

Governance Workgroup: Preliminary Recommendations

HIT Policy Committee: Governance Workgroup

Nationwide Health Information Network¹ (NW-HIN)

Preliminary Report and Recommendations on the Scope of Governance

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Introduction and Purpose

This report conveys a preliminary set of findings and recommendations of the Governance Workgroup (“Workgroup”) of the Health IT Policy Committee (HITPC) in response to a request from the Office of the National Coordinator for Health Information Technology (ONC) for advice in fulfilling Congress’s mandate in the Health Information Technology for Economic and Clinical Health (HITECH) Act that the ONC establish a governance mechanism for the nationwide health information network² (“NW-HIN”). This preliminary report addresses the principles, scope and functions of governance. The final report, which will be presented to the HITPC November 19, will make recommendations as to how the various governance functions should be implemented, and by whom.

Definition of the Nationwide Health Information Network

The nationwide health information network, a phrase used in HITECH Act, is currently defined as a set of standards, services and policies that enables and promotes the secure electronic exchange of health information over the Internet and across institutional and geographic barriers to improve health and health care.

Together, these standards, services and policies will support a broad collection of activities to enable a wide variety of users to exchange health information for different purposes. For example:

- Healthcare providers sharing information to support patient care.
- Individuals seeking access to their health records from their caregivers.
- Healthcare providers sending information to the Social Security Administration to support a patient’s disability claims.
- Healthcare providers reporting quality measures to improve quality assessments.
- Healthcare providers and others reporting immunization, notifiable diseases and biosurveillance reporting to public health departments to improve overall population health.

The Workgroup worked with the following set of assumptions regarding the NW-HIN:

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

² Health Information Technology for Economic and Clinical Health (HITECH) Act, as part of the American Recovery and Reinvestment Act, February 17, 2009. Pub. L. 111-5, 123 Stat.228 Section [3001 (c) (8)]

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- It is *not* a large database that houses patient records, nor is it a single physical network that runs on servers at the Department of Health and Human Services.
- It is put forward as potentially a preferred option for nationwide exchange of health information. Entities that wish to exchange through the NW-HIN would need to demonstrate compliance with a set of requirements as a precondition to using the NW-HIN.
- Potential levers to promote the exchange of health information through the NW-HIN include
 - Entities that wish to be recognized and use a “brand” (to be determined)
 - Entities that wish to receive federal funds
 - Entities that wish to receive federal health information

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 agreed upon business, policy and legal requirements, transparent oversight, enforcement and accountability, identity assurance and 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 on a nationwide basis, 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.

Aligning Governance Functions with Governance Objectives

The Workgroup based its deliberations on the 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 governance³.

³ For details regarding the gap analysis, see the document posted for the 10/12 Governance Workgroup call.

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Preliminary Recommendations: **Sound Governance Principles**

The Workgroup recommends that governance be based on core 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 and the resulting governance structures for the NW-HIN should be open and transparent. This should include transparency about the NW-HIN standards, services and policies themselves, including privacy protections, what information sharing they support, and the oversight, enforcement, and accountability mechanisms that are part of the NW-HIN. Openness and transparency support engagement from multiple constituencies including the general public and those who participate in information exchange, both public⁴ and private.

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. Recognizing that governance mechanisms must be scalable to accommodate large numbers of organizations who are likely to be involved in exchanging data, the use of models that consist of representatives of stakeholders will be encouraged.

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.
- Responsiveness: 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

⁴ Federal agencies today may only participate in groups that meet organizational characteristics for openness and transparency as identified in OMB Circular A119.

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

5. Federated governance and devolution

- Federated Governance: Governance should not necessarily be centralized. The multiple governance functions may be distributed across and among multiple entities (public and private). Such distribution requires careful attention to the issues of coordination at a national-level.
- Devolution: Decisions about an issue should generally be made by those closest to the issue and with the greatest stake in its successful resolution, in accordance with the goals of the NW-HIN.
- Retention or delegation of authority: The Federal government should perform functions that require centralized governmental control. 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 innovation or improvement if change is necessary.

