

Governance Workgroup: DRAFT Preliminary Recommendations

HIT Policy Committee: Governance Workgroup

Nationwide Health Information Network¹ (NW-HIN)

Preliminary Recommendations on the Scope of Governance

10/8/10 – Draft v5

Introduction

The Governance Workgroup 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 reflects discussions by the Workgroup on October 4, 2010.

What is NW-HIN governance and why is it necessary?

Governance is the mechanism that assures that the necessary policies, standards and services that enable the use of the Internet for secure and meaningful exchange of health information to improve health and health care are adequately and appropriately established, coordinated, overseen and enforced. The governance functions, taken together, must improve health while ensuring public trust, and enable interoperability while stimulating innovation.

In April 2010, the Health Information Technology Policy Committee approved recommendations to adopt an overarching national health information exchange trust framework. This framework identified five essential elements for trust in nationwide health information exchange, including:

1. Agreed Upon Business, Policy and Legal Requirements / Expectations
2. Transparent Oversight
3. Enforcement and Accountability
4. Identity Assurance
5. Minimum Technical Requirements

This framework established that all five elements are needed to support trust and interoperability at a national-level.

Today, a patchwork of these elements exists to varying degrees and is developed and overseen by many different public and private bodies. This creates overlap in some areas and gaps in others. For trust and interoperability at national scale, the roles of these bodies must be clearly specified and coordinated through a framework of governance that adheres to sound principles. Only with a sound governance framework in place can the NW-HIN serve its intended purpose and facilitate nationwide exchange of health information to improve health and healthcare.

¹ The “nationwide health information network” is in the process of being renamed.

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What are sound governance principles?

1. Transparency and openness

- Open and transparent processes are essential to building trust. The degree, type, and mechanisms for openness may vary depending on the function and stakeholder needs. To the extent possible, the process of developing governance mechanisms for the NW-HIN should be open and transparent. This should include transparency about the NW-HIN standards, services and policies themselves, what information sharing they support, and the oversight, enforcement, and accountability mechanisms that are part of the NW-HIN.

2. Inclusive Participation and Adequate Representation

- Inclusion preferred: There should be an explicit preference for processes that favor inclusion of the diverse set of stakeholders over exclusion.
- Representative governance: The governance mechanisms should permit and encourage robust participation by the diverse set of stakeholders, including consumers, whose interests are affected by the decisional processes.

3. Effectiveness and Efficiency

- Form should follow function: Choices among the many possible forms of governance mechanisms should reflect the functions over which authority will be exercised and the needs of the relevant stakeholders.
- Efficiency and effectiveness: All functions, including governance, should be conducted with the goal of maximizing their efficiency and effectiveness.
- Responsive: It is important that NW-HIN governance be understood as existing for the benefit of diverse stakeholders and as responsive to the needs and concerns of both governmental and non-governmental stakeholders. This responsiveness includes giving timely attention to addressing issues and remaining flexible enough to accommodate issues as they emerge.
- Minimization: Governance mechanisms should operate so that authority is exercised only over those issues whose resolution is necessary for the successful implementation and operation of the NW-HIN and the accomplishment of its goals. To the extent the governance mechanisms can build upon existing processes and procedures they should do so.

4. Accountability

- Participating stakeholders should be held accountable and should be able to hold their governance mechanisms accountable. Because of the important role to be played by the NW-HIN in the nation's health agenda, those involved in exchange using NW-HIN, as

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well as the NW-HIN governance mechanisms, must also be understood as having some responsibility to the nation at large.

5. Distributed governance and devolution

- Distributed Governance: Governance should not be centralized, but distributed among entities based upon their requisite expertise, capabilities, and standing
- Devolution: Decisions about an issue and should generally be made by those closest to the issue and with the greatest stake in its successful resolution.
- Retention or delegation of authority: The Federal government should retain functions that are inherently governmental. Federal governmental involvement is essential in certain areas to maintain public trust and to assure that the NW-HIN meets the stated goals of the national HIT agenda. Given its Congressional mandate the ONC should retain the right to exercise its authority over governance of the NW-HIN in the future to assure that the goals of the NW-HIN are met and critical public interests are protected. The retention of that right should not be equated with the intention to exercise this authority given the preference for minimization or if other user driven approaches can accomplish the same purposes.

6. Clarity of mission and consistency of actions

- Rights, responsibilities, and obligations must be well documented and clear to all stakeholders. Consistency in decision making is helpful for planning by stakeholders but should not be an obstacle to improvement if change is necessary.

7. Fairness and Due Process

- Fairness: Governance must operate in a way that is perceived to be fair to those who participate in governance processes and those affected by governance decisions.
- Due Process: The procedural mechanisms of due process should be reflected in governance mechanisms to ensure their fairness and responsiveness.

