX, SCRIPT, and HL7®.
- Electronic Lab Reporting (in support of public health)
    - o   Standard: HL7® Version 2.5.1 [ELR Implementation Guide]
- Syndromic Surveillance (in support of public health)
    - o   Standard: HL7® Version 2.5.1 [Public Health Information Network (PHIN) Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings
- Image Sharing
    - o   Cross-Enterprise Document Sharing for Imaging (XDS-I) –standard for HIE network
        - ▪   Document Source and Document Consumer
        - ▪   Registry and Repository
    - o   Cross-Community Access for Imaging (XCA-I) – standard to connect HIE networks

4.3.1 Version Update Frequency

Version updates may occur every couple of years, with a period for dual use and a final cutoff date, comparable to the approach used for HIPAA Transaction and Code Set standards. Participants who exchange for multiple use cases may need to support different versions for the same specification during the period of dual use

4.4 eHealth Exchange Approved Use Cases and Corresponding Standards

Use Case	Workflow	Standards / Specifications

Query / Retrieve Documents
• Supports multiple use cases including:
  o Treatment / care coordination
  o Transitions of care
  o Referrals
  o Social Security disability benefits determination
  o Life insurance determination
  o Individual access to health information, responder only
• Treatment includes the following sub-use cases:
  o Immunization – push of immunization data for treatment purposes *(This is not related to reporting to immunization registries)*
	Transmit clinical documentation to support treatment of an individual, care coordination or transitions of care
	
	Transmit clinical documentation to the Social Security Administration (SSA) for the purposes of supporting a claimant's eligibility for Social Security disability benefits
	
	Enables different types of networks (e.g. ROI companies, vendor intermediaries, etc.) to respond to transmit clinical documentation to another Participant. Participants supporting this profile may not initiate queries.
	
	Enables an individual using a PHR to request / receive a copy of his or her health information accompanied by a HIPAA-compliant authorization
		• Web Services Registry Web Service Interface Specification v 3.1
		• Messaging Platform v3.0
		• Patient Discovery v2.0
		• Query for Documents v3.0
		• Retrieve Documents v3.0
		• Authorization Framework v3.0
		• Deferred Patient Discovery
		• Immunization data requirements
		• HITSP C32
		• HL7® C-CDA Release 1.1 and Associated Companion Guide(s)
		• HL7® C-CDA Release 2.1 and Associated Companion Guide(s)
		• HL7® FHIR®
		• End Stage Renal Disease Implementation Guide Package [June 30]

• PDMP (treatment sub-use case)	• Enables exchange of Prescription Drug Monitoring Program Data	• NCPDP, PMIX, SCRIPT, and HL7®
• Submit Documentation to CMS	• Enables documentation and/or quality	• Messaging Platform v3.0 • Authorization Framework v3.0 • Administrative Distribution

Use Case	Workflow	Standards / Specifications
• Currently, CMS accepts data for the End Stage Renal Disease Program (ESRD)	measure reporting to CMS	• Document Submission • Required CMS content requirements (which varies by program)
• Authorized Release of Information – Individual Access to Health Information (e.g. via a Personal Health Record – PHR-DRAFT)	• Enables Clinical Exchange between Patient and Provider via a consumer application	• Web Services Registry Web Service Interface Specification v 3.1 • Messaging Platform v3.0 • Patient Discovery v2.0 • Query for Documents v3.0 • Retrieve Documents v3.0 • Authorization Framework v3.0 • Authorized Release of Information – Individual Access to Health Information (e.g. via a Personal Health Record – PHR-DRAFT)
• Encounter Alerts	• Enables event notification of clinical encounters to patient associated care team members	• VPN (transport)-DRAFT • HL7® v2 (content) • Direct Secure Transport v 2.1
• Electronic Lab Reporting (in support of public health)	• Enables electronic lab reporting to public health agencies	• HL7® Version 2.5.1 [ELR Implementation Guide]
• Syndromic Surveillance (in support of public health)	• Enables syndromic surveillance reporting to public health agencies	• HL7® Version 2.5.1 [Public Health Information Network (PHIN) Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings]
• Image Sharing	• Enables organizations to share images	• Cross-Enterprise Document Sharing for Imaging (XDS-I) • Cross-Community Access for Imaging (XCA-I)

