eHealth Exchange

Data Use and Reciprocal Support Agreement (DURSA)

June 19, 2013

Troutman Sanders

Steve Gravely, Healthcare Practice Group Leader

Healtheway

Mariann Yeager, Executive Director

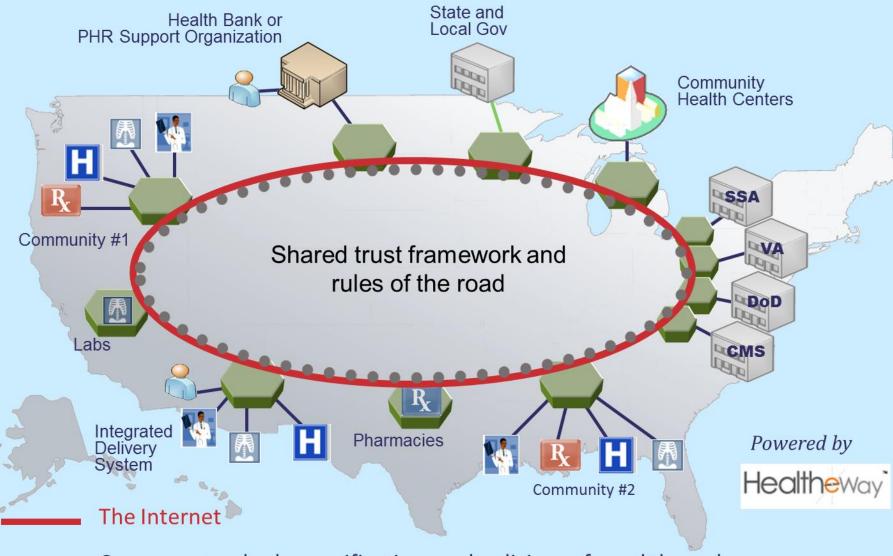


Topics

- eHealth Exchange Context
- DURSA Context
- DURSA Provisions Review
- Q&A



eHealth Exchange



Common standards, specifications and policies enforced through Data Use & Reciprocal Support Agreement (DURSA)

eHealth Exchange Anchor Participants





























eHealth Exchange Participants

- Alabama One Health Record
- Centers for Medicare and Medicaid Services (CMS)
- Childrens' Hospital of Dallas
- Community Health Information Collaborative (CHIC)
- Conemaugh Health System
- Department of Defense (DOD)
- Department of Veterans Affairs
- Dignity Health
- Douglas County Individual Practice Association (DCIPA)
- Eastern Tennessee Health Information Network (etHIN)
- EHR Doctors
- Hawaii Pacific Health
- HealthBridge
- HealtheConnections RHIO Central New York
- HEALTHeLINK (Western New York)
- Idaho Health Data Exchange
- Indiana Health Information Exchange (IHIE)
- Inland Northwest Health Services (INHS)
- Kaiser Permanente

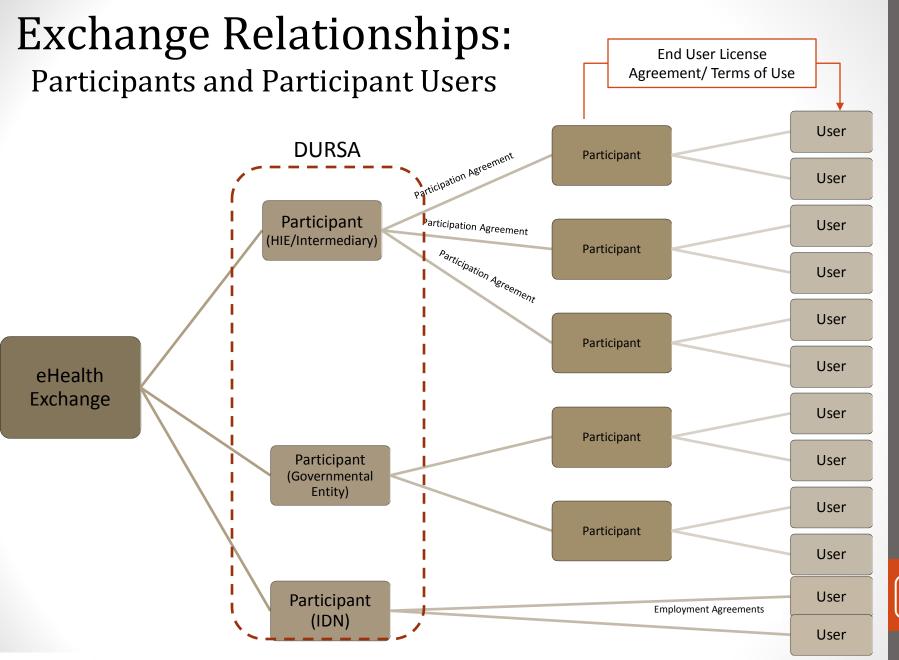
- Lancaster General Health
- Marshfield Clinic
- Medical University of South Carolina (MUSC)
- MedVirginia
- MultiCare Health System
- National Renal Administrators Association (NRAA)
- New Mexico Health Information Collaborative (NMHIC)
- North Carolina Healthcare Information and Communications Alliance, Inc. (NCHICA)
- OCHIN
- Quality Health Network
- Regenstrief Institute
- San Diego Beacon
- Social Security Administration (SSA)
- South Carolina Health Information Exchange (SCHIEx)
- South East Michigan Health Information Exchange (SEMHIE)
- Strategic Health Intelligence
- University of California, Davis
- Utah Health Information Network (UHIN)
- Wright State University



