

Coordinating Committee Operating Policy and Procedure

SUBJECT: PARTICIPATION – REVIEW AND DISPOSITION OF APPLICATIONS FOR PARTICIPATION AND DEFINITIVE PLANS		
STATUS: APPROVED by Coordinating Committee and Participants, 2.25.11	POLICY #: CC OP&P: 1	
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I. Purpose

The Coordinating Committee (CC) is responsible for supporting Participants who wish to transact Message Content with other Participants. Among the responsibilities granted to the Coordinating Committee by the Participants is the right to determine whether to admit new Participants who will be signatories to the DURSA. To fulfill this responsibility, the Coordinating Committee will review and act on applications for participation submitted by organizations that wish to become Participants. This policy outlines a framework for assessing the readiness of valid legal entities and governmental entities to become Participants in the Exchange or Members of the Coordinating Committee under a Definitive Plan.

II. Policy

Only entities that meet the eligibility requirements and are accepted by the Coordinating Committee may be Participants or Members of the Coordinating Committee.

III. Procedure

A. Eligibility Requirements

To be eligible to be a Participant or a Member of the Coordinating Committee under a Definitive Plan, the Applicant must meet all of the following general eligibility requirements:

- Be either (i) a valid legal entity, either public or private, that is a contractor, grantee or party to a cooperative agreement with a Federal government agency that addresses participation in the transaction of Message Content among Participants or (ii) a Federal agency;
- Be an organization or agency that oversees and conducts, on its own behalf and/or on behalf of its Participant Users, electronic transactions or exchanges of health information among groups of persons or organizations;
- Have the technical ability to meet the Performance and Service Specifications to electronically transact health information on its own behalf or on behalf of its Participant Users;
- 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 Participant Users to comply with applicable requirements of the DURSA;
- Intend to transact information with other Participants for a permitted purpose;
- Have sufficient financial, technical and operational resources to support the testing and operation of transactions among Participants; and
- Submit a completed Application for Participation and Definitive Plans.

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The following examples are provided as illustrations of the ways in which the Coordinating Committee may apply the general eligibility criteria to determine whether an Applicant is eligible to become a Participant. These examples are not intended to describe every entity that may submit an Application for Participation.

1. An entity that licenses gateway software to its clients that is compliant with the Performance and Service Specifications, but does not have an agreement with its clients that requires the clients to use the software to transact information only for the purposes allowed by the DURSA is not eligible to be a Participant because the entity does not have the legal authority to require its clients to comply with the applicable requirements of the DURSA.
2. An entity that facilitates the transaction of information among various parties by helping the parties to reach agreement on conduct expectations, but does not provide the gateway software that allows those parties to transact information is not eligible to be a Participant because it does not have the technical ability to meet the Performance and Service Specifications and it does not conduct exchanges of health information.
3. An entity that licenses gateway software to its clients that allows the clients to transact data with other Participants without the assistance of the entity as an intermediary is not eligible to be a Participant because the entity is not overseeing and conducting exchanges of health information.
4. An entity that licenses gateway 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 is eligible to be a Participant.

In addition to the above general eligibility requirements, to be accepted as a Member of the Coordinating Committee through a Definitive Plan, the Applicant must attest that it:

- Intends to become a signatory to the DURSA by signing the DURSA or a Joinder Agreement;
- Has written privacy and security policies as required by Section 7.01 of the DURSA;
- Meets all of the eligibility requirements set forth in this policy;
- Has a timeline for implementation of the exchange of data, which has significant milestones leading up to the live transaction of Message Content with other Participants before December 31, 2010; and
- Agrees to hold all information disclosed to it as a Member of the Coordinating Committee in confidence in accordance with Policy # CC OP&P: 6 – Information Handling.

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In addition to the above general eligibility requirements, to be accepted as a Participant, the Applicant must also:

- Execute the DURSA Joinder Agreement;
- Successfully complete the required technical validation testing in accordance with the Validation Plan;
- Be able to begin exchanging data with other Participants in production through the Participant’s successfully tested production system.

While an Applicant that submits an Application for Participation must submit a signed copy of the DURSA or Joinder Agreement with its application for participation, 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 a Participant and duly executes the Applicant’s Joinder Agreement following the Applicant’s production release of a validated system. The Coordinating Committee reserves the right to decline an Applicant admission even if such Applicant signs the DURSA.

B. Receipt of Applications

Applicants should forward an electronic copy of the completed Application and all supporting documents to onc.exchangeinfo@hhs.gov. Original signed hard copies of the Application and supporting documents should be sent to National eHealth Collaborative, ATTN: NHIN Program Manager
818 Connecticut Avenue, Suite 500, Washington, DC 20006.

ONC is requested to catalog all applications upon receipt. The record shall contain the date of receipt, the name of the Applicant, whether the application is to become a Participant or a Member of the Coordinating Committee through a Definitive Plan, and a brief description of the proposed exchange activities.

ONC is requested to verify that an Applicant has responded to each element of the application. If an Applicant has failed to respond to any applicable items on the application, ONC is requested to return the application for completion.

