

HIT Policy Committee: Governance Workgroup

Governance Analysis

10/6/10

Introduction

The Governance Workgroup has been asked to provide recommendations on the scope and focus of governance for the nationwide health information network (“NW-HIN”).

In order to help focus Workgroup deliberations, a small group convened to assess the current landscape of governance mechanisms and identify possible governance needs for the NW-HIN. The group undertook this analysis to help focus Workgroup deliberations on the proposed structure, process and scope of governance, as well as the functions and tasks that need to be governed.

Fundamental Governance Elements, Functions and Objectives

The following table illustrates the key governance functions used as the basis for the gap analysis. Governance functions were considered based upon to two primary objectives:

- 1) improving health while establishing trust; and
- 2) assuring interoperability while protecting innovation.

The gap analysis uses this framework to identify existing governance mechanisms and identify potential gaps or needs for NW-HIN governance. The list of existing policies and entities relevant for governance is not exhaustive, but seeks to illustrates key activities.

Governance Elements	Governance Functions	
	Objective 1: Improving Health While Establishing Trust	Objective 2: Assuring Interoperability While Protecting Innovation
Development of policy and technical requirements	1. Privacy and security policies and practices, based upon the HHS Privacy and Security Framework and reflected in technical design	2. Technical requirements to ensure policy and technical interoperability
Establishing appropriate mechanisms to ensure 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:</p> <ul style="list-style-type: none"> • Consumer protection provisions • Procurement and contractual agreements • Open rulemaking processes 	<p>4. Compliance and Accountability Measures:</p> <ul style="list-style-type: none"> • Validation of conformance to the extent necessary for interoperability • Measures in place to assure clear accountability <p>Enforcement Mechanisms:</p> <ul style="list-style-type: none"> • Procurement and contractual agreements • Open rulemaking processes
Oversight of the necessary compliance, accountability and enforcement mechanisms	<p>5. Monitoring, reporting and verification (e.g. certification, accreditation, auditing) for trust and interoperability</p> <ul style="list-style-type: none"> • Complaint process • Dispute resolution • Redress, remedies and sanctions (for trust) • Judicial oversight (for trust) 	

Gap Analysis Governance Functions

Governance Objective and Function	Existing Policies	Existing Governance Bodies or Coordinating Mechanisms	Existing Oversight, Accountability and Enforcement Bodies	Potential Gaps for NW-HIN Governance
Policy Development: Improving Health While Establishing Trust				
<i>1. At a minimum, privacy and security policies and practices are based upon the HHS Privacy and Security Framework and reflected in technical design</i>				
<p>Function: Develop policies and practices for privacy and security</p> <p>Objective: To assure that sufficient privacy protections and safeguards are in place to assure trust in the NW-HIN</p>	<p>Existing law (e.g. HIPAA, Privacy Act, eCommerce privacy rules, state laws, etc.)</p> <p>FACA process (for policy / standards recommendations)</p> <p>ONC rules for certification to the extent addressed as it relates to HIE</p> <p>Agreements by those conducting information exchange</p>	<p>POLICY and RULE FORMATION</p> <p>Congress/State Legislature</p> <p>White House (OSTP/CIO)</p> <p>Governors</p> <p>DHHS – ONC (Rule Making)</p> <p>COORDINATION</p> <p>HITPC</p> <p>ONC</p> <p>eGov initiatives</p> <p>Other?</p>	<p>DHHS – Office of Civil Rights (Enforcement) – to the extent entities are subject to HIPAA</p> <p>NIST (Security Conformance)</p> <p>DOJ (Adjudication/Enforcement) / FTC</p> <p>State Attorneys General</p> <p>Corporate Privacy Officers</p>	<p>Lack of national-level coordination to assure a minimum set of expectations for trust and interoperability are established that enable nationwide HIE.</p> <p>Lack of accountable entity tasked with specific enforcement of additional NW-HIN requirements</p>

Governance Objective and Function	Existing Policies	Existing Governance Bodies or Coordinating Mechanisms	Existing Oversight, Accountability and Enforcement Bodies	Potential Gaps for NW-HIN Governance
<p>Function: Define Additional Policies, Practices and Expectations</p> <p>(For example: Liability, dispute resolution, representations and warranties, cooperation, notices, governing law for the parties to the exchange, disclaimers, etc.)</p> <p>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.</p>	<p>Often addressed through contractual agreements or existing law governing these activities</p>	<p>Mechanisms established through contractual agreements or other applicable law</p>	<p>State and federal regulatory bodies</p>	<p>Should there be a process or coordination to assure consistency in a minimum set of expectations to build confidence and greater adoption of HIE?</p>

