Restatement II of the Data Use and Reciprocal Support Agreement (DURSA)

Version Date: August 13, 2019

Overview

Introduction

In 2008, as part of the Nationwide Health Information Network Phase II Trial Implementations, a multi-disciplinary team was assembled to develop a comprehensive agreement that would create a legal framework using existing law for the electronic exchange of health data. This agreement, called the Data Use and Reciprocal Support Agreement or DURSA, was first executed by a number of Federal agencies and non-Federal organizations (the "Participants") beginning in November 2009.

This Overview was prepared to facilitate the reader's understanding of the DURSA, and to place the DURSA into an appropriate context.

What is the eHealth Exchange?

The eHealth Exchange began as an initiative under the leadership of the Office of the National Coordinator for Health Information Technology (ONC) known as the Nationwide Health Information Network (NHIN or NwHIN). The successful development of the eHealth Exchange allowed it to be transferred from an ONC incubator to a public-private effort in 2012 supported by The Sequoia Project. The eHealth Exchange is a data sharing network of governmental and non-governmental exchange partners who share information under a multi-purpose set of standards and services which are designed to support a broad range of information exchange activities using various technical platforms and solutions. The eHealth Exchange does not favor any vendor, software, technology or particular approach to information exchange. It is open to anyone that agrees to comply with the eHealth Exchange Specifications and other requirements.

Why is a Data Use and Reciprocal Support Agreement (DURSA) Needed?

The DURSA is a legal agreement created to promote and establish trust among the Participants in the eHealth Exchange. It codifies a common set of trust expectations into an enforceable legal framework, and eliminates the need for point-to-point agreements.

What is the Data Use and Reciprocal Support Agreement (DURSA)?

The DURSA is the legal, multi-party trust agreement that is entered into voluntarily by all entities, organizations and Federal agencies that desire to engage in electronic health information exchange through the eHealth Exchange. Those who sign the DURSA or its Joinder Agreement are known as "Participants."

The DURSA builds upon the various legal requirements that Participants are already subject to and describes the mutual responsibilities, obligations and expectations of all Participants under the

Agreement. All of these responsibilities, obligations and expectations create a framework for safe and secure health information exchange, and are designed to promote trust among Participants and protect the privacy, confidentiality and security of the health data that is shared.

The DURSA is based upon the existing body of law (Federal, state, local) applicable to the privacy and security of health information and is supportive of the current policy framework for health information exchange. The DURSA is a legally enforceable contract that represents a framework for broad-based information exchange among a set of trusted entities. The Agreement reflects consensus among the state-level, federal and private entities who were involved in the development of the DURSA regarding the following issues:

- Multi-Party Agreement
- Participants Actively Engaged in Health Information Exchange
- Privacy and Security Obligations
- Requests for Information Based on a Permitted Purpose
- Duty to Respond
- Future Use of Data Received from Another Participant
- Respective Duties of Submitting and Receiving Participants
- Autonomy Principle for Access
- Use of Authorizations to Support Requests for Data
- Participant Adverse Security Event Notification
- Mandatory Non-Binding Dispute Resolution
- Allocation of Liability Risk

The DURSA is an organic, living document that will evolve over time.

An initial group of Participants executed the first production level DURSA in 2009 to support the first set of electronic health information exchange activities in production under the Agreement. Since then, other entities wishing to transact health information electronically using the agreed upon standards, services and policies have executed the DURSA. Additional entities are expected to execute the Agreement over time. The legal, policy, technical and business environment has changed since the first version of the DURSA and, there is every reason to think, that it will continue to change over time.

Below is a quick summary of the DURSA versions as of 2019. Prior versions of the DURSA can be found here: http://ehealthexchange.org/onboarding/dursa/

2009- The DURSA was signed by the very first eHealth Exchange Participants.

2011- The DURSA was amended in 2011 to remove all references to "Nationwide Health Information Network" and replace it with "Network;" modify the composition of the Coordinating Committee to better reflect the growth of the Network; strengthen Network security by requiring

all Participants to identity proof all Participant Users; and allow the Coordinating Committee to adopt Operating Policies and Procedures to supplement the DURSA.

2014- The DURSA was again amended in 2014 to remove the specific composition of the Coordinating Committee from the DURSA and include it in a new Operating Policy and Procedure, given that the type of organizations wishing to become Participants was changing and the expectation that the Coordinating Committee membership would need to change over time.

2019- The DURSA is being amended and restated to incorporate a number of revisions that eHealth Exchange has been tracking for several years. Some of these are very substantive, such as expanding the definition of Permitted Purposes, and others are more technical in nature. The timing of amending the DURSA now is driven by the desire for the eHealth Exchange to join Carequality as an Implementer. The eHealth Exchange Coordinating Committee has explored the merits of joining Carequality and has decided that doing so is in the best interests of eHealth Exchange. The DURSA, as currently written, does not give the Coordinating Committee the authority to sign the Carequality Coordination Agreement and become an Implementer. One of the amendments being proposed is to allow the Coordinating Committee to enter into agreements with other data sharing networks like Carequality.

Can the DURSA be Used for Other Purposes?

The DURSA was developed for a specific purpose – to establish the legal framework and to support the trust framework for health information exchange using an agreed upon set of standards, services and policies. Others may find this document helpful or informative for other purposes, for instance, when addressing practical issues related to other types of information exchange models. The DURSA is not intended to be used, however, for other purposes outside of the purpose for which it has been created. As a result, entities interested in using this Agreement for other information exchange purposes are encouraged to seek their own legal counsel regarding the applicability and appropriateness of the DURSA to other settings.

Data Use and Reciprocal Support Agreement

This Restatement II of the Data Use and Reciprocal Support Agreement ("DURSA" or the "Agreement") is made and entered into by and between the undersigned (hereinafter referred to individually as "Participant" and collectively as "Participants") as of the Effective Date.

WITNESSETH:

WHEREAS, the Participants who previously have executed the Data Use and Reciprocal Support Agreement dated September 30, 2014, desire to amend and restate the Agreement in its entirety in order to accommodate developments that have occurred since then for the promotion and expansion of health information exchange;

WHEREAS, the Participants desire to electronically Transact, on their own behalf or on behalf of their Participant Users, health information among Participants using the Performance and Service Specifications;

WHEREAS, the Participants are (i) organizations that oversee and conduct, on their own behalf and/or on behalf of their Participant Users, electronic transactions or exchanges of health information among groups of persons or organizations; (ii) federal, state, tribal or local governments, agencies or instrumentalities that need to exchange health information with others as part of their official function; (iii) organizations that support program activities or initiatives that are involved in healthcare in any capacity and have the technical ability to meet the applicable Performance and Service Specifications to electronically transact health information on their own behalf or on behalf of their Participant Users; and have the organizational infrastructure and legal authority to comply with the obligations in this Agreement and to require their Participant Users to comply with applicable requirements in this Agreement;

WHEREAS, the relationship between the Participant and the individuals whose records are available within or through their respective Systems varies from Participant to Participant and, in some cases, there is no relationship at all;

WHEREAS, as a condition of Transacting information with other Participants, each Participant must enter into this Data Use and Reciprocal Support Agreement and has agreed to do so by executing this Agreement or the Joinder Agreement;

NOW, THEREFORE, for and in consideration of the mutual covenants herein contained, the Participants hereto mutually agree as follows:

1. **Definitions.** For the purposes of this Agreement, the following terms shall have the meaning ascribed to them below. All defined terms are capitalized throughout this Agreement.
    a. **Applicant** shall mean anyone that submits an application to become an eHealth Exchange Participant.
    b. **Applicable Law** shall mean: (i) for the Participants that are not Federal Participants, all applicable statutes and regulations of the State(s) or

jurisdiction(s) in which the Participant operates, as well as all applicable Federal statutes, regulations, standards and policy requirements; (ii) for the Federal Participants, all applicable Federal statutes, regulations, standards and policy requirements.

c. **Authorization** shall have the meaning and include the requirements set forth at 45 CFR § 164.508 of the HIPAA Regulations and include any similar but additional requirements under Applicable Law.

d. **Adverse Security Event** shall mean the unauthorized acquisition, access, disclosure, or use of unencrypted Message Content while in the process of being transacted in a manner permitted by this Agreement by anyone who is not a Participant or Participant User or by a Participant or Participant User in any manner that is not a Permitted Purpose under this Agreement. For the avoidance of doubt, an "Adverse Security Event" under this Agreement does not include the following:

(i) any unintentional acquisition, access, disclosure, or use of Message Content by an employee or individual acting under the authority of a Participant or Participant User if—

(I) such acquisition, access, disclosure, or use was made in good faith and within the course and scope of the employment or other professional relationship of such employee or individual, respectively, with the Participant or Participant User; and

(II) such unencrypted Message Content is not further acquired, accessed, disclosed or used by such employee or individual; or

(ii) any acquisition, access, disclosure or use of information contained in or available through the Participant's System where such acquisition, access, disclosure or use was not directly related to Transacting Message Content.

e. **Business Associate** shall have the meaning set forth at 45 C.F.R. § 160.103 of the HIPAA Regulations.

f. **Common Participant Resources** shall mean software, utilities and automated tools made available for use in connection with the Transaction of Message Content pursuant to this Agreement and which have been designated as "Common Participant Resources" by the Coordinating Committee pursuant to the Operating Policies and Procedures.

g. **Confidential Participant Information**, for the purposes of this Agreement, shall mean proprietary or confidential materials or information of a Discloser in any medium or format that a Discloser labels as such upon disclosure. Confidential Participant Information includes, but is not limited to: (i) the Discloser's designs, drawings, procedures, trade secrets, processes, specifications, source code, System architecture, security measures, research and development, including, but not limited to, research protocols and findings, passwords and identifiers, new products, and marketing plans; (ii) proprietary financial and business information

of a Discloser; and (iii) information or reports provided by a Discloser to a Receiving Party pursuant to this Agreement. Notwithstanding any label to the contrary, Confidential Participant Information does not include Message Content; any information which is or becomes known publicly through no fault of a Receiving Party; is learned of by a Receiving Party from a third party entitled to disclose it; is already known to a Receiving Party before receipt from a Discloser as documented by Receiving Party's written records; or, is independently developed by Receiving Party without reference to, reliance on, or use of, Discloser's Confidential Participant Information. Message Content is excluded from the definition of Confidential Participant Information because other provisions of the DURSA address the appropriate protections for Message Content.

h. **Covered Entity** shall have the meaning set forth at 45 C.F.R. § 160.103 of the HIPAA Regulations.

i. **Digital Credentials** shall mean a mechanism that enables Participants to electronically prove their identity and their right to Transact Message Content with other Participants.

j. **Discloser** shall mean a Participant that discloses Confidential Participant Information to a Receiving Party.

k. **Dispute** shall mean any controversy, dispute, or disagreement arising out of or relating to this Agreement.

l. **Dispute Resolution Subcommittee** shall mean the subcommittee of the Coordinating Committee that is established pursuant to, and performs the tasks described in, Attachment 6 of this Agreement.

m. **eHealth Exchange** shall mean the data sharing network which was developed under the auspices of the Office of the National Coordinator for Health Information Technology and consists of governmental and non-governmental exchange partners who share information under a multi-purpose set of standards and services which are designed to support a broad range of information exchange activities using various technical platforms and solutions

n. **Effective Date** shall mean the date specified in Section 23.12 of this Agreement.

o. **Federal Participants** shall mean those Participants that are Federal agencies.

p. **Governmental Participants** shall mean collectively those Participants that are local, state or Federal agencies.

q. **Health Care Operations** shall have the meaning set forth at 45 C.F.R. § 164.501 of the HIPAA Regulations.

r. **Health Care Provider** shall have the meaning set forth at 45 C.F.R. § 160.103 of the HIPAA Regulations.

s. **Health Information Service Provider or HSP** shall mean a company or other organization that will support one or more Participants by providing them with operational, technical, or health information exchange services.

t. **Health Plan** shall have the meaning set forth at 45 C.F.R. § 160.103 of the HIPAA Regulations.

u. **HIPAA Regulations** shall mean the Standards for Privacy of Individually Identifiable Health Information, the Security Standards for the Protection of Electronic Protected Health Information and the Breach Notification Rule (45 C.F.R. Parts 160 and 164) promulgated by the U.S. Department of Health and Human Services under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, as in effect on the Effective Date of this Agreement and as may be amended, modified, or renumbered.

