Testimony to the HIT Policy Committee - Interoperability and HIE Workgroup, Governance Subgroup

8/22/14

1. **Please describe the governance approach used to support your information exchange activities. How do you establish and maintain the policy, trust and technical requirements which support information exchange? What issues do your requirements address?**

eHealth Exchange Governance: Coordinating Committee

Governance for the eHealth Exchange was initially developed as part of an ONC program initiative related to the nationwide health information network in 2007.

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, a legal infrastructure and other governance elements were developed to support the exchange of health information among Participants.

The Participants formalized their grant of authority to a governing body, the Coordinating Committee, through a legal agreement, the Data Use and Reciprocal Support Agreement (DURSA), specifically setting forth the Coordinating Committee's 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 eHealth 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 a trust framework for the 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 emerging specifications into the production environment used by the Participants to Transact Message Content;
k. Coordinating with ONC to help ensure the interoperability of the Performance and Service Specifications with other health information exchange initiatives including, but not limited to, providing input into the broader ONC specifications activities and ONC Standards and Interoperability Framework initiatives; and
l. Fulfilling all other responsibilities delegated by the Participants to the Coordinating Committee as set forth in the Agreement.

Evolving and Adaptable Governance

Since its inception, the Coordinating Committee and the eHealth Exchange governance model has been adapt to respond to a rapidly changing environment.

The Coordinating Committee and participants are able to adopt / refine the technical and policy requirements, operating policies and procedures, as well as the DURSA through a lightweight change process. Once participants are provided an opportunity for input, changes can often be implemented and rolled out within a 30-day timeframe. This type of nimble and responsive governance approach enables the eHealth Exchange to address clarifications, fix issues that arose in early days of implementation and to remain responsive and relevant to Participants.

As a result, changes often can made within weeks / months instead of years. The DURSA has been amended two times in response to rapidly changing market dynamics:

- In 2011 - to reflect ONC's evolving HIE / HIT strategy in light of HITECH.
- In 2014 - to change the composition of the Coordinating Committee and the eligibility criteria to assure balanced representation and to accommodate evolving HIE models.

The governance model and processes supporting the eHealth Exchange are very mature and continue to be improved as the network grows.

Carequality

Overview

Carequality, a public-private collaborative formed in early 2014 is focused on enabling interoperability between and among networks. Today, existing networks are generally defined by particular technology platforms, use cases or geographies. This has resulted in multiple networks that operate independent of one another.

Carequality will focus on bridging connectivity among these networks by facilitating agreement on common national-level business, policy and technical requirements that will enable providers to access patient data from other groups as easily and securely as today's bank customers connect to disparate banks and user accounts on the ATM / ACH network. Once achieved, this level of health data interoperability will represent a quantum leap in the quality of health care available and reduce the cost to support interoperability. Industry stakeholders have expressed a strong preference to have these requirements developed through an industry-driven consensus process, with support and participation by the Federal government.

Carequality Governance

Carequality has been established with a three-tiered governance model, including a Steering Committee, an Advisory Council and Work Groups. The following summarizes the role and function of each and explains how requirements are developed and maintained.

Steering Committee

In its role as the governing body for Carequality, the Carequality Steering Committee (CSC) will fulfill the following responsibilities:

- Govern the work of Carequality to assure that the process, Workgroup and Advisory Council activities are conducted in a manner consistent with Carequality's vision and principles.
- Manage the work of Carequality to maximize efficiency and effectiveness within an annual Carequality budget.
- Establish workgroups and corresponding workgroup charters that define the workgroup composition, scope, deliverables and timeframes for completing its work.
- Evaluate, prioritize and adopt new deliverables and other work facilitated by Carequality.
- Oversee the development and maintenance of its deliverables, such as use cases, trust framework, etc.
- Establish the Advisory Council and seek input and recommendations from the Carequality Advisory Council and other stakeholders, as the Steering Committee deems appropriate to assure broad stakeholder input.
- Maintain a definitive list of Use Cases and other deliverables, to assure clear versioning of such work, developed and maintained by Carequality.
- Coordinate with standards development organizations, policy-related endeavors and other federal and industry initiatives to help align the standards and specifications employed by the Carequality with other like efforts.
- Oversee other centralized functions supported for Carequality.
- Oversee a process, as needed, to address questions or disputes regarding the Carequality deliverables.
- Evaluate ongoing program effectiveness on a periodic basis and implement process improvements over time.

Advisory Council

The purpose of the Advisory Council is to inform the work of Carequality through its representation of broad constituent groups and a diverse array of perspectives.

The Advisory Council is responsible for representing a broad spectrum of health information exchange stakeholders to inform the Steering Committee's development of the Carequality interoperability framework. The Council is envisioned to serve a valuable role, to advise and assure the broadest set of interests are reflected in Carequality's work, such as:

- Provide input on proposed use cases prioritized and presented to the Steering Committee for approval.
- Weigh in and review draft deliverables and proposed final deliverables that will be presented to the Steering Committee for approval.

