

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

Version Date: May 3, 2011

~~Developed by:~~
~~**NHIN Cooperative DURSA Team**~~

~~November 18, 2009~~

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.

The executed DURSA contains a provision describing the creation of a Coordinating Committee that is charged with maintaining and evolving this Agreement. Pursuant to that charge, in 2010, the Coordinating Committee established a Task Group to suggest revisions to the Agreement based on the experience gained with the early implementations and to accommodate new opportunities for the promotion and expansion of health information exchange.

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

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. 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 with each other using an agreed upon set of national standards, services and policies developed in coordination with the Office of the National Coordinator for Health IT (ONC) in the U.S. Department of Health and Human Services. (Those who sign the DURSA 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 intended to be 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 Breach Notification
- Mandatory Non-Binding Dispute Resolution
- Allocation of Liability Risk

Will the DURSA continue to evolve?

Yes. An initial group of Participants executed the 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 November 2009 version of the DURSA is available at http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_910332_0_0_18/DURSA_2009_VersionforProductionPilots_20091123.pdf.) As a living document, the DURSA is being maintained using the process described in the Agreement. An amended and restated version of the DURSA will be available for execution in 2011.

When the Department of Health and Human Services issues final regulations addressing governance of the nationwide health information network, the Coordinating Committee will likely convene another Task Group to assess how the DURSA might need to be revised to accommodate the new regulations.

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 I 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”) ~~(the “DURSA” or the “Agreement”)~~ as of the Effective Date.

WITNESSETH:

~~WHEREAS, the Participants are either Health Information Exchanges that have each individually been accepted by the NHIN Coordinating Committee for participation in the Nationwide Health Information Network (“NHIN”) (“HIE Participants”), Integrated Delivery Systems that have each individually been accepted by the NHIN Coordinating Committee for participation in the NHIN (“IDS Participants”), State agencies that have each individually been accepted by the NHIN Coordinating Committee (“State Participants”), or Federal agencies that have each individually been accepted by the NHIN Coordinating Committee for participation in the NHIN (“Federal Participants”) (collectively State Participants and Federal Participants shall be referred to as “Governmental Participants”);~~

~~WHEREAS, all Participants facilitate and govern the exchange of health data among groups of persons or organizations that wish to request and/or receive health data from other Participants in the NHIN;~~

WHEREAS, the Participants who previously have executed the Data Use and Reciprocal Support Agreement dated November 18, 2009, 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 recognize that the Office of the National Coordinator for Health Information Technology (“ONC”) plans to conduct rule-making to establish a governance mechanism for the Network. This Agreement is not intended to preempt in any manner or presume any part of that rule-making process. Rather, the Participants enter into this Agreement to enable their voluntary participation in health information exchange activities, as set forth below;

WHEREAS, the Participants are 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; have the technical ability to meet the Performance and Service Specifications to electronically transact health information on their own behalf or on behalf of their Participant Users; 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; and have each individually been accepted by the Coordinating Committee as a Participant;

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 ~~participation in the NHIN, the~~ Transacting information with other Participants, each Participant must enter into this Data Use and Reciprocal Support Agreement ~~for purposes of electronic data exchange and have~~ 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. **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.
 - b. **Authorization** shall ~~meet~~ have the meaning and include the requirements ~~and have the meaning~~ set forth at 45 CFR § 164.508 of the HIPAA Regulations and include any similar but additional requirements under Applicable Law.
 - c. **Breach** shall mean the unauthorized acquisition, access, disclosure, or use of Message Content ~~through the NHIN~~ while Transacting such Message Content pursuant to this Agreement. The term “Breach” does not include the following:
 - (i) any unintentional acquisition, access, disclosure, or use of Message Content ~~through the NHIN~~ 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 Message Content is not further acquired, accessed, ~~used, or~~ disclosed or used by such employee or individual; or
 - (ii) any acquisition, access, ~~use or~~ disclosure or use of information contained in or available through the Participant’s System where such acquisition, access,

~~use or~~ disclosure or use was not directly related to ~~transmission of~~ Transacting Message Content ~~through the NHIN.~~

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

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

f. ~~e.~~ 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, ~~processes and~~ 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.

~~f. **Definitive Plan** shall mean a written summary, signed by all entities or agencies that will participate in at least a limited production pilot and become signatories to the DURSA, which attests to the planned timeline, including substantive milestones, that will allow the parties to the attestation to begin, no later than December 31, 2010, actively exchanging health information in compliance with the NHIN Specifications in at least a limited production pilot that is consistent with priorities set by the NHIN Technical Committee. The purpose of the Definitive Plan is to provide a mechanism for the NHIN Coordinating Committee to evaluate an entity's eligibility to serve on the Coordinating Committee, as described in Section 4.02 of the Agreement.~~

- g. Covered Entity shall have the meaning set forth at 45 C.F.R. § 160.103 of the HIPAA Regulations.
- h. ~~g.~~ **Digital Credentials** shall mean a ~~digital certificate issued by the NHIN Coordinating Committee or its designee to Participants who meet NHIN Participant requirements as defined in the NHIN Operating Policies and Procedures. The Digital Credentials will be presented electronically to Participants to~~ mechanism that enables Participants to electronically prove their identity and ~~the~~their right to access Transact Message Content through the NHIN and will include Server Certificates with other Participants.
- i. ~~h.~~ **Discloser** shall mean a Participant that discloses Confidential Participant Information to a Receiving Party.
- j. ~~i.~~ **Dispute** shall mean any controversy, dispute, or disagreement arising out of or relating to this Agreement.
- k. Dispute Resolution Subcommittee shall mean the standing subcommittee of the Coordinating Committee that is established pursuant to, and performs the tasks described in, Attachment 6 of this Agreement.
- l. ~~j.~~ **Effective Date** shall mean the date specified in Section ~~25.12~~23.12 of this Agreement.
- m. Emergent Specifications shall mean the technical specifications that a group of existing and/or potential Participants are prepared to implement to test the feasibility of the specifications, to identify whether the specifications reflect an appropriate capability for the Participants, and assess whether the specifications are sufficiently mature to add as a production capability that is available to the Participants.
- n. Federal Participants shall mean those Participants that are Federal agencies.
- o. Governmental Participants shall mean collectively those Participants that are local, state or Federal agencies.
- p. ~~k.~~ **Health Care Operations** shall have the meaning set forth at 45 C.F.R. § 164.501 of the HIPAA Regulations.
- ~~l.~~ ~~Health Information Exchange or HIE~~ shall mean an organization that oversees and governs the exchange of health-related information among organizations.
- q. Health Care Provider shall have the meaning set forth at 45 C.F.R. § 160.103 of the HIPAA Regulations.
- r. ~~m.~~ **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.

- s. Health Plan shall have the meaning set forth at 45 C.F.R. § 160.103 of the HIPAA Regulations.
- t. ~~n.~~ **HIPAA Regulations** shall mean the Standards for Privacy of Individually Identifiable Health Information and the Security Standards for the Protection of Electronic Protected Health Information (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 ~~date~~Effective Date of this Agreement and as may be amended, modified, or renumbered.
- ~~o. **Integrated Delivery System or IDS** shall mean a network of health care providers or organizations that provide a continuum of health care services to a defined population, or a health plan with care delivery components that represent a substantial proportion of its operations. An IDS may, but does not necessarily need to, include community and/ or tertiary hospitals, home health care and hospice services, primary and specialty outpatient care and surgery centers, social services, rehabilitation, preventive care, health education, and managed care financing.~~
- ~~p. **Material** shall mean, for the purposes of Section 11.03 only, the implementation of, or change to, a NHIN Performance and Service Specification that will: (i) have a significant adverse operational or financial impact on at least 20% of Participants; (ii) require at least 20% of Participants to materially modify their existing agreements with or policies or procedures that govern Participant Users or third parties as required by Sections 17.04 and 17.05; or (iii) require an amendment to this Agreement.~~
- u. 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.
- v. ~~q.~~ **Message** shall mean ~~a mechanism for exchanging an electronic transmission of Message Content~~ Transacted between Participants ~~through the NHIN, which complies with the NHIN Performance and Service~~ using the Specifications. Messages are intended to include all types of electronic transactions ~~in the exchange, including, but not limited to, requests, assertions, responses, and notifications~~ as specified in the Performance and Service Specifications, including the data or records transmitted with those transactions.
- w. ~~r.~~ **Message Content** shall mean that information ~~which is requested or sent by a Participant to another Participant through the NHIN. This~~ contained within a Message or accompanying a Message using the Specifications. This information includes, but is not limited to, Protected Health Information (PHI), ~~individually identifiable information,~~ 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.

