

eHealth Exchange[™]

Operating Policy & Procedure (OPP) & Validation Plan Revision Highlights

May 2020

eHealth Exchange Subcommittee: Review of Proposed OPP Revisions

- Over five (5) subcommittee meetings:
 - Attended by Marty Prah, Dr. Matthew Eisenberg, Jarrod Pearson, Jay Nakashima and various eHealth Exchange staff
 - Reviewed all 13 revised eHealth Exchange OPP documents:
 - Reviewed OPPs with “Housekeeping Only”
 - Reviewed OPP redlines necessitated by the DURSA amendment and Redlines necessitated by the DURSA amendment with a small “Substantive Change”
 - Reviewed OPPs with substantive redlines
 - Tracked and closed all action items from each meeting
 - Updated the OPP Revision Highlights PPT to reflect additional edits and additions to the OPPs
- Republished all newly updated draft OPPs
- Produced several work products:
 - OPP Template and Instructions
 - eHealth Exchange OPP Document Summary
 - OPP Glossary of Terms

eHealth Exchange Subcommittee: OPP Revision Overview

- While most of the proposed Operating Policy & Procedure (OPP) changes were necessitated by the 2019 DURSA Amendment, some of the changes were made to reflect the current eHealth Exchange environment and operations. Other OPPs were adjusted to improve clarity, readability and make the OPPs consistent.

- Each OPP change has been characterized as a:

Housekeeping
Change

» These edits are intended to improve formatting, readability and consistency

Clarifications
Change

» These edits are intended to provide clarity around terms and references unrelated to DURSA changes

DURSA-Driven
Change

» These edits are necessitated by the 2019 DURSA Amendment

Substantive
Change

» These edits are suggested to reflect the current environment and operations of eHealth Exchange unrelated to DURSA changes

- Appendix: [OPP Revision Overview](#)
- Appendix: [DURSA Amendment Overview](#)
- Questions or Concerns: administrator@ehealthexchange.org
- Proposed revision details are published on the bottom of <https://ehealthexchange.org/policies>

eHealth Exchange Subcommittee: Work Products

- OPP Template and Instructions:
 - Produced a standard template for capturing the Purpose, Policy, Procedure, Definitions, References, Related Policies and Procedures, and Version History for an OPP
 - Provides instructions and guidance on font, formatting, naming convention, general instructions for References, Definitions, Related Policies and Procedures, and other documents that may need to be kept up to date for new or amended OPP documents
- eHealth Exchange OPP Document Summary:
 - Created an OPP summary table that captures the OPP#, OPP document title, date created, date finalized, summary description and a link to the OPP document on the eHealth Exchange website
- OPP Glossary of Terms
 - Created a summary of all terms defined in the *V. Definitions* section of each OPP*

* Disclaimer: All other capitalized terms, if not defined within the OPP, have the same meaning set forth in the DURSA.

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Appendix: OPP Revision Overview

Overview

- While most of the proposed Operating Policy & Procedure (OPP) changes were necessitated by the 2019 DURSA Amendment, some of the changes were made to reflect the current eHealth Exchange environment and operations. Other OPPs were adjusted to improve clarity, readability and make the OPPs consistent
- Each OPP change has been characterized as a:
 -  » These edits are intended to improve formatting, readability and consistency
 -  » These edits are intended to provide clarity around terms and references unrelated to DURSA changes
 -  » These edits are necessitated by the 2019 DURSA Amendment
 -  » These edits are suggested to reflect the current environment and operations of eHealth Exchange unrelated to DURSA changes
- Proposed revision details are published on the bottom of <https://ehealthexchange.org/policies>
- Questions or Concerns: administrator@ehealthexchange.org
- Appendix: [DURSA Amendment Overview](#)

“Housekeeping” Changes

1. Upgraded all OPPs to the latest version of Microsoft Word 2016
2. Formatted all OPPs for consistency and readability (font, formatting, headers, footers, revision tables, OP&P=OPP, Ehealth Exchange=eHealth Exchange, etc.)
3. Updated all OPP Reference sections to reflect the most current DURSA document name and DURSA section titles

The following OPPs were only revised with “Housekeeping” adjustments:

- OPP #2: Coordinating Committee General Operating Procedure
- OPP #10: New Networks – Participant Opt-Out of New Data Sharing Agreements
- OPP #13: Safeguarding Controlled Unclassified Information (CUI)

OPP #1 – Review and Disposition of Applications for Participation

- Under OPP Procedure section, *D. Disposition Application*:
 - Removed reference to "UDDI/Web Service Registry" which are no longer valid terms and left "eHealth Exchange Directory" only, for consistency across all OPP documents

OPP #1 – Review and Disposition of Applications for Participation

- Under OPP Purpose section:
 - Updated language to reflect the Coordinating Committee’s responsibility to approve new networks (DURSA, Section 4)
- Under OPP Policy section, *A. General Eligibility Requirements*:
 - Updated language to reflect the expanded Definition of Participant (DURSA, Section 1)
 - Removed language that an applicant can only exchange solely as an agent of a Covered Entity (DURSA, Section 1)
 - Updated language to include Third Party Technology vendors (DURSA, Section 17.05)
- Under Definitions Section:
 - Defined Third Party Technology (DURSA, Section 17.05)

