

Governance Functions: Gap and Needs Assessment

HIT Policy Committee: Governance Workgroup

Nationwide Health Information Network* (NW-HIN)

Governance Gap and Needs Assessment

10/4/10

Introduction

The Subgroup undertook a gap analysis to identify existing governance mechanisms and bodies and identify potential gaps or unmet needs in nationwide health information network (“NW-HIN”) governance. For more details on the gap analysis, see Attachment #1.

The purpose of this document is to validate and prioritize the functions that should be addressed in NW-HIN governance based upon the gap analysis and governance hearing. The information covered in this document was reviewed with a small group of Workgroup representatives on 10/1/10.

For each of the five categories:

- Determine whether “NW-HIN” governance should address the identified gaps;
- Discuss the issues and considerations; and
- Provide preliminary recommendation on whether formal governance or coordination is needed. At this time, the Workgroup will not discuss specific governance execution. Recommendations for how governance should be implemented and by whom will be developed after the needs are confirmed.

Overarching questions:

1. Should there be a governance function for the NW-HIN that:
 - a. Defines policies and practices for trust and interoperability
 - b. Defines technical requirements
 - c. Addresses conformance with the requirements and policies for trust and interoperability
 - d. Defines how organizations would be accountable for compliance or accountable for validating compliance
 - e. Defines how enforcement would be addressed

* The name Nationwide Health Information Network will be changed.

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1. Category: Ensure privacy and policies for privacy and security		
Governance Objective: To assure that sufficient privacy protections and safeguards are in place to assure trust in the NW-HIN		
Proposed NW-HIN Governance Function There should be authoritative governance and/or coordination mechanism(s) to define privacy and security policies and practices for the NW-HIN that, at a minimum, are based upon the HHS Privacy and Security Framework and are reflected in technical design.		Rationale: The variance in state laws and insufficient level of specificity in national privacy and security laws creates burden and potentially impedes exchange of health information on a nationwide basis.
<i>Key Issues</i>	<i>Considerations / Options</i>	<i>Recommendation</i>
1.1 Coordination versus governance	Should there be coordination only or governance mechanisms? i. Convene stakeholders and facilitate consensus to adopt national-level policies for trust ii. Establish governance mechanism to define national-level policies for NW-HIN	
1.2 Different approaches for privacy and security	Should there be different types of mechanisms for privacy and for security? i. Establish the same approach for defining privacy policies and security policies ii. Focus on security only (as suggested by testimony) iii. Utilize different approaches for each (coordination for one; governance of the other) iv. Establish a coordinating mechanism only	
1.3 Role of states	Recognizing layers of governance fitting within a national framework, how should federal and state roles be addressed in defining policies? i. Defer to state authorities. ii. Federal-level coordination across states to facilitate a common set of privacy and security policies for the NW-HIN.	
1.4 Defining depth of policy compliance	Are there policies that should apply through the chain of trust (i.e. between <i>and</i> within the nodes)?	
1.5 Liability	Should the issue of liability be further studied to assess potential relevance for governance mechanisms?	

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2. Category: Establish other policies, practices or expectations for the NW-HIN		
Governance Objective: To assure that any other policies and practices necessary for trust and interoperability, beyond the privacy and security policies and practices addressed above, are defined to enable adoption of the NW-HIN (e.g. liability, coordinated breach notification, dispute resolution, other obligations, representations and warranties.)		
Proposed NW-HIN Governance Function There should be authoritative governance and/or coordination mechanism(s) to define other types of policies and practices for the NW-HIN, above and beyond privacy and security, that are necessary to assure interoperability, trust and to address barriers to adoption of the NW-HIN.		Rationale: These issues are largely addressed through contractual arrangements. The diversity, complexity and sheer number of contracts is a potential barrier to exchange. In addition, there may be other issues that are not addressed in contracts that may be necessary to promote use of exchange.
<i>Key Issues</i>	<i>Considerations / Options</i>	<i>Recommendation</i>
2.1 Other methods	Should methods other than contracts be considered to address the need for these other types of policies, practices or expectations?	
2.2 Coordinated enforcement	Should there be a coordinated enforcement strategy that addresses these types of issues?	
2.3 Common elements / Guidance	Should there be any common elements in these frameworks, guidance or templates?	
2.4 National Framework	Is there a role for governance at a national level to eliminate those barriers in a clear, consistent framework?	