5 eHealth Exchange Data Content Requirements and Conformance Expectations

eHealth Exchange Participants who share data in support of treatment / care coordination, including sub-use cases such as the sharing of immunization data for treatment purposes, HL7® and FHIR® transitions of care, and the SSA disability determination process are currently required to support, at a minimum, one or more of the following clinical documents and satisfy related testing:

- **C32/CCD, version 2.5 (Meaningful Use, Stage 1 2011 edition Standard)**
    - Applicants shall submit Document content that will be tested for conformance using the corresponding eHealth Exchange designated testing tool for meaningful use, stage 1 (2011 edition). Please reference the Clinical Content Testing Documentation for details.

- **Consolidated CDA (Meaningful Use, Stage 2 – 2014 edition Standard – US Realm Version 1.1) and associated Companion Guides**
    - Applicants shall submit Document content that will be tested for conformance using the corresponding eHealth Exchange designated testing tool for meaningful use, stage 2 (2014 edition).

- **Consolidated CDA (Meaningful Use, Stage 3 – 2015 edition Standard – US Realm Version 2.1) and associated Companion Guides**
    - Applicants shall submit Document content that will be tested for conformance using the corresponding eHealth Exchange designated testing tool, for meaningful use, stage 3 (2015 edition).

- **Immunization Data Requirements (for Treatment Sub-Use Case) leverage HL7® CDA Specification**

    eHealth Exchange Applicants who share immunization data for treatment purposes are subject to the following additional requirements:

    - Declare conformance with one of the content standards supported in the eHealth Exchange, and also comply with the corresponding vocabularies required for one of the ONC meaningful use editions.
    - Run sample files against the corresponding eHealth Exchange designated validator to validate 3 sections of the document (patient information, information source and immunizations).
    - Submit an attestation statement regarding whether the specimen validated by the eHealth Exchange designated tool was conformant with the content standard and vocabularies required by Meaningful Use.

    Supply the resulting eHealth Exchange designated tool test findings and content specimen submitted to The Sequoia Project for archival purposes

Participants may share other types of clinical content via the eHealth Exchange such as:

- HL7® v2.x message through the eHealth Exchange.

  - o Participants who would like to test HL7® v2.x messages (e.g. ADT event notifications, electronic lab reporting, sharing of Immunization data, etc.) are expected to address incompatibilities directly with each other.

The eHealth Exchange Content Testing Program may be expanded to support more robust testing of additional HL7® CDA®, Lab, Syndromic Surveillance and PDMP based and other content. Testing for other types of content are not currently required. In addition, it will apply to Participants, Vendors, and Participants that have multiple endpoints. Additional test materials must be approved by the eHealth Exchange Coordinating Committee.

Attachment #1 - Test Materials

The following list represents the set of service sets, test scenarios and test cases that are ready and available for the eHealth Exchange Testing Programs

For more details: http://sequoiaproject.org/ehealth-exchange/testing-overview/testing-references-2/

These materials reflect the following:

- Change Log - The eHealth Exchange Testing References page lists, near the top, the Official Technical Errata and Change Log and the Official eHealth Exchange Change / Service Advisory Log This is the single authoritative source for changes to the Testing Program, or Specifications.

- Product Testing Program Overview – A broad overview of the process, application, and documentation for the eHealth Exchange Product Testing Program. Includes the a link to the required and provisional product test cases, documentation, conformity assessment checklists, Testing data load set and documents, and a description of content tests.

- Participant Testing Program Overview - A broad overview of the process, application package, and documentation for the eHealth Exchange Participant Testing Program. Includes links to all participant test cases, documentation, provisional tests, conformity assessment checklists, Testing data load sets and documents and a description of content tests for the current eHealth Exchange Participant Testing Program
- Content Testing Program Overview – A broad overview of documentation, testing methodology and scenarios that will be required for interoperability testing to enable the exchange of clinical content between eHealth Exchange participants.

