# HIT Policy Committee/HIT Standards Committee Joint Meeting on January 29, 2013 Panel #3: Governance Barriers and Opportunities

January 24, 2013

# **Biography**

Michael Matthews, MSPH, CEO of MedVirginia, immediate past Chair of the eHealth Exchange Coordinating Committee and Chair of the Healtheway Board of Directors, is a seasoned healthcare executive with extensive experience in public health, health information technology, care management, healthcare administration, and research and evaluation. Mr. Matthews served as the Principal Investigator of the AHRQ-funded Rural Virginia eHealth Collaborative (RVEC); Principal Investigator for CenVaNet's Medicare Care Coordination Demonstration (MCCD) project with CMS; and Project Executive for MedVirginia's contract with HHS and SSA for the nationwide health information network and MEGAHIT. In 2006, under Mr. Matthews' leadership, MedVirginia stood up one of the first operational regional health information exchanges in the country. In 2009, he was appointed to the state's Health IT Advisory Commission by Gov. Kaine and was reappointed by Governor McDonnell. Mr. Matthews also served as Senior Advisor to the Governor's Office for Health IT, supporting Secretary of Technology, Aneesh Chopra, and Secretary of Health and Human Resources, Marilyn Tavenner. In January 2010, he received the "eHealth Advocate of the Year Award" from eHealth Initiative, the nation's leading HIE industry association. In 2011, Community Health Alliance, a company run by Mr. Matthews, was awarded a contract by the Virginia Department of Health to implement and operate the Virginia statewide health information exchange known as ConnectVirginia. In 2012, Mr. Matthews was elected the Chair of the Healtheway Board of Directors.

## Introduction

My name is Michael Matthews and I am the Chief Executive Officer of MedVirginia, one of the first Participants in the eHealth Exchange, immediate past Chair of the eHealth Exchange Coordinating Committee and the Chair of the Healtheway Board of Directors. I am pleased to have the opportunity to offer this testimony to both the Health Information Technology Policy Committee and the Health Information Technology Standards Committee on issues related existing HIE governance initiatives and challenges. I have been asked to provide testimony to inform the Committees about the existing work that is being done by the eHealth Exchange and Healtheway, the successes we have accomplished and the important work that still lies ahead. In my testimony, I will provide a brief background on the eHealth Exchange governance approach. The remainder of my testimony will be organized around the specific questions posed by the Committees.

## **Background on the eHealth Exchange**

In September 2007, nine health information exchange organizations (HIOs), including MedVirginia, were awarded contracts by the Department of Health and Human Services to engage in Trial Implementations of the Nationwide Health Information Network (NwHIN). In April 2008, six additional organizations were awarded grants for participation in the Trial Implementations. The Trial Implementations were designed to be a "proof of concept" project to

demonstrate the ability of various HIOs to participate in a network of networks and exchange health information on a nationwide basis.

The nine contractors, six grantees and eight Federal agencies, including the Social Security Administration, Department of Defense and the Veterans Health Administration, constituted the NwHIN Cooperative. According to the HHS website, "these organizations collaborated and achieved consensus to specify, build, and test demonstrate [sic] a core set of capabilities to enable basic exchange of health information between the different HIE networks, patients, and other stakeholders. The NwHIN Cooperative continued its work to agree to specifications, test and demonstrate seven breakthrough use cases in December 2008, as recommended by the AHIC and accepted by the Secretary."

The demonstrations definitively proved that diverse organizations could come together, build upon a core set of interoperable specifications and exchange clinical data in a network of networks. Proving that a network of networks model is viable was a phenomenally important finding given the emerging consensus that point-to-point arrangements were not scalable and would not result in the type of widespread data exchange that is essential to improve the quality and efficiency of health care.

In February 2009, MedVirginia and the Social Security Administration became the first two "Participants" in what is now known as the "eHealth Exchange" to exchange real patient data to support disability determinations. The Veterans Health Administration and Kaiser Permanente became Participants in the Exchange soon thereafter and began exchanging real patient data to support the care and treatment of our veterans. Today, close to forty (40) organizations participate in the eHealth Exchange, representing hundreds of hospitals and thousands of providers, with another 40+ organizations expected in the coming months. These Participants include Federal agencies; non-Federal organizations; state, regional and local HIOs; large integrated delivery systems; and physician practices. To participate in the Exchange, an organization must meet the eligibility criteria defined in the eHealth Exchange Operating Policies and Procedures, which require that Participants:

- 1. Be a valid business in good standing or a governmental agency, operating in the United States;
- 2. Meet all solvency and financial responsibility requirements imposed on the Applicant by applicable statutes and regulatory authorities;
- 3. Be an organization or agency that oversees and conducts, on its own behalf and/or on behalf of its Participant Users, electronic transactions or exchanges of health information among groups of persons or organizations;
- 4. Utilize a system which has been verified as compliant with the Performance and Service Specifications by the Compliance Testing Body (CTB);
- 5. Have the organizational infrastructure and legal authority (through statutes, regulations, organizational agreements, contracts or binding policies) to comply with the obligations in the Data Use and Reciprocal Support Agreement (DURSA) and to require its Participant Users to comply with applicable requirements of the DURSA;

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<sup>1</sup> For details, see eHealth Exchange OPP #1 – Review and Disposition of Applications for Participation: <a href="http://www.healthewayinc.org/index.php/exchange/onboarding">http://www.healthewayinc.org/index.php/exchange/onboarding</a> (last accessed September 24, 2010).

- 6. Intend to Transact information with other Participants for a Permitted Purpose;
- 7. Have sufficient financial, technical and operational resources to support the testing and operation of transactions among Participants;
- 8. Is not aware of any information that would preclude the Applicant from fully complying with the provisions of the DURSA; and
- 9. Submit the completed Application, the signed DURSA Joinder Agreement (Attachment 7 of the DURSA), and the eHealth Exchange Participation Agreement along with the applicable participation fees.

These eligibility criteria ensure that each Participant supports a common set of standards and specifications, which enable technical interoperability and promote trust in the network. Each organization wishing to participate in Exchange must prove compliance and the ability to interoperate with other Exchange participants through testing.