v. **Joinder Agreement** shall mean the agreement that each New Participant signs pursuant to which the New Participant agrees to be bound by this Agreement. The form of the Joinder Agreement is attached hereto as Attachment 7.

w. **Message** shall mean an electronic transmission of Message Content Transacted between Participants using the Specifications. Messages are intended to include all types of electronic transactions as specified in the Performance and Service Specifications, including the data or records transmitted with those transactions.

x. **Message Content** shall mean that information contained within a Message or accompanying a Message using the Specifications. This information includes, but is not limited to, Protected Health Information (PHI), de-identified data (as defined in the HIPAA Regulations at 45 C.F.R. § 164.514), individually identifiable information, pseudonymized data, metadata, Digital Credentials, and schema.

y. **Network** shall mean the eHealth Exchange.

z. **Network Utilities** shall mean any shared infrastructure used to facilitate the transmission of Message Content for the Network including, but not limited to, gateway services, healthcare directory, master patient indices, record locater services.

aa. **New Participant** shall mean an organization or agency that is approved as a Participant by the Coordinating Committee pursuant to the Operating Policies and Procedures and Section 23.03 of this Agreement.

bb. **Non-Federal Participants** shall mean collectively those Participants which are not Federal Participants.

cc. **Non-Governmental Participants** shall mean collectively those Participants which are not Governmental Participants.

dd. **Notice or Notification** shall mean a written communication, unless otherwise specified in this Agreement, sent to the appropriate Participant's representative at

the address listed in Attachment 4 or the Coordinating Committee in accordance with Section 22.

ee. **ONC** shall mean the Office of the National Coordinator for Health Information Technology in the Office of the Secretary, U.S. Department of Health and Human Services.

ff. **Operating Policies and Procedures** shall mean the policies and procedures adopted by the Coordinating Committee that describe (i) management, operation and maintenance of the Performance and Service Specifications; (ii) qualifications, requirements and activities of Participants when Transacting Message Content with other Participants; and (iii) support of the Participants who wish to Transact Message Content with other Participants. The Operating Policies and Procedures are attached hereto as Attachment 3, as amended from time to time in accordance with Section 11.03.

gg. **Participant** shall mean any (i) organization 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; (ii) federal, state, tribal or local governments, agencies or instrumentalities that need to exchange health information with others as part of their official function; (iii) organization that supports program activities or initiatives that are involved in healthcare in any capacity and has the technical ability to meet the applicable Performance and Service Specifications to electronically transact health information on its own behalf or on behalf of its Participant Users; has the organizational infrastructure and legal authority to comply with the obligations in this Agreement and to require their Participant Users to comply with applicable requirements in this Agreement.. Participants may act as either a Submitter, Recipient or both when Transacting Message Content.

hh. **Participant Access Policies** shall mean those policies and procedures of a Participant that govern the Participant Users' ability to transact information using the Participant's system including, but not limited to, the Transaction of Message Content.

ii. **Participant User** shall mean any person who has been authorized to Transact Message Content through the respective Participant's System in a manner defined by the respective Participant. "Participant Users" may include, but are not limited to, Health Care Providers; Health Plans; individuals whose health information is contained within, or available through, a Participant's System; and employees, contractors, or agents of a Participant. A Participant User may act as either a Submitter, Recipient or both when Transacting Message Content.

jj. **Payment** shall have the meaning set forth at 45 C.F.R. § 164.501 of the HIPAA Regulations.

kk. **Performance and Service Specifications** shall mean the Validation Plan and the Specifications, as well as any implementation guidance, migration plans and

other technical materials and resources approved by the Coordinating Committee in accordance with Section 10.03 of this Agreement.

ll. **Permitted Purpose** shall mean one of the following reasons for which Participants or Participant Users may legitimately Transact Message Content:

1. Treatment, Payment, Health Care Operations, and Authorization based disclosures as defined by HIPAA;

2. Transaction of Message Content related to value based payment models, alternative payment arrangements or financial risk sharing models of any nature whether for Medicare, Medicaid, other federal programs, commercial payers or employer self-insured arrangements. This could include, but is not limited to, participation in Medicare bundled payments, the Medicare Shared Savings Program, other Medicare Alternate Payment programs, Medicaid Managed Care programs or commercial value-based payment programs;

3. Transaction of Message Content for certain specialized government functions which are necessary to fulfill an agency's statutory obligations for programs the agency administers including, but not limited to: (i) activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission; (ii) for the purpose of the Department of Veterans Affairs determining the individual's eligibility or entitlement to benefits under the VA upon separation or discharge of the individual from military service; (iii) to determine eligibility for or entitlement to or provision of other government benefits; (iv) for activities related to eligibility for or enrollment in a health plan that is a government program; (v) for administering a government program providing public benefits, to coordinate covered functions; or, (vi) to improve administration and management relating to the covered functions of such government programs;

4. Public health activities and reporting as permitted by Applicable Law, including the HIPAA Regulations at 45 C.F.R. § 164.512(b) or 164.514(e);

5. Any purpose to demonstrate meaningful use of certified electronic health record technology by the (i) Submitter, (ii) Recipient or (iii) Covered Entity on whose behalf the Submitter or the Recipient may properly Transact Message Content under this Agreement, provided that the purpose is not otherwise described in subsections 1-46 of this definition and the purpose is permitted by Applicable Law, including but not limited to the HIPAA Regulations. "Meaningful use of certified electronic health record technology" shall have the meaning assigned to it in the regulations promulgated by the Department of Health and Human Services under the American Recovery and Reinvestment Act, Sections 4101 and 4102;

6. Transaction of Message Content in support of an individual's: (i) right to access their health information or (ii) right to direct with whom their

information can be shared or where their information should be sent. For the avoidance of doubt, a Participant may be prevented from disclosing information due to Applicable Law even though the individual asserts this Permitted Purpose;

mm. **Protected Health Information or PHI** shall have the meaning set forth at 45 C.F.R. § 160.103 of the HIPAA Regulations.

nn. **Receiving Party** shall mean a Participant that receives Confidential Participant Information in any capacity including, but not limited to, as a member of the Coordinating Committee, from a Discloser.

oo. **Recipient** shall mean the Participant(s) or Participant User(s) that receives Message Content through a Message from a Submitter for a Permitted Purpose. For purposes of illustration only, Recipients include, but are not limited to, Participants or Participant Users who receive queries, responses, subscriptions, publications or unsolicited Messages.

pp. **Specifications** shall mean the specifications adopted by the Coordinating Committee pursuant to this Agreement to prescribe the data content, technical, and security requirements to enable the Participants to Transact Message Content. Specifications may include, but are not limited to, specific Network standards, services and policies. The Specifications are attached hereto as Attachment 1, and may be amended from time to time in accordance with Sections 10.02 and 10.03.

qq. **Submitter** shall mean the Participant(s) or Participant User(s) who submits Message Content through a Message to a Recipient for a Permitted Purpose. For purposes of illustration only, Submitters include, but are not limited to, Participants or Participant Users who push Messages with Message Content, send Messages seeking Message Content, send Messages in response to a request, send subscription Messages, or publish Messages with Message Content in response to subscription Messages.

rr. **System** shall mean software, portal, platform, or other electronic medium controlled by a Participant through which the Participant conducts its health information exchange related activities. For purposes of this definition, it shall not matter whether the Participant controls the software, portal, platform, or medium through ownership, lease, license, or otherwise.

ss. **Testing** shall mean the tests and demonstrations of a Participant's System and processes used for interoperable health information exchange, to assess conformity with the Specifications and Validation Plan.

tt. **Transact** shall mean to send, request, receive, assert, respond to, submit, route, subscribe to, or publish Message Content using the Performance and Service Specifications.

uu. **Transaction Pattern** shall mean a type of information exchange service(s) enabled by the Specifications. The Validation Plan will identify the Transaction

Pattern(s) and the Specifications required to implement each Transaction Pattern. The Transaction Patterns may be amended from time to time through amendment of the Specifications and the Operating Policies and Procedures.

vv. **Treatment** shall have the meaning set forth at 45 C.F.R. § 164.501 of the HIPAA Regulations.

ww. **Use Case** shall mean a particular activity involving Transacting Message Content using the Network in order to support a specific function or facilitate an identified outcome.

xx. **Validation Plan** shall mean the framework for Testing and demonstrations for parties seeking to become Participants. The Validation Plan is attached hereto as Attachment 2, and as amended from time to time in accordance with Sections 10.02 and 10.03.

2. **Incorporation of Recitals.** The Recitals set forth above are hereby incorporated into this Agreement in their entirety and shall be given full force and effect as if set forth in the body of this Agreement.

3. **Purpose of the DURSA**.

3.01. The purpose of this Agreement is to provide a legal framework that will enable Participants to Transact Message Content with other Participants using the Performance and Service Specifications.

3.02. This Agreement hereby amends the Restatement I of the Data Use and Reciprocal Support Agreement dated September 30, 2014, in its entirety, which has been entered into by some of the Participants.

4. **Coordinating Committee**.

4.01. **Formation of the Coordinating Committee**. To support the Participants who wish to Transact Message Content with other Participants, there shall be a Coordinating Committee.

4.02. **Composition of the Coordinating Committee**. The Coordinating Committee shall be composed primarily of representatives of the Participants. To allow for future flexibility in response to the evolving health information exchange environment, the exact composition of the Coordinating Committee shall be set forth in Operating Policies and Procedures adopted pursuant to the process in Section 11.03, Operating Policies and Procedures Change Process."

4.03. **Grant of Authority**. The Participants hereby grant to the Coordinating Committee the right to provide oversight, facilitation and support for the Participants who Transact Message Content with other Participants by conducting activities including, but not limited to, the following:

a. Determining whether to admit a New Participant;

b. Maintaining a definitive list of all Transaction Patterns supported by each of the Participants;

c. Evaluating requests for and approving new Use Cases;

d. Developing and amending Operating Policies and Procedures in accordance with Section 11 of this Agreement;

e. Receiving reports of Adverse Security Events and acting upon such reports in accordance with Section 14.04 of this Agreement (Adverse Security Event Notification);

f. Suspending or terminating Participants in accordance with Section 19 of this Agreement (Suspension and Termination);

g. Resolving Disputes between Participants in accordance with Section 21 of this Agreement (Dispute Resolution);

h. Managing the amendment of this Agreement in accordance with Section 23.02 of this Agreement;

i. Approving the adoption of Network Utilities;

j. Evaluating, prioritizing and adopting new Performance and Service Specifications, changes to existing Performance and Service Specifications and the artifacts required by the Validation Plan in accordance with Section 10 of this Agreement;

k. Maintaining a process for managing versions of the Performance and Service Specifications, including migration planning;

l. Coordinating with ONC to help ensure the interoperability of the Performance and Service Specifications with other health information exchange initiatives including, but not limited to, providing input into the broader ONC specifications activities;

m. Entering into agreements to broaden access to data to enhance connectivity across platforms and networks as provided in accordance with Operating Policies and Procedures which shall include an express opt-out right for every Participant; and

n. Fulfilling all other responsibilities delegated by the Participants to the Coordinating Committee as set forth in this Agreement.

To the extent permitted under Applicable Law, this grant of authority to the Coordinating Committee is unconditional and does not require any further consideration or action by any Participant.

The Coordinating Committee shall have the authority to unilaterally delegate to the Chairperson of the Coordinating Committee or a subcommittee of the Coordinating Committee any of the authorities, duties or responsibilities granted to the Coordinating Committee by the Participants. Any delegation of the Coordinating Committee's authorities, duties or responsibilities to a designee other than the Chairperson of the Coordinating Committee or a subcommittee of the Coordinating Committee shall be

accomplished through the adoption of Operating Policies and Procedures pursuant to Section 11.03.

4.04. In no case shall a Participant be required to disclose PHI to the Coordinating Committee in violation of Applicable Law. The Coordinating Committee shall not retaliate against a Participant that decides not to disclose PHI upon the request of the Coordinating Committee.

4.05. Members of the Coordinating Committee shall carry out their duties in a diligent and responsible manner as more specifically identified in an applicable Operating Policy and Procedure.

5. **Use of Message Content**.

5.01. **Permitted Purpose**. Participants shall only Transact Message Content for a Permitted Purpose as defined in this Agreement. Each Participant shall require that its Participant Users comply with this Section 5.01.

