

Office of the National Coordinator for Health IT  
Health IT Policy Committee  
Governance Subgroup  
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The following remarks are submitted on behalf of the [National Association for Trusted Exchange](#) (NATE) by [Aaron Seib](#). We thank ONC and the Federal Advisory Committees for the opportunity to provide testimony. Our testimony is formatted to follow a question and answer pattern where our responses follow the questions (**emboldened**) prepared by the HITPC Governance Subgroup below.

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**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?**

NATE is a voluntary association of members who collaborate to find common solutions that optimize the appropriate exchange of health information for greater gains in adoption and outcomes. Our mission is to address the legal, policy and technical barriers that inhibit health information exchange between entities within a state and across states. NATE participates in a number of ongoing projects and emerging projects in the health information exchange (HIE) domain as prioritized by our members and informed by NATE capacities.

Working with members and others, NATE coordinates resources and different funding opportunities (NATE has been awarded two separate grants by ONC in relation to its governance activities) to effectively execute pilots of solutions that are considered most promising for a given need. NATE establishes diverse pilots with early participants from multiple states to ensure a sufficient diversity of environments, as multiple environments will expose interoperability challenges that may not be evident in simple pilots among pairs of environments. This diversity requirement affords the NATE governance process some assurance that the subsequent recommendations presented to the membership will include a solutions that have been demonstrated to interoperate broadly across boundaries, including boundaries of jurisdiction and types of enterprises. This approach is intended to elicit considerations of similar interoperability challenges from the membership that did not participate in the pilot to further vet proposed recommendations.

The process of pilot, document recommendations, vet with membership and make a go/no-go decision is repeated until the membership determines that a recommendation is mature enough to warrant consideration by NATE's Board of Directors. Once the Board of Directors approves a given solution set, the offering is made available beyond pilot participants and the ongoing support of the solution is ensured until retired by the Board of Directors.

NATE began pilot work in relation to Direct based exchange in 2011. On November 1, 2012, the first interstate exchange of a Direct message using a pilot trust bundle occurred. Subsequently, additional states participated in the pilot, ultimately resulting in approval of the related policies and procedures (P&P). This trust bundle is now available and related onboarding processes are open to all member states. NATE has periodically identified opportunities for improvement to the underlying policies of this

Trust Community. Recommendations to modify various policies have been presented to the NATE Board and ultimately approved.

NATE began pilot work in relation to leveraging Direct to support bidirectional exchange between providers (HISPs) and patients (user controlled PHRs) in August 2013. Following completion of a pilot funded in part by the ONC, the NATE Board of Directors have directed the NATE staff to work with the broader community to more widely vet the outputs of the pilot, in order to inform a recommendation to be presented to the Board by the end of 2014. NATE has established a work group to define the scope of work to be implemented to inform a final recommendation in that timeframe.

NATE has participated in a number of initiatives led by other organizations and made contributions related to projects in the Provider Directory, Governance and several Standards & Interoperability (S&I) Framework pilots in order to remain informed and current and to help ensure that priority setting by the organization is complimentary to ongoing activities of others in the domain.

In 2014, the NATE Board of Directors identified four priority areas, charging the organization's leadership with focusing their activities on continued work on NATE's Trust Bundle for Provider Directories and making patient participation in exchange practical with special attention paid to anticipated advancements in these areas:

1. Provider Directories
2. Identity Management
3. More Granular Framework (Trust Taxonomy)
4. Engaging additional member types

In addition to typical participatory activities of the NATE staff with ongoing initiatives such as the Data Provenance and Data Segmentation for Privacy S&I Work Groups, NATE has stepped up to volunteer to administer the Blue Button+ Trust Bundles for Providers and Consumers. NATE's leadership prioritizes evaluation of funding activities based on their alignment with these priorities and membership availability to directly participate in order to ensure diversity any pilots led by NATE.

With regards to priority 4, NATE has recently formed a representative work group made up of external stakeholders to discuss recommendations to modify NATE's bylaws and membership policies, in order to permit additional types of membership currently excluded from participating in NATE's governance activities.

### **How do you ensure participants adhere to your organizations requirements?**

By policy, NATE may require:

- Testing with peers as a condition to being included;
- Eligibility criteria based on the terms and conditions employed by the entities legal agreement;
- Periodic renewal of evidence considered when onboarding an entity, and
- For some criteria, notification of changes to be made to previously submitted evidence for consideration by the appropriate procedural process.

NATE retains the authority to modify policy as required from time to time and does so as evidence of need emerges.

**What enforcement mechanisms do you have for organizations that are out of compliance with your requirements?**

NATE is a voluntary governance model whose authority is limited to excluding participants from participation in the community.

**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)?**

NATE's membership is made up of adopters and operators of HIE organizations, the state level programs charged with the shepherding of HIE with and within their states as well as the vendors that serve them (NATE membership bylaws are currently being extended to support inclusion of new member types). NATE is responsive to its membership's priorities with regards to modifying existing programs within the context of approved policies. NATE relies on established and approved policies and procedures for maintaining the evolution of existing policies, procedures and the underlying standards and technology employed to facilitate their realization. We compliment this maintenance process with a fearless approach to piloting new ideas and either selecting promising concepts or failing fast.