# **Uses of eHealth Exchange**

The Exchange supports a range of exchange modalities, such as query/retrieve, document submission (push) and publish/subscription services. These functionalities enable Participants to use the Exchange for a variety of use cases including continuity of care and transitions of care. The Exchange facilitates sharing of data among private sector Participants, as well as, between private sector Participants and Federal agency Participants. A few examples highlight the current level of activity and the value being derived.

eHealth Exchange is being used by SSA to obtain medical evidence for disability determinations from over eighteen (18) private-sector Participants. In 2012, SSA made requests with a patient's authorization using the eHealth Exchange with 18 participants in 16 states (CA, HI, ID, IN, MA, MI, MN, NC, NM, OH, OR, PA, TX, VA, WA, WI). As of the end of 2012, SSA has made approximately 64,000 requests for medical records and received just over 45,000 CCDs electronically via the eHealth Exchange. SSA is also seeing rapid increase in utilization as connectivity grows and matures, with an increase of more than 250% in the number of medical records received electronically compared to 2011. While the volume of records received via the Exchange is still ramping up, it has already shown good potential to enhance the speed and effectiveness of SSA's disability decision-making process. For example, when records are obtained electronically:

- Initial case processing times are approximately 20-22 days quicker.
- Medical decisions for three percent of cases are decided within just 48 hours.
- Social Security is able to gather medical records more quickly and apply decision support logic to the disability determination process. This has the potential to increase efficiencies in the disability program to help offset increasing workloads and staffing constraints, while dramatically improving service to the public.

 This enhanced disability determination process has also shown positive financial impact for providers, with a documented impact of over \$2M for just one health system in Richmond, VA.

The Exchange is also being used by VA and DoD to support its Virtual Lifetime Electronic Record (VLER) initiative. This important initiative includes:

- 13 VA Medical Centers
- 12 eHealth Exchange partners
- 60,262 Veterans opted in for sharing their Veteran's health record
- VA has retrieved 4,583 Veteran health records from eHealth Exchange partners
- eHealth Exchange partners have retrieved 11,788 Veteran health records from the VA

In various conferences over the past few years, we have heard moving testimony from the families of our wounded warriors about the enormous burden upon their loved ones when the capability for electronic exchange of health records does not exist. As others, such as Dr. Tim Cromwell, can so powerfully communicate, we can and should do better for those who have sacrificed for our country. VLER and eHealth Exchange is a big step in the right direction.

The Centers of Medicare and Medicaid Services (CMS) is also using the Exchange in support of its End Stage Renal Disease, and we look forward to their expanded participation in the future.

The eHealth Exchange's objective over the next two years is to grow the community of Exchange participants, increase the quantity and quality of data available and accessible, and gradually expand the use cases supported by the Exchange. We also will continue to refine, mature, and build capabilities to support broader connectivity and nationwide data exchange.

## **Financial Model**

During the Trial Implementations, while ONC was financially and operationally supporting the Exchange, Participants were not charged a "participation fee." There were many reasons for this, including that the activity was a "proof of concept" that was being Federally supported and establishing the technical infrastructure to participate in Exchange was costly because the specifications, testing process and infrastructure were new and untested. In the fall of 2012, eHealth Exchange transitioned from being a pilot initiative wholly supported by the Office of the National Coordinator to being an independently sustainable, ongoing, public-private partnership supported by the Participants in the Exchange and other engaged stakeholders. Now that the Exchange is operating independently, it has adopted a sustainable business model that will support its operations. This business model includes requiring Participants in the Exchange to pay an annual participation fee beginning in 2014. The participation fee is proportional to an organization's annual combined revenue. For academic or governmental organizations, the fees are associated with annual operating budget. The participation fees will be applied to eHealth Exchange connectivity and infrastructure support. The current fee schedule is as follows:

Annual Revenue	Annual Participation Fee
Less than \$1 Million	\$4,750
\$1 Million to less than \$10 Million	\$9,950
\$10 Million or more	\$19,000

Of course, the eHealth Exchange business model would not be viable financial or programmatically without the strong support and participation of our Federal partners. We are delighted with the commitment of the SSA, VHA, DoD, and others to eHealth Exchange. To reference Dr. Cromwell once again, the Federal partners can be compared to "anchor tenants in the mall". While "anchor tenants" are critical, they do not alone define success in either a mall of nationwide health information exchange. I remain deeply grateful for their guidance and participation.

# **Governance of eHealth Exchange - The Coordinating Committee**

Early on, it was recognized that barriers to interoperability were not just technical, but included legal and policy impediments as well. To address such barriers, the NwHIN Cooperative took on the responsibility of developing the legal infrastructure to support the exchange of health information among Participants. ONC charged the Cooperative with assessing the current legal environment and developing an appropriate data sharing agreement. While many agreements existed for point-to-point data exchange, there did not appear to be a good model agreement to support the type of widespread, multi-party exchange in what was then termed a "network of networks", as envisioned for the Trial Implementations and the Exchange. ONC established a work group composed of legal and business representatives of members of the Cooperative to draft a Data Use and Reciprocal Support Agreement (DURSA) to support the exchange of test data in the Trial Implementations and, subsequently, production data in the Exchange.

The DURSA Work Group worked diligently to create a framework in which the Participants would feel comfortable exchanging data with each other. When the DURSA Work Group began its work in 2007, it did not have the benefit of the trust framework that was adopted by the NwHIN Work Group of the Health IT Policy Committee in 2010. Fortunately, they did have dedicated, experienced individuals drawn from the Cooperative members and expert facilitation, enabling the Work Group to start from the ground up to achieve consensus resolution on core issues that had to be addressed to establish trust among the Participants.

Throughout the DURSA Work Group's discussions, the Cooperative identified various governance and management functions that would have to be fulfilled in order for the Exchange to operate efficiently and effectively and to engender trust and accountability among the Participants. For the Cooperative, after extensive discussion among the members and ONC, these functions were assigned to a representative body known as the Coordinating Committee. The Participants formalized their grant of authority to the Coordinating Committee in the DURSA by specifically setting forth its roles and responsibilities. The delineation of these roles and responsibilities for the Coordinating Committee helped to establish and maintain trust among the Participants in the Exchange by providing for a mechanism for oversight, enforcement and accountability.

## **Role of the Coordinating Committee**

The overarching role of the Coordinating Committee is to provide the needed governance, oversight, management and support of the trust fabric for the Exchange Participants. The roles and responsibilities of the Coordinating Committee set forth in the DURSA include:

- a. Determining whether to admit a New Participant;
- b. Maintaining a definitive list of all Transaction Patterns supported by each of the Participants;
- c. Developing and amending Operating Policies and Procedures in accordance with Section 11 of the DURSA;

- d. Receiving reports of Breaches and acting upon such reports in accordance with Section 14.03 of the DURSA;
- e. Suspending or terminating Participants in accordance with Section 19 of the DURSA;
- f. Resolving Disputes between Participants in accordance with Section 21 of the DURSA;
- g. Managing the amendment of this Agreement in accordance with Section 23.02 of the DURSA;
- 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 the DURSA;
- 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
- 1. Fulfilling all other responsibilities delegated by the Participants to the Coordinating Committee as set forth in this Agreement.