OPP #1 – Review and Disposition of Applications for Participation

- Under OPP Policy section, *A. General Eligibility Requirements*:
 - Clarified that the gateway implemented must comply with the Performance and Service Specifications for each applicable use case. This is also updated under the Technical Requirements section
 - To better manage expectations, clarified that the submission of the signed Application and DURSA Joinder Agreement must also include a Business Associate Agreement. And that education regarding the BAAs purpose can be provided.
- Under Definitions Section:
 - Defined Business Associate Agreement (BAA) as it relates to the Participant agreements

OPP #1 – Disposition Application Section-Removed Conditional Acceptance

- OPP #1 outlines the Coordinating Committee’s standard process for a Participant onboarding to the eHealth Exchange, from application to go live.
- Current Challenge: Once an applicant using a Qualified Technology Solution (QTS) gateway has participated in a QTS kickoff teleconference, or an applicant has completed testing, **“Conditional Acceptance” is an unnecessary step**, so the OPP as currently written is outdated.
- Conditional Acceptance Includes:
 - Formal e-mail sent to Participants
 - 180-day deadline to complete remaining steps and go live
 - Notification to Coordinating Committee
 - Then organization is moved to activation phase
- **In the revised OPP the “Conditional Acceptance” requirement has been removed so relevant applicants move straight to the activation phase**, which includes:
 - Issuance of production certificates
 - DURSA, Participation Agreement, and Business Associate Agreement signatures
 - Addition to the production UDDI
 - Successful responder testing with the Hub
 - Go live
- Coordinating Committee would be notified once the above steps have been completed and a Participant is ready to go live.

Substantive
Change

OPP #3 – Participation-Changes, Suspension, Termination:

- Under the OPP Procedures section, *A. Service Changes*:
 - Replaced “Service Registry” with “eHealth Exchange Directory” for consistency across all OPPs. (Section IV. Definitions-also reflects this update)
- Under OPP Definitions section:
 - Added definition for Transaction Pattern
 - Added definition for Service Change

OPP #3 – Participation-Changes, Suspension, Termination:

- Under the OPP Procedures section, *A. Service Changes*:
 - Provided examples of a Service Change which includes support for opt in/opt out of Networks (DURSA, Section 12.05)
- Under OPP Related Policies and Procedures section:
 - Added reference to OPP #10, New Networks (DURSA, Section 12.05)

OPP #3 – Participation-Changes, Suspension, Termination:

- Under OPP Procedures section, *B. Suspension*:
 - To manage expectations, added clarification regarding longstanding practice & DURSA principle:
“Note that Healthway, Inc. (dba “The eHealth Exchange”) separately maintains authority to suspend Participants’ digital certificates (not their network Participation) for breach of the Participation Agreement (including non-payment), and for failure to enter into a Participation Agreement.”

OPP #4 – Change Process- Performance and Service Specifications:

- Under OPP Policy section:
 - Added language that compliance with Performance and Service specifications are expectations and requirements (DURSA, Section 7 and 12.01)

OPP #5 – Change Process-Operating Policies and Procedures:

- Under OPP Procedure section, *A. Retention, Maintenance and Dissemination of Operating Policies and Procedures*:
 - Added Language: *“A workgroup is to be appointed by the Coordinating Committee to review all OPPs at least every 3 years using a standard template for consistency, readability and applicability against current standards and processes.”*

OPP #6 – Confidential Information Handling:

- Changed the title and header of the OPP from *Information Handling* to *Confidential Information Handling* for better clarity of the OPP purpose
- Under OPP Definitions section:
 - Removed the Secure Site definition since it is not a valid term or mentioned in the OPP

OPP #6 – Confidential Information Handling:

- Under OPP Procedure section:
 - Replaced references of the label “Breach” to “Adverse Security Event” (DURSA, Section 1 and 14.04)

Substantive
Change

OPP #6 – Confidential Information Handling:

- Under OPP Procedure section:
 - Updated outdated language to reflect the obligations of handling, storing and deleting Confidential Information by the Coordinating Committee. The previous version of the OPP forbade Coordinating Committee members from storing confidential information (even emails) on work PCs which is not practical.