8. Promote and Support Innovation

- Innovation: Innovation is critical for the success of the NW-HIN and the improvement of health and healthcare in the U.S. The exercise of governance should be consistent with creating the conditions for innovation to flourish.
- Minimization: In order not to stifle innovation and with an awareness of the potential for unintended consequences, governance mechanisms should operate so that authority is exercised only over those issues whose resolution is necessary for the successful implementation and operation of the NW-HIN and the accomplishment of its goals.
- Prescriptive Rules: Governance mechanisms should allow autonomy and encourage innovation by focusing on those issues that require uniform treatment. The degree of

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specificity of rules and the consequences for non-compliance should be directly related to the criticality of the issue. Administrative burdens should be reduced to the absolute minimum and voluntary agreements should, in principle, be preferred.

- Standardization: The degree of uniformity in policies and standards should reflect the requirements of the particular issue. In some instances, such as in enabling electronic health information exchange across institutional and jurisdictional boundaries, standardization is necessary to enable innovation; in other instances premature standardization may inhibit innovation. Technical standards should not inadvertently set policy, but should support and be in service to policy goals.

9. Evaluation, Learning and Continuous Improvement

- Metrics: As with other functions, governance can benefit from the establishment of appropriate metrics.
- Governance as a learning system: There should be ongoing evaluation regarding the performance, effectiveness and efficiency of the governance mechanisms. Governance mechanisms should include processes to continuously adapt and improve to meet the evolving needs of the NW-HIN including changes in uses and technologies.
- Ensuring Safety: Given the critical nature of health care and the sensitivity of health care information, governance mechanisms should pay particular attention to issues implicating safety. There should also be a governance locus for review of systemic risk in the NW-HIN.

Preliminary Recommendations: Scope of NW-HIN Governance

A gap analysis was conducted to identify existing policies, governance bodies and mechanisms for the four core functions outlined in Table 1. This exercise was intended to help identify and prioritize the focus areas for NW-HIN governance. This analysis, while not exhaustive, did uncover myriad existing governance elements that could have impact on or be leveraged by NW-HIN governance. Not surprisingly, this helped illustrate the need for coordination or “governance of governances” and served as a tool to identify what needed to be addressed in this process. For details, see Attachment 1 – Governance Gap and Needs Assessment.

Initial High Level Findings

- Governance in health information technology is widely distributed, comprising both public and private entities at the national, state, and regional/community level.
- Policy development and the formulation of trust frameworks seem to be taking place in different Federal agencies (including the use of advisory committees), legislative bodies,

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states, existing data exchanges and some non-governmental organizations. Enforcement regimes and accountability mechanisms are also distributed.

- In the Federal HIT space, various agencies' jurisdiction, including those organizations associated with HHS, seems to overlap in some areas, potentially creating confusion and reducing effectiveness.
- ONC has the Congressional mandate to coordinate the numerous efforts of policy making and standards setting for health information technology, and has become a critical intermediary.
- Participation of the private sector in policy making seems to be taking place through consultations and through Federal Advisory Committee and Congressional hearings. It is unclear whether there are other sufficient institutionalized ways to get public engagement, especially by consumers, on a broader scale. While private entities are often represented in health information organizations, consumers are infrequently engaged in a meaningful way.

Recommendation: National Governance Framework for NW-HIN

- Based upon these findings, the Governance Workgroup would like to present a set of preliminary recommendation to ONC to establish a national framework for governance of the NW-HIN.
- This framework should include:
 - A set of core governance functions addressed in this paper.
 - National-level coordination and oversight across those functions.
 - Assure there is an opportunity for broad stakeholder input, including consumers, on the strategic direction for the NW-HIN.

General Considerations

As the Governance Workgroup began to consider the scope of a national governance framework for the NW-HIN, several overarching issues came to light:

- What type of clear, consistent framework should be established?
- Where are goals for the NW-HIN identified? How will the NW-HIN be evaluated to assess whether the goals were accomplished? How will success be measured? How will the strategy be adapted over time to meet changing needs for HIE?
- How should conditions for exchange be defined? How should questions regarding core / variable requirements be addressed?
- How should gaps and inconsistencies in policies and procedures be addressed?
- How should national-level planning and coordination of implementation efforts be facilitated to assure ongoing interoperability as requirements change?
- How can policy setting and technical requirements functions be aligned?

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- How to address coordinated oversight across multiple entities?
- How to address the role of contracts, funding and procurement as enforcement tools for governance, and provide resources, guidance or coordination to lessen the burden of a large number of diverse agreements?
- How to provide for governance at multiple levels, accounting for decision-making that occurs at varying points, while still providing a cohesive governance framework?
- How does the alignment of liability impact governance of the NW-HIN? For instance:
 - Where liability is traceable in the exchange of health information?
 - What is the impact on innovation?
 - What protections are provided to parties to the exchange
 - What entities have the incentive and ability to correct failures?