5.02. **Permitted Future Uses.** Subject to this Section 5.02 and Section 19.07, Recipients may retain, use and re-disclose Message Content in accordance with Applicable Law and the Recipient's record retention policies and procedures. If the Recipient is a Participant that is a Business Associate of its Participant Users, such Participant may retain, use and re-disclose Message Content in accordance with Applicable Law and the agreements between the Participant and its Participant Users.

5.03. **Management Uses**. The Coordinating Committee may request information from Participants, and Participants shall provide requested information, for the purposes listed in Section 4.03 of this Agreement. Notwithstanding the preceding sentence, in no case shall a Participant be required to disclose PHI to the Coordinating Committee in violation of Applicable Law. Any information, other than Message Content, provided by a Participant to the Coordinating Committee shall be labeled as Confidential Participant Information and shall be treated as such in accordance with Section 16.

6. **System Access Policies**.

6.01. **Autonomy Principle**. Each Participant shall have Participant Access Policies. Each Participant acknowledges that Participant Access Policies will differ among them as a result of differing Applicable Law and business practices. Each Participant shall be responsible for determining whether and how to Transact Message Content based on the application of its Participant Access Policies to the information contained in the Message. The Participants agree that each Participant shall comply with the Applicable Law, this Agreement, and all applicable Performance and Service Specifications in Transacting Message Content.

6.02. **Identification**. Each Participant shall employ a process by which the Participant, or its designee, validates sufficient information to uniquely identify each person seeking

to become a Participant User prior to issuing credentials that would grant the person access to the Participant's System.

6.03. **Authentication**. Each Participant shall employ a process by which the Participant, or its designee, uses the credentials issued pursuant to Section 6.02 to verify the identity of each Participant User prior to enabling such Participant User to Transact Message Content.

7. **Enterprise Security**.

7.01. **General**. Each Participant shall be responsible for maintaining a secure environment that supports the operation and continued development of the Performance and Service Specifications. Participants shall use appropriate safeguards to prevent use or disclosure of Message Content other than as permitted by this Agreement, including appropriate administrative, physical, and technical safeguards that protect the confidentiality, integrity, and availability of that Message Content. Appropriate safeguards for Non-Federal Participants shall be those identified in the HIPAA Security Rule, 45 C.F.R. Part 160 and Part 164, Subparts A and C, as safeguards, standards, "required" implementation specifications, and "addressable" implementation specifications to the extent that the "addressable" implementation specifications are reasonable and appropriate in the Participant's environment. If an "addressable" implementation specification is not reasonable and appropriate in the Participant's environment, then the Participant must document why it would not be reasonable and appropriate to implement the implementation specification and implement an equivalent alternative measure if reasonable and appropriate. Appropriate safeguards for Federal Participants shall be those required by Applicable Law related to information security. Each Participant shall, as appropriate under either the HIPAA Regulations, or under Applicable Law, have written privacy and security policies in place by the Participant's respective Effective Date. Participants shall also be required to comply with any Performance and Service Specifications or Operating Policies and Procedures adopted by the Coordinating Committee, respectively, that define requirements and expectations for Participants with respect to enterprise security.

7.02. **Malicious Software**. Each Participant shall ensure that it employs security controls that meet applicable industry or Federal standards so that the information and Message Content being Transacted and any method of Transacting such information and Message Content will not introduce any viruses, worms, unauthorized cookies, trojans, malicious software, "malware," or other program, routine, subroutine, or data designed to disrupt the proper operation of a System or any part thereof or any hardware or software used by a Participant in connection therewith, or which, upon the occurrence of a certain event, the passage of time, or the taking of or failure to take any action, will cause a System or any part thereof or any hardware, software or data used by a Participant in connection therewith, to be improperly accessed, destroyed, damaged, or otherwise made inoperable. In the absence of applicable industry standards, each Participant shall use all commercially reasonable efforts to comply with the requirements of this Section.

8. **Equipment and Software**. Each Participant shall be responsible for procuring, and assuring that its Participant Users have or have access to, all equipment and software necessary for it to Transact Message Content. Each Participant shall ensure that all computers and electronic devices owned or leased by the Participant and its Participant Users to be used to Transact Message Content are properly configured, including, but not limited to, the base workstation operating system, web browser, and Internet connectivity.

9. **Monitoring and Auditing**. eHealth Exchange, acting through its agents and independent contractors, in order to confirm compliance with this Agreement, shall have the right, but not the obligation, to monitor and audit Network exchange activities. Unless prohibited by Applicable Law or, in the case of a Governmental Participant that Participant's policies or internal guidelines that it has adopted in the normal course of business, Participant agrees to cooperate with eHealth Exchange in these monitoring and auditing activities and to provide, upon the reasonable request of eHealth Exchange, information in the furtherance of eHealth Exchange's monitoring and auditing including, but not limited to, audit logs of exchange transactions and summary reports of exchange activities, to the extent that Applicant possesses such information. Each Participant represents that, through its agents, employees, and independent contractors, it shall have the ability to monitor and audit all access to and use of its System related to this Agreement, for system administration, security, and other legitimate purposes. Each Participant shall perform those auditing activities required by the Performance and Service Specifications.

10. **Performance and Service Specifications**.

    10.01. **General Compliance.**

        a. **Transaction Patterns.** Each Participant shall implement and maintain at least one Transaction Pattern as a Submitter, a Recipient or both. Each Participant shall implement and maintain a Transaction Pattern only after appropriate approval and validation by the Coordinating Committee in accordance with the Operating Policies and Procedures.

        b. **Performance and Service Specifications**. Each Participant shall comply with (i) all of the Performance and Service Specifications applicable to the Transaction Pattern(s) that the Participant implements and maintains; and (ii) those Performance and Service Specifications identified by the Coordinating Committee as applicable to all Participants.

    10.02. **Adoption of Performance and Service Specifications**. The Participants hereby grant the Coordinating Committee or its designee the right to adopt new Performance and Service Specifications, and to adopt amendments to, or repeal and replacement of, the Performance and Service Specifications at any time through the Performance and Service Specification Change Process described in Section 10.03.

    10.03. **Performance and Service Specification Change Process**.

        a. **Participant Comment Period**. Prior to approving any new, amended, repealed or replaced Performance and Service Specification, the Coordinating Committee

shall solicit and consider comments from the Participants on the new, amended, repealed or replaced Performance and Service Specification.

b. **Objection Period**. Following the Coordinating Committee's approval of the new, amended, repealed or replaced Performance and Service Specification, the Participants shall be given thirty (30) calendar days to review the approved Performance and Service Specification and register an objection if the Participant believes that the new, amended, repealed or replaced Performance and Service Specification will have a significant adverse operational or financial impact on the Participant. Such objection shall be submitted to the Coordinating Committee and contain a summary of the Participant's reasons for the objection.

c. **Approval of Changes to the Performance and Service Specifications**.

1. **Less Than One-Third of Participants Object**. If the Coordinating Committee receives objections from less than one-third of the Participants during the thirty (30) calendar day objection period, the new, amended, repealed or replaced Performance and Service Specification shall go into effect as approved by the Coordinating Committee and on the date identified by the Coordinating Committee, unless the Coordinating Committee withdraws the new, amended, repealed or replaced Performance and Service Specification prior to such date. Consistent with Section 10.03(d), the effective date identified by the Coordinating Committee may not be any earlier than the end of the thirty (30) calendar day objection period.

2. **More Than One-Third of Participants Object**. If the Coordinating Committee receives objections from one-third or more of the Participants during such thirty (30) day period, the Coordinating Committee shall review the new, amended, repealed or replaced Performance and Service Specification in light of the objections and make a determination as to how to modify the new, amended, repealed or replaced Performance and Service Specification, if at all. Once the Coordinating Committee finalizes its determination, it shall communicate this determination to the Participants and seek their approval. At least two-thirds of the Non-Governmental Participants and at least two-thirds of the Governmental Participants must approve the new, amended, repealed or replaced Performance and Service Specification for it to become effective.

d. **Implementation**. The Coordinating Committee shall provide Notice of new, amended, repealed or replaced Performance and Service Specification at least thirty (30) calendar days prior to the effective date of such new, amended, repealed or replaced Performance and Service Specification. This thirty (30) calendar day period may run concurrently with the thirty (30) calendar day objection period. Within fifteen (15) calendar days of receiving Notice of the new, amended, repealed or replaced Performance and Service Specification, a Participant may request that the Coordinating Committee delay implementation of such new, amended, repealed or replaced Performance and Service Specification based on good cause. The Coordinating Committee shall respond

to a request to delay implementation within seven (7) calendar days of receiving the request.

e. **Participant Duty to Terminate Participation**. If, as a result of a change made by the Coordinating Committee in accordance with this Section 10.03, a Participant will not be able to comply with the Performance and Service Specifications or does not otherwise desire to continue to Transact Message Content with other Participants after such change becomes effective, then such Participant shall terminate this Agreement in accordance with Section 19.02.

11. **Operating Policies and Procedures**.

11.01. **General Compliance.** Each Participant shall comply with the Operating Policies and Procedures adopted by the Coordinating Committee in accordance with this Agreement.

11.02. **Development of the Operating Policies and Procedures.** The Participants hereby grant the Coordinating Committee the power to develop new Operating Policies and Procedures, and to amend, or repeal and replace, the Operating Policies and Procedures at any time through the Operating Policies and Procedures Change Process described in Section 11.03.

11.03. **Operating Policies and Procedures Change Process**.

a. **Participant Comment Period**. Prior to approving any new, amended, repealed or replaced Operating Policies and Procedures, the Coordinating Committee shall solicit and consider comments from the Participants on the new, amended, repealed or replaced Operating Policies and Procedures.

b. **Objection Period**. Following the Coordinating Committee's approval of the new, amended, repealed or replaced Operating Policies and Procedures, the Participants shall be given thirty (30) calendar days to review the approved Operating Policies and Procedures and register an objection if the Participant believes that the new, amended, repealed or replaced Operating Policies and Procedures will have a significant adverse operational or financial impact on the Participant. Such objection shall be submitted to the Coordinating Committee and contain a summary of the Participant's reasons for the objection.

c. **Approval of Changes to the Operating Policies and Procedures**.

1. **Less Than One-Third of Participants Object**. If the Coordinating Committee receives objections from less than one-third of the Participants during the thirty (30) calendar day objection period, the new, amended, repealed or replaced Operating Policies and Procedures shall go into effect as approved by the Coordinating Committee and on the date identified by the Coordinating Committee, unless the Coordinating Committee withdraws the new, amended, repealed or replaced Operating Policies and Procedures prior to such date. Consistent with Section 11.03(d), the effective date identified by the Coordinating Committee may not be any earlier than the end of the thirty (30) day calendar objection period.

2. **More Than One-Third of Participants Object**. If the Coordinating Committee receives objections from one-third or more of the Participants during such thirty (30) calendar day period, the Coordinating Committee shall review the new, amended, repealed or replaced Operating Policies and Procedures in light of the objections and make a determination as to how to modify the new, amended, repealed or replaced Operating Policies and Procedures, if at all. Once the Coordinating Committee finalizes its determination, it shall communicate this determination to the Participants and seek their approval. At least two-thirds of the Non-Governmental Participants and at least two-thirds of the Governmental Participants must approve the new, amended, repealed or replaced Operating Policies and Procedures for them to become effective.

d. **Implementation**. The Coordinating Committee shall provide Notice of new, amended, repealed or replaced Operating Policies and Procedures at least thirty (30) calendar days prior to the effective date of such new, amended, repealed or replaced Operating Policies and Procedures. This thirty (30) calendar day period may run concurrently with the thirty (30) calendar day objection period. Within fifteen (15) calendar days of receiving Notice of the new, amended, repealed or replaced Operating Policies and Procedures, a Participant may request that the Coordinating Committee delay implementation of such new, amended, repealed or replaced Operating Policies and Procedures based on good cause. The Coordinating Committee shall respond to a request to delay implementation within seven (7) calendar days of receiving the request.