OPP #7 – Adverse Security Event Notification:

- Under OPP Related Policies and Procedures section:
 - Added reference to OPP #9, Digital Credentials

OPP #7 – Adverse Security Event Notification:

- Replaced all “breach” references to “Adverse Security Event” to reflect the new Adverse Security Event definition (DURSA, Section 1d)
- Under OPP Procedure section, *B. One-Hour Adverse Security Event Alert* section, changed title to *B. Adverse Security Events involving Federal Participants: One-Hour Breach Adverse Security Event Alert* (DURSA, Section 14.04)
 - reiterated that within **one hour of** learning that an Adverse Security Event occurred and that such Event may involve a Federal Participant, Participant must **still** alert the Federal Participant, and (b) that within twenty-four (24) hours after determining that an Adverse Security Event has occurred and is likely to have an adverse impact on a Federal Participant(s), Participant shall provide a notification to all such Participants that are likely impacted by the Event, and the Coordinating Committee.
- Under OPP Procedure section, *C. Five-Business Day Notification of Adverse Security Event Alert*, changed title to *C. Adverse Security Events involving All Participants: Five Business Day Notification of Breach Adverse Security Event Determination* (DURSA, Section 14.04)
 - Explained that Participants should notify the Coordinating Committee within **5 business days** after determining that an Adverse Security Event (or “Event”) has occurred and is likely to have an adverse impact on the Network or another Participant.
- Under OPP Definitions section:
 - Updated Adverse Security Event definition with newest DURSA amendment definition (DURSA, Section 1d)

OPP #7 – Adverse Security Event Notification:

- Under OPP Procedure section, *C. Adverse Security Events involving All Participants: Five Business Day Notification of Breach Adverse Security Event Determination*
 - Added the dedicated Alert Email address (securityevent@ehealthexchange.org)
 - Removed language to exclude prescriptive secure methods (e.g. fax) for Adverse Security Event Reporting
 - Removed “Secure Site” language so Participants and Coordinating Committee members don’t have to navigate to a “secure web portal” to exchange and store information
- Under OPP Definitions section:
 - Removed Secure Site definition

OPP #8 – Data Use and Reciprocal Support Agreement and Amendment Process:

- Under OPP Definitions section:
 - Added Joinder Agreement definition

OPP #9 – eHealth Exchange Digital Credentials:

- Under OPP Definitions section:
 - Added Federal Bridge Certificate Authority (FBCA) definition
 - Updated Subscriber definition

OPP #9 – eHealth Exchange Digital Credentials:

- Under OPP Purpose section:
 - Updated language to reflect that credentials can be used to exchange Message Content with networks contracted for exchange, as governed by the DURSA and Coordinating Committee (DURSA, Section 4, Coordinating Committee)

Substantive
Change

OPP #9 – eHealth Exchange Digital Credentials:

- Under OPP Policy section:
 - Added clarifying language regarding Federal Bridge Certificate Authority (FBCA) root certificates
 - Removed language regarding security testing by eHealth Exchange Support Staff
- Under OPP Procedure section:
 - Added procedures for Subscriber and Renewal Information

OPP #11 – Service Levels and Operational Monitoring:

Please note that this OPP was significantly modified, so carefully reviewing the redlines is encouraged.

- Under OPP Purpose section:
 - Updated the language to reflect eHealth Exchange’s current hybrid network
 - Updated the language to reflect that operational monitoring is based on the use case
 - Updated the language to reflect the scope of the OPP and referenced the eHealth Exchange solution that is currently being used to capture metrics and share information
 - Updated the language to reflect real-time monitoring, 24x7x365 support, no PII/PHI, etc.
- Under the OPP Procedure section:
 - Updated the language to reflect the eHealth Exchange Hub Dashboard capabilities, staff access and responsibilities, and Participant access and capabilities, User Guide information, transaction retention, etc.
- Under the Definitions section:
 - Added definitions for the eHealth Exchange Hub and Hub Dashboard

OPP #12 – eHealth Exchange Vendor Participation:

- Under OPP Definitions section:
 - Added definition for Customer(s)

OPP #12 – eHealth Exchange Vendor Participation:

- Under OPP Policy section:
 - Updated language so that the Vendor Applicant agrees to facilitate exchange solely as an agent of its Customers and removed specific language regarding covered entity, healthcare provider or healthplan. (DURSA, Section 1)
 - Updated the BAA requirement to reflect “as required by law”

Substantive
Change

Validation Plan v8.1

- Removed references to PKI Certificate Testing since it is now up to Applicants and Participants to validate that their eHealth Exchange gateway only accepts inbound requests from other eHealth Exchange Participants and trusted networks as detailed in OPP9.

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Appendix: DURSA Amendment Overview

DURSA Amendment Overview

- The following slides will provide a **high-level summary** of the DURSA Amendment. This summary is meant to provide a quick review of the major changes. The redline draft DURSA Amendment includes ALL changes and will be distributed to Participants.
- The Draft DURSA Amendment includes changes to the following DURSA sections:
 - Section 1: Definitions
 - Section 4: Coordinating Committee
 - Section 9: Monitoring and Auditing
 - Section 12: Expectations of Participants
 - Section 13: Specific Duties of a Participant When Submitting a Message
 - Section 14: Privacy and Security (Applicability of HIPAA Regulations)
 - Section 14: Privacy and Security (Breach Notification)
 - Section 17: Disclaimers (Third Party Technology)
 - Section 18: Liability (Participant Liability)

