Dave Minch, California Association of Health Information Exchanges

Panel 3: State/Federal Perspectives

Responses from CAHIE (California Association of Health Information Exchanges) – David A. Minch, President and Board Chair

CAHIE is not a state or other government entity, rather, CAHIE is a voluntary collection of HIE-capable organizations, both enterprise-based and community-based, and other stakeholders interested in promoting HIE, who have come together at the request of our state administration (Pamela Lane) to improve the liquidity of data flow across California. CAHIE has developed the California version of the federal DURSA, which is the common trust agreement that all participant trading partners sign which allows access, after testing and certification, to the California Trusted Exchange Network (CTEN). CTEN combines the capabilities of the eHealth Exchange and DirectTrust trust bundles in a single, coordinated exchange network with associated policies and procedures which are administered by the California Interoperability Committee (CIC).

- *What exchange use cases do you support?*

  Initially, CAHIE supports both Exchange[1] and Direct protocols using nationally recognized and adopted standards and reference implementations, and also a federated Directory Service. We do not restrict use cases under the CalDURSA, but allow trading partners to self-determine which use cases they will support for Exchange query or Direct. Typically, all use cases encountered to date relate to patient care delivery.

  - *What challenges are inhibiting or slowing your ability to broadly deploy/support these use cases?*

    Having a uniform approach for each trading partner to "advertise" their trust attributes and responding restrictions would be extremely helpful in mitigating the out-of-band discussions, testing, and in some cases additional bilateral agreements. We proposed a strategy for such trust attribute development in the NeHC Governance committee work last year.

  - *What makes you different than the open market and do these differences advance or hinder exchange?*

[1] In the response text, I will use capitalized "Exchange" to reference the query protocols with that name, and I will use lower-case "exchange" as a verb referring to data interchange using any approved protocol.

Unlike a government agency, we are able to respond rapidly to a changing exchange environment, to adopt new exchange transactions and standards. As an organization that exercises voluntary self-governance, we cannot exert any regulatory authority. It is incumbent upon us, therefore, to focus and deliver solely on the policy, procedural, and technology needs of our members and stakeholders in promoting widespread HIE in a way that is sustainable, both for us and for our members.

The CTEN initially provides both Exchange and Direct capability, and also uses a light-weight federated Directory Service which allows any trading partner to query the directory services for either Direct addresses or Exchange services. Through the CIC, California will aggressively work on adoption of additional data exchange protocols such as FHIR and cross-organizational query to extend the ability of our participants to move more significant data sets as needed for the use cases trading partners determine useful.

- *What policy, trust and technical requirements do you require be met before agreeing to exchange with another exchange service provider?*

  Participants must sign the CalDURSA, submit their P&Ps for review, respond to a set of policy questions which contain self-attestations, and participate in and pass basic exchange testing before they are on-boarded. Testing is dependent on which services Participants sign up to provide, and is currently accomplished by peer-to-peer testing with other CTEN participants to allow new organizations to participate in exchange as rapidly as possible. Participants must also require each of their participant users to sign a participation agreement which we recommend use or be modelled after the California Model Modular Participation Agreement (MMPA) which is designed to accommodate nearly any form of HIE and is designed to accommodate federal DURSA and CalDURSA requirements.

  - *What if any assurances do you require that your trading partners are adhering to these requirements?*

    CAHIE requires that the CTEN participants submit any significant changes to their P&Ps as they happen, and depending on actions of the CIC may require additional testing based on feedback from other trading partners. If the participants use the MMPA as their participant-user agreement, less review work (and cost) is required for CAHIE to assure that the necessary contract protections are in place. Once on-boarded and operational, the CalDURSA provides

mechanisms for recording, researching, and resolving trading partner complaints.

- *What factors are limiting the exchange of health information?*

  Each organization participating in exchange establishes the specifics of exactly what data is packaged and moved and what trust attributes it exhibits. For example, one trading partner may allow its participants to post data received into a local HIE repository for further use by other local participant users, whereas this may be an unacceptable practice according to the policies of a potential data sender. In that situation, either a special accommodation must be made by the receiving participant, or exchange may not be allowed by the sender. Another simple example is the use of Direct – in one case, a Direct sender may want to send an unstructured message in plain text along with a CCDA, but another Direct receiver allows only CCDA-structured documents to be received. If exchange occurs, it could end up dropping the unstructured message and hence be an issue for both parties.

  Most of these inconsistencies in capability or function are not due to a lack of standards, but a combination of local policies of the data trading partners, and/or limitations / implementation choices of the software that they operate. A simple taxonomy of trust attributes and service availability / limitation which is computable could greatly improve the ability for otherwise unrelated organizations to interoperate.

- What governance challenges are putting patient safety and/or privacy at risk when health information exchange is occurring?

  Both the CalDURSA and the California MMPA are designed to work together to assure the maximum possible privacy protections for patient data while allowing any interaction permissible by law or regulation. The CalDURSA governs the process of exchange between HIE trading partners, and the MMPA provides the rules and contractual assurances between HIE participants and their users. The beauty and simplicity of the DURSA document, which we have copied with the California version, is that it focuses only on the trust elements of the exchange process itself, recognizing the simple yet obvious fact that once exchanged, the data must be protected and maintained according to the rule of law – both federal and state – which all receivers of patient-specific data are bound by.