12. **Expectations of Participants.**

12.01. **Minimum Requirement for Participants that request Message Content for Treatment**. eHealth Exchange exists to promote the seamless exchange of health information across a variety of technical platforms and Health Information Networks. A core principle of eHealth Exchange is that Participants make commitments to the minimum level of data sharing that they will support so that all other Participants can know, and rely on, each Participant's commitment. All Participants that choose to participate in a specific Use Case must comply with all of the Performance and Service Specifications for a Use Case and must take measures to require that its Participant Users comply with all of the Performance and Service Specifications for a Use Case.

a. Participants that request, or allow their respective Participant Users to request, Message Content for Treatment shall have a corresponding reciprocal duty to respond to Messages that request Message Content for Treatment. A Participant shall fulfill its duty to respond by either (i) responding to the Message with the requested Message Content or, (ii) responding with a standardized response that indicates the Message Content is not available or cannot be exchanged. Nothing in this Section 12.01(a) shall require a disclosure that is contrary to a restriction placed on the Message Content by a patient pursuant to Applicable Law.

b. Each Participant that requests, or allows its respective Participant Users to request, Message Content for Treatment shall Transact Message Content with all

other Participants for Treatment, in accordance with Sections 6, 12.01(a) and 14 of this Agreement. If a Participant desires to stop Transacting Message Content with another Participant based on the other Participant's acts or omissions in connection with this Agreement, the Participant may temporarily stop Transacting Message Content with such Participant either through modification of its Participant Access Policies or through some other mechanism, to the extent necessary to address the Participant's concerns. If any such cessation occurs, the Participant shall provide a Notification to the Coordinating Committee of such cessation and the reasons supporting the cessation. The Participants shall submit the Dispute leading to the cessation to the Dispute Resolution Process in Section 21. If the cessation is a result of an Adverse Security Event that was reported to, and deemed resolved by, the Coordinating Committee pursuant to Section 14.04, the Participants involved in the Adverse Security Event and the cessation shall engage in the Dispute Resolution Process in Section 21 in an effort to attempt to reestablish trust and resolve any security concerns arising from the Adverse Security Event.

12.02. **Participant Users and Technology Partners**. Each Participant shall require that all of its Participant Users and **Technology Partners** Transact Message Content only in accordance with the terms and conditions of this Agreement, including without limitation those governing the use, confidentiality, privacy, and security of Message Content. Each Participant shall discipline appropriately any of its employee Participant Users, or take appropriate contractual action with respect to contractor Participant Users or **Technology Partners**, who fail to act in accordance with the terms and conditions of this Agreement relating to the privacy and security of Message Content, in accordance with Participant's employee disciplinary policies and procedures and its contractor and vendor policies and contracts, respectively.

12.03. **License to Common Participant Resources.** Participant is hereby granted a nonexclusive, nontransferable, revocable and limited license to Common Participant Resources solely for use as a Participant in performance of this Agreement. Participant shall not (a) sell, sublicense, transfer, exploit or, other than pursuant to this Agreement, use any Common Participant Resources for Participant's own financial benefit or any commercial purpose, or (b) reverse engineer, decompile, disassemble, or otherwise attempt to discover the source code to any Common Participant Resources. THE COMMON PARTICIPANT RESOURCES ARE PROVIDED "AS IS" AND "AS AVAILABLE" WITHOUT ANY WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NONINFRINGEMENT.

12.04. **Network Utilities.** The Coordinating Committee may approve the use of various Network Utilities to support the operation of the Network. If necessary, the Coordinating Committee may develop an Operating Policy and Procedure for implementation and use of the Network Utility by Participants. The Network Performance and Service Specifications may be updated as needed to effectively implement a Network Utility. The procedures outlined in sections 10.03 and 11.03 of

this Agreement shall be followed in developing or updating Operating Policies and Procedures or Performance and Service Specifications.

12.05. **Opt-out for new networks.** If the Coordinating Committee exercises its authority, provided to it by section 4.03(m) of this Agreement, to enter into agreements to broaden access to data to enhance connectivity across platforms and networks, the Participant may choose to opt-out of participation in those platforms or networks for any reason. Participant shall provide the Coordinating Committee written notification of its decision to opt-out. At any time, a Participant may reverse its decision to opt-out.

13. **Specific Duties of a Participant When Submitting a Message**. Whenever a Participant or Participant User acts as a Submitter by submitting a Message to another Participant or Participant User, the Submitter shall be responsible for:

13.01. Submitting each Message in compliance with Applicable Law, this Agreement, the applicable Performance and Service Specifications, and Operating Policies and Procedures including, but not limited to, representing that the Message is:

(i) for a Permitted Purpose;

(ii) submitted by a Submitter who has the requisite authority to make such a submission;

(iii) supported by appropriate legal authority for Transacting the Message Content including, but not limited to, any consent or Authorization, if required by Applicable Law; and

(iv) submitted to the intended Recipient.

13.02. Representing that assertions or statements related to the submitted Message are true and accurate, if such assertions or statements are required by the Performance and Service Specifications or Operating Policies and Procedures;

13.03. Provide evidence that the Submitter has obtained an Authorization or other evidence of an individual directed transaction, if the Submitter is requesting Message Content from another Participant or Participant User based on the Permitted Purpose described in either Section 1 (ll)(1) or Section 1(ll)(6). Nothing in this Section shall be interpreted as requiring a Submitter who is requesting Message Content to obtain or transmit an Authorization for a request based on a Permitted Purpose other than the one described in Section 1(ll)(6), even though certain other Participants or Participant Users require such Authorization to comply with Applicable Law.

13.04. For Federal Participants only, in addition to complying with Sections 13.01 through 13.03, ensuring that Messages submitted by such Federal Participant adhere to interoperability standards adopted by the Secretary of Health and Human Services, and the National Institute of Standards and Technology (NIST) and the Federal Information Processing Standards (FIPS), as applicable.

14. **Privacy and Security**.

14.01. **Applicability of HIPAA Regulations**. Message Content may contain PHI. Furthermore, some, but not all, Participants are either a Covered Entity or a Business

Associate. To support the privacy, confidentiality, and security of the Message Content, each Participant agrees as follows:

a. If the Participant is a Covered Entity, the Participant does, and at all times shall, comply with the HIPAA Regulations to the extent applicable.

b. If the Participant is a Business Associate of a Covered Entity, the Participant does, and shall at all times, comply with the provisions of its Business Associate Agreements (or for governmental entities relying upon 45 C.F.R. §164.504(e)(3)(i)(A), its Memoranda of Understanding) and Applicable Law.

c. If the Participant is a Governmental Participant, the Participant does, and at all times shall, comply with the applicable privacy and security laws and regulations.

d. If the Participant is neither a Covered Entity, a Business Associate nor a Governmental Participant, the Participant shall, as a contractual standard, at all times, at a minimum, comply with the provisions of the HIPAA Regulations set forth in Attachment 5 as if it were acting in the capacity of a Covered Entity or such other standards as decided by the Coordinating Committee.

14.02. **Business Associate Agreement**. Some Use Cases will involve the Transaction of Message Content among Participants, or their Participant Users, that result in a Participant, or Participant User, being considered a Business Associate under the HIPAA Regulations. While this will not be the general rule, when it does occur, the Participants agree that they will enter into a Business Associate Agreement in substantially the same form included in Attachment 8. Compliance with this section's requirements may be satisfied by an existing business associate agreement that includes, at a minimum, the terms listed in Attachment 8, by adopting a Business Associate Addendum, in substantially the same form included in Attachment 8, to an existing agreement or by adopting a new Business Associate Agreement in substantially the same form included in Attachment 8.

14.03. **Safeguards**. In accordance with Sections 7, 8 and 9, Participant agrees to use reasonable and appropriate administrative, physical, and technical safeguards and any Performance and Service Specifications and Operating Policies and Procedures to protect Message Content and to prevent use or disclosure of Message Content other than as permitted by Section 5 of this Agreement.

14.04. **Adverse Security Event Notification**.

a. As soon as reasonably practicable, but no later than five (5) business days after determining that an Adverse Security Event (or "Event") has occurred and is likely to have an adverse impact on the Network or another Participant, Participant shall provide a notification to the Coordinating Committee and all Participants that are likely impacted by the Event. Participant shall supplement the information contained in the notification as it becomes available and cooperate with other Participants. Notwithstanding the foregoing, Participant agrees that (a) within one (1) hour of learning that an Adverse Security Event

occurred and that such Event may involve a Federal Participant, it shall alert the Federal Participant in accordance with the procedures and contacts provided by such Federal Participant, and (b) that within twenty-four (24) hours after determining that an Adverse Security Event has occurred and is likely to have an adverse impact on a Federal Participant(s), Participant shall provide a notification to all such Participants that are likely impacted by the Event, and the Coordinating Committee, in accordance with the procedures and contacts provided by such Federal Participant. The Notification should include sufficient information for the Coordinating Committee to understand the nature of the Adverse Security Event. For instance, such Notification could include, to the extent available at the time of the Notification, the following information:

- One or two sentence description of the Adverse Security Event
- Description of the roles of the people involved in the Adverse Security Event (e.g. employees, Participant Users, service providers, unauthorized persons, etc.)
- The type of Message Content involved in the Adverse Security Event
- Participants likely impacted by the Adverse Security Event
- Number of individuals or records impacted/estimated to be impacted by the Adverse Security Event
- Actions taken by the Participant to mitigate the any unauthorized access to, use or disclosure of PHI as a result of the Adverse Security Event
- Current Status of the Adverse Security Event (under investigation or resolved)
- Corrective action taken and steps planned to be taken to prevent a similar Adverse Security Event.

The Participant shall supplement the information contained in the Notification as it becomes available and cooperate with other Participants and the Coordinating Committee in accordance with Section 20(e) of this Agreement. The Notification required by this Section 14.04 shall not include any PHI. If, on the basis of the Notification, a Participant desires to stop Transacting Message Content with the Participant that reported an Adverse Security Event, it shall stop Transacting Message Content in accordance with Section 12.01(b) of this Agreement. If, on the basis of the notification, the Coordinating Committee determines that (i) the other Participants that have not been notified of the Adverse Security Event would benefit from a summary of the Notification or (ii) a summary of the Notification to the other Participants would enhance the security of the Performance and Service Specifications, it may provide, in a timely manner, a summary to such Participants that does not identify any of the Participants or individuals involved in the Adverse Security Event.

b. Information provided by a Participant in accordance with this Section 14.04, except Message Content, may be "Confidential Participant Information." Such "Confidential Participant Information" shall be treated in accordance with Section 16.

c. This Section 14.04 shall not be deemed to supersede a Participant's obligations (if any) under relevant security incident, Adverse Security Event notification or confidentiality provisions of Applicable Law.

d. Compliance with this Section 14.04 shall not relieve Participants of any other security incident or Adverse Security Event reporting requirements under Applicable Law including, but not limited to, HIPAA or those related to consumers.

15. **Representations and Warranties**. Each Participant hereby represents and warrants the following:

15.01. **Accurate Participant Information**. Except to the extent prohibited by Applicable Law, each Participant has provided, and shall continue to provide, the Coordinating Committee with all information reasonably requested by the Coordinating Committee and needed by the Coordinating Committee to discharge its duties under this Agreement or Applicable Law, including during the Dispute Resolution Process. Any information provided by a Participant to the Coordinating Committee shall be responsive and accurate. Each Participant shall provide Notice to the Coordinating Committee if any information provided by the Participant to the Coordinating Committee materially changes. Each Participant acknowledges that the Coordinating Committee reserves the right to confirm or otherwise verify or check, in its sole discretion, the completeness and accuracy of any information provided by a Participant at any time and each Participant shall reasonably cooperate with the Coordinating Committee in such actions, given reasonable prior notice.

15.02. **Execution of the DURSA**. Prior to Transacting Message Content with other Participants, each Participant shall have executed this Agreement and returned an executed copy of this Agreement to the Coordinating Committee. In doing so, the Participant affirms that it has full power and authority to enter into and perform this Agreement and has taken whatever measures necessary to obtain all required approvals or consents in order for it to execute this Agreement. The representatives signing this Agreement on behalf of the Participants affirm that they have been properly authorized and empowered to enter into this Agreement on behalf of the Participant.

15.03. **Compliance with this Agreement**. Except to the extent prohibited by Applicable Law, each Participant shall comply fully with all provisions of this Agreement. To the extent that a Participant delegates its duties under this Agreement to a third party (by contract or otherwise) and such third party will have access to Message Content, that delegation shall be in writing and require the third party, prior to Transacting Message Content with any Participants, to agree to the same restrictions and conditions that apply through this Agreement to a Participant.