Section 1 – New and Deleted Definitions

| PREVIOUS DURSA (9/30/14) | DURSA AMENDMENT (2/1/2020) | Why Changed |
|--|---|---|
| <p>o. 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.</p> <p>x. Network shall mean 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</p> <p>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.</p> | <p>a. Applicant means anyone that submits an application to become an eHealth Exchange Participant.</p> <p>m. eHealth Exchange shall mean the data sharing network which was developed under the auspices of the Office of the National Coordinator for Health Information Technology and consists of governmental and non-governmental exchange partners who share information under a multi-purpose set of standards and services which are designed to support a broad range of information exchange activities using various technical platforms and solutions</p> <p>n. Deleted Emergent Specifications</p> <p>y. Network shall mean the eHealth Exchange.</p> <p>z. Network Utilities shall mean any shared infrastructure used to facilitate the transmission of Message Content for the Network including, but not limited to, gateway services, healthcare directory, master patient indices, record locator services.</p> <p>uu. Transaction Pattern shall mean a type of information exchange service(s) enabled by the Specifications. The Validation Plan will identify the Transaction Pattern(s) and the Specifications required to implement each Transaction Pattern. The Transaction Patterns may be amended from time to time through amendment of the Specifications and the Operating Policies and Procedures.</p> <p>vv. Use Case shall mean a particular activity involving Transacting Message Content using the Network in order to support a specific function or facilitate an identified outcome.</p> | <p>Updated some definitions to reflect how the eHealth Exchange is operating and changes to the external environment.</p> |

Section 1 - Expanded Definition of Participant

| PREVIOUS DURSA (9/30/14) | DURSA AMENDMENT (2/1/2020) | Why Changed |
|--|--|--|
| <p>Definition of Participant</p> <p>e. Participant shall mean any (i) organization that (a) meets the requirements for participation as contained in the Operating Policies and Procedures; (b) is provided with Digital Credentials; and (c) is a signatory to this Agreement or a Joinder Agreement.</p> | <p>g. Participant shall mean any (i) organization that oversees and conducts, on its own behalf and/or on behalf of its Participant Users, electronic transactions or exchanges of health information among groups of persons or organizations; (ii) federal, state, tribal or local governments, agencies or instrumentalities that need to exchange health information with others as part of their official function; (iii) organization that supports program activities or initiatives that are involved in healthcare in any capacity and have the technical ability to meet the applicable Performance and Service Specifications to electronically transact health information on its own behalf or on behalf of its Participant Users; has the organizational infrastructure and legal authority to comply with the obligations in this Agreement and to require its Participant Users to comply with applicable requirements in this Agreement</p> | <p>Expand the types of organizations that are able to join the eHealth Exchange as Participants.</p> |

Section 1 - Updated Definition of Breach

| PREVIOUS DURSA (9/30/14) | DURSA AMENDMENT (2/1/2020) | Why Changed |
|--|---|---|
| <p>Definition of Breach</p> <p>c. Breach shall mean the unauthorized acquisition, access, disclosure, or use of Message Content while Transacting such Message Content pursuant to this Agreement. The term “Breach” does not include the following:</p> <p>(i) any unintentional acquisition, access, disclosure, or use of Message Content by an employee or individual acting under the authority of a Participant or Participant User if—</p> <p style="padding-left: 40px;">(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</p> <p style="padding-left: 40px;">(II) such Message Content is not further acquired, accessed, disclosed or used by such employee or individual; or</p> <p>(ii) any acquisition, access, disclosure or use of information contained in or available through the Participant’s System where such acquisition, access, disclosure or use was not directly related to Transacting Message Content.</p> | <p>Renamed Breach to Adverse Security Event</p> <p>d. Adverse Security Event shall mean the unauthorized acquisition, access, disclosure, or use of unencrypted Message Content in the process of being transacted in a manner permitted by this Agreement by anyone who is not a Participant or Participant User or by a Participant or Participant User in any manner that is not a Permitted Purpose under this Agreement. For the avoidance of doubt, an “Adverse Security Event” under this Agreement does not include the following:</p> <p>(i) any unintentional acquisition, access, disclosure, or use of Message Content by an employee or individual acting under the authority of a Participant or Participant User if—</p> <p style="padding-left: 40px;">(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</p> <p style="padding-left: 40px;">(II) such Message Content is not further acquired, accessed, disclosed or used by such employee or individual; or</p> <p>(ii) any acquisition, access, disclosure or use of information contained in or available through the Participant’s System where such acquisition, access, disclosure or use was not directly related to Transacting Message Content.</p> | <p>The term “breach” is actually a legal conclusion that a HIPAA covered entity, or its business associates make after they investigate the unauthorized access, use or disclosure of PHI. We want to make it clear that not every event is a breach. Hence, the change in terms.</p> <p>Under the HIPAA Breach Notification Rule, a covered entity is required to report a data breach if it determines there is less than a low probability that PHI was actually accessed by virtue of an unauthorized access, use or disclosure. The rule requires a covered entity to review every unauthorized access, use or disclosure of PHI incident to determine whether it resulted in a reportable breach. The eHealth Exchange received feedback that the DURSA definition of the term “breach” was confusing since it was broader than a HIPAA reportable breach.</p> <p>Therefore, we decided to change the label from “breach” to “adverse security event” to avoid this confusion. We did not substantively change the definition from what has been in the DURSA for many years. The definition is <u>still limited</u> to events that occur while Message Content is <u>being transacted</u> via eHealth Exchange. The DURSA does not apply (and never has applied) to anything that happens within a Participant’s data systems.</p> <p>We do <u>not</u> believe changing the label from “breach” to “adverse security event” broadens the scope at all.</p> |