- ~~s. **Nationwide Health Information Network (NHIN)** shall mean a secure, nationwide, interoperable health information infrastructure that allows for the exchange of Message Content between and among Participants in support of the provision and improvement of health and healthcare services.~~
- x. **Network** shall mean the all of the standards, services and policies identified by ONC that enables secure health information exchange over the Internet. As of December 2010, the group of ONC identified standards, services and policies is called the Nationwide Health Information Network, but may be renamed by ONC.
- y. ~~t. **NHIN**~~**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 ~~shall mean the policies and procedures adopted by the NHIN Coordinating Committee that describe management, operation, and participation in the NHIN, attached hereto as Attachment 3 and as amended from time to time in accordance with Section 12.03.~~ and Section 23.03 of this Agreement.
- ~~u. **NHIN Performance and Service Specifications** shall mean the NHIN Test Approach and the NHIN Specifications.~~
- ~~v. **NHIN Specifications** shall mean the specifications adopted by the NHIN Technical Committee to prescribe the data content, technical, and security requirements necessary to support information exchange among NHIN Participants. The NHIN Specifications are attached hereto as Attachment 1, and as amended from time to time in accordance with Sections 11.02 and 11.03.~~
- ~~w. **NHIN Test Approach** shall mean the framework for Testing and demonstrations for parties seeking to participate in the NHIN. The NHIN Test Approach is attached hereto as Attachment 2, and as amended from time to time in accordance with Sections 11.02 and 11.03.~~
- z. **Non-Federal Participants** shall mean collectively those Participants which are not Federal Participants.
- aa. **Non-Governmental Participants** shall mean collectively those Participants which are not Governmental Participants.
- bb. ~~x. **Notice or notify**~~**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 ~~NHIN~~ Coordinating Committee in accordance with Section ~~24.~~22.
- cc. ~~y. **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.
- dd. **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.

ee. ~~z.~~ **Participant** shall mean any organization that (i) meets the requirements for participation ~~in the NHIN~~ as contained in the ~~NHIN~~ Operating Policies and Procedures; (ii) is provided with Digital Credentials; and (iii) is a signatory to this Agreement or a Joinder Agreement. Participants may act as either a Submitter, Recipient or both when Transacting Message Content.

ff. **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.

gg. ~~aa.~~ **Participant Users** ~~User~~ shall mean ~~those persons~~ any person who ~~have~~ has been authorized to ~~access~~ Transact Message Content ~~in connection with the NHIN~~ through the respective Participant's System ~~and~~ in a manner defined by the respective Participant. "Participant Users" may include, but are not limited to, ~~health care providers~~ 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.

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

ii. **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.

jj. ~~ee.~~ **Permitted Purposes** ~~Purpose~~ shall mean one of the following reasons for which Participants or Participant Users may legitimately ~~exchange~~ Transact Message Content ~~through the NHIN~~:

1. ~~•~~ Treatment of the individual who is the subject of the Message ~~by the requesting Participant User or Recipient~~;
- ~~•~~ Payment, provided that: (i) the requesting Participant User is a Health Care Provider (as that term is defined at 45 C.F.R. § 160.103) of the individual who is the subject of the Message, and (ii) the requesting Participant User is requesting Message Content for its own use; and (iii) the Message Content is being transmitted to the requesting Participant User;

2. Payment activities of the Health Care Provider for the individual who is the subject of the Message which includes, but is not limited to, Transacting Message Content in response to or to support a claim for reimbursement submitted by a Health Care Provider to a Health Plan.
3. Health Care Operations of either
 - .01. the Submitter if the Submitter is a Covered Entity;
 - .02. a Covered Entity if the Submitter is Transacting Message Content on behalf of such Covered Entity; or
 - .03. ~~•the Recipient if (i) the Recipient is a Health Care Operations, provided that (i) the requesting Participant User Provider who~~ has an established Treatment relationship with the individual who is the subject of the Message; or the Recipient is Transacting Message Content on behalf of such Health Care Provider; and (ii) the purpose of the ~~request~~Transaction is for those Health Care Operations listed in paragraphs (1) or (2) of the definition of Health Care Operations in 45 C.F.R. § 164.501 or health care fraud and abuse detection or compliance; ~~and (iii) the requesting Participant User is requesting Message Content for its own use~~ of such Health Care Provider;
4. ~~•Public health activities and reporting as permitted by both~~Applicable Law, including the HIPAA Regulations at 45 C.F.R. § 164.512(b) ~~and other Applicable Law or 164.514(e);~~
5. ~~•Reporting on such clinical quality measures and such other measures~~Any purpose to demonstrate “meaningful use,” ~~as specified in~~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 1-4 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 ~~and as permitted by both the HIPAA Regulations and other Applicable Law; and ; and~~
6. ~~•Uses and disclosures pursuant to an Authorization provided by the individual who is the subject of the Message or such individual’s personal representative~~ as described ~~in accordance with~~ 45 C.F.R. § 164.502(g) of the HIPAA Regulations.

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

- ~~ll. ee.~~ **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.
- ~~mm. ff.~~ **Recipient** shall mean the ~~person~~ Participant(s) or ~~organization~~ Participant User(s) that receives Message Content through a Message from a ~~Responding Participant~~ Submitter for a Permitted Purpose. “For purposes of illustration only, Recipients” ~~may~~ include, but are not limited to, Participants or Participant Users ~~and Requesting Participants who receive queries, responses, subscriptions, publications or unsolicited Messages.~~
- ~~gg. Requesting Participant~~ shall mean ~~the Participant that submits a Message, on behalf of a Participant User, which initiates an exchange of Message Content. A Requesting Participant is also a Recipient upon receipt of Message Content from a Responding Participant.~~
- ~~hh. Responding Participant~~ shall mean ~~the Participant that receives or responds to a Message from a Requesting Participant.~~
- ~~ii. Server Certificates~~ shall mean ~~a digital certificate that enables web servers to operate in a secure mode by unambiguously identifying and authenticating a server and encrypting any information passed between the server and a web browser.~~
- ~~nn. 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.
- ~~oo. 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.
- ~~pp. jj.~~ **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.
- ~~qq. kk.~~ **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 ~~NHIN~~ Specifications and ~~NHIN Test Approach~~ Validation Plan.

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

ss. Transaction Pattern shall mean a type of information exchange service(s) enabled by the Specifications. The Operating Policies and Procedures will identify the Transaction Pattern(s) and the Specifications required to implement each Transaction Pattern. As of December 2010, the Transaction Patterns are submission, query and respond, publish and subscribe, and routing. The Transaction Patterns may be amended from time to time through amendment of the Specifications and the Operating Policies and Procedures.

tt. ~~H-Treatment~~ shall have the meaning set forth at 45 C.F.R. § 164.501 of the HIPAA Regulations.

uu. 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. ~~3. Purpose of the DURSA.~~ The purpose of this Agreement is to provide a legal framework that will enable Participants to ~~exchange Message Content through the NHIN~~ Transact Message Content with other Participants using the Performance and Service Specifications.

3.02. This Agreement hereby amends the November 18, 2009 Data Use and Reciprocal Support Agreement in its entirety, which has been entered into by some of the Participants.

4. **NHIN Coordinating Committee.**

4.01. **Formation of the ~~NHIN~~ Coordinating Committee.** To ~~accomplish the necessary planning, consensus building, and consistent approaches to developing, implementing, and operating the NHIN, there will be a NHIN~~ support the Participants who wish to Transact Message Content with other Participants, there shall be a Coordinating Committee.