15.04. **Agreements with Participant Users**. Each Participant has valid and enforceable agreements with each of its Participant Users that require the Participant User to, at a minimum: (i) comply with all Applicable Law; (ii) reasonably cooperate with the Participant on issues related to this Agreement; (iii) Transact Message Content only for a Permitted Purpose; (iv) use Message Content received from another Participant or

Participant User in accordance with the terms and conditions of this Agreement; (v) as soon as reasonably practicable after determining that an Adverse Security Event occurred, report such Adverse Security Event to the Participant; and (vi) refrain from disclosing to any other person any passwords or other security measures issued to the Participant User by the Participant. Notwithstanding the foregoing, for Participant Users who are employed by a Participant or who are independent contractors of a Participant, compliance with this Section 15.04 may be satisfied through written policies and procedures that address items (i) through (vi) of this Section 15.04 so long as the Participant can document that there is a written requirement that the Participant User must comply with the policies and procedures.

15.05. **Agreements with Technology Partners**. To the extent that a Participant uses technology partners in connection with the Participant's Transaction of Message Content, each Participant affirms that it has valid and enforceable agreements with each of its technology partners, including HSPs, that require the technology partner to, at a minimum: (i) comply with Applicable Law; (ii) protect the privacy and security of any Message Content to which it has access; (iii) as soon as reasonably practicable after determining that an Adverse Security Event occurred, report such Adverse Security Event to the Participant; and (iv) reasonably cooperate with the other Participants to this Agreement on issues related to this Agreement, under the direction of the Participant.

15.06. **Compliance with Specifications, Policies and Procedures.** Each Participant affirms that it fully complies with the Performance and Service Specifications and the Operating Policies and Procedures as more fully discussed in Sections 10.01 and 11.01 of this Agreement.

15.07. **Creation of Test Data**. Certain Participants agreed to anonymize PHI to create Test Data to be used by other Participants for Testing. Any Test Data that has been created, or will be created in the future, shall not contain PHI and has been, or will be, created in accordance with the Validation Plan.

15.08. **Accuracy of Message Content**. When acting as a Submitter, each Participant, in accordance with Section 17.02, hereby represents that at the time of transmission, the Message Content it provides is (a) an accurate representation of the data contained in, or available through, its System, (b) sent from a System that employs security controls that meet industry standards so that the information and Message Content being transmitted are intended to be free from malicious software in accordance with Section 7.02, and (c) provided in a timely manner and in accordance with the Performance and Service Specifications and Operating Policies and Procedures. Other than those representations in Sections 15.08, 15.09, and 15.10, the Submitter makes no other representation, express or implied, about the Message Content.

15.09. **Express Warranty of Authority to Transact Message Content**. To the extent each Participant is a Submitter and is providing Message Content to a Recipient, each Participant represents and warrants that it has sufficient authority to Transact such Message Content.

15.10. **Use of Message Content**. Each Participant hereby represents and warrants that it shall use the Message Content only in accordance with the provisions of this Agreement.

15.11. **Compliance with Laws**. Each Participant shall, at all times, fully comply with all Applicable Law relating to this Agreement, the Transaction of Message Content for a Permitted Purpose and the use of Message Content.

15.12. **Absence of Final Orders.** Each Participant hereby represents and warrants that, as of the Effective Date, it is not subject to a final order issued by any Federal, State, local or international court of competent jurisdiction or regulatory or law enforcement organization, which will materially impact the Participant's ability to fulfill its obligations under this Agreement. Each Participant shall inform the Coordinating Committee if at any point during the term of this Agreement it becomes subject to such an order.

15.13. **Federal Program Participation.** Each non-Federal Participant hereby represents and warrants that it is not excluded, debarred, or otherwise ineligible from participating in Federal contracts, subcontracts, grants, and nonprocurement transactions ("Federal Programs"). Each non-Federal Participant shall immediately provide written Notice to the Coordinating Committee if it is suspended, proposed for debarment or other exclusion, or otherwise disqualified or declared ineligible from participating in a Federal Program for any reason, or is a party to a legal proceeding that may result in any such action.

16. **Confidential Participant Information**.

16.01. Each Receiving Party shall hold all Confidential Participant Information in confidence and agrees that it shall not, during the term or after the termination of this Agreement, redisclose to any person or entity, nor use for its own business or benefit, any information obtained by it in connection with this Agreement, unless such use or redisclosure is permitted by the terms of this Agreement.

16.02. Confidential Participant Information may be redisclosed as required by operation of law, provided that the Receiving Party immediately notifies the Discloser of the existence, terms and circumstances surrounding such operation of law to allow the Discloser its rights to object to such disclosure. If after Discloser's objection, the Receiving Party is still required by operation of law to redisclose Discloser's Confidential Participant Information, it shall do so only to the minimum extent necessary to comply with the operation of the law and shall request that the Confidential Participant Information be treated as such.

17. **Disclaimers**.

17.01. **Reliance on a System**. Each Participant acknowledges and agrees that: (i) the Message Content provided by, or through, its System is drawn from numerous sources, and (ii) it can only confirm that, at the time Message Content is Transacted, the information and Message Content Transacted are an accurate representation of data contained in, or available through, its System. Nothing in this Agreement shall be deemed to impose

responsibility or liability on a Participant related to the clinical accuracy, content or completeness of any Message Content provided pursuant to this Agreement. The Participants acknowledge that other Participants' Digital Credentials may be activated, suspended or revoked at any time or the Participant may suspend its participation; therefore, Participants may not rely upon the availability of a particular Participant's Message Content.

17.02. **Incomplete Medical Record**. Each Participant acknowledges that Message Content Transacted by Participants may not include the individual's full and complete medical record or history. Such Message Content will only include that data which is the subject of the Message and available for exchange among Participants.

17.03. **Patient Care.** Message Content obtained through a Message is not a substitute for any Participant or Participant User, if that person/entity is a Health Care Provider, obtaining whatever information he/she/it deems necessary, in his/her professional judgment, for the proper treatment of a patient. The Participant or Participant User, if he/she/it is a Health Care Provider, shall be responsible for all decisions and actions taken or not taken involving patient care, utilization management, and quality management for his/her/its respective patients and clients resulting from, or in any way related to, the use of the Network standards, services and policies agreed to by the Participants pursuant to this Agreement or the Message Content made available thereby. None of the Participants, by virtue of executing this Agreement, assume any role in the care of any patient.

17.04. **Carrier lines**. All Participants acknowledge that the Transaction of Message Content between Participants is to be provided over various facilities and communications lines, and information shall be transmitted over local exchange and Internet backbone carrier lines and through routers, switches, and other devices (collectively, "carrier lines") owned, maintained, and serviced by third-party carriers, utilities, and Internet service providers, all of which may be beyond the Participants' control. Provided a Participant uses reasonable security measures, no less stringent than those directives, instructions, and specifications contained in this Agreement, the Performance and Service Specifications, and the Operating Policies and Procedures, the Participants assume no liability for or relating to the integrity, privacy, security, confidentiality, or use of any information while it is transmitted over those carrier lines, which are beyond the Participants' control, or any delay, failure, interruption, interception, loss, transmission, or corruption of any Message Content or other information attributable to transmission over those carrier lines which are beyond the Participants' control. Use of the carrier lines is solely at the Participants' risk and is subject to all Applicable Law.

17.05. **Third Party Technology**. All Participants acknowledge that other Participants use technology solutions, applications, interfaces, software, platforms, clearinghouses and other IT resources to support exchange of message content that may be provided by third parties (Third Party Technology). Each Participant shall have agreements in place that require Third Party Technology vendors to provide reliable, stable and secure services to the Participant. However, all Participants acknowledge that Third Party Technology may be non-functional or not available at times and that this could prevent

a Participant from Transacting Message Content. Participants do not make any representations or warranties as to their Third Party Technology.

17.06. **No Warranties**. EXCEPT AS REPRESENTED IN SECTIONS 13.02 AND 15.08, MESSAGE CONTENT IS PROVIDED "AS IS" AND "AS AVAILABLE" WITHOUT ANY WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NONINFRINGEMENT. IT IS EXPRESSLY AGREED THAT IN NO EVENT SHALL THE PARTICIPANT BE LIABLE FOR ANY SPECIAL, INDIRECT, CONSEQUENTIAL, OR EXEMPLARY DAMAGES, INCLUDING BUT NOT LIMITED TO, LOSS OF PROFITS OR REVENUES, LOSS OF USE, OR LOSS OF INFORMATION OR DATA, WHETHER A CLAIM FOR ANY SUCH LIABILITY OR DAMAGES IS PREMISED UPON BREACH OF CONTRACT, BREACH OF WARRANTY, NEGLIGENCE, STRICT LIABILITY, OR ANY OTHER THEORIES OF LIABILITY, EVEN IF THE PARTICIPANT HAS BEEN APPRISED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OCCURRING. THE PARTICIPANT DISCLAIMS ANY AND ALL LIABILITY FOR ERRONEOUS TRANSMISSIONS AND LOSS OF SERVICE RESULTING FROM COMMUNICATION FAILURES BY TELECOMMUNICATION SERVICE PROVIDERS OR OTHER THIRD PARTIES.

17.07. **Performance of the Network Standards, Services and Policies.** The Participant makes no representation, express or implied, as to the performance of the Network standards, services and policies agreed to by the Participants pursuant to this Agreement. This disclaimer is not intended to diminish or limit in any way the other representations and warranties that the Participant is making in this Agreement. It is intended to recognize that the overall performance of the Network standards, services and policies agreed to by the Participants is beyond the power of any individual Participant to control.

18. **Liability.**

18.01. **Participant Liability**. As between Participants to this Agreement: Each Participant shall be responsible for its acts and omissions and not for the acts or omissions of any other Participant. In circumstances involving harm to other Participants caused by the acts or omissions of individuals who: (i) Transact Message Content or Confidential Participant Information through the Participant; (ii) improperly and without permission access a Participant's system whether directly or indirectly, lawfully or unlawfully; or (iii) use the digital credentials of a Participant or Participant User to access Message Content or Confidential Participant Information, each Participant shall be responsible for such harm to the extent that the individual's access was caused by the Participant's breach of the Agreement or its negligent conduct for which there is a civil remedy under Applicable Law. Notwithstanding any provision in this Agreement to the contrary, Participant shall not be liable for any act or omission if a cause of action for such act

or omission is otherwise prohibited by Applicable Law. This section shall not be construed as a hold harmless or indemnification provision.

18.02. **Effect of Agreement**. Except as provided in Section 17.06 ("No Warranties") and Section 21 ("Dispute Resolution"), nothing in this Agreement shall be construed to restrict a Participant's right to pursue all remedies available under law for damages or other relief arising from acts or omissions of other Participants related to this Agreement, or to limit any rights, immunities or defenses to which a Participant or Participant User may be entitled under Applicable Law.

18.03. **Coordinating Committee Liability**. Each Participant has agreed to comply with this Agreement. Accordingly, the Participants shall not hold the Coordinating Committee or any of their members liable for or relating to any impairment of the privacy, security, confidentiality, integrity, availability, or restricted use of any information on a Participant's System resulting from any Participant's actions or failures to act, except to the extent such action or failure to act was directed by the Coordinating Committee.

19. **Term, Suspension and Termination**.

19.01. **Term**. The initial term of this Agreement shall be for a period of one year commencing on the Effective Date. Upon the expiration of the initial term, this Agreement shall automatically renew for successive one-year terms unless terminated pursuant to this Section 19.

19.02. **Suspension or Termination by Participant**.

a. A Participant may voluntarily suspend its own right to Transact Message Content for a valid purpose, as determined by the Coordinating Committee, by informing the Coordinating Committee and other Participants of its voluntary suspension in accordance with the Operating Policies and Procedures. Once a Participant has properly informed the Coordinating Committee and other Participants of its voluntary suspension, neither the Participant, nor its Participant Users, shall Transact Message Content until the voluntary suspension has ended and the Participant has informed the Coordinating Committee and other Participants that the suspension has ended in accordance with the Operating Policies and Procedures. During the period of the voluntary suspension, the Participant's inability to Transact Message Content and comply with those terms of this Agreement that require Transaction of Message Content shall not be deemed a breach of this Agreement. Any voluntary suspension shall be for no longer than ten (10) consecutive calendar days or for more than forty (40) calendar days during any twelve (12) month period, unless a longer period is agreed to by the Coordinating Committee.

b. A Participant may terminate its own right to Transact Message Content by terminating this Agreement, with or without cause, by giving the Coordinating Committee at least five (5) business days prior written Notice. Once proper Notice is given, the Coordinating Committee shall be empowered to revoke the Participant's Digital Credentials as of the date of termination specified in the Notice. Once the Coordinating Committee revokes the Participant's Digital

Credentials, the Coordinating Committee shall provide Notice of such revocation to the remaining Participants.