eHealth Exchange Growth

- Participation reaching critical mass
 - 40 Participants
 - More than 800 hospitals, 7000 physician practices
 - 120 million patients+
 - More than 85 preparing to onboard
- National-level coverage increasing
 - Footprint in all 50 states, with records securely exchanged across
 23 states
- Collaboration extending breadth and depth of connectivity
 - Care Connectivity Consortium Kaiser Permanente, Mayo Clinic,
 Geisinger, Group Health Cooperative, Intermountain Healthcare
- Meaningful Use (Stage 2) driving adoption among vendors and providers

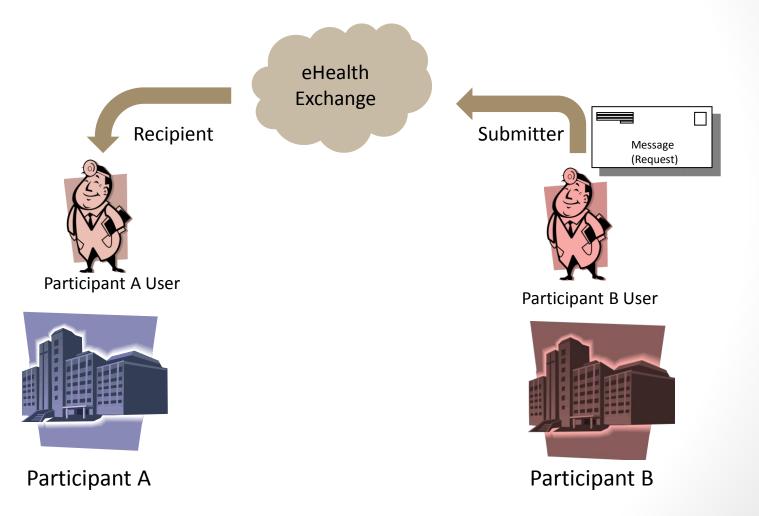






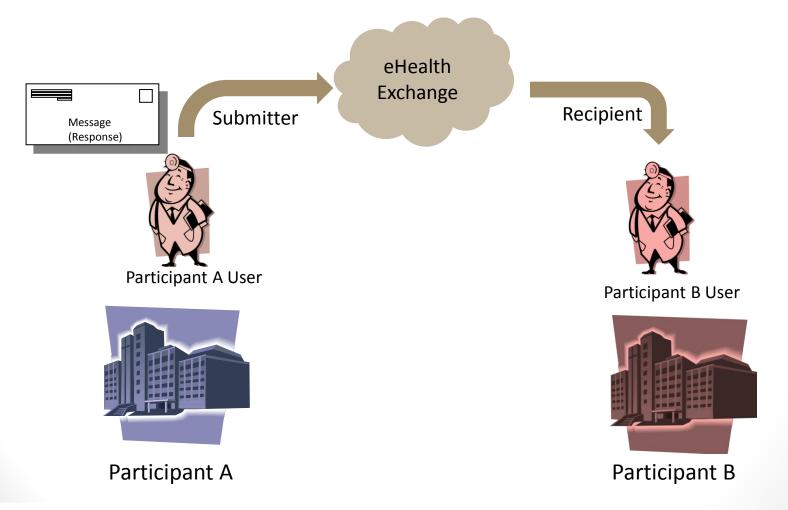
Exchange Relationships:

Submitters and Recipients: Request for Documents



Exchange Relationships:

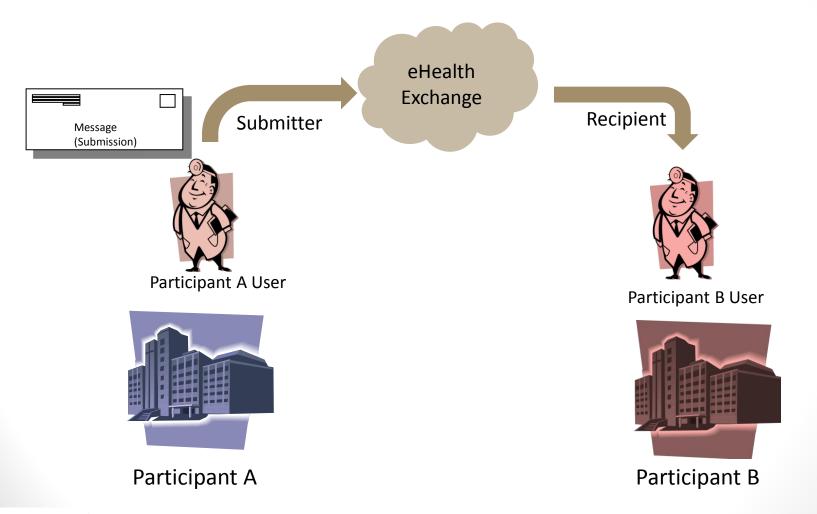
Submitters and Recipients: Respond to Request for Documents





Exchange Relationships:

Submitters and Recipients: Push Scenario





DURSA

CONTEXT AND DRILL-DOWN

Healtheway

What is the DURSA?

- A comprehensive, multi-party trust agreement that is signed by all eligible entities who wish to exchange data among Participants
- A scalable alternative to multiple "point-to-point" agreements, which not sustainable for widespread information exchange
- Requires signatories to abide by common set of terms and conditions that establish Participants' obligations, responsibilities and expectations
- The obligations, responsibilities 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 was developed through an intensive effort facilitated by ONC, with consensus among a diverse group of private and state entities and federal agencies. As a living document, the agreement will be modified over time under the direction of the Coordinating Committee.



12

Important Terms

- Applicable Law: the law of the jurisdiction in which the Participant operates
 - For non-Federal Participants, this means the law in the state(s) in which the Participant operates and any applicable Federal law.
 - For Federal Participants, this means applicable Federal law.
- Message: electronic transmission of Message Content Transacted between Participants using the Specifications
- Message Content: information contained within a Message or accompanying a Message
- Participant: a signatory to the DURSA
- Participant Users: any person who is authorized to Transact Message Content through the respective Participant's system
- Permitted Purposes: the reasons for which Participants may legitimately Transact Message Content
- Performance & Service Specifications: technical specifications and testing requirements adopted by the Coordinating Committee to prescribe data content, technical and security requirements, and test plans for the Participants
- **Submitter**: the Participant who submits Message Content through a Message to a Recipient for a Permitted Purpose
- Transact: to send, request, receive, assert, respond to, submit, route, subscribe to, or publish Message Content during the Specifications



13

Basic Premises

- Assumes that each Participant has trust relationships in place with its agents, employees and data connections (end users, systems, data suppliers, networks, etc.).
- Each Participant must comply with Applicable Law. Nothing in the DURSA is intended to conflict with Applicable Law.
- Each Participant will comply with the HIPAA Privacy and Security rules either because it is a Covered Entity, a Business Associate or because it is required to do so by the DURSA.
- The Coordinating Committee provides oversight of eHealth Exchange and support for the Participants.
- Participants choose which use cases they wish to support in production, which includes a variety of exchange methods, such as: push, query / retrieve and publish/subscribe. The DURSA is written to apply to all types of transactions, not just query/retrieve.