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

NATE is a not-for-profit organization with limited resources. In evaluating priorities, NATE is conservative in only committing to efforts that it can support either directly through the organization's budget or via in-kind contributions and volunteer participation. NATE's process of piloting before approving and iteratively enhancing is a conservative approach that not only makes fiscal sense but also makes for good governance and discovery practices. Members pay an annual membership fee, which is used to support the recurring activities of the organization, including a small amount of infrastructure to maintain the various Trust Bundles deployed by the organization. Beyond Trust Bundle administration, the NATE mission and organization is aligned to support similar services for relying parties, such as Common Terminology Services, Identity Services and Knowledge Repositories that ameliorate or otherwise eliminate barriers to trusted exchange.

**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 risk to patient safety and/or privacy when exchange is occurring?**

The nation has learned that a great deal of appropriate standards based exchange is being achieved at the local, state and regional level, both in compliment to or independent of federally fostered governance entities. Where successful governance practices have been employed among otherwise independent stakeholders, privacy preserving, patient safety enhancing and cost reducing applications of health information technology have organically emerged.

We believe that if the mission of the ONC is to be a resource to the entire health system for supporting the adoption of health information technology and the promotion of nationwide health information exchange to improve healthcare, there are a number of beneficial actions the ONC can take to help address the governance challenges that are inhibiting HIE among unaffiliated entities, specifically the governance organizations thereof.

1. Work to improve the ability of local policy decision makers (LPDMs) to subscribe to **both** nationally fostered governance entities **and** those governance entities with a different scale or mechanisms of ensuring trustworthiness of the governed.
2. Support and contribute to the ongoing work on common barriers to exchange among unaffiliated entities (and the governance mechanisms that aggregate them) - especially by acting as a conduit between governance entities and the Federal Administration's health IT efforts.
  - a. Examples of common barriers include those related to Identity, Consent, Legal Agreements, Testing/Certification and the use of computable policy processing at a more granular level.
  - b. For more on computable processing at a more granular level, see the National HIE Governance Forum recommendations on Trust Taxonomy and the LOA Escalator which included significant contributions from NATE.
3. Simplify the LPDM's process of determining which governance entities meet or exceed their local requirements.
4. Promote the emergence of improved tools for enabling exchange among unaffiliated entities by incentivizing desired outcomes for prioritized use cases, rather than specifying specific requirements related to how.

Ultimately the people who will be held accountable for implementing HIE (i.e. holding the liability bag when the music stops) must be empowered to select those governance mechanisms that best align with their institution's capabilities and tolerance for risk. Unless legislation empowering national safe-harbors from liability are enacted, the most appropriate means at the disposal of the ONC for eliminating the barriers to optimal exchange would seem to be the harnessing of the numerous organic governance efforts emerging today.

By way of illustration, the following example describes a common impasse for users of the Direct mode of exchange:

LPDMs would like to enable the users of HIE within their authority to perform as much appropriate electronic exchange as possible, so long as they are confident that:

1. Their institution's policy requirements with regards to conditions for trusted exchange are met or exceeded; and
2. The capabilities of their institution to utilize these exchange channels do not encumber their organization with inordinate costs or disruptions to service.

With regards to both of these conditions, the ONC can help the LPDMs in a number of ways. At the highest level there are three apparent categories of barriers:

- Policy – Today it is difficult for LPDMs to learn about and compare the pros and cons of different Trust Communities that may help them enable as much appropriate exchange as possible. The ONC could facilitate the process by which LPDMs learn about different governance offerings and how they compare to the needs of the LPDM’s institution. ONC could establish a hub or clearinghouse of qualified governance entities and make it more facile for LPDMs to understand the appropriateness of the various approaches to their local requirements.
- Technical – The current Direct Implementation Guidance as recognized by the Meaningful Use (MU) program is silent on how trust stores should be operated. The ONC should endeavor to have the implementation guidance extended to better enable LPDM self-service with regard to which trust bundles are stored for those accounts that fall under their authority to operate. In the best of all possible worlds, the materials developed to address the policy barrier would be integrated with the self-service enhancement so that those at the local level could make the decisions and maintain their choices over time – eliminating a burden on the vendor community and putting control over policy in the hands of those at risk, specifically the LPDM.
- Education – The ONC could support education of LPDMs about the various considerations that would impact their selection of governance models. This would allow LPDMs to make meaningful choices amongst governance alternatives and avoid engagement in products or governance models that practice exclusionary approaches or otherwise artificially constrain the amount of appropriate exchange that could be realized by their institution.

