Validation Plan

Version 4.0

September 8, 2014

eHealth Exchange

Status: FINAL – Approved by CC		
Effective Date: 9/8/14	**Version: 4.0 Final**	

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
- Developers of Systems who wish to have their product 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.

- **Breaking Changes** mean issues that are identified while Testing an applicant or participant. Issues uncovered real-time during the Testing process.
- **Messages** are intended to mean the transactions that are exchanged.
- **Modified System** shall mean changes made to a System that impact compliance with the Performance and Service Specifications.
- **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.
- **Specifications** shall mean the set of implementation specifications adopted by the Coordinating Committee pursuant to the DURSA to prescribe the data content, technical, and security requirements to enable the Applicants to Transact Message Content. Specifications may include, but are not limited to, specific Network standards, services and policies.
- **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. 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** shall mean identification of which underlying Systems, such as HIE or EHR System and/or gateway to be tested and used in production. This should include the System components that are relevant to validation, including those components used to create or modify Messages in accordance with the Performance and Service Specifications, as well as generating the clinical documentation 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, conformance checklists, etc.
- **Test Report** means a written report issued by Healtheway that documents the outcomes of the Testing Process; that is, the Applicant's compliance with the Specifications and Test Materials.
- **Testing** shall mean validation of Applicant's HIE Technology used for interoperable health information exchange, to assess conformity with the 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.

1.2 Scope

The scope of the eHealth Exchange Testing program is limited to the Specifications; the information outlined in 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 conduct health information exchange (HIE) via the eHealth Exchange comply with the eHealth Exchange Specifications and Test Materials. Systems brought forward for Testing must be Production Ready. Healtheway currently supports two Testing programs:

1) **eHealth Exchange Participant Testing Program:** This process verifies that Systems used by organizations who wish to participate in the eHealth Exchange ("Applicants"), or those who wish to

remain a participant in the eHealth Exchange ("Participants") satisfy the requirements established by the DURSA. The Testing program verifies that the System used by Applicants and Participants comply with the Specifications.

2) **eHealth Exchange Validated Product:** This process verifies that the Systems used by Applicants and Participants comply with the Specifications prior to being implemented in the Applicant's and 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.

2 eHealth Exchange Testing Process

2.1 Overview

Healtheway supports a highly automated Testing process and augments the automated approach with some manual review to verify conformance of Systems used in the eHealth Exchange. Healtheway has partnered with AEGIS to provide an automated Testing environment called the Developers Integration Lab (DIL). The DIL Testing environment facilitates gateway-to-gateway Testing. The DIL Testing platform automates the tests and enables Applicants to conduct practice Testing on a self-service basis, with real-time feedback regarding issues of non-compliance.

In addition, Healtheway uses additional mechanisms to validate that Systems comply with the Specifications. The following two sections describe how Testing process works, including the steps that Applicants, eHealth Exchange Participants and Vendors must follow to complete the Testing process.

2.2 eHealth Exchange Participant Testing and Onboarding Process

To join the eHealth Exchange, Applicants must follow an eight-step process, as described below. 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. A copy of this OPP is found here: http://healthewayinc.org/index.php/exchange/onboarding.

1. **Apply to eHealth Exchange**

   - Complete and submit an Application Package which includes the below documents to: admin@healthewayinc.org
     - eHealth Exchange Application (New Applicants: The Testing Services Agreement is included in the Application)
     - DURSA (Version May 3, 2011)
     - DURSA Amendment (Version September 30, 2014)
     - eHealth Exchange Participation Agreement

- Testing Services Agreement
- Healtheway Testing Readiness Checklist (Applicants may need to enlist help from the HIT vendor to complete this checklist)

- Pay Testing Fees (listed in the Healtheway Testing Agreement) to Healtheway via check, ACH or credit card:
  - Mail checks (payable to Healtheway, Inc.) to:

    Healtheway, Inc.
    1600 Tysons Boulevard, 8th Floor
    McLean, Virginia, 22102

  - To pay via credit card or for ACH & Wire instructions or to request an invoice, please contact admin@healthewayinc.org

Note: Applicants may also pay the eHealth Exchange participation fees at this time. Payment of the participation fees can either be made in conjunction with the Testing fees or separately once in production on the eHealth Exchange.

