Operating Policy and Procedure

| Subject: Participation-Review and Disposition of Applications for Participation |
|---------------------------------|---------------------------------|
| Status: FINAL-Approved by CC    | Policy #: OPP-1                 |
| Effective Date: 5/6/16           | Version: v4.0                  |
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I. **Purpose**

The Coordinating Committee is responsible for supporting eHealth Exchange Participants who wish to Transact Message Content with other eHealth Exchange Participants and approved networks that eHealth Exchange has joined. Among the responsibilities granted to the Coordinating Committee by the eHealth Exchange Participants is the right to determine whether to admit new eHealth Exchange Participants who will be signatories to the DURSA. To fulfill this responsibility, the Coordinating Committee will review and act on applications for Participation ("Application(s)") submitted by organizations that wish to become eHealth Exchange Participants ("Applicants"). This policy outlines a framework for assessing the qualifications, eligibility and readiness of valid legal entities and governmental entities to become eHealth Exchange Participants.

II. **Policy**

The Coordinating Committee will review and make a decision to accept, reject, or request clarification on Applicants as eHealth Exchange Participants.

A. **General Eligibility Requirements (Administrative)***

1. To be accepted as an eHealth Exchange Participant, an Applicant must meet all of the following administrative criteria, hereinafter referred to as “General Eligibility Requirements”:

   a. Be a valid business in good standing or a federal, state, tribal or local government, agency or instrumentalities governmental agency, operating in the United States;

   b. Meet all solvency and financial responsibility requirements imposed on the Applicant by applicable statutes and regulatory authorities;

   c. Be an organization or agency that oversees and conducts, on its own behalf and/or on behalf of its eHealth Exchange Participant Users, electronic transactions or exchanges of health information among groups of persons or organizations;

   d. Facilitate exchange solely as an agent of its covered entity.
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g. d. Have formal contractual mechanisms in place authorizing the Participant to initiate and respond to requests on behalf of their customers through eHealth Exchange.

h. Have established mechanisms to assure its eHealth Exchange Participant Users (e.g. healthcare providers, health plans) are aware of and understand the Participant’s obligations under the DURSA (e.g. how patient / member information would be used and exchanged, the eHealth Exchange Participant’s accountability to the eHealth Exchange Participant User, etc.)

m. Utilize a system which has been verified as compliant with the Performance and Service Specifications for a use case;

f. Have the authority to make commitments to the minimum level of data sharing that the organization is willing to support for a use case so that all other Participants can know, and rely on, the organization’s commitment.

p. Have the organizational infrastructure and legal authority (through statutes, regulations, organizational agreements, contracts or binding policies) to comply with the obligations in the DURSA and to require its eHealth Exchange Participant Users and Third Party Technology vendors to comply with applicable requirements of the DURSA;

q. Intend to Transact information with other eHealth Exchange Participants for a Permitted Purpose;

s. Have sufficient financial, technical and operational resources to support the testing and operation of transactions among eHealth Exchange Participants;

t. Is not aware of any information that would preclude the Applicant from fully complying with the provisions of the DURSA; and

u. Submit the completed Application, the signed DURSA Joinder Agreement (Attachment 7 of the DURSA), and the eHealth Exchange Participation Agreement and Business Associate Agreement along with the applicable
participation fees. eHealth Exchange staff will educate Applicant regarding the purpose of the BAA as needed.

2. General Eligibility Requirements may be amended from time to time, as determined by the Coordinating Committee. In addition, the Coordinating Committee may consider an Applicant’s past activities as an eHealth Exchange Participant.

While an Applicant’s Application must include a signed copy of the DURSA Joinder Agreement, such signature does not make the Applicant a party to the DURSA. The Applicant does not become a party to the DURSA until the Coordinating Committee accepts the Applicant as an eHealth Exchange Participant and duly executes the Applicant’s Joinder Agreement. The Coordinating Committee reserves the right to decline an Applicant participation even if such Applicant signs the DURSA Joinder Agreement in the exercise of the Coordinating Committee’s discretion in applying the criteria set forth in this document.

B. Technical Requirements

In addition to the General Eligibility Requirements, to be accepted as an eHealth Exchange Participant, the Applicant must also satisfy the following Technical Requirements:

1. Has a system implemented in a production-ready environment that complies with the Performance and Service Specifications for each applicable use case;
2. Successfully complete the required technical testing of Applicant’s system in accordance with the Validation Plan; and
3. Certify the Applicant is ready to begin exchanging data with other eHealth Exchange Participants in production through the Applicant’s successfully tested system.

III. Procedure

The following procedures outline the steps for determining whether an Applicant has satisfied the eligibility requirements to be an eHealth Exchange Participant. The process for testing and determining whether a system complies with the Performance and Service Specifications is addressed in the Validation Plan.
A. Delegation of Rights

1. The Coordinating Committee has designated Healthway, Inc. (d/b/a/ “The eHealth Exchange” and its “eHealth Exchange support staff”) to provide operational support to eHealth Exchange Participants and the Coordinating Committee.

   a. The Coordinating Committee has chosen to delegate certain authorities, duties or responsibilities to The eHealth Exchange including but not limited to: the receipt, processing, and review and disposition of Applications; coordinating with Applicants and the Coordinating Committee in the Applicant testing process; conducting all testing with Applicants and Applicant Technology Partners in accordance with the Validation Plan; issuing and maintaining Digital Credentials; and establishing maintaining the eHealth Exchange Directory.

