HealtheWay™

eHealth Exchange Validation Plan Update

Mariann Yeager. Chief Executive Officer (CEO)
Didi Davis, Testing Program Manager

Validation Plan Change Process Milestones

Approval Milestones	Target Date	Status
Present Draft to CC for review:	7/8	
Participant Input (Post draft to eHealth Exchange Wiki):	7/14	
Participant Input (Webinar to review updates):	7/30	
CC Approval:	8/12	
30 day notice to participants:	8/12	
Objection Period Ends:	9/11	
Target Effective Date:	9/12	

Validation Plan Outline

1. Purpose and Scope
2. eHealth Exchange Testing Process
3. eHealth Exchange Testing Policies
   - 3.1 System Under Test
   - 3.2 Retesting Due to System Changes (New)
   - 3.3 Retesting When Specifications and Test Materials Change (Updated)
   - 3.4 Breaking Changes (Updated)
   - 3.5 eHealth Exchange Digital Credentials
4. eHealth Exchange Profiles and Data Content Requirements
   - 4.1 Profile Definition
   - 4.2 Universal Requirements
   - 4.3 Optional Service-Related Specifications
   - 4.4 eHealth Exchange Profiles (Updated to include Immunization profile)
   - 4.5 eHealth Exchange Data Content Requirements and Conformance Expectations

SECTION 1 – PURPOSE AND SCOPE

Context

- **Purpose:**
  - 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.
  - Describes the expectations for Participant Testing and now includes Product Testing
  - Incorporates all of the testing policies that have been effect and clarifies new policies
  - Identifies the authoritative set of testing requirements adopted for the eHealth Exchange

- **Summary of Changes:**
  - Incorporates both the Participant and Product Testing Program policies
  - Clarifies the Participant and Product Re-Testing policy

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

Approach

- 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.
- 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;
  - Developers of Systems who wish to have their product validated as eHealth Exchange compliant; and
  - Limited to the approved Performance and Service Specifications.

SECTION 2 – EHEALTH EXCHANGE TESTING PROCESS

eHealth Exchange Testing Programs

- **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.

- **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.

SECTION 3 – EHEALTH EXCHANGE TESTING POLICIES (INCLUDES NEW POLICIES)

3.1 - System Under Test

- 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.

3.2 - Retesting Due to System Changes (NEW)

- 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.
- eHealth Exchange Validated products must also remain compliant with the Specifications to retain eHealth Exchange Validated status.
- In lieu of having Participants and Vendors retest with each release of a System, the following policies shall apply:
  - Ongoing Monitoring for Compliance
  - Retesting upon Finding Non-Compliance
  - Validation Period
  - Retesting after Validation Period

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.
- 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 Finding 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 (Updated)

- 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 (Updated)

- Testing program is designed to 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.
- Breaking Changes may be discovered real-time during the Testing process
  - If errors are discovered due to ambiguity / errors in the Specifications, seek guidance from Coordinating Committee and address through change management process.
  - If there is an error in the test scripts or test lab, but the entity is conforming to the Specifications, applicant should be found compliant.
  - The testing process is not intended to de-bug products or to address partner-specific requirements.

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.)

SECTION 4 - PROFILES AND DATA CONTENT REQUIREMENTS

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.

eHealth Exchange Supported Profiles

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 End Stage Renal Disease Program (ESRD)**	- Authorization framework - Messaging platform - Administrative Distribution - Document Submission - Required CMS content requirements (which varies by program)	- Web Services Registry

Data Content Requirements and Conformance Expectations (1)

- Minimum requirement: Support at least one of the following:
  - CCD, version 2.5 (Meaningful Use, Stage 1 2011 edition Standard)
  - 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.
  - HL7 C-CDA v1.1 US Realm (2014 Edition of EHR Certification Criteria for Stage 2 Meaningful Use)
- Additional requirements for Treatment Sub-Use Case for immunization data)
- Content Testing waived if system 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).

Data Content Requirements and Conformance Expectations (2)

- **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.

Test Materials

- 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.
- 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.
- 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

Discussion

For more information:

Test Materials:
http://www.healthewayinc.org/index.php/resources/Testing-program-resources

Web Site: www.healthewayinc.org

E-mail: admin “at” healthewayinc.org (admin@healthewayinc.org)

Wiki: Documents Posted for 30 Day Comment