4.02. **Composition of the ~~NHIN~~ Coordinating Committee.** ~~The NHIN Coordinating Committee shall be composed of (i) one representative from ONC; (ii) one representative from each signatory to the DURSA that is actively engaged in the exchange of Message Content in at least a limited production pilot; (iii) one~~

~~representative from each entity or agency that is a party to a Definitive Plan that has been accepted by the NHIN Coordinating Committee; and (iv) two representatives chosen by the Cooperative's Leadership Group. An entity or agency shall have only one representative on the NHIN Coordinating Committee even if it meets the requirements of multiple categories of membership as listed above. No entity or agency shall be party to a Definitive Plan unless it can demonstrate to the satisfaction of the NHIN Coordinating Committee that, at the time the Definitive Plan is submitted, it is conducting electronic transactions or exchanges of health information through production systems on a routine and on-going basis, with sufficient data to support priorities as defined by the NHIN Technical Committee.~~ **Coordinating Committee.** The Coordinating Committee shall be composed of representatives of the Charter Participants and the Affiliation Groups as described more specifically herein. The Coordinating Committee is authorized to adopt, pursuant to the process in Section 11.03, Operating Policies and Procedures that modify the composition of the Coordinating Committee in response to a change in Federal law or regulation that results in a modification of the Participant eligibility requirements set forth in the Operating Policies and Procedures.

- a. **Charter Participant Representatives.** “Charter Participants” shall mean the first five Federal Participants and the first five Non-Federal Participants that actively engage in Transacting Message Content.

Until September 30, 2014, each of the Charter Participants shall be entitled to appoint one individual to serve as that Charter Participant’s representative on the Coordinating Committee so long as the Charter Participant continues to be a Participant. Prior to September 30, 2013, the **Coordinating Committee shall determine** a process for evaluating continuation of the Charter Participants’ representation on the Coordinating Committee after September 30, 2014.

- b. **Affiliation Group Representatives.** “Affiliation Group” shall mean (i) all those Non-Federal Participants who are eligible to Transact Message Content in connection with a contract, grant, or cooperative agreement issued by the same Federal agency; or (ii) a Federal Participant and those Non-Federal Participants who are Transacting Message Content with it. By way of example only, all those Non-Federal Participants who are eligible to Transact Message Content in connection with a contract issued by ONC would be considered an “Affiliation Group.” By way of example only, the Social Security Administration (SSA) and those Non-Federal Participants who are Transacting Message Content with SSA would be considered an “Affiliation Group.”

Annually, each Affiliation Group shall be entitled to select one individual to serve as the Affiliation Group’s representative on the Coordinating Committee. The initial term of an Affiliation Group representative shall commence upon that person’s selection by the Affiliation Group and end on September 30th of the following year. After this initial term, the selected representative of an Affiliation Group shall serve a one-year term from October 1 of one year until

September 30th of the following year. The Coordinating Committee shall adopt Operating Policies and Procedures to define the manner in which the selection of a representative of an Affiliation Group is conducted.

The selected individual shall be either an employee or contractor of a Participant in that Affiliation Group. If the selected individual ceases to be an employee or contractor of a Participant in that Affiliation Group, the Affiliation Group shall be entitled to select a new representative on the Coordinating Committee to serve the remaining term of that individual.

The Coordinating Committee is authorized to adopt, pursuant to the process in Section 11.03, Operating Policies and Procedures to allow one or more Affiliation Groups to each select more than one representative if the number of Participants in the smallest Affiliation Group is less than 25% of the number of Participants in the largest Affiliation Group. In no case, however, may the Coordinating Committee adopt Operating Policies and Procedures that expand membership of the Coordinating Committee beyond twenty-one voting members.

c. **ONC Representative.** ONC shall be entitled to appoint an ex-officio, non-voting representative to serve on the Coordinating Committee.

d. In no case shall a Participant have more than one employee or contractor serving concurrently as representatives on the Coordinating Committee.

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

~~a. Reviewing, evaluating, and acting upon Definitive Plans submitted by organizations that want to become members of the NHIN Coordinating Committee;~~

~~a. b.~~ Determining whether to admit ~~new participants to the NHIN~~ a New Participant;

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

~~c. Suspending or terminating Participants~~ Developing and amending Operating Policies and Procedures in accordance with Section ~~24~~ 11 of this Agreement ~~(Suspension and Termination);~~

d. Receiving reports of Breaches and acting upon such reports in accordance with Section ~~16.03~~ 14.03 of this Agreement (Breach Notification);

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

- ~~f. e.~~ Resolving Disputes between Participants in accordance with Section ~~23~~21 of this Agreement (Dispute Resolution);
- ~~f.~~ ~~Determining materiality of proposed new, or changes to existing, NHIN Performance and Service Specifications in accordance with Section 11.03 of this Agreement;~~
- ~~g.~~ ~~Developing and amending NHIN Operating Policies and Procedures in accordance with Section 12 of this Agreement;~~
- ~~g.~~ ~~h.~~ Managing the amendment of this Agreement in accordance with Section ~~25.02~~23.02 of this Agreement;
- h. 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;
- i. Maintaining a process for managing versions of the Performance and Service Specifications, including migration planning;
- j. Evaluating requests for the introduction of Emergent Specifications into the production environment used by the Participants to Transact Message Content;
- k. 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 and ONC Standards and Interoperability Framework initiatives; and
- l. ~~i.~~ Fulfilling all other responsibilities delegated by the Participants to the ~~NHIN~~ Coordinating Committee as set forth in this Agreement.

To the extent permitted under Applicable Law, this grant of authority to the ~~NHIN~~ 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.

~~5. NHIN Technical Committee.~~

~~5.01. Formation of the NHIN Technical Committee.~~ To accomplish the necessary priority setting and oversight of changes to the NHIN Performance and Service Specifications, the parties to this Agreement acknowledge that ONC will arrange for the formation of a NHIN Technical Committee.

~~5.02. Composition of the NHIN Technical Committee.~~ The NHIN Technical Committee shall be composed of no more than six ONC officials or personnel, including the individuals serving as the NHIN program lead and Federal Health Architecture (FHA) lead, and technical experts with appropriate expertise in the following areas: (i) standards and interoperability; (ii) policy and NHIN technical matters; and (iii) FHA technical matters. The NHIN Technical Committee shall also include five representatives chosen by the NHIN Cooperative Leadership Group. The NHIN Program Lead shall be the Chairperson of the NHIN Technical Committee.

~~5.03. Grant of Authority.~~ The Participants hereby grant to the NHIN Technical Committee the right to prioritize NHIN functions and capabilities, including NHIN Performance and Service Specifications to be developed or modified; and, oversee and adopt changes to NHIN Performance and Service Specifications in accordance with Section 11.03 of this Agreement. To the extent permitted under Applicable Law, this grant of authority to the NHIN Technical Committee is unconditional and does not require any further consideration or action by any Participant.

5. ~~6.~~ Use of Message Content.

~~5.01. 6.01. Permitted Purposes.~~ The NHIN Purpose. Participants shall ~~be used only~~ Transact Message Content for a Permitted Purposes ~~Purpose~~ as defined in this Agreement. Each Participant shall require that its Participant Users ~~only use the NHIN for the Permitted Purposes.~~ comply with this Section 5.01.

~~5.02. 6.02. Permitted Future Uses.~~ Subject to this Section ~~6.02~~ 5.02 and Section ~~21.07, 19.07,~~ Recipients may retain, use and re-disclose Message Content ~~received in response to a Message~~ 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 ~~received in response to a Message~~ in accordance with Applicable Law and the agreements between the Participant and its Participant Users.

~~5.03. 6.03. Management Uses.~~ The ~~NHIN~~ 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 ~~NHIN~~ Coordinating Committee shall be labeled as Confidential Participant Information and shall be treated as such in accordance with Section ~~18.16.~~ 16.

6. ~~7.~~ System Access Policies.