Governance Objective and Function	Existing Policies	Existing Governance Bodies or Coordinating Mechanisms	Existing Oversight, Accountability and Enforcement Bodies	Potential Gaps for NW-HIN Governance
Policy Development: Ensuring Interoperability While Protecting Innovation				
<i>2. Technical requirements to ensure interoperability</i>				
<p>Define Technical Requirements (e.g. Data Transmission, Data Content Standards, etc.)</p> <p>Objective: To assure a minimum level conformance to NW-HIN technical requirements to accomplish interoperability objectives</p>	<p>ONC / FACA process to define meaningful use criteria</p> <p>Exchange Technical Committee and Coordinating Committee processes</p> <p>HIPAA Transaction and Code Set Rules</p>	<p>FACA process</p> <p>Meaningful use rules (to the extent technical requirements for NW-HIN included</p> <p>ONC – Standards and Interoperability Framework</p>	<p>CMS (for meaningful use and HPA compliance)</p> <p>ONC</p>	<p>Lack of a designated authoritative process or coordinating mechanism(s) that establishes interoperability policies for the NW-HIN</p> <p>Lack of a designated authoritative process to develop NW-HIN technical requirements.</p>

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<p>Define technical requirements for privacy and security (e.g. Authentication, Identification, Access Controls, Audit Controls, Integrity Controls)</p> <p>Objective: Governance should assure that sufficient safeguards are in place based upon a defined security level of assurance for the NW-HIN</p>	<p>Existing law (e.g. HIPAA, FISMA, eCommerce privacy rules, state laws, etc.)</p> <p>FACA process (for policy / standards recommendations)</p> <p>Federal Bridge (for CAs)</p> <p>ONC – Standards and Interoperability Framework</p> <p>ONC rules for certification to the extent that authentication is addressed</p> <p>Agreements by those conducting information exchange</p>	<p>POLICY and RULE FORMATION</p> <p>Congress/State Legislature</p> <p>White House (OSTP/CIO)</p> <p>Governors</p> <p>DHHS – ONC (Rule Making)</p> <p>COORDINATION</p> <p>Unclear HITSC?</p> <p>ONC?</p> <p>Other?</p>	<p>DHHS – CMS</p> <p>NIST (Security Conformance)</p> <p>DHHS – Office of Civil Rights (Enforcement)</p> <p>DOJ (Adjudication/Enforcement) / FTC</p> <p>State Attorneys General</p> <p>Corporate Privacy Officers</p>	<p>Lack of authoritative process or coordinating mechanism(s) to endorse specific requirements for authentication for NW-HIN that further specify a standard expectation for authentication</p> <p>Lack of accountable entity tasked with specific enforcement of these requirements</p>

Governance Objective and Function	Existing Policies	Existing Governance Bodies or Coordinating Mechanisms	Existing Oversight, Accountability and Enforcement Bodies	Potential Gaps for NW-HIN Governance
Establishing appropriate mechanisms to ensure compliance, accountability and enforcement: Improving Health While Establishing Trust				
<i>3. Compliance and Accountability Measures</i>				
<p>Validation that minimum set of expectations are met</p> <p>Objective: To assure there are designated, authoritative and trusted mechanism(s) to validate conditions for trust and interoperability to enable nationwide exchange are met, assure accountability and enforce appropriately</p>	<p>Certification process for meaningful use where criteria address policies for trust and interoperability for nationwide HIE</p> <p>Coordinated process to validate that parties to exchange meet certain requirements and, if successful, receive a certain status or digital credentials</p> <p>Contracts</p>	<p>Procurement and contractual agreement</p> <p>Open rulemaking processes</p> <p>Authorized certification bodies</p>	<p>ONC – Oversight of Certifiers</p> <p>Interim measures for Exchange: ONC / Coordinating Committee – support and oversee validation process</p> <p>NIST (Security Conformance)</p> <p>DOJ (Adjudication/Enforcement) / FTC</p> <p>State Attorneys General</p> <p>Corporate Privacy Officers</p> <p>Consumer protection provisions</p>	<p>Lack of designated authoritative mechanism(s) to validate that conditions for trust and interoperability are met for the NW-HIN</p> <p>Lack of designated authoritative mechanism(s) to provide NW-HIN status or digital credentials once satisfactorily completing validation</p>