C. Evaluation of Applications

The Coordinating Committee shall consider, at a regularly scheduled meeting, all applications which are received by ONC at least two (2) weeks prior to the Coordinating Committee’s meeting. ONC is requested to forward applications for consideration by the Coordinating Committee to the CC Secretary for distribution to committee members at least one week prior to the meeting at which the application will be considered. Through the application, the

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Applicant shall demonstrate to the satisfaction of the Coordinating Committee that, at the time the application is submitted, it meets the applicable eligibility requirements set forth in Section III.A. of this policy or will meet such requirements at the time it becomes a Participant. When determining whether an Applicant meets the eligibility requirements, the Coordinating Committee may consider the Applicant’s past activities as a Participant, if any.

As the application is under review, the Coordinating Committee may consult with the Applicant, request additional information regarding the application and proposed services and/or transactions, suggest changes or modifications to the application including the supporting documentation or make other recommendations the Coordinating Committee deems reasonably necessary during the evaluation. In addition, the Coordinating Committee may request verification of elements of the application including screen shots, audit log excerpts, metrics or system demonstrations. The Coordinating Committee may request that the Applicant modify and resubmit the application and/or supporting documentation. If an Applicant fails, or declines, to provide requested information or modify its application, then the Coordinating Committee may defer or decline the application.

Any Applicant may withdraw its application at any time by informing the Coordinating Committee of such withdrawal. With respect to applications for participation on the Coordinating Committee through a Definitive Plan, the Coordinating Committee may consult with the remaining parties in the Definitive Plan to determine how such withdrawal impacts the status of the remaining parties and whether the Definitive Plan should continue, be modified and resubmitted, or withdrawn. If the Definitive Plan is continued or resubmitted, the Coordinating Committee will review it in accordance with this policy.

With respect to applications for participation on the Coordinating Committee through Definitive Plans, all communication by the Coordinating Committee regarding the overall contents of the application shall be with all Applicants party to the Definitive Plan unless waived by one or more of the Applicants. The Coordinating Committee may address any issues or concerns that relate primarily to one or more of the Applicants with those Applicants only.

Upon any determination for acceptance or rejection of an application, the Applicant shall be informed of the decision of the Coordinating Committee as well as supporting reasoning for the decision. If rejected, the Applicant may submit a new application for consideration by the Coordinating Committee after correcting the identified deficiencies.

In any event, ONC is requested to update the application record maintained by ONC under Section III.B., above with the decision of the Coordinating Committee.

1. Applications for Participation

Upon a determination by the Coordinating Committee that an Application for Participation is complete, the Coordinating Committee shall determine, consistent with its

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Operating Procedures, whether to preliminarily accept or reject the application and communicate this decision to ONC. The CC Secretary will communicate this determination to the Applicant.

Upon a determination by the Coordinating Committee that the Applicant meets the Eligibility Criteria in Section III.A and its responses on the application and any supporting documentation are adequate for acceptance of the Applicant as a Participant, it will request the Applicant complete all technical validation testing in accordance with the Validation Plan to assess compliance with the applicable Performance and Service Specifications for those services the Applicant will support.

At the next scheduled meeting of the Coordinating Committee after results of technical validation testing are complete and received by ONC, the Coordinating Committee shall consider the results. During consideration of the technical validation testing results, the Coordinating Committee may consult with the Applicant, 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. The Applicant shall notify the Coordinating Committee of its election to remediate or not remediate any non-conformance of its implementation of the Performance and Service Specifications: (http://healthit.hhs.gov/portal/server.pt?open=512&objID=1194&parentname=CommunityPage&parentid=6&mode=2&in_hi_userid=10882&cached=true).

If the Applicant elects not to remediate any non-conformance, the application shall be considered to be withdrawn. The Coordinating Committee may hold an application pending completion of any needed remediation, changes or modifications as well as any needed follow up technical validation testing to ensure the Applicant is able to meet the Performance and Service Specifications.

a. Acceptance

If the Applicant meets the Eligibility Criteria in Section III.A, the Applicant's responses on the application and any supporting documentation are adequate for acceptance, and the Applicant has successfully completed all technical validation testing, the Coordinating Committee shall conditionally accept the Applicant as a Participant.

The Coordinating Committee's acceptance of the Applicant as a Participant is conditioned on the Applicant being able to begin exchanging data in production with other Participants within one-hundred and twenty (120) calendar days following the date the Coordinating Committee conditionally accepts the Applicant as a Participant. Between the time that the Coordinating Committee conditionally accepts the Applicant as a Participant and the Applicant becomes a Participant, the following activities will occur:

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- ONC shall coordinate with the Applicant regarding the specific date on which the Applicant’s system will be operational, in production and ready to exchange information with other Participants in production.
- No more than thirty (30) days before an Applicant is scheduled to begin exchanging information with Participants in production, ONC will arrange for the Coordinating Committee Chair to execute the DURSA Joinder Agreement. The National eHealth Collaborative (NeHC) will maintain documentation related to the application process, including copies of the executed DURSA Joinder Agreements.
- ONC will issue the Applicant its Production Digital Credentials.
- Applicant shall provide ONC the required information to add the Applicant to the service registry. ONC will confirm that the information supplied is accurate by testing the information provided.
- ONC will publish the Applicant’s Digital Credentials in the production registry. At this point the Applicant becomes activated as a Participant. Other Participants will be able to identify the new Participant and begin transacting health information with that new Participant.