- 6.01. **Autonomy Principle.** Each Participant shall have ~~policies and procedures in place that govern its Participant Users' ability to access information on or through the Participant's System and through the NHIN~~ ("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 ~~respond to a~~Transact Message Content based on the application of its Participant Access Policies to the information contained in the ~~assertions that accompany the Message as required by the NHIN Performance and Service Specifications~~Message. The Participants agree that each Participant shall comply with the Applicable Law, this Agreement, and ~~the NHIN~~all applicable Performance and Service Specifications in ~~responding to Messages.~~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. **8-Enterprise Security.**

- 7.01. **8.01-General.** Each Participant shall be responsible for maintaining a secure environment that supports the operation and continued development of the ~~NHIN~~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~~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”~~“required” implementation specifications, and ~~“addressable”~~“addressable” implementation specifications to the extent that the ~~“addressable”~~“addressable” implementation specifications are reasonable and appropriate in the Participant's environment. If an ~~“addressable”~~“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 ~~earlier of the~~ Participant's respective Effective Date ~~or the date on which its submits a Definitive Plan to the NHIN Coordinating Committee.~~ Participants shall also be required to comply with

any ~~NHIN~~ Performance and Service Specifications or ~~NHIN~~ Operating Policies and Procedures adopted by the ~~NHIN Technical Committee or NHIN~~ Coordinating Committee, respectively, that define expectations for Participants with respect to enterprise security.

~~7.02.~~ **8.02. Malicious Software.** ~~In participating in the NHIN, each~~ Each Participant shall ensure that it employs security controls that meet applicable industry or Federal standards so that the information and Message Content being ~~transmitted~~ Transacted and any method of ~~transmitting~~ 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.~~ **9. 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 ~~participate in the NHIN~~ 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 ~~in connection with the NHIN~~ to Transact Message Content are properly configured, including, but not limited to, the base workstation operating system, web browser, and Internet connectivity.

~~9.~~ **10. Auditing.** 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 ~~NHIN~~ Performance and Service Specifications.

~~10.~~ **11. Performance and Service Specifications.**

~~10.01.~~ **11.01. 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) the NHIN Specifications; and (ii) the NHIN Test Approach. The NHIN Specifications and NHIN Test Approach are collectively referred to as the ‘NHIN~~ (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.”~~2~~ identified by the Coordinating Committee as applicable to all Participants.

10.02. ~~11.02.~~ **Adoption of Performance and Service Specifications.** The Participants hereby grant the ~~NHIN Technical~~Coordinating Committee or its designee the ~~power~~right to adopt new ~~NHIN~~ Performance and Service Specifications, and to adopt amendments to, or repeal and replacement of, the ~~NHIN~~ Performance and Service Specifications at any time through the ~~NHIN~~ Performance and Service Specification Change Process described in Section ~~11.03.~~10.03.

10.03. ~~11.03.~~ **NHIN Performance and Service Specification Change Process.**

- a. ~~Determination of Materiality.~~ The ~~NHIN Technical~~ ~~Committee shall provide~~ reasonable advance notification to the ~~NHIN Coordinating Committee of any proposed new, or change to existing, NHIN Performance and Service Specifications.~~ Upon receiving such notification, the ~~NHIN Coordinating Committee shall determine, in its sole discretion, whether such proposal is Material.~~ If the ~~NHIN Coordinating Committee determines that the proposed NHIN Performance and Service Specification is not Material, then the NHIN Technical Committee shall follow the change process in Section 11.03(b).~~ If the ~~NHIN Coordinating Committee determines that the proposed NHIN Performance and Service Specification is Material, then the NHIN Technical Committee shall follow the change process in Section 11.03(c).~~ 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. **Non-Material Changes to NHIN Performance and Service Specifications.** The NHIN Technical Committee may implement any new NHIN Performance and Service Specification, or amend, or repeal and replace any existing NHIN Performance and Service Specifications, at any time by providing the Participants notice of the change~~**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 the change so long as the new or amended NHIN Performance and Service Specification is not Material. Within fifteen (15) days of receiving notice of the non-Material change~~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 NHIN Technical~~Coordinating Committee delay implementation of the change based on unforeseen complications or other~~such the new, amended, repealed or replaced Performance and Service Specification based on good cause. The NHIN Technical~~Coordinating Committee shall respond to a request to delay implementation within seven (7) calendar days of receiving the request.

~~e. **Material Changes to NHIN Performance and Service Specifications.** If the implementation of a new NHIN Performance and Service Specification, or change to any existing NHIN Performance and Service Specification, is Material, the NHIN Technical Committee shall notify Participants of the proposed Material change and allow Participants thirty (30) days to submit written comments to the NHIN Technical Committee regarding the proposed~~

~~Material change. Within sixty (60) days of issuing notice of the proposed Material change, but not before either the end of the thirty (30) day written comment period or acknowledgement that all Participants have responded, the NHIN Technical Committee shall convene a meeting at which the Participants will be allowed to present information on the proposed Material change to the NHIN Technical Committee. Within ninety (90) days of issuing notice of the proposed Material change, the NHIN Technical Committee shall consider and evaluate both written comments received during the comment period and information presented at the meeting, make any revisions to the proposed Material change that are necessary, and provide the Participants final notice of the Material change. Participants shall be given at least one hundred and twenty (120) days after the NHIN Technical Committee provides the final notice to comply with the Material change.~~

- ~~d. **Change Required to Comply with Federal Statutes or Regulations or the Stability of the NHIN.** If a new or changed NHIN Performance and Service Specification is required for the NHIN or Participants to comply with Federal statute or regulations or to maintain the stability of the NHIN (e.g. the performance and integrity of data exchanged among NHIN Participants), the NHIN Technical Committee shall seek input from the NHIN Coordinating Committee prior to implementing such change, but is not required to follow the processes required by Sections 11.03(b) and (c). The NHIN Technical Committee shall not require Participants to comply with such new or changed NHIN Performance and Service Specification prior to the legally required effective date of such Federal statutes or regulations. The NHIN Technical Committee shall notify Participants immediately in the event of a change that is required in order to comply with Federal statutes or regulations or to maintain the stability of the NHIN.~~
- e. **Participant Duty to Terminate Participation.** If, as a result of a change made by the ~~NHIN Technical~~Coordinating Committee in accordance with this Section ~~11.03, 10.03,~~ a Participant will not be able to comply with the ~~NHIN~~ Performance and Service Specifications or does not otherwise desire to continue ~~participating in the NHIN~~to Transact Message Content with other Participants after such change becomes effective, then such Participant shall terminate ~~its participation in the NHIN in this Agreement~~ accordance with Section ~~21.02, 19.02.~~

11. ~~12.~~ NHIN Operating Policies and Procedures.

- 11.01. ~~12.01.~~ General Compliance. Each Participant shall comply with the ~~NHIN~~ Operating Policies and Procedures adopted by the Coordinating Committee in accordance with this Agreement.
- 11.02. ~~12.02.~~ Development of the NHIN Operating Policies and Procedures. The Participants hereby grant the ~~NHIN~~ Coordinating Committee the power to develop ~~the NHIN~~new Operating Policies and Procedures, and to amend, or repeal and

replace, the ~~NHIN~~ Operating Policies and Procedures at any time through the ~~NHIN~~ Operating ~~Policy~~Policies and ~~Procedure~~Procedures Change Process described in Section ~~12.03~~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. ~~12.03. NHIN Operating Policy and Procedures Change Process. The NHIN Coordinating Committee may implement any new NHIN Operating Policy and~~

~~Procedure, or amend, or repeal and replace any existing NHIN Operating Policy and Procedure, at any time by obtaining the approval of at least two thirds of the non-governmental Participants and at least two thirds of the Governmental Participants. The NHIN~~Implementation. The Coordinating Committee shall provide ~~notice of the change~~Notice of new, amended, repealed or replaced Operating Policies and Procedures at least thirty (30) calendar days prior to the effective date of ~~the change~~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 change~~Notice of the new, amended, repealed or replaced Operating Policies and Procedures, a Participant may request that the ~~NHIN~~Coordinating Committee delay implementation of ~~the change based on unforeseen complications or other~~such the new, amended, repealed or replaced Operating Policies and Procedures based on good cause. The ~~NHIN~~Coordinating Committee shall respond to a request to delay implementation within seven (7) calendar days of receiving the request.