Section 1 - Expanded Definition of Permitted Purpose

| PREVIOUS DURSA (9/30/14) | DURSA AMENDMENT (2/1/2020) | Why Changed |
|--|---|--|
| <ol style="list-style-type: none"> 1. Treatment of individual who is the subject of the message 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 <ol style="list-style-type: none"> .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 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 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 of such Health Care Provider; 4. Public health activities and reporting as permitted by Applicable Law, including the HIPAA Regulations at 45 C.F.R. § 164.512(b) or 164.514(e); | <ol style="list-style-type: none"> 1. Treatment of individual who is the subject of the message 2. Payment as defined by HIPAA 3. Transaction of Message Content related to value based payment models, alternative payment arrangements or financial risk sharing models of any nature whether for Medicare, Medicaid, other federal programs, commercial payers or employer self-insured arrangements. This could include, but is not limited to, participation in Medicare bundled payments, the Medicare Shared Savings Program, other Medicare Alternate Payment programs, Medicaid Managed Care programs or commercial value-based payment programs 4. Health Care Operations as defined by HIPAA; 5. Transaction of Message Content for certain specialized government functions which are necessary to fulfill an agency's statutory obligations for programs the agency administers including, but not limited to : (i) activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission; (ii) for the purpose of the Department of Veterans Affairs determining the individual's eligibility or entitlement to benefits under the VA upon separation or discharge of the individual from military service; (iii) to determine eligibility for or entitlement to or provision of other government benefits; (iv) for activities related to eligibility for or enrollment in a health plan that is a government program; (v) for administering a government program providing public benefits, to coordinate covered functions; or, (vi) to improve administration and management relating to the covered functions of such government programs; 6. Public health activities and reporting as permitted by Applicable Law, including the HIPAA Regulations at 45 C.F.R. § 164.512(b) or 164.514(e); | <p>We are expanding the definition of Permitted Purposes to include new exchange opportunities such as value-based care.</p> |

Section 1 - Expanded Definition of Permitted Purpose (2)

| PREVIOUS DURSA (9/30/14) | DURSA AMENDMENT (2/1/2020) | Why Changed |
|--|--|-------------|
| <p>5. Any purpose to demonstrate meaningful use of certified electronic health record technology by the (i) Submitter, (ii) Recipient or (iii) Covered Entity on whose behalf the Submitter or the Recipient may properly Transact Message Content under this Agreement, provided that the purpose is not otherwise described in subsections 1-4 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</p> <p>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 45 C.F.R. § 164.502(g) of the HIPAA Regulations.</p> | <p>7. Any purpose to demonstrate meaningful use of certified electronic health record technology by the (i) Submitter, (ii) Recipient or (iii) Covered Entity on whose behalf the Submitter or the Recipient may properly Transact Message Content under this Agreement, provided that the purpose is not otherwise described in subsections 1-4⁶ of this definition and the purpose is permitted by Applicable Law, including but not limited to the HIPAA Regulations. “Meaningful use of certified electronic health record technology” shall have the meaning assigned to it in the regulations promulgated by the Department of Health and Human Services under the American Recovery and Reinvestment Act, Sections 4101 and 4102; and</p> <p>8. Transaction of Message Content in support of an individual’s: (i) right to access their health information or (ii) right to direct with whom their information can be shared or where their information should be sent. For the avoidance of doubt, a Participant may be prevented from disclosing information due to Applicable Law even though the individual asserts this Permitted Purpose;</p> <p>9. 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 45 C.F.R. § 164.502(g) of the HIPAA Regulations.</p> | |

Section 4 - Coordinating Committee

| PREVIOUS DURSA (9/30/14) | DURSA AMENDMENT (2/1/2020) | Why Changed |
|--|---|--|
| <p>Section 4.03 is the Grant of Authority to the CC which is to “provide oversight, facilitation and support to Participants Transacting Message Content with other Participants”</p> <p>Section 4.03 lists specific activities the CC is authorized to do</p> | <ul style="list-style-type: none"> • Evaluating requests for and approving new Use Cases; • Approving the type, source and use of Network Utilities. • Deleted Evaluating requests for the introduction of Emergent Specifications into the production environment used by the Participants to Transact Message Content; • Entering into agreements to broaden access to data to enhance connectivity across platforms and networks as provided in accordance with Operating Policies and Procedures which shall include an express opt-out right for every Participant; • Section 4.05 Members of the Coordinating Committee shall carry out their duties in a diligent and responsible manner as more specifically identified in an applicable Operating Policy and Procedure. | <p>We are giving the CC the authority to approve new Use Cases for the eHealth Exchange to expand the scope of what the Exchange can be used for.</p> <p>We are also allowing the CC to approve new Network Utilities, such as potentially future iterations of the Hub for use in the eHealth Exchange.</p> <p>We are also giving the CC the authority to sign data sharing agreements with other networks.</p> |