# **Composition of the Coordinating Committee**

When the Cooperative originally designed the Coordinating Committee, the Exchange was in its infancy and it was important that stakeholders have a voice. Initially, the Coordinating Committee was structured to have representatives of each Participant (i.e., those who had signed the DURSA and were actively transacting health information through the Exchange) since these were the organizations that had invested the most in the Exchange and had the most stake in its success. Those who were on track to become Participants in the near future also had a stake in the Coordinating Committee activities and it was believed that they should have the opportunity to participate. Furthermore, members of the Cooperative who were not Participants and did not yet have definitive plans to become Participants still wanted to have a voice in Coordinating Committee activities. Finally, since remaining in lock step with ONC was critical to the success of the Exchange, the Coordinating Committee needed to have representation from ONC. As a result of the need to engage these stakeholders, the original Coordinating Committee (as defined in the November 2009 version of the DURSA) was composed of the following:

- One representative from each Participant in the Exchange;
- One representative from each organization that had submitted a Definitive Plan<sup>2</sup> that has been accepted by the Coordinating Committee;
- Two representatives elected by the Cooperative; and

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<sup>&</sup>lt;sup>2</sup> A "Definitive Plan" was defined in the original DURSA as "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 NwHIN Specifications in at least a limited production pilot that is consistent with priorities set by the NwHIN Technical Committee." The only purpose of the Definitive Plan was to provide a mechanism for the Coordinating Committee to evaluate an entity's eligibility to serve on the Coordinating Committee prior to that entity becoming a Participant.

• One representative from ONC.

When the Cooperative created this structure for the Coordinating Committee, they understood that it was not infinitely scalable and would have to be revisited in the future once there was broader participation in the Exchange. To everyone's pleasant surprise, this future arrived more quickly than was expected. In 2010, the Coordinating Committee recognized that the rate at which new Participants were joining the Exchange would soon result in a Coordinating Committee that was too large to support the Exchange effectively and efficiently. The Coordinating Committee created a Strategic Issues Task Group to recommend a new model for Coordinating Committee composition based primarily on the assumption that the Exchange would have more numerous and more diverse Participants.

The Strategic Issues Task Group undertook a comprehensive, intensive process to develop its recommendations on composition of the Coordinating Committee. The Strategic Issues Task Group reviewed the role of the Coordinating Committee and, based upon the practical experiences over the previous year, assumed that its functions would be largely unchanged. The Task Group then identified: (i) a set of key foundational governance principles against which all potential structures would be evaluated; and (ii) a list of "givens" – those threshold matters on which all members of the Task Group agreed. While the list of key foundational principles and "givens" is too long to recite here<sup>3</sup>, there are four foundational principles that I would like to highlight.

- Consent of the Participants: The Coordinating Committee's roles and responsibilities are derived from the DURSA and flow from the consent of the Participants who sign the DURSA. Without their assent, the Coordinating Committee has no role, responsibility or authority and its actions will be inconsequential and fail. As a result, obtaining the "buy-in" of the current and future Participants in the Exchange is crucial to the ability of the Coordinating Committee to effectively operate.
- Representation: One of the hallmarks of the Exchange is its diversity of Participants. The Coordinating Committee should be composed of representatives of Participants, including long time Participants, new Participants and those Participants that have unique interests related to the Exchange or whose engagement at the Coordinating Committee level is critical to the success of the Exchange.
- Participation: The Coordinating Committee acts as an executive level "board of directors" that is actively engaged in the strategy, policy framework and oversight of the operations of the Exchange. The Coordinating Committee has various committees and subcommittees made up of representatives of the Participants. While membership on Coordinating Committee is limited due to size and efficiency constraints, participation in committees and subcommittees will not necessarily have to be likewise constrained. In fact, even representatives of organizations that are not Participants could participate in these subcommittee activities.
- <u>Continuity and Innovation</u>: Preserving institutional memory through continuity of membership allows a board or committee to continue operating effectively even with the introduction of new members. Continuity will be particularly important for the

<sup>&</sup>lt;sup>3</sup> Upon request, I am happy to share with the Work Group a whitepaper drafted by the Strategic Issues Task Group which sets forth all of the key principles, givens and issues that were considered during the development of the revised Coordinating Committee structure.

Coordinating Committee as the Exchange continues to evolve. The desire for continuity, however, must be balanced against rotation of new members who can help the Coordinating Committee and the Exchange evolve and innovate.

The Task Group met over a period of several months and successfully developed a consensus recommendation for a revised composition for the Coordinating Committee, which was accepted by the Coordinating Committee and has been incorporated into the Restatement I of the DURSA, which is the version of the DURSA that is currently in effect (dated May 2011). Today, the Coordinating Committee is composed of the following:

- At least one representative selected by each "Affiliation Group;"
- One representative from each of the ten "Charter Participants;"
- One representative from ONC.

The "Affiliation Group" model was designed by the Strategic Issues Task Group to effectively group and align the interests of Participants that share similar interests, objectives and structures. This is a first generation representational model. When the model was first developed, each non-Federal Exchange Participant was required to be sponsored by a Federal agency through a contract vehicle based upon an ONC policy requirement. As a result, the Task Group determined that the Participant's agency affiliation (both in terms of contract and exchange activities) was the most objective way to sort Participants into Affiliation Groups. It provided a rational way of aligning Participants' interests and grouping them with others who are working towards the same performance targets and implementing the same technical specifications. Now that the contract requirement has been removed, the Coordinating Committee will consider redefining the affiliation groups based on other relevant characteristics and metrics.

The "Charter Participants" have vital institutional knowledge about the origins of the Coordinating Committee and evolution of the Exchange, expertise in the operations of the Coordinating Committee, and have exhibited dedication to the Exchange. Keeping them engaged on the Coordinating Committee will ensure the continuity that is critical to the success of any board or committee. Later this year, the Coordinating Committee will revisit the role of the Charter Participant representatives to how to address them when their terms end in 2014.

This representational model has served the Coordinating Committee well since it was implemented in 2011. The Coordinating Committee has active engagement from those who sit on the Committee as well as from other Participants who attend the meetings of the Coordinating Committee. The Committee is small enough to be agile, flexible and able to respond to an evolving landscape, but large enough to have broad representation of varying perspectives. While the composition of the Affiliation Groups may be revised, the Coordinating Committee will likely maintain this representational model for the foreseeable future.

# **Healtheway**

In the fall of 2012, eHealth Exchange transitioned from being a pilot initiative wholly supported by the Office of the National Coordinator to being an independently sustainable, ongoing public-private partnership supported by the Participants in the Exchange and other engaged stakeholders. eHealth Exchange engaged in a lengthy strategic planning process involving the Participants, ONC and other interested stakeholders, resulting in the determination that a public-private partnership would be the best model to support eHealth Exchange going forward. Healtheway was formed in April 2012 to serve this function.