12. ~~13.~~ Expectations of Participants.

12.01. ~~13.01.~~ Minimum Requirement for ~~All~~ Participants that request Message Content for Treatment.

- a. All Participants that request, or allow their respective Participant Users to ~~submit Messages that seek~~request, Message Content for Treatment shall have a corresponding reciprocal duty to respond to Messages that ~~seek~~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. All responses to Messages shall comply with ~~NHIN~~Performance and Service Specifications, this Agreement, any agreements between Participants and their Participant Users, and Applicable Law. Participants may, but are not required to, ~~respond to Messages that seek~~Transact Message Content for a Permitted ~~Purposes~~Purpose other than Treatment. Nothing in this Section ~~13.01~~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 ~~submit Messages that seek~~request, Message Content for Treatment shall ~~exchange~~Transact Message Content with all other Participants for Treatment, in accordance with Sections ~~7, 13.01~~6, 12.01(a) and ~~15~~14 of this Agreement. If a Participant desires to stop ~~exchanging~~Transacting Message Content with another Participant based on the other Participant's acts or omissions in connection with ~~the NHIN or~~ this Agreement, the Participant may temporarily stop ~~exchanging~~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, ~~and shall notify the NHIN.~~ 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 ~~23.21~~. If the cessation is a result of a Breach that was reported to, and deemed resolved by, the ~~NHIN~~-Coordinating Committee pursuant to Section ~~16.03, 14.03~~, the Participants involved in the Breach and the cessation shall engage in the Dispute Resolution Process in Section ~~23.21~~ in an effort to attempt to reestablish trust and resolve any security concerns arising from the Breach.

~~12.02. 13.02.~~ **Participant Users and HSPs.** Each Participant shall require that all of its Participant Users and HSPs ~~use the NHIN~~ 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 HSPs, 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. 13.03.~~ **License to Common ~~NHIN~~Participant Resources.** Participant is hereby granted a nonexclusive, nontransferable, revocable and limited license to Common ~~NHIN~~Participant Resources solely for use as a ~~Requesting Participant or a Responding~~ Participant in performance of this Agreement. Participant shall not (a) sell, sublicense, transfer, exploit or, other than pursuant to this Agreement, use any Common ~~NHIN~~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 ~~NHIN~~Participant Resources. THE COMMON ~~NHIN~~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.

~~13. 14.~~ **Specific Duties of a ~~Requesting Participant.~~ A ~~Requesting Participant~~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. 14.01.~~ Submitting each Message to the NHIN in compliance with the ~~NHIN~~Applicable Law, this Agreement, the applicable Performance and Service Specifications, and ~~NHIN~~OperationalOperating Policies and Procedures, including, but not limited to, representing that the Message is: (i) ~~for a Permitted Purpose;~~ (ii)

~~supported by appropriate legal authority for obtaining the Message Content; and (iii) submitted by a Participant User with the legal authority to make such a request;~~

~~14.02. Authenticating that Recipient is an authorized Participant User within the Participant's System and that Recipient has represented that it has requested the Message Content for a Permitted Purpose in accordance with the NHIN~~

~~(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;~~

~~14.03. Sending any assertions required by the NHIN Performance and Service Specifications or NHIN Operational Policies and Procedures with the Message; and or Operating Policies and Procedures;~~

~~13.03. 14.04. Transmitting Submitting a copy of the Authorization, if ~~such Authorization forms the sole legal basis for~~ the Submitter is requesting Message Content from another Participant or Participant User based on the Permitted Purpose described in Section 1(jj)(6). Nothing in this Section shall be interpreted as requiring a ~~Requesting Participant~~ Submitter who is requesting Message Content to obtain or transmit an Authorization for ~~Message Content related to Treatment, Payment, or Health Care Operations, consistent with the Permitted Purposes~~ a request based on a Permitted Purpose other than the one described in Section 1(jj)(6), even though certain ~~Responding other~~ Participants or Participant Users require such Authorization to comply with Applicable Law.~~

~~**15. Specific Duties of a Responding Participant.** A Responding Participant shall be responsible for:~~

~~15.01. Authenticating requests for Message Content, meaning that the Responding Participant shall confirm and verify that the request was submitted by a Requesting Participant, in accordance with the NHIN Performance and Service Specifications and NHIN Operating Policies and Procedures;~~

~~15.02. In accordance with Section 7, determining whether and how to respond to a Message based on the application of its Participant Access Policies to the information contained in the assertions that accompany a Message;~~

~~15.03. Responding to all authenticated Messages that seek Message Content for Treatment, in accordance with this Agreement, the NHIN Performance and Service~~

~~Specifications, and the NHIN Operating Policies and Procedures. The Participant may respond to Messages that seek Message Content for a Permitted Purpose other than Treatment, in accordance with this Agreement, the NHIN Performance and Service Specifications, and the NHIN Operating Policies and Procedures;~~

~~15.04. Authenticating its response to a Message by confirming and verifying that it is transmitting the requested Message Content to the Requesting Participant, in accordance with NHIN Performance and Service Specifications;~~

~~15.05. Ensuring that any requirements under the Responding Participant's Applicable Law, the NHIN Performance and Services Specifications, or the NHIN Operating Policies and Procedures including, but not limited to, obtaining consent and Authorization, if required, have been met before making Message Content available for exchange through the NHIN; and~~

~~13.04. 15.06.~~ For Federal Participants only, in addition to complying with Sections ~~15.04~~13.01 through ~~15.05~~,13.03, ensuring that ~~Message Content transmitted~~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. 16. Privacy and Security.

~~14.01. 16.01.~~ **Applicability of HIPAA Regulations.** ~~The Message Content exchanged through the NHIN and in accordance with this Agreement~~ may contain PHI. Furthermore, some, but not all, Participants are either a Covered Entity or a Business Associate of Covered Entities, as those terms are defined in the HIPAA Regulations~~Entity or a Business Associate~~. Because the Participants are limited to ~~exchanging~~Transacting Message Content ~~through the NHIN~~ for only a Permitted Purpose~~Purpose~~, the Participants do not intend to become ~~Business Associates of each other's Business Associate~~ by virtue of signing this Agreement or ~~exchanging~~Transacting Message Content. As a result, the DURSA is not intended to serve as a Business Associate Agreement among the Participants. To support the privacy, confidentiality, and security of the Message Content ~~and the NHIN~~, 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 ~~to which it is subject~~.

- 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 ~~NHIN~~ Coordinating Committee.

14.02. ~~16.02.~~ **Safeguards.** In accordance with Sections ~~8, 9, 7, 8~~ and ~~10, 9~~, Participant agrees to use reasonable and appropriate administrative, physical, and technical safeguards and any ~~NHIN~~ Performance and Service Specifications and ~~NHIN~~ Operating Policies and Procedures to protect Message Content and to prevent use or disclosure of Message Content other than as permitted by Section 65 of this Agreement.

14.03. ~~16.03.~~ **Breach Notification.**

- a. Each Participant agrees that within one (1) hour of discovering information that leads the Participant to reasonably believe that a Breach may have occurred, it ~~will~~shall alert other Participants whose Message Content may have been Breached and the ~~NHIN~~ Coordinating Committee to such information. As soon as reasonably practicable, but no later than twenty-four (24) hours after determining that a Breach has occurred, the Participant ~~will notify~~shall provide a Notification to all Participants likely impacted by the Breach and the ~~NHIN~~ Coordinating Committee ~~or its designee~~ of such Breach. The ~~notification~~Notification should include sufficient information for the ~~NHIN~~ Coordinating Committee to understand the nature of the Breach. For instance, such ~~notification~~Notification could include, to the extent available at the time of the ~~notification~~Notification, the following information:

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

The Participant shall ~~have a duty to~~ supplement the information contained in the ~~notification~~Notification as it becomes available and cooperate with other Participants and the ~~NHIN~~ Coordinating Committee ~~or its designee~~ in accordance with Section ~~22~~20(e) of this Agreement. The ~~notification~~Notification required by this Section ~~16.03~~14.03 shall not include any PHI. If, on the basis of the ~~notification~~Notification, a Participant desires to stop ~~exchanging~~Transacting Message Content with the Participant that reported a Breach, it shall stop

~~exchanging~~Transacting Message Content in accordance with Section ~~13.01~~12.01(b) of this Agreement. If, on the basis of the notification, the ~~NHIN~~ Coordinating Committee ~~or its designee~~ determines that (i) the other Participants that have not been notified of the Breach would benefit from a summary of the ~~notification~~Notification or (ii) a summary of the ~~notification~~Notification to the other Participants would enhance the security of the ~~NHIN~~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 Breach.