Section 7 – Enterprise Security

| PREVIOUS DURSA (9/30/14) | DURSA AMENDMENT (2/1/2020) | Why Changed |
|--|---|--|
| Section 7.01 states that Participants are required to comply with Performance and Service Specifications and/or Operating Policies and Procedures related to enterprise security | <ul style="list-style-type: none">Clarified that Performance and Service Specifications and OPPs don't simply define expectations, but also identify requirements. | We wanted the DURSA language to conform to how the CC has always interpreted this issue. |

Section 9 – Monitoring and Auditing

| PREVIOUS DURSA (9/30/14) | DURSA AMENDMENT (2/1/2020) | Why Changed |
|--|--|---|
| <p>Auditing</p> <ul style="list-style-type: none"> Each Participant represents that, through its agents, employees, and independent contractors, it shall have the ability to monitor and audit all access to and use of its System related to this Agreement, for system administration, security, and other legitimate purposes. Each Participant shall perform those auditing activities required by the Performance and Service Specifications. | <p>Renamed to Monitoring and Auditing with additional language added.</p> <ul style="list-style-type: none"> eHealth Exchange, acting through its agents and independent contractors, in order to confirm compliance with this Agreement, shall have the right, but not the obligation, to monitor and audit Network exchange activities. Unless prohibited by Applicable Law or, in the case of a Governmental Participant that Participant’s policies or internal guidelines that it has adopted in the normal course of business, Participant agrees to cooperate with eHealth Exchange in these monitoring and auditing activities and to provide, upon the reasonable request of eHealth Exchange, information in the furtherance of eHealth Exchange’s monitoring and auditing including, but not limited to, audit logs of exchange transactions and summary reports of exchange activities, to the extent that Participant possesses such information. Each Participant represents that, through its agents, employees, and independent contractors, it shall have the ability to monitor and audit all access to and use of its System related to this Agreement, for system administration, security, and other legitimate purposes. Each Participant shall perform those auditing activities required by the Performance and Service Specifications. | <p>The ability to monitor the new HUB is necessary for cyber-security and system performance.</p> |

Section 12 – Expectations of Participants

| PREVIOUS DURSA (9/30/14) | DURSA AMENDMENT (2/1/2020) | Why Changed |
|--|---|---|
| <p>Sec. 12.01 Minimum Requirement for Participants that request Message Content for Treatment.</p> <p>Participants that request, or allow their Participant Users, to request data for Treatment must respond to other Participant’s requests for Treatment.</p> <p>a. All Participants that request, or allow their respective Participant Users to request, Message Content for Treatment shall have a corresponding reciprocal duty to respond to Messages that request Message Content for Treatment. A Participant shall fulfill its duty to respond by either (i) responding to the Message with the requested Message Content or, (ii) responding with a standardized response that indicates the Message Content is not available or cannot be exchanged. All responses to Messages shall comply with Performance and Service Specifications, this Agreement, any agreements between Participants and their Participant Users, and Applicable Law. Participants may, but are not required to, Transact Message Content for a Permitted Purpose other than Treatment. Nothing in this Section 12.01(a) shall require a disclosure that is contrary to a restriction placed on the Message Content by a patient pursuant to Applicable Law.</p> <p>12.02. Participant Users and HSPs</p> | <p>Added additional language.</p> <p>12.01. eHealth Exchange exists to promote the seamless exchange of health information across a variety of technical platforms and Health Information Networks. A core principle of eHealth Exchange is that Participants make commitments to the minimum level of data sharing that they will support so that all other Participants can know, and rely on, each Participant’s commitment. All Participants that choose to participate in a specific Use Case must comply with all of the Performance and Service Specifications for a Use Case and must take measures to require that its Participant Users comply with all of the Performance and Service Specifications for a Use Case.</p> <p>12.01b – Changed Breach to Adverse Security Event</p> <p>12.02 – Changed HSPs to Technology Partners</p> <p>Added new provisions:</p> <p>12.04. Network Utilities. The Coordinating Committee may approve the use of various Network Utilities to support the operation of the Network. If necessary, the Coordinating Committee may develop an Operating Policy and Procedure for implementation and use of the Network Utility by Participants. The Network Performance and Service Specifications may be updated as needed to effectively implement a Network Utility. The procedures outlined in sections 10.03 and 11.03 of this Agreement shall be followed in developing or updating Operating Policies and Procedures or Performance and Service Specifications.</p> | <p>These amendments reflect the expanded scope of exchange activity using eHealth Exchange.</p> |