7. Fairness and due process

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

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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 and reflect an awareness of the potential for unintended consequences.
- Prescriptive Rules: Governance mechanisms should recognize the value of autonomy and encourage innovation by focusing on those issues that require uniform treatment. The degree of 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: Governance should be evaluated based upon appropriate performance and effectiveness measures. For example, this could include quantifiable measures, such as transaction volumes exchanged through the NW-HIN. It could also include metrics regarding utilization of particular governance functions, and other measures that assess the effectiveness and performance of governance functions.
- 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 a variety of existing governance elements that could affect 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.

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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 via the use of advisory committees), legislative bodies, states, existing data exchanges and non-governmental organizations. Enforcement regimes and accountability mechanisms are also distributed but are sometimes lacking.
- In the Federal HIT space, various agencies' jurisdiction, including those organizations associated with HHS, may appear to overlap, 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, Congressional hearings and communications efforts. 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.
 - Opportunities for broad stakeholder input, including consumers, on the strategic direction for the NW-HIN.

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Table 1. Governance Functions, Objectives and Activities

Governance Function	Description	Rationale	Governance Objective	Activities
<p>1. Establish policies for privacy, security, interoperability and to promote adoption of the NW-HIN.</p>	<p>Define 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.</p>	<p>Variance in state laws and insufficient level of specificity in national privacy and security laws creates burden and potentially impedes exchange. Varying application of standards and different expectations regarding exchange of health information can also limit exchange.</p>	<p>To assure that sufficient privacy protections and safeguards are in place to facilitate and promote nationwide exchange while promoting necessary interoperability.</p>	<ul style="list-style-type: none"> • Define or adopt a core set of policies and practices for the NW-HIN that, at a minimum cover: privacy, security, interoperability, eligibility criteria, compliance expectations and jurisdiction and that are reflected in technical design. • Address gaps in policies and practices to assure there is a uniform set of standards followed by entities exchanging health information through the NW-HIN. • Coordinate to assure policies and technical requirements are consistent.
<p>2. Establish technical requirements to assure policy and technical interoperability.</p>	<p>Define NW-HIN technical requirements and related implementation guidance to support policy and assure technical interoperability.</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>	<p>To assure that technical requirements are established to accomplish interoperability and policy objectives for trust, including a defined security level of assurance.</p>	<ul style="list-style-type: none"> • Adopt technical requirements for the NW-HIN through a recognized process that coordinates and harmonizes standards and that provides for stakeholder input, including consumers. • Establish transition processes as technical requirements change. • Authorize technical resources for use in NW-HIN (e.g. provider directories, certificate authority, registries.)

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Governance Function	Description	Rationale	Governance Objective	Activities
3. Establishing appropriate mechanisms to assure compliance, accountability and enforcement	Assure that eligibility criteria are satisfied and that compliance with conditions for trust and interoperability are met, as well as clear accountability and appropriate enforcement.	Validating compliance provides some assurance that those exchanging under the auspices of the NW-HIN have met the requirements for trust and interoperability.	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.	<ul style="list-style-type: none"> • Establish and conduct validation to determine eligibility and verify compliance with policy and technical requirements as a condition of exchanging information through the NW-HIN. • Determine consequences of non-compliance with policies, practices and technical requirements. • Provide a mechanism to address disputes, concerns or complaints, taking into account measures provided for under existing law. • Determine how mechanisms for redress, remedies and sanctions would be applied. • Consider need for coordinated investigation, enforcement and breach notification.
4. Oversight of the governance mechanisms	Oversight is intended to mean, “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.).	Oversight is necessary to assure governance objectives are met and to assure governance mechanisms are effective and able to adapt over time.	To determine how governance processes are performing and adjusting to new circumstances and provide for continuing improvement.	<ul style="list-style-type: none"> • Track or measure certain issues or activities in support of overseeing the effectiveness and efficiency of NW-HIN governance • Oversee ongoing compliance. • Conduct ongoing assessments of risks and benefits for the NW-HIN governance, including prevention of harm. • Periodically evaluate the performance of the overall governance mechanisms and incorporate the findings into continuous improvement • Resolve disputes regarding decision rights among federated governance functions.