  Patient safety can, however, be impacted by incomplete data, or the inability to exchange data because the potential trading partners have not worked through the trust and service availability details. Another excellent example of incomplete data is the approved transfer of clinical data about

a patient for treatment purposes, but the withholding of psychotropic medications because of the restricted nature of the disease being treated.

- *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?*

  As discussed earlier, it would be extremely helpful to have a nationally-recognized and standardized computable taxonomy of trust and service attributes, and a means of discovering the attributes which reflect the policy and technology nuances and limitations of data trading partners – those providers who are also enterprise-based HIEs, those that are participants in community-based HIEs as well as the HIEs themselves. These attributes are largely known today, and it would take little effort to first create a manual human-readable taxonomy, form a computable version using ebXML or another policy representation, and incorporate them into directory services or some other discovery mechanism.

  Through voluntary adoption of the MMPA in California, we have experienced that more uniformity in the structure of participant agreements is very helpful toward achieving a more interoperable landscape of healthcare organizations. The California MMPA is now actually structured to work in concert with the CalDURSA to create more consistency in participant agreements with participant users, and as more organizations use the MMPA for their participation agreements, we will have less inconsistency in the required trust attributes required from each.

  - *What role should ONC or other federal agencies play?*

    We maintain that such a computable taxonomy would have little relevance if it were not developed to fit a national landscape of healthcare entities. This would seem to us to be dead-center in the realm of ONC to champion its development, piloting, and deployment. Once ready for deployment, we think it should be incumbent for any healthcare organization who wants to be interoperable to implement, yet it must be simple enough to understand and implement that organizations of any size and capability can participate.

    We would also recommend exploration and adoption of some form of modular participation agreement nationally that can work in conjunction with the DURSA and other state- or network-specific versions of the DURSA to achieve more uniformity in the agreements that HIE organizations have with their participants, and

more uniformity in the ways that users are bound to the agreement since the DURSA documents require such of their participants.

- *What role should states play?*

  Many states all have differing laws when it comes to privacy, security and access to patient data. Many of the trust and even some service attributes may be impacted by state law and regulation. States should participate in the taxonomy development and also be champions of its use. States may also find that through deployment of such a taxonomy they may be able to simplify regulation where the taxonomy is deployed.

- *What role should the private sector play?*

  As a private sector organization we would be interested in working with ONC toward the furthering of these concepts. We also know of other "networks" similar to ours (many are either state-sponsored, or collaborations such as we are) who may be interested in furthering these concepts.

- *Would it be beneficial if ONC monitored the information exchange market to identify successes, challenges, and abuses?*

  ONC by its very charter is the focal point for interoperability on a national scale. As such, development of a method for routine self-reporting of information relative to HIE activity would be both informative and useful to states and networks such as ours in understanding accomplishments and challenges by other HIEs and HIE networks. Having a single central repository of information that can be self-reported and updated could be very useful to all of us – if for no other reason than as a national directory for organizations to research potential data trading partners who have implemented the computable taxonomy of attributes. We would at the same time caution that such a repository must be kept uncluttered – the information contained must be relevant to many uses and the information value must exceed the individual costs of supplying it.

  - *If so, what methods of monitoring would be effective; and, what actions should ONC take based upon findings from monitoring?*

    We suggest that a web-based self-reporting tool and services directory would be appropriate. Content would have to be developed, and ONC could look to organizations like HIMSS and eHI who have developed comprehensive surveys in the past. We would caution ONC, however, when it comes to trying to capture abuses in that there are other federal and state agencies that cover

that domain quite thoroughly, and it may blunt the effect of having a national repository of information on HIEs if organizations feel threatened by their inclusion.

- *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?*

  The CalDURSA is the contract that all participants must sign which governs the process of exchange and references the technical standards and policies used. The CIC is the CAHIE body that manages the CTEN and responds to all issues with its use. The CIC in turn is comprised of exchange partners actually transacting over the CTEN.

- *How do your ensure participants adhere to your organization's requirements? What enforcement mechanisms do you have for organizations that are out of compliance with your requirements?*

  The CIC has the authority to suspend any participant who is not managing their users appropriately, or who is otherwise not fulfilling the terms and conditions they agreed to in the CalDURSA – such as the duty to respond. The CalDURSA defines mechanisms for dispute resolution to address concerns of CTEN participants.

- *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)?*

  The CIC also manages the library of technical specifications which are referenced in the CalDURSA. As noted earlier, while we are starting with the nationally-published specifications for Exchange and Direct, and have added a federated structure for directory services, we intend to expand the CTEN service capabilities adding new transaction patterns and protocols as they are approved by the CIC to meet the needs of CTEN participants.

- *What expenses do you experience to govern exchange?*

  CAHIE intends to manage the CTEN with a very light-weight infrastructure and staffing. The CIC, as are all of our operating committees, are all volunteer, and the intention is to keep the organization lean and focused. We have started with contract staff, and will add employees as needed and when appropriate based on workload. The initial operating budget is well under $1 million annually.