Section 12 – Expectations of Participants

| PREVIOUS DURSA (9/30/14) | DURSA AMENDMENT (2/1/2020) | Why Changed |
|--|---|---|
| <p>Sec. 12.01 Minimum Requirement for Participants that request Message Content for Treatment.</p> | <p>Added additional provisions.</p> <p>12.05. Opt-out for new networks. If the Coordinating Committee exercises its authority, provided to it by section 4.03(m) of this Agreement, to enter into agreements to broaden access to data to enhance connectivity across platforms and networks, the Participant may choose to opt-out of participation in those platforms or networks for any reason. Participant shall provide the Coordinating Committee written notification of its decision to opt-out. At any time, a Participant may reverse its decision to opt-out.</p> | <p>This new section allows an eHealth Exchange Participant to opt-out of new networks that the Coordinating Committee joins .</p> |

Section 13 - Specific Duties of a Participant When Submitting a Message

| PREVIOUS DURSA (9/30/14) | DURSA AMENDMENT (2/1/2020) | Why Changed |
|---|--|--|
| <p>Section 13 – Specific Duties when Submitting a Message</p> <p>13.03. Submitting a copy of the Authorization, if 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 Submitter who is requesting Message Content to obtain or transmit an Authorization for a request based on a Permitted Purpose other than the one described in Section 1(jj)(6), even though certain other Participants or Participant Users require such Authorization to comply with Applicable Law.</p> | <ul style="list-style-type: none"> Provide evidence that the Submitter has obtained an Authorization or other evidence of an individual directed transaction if the Submitter is requesting Message Content from another Participant or Participant User based on the Permitted Purpose described in Sections 1(jkk)(8) or (9). Nothing in this Section shall be interpreted as requiring a Submitter who is requesting Message Content to obtain or transmit an Authorization for a request based on a Permitted Purpose other than the one described in Section 1(kk)(9), even though certain other Participants or Participant Users require such Authorization to comply with Applicable Law. | <p>This is mainly a clean-up change.</p> |

Section 14 - Privacy and Security (Applicability of HIPAA Regulations)

| PREVIOUS DURSA (9/30/14) | DURSA AMENDMENT (2/1/2020) | Why Changed |
|---|--|---|
| <p>Section 14.01 Applicability of HIPAA Regulations. Message Content may contain PHI. Furthermore, some, but not all, Participants are either a Covered Entity or a Business Associate. Because the Participants are limited to Transacting Message Content for only a Permitted Purpose, the Participants do not intend to become each other’s Business Associate by virtue of signing this Agreement or Transacting Message Content. As a result, the DURSA is not intended to serve as a Business Associate Agreement among the Participants</p> | <p>New Section 14.02</p> <ul style="list-style-type: none"> Business Associate Agreement. Some Use Cases will involve the Transaction of Message Content among Participants, or their Participant Users, that result in a Participant, or Participant User, being considered a Business Associate under the HIPAA Regulations. While this will not be the general rule, when it does occur, the Participants agree that they will enter into a Business Associate Agreement in substantially the same form included in Attachment 8. Compliance with this section’s requirements may be satisfied by an existing business associate agreement that includes, at a minimum, the terms listed in Attachment 8, by adopting a Business Associate Addendum, in substantially the same form included in Attachment 8, to an existing agreement or by adopting a new Business Associate Agreement in substantially the same form included in Attachment 8. <p><i>NOTE: Given the expansion of the definition of Permitted Purposes, we expect that for some Use Cases it will be necessary for Participants to have a Business Associate Agreement with each other. Therefore, we have deleted this language which specifically disavows a business associate relationship. We have inserted a new section below to address situations in which a business associate agreement is required.</i></p> | <p>In currently rare situations, Participants might want to exchange PHI in a way that results in the recipient of PHI be considered a business associate of the sending Participant.</p> <p>For example, a Participant may provide PHI to another Participant so that the recipient Participant can evaluate what community services a patient might qualify for. Available services would be shared with the Participant that provided the PHI to help it properly disposition the patient. This might result in the recipient Participant being considered a business associate of the sending Participant. We do not anticipate this being a regular occurrence, but it may happen. We wanted the DURSA to recognize this situation and provide a neutral template BAA for the Participants to use.</p> <p>If two Participants determine that a BAA is in fact needed, this new Business Associate Agreement template is intended to address HIPAA’s BAA requirements without additional, potentially controversial requirements. This BAA template may be modified, but would need to be in substantially the same form.</p> |