Attachment #2 – Summary of eHealth Exchange Testing Requirements

	Baseline Participant Testing	Validated eHealth Exchange	qts Basic	qts Intermediate	qts Advanced
Criteria	Participants not using a "Validated Product" must **complete three testing protocols**.	Participants whose vendors have validated their gateway with the eHealth Exchange **do not have to complete Security testing** resulting in reduced testing fees.	Participants pay $0 for testing and **complete transport & content testing** when recognized as a Federal Fast Track (or equivalent) program partner, using a standard gateway configuration, when the vendor has validated their gateway with the eHealth Exchange, where 4+ other Participants using the same gateway completed testing with no failures or outstanding technical issues	Participants pay $0 for testing and **only complete content testing** when using gateway that meets all QTS Basic requirements, AND their vendor has successfully submitted QTS Basic test results with no issues for 6+ months	Participants pay $0 for testing and **complete no testing** when using gateway that meets all QTS Basic requirements AND all QTS Intermediate testing, and ALL Participants using the vendor's approved QTS Intermediate solution receive no errors when performing content testing
Scope	• Transport • Security • Content	• Transport • Content	• Transport • Content	• Content	
Cost	• Participant : $19,000	• Vendor $34,000 • Participant $11,000	• Vendor $0 • Participant $0	• Vendor $0 • Participant $0	• Vendor $0 • Participant $0

Appendix A – Document Change History

Version	Date	Items Changed Since Previous Approved Version
1.0	12/17/09	Approved by Coordinating Committee on 12/17/09.
2.0	5/7/10	Modified to allow simpler updating as new specification service sets come online; redefined HIEM service set definition. Simplified process description. Added information regarding product conformance. Clarified pre-application validation process.
3.0	04/01/2012	Updated Testing approach. Removed references to NHIN acronym. Updated process description; removed reference to Technical Committee in roles and responsibilities table; updated "Technical Qualification" System to include Task Group recommendations concerning Participant System expectations.
4.0	9/8/2014	Revised to reflect new validation logo, Healtheway copyright, removed references to CCHIT, clarified retesting policy, added breaking changes policy information, added Digital Credential information and added product testing program information
5.0	04/18/17	General: Removed terms in Section 1.1 that are already defined in the DURSA, removed references to Healtheway, updated email addresses, changed references to 'profiles' to 'use cases' and other general edits to simplify the document. Removed detailed onboarding process references and referenced the eHealth Exchange website for detailed onboarding and testing process steps. Section 2 - Added eHealth Exchange Content Testing Process Added additional testing policies approved by the Coordinating Committee (i.e. Section 3.2 Peer to Peer Testing for Applicants Who Support 2010 Specifications, Section 3.3 Peer to Peer Testing for Qualified Technology Solutions (QTS), Section 3.4 Production Security Testing) Updated Section 4 to reference use cases instead of profiles and updated the list of approved specifications Updated data content requirements and test materials
6.0	1/31/18	Added the following new terms in Section 1.1: QTS Basic, QTS Intermediate, QTS Advanced Renamed Production Security Testing to PKI Certificate Testing

Version	Date	Items Changed Since Previous Approved Version
		Updated Section 3.3 to include the testing policies for all QTS Levels Added Attachment #2 – Summary of eHealth Exchange Testing Requirements
7.0	7/16/2019	Updated Content Testing Process section 2.4: 1. Participants who do not pass content validation and remediate conformance issues must retest within 18 months from the date of initial test result submission to confirm conformance issues have been resolved. 2. Participants who do not submit completed validation results by October 1, 2019 will have their digital certificates suspended until they submit completed validation results. 3. Participants who do not remediate conformance issues within 18 months from the date of initial test result submission must submit a remediation plan and/or a conformance waiver request within two months of the 18 month deadline for Coordinating Committee approval. The Coordinating Committee can either accept the proposal or request changes.
8.0	10/15/2019	Updated Content Testing Process section 2.4: 1. To simplify the content remediation deadline by requiring content remediation for all Participants by 5/1/2021 worst-case, while still encouraging earlier remediation (with 18 months of submitting failed content testing results. 2. For Participants who do not remediate conformance issues by the deadline, to simplify the remediation plan and/or conformance waiver request deadline to 3/1/2021 worst-case, while still encouraging earlier submission (with 16 months of submitting failed content testing results.
9.0	01/30/20	Removed all references to PKI Certificate Testing previously outlined in section 3.4 and referenced under the QTS sections.