Healtheway is a not-for-profit, public-private partnership that operationally supports the eHealth Exchange. Healtheway's vision is to improve the health and welfare of all Americans by

supporting and enabling secure health information exchange that is trusted, that scales, and that enhances quality of care and health outcomes by supporting comprehensive longitudinal health records. Healtheway has adopted a mission to support its vision: to expand trusted, secure and interoperable exchange of health information across the nation by fostering cross-industry collaboration and by providing shared governance and necessary shared service to public and private organizations who wish to interconnect as a network of networks.

# Healtheway's core values include

- Leading in national-level exchange of health information to establish HIE as a standard of care, while fostering and supporting innovation;
- Maintaining openness and transparency in the conduct of operations;
- Cultivating trust and protection of information exchanged;
- Encouraging participation and inclusiveness across a diverse set of stakeholders;
- Maximizing effectiveness and efficiency in the exchange of health information;
- Providing for accountability, fairness and due process; and
- Evaluating, learning and promoting continuous improvement in its own operations.

To further its mission of fostering cross-industry collaboration, Healtheway adopted a structure in which vendors and implementers can become corporate members of Healtheway. Currently, Healtheway has 6 members consisting of 2 vendors, 2 HIEs, and 2 others, with many others in the process of joining. The members of Healtheway are eligible to serve on the Healtheway Board of Directors, elect Directors and actively participate in Healtheway's collaborative initiatives. The membership fee paid by the members helps to financially support Healtheway's activities. It should be noted that the Board of Directors of Healtheway is the governing body for Healtheway activities only, and does not in any manner overlap with the governance responsibilities of the Coordinating Committee for eHealth Exchange.

Healtheway's activities enable its members and the eHealth Exchange participants to further their respective missions to:

- Improve clinical decision making and coordination, quality and affordability of care;
- Support meaningful use;
- Enhance disease surveillance, support preparedness and routine public health missions to improve public health; and
- Realize efficiencies and expedite provision of funding and services to individuals to support their care and well-being.

To support eHealth Exchange, Healtheway has undertaken a number of activities. Healtheway is supporting the shared infrastructure used by eHealth Exchange Participants, including the service registry that enables Participants to identify other Participants and the digital certificates that Participants use as part of the authentication process. Healtheway will also support the maintenance of the eHealth Exchange trust framework. This work includes maintaining the DURSA and the Policies and Procedures and providing organizational infrastructure support to the Coordinating Committee.

Healtheway is also managing and facilitating the eHealth Exchange's implementation level task groups. These task groups, which are similar to the Cooperative Work Groups that were used in the early days of the Exchange, provide a forum and mechanism in which the Participants

can collaboratively work through issues that affect all Participants. The Participant representatives in these task groups all have real world experience with health information exchange, allowing them to develop reasonable and realistic solutions to the issues with which they are tasked.

Healtheway is also dedicated to cross industry collaboration. Healtheway supports a range of initiatives to collaborate with others in the industry to solve HIE implementation issues necessary for secure, trusted and scalable HIE at a nationwide level. One example of this is Healtheway's close collaboration and joint work with the EHR | HIE Interoperability Work Group (IWG). Together, Healtheway and the IWG, which represents 41 vendors and 18 state HIEs, developed a shared set of testing requirements for query/retrieve and directed exchange, as well as content, for the HIE product and network certification program.

Healtheway has also been working diligently, in partnership with the EHR | HIE Interoperability Work Group (IWG) and CCHIT, to pilot and launch a robust certification program for HIE products and eHealth Exchange Participants. The certification program, which is currently in the pilot and ramp up stage and is expected to be available within the next couple months, will present an efficient, effective and scalable mechanism for testing and confirming an applicant's compliance with the eHealth Exchange technical specifications. This program is part of a broader eco-system that includes a feedback loop among CCHIT, implementers and specification development.

The willingness of these vendors and implementers to work together to promote interoperability and trust is an illustration of how the market is recognizing the importance of information exchange.

# **Responses to HITPC / HITSC Questions**

- 1. What are the goals and problems you are solving for participants?
  - a. How are you achieving these goals? What are your measures of success to date?
  - b. How do your efforts reduce the cost and complexity of exchange for participants?

eHealth Exchange's overarching goal is to provide an infrastructure that allows for the safe and secure exchange of electronic health information to enable Participants to recognize such benefits as:

- improved clinical decision-making;
- enhanced coordination, quality and affordability of care;
- support for meaningful use; and
- expedited benefit determinations, enabling individuals to realize more quickly the disability and healthcare benefits to which they are entitled.

For organizations to recognize these benefits, it was critical that the eHealth Exchange be organized as a "network of networks." While point-to-point exchange models continue to be used today, there is a consensus that these arrangements are not scalable (due to both technical and policy issues) and will not result in the type of widespread data exchange that is essential to improve the quality and reduce the cost of healthcare. As compared to establishing a network,

point-to-point arrangements are relatively easy for two organizations to implement. The two organizations agree upon the technical specifications for the connection and the business rules governing the use of the connection. They each expend resources – both financial and human – to establish the connection but, they can only exchange data with each other and no one else. While this is appropriate in some circumstances, it is certainly not ideal, especially for organizations that need to be able to exchange data with a significant number of other organizations, including Federal agencies.

From the beginning, confronting and addressing the challenges of establishing and supporting an operational "network of networks" that would include private, state and Federal partners was challenging. We had to address the many difficult, complex, cutting-edge issues that are created by widespread data exchange in a "network of networks." We were able to successfully address the myriad issues due in large part to the dedication of the Participants and their willingness to bring to bear the best and the brightest from their respective organizations.

The Participants and the individuals who represent them are actively involved in information exchange both within eHealth Exchange and outside of eHealth Exchange. The fact that the Participants have real world experience with health information exchange has been critical to eHealth Exchange's success. Instead of discussing theoretical issues, whether policy or technology, the Participants and their representatives were able to focus on practical issues using concrete, realistic examples based on their experiences. These discussions allowed the Participants to reach realistic and implementable resolutions, both interim and permanent, on issues that are essential to establishing trust and interoperability.

The Participants brought to the table experience with health information exchange at the enterprise, local, regional and state levels. As the eHealth Exchange was being developed, the Participants recognized that leveraging and supporting these existing exchange activities--instead of duplicating them--was crucial. It was also critically important that the eHealth Exchange respect the local autonomy of each network that would be joining the Exchange. Healthcare remains a relatively local activity. The various networks that participate in eHealth Exchange are successful because they have been built to meet the needs of their local community and the eHealth Exchange did not want to disrupt this. Instead, the goal of the eHealth Exchange was to create a community of trust in which all of these enterprise, local, regional and state level networks could come together and exchange data with each other.