Section 14 – Privacy and Security (Breach Notification)

| PREVIOUS DURSA (9/30/14) | DURSA AMENDMENT (2/1/2020) | Why Changed |
|--|---|--|
| <p>The DURSA defines a Breach very narrowly to only include unauthorized access, use or disclosure of Message Content while it is being transacted.</p> <p>14.03 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 shall alert other Participants whose Message Content may have been Breached and the 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 shall provide a Notification to all Participants likely impacted by the Breach and the Coordinating Committee of such Breach.</p> | <p>Changed the term ‘Breach’ to Adverse Security Event and clarified the definition.</p> <p>14.04 a. As soon as reasonably practicable, but no later than five (5) business days after determining that an Adverse Security Event (or “Event”) has occurred and is likely to have an adverse impact on the Network or another Participant, Participant shall provide a notification to the Coordinating Committee and all Participants that are likely impacted by the Event. Participant shall supplement the information contained in the notification as it becomes available and cooperate with other Participants. Notwithstanding the foregoing, Participant agrees that (a) within one (1) hour of learning that an Adverse Security Event occurred and that such Event may involve a Federal Participant, it shall alert the Federal Participant in accordance with the procedures and contacts provided by such Federal Participant, and (b) that within twenty-four (24) hours after determining that an Adverse Security Event has occurred and is likely to have an adverse impact on a Federal Participant(s), Participant shall provide a notification to all such Participants that are likely impacted by the Event, and the Coordinating Committee, in accordance with the procedures and contacts provided by such Federal Participant.</p> <p><i>NOTE: We have revised this section to conform it to the approach followed in the Carequality Connected Agreement. Most notably, Participants have a longer amount of time to report incidents if no federal government Participants are involved. We are retaining the 1-hour and 24-hour reporting requirements for incidents involving all federal government Participants.</i></p> | <p>The short timeframe for reporting a data breach is the number one objection that we hear from new Participants. We are revising this to only require the 1-hour reporting for federal data and allowing a more generous timeline for everyone else.</p> |

Section 14 – BAA

| PREVIOUS DURSA (9/30/14) | DURSA AMENDMENT (2/1/2020) | Why Changed |
|--------------------------|--|-------------|
| Section 14.02 | <ul style="list-style-type: none">• <u>New section</u> to support use cases in which one Participant is providing a service to another Participant and has access to PHI. This makes the Participant receiving the PHI a business associate under HIPAA. The DURSA recognizes this situation and provides a template business associate agreement for the Participants to use so that they do not get locked into a disagreement over their respective business associate agreements. | |

Section 17 – Disclaimers (Patient Care)

| PREVIOUS DURSA (9/30/14) | DURSA AMENDMENT (2/1/2020) | Why Changed |
|---|---|-------------|
| <p>Section 17.03 states that Message Content is not a substitute for any Participant or Participant User, if that person/entity is a Health Care Provider, obtaining whatever information he/she/it deems necessary, in his/her professional judgment, for the proper treatment of a patient.</p> | <ul style="list-style-type: none">Corrected typo by replacing “through” with “through” | |

Section 17 - Disclaimers (Third Party Technology)

| PREVIOUS DURSA (9/30/14) | DURSA AMENDMENT (2/1/2020) | Why Changed |
|--------------------------|--|--|
| N/A | <p>New Section 17.05</p> <ul style="list-style-type: none"> Third Party Technology. All Participants acknowledge that other Participants use technology solutions, applications, interfaces, software, platforms, clearinghouses and other IT resources that are provided by third parties (Third Party Technology). Each Participant shall have agreements in place that require Third Party Technology vendors to provide reliable, stable and secure services to the Participant. However, all Participants acknowledge that Third Party Technology may be non-functional or not available at times and that this could prevent a Participant from Transacting Message Content. Participants do not make any representations or warranties as to their Third Party Technology. | <p>We want to be certain that all Participants require their third-party technology vendors to provide reliable, stable and secure services. We think that all Participants already have these in place.</p> |

Section 18 – Liability (Participant Liability)

| PREVIOUS DURSA (9/30/14) | DURSA AMENDMENT (2/1/2020) | Why Changed |
|---|--|--|
| <p>Sec. 18.01 – Participant Liability As between Participants to this Agreement: Each Participant shall be responsible for its acts and omissions and not for the acts or omissions of any other Participant. In circumstances involving harm to other Participants caused by the acts or omissions of individuals who 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.</p> | <p>As between Participants to this Agreement: Each Participant shall be responsible for its acts and omissions and not for the acts or omissions of any other Participant. In circumstances involving harm to other Participants caused by the acts or omissions of individuals who: (i) Transact Message Content or Confidential Participant Information through the Participant; (ii) improperly and without permission access a Participant's system whether directly or indirectly, lawfully or unlawfully; or, (iii) use the digital credentials of a Participant or Participant User to access Message Content or Confidential Participant Information, each Participant shall be responsible for such harm to the extent that the individual's access was caused by the Participant's breach of the Agreement or its negligent conduct for which there is a civil remedy under Applicable Law. Notwithstanding any provision in this Agreement to the contrary, Participant shall not be liable for any act or omission if a cause of action for such act or omission is otherwise prohibited by Applicable Law. This section shall not be construed as a hold harmless or indemnification provision.</p> | <p>Clarify when a Participant is liable to other Participants.</p> |

Copies of the amended DURSA

The previous version of the DURSA, the amended DURSA (redlined), and the amended DURSA (clean, executable version) are all available at <https://ehealthexchange.org/onboarding/dursa>