2. Coordinating Committee Approves Application for Participation and Refers Applicant to Begin Practice Testing

- The Coordinating Committee will review an Application for Participation and determine whether an Applicant satisfies the eligibility criteria. (For details, see Operating Policy and Procedure #1).
- If approved as eligible, Healtheway will verify whether the Applicant's Testing Readiness Checklist is complete.
- If complete and the Applicant has paid Testing fees, Applicant will be directed to get set up in the Developers Integration Lab (DIL). See Step #3 below for details.
- If an Applicant wishes to connect to the Social Security Administration (SSA) and/or Veterans Health Administration (VHA), the SSA and VHA will require Applicant to do additional partner testing. See Step #7 below for details.

3. Set up and Conduct Practice Testing in the Developers Integration Lab (DIL)

- Complete DIL Setup Checklist:

  Applicants should work with the HIT System vendor to complete the DIL Setup Checklist, which outlines the required steps to get set up in the DIL Testing environment. Completed DIL Setup Checklists should be sent to Testing@healthewayinc.org

  - Applicants who are new to the DIL are encouraged to review this information:

    http://healthewayinc.org/index.php/exchange/participant-Testing/12-Testing/90-dil-guides

- DIL Setup Checklist
- Test Case Documentation and Data Load Set

- Register in the DIL:

  Applicant's vendor may assist or register the Applicant organization in the DIL; however only the Applicant's name should be registered in the DIL, not the vendor.

  - DIL
  - DIL Training and Demonstration Video
  - DIL User Guide
  - DIL UDDI Registration Guide
  - DIL Certificate Instructions
  - Updated Patient Mapping Guide

- Conduct Practice Testing:

  If Applicant's vendor is assisting the Applicant with practice Testing, the vendor should notify Applicant when practice Testing is completed.

- Any questions or issues regarding DIL set up or issues encountered during practice Testing may be referred to the DIL Support Team: dil_support@aegis.net.

4. Run Tests and Submit Results

- Applicant is expected to complete practice Testing and determine when the Applicant can successfully pass all of the tests. When the Applicant is ready to have the results formally evaluated by Healtheway, Applicant should run the tests and "Submit" results in the DIL to have the results validated.
  - Applicant must notify testing@healthewayinc.org once the tests have been submitted, along with the corresponding DIL Execution Unique ID.
- If Applicant is testing for content (i.e. C32, C-CDA), Applicant must submit sample documents to the corresponding NIST validator tool and verify that the document complies accordingly.
  - Once Applicant is satisfied that the document meets the content requirements, Applicant should submit a sample document to testing@healthewayinc.org for formal evaluation.
- Healtheway will review the test results, including any test evidence submitted, and identify issues of non-compliance.

5. Coordinating Committee Approves Applicant Test Results

- Healtheway will verify that all Applicant test results have been received and will submit a Test Report to the Coordinating Committee for approval.
- 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.
- Applicant will be notified regarding the Coordinating Committee's decision.

6. Activate in Production Environment

- If Applicant is formally notified by Healtheway that Applicant has been approved as a Participant in the eHealth Exchange, Applicant must file a support ticket to get provisioned in the eHealth Exchange production environment.
  - To file a ticket, send an email to techsupport@healthewayinc.org
  - Applicant will receive a support ticket #, as well as instructions and forms to complete the set up process, including:
    - i) issuance of an x.509 certificate, which must be successfully installed in Participant's production environment;
    - ii) entries into the production eHealth Exchange web services registry (i.e. UDDI registry); and
    - iii) identification of the Participant's operational points of contact.
- Healtheway will schedule an activation briefing with the Applicant to review production operations, obligations, and to learn more about participating in the eHealth Exchange community.