The eHealth Exchange accomplished this by developing and adopting a comprehensive trust framework that includes: (1) an agreed upon set of technical specifications for interoperability; and (2) a trust agreement (i.e., the DURSA) that memorializes a code of conduct and governance structure for the Exchange. The technical specifications and the DURSA allow each Participant to trust that all of the other Participants have agreed to the same code of conduct and rules for participation.

Because of this trust infrastructure, each Participant does not have to independently verify the credentials of each other Participant. Each Participant does not have to agree upon one-off technical specifications with each other Participant or conduct point-to-point testing. Each Participant does not have to independently negotiate a separate data exchange agreement with each other Participant. Utilizing a model with a common trust and policy framework greatly reduces the cost and complexity of exchange for the Participants since each Participant implements one set of technical specifications, goes through one rigorous testing process and signs one agreement and can then exchange with all of the other Participants in eHealth Exchange.

The benefits of a network-of-networks approach, with shared governance and infrastructure include:

- the ability to implement and test once, in order to exchange with any other participant in the network;
- recognition of being a trusted exchange partner and being part of a trusted exchange community;
- enables expanded connectivity beyond geographic, system or organizational boundaries through scalable shared services;
- cost-effective and efficient to use shared infrastructure and shared governance, since it minimizes the need for costly point-to-point negotiations; and
- assurance that there are mechanisms to enforce compliance and hold Participants accountable.

Much effort has gone into defining and measuring the success of HIE initiatives. Various industry groups have looked at performance measures, and these can be generally grouped into the categories of: users; usage; and usefulness. We are delighted with the growth of eHealth Exchange, as measured in the number of production Participants and in the number of stakeholders in the on-boarding queue. That in itself is a measure of success tracked closely on a monthly basis by the Coordinating Committee. The users associated with each of the eHealth Exchange "nodes" is not a measure tracked by Exchange itself, but is expected to be correlate closely with the increase in the number of Participants. Usage is tracked in certain specific use cases and organizations. For example, over 16,000 patient records have been exchanged between the VA and eHealth Exchange Participants. Methodologies for measuring "usefulness" and ROI continue to be refined, but certain case studies demonstrate the value proposition for eHealth Exchange. A prime example is the independent case study commissioned by the SSA that examined the impact of use of eHealth Exchange in the disability determination process. Use of this more automated process resulted in significantly lower processing time for disability determination; reduced cost for SSA; and of course, patient and family benefit reducing the amount of time waiting for a decision. Also determined was an impressive financial impact for the four-hospital system that was the focus of the study. This one system achieved an annual revenue impact of over \$2M, driven by expedited benefit determinations not just for disability benefits, but also Medicaid. While these early successes build our confidence that eHealth Exchange brings value to myriad stakeholders, we also recognize that we are building a foundation that must be leverage for ever greater use and impact. Dr. John Mattison introduced us to Metcalfe's Law that states that the value of a telecommunications network is proportional to the square of the number of users of the system. While some have pointed out that this does not precisely relate to HIE, it is a useful construct for considering the disproportional value of eHealth Exchange as we continue to expand. In the meantime, virtually every private sector Participant has stated the importance of connecting to the Federal Participants in eHealth Exchange....our "anchor tenants in the mall". From their perspective, clearly, "success" includes the ability to support the disabled and wounded warriors in part through the use of eHealth Exchange. As we continue to define and measure success for eHealth Exchange, we would welcome the opportunity to share these results with you in the future.

# 2. How does your organization support the secure, interoperable and trusted exchange of data among participants? In each of the areas below, please describe your approach, including its strengths and challenges

# a. Cross organization, cross HIO/HISP exchange

As a "network of networks," eHealth Exchange exists to enable cross organization, cross HIO exchange. It can do this because it has established a community in which data exchange occurs in a secure, interoperable, trusted manner. Interoperability among Participants and strong security for the data exchanges are achieved through the use of common implementation-level technical specifications and test cases, as well as a robust HIE product and network certification program. The technical specifications have been used in production for three years and will continue to be refined based upon input from implementers and the eHealth Exchange testing and certification body, CCHIT.

Trust is supported by each Participant's agreement to be bound by the terms of the Data Use and Reciprocal Support Agreement (DURSA). As described above, throughout the Trial Implementations, the members of the Cooperative worked together in the DURSA Work Group to address the complex legal and business issues associated with the exchange of data and the policies that would govern eHealth Exchange. As the DURSA Work Group discussed and reached consensus on an issue, they would then work together to craft the contract language that would memorialize the consensus. This iterative process led to the creation of the comprehensive trust agreement – the DURSA.

The DURSA addresses the core set of policy issues necessary to establish trust among the Participants:

- <u>Requirements/Expectations</u>: The DURSA sets forth a series of requirements and expectations for Participants in eHealth Exchange including, but not limited to, the following:
  - o the reasons for which eHealth Exchange can be used to exchange data ("Permitted Purposes");
  - o a duty to respond to requests based on treatment if the Participant makes requests based on treatment (the "minimum level of participation");
  - o a recognition that each Participant will determine how to transact data based on its local rules (the "autonomy principle");
  - o an acknowledgment that once a Participant receives data it can use and redisclose that data in accordance with applicable law; and,
  - o a requirement that each Participant secure whatever consent or authorization it is required by law to secure prior to exchanging the data.
- <u>Identity/Authentication</u>: The eHealth Exchange uses a system-level trust model with delegated administration. As such, Healtheway serves as the registration authority for the eHealth Exchange participant gateways and issues digital certificates to each eHealth Exchange Participant once approved by the Coordinating Committee. Each participant is required to have the individual who will install the certificate to be identity proofed. The digital certificates are provided by a Certification Authority that has been cross-certified to the federal bridge. eHealth Exchange certificates are used by participants to identify and authenticate to each other prior to securely exchanging data. Participants are also

required to identity proof and authenticate their respective users prior to granting access to systems that use the Exchange.

- <u>Transparent Oversight</u>: eHealth Exchange is governed by the Coordinating Committee, which is established and empowered by the Participants through the DURSA. Monthly meetings of the Coordinating Committee are open to all participants, applicants and their technology partners, with time allotted in each meeting for questions and comments. Monthly meeting notes have been posted on a public web site since the Coordinating Committee's inception. The Coordinating Committee, now with the support of Healtheway, is able to also support periodic meetings which will be open to the public.
- <u>Accountability and Enforcement</u>: The DURSA establishes the obligations of participants, including the mechanisms for enforcing compliance. There is a process for matters to be brought forward to the Coordinating Committee for consideration, as well as a formal dispute resolution process. The Coordinating Committee also has the ability to suspend or terminate a Participant if that Participant fails to comply with the DURSA.
- <u>Technical Requirements</u>: All Participants are required to implement and comply with a standard set of technical specifications and testing requirements, referred to as "Performance and Service Specifications" in the DURSA.