Governance Objective and Function	Existing Policies	Existing Governance Bodies or Coordinating Mechanisms	Existing Oversight, Accountability and Enforcement Bodies	Potential Gaps for NW-HIN Governance
Management and Operational Support	<p>Certificate management</p> <p>Coordinated support and operation of service registry as a shared service</p> <p>Coordinated implementation efforts for multi-party exchange</p> <p>Organizational-level oversight by the entities exchanging information</p>	<p>ONC</p> <p>Self-governed networks and exchanges</p>	<p>Self governance</p> <p>Interim measures for Exchange:</p> <p>ONC oversees management and support of certificates, service registry, on boarding and validation.</p>	<p>Coordinated mechanism(s) needed to track NW-HIN status or issuance of “digital credentials”- particularly if level of interoperability and trust are assured at implementation-level.</p> <p>Need for recognized mechanism(s) to assure appropriate management and operation for the NW-HIN</p>
Maintain implementation-level guidance and any related operating policies, procedures and legal agreements	<p>Agreements by those conducting information exchange</p>	<p>Self-governance structures established by those exchange health information</p>	<p>Self governed</p>	<p>Lack of a process to develop and maintain additional tools essential for trust interoperability to supplement NW-HIN standards and policies.</p>

Governance Objective and Function	Existing Policies	Existing Governance Bodies or Coordinating Mechanisms	Existing Oversight, Accountability and Enforcement Bodies	Potential Gaps for NW-HIN Governance
4. Establishing appropriate mechanisms to ensure compliance, accountability and enforcement: Ensuring Interoperability While Protecting Innovation				
<p>Validation that minimum set of policy and technical requirements for interoperability are met</p> <p>Objective: To assure there are designated, authoritative and trusted mechanism(s) to validate conditions for trust and interoperability to enable nationwide exchange are met, assure accountability and enforce appropriately.</p>	<p>Certification process for meaningful use to extent that criteria address technical requirements for trust and interoperability for nationwide HIE</p> <p>Contracts</p>	<p>Procurement and contractual agreement</p> <p>Open rulemaking processes</p> <p>Authorized certification bodies</p>	<p>ONC – Oversight of Certifiers</p> <p>NIST (Security Conformance)</p> <p>DOJ (Adjudication/Enforcement) / FTC</p> <p>State Attorneys General</p> <p>Corporate Privacy Officers</p> <p>Consumer protection provisions</p> <p>Parties to the exchange</p>	<p>Lack of designated authoritative mechanism(s) to validate policies and practices for trust and other minimum expectations are satisfied</p> <p>Technical and policy requirements for interoperability are satisfied before granting NW-HIN status</p>
<p>Coordinated implementation for new and revised requirements</p> <ul style="list-style-type: none"> - Determine scope and impact of changes - Identify implementation timeframe and migration plan 	<p>HIPAA Transaction and Code Set Rules – administrative transactions</p> <p>Agreements by those conducting information exchange</p>	<p>CMS</p> <p>Workgroup for Electronic Data Interchange (<i>to advise on HIPAA implementation</i>)</p> <p>Self-governance structures established by those exchanging health information</p>	<p>CMS</p> <p>Self-governance</p>	<p>Lack of oversight or coordination mechanism(s) for implementation of new or changed requirements – to assure continued interoperability, minimize disruptions in exchange or loss of data</p>

Governance Objective and Function	Existing Policies	Existing Governance Bodies or Coordinating Mechanisms	Existing Oversight, Accountability and Enforcement Bodies	Potential Gaps for NW-HIN Governance
5. Oversight: Improving Health While Establishing Trust and Interoperability				
<i>Determining how processes are performing and adjusting to new circumstances</i>				
<p>Evaluation and ongoing improvement of governance, oversight, accountability, enforcement or coordination mechanisms</p> <p>Objective: To determine how governance processes are performing and adjusting to new circumstances.</p>	<p>Agreements by those conducting information exchange</p>	<p>Self-governance structures established by those exchange health information</p>	<p>Self governed</p>	<p>Lack of mechanism(s) to evaluate and improvement NW-HIN governance on an ongoing basis</p>