- b. Information provided by a Participant in accordance with this Section ~~16.03~~14.03, except Message Content, may be “Confidential Participant Information.” Such “Confidential Participant Information” shall be treated in accordance with Section ~~18.16~~.
- c. This Section ~~16.03~~14.03 shall not be deemed to supersede a Participant’s obligations (if any) under relevant security incident, breach notification or confidentiality provisions of Applicable Law.
- d. Compliance with this Section ~~16.03~~14.03 shall not relieve Participants of any other security incident or breach reporting requirements under Applicable Law including, but not limited to, those related to consumers.

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

15.01. 17.01.—Accurate Participant Information. Except to the extent prohibited by Applicable Law, each Participant has provided, and ~~will~~shall continue to provide, the ~~NHIN~~ Coordinating Committee with all information reasonably requested by the ~~NHIN~~ Coordinating Committee and needed by the ~~NHIN~~ 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 ~~NHIN~~ Coordinating Committee shall be responsive and accurate. Each Participant shall provide ~~notice~~Notice to the ~~NHIN~~ Coordinating Committee if any information provided by the Participant to the ~~NHIN~~ Coordinating Committee materially changes. Each Participant acknowledges that the ~~NHIN~~ 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 ~~will~~shall reasonably cooperate with the ~~NHIN~~ Coordinating Committee in such actions, given reasonable prior notice.

15.02. 17.02.—Execution of the DURSA. Prior to ~~participating in the NHIN~~Transacting Message Content with other Participants, each Participant shall have executed this Agreement and returned an executed copy of this Agreement to the ~~NHIN~~ 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. ~~17.03.~~ **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. ~~17.04.~~ **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) ~~submit a Transact Message through the NHIN Content~~ only for a Permitted Purpose; (iv) use Message Content received ~~through the NHIN~~ 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 a Breach occurred, report such Breach 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 have agreements with the Participant which became effective prior to the Effective Date, compliance with this Section ~~17.04~~ 15.04 may be satisfied through written policies and procedures that address items (i) through (vi) of this Section ~~17.04~~ 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. ~~17.05.~~ **Agreements with Technology Partners.** To the extent that a Participant uses technology partners in connection with the ~~NHIN~~ 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 a Breach occurred, report such Breach to the Participant; and (iv) reasonably cooperate with the other Participants to this Agreement on issues related to ~~the NHIN~~ this Agreement, under the direction of the Participant.

15.06. ~~17.06.~~ **Compliance with Specifications, Policies and Procedures.** Each Participant affirms that it fully complies with the ~~NHIN~~ Performance and Service Specifications and the ~~NHIN~~ Operating Policies and Procedures as more fully discussed in Sections ~~11.01~~ 10.01 and ~~12.01~~ 11.01 of this Agreement.

15.07. ~~17.07.~~ **Creation of Test Data.** Certain Participants ~~have~~ agreed to anonymize PHI to create Test Data to be used by other Participants for Testing. ~~Each Participant that~~

~~has so agreed represents that the Test Data do~~ Any Test Data that has been created, or will be created in the future, shall not contain PHI and ~~further represents that it has been, or will be, created—the Test Data~~ in accordance with the ~~Test Approach~~ Validation Plan.

- 15.08. ~~17.08.~~ **Accuracy of Message Content.** When acting as a ~~Responding Participant~~ Submitter, each Participant, in accordance with Section ~~19.02,~~ 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 ~~8.02,~~ 7.02, and (c) provided in a timely manner and in accordance with the ~~NHIN~~ Performance and Service Specifications and ~~NHIN~~ Operating Policies and Procedures. Other than those representations in Sections ~~17.07, 17.08~~ 16.07, 16.08 and ~~17.09,~~ 16.09, the ~~Responding Participant~~ Submitter makes no other representation, express or implied, about the Message Content.
- 15.09. ~~17.09.~~ **Express Warranty of Authority to ~~Transmit~~ Transact Message Content.** To the extent each Participant is a ~~Responding Participant~~ Submitter and is providing Message Content to a Recipient, each Participant represents and warrants that it has sufficient authority to ~~provide or make~~ Transact such Message Content ~~available to Recipient~~.
- 15.10. ~~17.10.~~ **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. ~~17.11.~~ **Compliance with Laws.** Each Participant ~~will~~ shall, at all times, fully comply with all Applicable Law relating to this Agreement, the ~~exchange~~ Transaction of Message Content for a Permitted ~~Purposes~~ Purpose and the use of Message Content.
- 15.12. ~~17.12.~~ **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 ~~NHIN~~ Coordinating Committee if at any point during ~~its participation in the NHIN~~ the term of this Agreement it becomes subject to such an order.
- 15.13. ~~17.13.~~ **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 ~~will~~ shall immediately provide written ~~notice~~ Notice to the ~~NHIN~~ 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. 18. Confidential Participant Information.

16.01. 18.01. 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. 18.02. Confidential Participant Information may be redisclosed ~~under~~ 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. 19. Disclaimers.

17.01. 19.01. 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 ~~transmitted by the Responding Participant~~ Transacted, the information and Message Content ~~transmitted~~ 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. 19.02. Incomplete Medical Record. Each Participant acknowledges that Message Content ~~received in response to a Message~~ 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 ~~in the NHIN~~.

17.03. 19.03. 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~~ 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~~Health Care Provider, shall be responsible for all decisions and actions taken or not taken involving patient care, utilization management, and quality management for ~~the~~his/her/its respective patients and clients resulting from, or in any way related to, the use of the ~~NHIN~~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. ~~19.04.~~ **Carrier lines.** All Participants acknowledge that the ~~exchange~~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 ~~NHIN~~ Performance and Service Specifications, and the ~~NHIN~~ 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. ~~19.05.~~ **No Warranties.** EXCEPT AS REPRESENTED IN ~~SECTION 17.08,~~ THE SECTIONS 13.02 AND 15.08, MESSAGE CONTENT ~~OBTAINED BY A RECIPIENT ARE~~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 NON-INFRINGEMENT. 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.

~~17.06. 19.06.~~ **Performance of the NHIN Network Standards, Services and Policies.** The Participant makes no representation, express or implied, as to the performance of the NHIN 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 NHIN Network standards, services and policies agreed to by the Participants is beyond the power of any individual Participant to control.

18. 20. Liability.

~~18.01. 20.01.~~ **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 ~~access the~~ NHIN, Transact Message Content or Confidential Participant Information through the Participant or by use of any password, identifier, or log-on received or obtained directly or indirectly, lawfully or unlawfully, from the Participant or any of the Participant Users, 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. 20.02.~~ **Effect of Agreement.** Except as provided in Section ~~19.05~~ 17.05 (“No Warranties”) and Article ~~23.22~~ (“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 ~~the NHIN or~~ 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. 20.03.~~ **Coordinating ~~Committee and Technical~~ Committee Liability.** Each Participant has agreed to comply with this Agreement. Accordingly, the Participants shall not hold the ~~NHIN~~ Coordinating Committee or ~~NHIN Technical Committee~~ 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 ~~NHIN~~ Coordinating ~~Committee or the NHIN Technical~~ Committee.

19. 21. Term, Suspension and Termination.