# Lessons Learned:

Initially, the comprehensive, intensive process in which the members of the Cooperative participated (including the DURSA Work Group) helped to establish trust among the parties. The members of the Cooperative recognized, however, that they could not go through the same process of discussing and resolving issues with each new Participant that joined nor would each new Participant have had the benefit in participating in the Cooperative's work, including the design and drafting of the DURSA. Because the Cooperative had engaged in such a comprehensive process, including several rounds of a multi-agency federal clearance process, there was acceptance and trust in the specifications, standards and DURSA that had been developed. Consequently, if another organization signed the DURSA--thereby agreeing to be bound by the same specifications and standards--then the Participants could trust that new organization and have confidence in the exchange of data.

Today, new eHealth Exchange applicants are signing the DURSA and agreeing to implement the technical specifications and testing requirements without many, if any, questions because they understand that these have been proven in production for nearly four years and form the foundations of trust in eHealth Exchange. Based upon this experience, the DURSA has proven to be an efficient mechanism for memorializing the obligations of participants to each other, as well as the technical and policy-related eHealth Exchange "rules of the road".

# b. Patient matching

The eHealth Exchange has implemented a set of services to enable the lookup and discovery of patient records employing a set of specifications which were recognized and adopted by the Secretary of HHS. One of these services, the Patient Discovery Service, is intended to provide a mechanism to enable participants to efficiently and reliably establish the identity of mutual patients prior to exchanging patients' health information. This specification is intended to address the following challenges:

• Lack of National Patient Identifier

- Inconsistent patient demographic attributes among HIOs and their data sources
- Disparate and disconnected Master Person Indexes (MPIs) and independent matching algorithms
- Consumer privacy restrictions and support of local policy

# c. Lessons Learned

In 2011, a couple of eHealth Exchange participants reported challenges with successful identity correlation. The Coordinating Committee formed a Task Group to further study the matter and assess whether additional work was needed. The Coordinating Committee approved a set of findings and recommendations in March 2012, and determined that the Patient Discovery specification is, indeed, implementable and scalable, and that several initial steps could be taken to dispel misconceptions and improve identity correlation by:

- 1. Sharing lessons learned from the eHealth Exchange, (e.g. educational sessions, testimony to the HIT Standards Committee and HIT Policy Committee, etc.);
- 2. Standardizing the list of identity attributes used for correlation purposes;
- 3. Develop best practices for incorporating patient discovery into clinical workflow (e.g. checking as patients make appointments, etc.);
- 4. Expanding the use and testing of IHE Patient Discovery Profile to leverage additional attributes (e.g. use of past identifiers);
- 5. Further explore whether / how broadcast queries may be used among Exchange participants, and if so, the parameters under which global queries are necessary and appropriate.

Efforts are under way to develop a recommended set of identity attributes and best practices for correlation purposes and other refinements being made among eHealth Exchange Participants to overcome the challenges reported by some participants.

That said, it was acknowledged that a voluntary universal patient identifier would greatly simplify and improve identity correlation.

# d. Patient choice, access and correction

As described above, eHealth Exchange is a "network of networks." One of its central goals was to bring together disparate networks while respecting the fact that each of these networks was an established, operational entity. To do this, eHealth Exchange adopted a "local autonomy" principle. This means that each Participant is entitled to establish its own local access policies and apply these policies when determining whether and how to respond to a request for data. In terms of patient choice, this means that a Participant must meet all applicable legal requirements before disclosing data through eHealth Exchange. The applicable legal requirements are those imposed on the Participant by Federal law and the state law of the state in which the Participant operates. (State law is not a consideration for the Federal agency Participants.) This model allows eHealth Exchange to accommodate various patient choice models. Each Participant determines for themselves which patient choice model is appropriate and consistent with its applicable law. Participants may and typically do support patient choice in production today, based upon applicable law and local policy. The Participant does not have to change its patient choice model to participate in eHealth Exchange.

This consent policy for eHealth Exchange was developed after much discussion and debate. Each Participant wanted the eHealth Exchange consent model to follow the law of that Participant's state. In the end, it was decided that the only way that eHealth Exchange could successfully operate was if it respected each Participant's decision and respective legal obligations about the consent model that was right for it and did not try to impose one uniform consent model on all Participants. In practice, this means that Participants in eHealth Exchange have a range of consent models. For instance, MedVirginia has adopted an opt-out consent model. This was chosen after much discussion with MedVirginia's participants and we believe it is right for our local exchange. Conversely, ConnectVirginia, the Virginia statewide HIE, has chosen an opt-in model. This model was selected after careful consideration by the Virginia Health Information Technology Advisory Commission. Despite differences in these models, both MedVirginia and ConnectVirginia can participate in eHealth Exchange. The ability to accommodate differing local consent models is a significant strength for eHealth Exchange.

While eHealth Exchange does not dictate a specific patient choice model, it does require that when a Participant requests data based on a purpose for which an authorization is required under HIPAA, the Participant send a copy of that authorization with the request. The theory is that regardless of state law, the Participant receiving the request cannot respond without first receiving a copy of the authorization so the authorization should accompany the request. This rule is used most often in the context of requests from the Social Security Administration for medical records in connection with a benefits determination. SSA must send a copy of the authorization from the patient/claimant along with the request. Importantly, requesting Participants are not obligated to send a copy of an authorization or consent when requesting data for treatment purposes because HIPAA does not require an authorization to disclose records for treatment.

One Exchange Participant provides authorization documents using an unstructured PDF document to reflect the patient's authorization. A challenge has arisen in that this is not fully computable; in other words, a computer program cannot be devised to automatically understand the patient's authorization and/or other preferences which often necessitate human intervention. Several standards exist that will allow for the expression of complex patient preferences in a computable manner thus avoiding manual workflow steps. We are carefully monitoring the industry in this regard and expect to offer recommendations and a path forward over the next 12-24 months on this topic. Resolving this issue will further decrease the cost and increase the speed at which patients preferences can be respected during exchange.

With respect to patient access, eHealth Exchange does not currently provide direct access by individual patients. When the initiative first began over six years ago, ONC envisioned that a patient's connection to the eHealth Exchange would be accomplished through a personal health record (PHR) system. In addition, it was understood that HIPAA covered entities were still obligated to provide individuals access to their respective designated record sets, which may include information retrieved and incorporated into a patient's record held by the covered entity. To date, PHR providers have not joined the eHealth Exchange. As a result, the eHealth Exchange does not currently provide direct access by individual patients.

With respect to an individual's right to propose amendments to his or her health information, eHealth Exchange does not maintain any medical records. All of these records are held locally by the Participants since eHealth Exchange operates as a federated model. As a result, eHealth Exchange cannot make any "corrections." Rather, these corrections have to be made by the appropriate Participant (or Participant User depending on the Participant's structure).