19.03. **Suspension by Coordinating Committee**. Upon the Coordinating Committee completing a preliminary investigation and determining that there is a substantial likelihood that a Participant's acts or omissions create an immediate threat or will cause irreparable harm to another party including, but not limited to, a Participant; a Participant User; the integrity or operation of the Performance and Service Specifications; or an individual whose Message Content is Transacted using the Performance and Service Specifications; the Participants hereby grant to the Coordinating Committee the power to summarily suspend, to the extent necessary to address the threat posed by the Participant, a Participant's Digital Credentials, pending the submission and approval of a corrective action plan, as provided in this Section. Upon suspension, the Coordinating Committee shall immediately suspend the Participant's Digital Credentials and within twelve (12) hours of suspending a Participant's right to Transact Message Content (i) provide Notice of such suspension to all Participants; and (ii) provide to the suspended Participant a written summary of the reasons for the suspension. The Participant shall use reasonable efforts to respond to the suspension notice with a detailed plan of correction or an objection to the suspension within three (3) business days or, if such submission is not reasonably feasible within three (3) business days, then at the earliest practicable time. If the Participant submits a plan of correction, the Coordinating Committee shall, within five (5) business days, review and either accept or reject the plan of correction. If the plan of correction is accepted, the Coordinating Committee shall, upon completion of the plan of correction, reinstate the Participant's Digital Credentials and provide Notice to all Participants of such reinstatement. If the plan of correction is rejected, the Participant's suspension will continue, during which time the Coordinating Committee and the Participant shall work in good faith to develop a plan of correction that is acceptable to both the Participant and the Coordinating Committee. At any time after the Coordinating Committee rejects a Participant's plan of correction, either the Participant or the Coordinating Committee may submit a Dispute to the Dispute Resolution Process described in Section 21. If the Coordinating Committee and the Participant cannot reach agreement on a plan of correction through the Dispute Resolution Process, the Coordinating Committee may terminate the Participant in accordance with Section 19.04.

19.04. **Termination by Coordinating Committee**. The Participants hereby grant to the Coordinating Committee the power to terminate a Participant's right to Transact Message Content as follows:

a. After taking a suspension action in accordance with Section 19.03 when there is a substantial likelihood that the Participant's acts or omissions create an immediate threat or will cause irreparable harm to another party including, but not limited to, a Participant, a Participant User, integrity or operation of the Performance and Service Specifications, or an individual whose Message Content is Transacted using the Performance and Service Specifications; or

b. In the event a Participant is in material default of the performance of a duty or obligation imposed upon it by this Agreement and such default has not been substantially cured within thirty (30) calendar days following receipt by the defaulting Participant of written Notice thereof from the Coordinating Committee.

A Participant whose Digital Credentials are revoked by virtue of termination may appeal such revocation through the Dispute Resolution Process. However, during the pendency of any such appeal, the Participant's Digital Credentials may continue to be revoked at the discretion of the Coordinating Committee.

19.05. **Effect of Termination.** Upon any termination of this Agreement for any reason, the terminated party shall cease to be a Participant and thereupon and thereafter neither that party nor its Participant Users shall have any rights to Transact Message Content with other Participants (unless such Participant Users have an independent right to Transact Message Content through another Participant). The Coordinating Committee shall revoke a terminated Participant's Digital Credentials, which will terminate Participant's ability to Transact Message Content. Once the Coordinating Committee revokes the Participant's Digital Credentials, the Coordinating Committee shall provide Notice of such revocation to the remaining Participants. In the event that any Participant(s) is terminated, this Agreement will remain in full force and effect with respect to all other Participants. Certain provisions of this Agreement survive termination, as more fully described in Section 23.05 (Survival Provisions).

19.06. **Confidential Participant Information**. All information used, provided, or created in accordance with this Section 19, except for Message Content, shall be labeled as "Confidential Participant Information" and shall be treated as such in accordance with Section 16.

19.07. **Disposition of Message Content on Termination**. At the time of termination, Recipient may, at its election, retain Message Content on Recipient's System in accordance with the Recipient's document and data retention policies and procedures, Applicable Law, and the terms and conditions of this Agreement, including Section 5.02.

20. **Cooperation**. Each Participant understands and acknowledges that numerous activities with respect to this Agreement shall likely involve another Participant's employees, agents, and third party contractors, vendors, or consultants. To the extent not legally prohibited, each Participant shall: (a) cooperate fully with the Coordinating Committee, each other Participant, and any such third parties with respect to such activities as they relate to this Agreement; (b) provide such information to the Coordinating Committee, each other Participant, or such third parties as they may reasonably request for purposes of performing activities related to this Agreement; (c) devote such time as may reasonably be requested by the Coordinating Committee to review information, meet with, respond to, and advise the Coordinating Committee or other Participants with respect to activities as they relate to this Agreement; (d) provide such reasonable assistance as may be requested by the Coordinating Committee when performing activities as they relate to this Agreement; and (e) subject to a Participant's right to restrict or condition its cooperation or disclosure of information in the interest of preserving

privileges in any foreseeable dispute or litigation or protecting a Participant's Confidential Participant Information, provide information and assistance to the Coordinating Committee or other Participants in the investigation of Adverse Security Events and Disputes. In no case shall a Participant be required to disclose PHI in violation of Applicable Law. In seeking another Participant's cooperation, each Participant shall make all reasonable efforts to accommodate the other Participant's schedules and reasonable operational concerns. A Participant shall promptly report, in writing, to any other Participant and the Coordinating Committee, any problems or issues that arise in working with the other Participant's employees, agents, or subcontractors that threaten to delay or otherwise adversely impact a Participant's ability to fulfill its responsibilities under this Agreement. This writing shall set forth in detail and with clarity the problems that the Participant has identified.

21. **Dispute Resolution**.

21.01. **General**. The Participants acknowledge that it may be in their best interest to resolve Disputes through an alternative dispute resolution process rather than through civil litigation. The Participants have reached this conclusion based upon the fact that the legal and factual issues involved in this Agreement are unique, novel, and complex and limited case law exists which addresses the legal issues that could arise from this Agreement. Therefore, the Participants shall submit Disputes related to this Agreement to the non-binding Dispute Resolution Process attached hereto as Attachment 6 and incorporated herein. Except in accordance with Section 21.02(a), if a Participant refuses to participate in the Dispute Resolution Process, such refusal shall constitute a material breach of this Agreement and may be grounds for termination in accordance with Section 19.04(b).

21.02. **Immediate Injunctive Relief**.

a. Notwithstanding Section 21.01, a Participant may be relieved of its obligation to participate in the Dispute Resolution Process if such Participant (i) believes that another Participant's acts or omissions create an immediate threat to the confidentiality, privacy or security of Message Content or will cause irreparable harm to another party (Participant, Participant User, the integrity or operation of the Performance and Service Specifications, or consumer) and (ii) pursues immediate injunctive relief against such other Participant in a court of competent jurisdiction. The Participant pursuing immediate injunctive relief must provide a Notification to the Coordinating Committee of such action within 24 hours of filing for the injunctive relief and of the result of the action within 24 hours of learning of same.

b. If the injunctive relief sought in Section 21.02(a) is not granted and the Participant seeking such relief chooses to pursue the Dispute, the Participants must then submit to the Dispute Resolution Process in accordance with Section 21.01.

21.03. **Activities during Dispute Resolution Process**. Pending resolution of any Dispute under this Agreement, the Participants agree to fulfill their responsibilities in accordance with this Agreement, unless the Participant voluntarily suspends its right to

Transact Message Content in accordance with Section 19.02(a), is suspended in accordance with Section 19.03, or exercises its right to cease Transacting Message Content in accordance with Section 12.01(b).

21.04. **Implementation of Agreed Upon Resolution**. If, at any point during the Dispute Resolution Process, all of the Participants to the Dispute accept a proposed resolution of the Dispute, the Participants agree to implement the terms of the resolution in the agreed upon timeframe.

21.05. **Reservation of Rights**. If, following the Dispute Resolution Process, in the opinion of any involved Participant, the mandatory Dispute Resolution Process failed to adequately resolve the Dispute, the Participant(s) may pursue any remedies available to it in a court of competent jurisdiction.

22. **Notices**. All Notices to be made under this Agreement shall be given in writing to the appropriate Participant's representative at the address listed in Attachment 4 or the Coordinating Committee, and shall be deemed given: (i) upon delivery, if personally delivered; (ii) upon the date indicated on the return receipt, when sent by the United States Postal Service Certified Mail, return receipt requested; and (iii) if by electronic mail, facsimile telecommunication or other form of electronic transmission, upon receipt when the Notice is directed to a facsimile telecommunication number or electronic mail address listed on Attachment 4 and the sending facsimile machine or electronic mail address receives confirmation of receipt by the receiving facsimile machine or electronic mail address.

23. **Miscellaneous/General**.

23.01. **Governing Law**. In the event of a Dispute between or among the Participants arising out of this Agreement, the applicable Federal and State conflicts of law provisions that govern the operations of the Participants involved in the Dispute shall determine governing law.

23.02. **Amendment**. This Agreement may be amended by agreement of at least two-thirds of the Non-Governmental Participants and at least two-thirds of the Governmental Participants. However, if the change is required for the Coordinating Committee or Participants to comply with Applicable Law, the Coordinating Committee may implement the change with approval of at least a majority of Non-Governmental Participants and at least a majority of Governmental Participants and within a time period the Coordinating Committee determines is appropriate under the circumstances. All Participants shall be required to sign an amendment adopted in accordance with the provisions of this Section or terminate participation in accordance with Section 19.02.

23.03. **New Participants**. Upon the Coordinating Committee's acceptance of a New Participant, the Coordinating Committee shall have the New Participant execute a Joinder Agreement, the form of which is attached hereto as Attachment 7. The Participants agree that upon execution of the Joinder Agreement by a duly authorized representative of the Coordinating Committee, all then-current Participants shall be deemed to be signatories to the Joinder Agreement with the result being that current Participants and the New Participant are all bound by this Agreement. The New

Participant shall not be granted the right to Transact Message Content until both it and the Coordinating Committee execute the Joinder Agreement.

23.04. **Assignment**. No Party shall assign or transfer this Agreement, or any part thereof, without the express written consent of the Coordinating Committee. Any assignment that does not comply with the requirements of this Section 23.04 shall be void and have no binding effect.

23.05. **Survival**. The provisions of Sections 1, 5.02, 5.03, 14, 15.10, 16, 18, 19.06, 19.07, 20 and 21 shall survive the termination of this Agreement for any reason.

23.06. **Waiver**. No failure or delay by any Participant in exercising its rights under this Agreement shall operate as a waiver of such rights, and no waiver of any right shall constitute a waiver of any prior, concurrent, or subsequent right.

23.07. **Entire Agreement**. This Agreement, together with all Attachments, sets forth the entire and only Agreement among the Participants relative to the subject matter hereof. Any representation, promise, or condition, whether oral or written, not incorporated herein, shall not be binding upon any Participant.

23.08. **Validity of Provisions**. In the event that a court of competent jurisdiction shall hold any Section, or any part or portion of any Section of this Agreement, invalid, void or otherwise unenforceable, each and every remaining Section or part or portion thereof shall remain in full force and effect.

23.09. **Priority.** In the event of any conflict or inconsistency between a provision in the body of this Agreement and any attachment hereto, the terms contained in the body of this Agreement shall prevail.

23.10. **Headings.** The headings throughout this Agreement are for reference purposes only, and the words contained therein may in no way be held to explain, modify, amplify, or aid in the interpretation or construction of meaning of the provisions of this Agreement. All references in this instrument to designated "Sections" and other subdivisions are to the designated Sections and other subdivisions of this Agreement. The words "herein," "hereof," "hereunder," and other words of similar import refer to this Agreement as a whole and not to any particular Section or other subdivision.

23.11. **Relationship of the Participants.** The Participants are independent contracting entities. Nothing in this Agreement shall be construed to create a partnership, agency relationship, or joint venture among the Parties. Neither the Coordinating Committee nor any Participant shall have any authority to bind or make commitments on behalf of another Participant for any purpose, nor shall any such Party hold itself out as having such authority. No Participant shall be held liable for the acts or omissions of another Participant.