- Make recommendations to the Steering Committee regarding approval of use cases and work products, as well as recommendations for new use cases.

To assure the broadest perspectives are reflected, the Advisory Council has been established with representatives from the following:

- Behavioral health
- Networks (e.g. HIOs, eprescribing networks, etc.)
- Other type of healthcare settings (e.g. pharmacy, post-acute care)
- Governmental
- Healthcare physicians
- Healthcare provider organization
- Vendor
- Public health
- Consumer
- Health plan
- Standards development organizations
- Patient safety organization
- Research
- Testing / Certification / Accreditation
- Subject matter experts

Work Group

Work Groups will be formed to address specific projects as determined by the Steering Committee. Carequality is starting with two initial Work Groups The Trust Framework Work Group is responsible for developing the replicable model for other Work Groups to follow so that trust principles are appropriately addressed by every Work Group. The Trust Framework Work Group will develop:

- A universal set of policy principles that apply across all Carequality use cases
- A set of customizable policy principles which can be tailored to specific use cases
- The Query Use Case Work Group, and subsequent Work Groups, will apply these universal and customizable principles to develop business, policy and technical requirements to enable simple query as well as record-locator service facilitated query.

As the query use case and policies are implemented, there will be feedback loops form the implementation community and testing process to continue to refine and adapt the requirements.

Summary

Experience has shown that interoperability occurs when there is a well-defined, tightly constrained set of requirements, built upon solid underpinnings of business requirements, use cases and policy requirements. But to stand the test of time, interoperability must be supported by a nimble, responsive governance process, driven by industry, in partnership with the federal government and grounded in the practical realities that implementers have to face to make HIE / HIT work in the real world.

2. How do you ensure participants adhere to your organizations requirements? What enforcement mechanisms do you have for organizations that are out of compliance with your requirements?

eHealth Exchange

eHealth Exchange has adopted a multi-faceted approach to assure that its participants comply with the eHealth Exchange requirements. They work together to create a comprehensive trust framework that has delivered a very high level of compliance with the eHealth Exchange requirements. I think that it is important to briefly discuss each facet of this approach.

- Eligibility Criteria: Before an organization becomes a participant in eHealth Exchange, it must demonstrate that it meets specific eligibility criteria in order to submit an application for participation. The eligibility criteria both define the types of organizations that can participate in eHealth Exchange and inform prospective applicants of what will be expected of them as members of the trust community.
- Testing: Applicants to the eHealth Exchange must use certified EHR technology that has been tested and approved by eHealth Exchange using our Product Testing program. This assures a uniform level of technical performance across all participants. Each applicant must also successfully pass Participant Testing which assures that the applicant's implementation of its EHR product will support exchange with other Participants.
- Compliance Obligations: Every Participant is contractually obligated to comply with a set of implementation specifications, testing requirements, and operating policies and procedures. These requirements cover a broad range of eHealth Exchange network operations including privacy, security, confidentially of information, cooperation with the Coordinating Committee and other Participants, malware and breach reporting. The Coordinating Committee is responsible for keeping the requirements current and it has revised them several times since they were first adopted in 2009. New Operating Policies and Procedures have been added as the eHealth Exchange has grown and the technical and policy landscape has evolved. Importantly, all Participants are kept informed as existing Operating Policies and Procedures are revised and new Operating Policies and Procedures are created so that they can have meaningful input. Participants must approve revised or new Operating Policies and Procedures by a two-thirds majority vote, which has been an effective way of keeping Participants engaged with a sense of genuine ownership.
- Self-policing: The eHealth Exchange requires each Participant to be responsible for their own actions. This is codified in the DURSA in terms of the allocation of liability among Participants. However, it is also built into the Operating Policies and Procedures of eHealth Exchange by specifically permitting a Participant to voluntarily suspend its use of the network if the Participant encounters technical or operational issues. Allowing Participants to voluntarily suspend use of the network without sanction encourages accountability by each Participant. Participants are required to report all voluntary suspensions to the Coordinating Committee and, in some cases, obtain prior approval for a voluntary suspension. This tool has been used by several Participants over the years and has been effective.

- Dispute Resolution: eHealth Exchange is a community composed of very sophisticated organizations involved in all aspects of health care delivery and federal agencies. The DURSA includes a formal dispute resolution process that all Participants agree to follow in the hopes of being able to resolve any disputes without the need for litigation. eHealth Exchange has been operation since 2009 and has never needed to activate the formal dispute resolution process because Participants have been able to informally resolve any disagreements. I believe that having a formal dispute resolution process gives all Participants comfort and actually encourages them to resolve any misunderstandings informally.
- Enforcement: The Coordinating Committee is vested by the DURSA with the authority to take action against Participants if they do not comply with the eHealth Exchange requirements. The Coordinating Committee has the authority to suspend a Participant's ability to exchange information through the network until the non-compliance is corrected or to terminate a Participant's use of the network if the non-compliance is not corrected. The Coordinating Committee encourages Participants to work collaboratively to address any issues of concern. However, the Coordinating Committee has the specific authority to act as needed to protect the integrity of the eHealth Exchange.