B. Verify General Eligibility Requirements (Administrative)

1. Application Submission

   a. Applicants shall prepare and submit their Application online or via e-mail to the eHealth Exchange by sending an e-mail to: administrator@ehealthexchange.com

   b. The Application supports the verification of eligibility requirements set forth in the Policy Section above.

2. Review and Disposition of eHealth Exchange Application

   a. The Coordinating Committee or its designee shall review the Application and determine whether an Applicant meets the General Eligibility Requirements. So long as the Applicant provides timely responses, it is anticipated that this process will usually be completed within five business days.

   b. The Coordinating Committee or its designee may consult with the Applicant to request additional information regarding the Application and proposed services and/or transactions, suggest changes or modifications to the Application including the supporting documentation, request verification of elements of the Application including screen shots, audit log excerpts, metrics or system
demonstrations, or make other recommendations the deemed reasonably necessary during the review.

   i. If the Applicant fails, or declines, to respond to the request, provide requested information or modify its Application within ninety business (90) calendar days of the request, the Application may be considered withdrawn.

   ii. If the Coordinating Committee or its designee determines that the Applicant meets the General Eligibility Requirements, the Applicant will be directed to complete requisite testing in compliance with the Validation Plan.

   c. If the Application does not meet the General Eligibility Requirements, the Applicant will be notified in writing. An Applicant may submit a new Application for future consideration by the Coordinating Committee or its designee after correcting the identified deficiencies.

   d. Any Applicant may withdraw its Application at any time by informing the Coordinating Committee or its designee of such withdrawal at administrator@ehealthexchange.com.

   e. Once the determination for acceptance or rejection of an Application has been made, the Applicant shall be informed in writing of the decision as well as supporting rationale.

C. Verify Technical Requirements

1. Receive and Evaluate Applicant Test Results

   a. The Coordinating Committee or its designee will be provided with a copy of Applicant’s test results following completion of the testing process set forth in the Validation Plan. The test results will indicate whether the Applicant’s system is compliant with the Performance and Service Specifications and contain a recommendation regarding whether to accept the Applicant as an eHealth Exchange Participant based upon the Performance and Service Specifications and the Validation Plan.
b. The Coordinating Committee may designate the review and approval of test results to eHealth Exchange support staff or to a sub-committee. During consideration of the test results, the Coordinating Committee or its designee may consult with the Applicant or the eHealth Exchange support staff to request additional information, notify the Applicant of items that require remediation to comply with the Performance and Service Specifications or suggest changes to the Applicant’s implementation of the Performance and Service Specifications.

c. The Applicant shall notify the Coordinating Committee or its designee of its election to remediate or not remediate any non-conformance of its implementation of the Performance and Service Specifications.

d. If the Applicant elects not to remediate any non-conformance, the Application shall be considered to be withdrawn.

e. The Coordinating Committee or its designee may hold an Application pending completion of any needed remediation, changes or modifications as well as any needed follow up testing to ensure the Applicant is able to meet the Performance and Service Specifications.

D. Disposition Application

1. If the Applicant meets the General Eligibility Requirements and has successfully completed all required testing, the Applicant shall be conditionally accepted as an eHealth Exchange Participant—moved into the activation phase.

2. The activation phase consists of:

   a. The Applicant’s acceptance as an eHealth Exchange Participant is conditioned on the Applicant’s being able to begin exchanging data in production with other eHealth Exchange Participants within one-hundred and twenty (180) calendar days following the date the Applicant was conditionally accepted as an eHealth Exchange Participant. During that time the following activities will occur:

   b. No more than thirty (30) days before an Applicant is scheduled to be activated to begin exchanging information with eHealth Exchange Participants in production, the Coordinating Committee Chair (or Chair’s Designee) will
execute the DURSA Joinder Agreement. The Chair shall notify the Coordinating Committee of any designee to execute the Joinder agreement and may designate an individual who is not a member of the Coordinating Committee.

a. The Applicant will be issued its Digital Credentials.

c. The Coordinating Committee Chair (or Chair's Designee) will execute the DURSA Joinder Agreement. The Chair shall notify the Coordinating Committee of any designee to execute the Joinder Agreement and may designate an individual who is not a member of the Coordinating Committee.

d. The Applicant must successfully install the Digital Credentials in its production environment.

e. The Applicant shall provide the information required to setup the Applicant in the eHealth Exchange Directory (e.g., UDDI / web service registry).  

f. The Applicant’s information will be added to the eHealth Exchange Directory (e.g., UDDI / web services registry) within two (2) business days of receiving such required information.