Governance Objective and Function	Existing Policies	Existing Governance Bodies or Coordinating Mechanisms	Existing Oversight, Accountability and Enforcement Bodies	Potential Gaps for NW-HIN Governance
Monitoring, reporting and verification (e.g. certification, accreditation, auditing)	<p>Monitoring / Reporting: Agreements by those conducting information exchange</p> <p>Verification (certification / accreditation): ATCB - for certification of EHRs</p> <p>Auditing: Compliance with HIPAA Privacy and Security Rules</p>	<p>Structures established by those exchanging information</p> <p>ATCB processes to maintaining and overseeing certification program</p> <p>OCR: For HIPAA compliance</p>	<p>Self-governed</p> <p>Accredited Testing and Certification Bodies (ATCBs)</p> <p>OCR</p>	<p>Lack of a process to oversee mechanisms for NW-HIN trust – monitoring participant behavior,</p> <p>Lack of required reporting to track issues, complaints, disputes or breaches relative to the NW-HIN</p> <p>Lack of oversight process to assure ongoing compliance with requirements for trust</p> <p>Lack of auditing for compliance</p>
Coordinated breach notification among those exchanging health information	<p>Agreements by those conducting information exchange</p>	<p>Self-governance structures established by those exchange health information</p>	<p>Self-governed</p>	<p>Lack of coordinated process to notify other entities exchanging health information of a suspected or known breach related to the NW-HIN</p>
Complaint process (<i>from users, individuals or other NW-HIN participants</i>)	<p>HIPAA complaint process – for privacy</p> <p>Agreements by those exchanging information</p>	<p>OCR – for privacy</p> <p>Self governance structures established by those exchanging health information</p>	<p>OCR</p> <p>Self-governed</p>	<p>Lack of coordinated process to collect and address complaints</p>

Governance Objective and Function	Existing Policies	Existing Governance Bodies or Coordinating Mechanisms	Existing Oversight, Accountability and Enforcement Bodies	Potential Gaps for NW-HIN Governance
Dispute resolution	Agreements by those conducting information exchange – for other issues	Self governance structures established by those exchanging health information	Self-governed	Lack of alternative dispute resolution mechanism(s) that would encourage resolution of issues outside of litigation
Redress, remedies and sanctions	<p>HIPAA Administrative Simplification Rules – for transactions and code sets, identifiers, privacy and security rules</p> <p>Meaningful use rules (<i>to the extent that they address requirements for the NW-HIN</i>)</p> <p>Agreements by those conducting information exchange</p>	<p>HIPAA: CMS and OCR</p> <p>Meaningful use: CMS, ONC, Authorized Testing and Certification Body (ATCB)</p> <p>Self-governance structures established by those exchanging health information</p>	<p>HIPAA: CMS and OCR</p> <p>Meaningful Use: CMS, ATCB</p> <p>Self-governed</p>	<p>What is necessary beyond applicable law that would apply to all parties to the Exchange beyond existing law or contractual agreements</p>

Other Governance Models and Initiatives Considered:

1. ISO / IEC 38500 standard that provides broad guidance on corporate governance of IT - <http://www.iso.org/iso/pressrelease.htm?refid=Ref1135>

2. Federal efforts with governance implications to the NW-HIN:
 - White House - Office of Science and Technology Policy (OSTP)/ Chief Technology Officer
 - White House - CIO Council/Chief Information Officer
 - White House - Special Assistant to the President and Cybersecurity Coordinator
 - Office of Management and Budget (OMB) - HIT Task Force
 - Office of the National Coordinator for Health Information Technology (ONC-HIT), HHS
 - HHS – Office for Civil Rights
 - Centers for Disease Control and Prevention (CDC) Public Health Information Network (PHIN)
 - Centers for Medicare and Medicaid Services (CMS) – HITECH EHR Incentives for Medicare and Medicaid
 - National Institutes of Health – National Library of Medicine (MLM)
 - [CaBIG \(Cancer Biomedical Informatics Grid\)](#)
 - Food and Drug Administration – Sentinel Initiative
 - Agency for Healthcare Research and Quality (AHRQ)
 - National Committee on Vital and Health Statistics
 - Federal Trade Commission - Bureau of Consumer Protection and enforcement of breach notification provisions in HITECH
 - Federal Communications Commission (FCC) – pilot to create a national broadband network for healthcare
 - *DoD/VA- Virtual Lifetime Electronic Record - Interagency Program Office (IPO) and Interagency Clinical Information Board (ICIB) – established by the National Defense Authorization Act (NDAA)*

3. International governance models evaluated for:
 - UK
 - Canada

4. ONC report summarizing Fed laws/regs about privacy
http://healthit.hhs.gov/portal/server.pt?open=512&objID=1147&parentname=CommunityPage&parentid=32&mode=2&in_hi_userid=11113&cached=true