7. Applicant Completes Partner Testing (Optional)

- The SSA and VHA require additional partner testing prior to exchanging data. If Applicant wishes to exchange data with the SSA and VHA, Applicant must be provisioned in the eHealth Exchange test environment (i.e. with a test x.509 certificate and entries into the Test version of the UDDI web services registry).
- To be provisioned in the Test environment, submit an e-mail to the Healtheway Technical Support Team at techsupport@healthewayinc.org with a request to issue a validation digital certificate and to be set up in the validation web services registry (the UDDI). Applicant will receive a support ticket, as well as instructions and forms to complete the set up process.
- Applicant may conduct partner testing with SSA before, after, or in parallel with Testing in the DIL. Partner Testing with VHA will begin after Applicant completes Testing in the DIL.

8. **Post-Production Monitoring Period**
    - eHealth Exchange Participants are subject to a 90-day postproduction-monitoring period. This is a probationary period during which an eHealth Exchange Participant's compliance with Performance and Service Specifications is assessed.
        - Issues of non-compliance should be reported to admin@heathewayinc.org.
        - Healtheway will triage reported issues 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 to verify that Systems used by Participants in the eHealth Exchange comply with the Specifications. By Testing that the underlying System complies, Participants should have greater assurance that the System complies when implemented and used in production. In addition to mitigating risks to production, using eHealth Exchange Validated Systems will significantly off-set the tests that Participants must complete to participate in the eHealth Exchange.

The process outlined below reflects the steps that developers of HIE Systems ("Vendors") must follow to their System tested and verified by Healtheway as being eHealth Exchange Validated.

1. **Complete the Product Testing Application.** The application includes the Product Testing Services Agreement. Once completed, and executed, the applicants and Product Testing Services Agreement should be submitted to **admin@healthwayinc.org**
2. **Pay Testing Fees (listed in the Healtheway Testing Agreement) to Healtheway via check, ACH or credit card:**
    - Mail checks (payable to Healtheway, Inc.) to:

      Healtheway, Inc.
      1600 Tysons Boulevard, 8th Floor
      McLean, Virginia, 22102

    - To pay via credit card or for ACH & Wire instructions or to request an invoice, please contact admin@healthewayinc.org
3. **Set up and Conduct Practice Testing in the Developers Integration Lab (DIL)**
    - Complete DIL Setup Checklist:

Vendor should complete the DIL Setup Checklist, which outlines the required steps to get set up in the DIL Testing environment. Completed DIL Setup Checklists should be sent to testing@healthewayinc.org

- Vendors who are new to the DIL are encouraged to review this information:

  http://healthewayinc.org/index.php/exchange/participant-Testing/12-Testing/90-dil-guides

- DIL Setup Checklist
- Test Case Documentation and Data Load Set

- Register in the DIL:

  The following provides additional instructions for the registration process, as well as use of the DIL:

  - DIL
  - DIL Training and Demonstration Video
  - DIL User Guide
  - DIL UDDI Registration Guide
  - DIL Certificate Instructions
  - Updated Patient Mapping Guide

- Conduct Practice Testing:

  The vendor should conduct practice Testing and verify that that product can successfully pass all tests. Any questions or issues regarding DIL set up or issues encountered during practice Testing may be referred to the DIL Support Team: dil_support@aegis.net.

4. Run Tests and Submit Results

- The vendor is expected to complete practice Testing and determine when the vendor's product can successfully pass all of the tests. When the vendor is ready to have the results formally evaluated by Healtheway, vendor should run the tests and "Submit" results in the DIL to have the results validated.
  - Vendor must notify testing@healthewayinc.org once the tests have been submitted, along with the corresponding DIL Execution Unique ID.
- If the vendor is testing for content (i.e. C32, C-CDA), vendor must submit sample documents to the corresponding NIST validator tool and verify that the document complies accordingly.
  - Once vendor is satisfied that the document meets the content requirements, vendor should submit a sample document to testing@healthewayinc.org for formal evaluation.

- Healtheway will review the test results, including any test evidence submitted, and identify issues of non-compliance.
- Vendor will have an opportunity to retest in accordance with the terms of the eHealth Exchange Product Testing Agreement.

5. Test Results Report

- Once all Testing and retesting is completed, Healtheway will determine whether the product has successfully demonstrated compliance with the Specifications and Test Materials and will document such results in a Test Report.
- Healtheway will send the vendor a copy of the final Test Report.
- If vendor's product does not pass testing, vendor may re-apply at a later date and pay the Testing fees in effect at the time the new application is submitted.
- If the Applicant's product successfully passes all tests, Healtheway will work with vendor to have its validated product added to the eHealth Exchange Validated Product List.