19.01. ~~21.01.~~ **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 ~~21.19.~~

19.02. ~~21.02.~~ **Suspension or Termination by Participant.**

- a. A Participant may voluntarily suspend its own ~~participation in the NHIN~~ right to Transact Message Content for a valid purpose, as determined by the ~~NHIN~~ Coordinating Committee, by ~~giving the NHIN Coordinating Committee at least twenty four (24) hours prior written notice. Once proper notice is given, the NHIN Coordinating Committee shall be empowered to suspend the Participant's Digital Credentials as of the date of suspension specified in the notice. Once the NHIN Coordinating Committee suspends the Participant's Digital Credentials, the NHIN Coordinating Committee shall provide notice of such voluntary suspension to all other Participants. During the~~ 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 access the NHIN or be responsible for complying with the terms of this Agreement except those terms that survive termination of this Agreement in accordance with Section 25.05. 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 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 ~~fiveten (510)~~ twentyfour (2040) consecutive calendar days or for more than ~~twentyfour (2040)~~ calendar days during any twelve (12) month period, unless a longer period is agreed to by the ~~NHIN~~ Coordinating Committee.
- b. A Participant may terminate its ~~participation in the NHIN~~ own right to Transact Message Content by terminating this Agreement, with or without cause, by giving the ~~NHIN~~ Coordinating Committee at least five (5) business days prior written ~~notice~~ Notice. Once proper ~~notice~~ Notice is given, the ~~NHIN~~ Coordinating Committee shall be empowered to revoke the Participant's Digital Credentials as of the date of termination specified in the ~~notice~~ Notice. Once the ~~NHIN~~ Coordinating Committee revokes the Participant's Digital Credentials, the ~~NHIN~~ Coordinating Committee shall provide ~~notice~~ Notice of such revocation to the remaining Participants.

19.03. ~~21.03.~~ **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 NHIN~~; the integrity or operation of the Performance and Service Specifications; or an individual whose Message Content is ~~exchanged through the NHIN~~; 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 ~~participate in the NHIN~~ Transact Message Content (i) provide ~~notice~~ 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 ~~will~~ 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 ~~will~~ shall, upon completion of the plan of correction, reinstate the Participant's Digital Credentials and provide ~~notice~~ Notice to all Participants of such reinstatement. If the plan of correction is rejected, the Participant's suspension will continue, during which time the ~~NHIN~~ 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 ~~NHIN~~ Coordinating Committee. At any time after the ~~NHIN~~ Coordinating Committee rejects a Participant's plan of correction, either the Participant or the ~~NHIN~~ Coordinating Committee may submit a Dispute to the Dispute Resolution Process described in Section ~~23-21~~. 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 ~~21.04~~. 19.04.

19.04. ~~21.04~~ **Termination by Coordinating Committee.** The Participants hereby grant to the Coordinating Committee the power to terminate a Participant's ~~participation in the NHIN~~ right to Transact Message Content as follows:

- a. After taking a suspension action in accordance with Section ~~21.03~~ 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, ~~the NHIN~~ integrity or operation of the Performance and Service Specifications, or an individual whose Message Content is ~~exchanged through the NHIN~~ 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~~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 ~~NHIN~~-Coordinating Committee.

19.05. ~~21.05.~~ **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 ~~use the NHIN~~Transact Message Content with other Participants (unless such Participant Users have an independent right to ~~access the NHIN~~Transact Message Content through another Participant). The Coordinating Committee shall revoke a terminated Participant's Digital Credentials, which will terminate Participant's ability to ~~access the NHIN~~Transact Message Content. Once the Coordinating Committee revokes the Participant's Digital Credentials, the Coordinating Committee shall provide ~~notice~~Notice of such revocation to the remaining Participants. In the event that any Participant(s) ~~are~~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 ~~25.05~~23.05 (Survival Provisions).

19.06. ~~21.06.~~ **Confidential Participant Information.** All information used, provided, or created in accordance with this Section ~~21,~~19, except for Message Content, shall be labeled as "Confidential Participant Information" and shall be treated as such in accordance with Section ~~18,~~16.

19.07. ~~21.07.~~ **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 ~~6.02,~~5.02.

20. ~~22.~~ **Cooperation.** Each Participant understands and acknowledges that numerous activities with respect to ~~the NHIN~~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 ~~NHIN~~-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 ~~NHIN~~-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 ~~NHIN~~-Coordinating Committee to review information, meet with, respond to, and advise the ~~NHIN~~-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 ~~NHIN~~-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 ~~NHIN~~ Coordinating Committee or other Participants in the investigation of Breaches 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 ~~NHIN~~ 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. ~~23.~~ Dispute Resolution.

21.01. ~~23.01.~~ 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 ~~23.02~~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 ~~21.04~~19.04(b).

21.02. ~~23.02.~~ Immediate Injunctive Relief.

- a. Notwithstanding Section ~~23.01~~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 ~~exchanged through the NHIN~~ or will cause irreparable harm to another party (Participant, Participant User, ~~NHIN~~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 ~~notify~~provide a Notification to the ~~NHIN~~ 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 ~~23.02~~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 ~~23.01~~21.01.

~~21.03. 23.03.~~ **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 ~~participation in the NHIN~~right to Transact Message Content in accordance with Section ~~21.02~~19.02(a), is suspended in accordance with Section ~~21.03~~19.03, or exercises its right to cease ~~exchanging~~Transacting Message Content in accordance with Section ~~13.01~~12.01(b).

~~21.04. 23.04.~~ **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. 23.05.~~ **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. 24.~~ **Notices.** All ~~notices~~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 ~~NHIN~~ 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 facsimile telecommunication or other form of electronic transmission, upon receipt when the ~~notice~~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. 25.~~ **Miscellaneous/General.**

~~23.01. 25.01.~~ **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. 25.02.~~ **Amendment.** This Agreement may be amended ~~in accordance with the Change Process described in Section 12.03~~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 ~~NHIN, the NHIN~~ Coordinating Committee, or Participants to comply with Applicable Law, the ~~NHIN~~ Coordinating Committee may implement the change with approval of at least a majority of ~~non-governmental~~Non-Governmental Participants and at least a majority of Governmental Participants and within a time period the ~~NHIN~~ 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 ~~the NHIN in~~ accordance with Section ~~21.02.19.02.~~

- 23.03. ~~25.03.~~ **Additional**New Participants. Upon the ~~NHIN~~ Coordinating Committee's acceptance of ~~new participant in the NHIN~~ a New Participant, the ~~NHIN~~ Coordinating Committee shall have the ~~new participant execute and become bound by this Agreement. To accomplish this, the new participant will enter into~~ New Participant execute a Joinder Agreement, the form of which is attached hereto as Attachment ~~7,~~ 7, ~~pursuant to which the new participant agrees to be bound by this Agreement.~~ 7. The Participants agree that upon execution of the Joinder Agreement by a duly authorized representative of the ~~NHIN~~ 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~~ New Participant are all bound by this Agreement. The ~~new participant~~ New Participant shall not be granted the right to ~~participate in the NHIN~~ Transact Message Content until both it and the ~~NHIN~~ Coordinating Committee execute the Joinder Agreement.
- 23.04. ~~25.04.~~ **Assignment.** No Party shall assign or transfer this Agreement, or any part thereof, without the express written consent of the ~~NHIN~~ Coordinating Committee. Any assignment that does not comply with the requirements of this Section ~~25.04~~ 23.04 shall be void and have no binding effect.
- 23.05. ~~25.05.~~ **Survival.** The provisions of Sections ~~6.02, 6.03, 1, 5.02, 5.03, 14, 15.10, 16, 17.10, 18, 20, 21.06, 21.07, 22~~ 18, 19.06, 19.07, 20 and ~~23~~ 21 shall survive the termination of this Agreement for any reason.
- 23.06. ~~25.06.~~ **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. ~~25.07.~~ **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. ~~25.08.~~ **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. ~~25.09.~~ **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. ~~25.10.~~ **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. ~~25.11.~~ **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 ~~NHIN~~-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. ~~25.12.~~ **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 ~~25.03-~~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. ~~25.13.~~ **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. ~~25.14.~~ **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 ~~25.14~~23.14 shall not apply to obligations imposed under Applicable Law.