If an Applicant is unable to go into production as a Participant within the one hundred and twenty (120) calendar day timeframe or on another date mutually agreed upon by the Coordinating Committee and Participant, the Applicant may request an extension from the Coordinating Committee. The Coordinating Committee may accept or deny the extension request. If the extension request is denied, it shall have the same effect as a rejection and be treated in accordance with Section III.C.1.b. of this policy. If the extension request is accepted, it shall result in the extension of the timeframe for the Applicant to go into production. The Coordinating Committee, Applicant and ONC will work together to identify a new specific date on which the Applicant's system will be operational, in production and ready to exchange information with other Participants in production. Applicants shall have the ability to submit multiple extension requests, each of which the Coordinating Committee will review and disposition.

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

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b. Rejection

If, after reasonable consultation and requests and the reasonable opportunity to do so, the Applicant has been unable to meet the eligibility criteria or to provide adequate responses to those items on the application or sufficient supporting documentation as reasonably requested by the Coordinating Committee; has been unable to successfully complete all technical validation testing and/or remediation; or has been unable to go into production transacting data with other Participants by the agreed upon date, the Applicant's Application for Participation may be rejected.

2. Applications to Serve on the Coordinating Committee Through a Definitive Plan

Upon a determination by the Coordinating Committee that an application to serve on the Coordinating Committee through a Definitive Plan ("Definitive Plan") is complete, the Coordinating Committee shall determine, consistent with its Operating Procedures, whether to accept or reject the Definitive Plan and request that the CC Secretary communicate this decision to the Applicant. Acceptance may be unconditional or may be conditioned upon the Applicant reasonably achieving milestones set forth in the Definitive Plan or other requirements the Coordinating Committee deems reasonably necessary to best assure that the Definitive Plan is met.

a. Acceptance

If the Applicant meets the Eligibility Criteria in Section III.A and the Applicant's responses on the application and any supporting documentation are adequate for acceptance, the Coordinating Committee may accept the Applicant as a member of the Coordinating Committee through a Definitive Plan. Upon acceptance, each Applicant (now a "Definitive Plan Member of the CC") shall be promptly notified of the acceptance including any conditions placed upon the acceptance of the Definitive Plan by the Coordinating Committee. Each Definitive Plan Member of the CC shall appoint an individual representative to be added to the Coordinating Committee after which the Definitive Plan Member of the CC may enjoy the full benefits of membership on the Coordinating Committee consistent with the Coordinating Committee's Operating Procedures.

After conditional acceptance of a Definitive Plan, should the conditions not be reasonably met given all the facts and circumstances surrounding the Definitive Plan and upon reasonable notice and discussion, the Coordinating Committee may terminate a Definitive Plan consistent with its Operating Procedures.

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b. Rejection

If, after reasonable consultation and requests and the reasonable opportunity to do so, the Applicant has been unable to meet the Eligibility Criteria or provide adequate responses to those items on the application or sufficient supporting documentation as reasonably requested by the Coordinating Committee, the Applicant's application to serve as a member of the Coordinating Committee through a Definitive Plan may be rejected.

IV Definitions:

Applicant: The entity or agency that submits an Application for Participation or an Application to Serve on the Coordinating Committee through a Definitive Plan.

Application for Participation: The document that serves as an application to participate in the electronic exchange of health information with other organizations, entities and governmental agencies using an agreed upon set of national standards, services and policies developed by or under the auspices of the Office of the National Coordinator for Health IT (ONC) in the U.S. Department of Health and Human Services.

DURSA: Data Use and Reciprocal Support Agreement

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

VI References:

DURSA
Application for Participation

VII Related Policies and Procedures:

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VIII Version History:

Date	Author	Comment
1 6/24/09	Randy Sermons	Original – NHIN Review and Acceptance Operating Policies and Procedures for Participation and Definitive Plan were separate.
2 10/19/09	Mariann Yeager	Combined the two operating policies and procedures into a single document. Created a separate document for Participation Changes, Suspension and Termination.
3 10/21/09	Mariann Yeager	Included edits / comments from the 10/20 Team review call.
4 10/28/09	Mariann Yeager	Revised based upon input from the 10/28 Team review call.
5 11/4/09	Aaron Seib, Randy Sermons, Erin Whaley, Mariann Yeager	Revised based upon input from the 11/3 Team review call.
6 11/27/09	Erin Whaley and Steve Gravely	Revised based on input from the 11/5 and 11/19 CC calls.
7 12/2/09		Approved by CC
8 10/11/10	Erin Whaley and Steve Gravely	Revised to included refined eligibility criteria, remove the term “NHIN” and clearly describe the sequence of events once an Application has been conditionally accepted as a Participant.
9 2/15/11	Erin Whaley and Steve Gravely	Revisions based on recommendations from Operations Tiger Team.
10 2/25/11		Approved by CC