6. eHealth Exchange Validated Product Listing

- Healtheway will send vendor a copy of the eHealth Exchange Validated logo, and usage guidelines.
- Vendor may only use the eHealth Exchange Validated logo as permitted by the usage guidelines and in accordance with the eHealth Exchange Product Testing Agreement.

3 eHealth Exchange Testing Policies

3.1 System Under Test

Applicants and Vendors shall:

- Bring forth a Production-Ready System for validation.
- Identify and include the System components that are relevant to validation, 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 it makes System changes 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 and Participants should retest in order to confirm that System modifications have not introduced non-compliant behaviors. To request guidance, retesting or revalidation, the Applicant and/or Participant should contact the eHealth Exchange Testing Program Manager at testing@healthewayinc.org.

3.2 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.

It is acknowledged that Participant 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 Vendors and Participants, 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:

3.2.1 Ongoing Monitoring for Compliance

Healtheway shall have the right to monitor, audit and inspect Participant and Vendor Systems which have been validated for the eHealth Exchange to verify that the System remains in compliance with the Specifications. Such monitoring, auditing and inspections may be undertaken by Healtheway at any time including, but not limited to, in response to a complaint submitted to Healtheway 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. Healtheway shall provide reasonable advance notice to Applicant prior to any such inspection or audit,

unless such advance notice, in Healtheway's opinion, would prejudice Healtheway's ability to ascertain the information desired from the inspection or audit.

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

3.2.2 Retesting Upon a Finding of Non-Compliance

If, after reasonable monitoring, auditing or inspection, Healtheway determines 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.

3.2.3 Validation Period

Once a System has successfully been tested by Healtheway, 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 Healtheway provides official notice to the Vendor that the System has been approved as an eHealth Exchange Validated System.

3.2.4 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. 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: Healtheway may revoke the eHealth Exchange Validated status for a non-compliant System; or require that the Vendor implement a remediation plan acceptable to Healtheway and successfully complete and pass retesting in a timeframe to be determined by Healtheway.

3.3 Retesting When Specifications and Test Materials Change

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 Performance and Service Specifications, the Coordinating Committee shall, with Participant and Vendor input, assess the impact of changes product exchange among eHealth Exchange Participants and establish a rationale should retesting be warranted.

3.4 Breaking Changes

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

- Validation 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 issue 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 scripts or test lab, but the entity is conforming to the Specifications:
    - The entity should be found conformant. An error in the lab or test cases should not prevent a System from proceeding through the Testing process or going into production if the System complies with the Specifications.
    - The testing process is not intended to de-bug issues in Systems. Systems brought forward for Testing are expected to be Production-Ready. The eHealth Exchange testing process is not intended to partner-specific requirements or to debug and test System-specific issues.

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 artifacts, such as:

- Add coverage within a given feature (e.g. more Testing of negative paths)
- Changes to Testing methods that also include substantive changes (e.g. Automate a previously manual test)
- Update a test case
- Add Testing for a new feature (e.g. asynch, or Query for Docs (FindAssociations))
- Add Testing for a new spec
- Add Testing for a new version of a spec
- 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.
  - Changes to test data
  - Fixes to testing tools or the test lab that do not otherwise change the test requirements and expected outcomes.
  - Editorial changes (e.g. to Test Materials should not be subject to the change management process.)

4 eHealth Exchange Profiles and Data Content Requirements

The eHealth Exchange has adopted a profile-based approach, which enables participants to determine which use cases and related specifications / content requirements they wish to support in production. eHealth Exchange profiles define how a community of eHealth Exchange Participants wishes to exchange data using transport, service and content specifications to support their business needs. This approach enables the eHealth Exchange to support a myriad of use cases, based upon a common set of standards and specifications.

4.1 Profile Definition

- Profiles shall identify and describe business purpose and specifications required and specify how to constrain or implement those specifications.
- Profiles 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.

- Profiles may be updated to reflect new versions of specifications adopted for the eHealth Exchange.