# Lessons Learned

- The approaches outlined above have worked exceptionally well across a very diverse group of governmental and private sector organizations, and across diverse body of law and local policy.
- Uniform consent is not necessary to enable exchange at a national scale.
- Uniform policy is necessary though to establish common trust frameworks and rules-ofthe-road.
- Consent, authorization, and other patient preferences should be implemented in such a way that they can be automated.

# e. Liability and other legal issues

As has been discussed in other areas of my testimony, the Cooperative members spent a great deal of time addressing the legal issues presented by data exchange through a "network of networks." Addressing these legal issues in a concrete, uniform manner is key to establishing trust among the Participants and mitigating the risk of participating in data exchange. The discussions were particularly challenging give that the Cooperative members operated in many different states and the Federal agency members were governed by Federal laws.

Among the issues discussed by the DURSA Work Group was what law should govern Participants. The Work Group agreed that the DURSA should not attempt to change the law that currently governs Participants – it should only recognize and memorialize this. As a result, the DURSA provides that each Participant continues to be bound by any applicable Federal law (e.g. HIPAA) as well as the law of the state(s) in which it operates.

The Work Group also addressed the issue of what law governs disputes arising between eHealth Exchange Participants. A "governing law" provision is a fairly standard contractual term and there was consensus that it needed to be addressed in the DURSA. We explored a variety of different ways to address this, but, in the end, the only viable way to address it was to say that in the event of a dispute between Participants, the applicable Federal and state conflicts of law provisions that govern the operations of those Participants would determine governing law. This leaves some uncertainty for the Participants, but they were willing to accept this level of uncertainty recognizing that it was necessary and unavoidable.

In addition to discussing governing law issues, the DURSA Work Group also spent a great deal of time discussing issues related to liability and allocation of risk. Typically in a contract, liability is allocated through hold harmless and indemnification provisions. Federal and some state agencies, however, cannot agree to such provisions in an agreement. Recognizing that Federal and state agencies were very important Participants in eHealth Exchange, the DURSA Work Group did not want to adopt a provision that would alienate or establish a separate standard for governmental agencies. The uniform application of the DURSA is critical to its ability to engender trust among the Participants. Recognizing that indemnification provisions could not be included, the Work Group members modeled out a series of scenarios that would result in potential liability for Participants to try to determine how this liability should be allocated. After many hours of discussion, the DURSA Work Group members arrived at a seemingly simple solution - each Participant is responsible for its own acts or omissions. Further, each Participant is also responsible for any harm caused by its users, if its users gained access to eHealth Exchange as a result of the Participant's breach of the DURSA or its negligent conduct. The Participant is free to allocate this risk among its users as it deems appropriate. This common

sense approach to the allocation of liability has been accepted by all of the eHealth Exchange Participants. Fortunately, none of the Participants have ever had a reason to test the application of this provision in court.

## Lessons Learned

- The DURSA has worked exceptionally to simplify and overcome a common set of legal matters that must be addressed in order to facilitate the exchange of health information. While the comments above largely focus on liability, allocation of risk and governing law, the DURSA also helped establish a common understanding and expectation on a host of other legal provisions that are typically negotiated on a case-by-case basis.
- The simplicity of this approach has enabled organizations to focus on every important implementation and deployment strategies in lieu of costly and time-consuming legal negotiations with each exchange partner.
- We respect and share the desire to establish a national set of rules of the road that enable HIE without legal agreements. Based upon our experiences in collectively developing and utilizing the DURSA over the past several years, there are a number of other legal provisions in the DURSA which participants asserted were essential before they would agree to exchange data with another partner (e.g. Section 15 representations and warranties, Section 17 disclaimers, Section 23.)

# **HIE Governance Perspectives**

# 3. What are the key near-term challenges and opportunities to create a trusted environment for securely sharing health information across providers, vendors and HIOs/HISPs

Today, there are many resources available to new and emerging health information exchange organizations (HIOs). All of the work done for the Trial Implementations is publicly available including the technical specifications, the DURSA and the Operating Policies and Procedures adopted by the Coordinating Committee. Many, if not all, of the state-level HIEs have made their materials publicly available so that all can benefit from the good work that has been done. There is a growing recognition that while these resources are available and should be leveraged, they cannot be simply be adopted by a new health information exchange organization without thorough examination and customization.

Even with the use of existing interoperability specifications and the development of a strong trust agreement and governance infrastructure, health information exchanges cannot survive without funding. Developing workable, scalable and realistic financial sustainability models for HIOs remains a challenge that must be addressed if we are to recognize the benefits of robust information exchange. Most healthcare stakeholders recognize that there will be some benefit derived from health information exchange; however, the perceptions about this benefit vary dramatically between different stakeholders. The value proposition is continuing to evolve as existing use cases are refined and new use cases are discovered.

Provider engagement also remains a key issue. Some success has been realized in the incorporation of HIE into a provider's workflow, but much more work has to be done on this need. Even when a practitioner recognizes the value of HIE, if an unacceptable level of effort to access such information is required, then the benefits of HIE will not be fully realized.

We are very fortunate that the Federal agency Participants recognize the value and benefit of eHealth Exchange. The commitment of these Federal agencies to exchanging information through eHealth Exchange sends a powerful message as to its value and sustainability. It is because of this Federal agency support that eHealth Exchange has been able to survive and evolve to the point of independence. This has encouraged other HIOs to engage so that their respective members can exchange data with the Federal agencies via eHealth Exchange, and bring the benefit of doing so to its respective stakeholders.

- 4. ONC wishes to encourage health information exchange governance entities to come together voluntarily to identify common solutions to common problems
  - a. What deliverables and goals should the group have?
  - b. What issues should the group focus on?
  - c. What other considerations are critical for the success of such an activity?

eHealth Exchange was born out of ONC's initiative to bring together those involved in health information exchange to discuss and address common solutions to the common problems posed by the proliferation of point-to-point exchanges. The role of ONC as convener was absolutely essential six years ago when the health information exchange market was still in its infancy and healthcare stakeholders at large had not yet embraced the importance of health information exchange. Since that time, however, healthcare stakeholders, including vendors, are increasingly recognizing the importance of health information exchange. This was helped in part by the success of eHealth Exchange, in part by the promulgation of the meaningful use rules, in part by the advent of state-level HIEs and in part by the continued evolution of our digital culture. As meaningful use progresses and includes an increasing number of information exchange objectives and measures, healthcare stakeholders' belief in information exchange will be reinforced.