If the ONC has the authority to set a minimum bar for qualified entities, the ONC would be able to simplify the LPDM’s evaluation process. Lacking the authority to do so – the ONC could support or otherwise encourage an independent unbiased entity in establishing the criteria required for Governance entities to be characterized as qualified. The act of qualifying Governance entities should not indicate endorsement by the ONC or another federal agency but rather indicate that the Governance entity so qualified would continue to be monitored by the program and information about the Governance entity maintained and distributed through time and be considered sufficient from a MU evaluation perspective. The ONC should make a policy decision about the implication of Governance approaches that do not participate in the program based on the nation’s needs and experience.

Finally, the ONC could incentivize innovation - not by deeming certain governance entities as appropriate for certain use cases, but by linking MU certification and other programs to qualified governance entities that have proven ways to satisfy the needs of the use case.

**What role should ONC or other federal agencies play? What role should states play? What role should the private sector play?**

Federal Agencies, states and the private sector should play a role in aligning, where possible, to ensure the greatest amount of appropriate health information exchange. A leadership role that the ONC could play is to acknowledge that each sector has limits on its authority to change how it aligns or not with any of the others. Where alignment does not exist, the ONC must support the development of solutions

that can bridge these gaps. It is time for all of us to recognize that there is no single silver bullet that will enable any end-point to communicate with any other end-point for all use cases to the satisfaction of all local policy decision makers.

Where the states remain sovereign with regards to establishing local applicable law that exceeds applicable federal requirements, and the private sector risk running afoul of state's authority to enforce its laws, it is important that the ONC invest in ways to make it easy for LPDMs to understand how to select solutions that support applicable state law and to know the risks otherwise. As the 10 year Roadmap expands, the ONC should endeavor to be inclusive of such state based requirements.

The ONC is uniquely positioned with the ability to influence the direction of the nation with regards to governance. Its role should be to support the LPDM in selecting governance models that align with their needs, and to the extent possible, the ONC should work to eliminate barriers that inhibit otherwise appropriate exchange.

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

As described in the illustrative example above, the format should be integrated in such a way as to make it simple for the LPDM to choose among qualified alternatives and leverage complimentary offerings to enable as much appropriate exchange as possible.

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

Building on the earlier example, an unintended consequence of not being specific in the Direct Implementation Guide regarding the relationship between Trust Stores and the LPDM's responsible<sup>1</sup> has unintentionally resulted in groups of providers being entrapped to the policy decisions made by the operator of the HISP rather than the LPDMs. As a result, the Trust Store can only contain the least common denominator, or worse, only enable exchange with those parties associated with the policy decisions of the vendor.

Originally, Direct was envisioned as an easy way for two doctors who already had established trust to exchange with one another. Over time, the wisdom of the crowd found that this may not be sufficient and we began to investigate how we could mitigate technical risks in transport (via accreditation or otherwise). Since then, a number of Trust Communities have emerged – some attuned to specific use cases or relying on pre-existing trust relationships, all likely trustworthy and valid for the use that they were intended to support.

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<sup>1</sup> The applicability statement is silent on this relationship and as a result it is completely compliant for a single trust store to map too many LPDMs. Historically, there was a great deal of concern about a single certificate being used in association with many LPDMs but to date this shoe-horning of LPDMs into a single trust store has not been corrected. This mismatch unfortunately results in requiring a least common denominator to trust for some Direct Implementations with the unintended consequence of excluding local trust decisions that are not applicable to all LPDMs associated with an HIO that has implemented Direct.

Unfortunately, as the number of LPDMs being supported by a given vendor increases, the cost associated with maintaining client specific configurations of Trust Stores increases (especially given today's lack of specificity around how trust stores are best implemented). A trade off exists today between economic decisions about how to operate HISPs at scale and making it easy for LPDMs to pick a broad selection of communities that meet or exceed their local policy requirements. It is imprecise to label this as business practice, as the intent of the approach was most likely not to be exclusionary (likely many of those in this boat today were architected well before the emergence of numerous trust communities) but rather based on assumptions about adoption rates of specific approaches that have not resulted in near unanimous adoption.

It has become self-evident that one size does not fit all with regards to the governance of HIE. LPDMs need to have alternatives from which to choose. Not all parties that may benefit from exchanging electronically will have a need to exchange with everyone that has a Direct address, and their local priorities may not justify the added cost of being able to do so. Situations such as this, where an organization would otherwise exchange with another but doesn't have the choice to do so is something that should be corrected intentionally else non-standard circumventions will be implemented by those that need to be able to exchange and the trust in the entire system will be jeopardized.

**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?**

In an environment similar to the one proposed by our response, monitoring of the information exchange market is a critical trust enabler and has the potential to create a community of practice that ratchets up the nation's 'Governance Maturity Level'. This kind of monitoring would prove a critical channel to inform the ONC's Roadmap process of needed course corrections and the ability to recognize previously unknown opportunities to accelerate.

As healthcare itself is a broadly dispersed and highly context sensitive service, the monitoring of the continued evolution of health information exchange will also need to be based on broadly dispersed sources, and must reward those who contribute information about successes (and failures!), changes, new risks and abuses.