23.12. **Counterparts.** With respect to the first two Participants to this Agreement, the Effective Date shall be the date on which the second Participant executes this Agreement. For all Participants thereafter, the Effective Date shall be the date that the Participant executes this Agreement or the Joinder Agreement, in accordance with Section 23.03. This Agreement or the Joinder Agreement may be executed in any

number of counterparts, each of which shall be deemed an original as against the Participant whose signature appears thereon, but all of which taken together shall constitute but one and the same instrument.

23.13. **Third-Party Beneficiaries**. With the exception of the Participants to this Agreement, there shall exist no right of any person to claim a beneficial interest in this Agreement or any rights occurring by virtue of this Agreement.

23.14. **Force Majeure.** A Participant shall not be deemed in violation of any provision of this Agreement if it is prevented from performing any of its obligations by reason of: (a) severe weather and storms; (b) earthquakes or other disruptive natural occurrences; (c) strikes or other labor unrest; (d) power failures; (e) nuclear or other civil or military emergencies; (f) terrorist attacks; (g) acts of legislative, judicial, executive, or administrative authorities; or (h) any other circumstances that are not within its reasonable control. This Section 23.14 shall not apply to obligations imposed under Applicable Law.

23.15. **Time Periods.** Any of the time periods specified in this Agreement may be changed pursuant to the mutual written consent of the Coordinating Committee and the affected Participant(s).

This Agreement has been entered into and executed by officials duly authorized to bind their respective parties.

Coordinating Committee	**Participant**
	_____
	Participant Name
_____	_____
Signature	Signature
_____	_____
Printed Name	Printed Name
_____	_____
Date	Date

Attachment 1 - Specifications

Accessible at: https://ehealthexchange.org/testing-program/exchange-specifications/

Attachment 2 - Validation Plan and Test Materials

Accessible at: https://ehealthexchange.org/testing-program/

Attachment 3 - Operating Policies and Procedures

Accessible at: https://ehealthexchange.org/policies/

Attachment 4 - Participant Addresses for Notice

	Primary Contact	Alternate Contact
Name		
Title		
Organization		
Address		
City, State Zip		
Phone		
Fax		
E-mail		

Attachment 5 – Applicable HIPAA provisions for Participants that are neither Covered Entities, Business Associates nor Governmental Participants

Pursuant to Section 14.01(d), the following HIPAA provisions are applicable to each Participant that is neither a Covered Entity, a Business Associate nor a Governmental Participant as if they were acting in the capacity of a Covered Entity. Definitions contained in the various provisions of 45 C.F.R. Parts 160 through 164 apply to the provisions listed in this Attachment 5 to the extent they are used in said sections.

- 45 C.F.R. § 164.306 (Security Rule – General rules)
- 45 C.F.R. § 164.308 (Security Rule – Administrative Safeguards)
- 45 C.F.R. § 164.310 (Security Rule – Physical Safeguards)
- 45 C.F.R. § 164.312 (Security Rule – Technical Safeguards)
- 45 C.F.R. § 164.314 (Security Rule – Organizational requirements)
- 45 C.F.R. § 164.316 (Security Rule – Policies and procedures and documentation requirements)
- 45 C.F.R. § 164.502, other than paragraphs (h), and (i) (Privacy Rule – Uses and disclosures of PHI: general rules) *[see notes below for descriptions of excluded subsections]*
- 45 C.F.R. § 164.504 (Privacy Rule – Uses and disclosures: Organizational requirements)
- 45 C.F.R. § 164.506 (Privacy Rule – Uses and disclosures to carry out treatment, payment, or health care operations)
- 45 C.F.R. § 164.508 (Privacy Rule – Uses and disclosures for which an authorization is required)
- 45 C.F.R. § 164.510 (Privacy Rule – Uses and disclosures requiring an opportunity to agree or to object)
- 45 C.F.R. § 164.512 (Privacy Rule – Uses and disclosures for which an authorization or opportunity to agree or object is not required)
- 45 C.F.R. § 164.514 (Privacy Rule – Other requirements relating to uses and disclosures of PHI)
- 45 C.F.R. § 164.520 (Privacy Rule – Notice of privacy practices for PHI)
- 45 C.F.R. § 164.522 (Privacy Rule – Rights to request privacy protection for PHI)
- 45 C.F.R. § 164.524 (Privacy Rule – Access of individuals to PHI)
- 45 C.F.R. § 164.528 (Privacy Rule – Accounting of disclosures of PHI)
- The following provisions of 45 C.F.R. § 160.530, but only to the extent that they relate to the above provisions. For example, with respect to 45 C.F.R. § 164.530(b), the Participant must provide training with respect to the above provisions, such as § 164.506, but not with respect to other provisions of the HIPAA Regulations, such as § 164.522.

- 45 C.F.R. § 164.530(b) (Privacy Rule – Administrative Requirements, Training)
- 45 C.F.R. § 164.530(c) (Privacy Rule – Administrative Requirements, Safeguards)
- 45 C.F.R. § 164.530(d) (Privacy Rule – Administrative Requirements, Complaints to the Covered Entity)
- 45 C.F.R. § 164.530(e) (Privacy Rule – Administrative Requirements, Sanctions)
- 45 C.F.R. § 164.530(f) (Privacy Rule – Administrative Requirements, Mitigation)
- 45 C.F.R. § 164.530(g) (Privacy Rule – Administrative Requirements, Refraining from intimidating or retaliatory acts)
- 45 C.F.R. § 164.530(h) (Privacy Rule – Administrative Requirements, Waiver of rights)
- 45 C.F.R. § 164.530(i) (Privacy Rule – Administrative Requirements, Policies and procedures)
- 45 C.F.R. § 164.530(j) (Privacy Rule – Administrative Requirements, Documentation)
- 45 CFR §§ 164.400-414 (HIPAA Breach Notification Rule)

Notes:
The following requirements have not been included:

- 45 C.F.R. § 164.302 (Security Rule – Applicability)
- 45 C.F.R. § 164.304 (Security Rule – Definitions)
- 45 C.F.R. § 164.500 (Privacy Rule – Applicability)
- 45 C.F.R. § 164.501 (Privacy Rule – Definitions)
- 45 C.F.R. § 164.502(h) (Confidential communications), and (i) (Uses and disclosures consistent with notice)
- 45 C.F.R. § 164.526 (Privacy Rule – Amendment of PHI)
- 45 C.F.R. § 164.530(a) (Privacy Rule – Administrative Requirements, Personnel designations)
- 45 C.F.R. § 164.530(k) (Privacy Rule – Administrative Requirements, Group health plans)
- 45 C.F.R. § 164.532 (Privacy Rule – Transition provisions)

Attachment 6 - Dispute Resolution Process

- When a Dispute arises, a Participant shall send written Notice, in accordance with the Notice provision in the DURSA, to the other Participant(s) involved in the Dispute. The notice must contain a summary of the issue as well as a recommendation for resolution. The Participant must send a copy of the notice to the Dispute Resolution Subcommittee (see below) for informational purposes.
- Within thirty (30) calendar days of receiving the notice, the Participants are obligated to meet and confer with each other, at least once in good faith and at a mutually agreeable location (or by telephone), to try to reach resolution (the "Informal Conference"). If the Participants reach a resolution at the Informal Conference, they shall provide Notification to that effect to the Dispute Resolution Committee.
- If the Participants are unable to participate in an Informal Conference during the thirty (30) calendar day period or to reach resolution at the Informal Conference, they have ten (10) business days following the end of the thirty (30) calendar day period or the Informal Conference, respectively, in which to escalate the Dispute to the Dispute Resolution Subcommittee in writing.
    - The Dispute Resolution Subcommittee (the “Subcommittee”) will be a five (5) member standing subcommittee of the Coordinating Committee. The Coordinating Committee shall appoint each member of the Subcommittee for a definite term. The members must be representative of the Participants, have diverse skill sets, and be able to help facilitate and reach resolution on conflicts between the Participants. The Subcommittee must have access to legal counsel to advise it on the law relevant to matters before it.
    - In addition to appointing the five (5) members of the Subcommittee, the Coordinating Committee must also appoint three (3) to five (5) alternates for the Subcommittee. Alternates will serve on the Subcommittee should any of the members have a conflict on a particular Dispute or in the event that a member(s) is unavailable. Subcommittee members are required to declare any conflicts in accordance with the Coordinating Committee’s conflict of interest policy. Once a Subcommittee member declares a conflict, the remaining Subcommittee members shall decide amongst themselves whether such member must withdraw from the Subcommittee for the dispute in question.
    - The Subcommittee must also have access to panels of subject matter experts, as identified by the Coordinating Committee, for a variety of topics that may be implicated by a Dispute. Each subject matter expert panel must have at least three (3) experts on it who will rotate as advisors to the Subcommittee.
- Once a Participant escalates a Dispute to the Subcommittee, the Subcommittee will have thirty (30) calendar days in which to convene a meeting of the involved Participants (“Committee Meeting”). During this meeting, each Participant shall be able to present its version of the Dispute and any information that it believes is pertinent to the Subcommittee’s decision.

- The Subcommittee shall have the ability to request additional information from the Participants to help it make its determination. The Subcommittee, however, shall not have the authority to compel a response or the production of testimony or documents by the Participants. To the extent that the Participants do respond to requests of the Subcommittee by producing documents, Participants shall have the ability to mark the documents produced as "Confidential Participant Information" and the Subcommittee shall treat those documents in accordance with Section 16 of the DURSA.
- The Subcommittee is encouraged to develop an appropriate and equitable resolution of each submitted Dispute, considering all available evidence, the goals of the Agreement and other relevant considerations. The Subcommittee must also have the authority to recommend sanctions for the breaching Participant. These sanctions include developing corrective action plans, suspension of participation rights, and termination of participation rights. The type of sanction will depend on the nature and severity of the breach.
- Within fifteen (15) calendar days of the Subcommittee Meeting, the Subcommittee shall issue a written recommendation for resolution, including an explanation of the basis and rationale of its recommendation. If either Participant is dissatisfied with the Subcommittee's recommendation for resolution, it shall have five (5) business days in which to escalate the Dispute to the Coordinating Committee.
- Within twenty (20) calendar days of receiving notice of escalation from a Participant, the Coordinating Committee shall review the Subcommittee's recommendation along with the information on which such recommendation was based and issue a final resolution. The Coordinating Committee may seek additional information from the Participants to aid its resolution of the Dispute.
- Within seven (7) calendar days of receiving the final resolution from the Coordinating Committee, the Participants shall determine whether to accept or reject the resolution and so notify the Coordinating Committee.
- The Coordinating Committee shall send a written summary of the resolution of the Dispute to all Participants. The summary will not identify the Participants involved, but will contain sufficient detail about the resolution to serve as an instructive resource for other Participants.
- In no case shall a Participant be required to disclose PHI in violation of Applicable Law as part of its participation in the Dispute Resolution Process. The decision to not disclose PHI shall not be held against a Participant in the Dispute Resolution Process.

Attachment 7 – Joinder Agreement

THIS JOINDER AGREEMENT made as of the last date set forth below, by and between the Coordinating Committee on behalf of the Participants ("Coordinating Committee") and _____ (the "New Participant") makes New Participant a party to that certain Data Use and Reciprocal Support Agreement dated _____ , 20__ among the Participants, as amended through the date hereof (the "DURSA").

RECITALS:

A. The New Participant desires to become a Participant and Transact Message Content with other Participants.

B. The Coordinating Committee has accepted and approved the New Participant's application to become a Participant and Transact Message Content with other Participants, with the condition precedent that the New Participant executes this Joinder Agreement.

AGREEMENT:

NOW, THEREFORE, in consideration of good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned hereby agree as follows:

1. JOINDER. The New Participant is hereby made a party to the DURSA, and agrees to be bound by, and shall comply with, the terms thereof. From the date hereof, the New Participant shall be a "Participant" as that term is defined in the DURSA and shall be subject to all of the duties and obligations and entitled to the rights and benefits of a "Participant" as provided therein.

2. ACKNOWLEDGEMENT. The New Participant hereby acknowledges that it has received and reviewed a copy of the DURSA.

3. REAFFIRMATION. The terms and provisions of the DURSA remain in full force and effect in all respects.

4. COUNTERPARTS. This Joinder Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which taken together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the undersigned have caused this Joinder Agreement to be executed, all as of the day and year first written above.