Because of the proliferation of health information exchange activities, many healthcare stakeholders have taken it upon themselves to self-organize to address common problems. There are many forums in which this important work takes place. You have heard from the Care Connectivity Consortium, an interoperability collaboration with the goal of creating comprehensive, secure, reliable and innovative electronic health information exchange across the country. The National eHealth Collaborative serves as a vehicle for bringing together industry stakeholders to discuss and educate others on important health information exchange topics. The EHR | HIE Interoperability Work Group (IWG) brought together 41 vendors and 18 states to reach consensus on HIE testing and certification strategy that aligns with both the eHealth Exchange and directed exchange. Late last year, Healtheway emerged as not only the support organization for eHealth Exchange but a convener of health information exchange stakeholders and collaborator with other initiatives like the IWG. Healtheway is dedicated to cross industry collaboration and supporting a range of initiatives to collaborate with stakeholders in the industry

to solve HIE implementation issues necessary for secure, trusted and scalable HIE at a nationwide level. ONC and other Federal agencies have liaisons with the Healtheway board of directors to help facilitate appropriate inclusion of the perspective of the Federal agencies and to truly operate as a public-private partnership.

We believe that stakeholders are actively collaborating and making substantial progress through collaboration. In that spirit, we believe ONC should continue to support the initiative industry is taking. Areas of support could include:

- Directories that support both discovery of providers as well as service discovery
  - The eHealth Exchange currently uses a web services registry to enable participants to find exchange partners who support compatible data types and services. We believe this should be a national priority since others will need such services to support widespread adoption of HIE.
- Support an experienced industry convener to develop best practices for incorporating HIE into provider workflow; build awareness and develop value cases and return on investment models to demonstrate value of HIE and that maximize utilization of HIE, much like the role that CMS and the Workgroup for Electronic Data Interchange (WEDI) had in educating industry about use of electronic administrative transactions.
- Explore additional value cases for nationwide HIE, building upon the evolving healthcare eco-system (e.g. ACOs, etc).
- Convene HIEs to continue to support and build sustainability models that focus on valueadded services and not just basic connectivity services, which is rapidly becoming a utility function.
  - 5. What policies, technical requirements, funding or convening at the national level would most effectively mobilize trusted exchange across vendor and organizational boundaries and address goals of governance including:
    - a. Increase interoperability
    - b. Decrease the cost and complexity of exchange
    - c. Increase trust among participants

Through efforts like Healtheway and the EHR | HIE Interoperability Work Group, vendors and implementers are coming together to address issues related to technical interoperability. There are excellent models for how to establish trust among participants in a network. As evidenced by comments to the Governance RFI, health information exchange is occurring and best governance practices are evolving.

Even with interoperability, trust and governance, health information exchanges cannot survive without funding. One of the greatest challenges to robust health information exchange is a financing model that can equitably and efficiently align the costs of operations with those deriving the benefits. To date, HIE initiatives have been supported through various financing mechanisms, including enterprise-based connectivity; one-time grants and contracts; value-added complementary services, such as results routing; transaction fees; and subscription-based services. Some of the more mature HIOs participate in a combination of these mechanisms.

As discussed previously, there have been some case studies demonstrating value of HIE for various stakeholders. To date, however, my belief is that: (1) these studies have not been numerous enough or compelling enough to gain industry acceptance; and (2) even if acceptance were gained, we still are faced with the need for an equitable funding strategy that aligns benefits with costs of participation. Without both, health systems and other HIE sponsors will continue to try to justify HIE initiatives based on a financial ROI. If truly HIE is a standard of care (and I recognize not all agree with that point), then we should make every effort to ensure it is ubiquitous. If it is not a standard of care, then we are all putting in a lot of effort to an exercise that is at best discretionary.

These foundational questions must be addressed and resolved once and for all. Only then can we move past viewing HIE as some interesting "lab experiment" or "pilot", that is, interesting perhaps but not critical to my mission of healthcare excellence. And I believe ONC can and should have a leadership role in this regard, and can do so in several ways. First, despite my previous comments regarding financial ROI, I do believe ONC should fund studies designed to quantify the financial impact associated with robust data exchange. My earlier reference to the SSA's study on value of automated disability determinations is an example that should be replicated.

ONC could also be a neutral convener to engage the payer community as to how best to participate in HIE. Many providers have been resistant to partnering with payers in HIE, even while recognizing that payers are one of the key stakeholders deriving the benefits of such. We have to determine an approach for how such participation (and concomitant funding) can occur while maintaining the framework of trust so essential for viability and success.

ONC could also work with SAMHSA to address the intractable problems for Part 2 providers. Because of the severe restrictions on disclosure in the Part 2 regulations, Part 2 providers are essentially prohibited from participating in any large scale health information exchange activity. Not only do these regulations pose issues for the Part 2 provider, they also pose issues for any provider that has Part 2 records in its medical record. HIEs across the country have had to contend with this use and typically decide to simply exclude these records from the exchange. To truly enable all information about a patient to be shared in a safe, secure and trusted manner, the Part 2 regulations must be revised to recognize the realities of robust health information exchange.

One of the complexities of health information exchange that is not often discussed is how providers are expected to handle the large quantities of data that will become available to them. I have heard from a number of providers who participate in one or more health information exchanges that the volume of data that the provider can obtain on a patient can be overwhelming. Sometimes there is simply too much data to absorb and assimilate in the short amount of time spent with a patient. Those of us who have been involved in health information exchange for the last ten years think that this is a welcome challenge, but a challenge nonetheless. We must work with our providers to understand what data will truly be helpful to them and how to present that data in the most efficient and effective manner.

We must also recognize that querying for information on a patient is a new step in the provider's workflow. New processes will have to be put into place to ensure that information on the patient is queried and available when the physician comes into the room (or even beforehand in a patient-centered medical home context). Developing new processes takes time and effort and we cannot expect our providers to do this without some assistance. ONC could fund studies or pilot projects designed to identify best practices for incorporating data exchange into existing workflows and identifying the types of data that are most beneficial in common situations. These

types of projects will help us to take data exchange to the next level and recognize the benefits we all know are possible.

In summary, a solid foundation has been built for HIE in this country and there is growing evidence of the resulting positive impact. For continued success, eHealth Exchange, like many HIE initiatives across the country, must "win" on three critical fronts: (1) operational excellence; (2) financial sustainability; and (3) technological innovation. We're at perhaps the most critical point in the HIE industry's evolutionary curve: big enough to have become essential for many mission-critical activities, yet not big enough to be considered the new "business as usual" that must be funded on an ongoing basis.

Many have described HIE as a "team sport". This is perhaps even more true as we look to the future. I am confident this work will be done, and I'm inspired by the dedication, commitment, and expertise of all those who work so tirelessly for this most worthwhile cause.

I would like to thank the HIT Policy Committee and the HIT Standards Committee for allowing me the opportunity to present this testimony. I am available to provide any additional information that the Committees may find helpful.

Respectfully submitted,

Michael B. Matthews, President Healtheway Board of Directors