Performance and Service Specifications

- Each Participant identifies the Transaction Pattern(s) that it will support.
- For each Transaction Pattern it supports, the Participant will choose whether it will be a Submitter, a Recipient or both.
- Participants must comply with a core set of mandatory specifications.
- In addition, Participants must comply with the additional Specifications associated with the supported Transaction Pattern(s).



Operating Policies and Procedures (OP&Ps)

- All Participants must comply with OP&Ps.
- OP&Ps address:
 - Qualifications, requirements and activities of Participants when transacting Message Content with other Participants.
 - Support of the Participants who wish to transact Message Content with other Participants.
 - Management, operation and maintenance of the Performance and Service Specifications.



DURSA Flow-Down Provisions (Sections 15.04 & 15.05)

Each Participant has the duty to make sure their users, participating organizations and/or technology partners comply with certain DURSA provisions.

Section 15.04: Enforceable Agreements or user policies with participating organizations or users that:

- Comply with Applicable Law
- Reasonably cooperate with issues related to the DURSA
- Permitted Purpose
- Use of data in accordance w/DURSA
- 1hr/24hr breach notification
- Protect passwords and security measures

Section 15.05: Enforceable agreements with technology partners that:

- Comply with Applicable Law
- Protect privacy and security of Message Content
- Breach notification as soon as reasonably practicable
- Reasonably cooperate on issues related to the DURSA



Ways to Implement the DURSA Flow-Down Provisions

- If your organization does not have any enforceable agreements or policies that cover all of the provisions at this time, explain whether/how your organization will modify/create policies and procedures to cover the elements in Section 15.03 and 15.04?
 - Involve your legal department.
 - Develop an addendum to existing agreements with other organizations and technology partners to ensure that each of the provisions are covered contractually.
 - Establish a training program to train employees and other organizations and technology partners.
 - Provide education regarding the responsibilities to the DURSA
 - Update internal policies, procedures, and forms to include all of the provisions.
 - Provide evidence that the plan has been implemented prior to Go-Live.



DURSA Flow-Down Guidance

- Provide a statement which explains whether / how applicant's policies and procedures and/or agreements obligate users with eHealth Exchange connectivity to:
 - Comply with all applicable law
 - Reasonably cooperate with your Organization regarding any issues related to the DURSA
 - Only transmit data for permitted purposes defined in the DURSA, which are more narrow than what is permitted in HIPAA
 - Only use data received from your Organization or other Exchange Participants in accordance with the terms and conditions of the DURSA
 - Appropriately report Breaches (as defined in the DURSA) within the 1 hour / 24 hour timeframes as specified in the DURSA.
 - NOTE: The reportable breaches in the DURSA are different than those that must be reported for HIPAA. Breaches are defined very narrowly to apply to inappropriate access/use/disclosure as it relates to the transmission of data with other eHealth Exchange participants.
 - Refrain from disclosing to anyone, any passwords or other security measures issued to that user/partner by your Organization.



Autonomy Principle

- Participants determine their own access policies based on Applicable Law and business practices.
- These access policies are used to determine whether and how to Transact Message Content.



Identification and Authentication

Identity Proof Users:

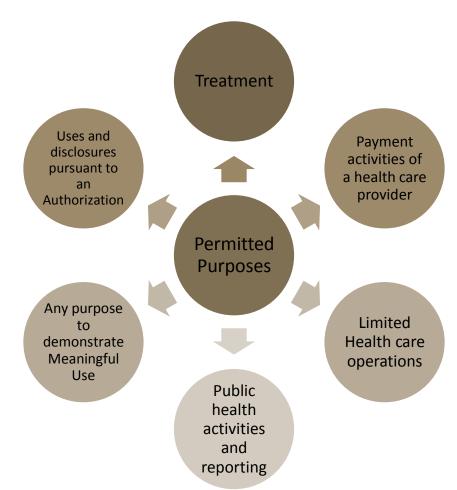
Validate information about Users prior to issuing the User credentials

Authenticate Users:

Use the credentials to verify the identity of Users before enabling the User to transact Message Content



Exchange Only for "Permitted Purposes"



The DURSA limits treatment, payment and operations beyond what HIPAA permits.