Coordinating Committee	**New Participant**
	_____ Participant Name
_____ Signature	_____ Signature
_____ Printed Name	_____ Printed Name
_____ Date	_____ Date

Attachment 8 – Business Associate Agreement

This Business Associate Addendum is made by and between INSERT NAME OF PARTICIPANT THAT WILL BE SHARING PHI AS PART OF THE USE CASE (REFERRED TO IN THIS TEMPLATE AS PARTICIPANT #1 FOR CLARITY) and INSERT NAME OF PARTICIPANT THAT WILL BE RECEIVING PHI AS PART OF THE USE CASE (REFERRED TO IN THIS TEMPLATE AS PARTICIPANT #2 FOR CLARITY). Each of PARTICIPANT #1 and PARTICIPANT #2 may be referred to herein as a "Party" or collectively as "Parties."

WHEREAS, PARTICIPANT #1 and PARTICIPANT #2 are each signatories to the Data Use Reciprocal Support Agreement (DURSA) which governs the Transaction of Message Content using the eHealth Exchange;

WHEREAS, PARTICIPANT #1, in its capacity as a Participant in the eHealth Exchange, will be providing Protected Health Information (PHI) as part of Transacting Message Content with Participant #2 as part of its participation in the eHealth Exchange INSERT NAME OF USE CASE Use Case;

WHEREAS, the Parties have determined that they should have a business associate agreement among them to govern the use or disclosure of all PHI that is Transacted as part of the Use Case in which they are engaged.

NOW, THEREFORE, in consideration of the mutual promises contained in this Addendum, and other valuable consideration, the Parties agree as follows:

1. **Defined Terms**. Unless otherwise indicated below or elsewhere in this Addendum, all capitalized terms shall have the meanings provided in the DURSA or 45 C.F.R 160.103, 164.103 and 164.501.

   a. "Privacy Rule" means 45 C.F.R. Part 160 and 45 C.F.R. Part 164, Subparts A and E, Standards for Privacy of Individually Identifiable Health Information.

   b. "Protected Health Information" or "PHI" means individually identifiable health information as defined in 45 C.F.R 160.103 that Participant receives or to which Participant has access.

   c. "Security Rule" means 45 C.F.R. Part 164, Subpart C, Security Standards for the Protection of Electronic Protected Health Information.

2. **Modification of Agreement.** This Business Associate Addendum supplements the DURSA. The terms and provisions of this Business Associate Addendum shall control to the extent they are contrary, contradictory or inconsistent with the terms of the DURSA. Otherwise, the terms and provisions of the DURSA shall remain in full force and effect.

3. Mutual Obligations.

a. **Compliance with Privacy and Security Obligations**. Each Party agrees that the requirements of HIPAA and the HITECH Act that relate to the privacy and security of PHI, and are made applicable with respect to business associates, shall be applicable to them with respect to their participation in the Use Case.

b. **Limits on Use and Disclosure**. Except as otherwise limited in this Addendum, the Participant #2 may only use or disclose PHI to perform functions, activities, or services for, or on behalf of Participant #1 as specified in the Use Case and as permitted or required by applicable law and regulations. Except as otherwise limited in this Addendum, Participant #2 may also:

i. Use PHI for its proper management and administration or to carry out its legal responsibilities under the laws of the United States; and

ii. Disclose PHI for its proper management and administration, provided that disclosures are Required by Law, or Participant #2 obtains reasonable assurances from the person to whom the information is disclosed that the information will remain confidential and be used or further disclosed only as Required by Law or for the purpose for which it was disclosed to the person, and that the person will notify Participant #2 of any instances of which it is aware in which the confidentiality of the information may have been breached. The Participant #2 shall remain liable to Participant #1 for all acts or omissions of any third party to which it discloses PHI. Participant #1's written consent to such disclosure shall not relieve any other Participant #2 of such liability.

c. **Minimum Necessary**. Any use or disclosure of the PHI will be limited to the minimum PHI necessary for the permitted purpose and restricted to those employees, subcontractors or agents subject to a written obligation of confidentiality with Participant that is at least as protective of the PHI as this Addendum and permitted and/or required by Applicable Law. Participant #2 shall comply with any guidance issued by the Secretary regarding compliance with the minimum necessary standard.

d. **Safeguards.** Each Party will comply with all applicable provisions of Applicable Law including, but not limited to, the Privacy Rule and the Security Rule and will implement and maintain reasonable and appropriate administrative, physical and technical safeguards to protect the availability, integrity and confidentiality of the PHI as permitted and/or required by Applicable Law. Each Party shall also develop and implement policies and procedures and maintain documentation of such policies and procedures to assure compliance with Applicable Law including, but not limited to, the Privacy Rule and the Security Rule.

e. **Reports of Unauthorized Access, Use or Disclosure**. Participant #2 shall report in writing to Participant #1, without unreasonable delay, (i) any use or disclosure of PHI that is not authorized by this Addendum or the DURSA including, but not limited to, Adverse Security Events, defined in the DURSA, and (ii) any Breach of Unsecured

Protected Health Information. Participant #2 shall deliver such notice no later than five (5) calendar days after the date on which Participant #2 (or any member of its workforce or its agent, except the person(s) responsible for the unauthorized use or disclosure or Breach, became aware, or in the exercise of reasonable diligence should have become aware, of such unauthorized use or disclosure or Breach. Notice of any unauthorized use or disclosure or Breach shall, if known, (i) describe the event resulting in the unauthorized use or disclosure or Breach; (ii) describe the types of PHI that were involved in the unauthorized use or disclosure or Breach; and (iii) describe what Participant #2 is doing to investigate, mitigate losses arising from and protect against any further unauthorized use or disclosure or Breach. Participant #2 shall maintain all documentation associated with the investigation of a potential unauthorized use or disclosure or Breach, including any information influencing its determination that the use or disclosure was or was not a Breach and any exceptions applied to the use or disclosure. On request, Participant #2 shall provide Participant #1 with the documentation relevant to the circumstances surrounding the unauthorized use or disclosure or Breach.

f. **Mitigation Procedures**. In the event of any improper use and/or disclosure of Protected Health Information, Participant #2 shall work cooperatively with Participant #1 to implement procedures for mitigating the harmful effects of such improper use and/or disclosure.

g. **Accounting of Disclosures**. In accordance with 45 C.F.R. § 164.528, Participant #2 agrees to produce, and maintain for at least six (6) years, a record of any disclosure of the PHI, which record will include, for each disclosure, the date of disclosure, the name and address of the recipient, a description of the PHI disclosed (if known), the name of the individual who is the subject of the PHI (if known) and the reason for disclosure. Upon request from Participant #1, Participant #2 will make its record of disclosure available to Participant #1 within the time frame and in the manner permitted and/or required by Applicable Law or as otherwise agreed by the Parties in writing. In the event the request for an accounting is delivered by an Individual directly to Participant #2, it shall forward such request to Participant #1.

h. **Access to Individuals**. Participant #2 agrees to provide Individuals with access to their Protected Health Information, as held in a Designated Record Set by Participant #2, in order to meet the requirements under 45 CFR § 164.524, including in the electronic form or format requested by the Individual, as required by 45 CFR § 164.524. In the event any individual requests access to Protected Health Information directly from Participant #2, it shall forward such request to Participant #1.

i. **Amendment of Protected Health Information**. Participant #2 agrees to make any amendment(s) to Protected Health Information it holds in a Designated Record Set, as requested by an Individual or directed by Participant #1 pursuant to 45 CFR § 164.526. In the event the request for an amendment is delivered by an individual directly to Participant #2, it will promptly forward the request to Participant #1 and upon approval Participant #1, amend the Protected Health Information and incorporate the amendment into its records.

j. **Right to Restrict**. Participant #2 agrees to comply with, upon communication from Participant #1, any restrictions to the use or disclosure of Protected Health Information that Participant #1 has agreed to in accordance with 45 CFR § 164.522.

k. **Marketing/Sale of Protected Health Information.** Participant #2 shall not directly or indirectly receive remuneration in exchange for any Protected Health Information and shall not engage in marketing activities or the sale of Protected Health Information, as defined in the HIPAA Privacy & Security Rules, without the prior written consent of Participant #2 and individual written authorization, as required by law.

l. **De-Identification.** Upon the prior written approval of Participant #1, Participant #2 may use Protected Health Information to de-identify such information in accordance with 45 CFR § 164.514.

m. **Aggregation.** Upon the prior written approval of Participant #1, Participant #2 may use Protected Health Information to provide Data Aggregation Services related to Participant #1's Health Care Operations, as permitted by 45 CFR § 164.504(e)(2)(i)(B).

n. **Subcontractors**. Participant #2 shall ensure that any subcontractor to whom it provides PHI agrees to the same restrictions and conditions that apply through this Addendum and under Applicable Law to Participant #2. Participant #2 shall remain liable to Participant #1 for all acts or omissions of any subcontractor or agent to which Participant #2 discloses PHI; however, in no case shall Participant #2 be liable for any party who is under a direct contract with Participant #1. Participant #1's written consent to the use of subcontractors shall not relieve Participant #2 of liability under this section.

o. **Availability of Books and Records**. Participant #2 agrees to make its internal practices, books and records relating to its uses or disclosures of the PHI available to Participant #1, or, if directed in writing, the Secretary for purposes of determining compliance with Applicable Law, subject to attorney-client and other applicable privileges.

p. **Participant #2's Performance of Participant #1's Obligations.** To the extent Participant #2 is to carry out one or more of Participant #1's or a Covered Entity's obligations under the Privacy Rule, at Subpart E of 45 C.F.R. Part 164, Participant #2 will comply with the requirements of the Privacy Rule that apply to Covered Entities in the performance of such obligations.

4. Term and Termination.

a. **Term.** This Addendum shall become effective on the Effective Date of the implementation of the Use Case, unless the Parties otherwise mutually agree in writing to an alternative effective date.

b. **Termination.**

i. **Automatic Termination.** This Addendum will automatically terminate upon the termination or expiration of Participant #2's participation in the applicable Use Case or the termination of Participant #2's participation in eHealth Exchange.

ii. **Material Breach of Business Associate Addendum.** Notwithstanding any provisions in this Addendum, any Party may terminate this Addendum if it determines that another Party has breached a material term of this Addendum and has not cured such breach within thirty (30) days of receiving notice of the breach.

iii. **Effect of Termination.** Upon termination of the DURSA or this Addendum, Participant #2 will return or destroy the PHI, unless required otherwise by Applicable Law. If return or destruction of the PHI is not feasible, Participant #2 will extend the protections of this Addendum until the PHI can be returned or destroyed. If Participant #2 elects to destroy the PHI, it will certify destruction upon Participant #1's written request.

5. **Independent Contractors.** In participating in the Use Case, Participant #2 will be acting as an independent contractor. Nothing contained in the DURSA or this Addendum shall be construed to create a partnership or a joint venture or to authorize Participant #2 to act as a general or special agent of Participant #1, except as specifically set forth in this Addendum or the DURSA.

6. **Miscellaneous Terms.** This Addendum supersedes all prior understandings and agreements, written or oral, between the Parties with respect to its subject matter. This Addendum is incorporated into the DURSA. The section titles used in this Addendum are provided for convenience only and are not intended to affect the interpretation of any provision. Any ambiguity in this Addendum shall be resolved in favor of a meaning that permits the Parties to comply with Applicable Law. Any and all references in this Addendum to a statute or regulation mean the section as in effect or as amended. The Parties agree that if Applicable Law changes, this Addendum will be deemed to incorporate such changes as necessary for the Parties to operate in compliance with the amended or modified requirements of Applicable Law. Otherwise, this Addendum may only be amended by a written instrument signed by the Parties. Nothing in this Addendum is to be construed as conferring any right, remedy or claim on any person or entity other than the Parties and their respective successors and assigns. This Addendum may not be assigned by any Party without express written consent of all other Parties. The unenforceability of any provision in this Addendum will not affect the enforceability of any other provision. The waiver of any right or obligation under this Addendum will not be deemed to be a continuing waiver or the waiver of another right or obligation. All waivers must be in writing signed by both Parties. This Addendum may be executed in counterparts, which when considered together will constitute one and the same document. Facsimile or email transmission of a signed photocopy, facsimile document or other electronic image of this Addendum will be deemed delivery of an original.

The Parties hereby cause this Addendum to be signed by their duly authorized representative as of

the date(s) below.

Participant #1	**Participant #2**
Organization:	Organization:
Signature of Authorized Representative:	Signature of Authorized Representative:
Printed Name:	Printed Name:
Title:	Title:
Date:	Date:

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