4.2 Universal Requirements

All eHealth Exchange profiles must support the Universal Requirements outlined in this policy. Universal requirements may be revisited over time.

4.2.1 Secure Transport – must specify the current version in effect for eHealth Exchange and be updated to reflect new versions.

- **Authorization framework**
- **Messaging platform**

4.2.2 Service specifications – must specify at least one exchange pattern used and require the version in effect for the eHealth Exchange.

- **Patient discovery / Query / Retrieve**
- **Document submission**
- **Publish / subscribe**

4.2.3 Version Frequency: Version updates may occur every couple years, with a period for dual use and a final cutoff date, comparable to the approach used for HIPAA Transaction and Code Set standards.

4.3 Optional Service-Related Specifications:

4.3.1 Optional Specifications

Two other specifications may be used by eHealth Exchange Participants, but are not required:

- Web services registry (UDDI)
- Access consent policies (ACP)

4.3.2 Support for Multiple Use Cases: Optional service-related specifications are not intended to be linked to any particular profile, but are available for implementation across a myriad of use cases.

4.3.3 Version Frequency: Version updates should occur on a regular basis (e.g. annually), with a period for dual use and a final cutoff date, comparable to the approach used for HIPAA Transaction and Code Set standards.

4.3.4 Implementation Implications: 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 Profiles

There are currently three profiles supported in the eHealth Exchange. The following table describes each profile and identifies the corresponding implementation specifications.

Profile	Required Specifications	Optional Specifications
Query and Retrieve Documents Supports multiple use cases, such as: treatment, transitions of care, care coordination, referrals and Social Security disability benefits determination	- Authorization framework - Messaging platform - Patient Discovery - Query for Documents - Retrieve Documents - One or more of the Summary Patient Record Document content standards	- Web Services Registry - Access Consent Policies - Deferred Patient Discovery
Query and Retrieval of Immunization Data for Treatment Purposes Providers with immunization data may respond to queries from other participants for treatment purposes. *NOTE: This is not related to reporting to immunization registries*	- Authorization framework - Messaging platform - Patient Discovery - Query for Documents - Retrieve Documents - Immunization data requirements in C32 and C-CDA	- Web Services Registry - Access Consent Policies - Deferred Patient Discovery
Submit Documentation to CMS Currently, CMS accepts data for the	- Authorization framework - Messaging platform - Administrative	- Web Services Registry

Profile	Required Specifications	Optional Specifications
End Stage Renal Disease Program (ESRD)	Distribution - Document Submission - Required CMS content requirements (which varies by program)	

Other profiles may be added to the eHealth Exchange over time.

4.5 eHealth Exchange Data Content Requirements and Conformance Expectations

eHealth Exchange participants who share data in support of care coordination, including sub use cases such as the sharing of immunization data for treatment purposes, transitions of care, and the SSA disability determination process shall, at a minimum, support one or more of the following documents and satisfy related Testing:

- **CCD, version 2.5 (Meaningful Use, Stage 1 2011 edition Standard)**
    - Participant shall attest that participant has successfully pass conformance Testing using the corresponding Healtheway designated validator tool, or that the participant uses a System which was certified for meaningful use, stage 1 (2011 edition.

- **Bridge C32 Summary Patient Record Content Specification** (eHealth Exchange – EHR | HIE Interoperability Workgroup (IWG) Harmonized Content Specification, dated April 2013).
    - Participant shall be required to test with Healtheway, to demonstrate compliance with this specification.

- **Consolidated CDA (Meaningful Use, Stage 2 – 2014 edition Standard – US Realm Version 1.1)**
    - Participant shall attest that participant has successfully passed conformance Testing using the corresponding Healtheway designated validator tool, or that the participant uses a System which was certified for meaningful use, stage 2.