Carequality

Carequality is in the early stages of deciding how to assure that its implementers comply with all applicable requirements. The Carequality Steering Committee will seek input from a diverse range of stakeholders to identify the best approach.

3. How do you manage the evolution of policy and technology requirements (i.e. how do you adopt new standards and retire those that are no longer in use)? What expenses do you experience to govern exchange?

eHealth Exchange

The Coordinating Committee recognizes that change is the one constant when it comes to electronic health information exchange. eHealth Exchange has adopted very specific change management processes to assure that it is keeping current in a rapidly changing environment and to assure that Participants are included in the change management process. This is such a foundational concept that it was codified in the DURSA so that Participants were assured of a meaningful role in the inevitable changes that would be made to specifications and Operating Policies and Procedures.

The Coordinating Committee is responsible for evaluating proposed changes to the specifications or the Operating Policies and Procedures to determine if a change is warranted. Participant input to this decision is required before the Coordinating Committee makes its decision. All Participants are given a 30 day objection period to evaluate any proposed changes to current specifications or Operating Policies and Procedures and to provide the Coordinating Committee with any objections. If more than one-third of Participants note objections, the Coordinating Committee is required to address the objections and submit the proposed revisions to all Participants for a vote.

The transparency of this change management process is very important to maintaining the integrity of eHealth Exchange. Participants can be assured that specifications and policies will not be arbitrarily changed and that they will have meaningful input on all changes. The Coordinating Committee has used this process successfully on numerous occasions since eHealth Exchange began and it has worked very well.

Carequality

Carequality is governed by a Steering Committee composed of individuals who represent the Carequality Founding Members and other key stakeholders such as ONC, other federal agencies and users of EHRs. The Steering Committee has created Work Groups that are responsible for developing the specific technical and business requirements that will govern each specific Carequality product. The Steering Committee has also established an Advisory Committee with subject matter experts and thought leaders from key disciplines to provide ongoing input to the Steering Committee.

4. **What, if any, actions should be taken at the national level to help address the governance challenges that are inhibiting the exchange of health information across entities or to mitigate risks to patient safety and/or privacy when exchange is occurring? What role should ONC or other federal agencies play? What role should states play? What role should the private sector play?**

   eHealth Exchange recognizes ONC's vision and leadership in promoting the development of electronic health information exchange on a national scale. The public-private collaborative model that ONC followed has led to a strong nationwide health information network in the form of eHealth Exchange and Healtheway that is growing rapidly. By the end of 2014, eHealth Exchange will have over 100 Participants representing approximately 1600 hospitals, 10,000 medical groups, 4 federal agencies and health records for over 100 million Americans. Several states have successfully transitioned from federal funding and are developing sustainable business and technical models for state level health information exchange. The private sector has many examples of large scale networks that are successfully exchanging large amounts of electronic health information.

   We applaud ONCs thoughtfulness around the use of rulemaking to not burden this developing market with regulations. While challenges certainly exist, we believe that best solution is a continuation of the public-private collaboration that ONC has pursued with such good effect. The new Carequality initiative recently launched under Healtheway is an excellent opportunity for the private sector, government and the public to come together to discuss some of the complex technical and policy issues that have delayed the complete interoperability of EHR systems.

5. **What is the right format for resulting products – requirements, federal standards, and federal recommendations?**

   We believe that the emphasis should be on process and not products. ONC provides tremendous value by engaging in the process of defining the tools to support the widespread exchange of health information across interoperable systems. Through this process, there will likely be specific products that ONC is uniquely positioned to provide, such as specific requirements, standards or recommendations. However, we suggest that it is premature to declare what form these products should take.

Do we have any specific examples that we are willing to share?

6. **What business practices by providers and vendors are currently blocking information following patients to support patient care?**

   eHealth Exchange and Healtheway are not in the position to have observed specific practices by providers or vendors that block the flow of information.

7. **Would it be beneficial if ONC monitored the information exchange market to identify successes, challenges and abuses? If so, what methods of monitoring would be effective; and, what actions should ONC take based upon findings from monitoring?**

   We are not clear on exactly what type of "monitoring" ONC is considering. The sharing of successes and challenges is always helpful. In terms of network operations, we believe that it is the responsibility of the network to have systems in place to respond to non-compliance by network participants. For example, the eHealth Exchange Coordinating Committee is responsible for addressing non-compliance by an eHealth Exchange Participant with the DURSA or an Operating Policies and Procedures or specifications. We believe that oversight and enforcement are essential components of every trust community and should not be delegated outside of the community. One of the primary goals of the Carequality initiative is for EHR vendors, customers, government partners and the public to agree on common principles that will promote interoperability. We urge ONC to actively participate in Carequality at the Steering Committee level and elsewhere so that the best possible products can be achieved.