23.15. ~~25.15.~~ **Time Periods.** Any of the time periods specified in this Agreement may be changed pursuant to the mutual written consent of the ~~NHIN~~-Coordinating Committee and the affected Participant(s).

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

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

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

Michael Matthews	Date:
Chief Executive Officer	MedVirginia

	Date:
	Social Security Administration

W. Scott Gould	Date:
Deputy Secretary	US Department of Veterans Affairs

Robert A. Petzel, M.D.	Date:
Under Secretary for Health	Veterans Health Administration

Stephen B. Thacker, M.D., M.Sc. RADM (Ret.), USPHS	Date:
Acting Deputy Director Office of Surveillance, Epidemiology and Laboratory Services	Centers for Disease Control and Prevention

Richard D. Daniels	Date:
Senior Vice President and Business Information Officer	Kaiser Permanente

Attachment 1 - ~~NHIN~~ Specifications

Accessible ~~on the NHIN Resources Page~~ at:

http://healthit.hhs.gov/portal/server.pt?open=512&objID=1194&parentname=CommunityPage&parentid=18&mode=2&in_hi_userid=10882&cached=true [nhinexchange](#)

Attachment 2 - ~~NHIN Test Approach~~ Validation Plan and Test Materials

Accessible on the NHIN Resources Page at: <http://healthit.hhs.gov/nhinexchange>
~~http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10731_848165_0_0_18/NHIN%20Trial%20Implementation%20Test%20Approach%20and%20Test%20Materials%20V2.0%2012.12.08%20FINAL-3.pdf~~

Attachment 3 - ~~NHIN~~ Operating Policies and Procedures

Accessible ~~on the NHIN Resources Page~~ at: <http://healthit.hhs.gov/nhinexchange>

http://healthit.hhs.gov/portal/server.pt?open=512&objID=1407&parentname=CommunityPage&parentid=5&mode=2&in_hi_userid=10741&cached=true

Attachment 4 - Participant Addresses for Notice

Primary Contact	Alternate Contact
<p>Centers for Disease Control and Prevention Charles Magruder Senior Advisor CENT Bldg 2500 Rm 2319 MS E68 Atlanta, GA 30333 Phone: 404 498 2443 E-mail: zgu4@cdc.gov Fax: 404 498 6565</p>	<p>Centers for Disease Control and Prevention Sudevi Ghosh Attorney Advisor CLFT Bldg 21 Rm 10119 MS D53 Atlanta, GA 30333 Phone: 404 639 7016 E-mail: ggq4@cdc.gov Fax: 404 639 7351</p>
<p>MedVirginia Attn: Michael Matthews Chief Executive Officer 2201 West Broad Street, #202 Richmond VA 23220 Phone: 804 359 4500 x 225 E-mail: mmathews@evhn.com Fax: 804 359 1021</p>	<p>MedVirginia Attn: Jean McGraw Chief Operations Officer 2201 West Broad Street, #202 Richmond VA 23220 Phone: 804.359.4500 x229 E-mail: jmcgraw@evhn.com Fax: 804 359 1021</p>
<p>Kaiser Permanente Attn: Richard D. Daniels Senior Vice President and Business Information Officer 1800 Harrison St., 24th floor Oakland, CA 94612 Phone (510) 267 5317 E-mail: richard.d.daniels@kp.org Fax: (510) 267 2155</p>	<p>Kaiser Permanente Attn: Allen Samelson Senior Counsel One Kaiser Plaza, 21 Lakeside Oakland, CA 94612 Phone (510) 271 6927 E-mail: allen.samelson@kp.org Fax: (510) 267 2128</p>
<p>Social Security Administration Name: Title: 416 Altmeyer 6401 Security Blvd. Baltimore, MD 21235 Phone</p>	<p>Social Security Administration Name: Title: 416 Altmeyer 6401 Security Blvd. Baltimore, MD 21235 Phone</p>

E-mail: Fax:	E-mail: Fax:
Veterans Administration Gerald M. Cross, MD, SAAFP Acting Under Secretary for Health Veterans Health Administration 810 Vermont Avenue, NW Washington, DC 20420 Phone: (202) 461-7008 Email: Gerald.m.cross@va.gov Fax: (202) 273-5787	Veterans Administration Will A. Gunn General Counsel Office of General Counsel 810 Vermont Avenue, NW Washington, DC 20420 Phone: (202) 461-4995 Email: will.gunn@va.gov Fax: (202) 273-6671

<u>Primary Contact</u>	<u>Alternate Contact</u>

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

Pursuant to Section ~~16.01~~14.01(d), the following HIPAA provisions are applicable to ~~Participants~~each Participant that ~~are~~is neither a Covered ~~Entities,~~Entity, a Business ~~Associates~~Associate nor a Governmental ~~Participants~~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 1 to the extent they are used in said sections.

- 45 C.F.R. § 164.306 (Security Rule – General rules) ~~*{This is not required of BAs by the HITECH Act, but it nevertheless appears to be appropriate to include here, e.g., “Covered entities must ... Ensure the confidentiality, integrity, and availability of all electronic [PHI] the covered entity creates, receives, maintains, or transmits.”}*~~
- 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)

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 ~~will~~shall send written ~~notice~~Notice, in accordance with the ~~notice~~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 ~~will~~shall provide ~~notification~~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 ~~Committee~~Subcommittee in writing.
 - The Dispute Resolution Subcommittee (the "Subcommittee") will be a five (5) member standing subcommittee of the ~~NHIN~~-Coordinating Committee. The ~~NHIN~~ Coordinating Committee ~~will~~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 ~~NHIN~~ 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) ~~are~~is unavailable. Subcommittee members are required to declare any conflicts in accordance with the ~~NHIN~~-Coordinating Committee's conflict of interest policy. Once a Subcommittee member declares a conflict, the remaining Subcommittee members ~~will~~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 ~~NHIN~~ 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 ~~will~~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 ~~will~~shall have the ability to request additional information from the Participants to help it make its determination. The Subcommittee, however, ~~will~~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 ~~will~~shall have the ability to mark the documents produced as “Confidential Participant Information” and the Subcommittee ~~will~~shall treat those documents in accordance with Section ~~18~~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 ~~NHIN~~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 ~~will~~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 ~~will~~shall have five (5) business days in which to escalate the Dispute to the ~~NHIN~~-Coordinating Committee.
- Within twenty (20) calendar days of receiving notice of escalation from a Participant, the ~~NHIN~~-Coordinating Committee ~~will~~shall review the Subcommittee's recommendation along with the information on which such recommendation was based and issue a final resolution. The ~~NHIN~~-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 ~~NHIN~~ Coordinating Committee, the Participants ~~will~~shall determine whether to accept or reject the resolution and so notify the ~~NHIN~~ Coordinating Committee.
- The ~~NHIN~~-Coordinating Committee ~~will~~shall send a written summary of the resolution of the Dispute to all ~~NHIN~~ 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 (~~this “Joinder”~~), made as of _____, 20____ ~~the last date set forth below~~, by and between _____ (the “~~NHIN~~—Coordinating Committee”) and _____ (the “New Participant”) makes New Participant a party to that certain Data Use and Reciprocal Support Agreement dated _____ among the ~~participants in the Nationwide Health Information Network (“NHIN”)~~ Participants, as amended through the date hereof (the “DURSA”).

RECITALS:

A. The New Participant desires to become a ~~participant in the NHIN~~ Participant and Transact Message Content with other Participants.

B. The ~~NHIN~~—Coordinating Committee has accepted and approved the New Participant’s application to ~~participate in the NHIN~~ 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.

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

5. **COUNTERPARTS.** This Joinder Agreement may be executed in any number of counterparts, each of which ~~will~~shall be an original, but all of which taken together ~~will~~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.

~~NHIN~~ COORDINATING COMMITTEE

NEW PARTICIPANT

By: _____

By: _____

Name: _____

Name: _____

Date: _____

Date: _____

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Padding cell	

Statistics:	
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