Aligning Governance Functions with Governance Objectives

To help address these and other questions, the Workgroup grounded its deliberations to foundational objectives for governance. Governance should help reduce the barriers to nationwide exchange and aim to:

1. Improve Health While Establishing Trust
2. Assure Interoperability While Protecting Innovation

The Workgroup identified a set of governance functions potentially needed for the NW-HIN and evaluated how each function helped accomplish one or both of these overarching objectives. The four functions identified in Table 1 were then used as the basis for an environmental scan.

The environmental scan considered where mechanisms already exist, as well as, potential gaps and needs for NW-HIN governance. For details on the functions more closely considered in the gap analysis, see Attachment 1 – Detailed Governance Gap Analysis.

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Table 1. Identifying Functions Needed to Accomplish Governance Objectives

| Governance Elements | NW-HIN Governance Objectives | |
|--|--|--|
| | Improving Health While Establishing Trust | Assuring Interoperability While Protecting Innovation |
| Development of policy and technical requirements | <p>1. Establish policies for privacy, security, interoperability and to promote adoption of the NW-HIN.</p> <p>Objective of this function: To assure that sufficient privacy protections and safeguards are in place to facilitate and promote nationwide exchange while promoting necessary interoperability</p> | <p>2. Establish technical requirements to assure policy and technical interoperability.</p> <p>Objective of this function: To assure that technical requirements are established to accomplish interoperability and policy objectives for trust, including a defined security level of assurance.</p> |
| Establishing appropriate mechanisms to assure compliance, accountability and enforcement | <p>3. Compliance and Accountability Measures:</p> <ul style="list-style-type: none"> • Validation that minimum set of expectations are adhered to. • Measures in place to assure clear accountability • Management and operational practices in place to assure governance objectives met <p>Enforcement Mechanisms: (For Trust and Interoperability)</p> <ul style="list-style-type: none"> • Procurement and contractual agreements • Open rulemaking processes <p>Enforcement Mechanisms: (For Trust Only)</p> <ul style="list-style-type: none"> • Consumer protection provisions • Complaint process • Dispute resolution • Redress, remedies and sanctions (for trust) • Risk detection, avoidance and mitigation • Judicial oversight (for trust) <p>Objective of this function: To assure there are designated, authoritative and trusted mechanism(s) to validate conditions for trust and interoperability are met, to assure accountability and provide appropriate enforcement.</p> | |
| Oversight of the governance mechanisms | <p>4. Develop strategy, monitor effectiveness, ongoing improvement</p> <ul style="list-style-type: none"> • Developing strategy for NW-HIN, including governance • Monitoring and reporting • Ongoing compliance • Overseeing systemic risk • Evaluation, learning, and improvement <p>Objective of the Function: To determine how governance processes are performing and adjusting to new circumstances and provide for continuing improvement.</p> | |

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Recommended NW-HIN Governance Functions

1. Establish policies for privacy, security, interoperability and to promote adoption of the NW-HIN

Description: There is a need for a governance mechanism that defines policies and practices for the NW-HIN to assure trust and interoperability and also address barriers to nationwide exchange of health information. NW-HIN policies and practices should be followed as a condition of exchanging health information through the NW-HIN and should be 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. Similarly, varying application of standards and different expectations regarding exchange of health information can also limit exchange.

Governance decisions addressed by this function:

- 1.1 Define or adopt a core set of policies and practices for the NW-HIN that, at a minimum, cover the following and that are reflected in technical design:
 - Privacy – based upon, at a minimum, the HHS Privacy and Security Framework
 - Security (i.e. confidentiality, integrity and availability of data in addition safeguards to assure privacy of the information exchanged)
 - Interoperability
 - Compliance expectations (e.g. to whom would these rules apply, under what circumstances, etc.)
- 1.2 Identify when there may need to be variability in policies and practices based upon certain factors (e.g. type of information exchanged, exposure to Protected Health Information, services provided, etc.)
- 1.3 Determine to what extent there should be compliance within nodes to accomplish common objective for trust and interoperability in exchange.
- 1.4 Address gaps in policies and practices to assure there is a uniform set of performance standards by which entities exchanging health information through the NW-HIN abide.
- 1.5 Coordinate between policy and technical requirements setting bodies to address issues with both policy and technical implications before decisions are made to assure cohesiveness and consistency in policies and technical requirements.
- 1.6 For purposes of devolution, consider how to establish a uniform set of performance standards for policies given the multiple layers of governance that currently exist.

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2. Establish Technical Requirements for the NW-HIN

Description:

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.