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3. Category: Establish Technical Requirements for the NW-HIN		
<p>Governance Objective: To assure a minimum level conformance to NW-HIN technical requirements to accomplish interoperability and policy objectives for trust, including a defined security level of assurance for the NW-HIN.</p>		
<p>Proposed NW-HIN Governance Functions</p> <p>There is a need for a governance mechanism that defines NW-HIN technical requirements and related implementation guidance to support policy and assure technical interoperability.</p> <p>Technical requirements could cover data content, data transmission, security functionality (e.g. authentication, identification, access / audit / integrity controls), including specifying levels of conformance to promote interoperability.</p>		<p>Rationale:</p> <p>A designated set of technical requirements is essential for interoperability and to enable exchange of health information in a highly fragmented industry.</p>
<i>Key Issues</i>	<i>Considerations / Options</i>	<i>Recommendation</i>
3.1 Coordinating Policy – Technical Governance	How to assure that policy and technology governance mechanisms are cohesive.	
3.2 National-Level Implementation Planning	<p>Is there a need for coordinated national-level implementation planning to assure ongoing interoperability as requirements change?</p> <ul style="list-style-type: none"> i. Address through coordination mechanisms; or ii. Address through guidance only 	
3.3 Shared NW-HIN Resources	Should there be a mechanism to deem certain technical resources (e.g. certificate authority, registries, provider directories, etc.) for use in the NW-HIN?	
3.4 Focus on core elements	Consider governance of core elements to avoid fragmentation, but allow for innovation in other areas.	

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4. Category: Compliance, Accountability and Enforcement		
<p>Governance Objective: To assure there are designated, authoritative and trusted mechanism(s) to validate that conditions for trust and interoperability to enable nationwide exchange are met, assure accountability and enforce appropriately.</p>		
<p>Proposed NW-HIN Governance Functions</p> <p>There is a need for governance mechanisms to assure compliance, accountability and enforcement, including validation that conditions for trust and interoperability are met, measures in place to assure clear accountability and appropriate enforcement.</p>		<p>Rationale:</p> <p>Validating compliance provides assurances that conditions for interoperability and trust are met. Measures to assure ongoing compliance and that parties are appropriately accountable reinforce trust in the NW-HIN.</p>
<i>Key Issues</i>	<i>Considerations / Options</i>	<i>Recommendation</i>
4.1 Scope	How far down in an organization does governance reach?	
4.2 Accountability of validation bodies	Should NW-HIN governance put forward expectations for governance of a certification / accreditation body (e.g. adherence to a set of governance principles, etc.)?	
4.3 NW-HIN Brand	Should there be designated mechanism(s) to authorize use of NW-HIN brand	
4.4 Accountability mechanisms – operations and management	Should there be accountability measures for operations and management of shared technical resources or services for the NW-HIN?	
4.5 Ongoing Compliance	Should there be a mechanism to verify ongoing compliance, or repercussions of non-compliance?	
4.6 Coordinated enforcement	Should there be coordinated enforcement of policies regarding compliance with NW-HIN policies and technical requirements for trust (e.g. across existing authorities – states, FTC, OCR, etc.)?	
4.7 – Coordinated breach notification	Should there be a coordinated process to notify other participants exchanging health information of a suspected or known breach related to that entity's participation in the NW-HIN?	
4.8 Complaints	Should there be a mechanism to address complaints?	
4.9 Alternative dispute resolution	Should there be mechanisms to address disputes to encourage resolution of issues outside of litigation (e.g. appeals process if entity is denied use of NW-HIN brand)?	
4.10 – Redress, remedies, sanctions	Should there be additional mechanisms for redress, remedies and sanctions beyond existing law or contractual agreements?	

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5. Category: Oversight of NW-HIN governance mechanisms		
Governance Objective: To determine how governance processes are performing and adjusting to new circumstances.		
Proposed NW-HIN Governance Functions Oversight of the NW-HIN governance mechanisms is necessary to assure effective governance.		Rationale: Oversight is necessary to assure governance objectives are met and to assure governance mechanisms are effective and able to adapt over time.
<i>Key Issues</i>	<i>Considerations / Options</i>	<i>Recommendation</i>
5.1 Monitoring	Should there be reporting or monitoring of NW-HIN governance mechanisms? If so, how deep should the monitoring go (e.g. monitoring of governance mechanisms, participant behavior, etc.)?	
5.2 Reporting	Should governance mechanisms include reporting to track issues, complaints, disputes or breaches relative to the NW-HIN?	
5.3 Ongoing compliance	Should there be oversight of ongoing compliance efforts? If so, should there be: <ul style="list-style-type: none"> • Voluntary reporting • Routine revalidation • Auditing for compliance • Etc. 	
5.4 Coordinated oversight	Should there be coordinated oversight across the various existing governance authorities (e.g. OCR, FTC, etc.).	