- **Immunization Data Requirements (for Treatment Sub-Use Case)**

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

- Declare conformance with one of the 3 content standards supported in the eHealth Exchange, and also comply with the corresponding vocabularies required for meaningful use.
- Run sample files against the corresponding Healtheway 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 Healtheway designated tool was conformant with the content standard and vocabularies and Meaningful Use
- Supply the resulting Healtheway designated tool log files and content specimen submitted to Healtheway for archival purposes

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

- Other versions of the CCD through the eHealth Exchange.
  - Testing of non-standard CCDs is not required. In this scenario, eHealth Exchange Participants who use nonstandard data content are expected to address incompatibilities directly with each out.
- Unstructured documents, in accordance with available standards; however, testing of unstructured documents is not within the scope of the current eHealth Exchange testing program.

eHealth Exchange

Attachment #1: eHealth Exchange Profiles, Specifications and Test Cases

Profile	Description	Specifications	Summary of Test Cases	Test Method
Treatment Authorized Release of Information (SSA)	Transmitting 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	2010 version of the following • Messaging Platform • Authorization Framework • Patient Discovery • Query for Documents • Retrieve Documents	• Smoke tests (2010)	Run tests against Developers Integration Lab (DIL) Testing environment Results validated by Healtheway
		2011 version of the following • Messaging Platform • Authorization Framework • Patient Discovery • Query for Documents	• Smoke tests (2011) • Security interoperability tests (2011)	Run tests against Developers Integration Lab (DIL) Testing environment Results validated by Healtheway

Profile	Description	Specifications	Summary of Test Cases	Test Method
		• Retrieve Documents		
		At least one of the following clinical document types • Basic C32 • Bridge C32 • HL7 C-CDA v1.1 US Realm	Set up test data Generate sample Message	Run sample Message through the corresponding NIST validator tool Results validated by Healtheway

For a detailed list of test cases, please refer to Attachment #2.

- **2010 eHealth Exchange Specifications** – These initial production specifications are in limited use and the participants currently using the 2010 specification are migrating to support 2011 specifications in preparation for their future sunset. The sunset date is yet to be determined. Organizations using a previously validated System under the prior onboarding program have the option of only conducting the below tests:
- **2011 eHealth Exchange Specifications** – These production specifications are currently in effect and are required for organizations that are not using a previously validated System under the prior onboarding program and use a System supporting the 2011 specifications.
    - 6 smoke tests interoperability tests (2011)

- 19 security interoperability test sets
- 52 Provisional Security Test (Product Testing Program ONLY)

- **Content** – At a minimum, Participants who support content must test at least one of the below content specifications. Content Testing is waived if an organization uses a product that was certified for Stage 1 / 2 Meaningful Use or if they will only be transporting content provided by connected certified electronic health record products identified in the Certified Health IT Product Listing (CHPL).

  - Basic C32 (2011 Edition of EHR Certification Criteria for Stage 1 Meaningful Use)
  - Bridge C32
  - HL7 C-CDA v1.1 US Realm (2014 Edition of EHR Certification Criteria for Stage 2 Meaningful Use)

eHealth Exchange

Attachment #2 - 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://www.healthewayinc.org/index.php/resources/Testing-program-resources

These materials reflect the following:

- Change Log - The Official eHealth Exchange Specifications page lists, near the top, the Official Technical Errata and Change Log. This is the single authoritative source for changes to the Testing program, or specifications.
- Product Test Case Documentation - List of documents for the required and provisional Healtheway Product Testing Program. Includes the applications required and listing of all product test cases, documentation, provisional tests, 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, applications and documentation for the Participant Testing Program. List of 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 Healtheway Participant Testing Program
- Healtheway AEGIS Developers Integration Lab (DIL) Guides

Appendix A - Document Change History

Version	Date	Items Changed Since Previous Version	Changed By
1.0	12/17/09	Approved by Coordinating Committee on 12/17/09.	ONC
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.	ONC
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.	ONC
4.0 – DRAFT rev. 6	07/05/2014	Revised to reflect new Testing program supported by Healtheway, consolidated policies and Testing process into single document. Added Product Testing Program.	Healtheway
4.0 – DRAFT rev. 7	7/9/2014	Added TOC and correct Heading links for formatting purposes.	Healtheway
4.0 – DRAFT rev. 8	7/14/2014	Removed Section 3.5 – Digital Credentials. This policy wasn't specific to testing and Healtheway will develop a more general policy artifact for this type of documents.	Healtheway