Duty to Respond for Treatment

- Participants that allow their respective end users to request data for treatment purposes have a duty to respond to requests for data for treatment purposes.
- This duty to respond means that if actual data is not sent in response, the Participant will at a minimum send a standardized response to the requesting Participant.
- Participants are permitted, but not required, to respond to all other (non-treatment) requests.
- The DURSA does not require a Participant to disclose data when such a disclosure would conflict with Applicable Law or its access policies.



Consent and Authorization

- A Submitter must meet all legal requirements before disclosing the data, including, but not limited to, obtaining any consent or authorization that is required by law applicable to the responding Participant.
- When a request is based on a purpose for which authorization is required under HIPAA (e.g. for SSA benefits determination), the requesting Participant must send a copy of the authorization with the request for data. Requesting Participants are not obligated to send a copy of an authorization or consent when requesting data for treatment purposes.



Submitter Responsibilities

- Must submit the information in compliance with applicable law and represent that the message is:
 - for a Permitted Purpose;
 - sent by the Participant who has requisite authority to do so;
 - supported by appropriate legal authority, such as consent or authorization, if required by Applicable Law; and
 - sent to the intended recipient.
- Represent that assertions or statements related to the submitted Message, if required by the Performance and Service Specification or Operating Policies and Procedures, are true and accurate

Future Use of Data

- Once the Participant or Participant's end user receives data from another Participant (i.e. a copy of the other Participant's records), the recipient may incorporate that data into its records and retain that information in accordance with the recipient's record retention policies and procedures.
- The recipient can re-use and re-disclose that data in accordance with all applicable law and the agreements between a Participant and its end users.



Breach: Definition

- Breach: "the unauthorized acquisition, access, disclosure, or use of Message Content while Transacting such Message Content"
- A breach does not include either of the following:
 - 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 —
 - Made in good faith and within the course / scope of that individual's employment / engagement; and
 - The information is not further acquired, accessed, disclosed or used by the individual;
 - any acquisition, access, disclosure or use of information contained in or available through the Participant's System that was not directly related to Transacting Message Content.
- The breach reporting process is NOT intended to address any obligations for notifying consumers of breaches, but simply establishes an obligation for Participants to notify each other and the Coordinating Committee when Breaches occur to facilitate an appropriate response.



Breach Reporting

 Participants are required to notify the eHealth Exchange Coordinating Committee and other impacted Participants of Breaches within specific timeframes.

Within 1 hour of suspected Breach

 Participants are required to notify the CC and other impacted Participants

Within 24 hours of confirmed Breach

- Provide notification to CC
- Take steps to mitigate the Breach
- Implement corrective action plans to prevent such Breaches in the future



Self-Auditing Capability

- Each participant shall have the ability to monitor and audit all access to and use of its System related to the DURSA, for system administration, security, and other legitimate purposes.
- Each Participant shall perform those auditing activities required by the Performance and Service Specifications.



Allocation of Risk

- With respect to liability, each Participant is responsible for its own acts or omissions and not for the acts or omissions of any other Participant.
- Each Participant is responsible for any harm caused by its
 Users, if its Users gained access to the Exchange as a result of
 the Participant's breach of the Agreement or its negligent
 conduct.
- There are no hold harmless or indemnification provisions because the Governmental Participants cannot agree to indemnify.



Representations & Warranties

- Protected Health Information (PHI) may not be used for eHealth Exchange testing and may not be sent to the Coordinating Committee.
- Participants represent data transmitted are an accurate representation of the data in their system at the time of transmission.
- Participants warrant that they have the authority to transmit information.
- Participants assert that they are not subject to a final order related to its obligations in the DURSA
- Participants represent that they are not excluded, debarred or ineligible for participating in federal contracts, or grants.
- Participants do not guarantee clinical accuracy, content or completeness of the messages transmitted.
- Participants, by virtue of signing the DURSA, do not assume any role in the care of an individual.
- Participants are not accountable for failure of carrier lines which are beyond the Participant's control.
- Data are provided "as is" and "as available", without a warranty of its "fitness for a particular purpose".
- Participants are not liable for erroneous transmissions, and loss of service resulting from communication failures by telecommunication service providers or other third parties.



Discussion

For more information:

Troutman Sanders

Steve.gravely "at" troutmansanders.com

Healtheway

Web Site: www.healthewayinc.org

E-mail: admin "at" healthewayinc.org