2.3 At this point the Applicant becomes activated as an eHealth Exchange Participant. Other eHealth Exchange Participants will be able to identify the new eHealth Exchange Participant and begin transacting health information with that new eHealth Exchange Participant.

a. If an Applicant or existing Participant deploying a new gateway has completed all of the above steps, but is unable to begin transacting health information, they may be subject to additional expectations for up to 90 days once they have been issued their production digital credentials, and entered into the eHealth Exchange production directory, “Limited Production Period”.

b. During the “Limited Production Period”, Participants must successfully test with, and enter into full production exchange, with two or more other production Participants, of their choice, before they are officially recognized as “full production” Participants.

c. If Participants do not successfully enter into full production exchange with another Participant within the 90–day Limited Production Period, then they may request an extension from the eHealth Exchange Coordinating Committee.
d. Limited Production Participants may use technical and business whitelisting practices to control those they interact with while they complete additional testing in the production environment.

3.4 If an Applicant is unable to go into production as an eHealth Exchange Participant within the one hundred and eighty (180) calendar-day timeframe or on another date mutually agreed upon by the Coordinating Committee and Applicant, the Applicant may request an extension.

a. Extension requests must be made in writing prior to end of the original 180-day period or the expiration of a previous acquired extension and submitted to administrator@ehealthexchange.com. The request shall include the rationale of the extension and the number of days requested. The extension request will be reviewed for completeness and presented to the Coordinating Committee for approval.

b. If the extension request is denied, it shall have the same effect as a rejection of the Applicant’s Application.

c. If the extension request is accepted, it shall result in the extension of the timeframe for the Applicant to identify a specific effective date on which the Applicant’s system will be operational, in production and ready to exchange information with other eHealth Exchange Participants in production.

d. Applicants may submit multiple extension requests, each of which the Coordinating Committee will review and disposition.

4.5 An Applicant’s formal acceptance as a full eHealth Exchange Participant takes effect on the date the Applicant’s system is operational in a production environment and able to transact Message Content with other eHealth Exchange Participants and when the Applicant’s Digital Credentials are activated.

E. Examples

The following are several examples that illustrate ways in which the Coordinating Committee may apply the General Eligibility Requirements. These examples are not intended to describe all possible scenarios.

- **Scenario 1**: An entity that licenses system software to its clients, but has not confirmed it has an agreement with its clients that requires the clients to use the
software to transact information in accordance with the DURSA (e.g. comply with permitted purposes, etc.).

Scenario 1 – Eligibility Implications: The entity is not eligible to be an eHealth Exchange Participant because the entity does not have the legal authority to require its clients to comply with the applicable requirements of the DURSA.

• Scenario 2: An entity that facilitates the transaction of information among various parties by establishing legally binding expectations in accordance with the DURSA, but does not provide the software or technical connection that allows those parties to transact information.

  Scenario 2 – Eligibility Implications: The entity may be eligible to be an eHealth Exchange Participant if it has the authority to obligate its Participant / Participant Users to comply with the DURSA and Performance and Service Specifications.

• Scenario 3: An entity that licenses software to its clients, acts as its clients’ intermediary in the exchange of information with others, and has agreements with its clients that require the clients to use the software in accordance with the terms of the DURSA.

  Scenario 3 – Eligibility Implications: The entity is eligible to be an eHealth Exchange Participant.

IV. Definitions

Applicant: The entity or agency that submits an Application for Participation.

Application for Participation (“Application”): The document that serves as an application to participate in the eHealth Exchange.

Business Associate Agreement: The document that is attached to the eHealth Exchange Participant Agreement as Addendum 1. Anyone that provides a service to a HIPAA covered entity and has access to PHI as part of providing that service is a business associate of the covered entity. eHealth Exchange is a business associate of every eHealth Exchange Participant that uses the Hub and has entered into Business Associate Agreements with every eHealth Exchange Participant.
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DURSA: Data Use and Reciprocal Support Agreement

eHealth Exchange: A network of Participants who share data in accordance with the DURSA.

Limited Production Period: A designated period of time after an organization has been issued their production digital credentials and been entered into the eHealth Exchange production directory, but is unable to begin transacting health information.

Third Party Technology: technology solutions, applications, interfaces, software, platforms, clearinghouses and other IT resources utilized by Participants to facilitate exchange.

All other capitalized terms, if not defined herein, shall have the same meaning as set forth in the DURSA.

V. References

“Restatement II of the Data Use and Reciprocal Support Agreement (DURSA)”, Version Date: August 13, 2019

VI. Related Policies and Procedures

VII. Version History

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<tr>
<th>Date</th>
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<tbody>
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<td>2/12/16</td>
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<tr>
<td></td>
<td>• Removed references to the Certified Testing Body or CTB.</td>
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<td>• Clarified roles and responsibilities of the Coordinating Committee and eHealth Exchange support staff.</td>
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<td>• Delegated authority for disposition of applications and the review and evaluation of test results by eHealth Exchange Support Staff or a subcommittee.</td>
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<td>• Increased the conditional acceptance period from 120 days to 180 days.</td>
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<td>• Added a new status called a “Limited Production Period”</td>
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<td>• Updated language to reflect newest DURSA amendment changes; Updated formatting for consistency and readability; Updated to reflect current environment and operations of eHealth Exchange</td>
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