Rationale: A designated set of technical requirements is essential for interoperability and to enable exchange of health information in a highly fragmented industry.

Governance decisions addressed by this function:

- 2.1 Identify technical requirements for the NW-HIN, providing for stakeholder input, including consumers. The types of technical requirements should at a minimum include:
 - Data content
 - Data transmission
 - Security functionality (e.g. authentication, identification, access / audit / integrity controls)
 - Specifying levels of conformance to promote interoperability
- 2.2 Coordinate with policy setting function
- 2.3 Consider national-level implementation planning to assess impact as technical requirements change, based upon input from stakeholders, including current and potential implementers, to assess impact, timeframes and migration methods as technical requirements change.
- 2.4 Mechanism to evaluate and authorize or recognize certain technical resources (e.g. provider directories, certificate authority, registries, etc.) for use in the NW-HIN.

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3. Compliance, Accountability and Enforcement

Description: There should be governance mechanisms to assure compliance, including validation that conditions for trust and interoperability are met, as well as clear accountability and appropriate enforcement.

Rationale: Validating compliance provides some assurance of trust in the NW-HIN that the requirements for trust and interoperability do indeed exist.

Governance decisions addressed by this function:

- 3.1 Establish validation criteria that would be used to verify compliance.
- 3.2 Verify compliance with NW-HIN policies, practices and technical requirements as a condition of using the NW-HIN brand and determine when to assess ongoing compliance.
- 3.3 Define level of verification needed to assure that expectations are met. For example, this could include methods such as: affirmation / self attestation, affirmation and enforcement through contracts, self-testing, verification by an independent third party through testing / documentation review, verification by an independent third party that mechanisms in place and followed, etc.
- 3.4 Determine when validation should be distributed to organizations that oversee the data exchange activities and when validation needs to occur through some other mechanism.
- 3.5 If there is a need for validation by a third party, define criteria for accrediting authorized validation bodies for the NW-HIN (e.g. adherence to a set of governance principles, etc.)
- 3.6 Determine whether more than one entity could be authorized to validate for the NW-HIN.
- 3.7 Determine consequences of non-compliance with policies, practices and technical requirements.
- 3.8 Determine accountability measures or criteria to assure that appropriate management and operational practices are in place to assure governance objectives are met.
- 3.9 Determine accountability measures for shared NW-HIN technical resources (e.g. provider directories supported by non-federal entities).
- 3.10 Provide mechanisms to address issues, concerns or complaints, above and beyond those measures provided for under existing law (e.g. HIPAA, FTC, etc.), including the types of matters that would be addressed through this process.
- 3.11 Determine need for coordinated investigation and enforcement and circumstances where this would apply (e.g. if an NW-HIN related breach should be reported to another governing authority, such as the FTC, OCR, etc.).

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- 3.12 Consider when coordinated breach notification may be necessary (e.g. when parties to exchange notify other exchange entities of a suspected or known breach related to exchange through the NW-HIN).
- 3.13 Provide a mechanism to address disputes in a manner that encourages resolution of issues outside of litigation (e.g. appeals process if entity is denied use of NW-HIN brand). While governmental entities cannot agree to a binding resolution, they may be able to engage in a mandatory dispute resolution process.
- 3.14 Evaluate the need for mechanisms for redress, remedies and sanctions, and the circumstances where this would apply, if above and beyond existing law or contractual agreements.

4. Oversight of NW-HIN governance mechanisms

Description

Oversight is intended to have the meaning put forth by the NHIN Workgroup in their April 2010 recommendations, “management, maintenance, supervision, and monitoring of the trust relationship and exchange activities.” Oversight will operate at multiple levels (e.g. parties to the exchange, individual subject of the information, third parties, government, etc.)

Rationale:

Oversight is necessary to assure governance objectives are met and to assure governance mechanisms are effective and able to adapt over time.

Governance decisions addressed by this function:

- 4.1 There should be some mechanism to track or measure certain issues or activities in support of overseeing the effectiveness and efficiency of NW-HIN governance. For example, this function would determine the methods for identifying, tracking and overseeing a set of defined issues, as well as the types of issues tracked. Measures could be prospective (e.g. preventing issues) and/or retrospective (e.g. tracking issues, complaints, disputes, breaches, etc.).
- 4.2 There should be oversight be for ongoing compliance. This function could be addressed through various means. For example, this could include coordinating with validation bodies, voluntary reporting, routine revalidation, auditing for compliance, etc.)
- 4.3 There should be a mechanism for ongoing assessment of risks and benefits for the NW-HIN governance, including prevention of harm.
- 4.4 There should be mechanisms to evaluate the performance of the overall governance mechanisms and incorporate the findings into continuous improvement.