

December 16, 2010

David Blumenthal, MD, MPP National Coordinator for Health Information Technology Department of Health and Human Services 200 Independence Avenue, S.W. Washington, DC 20201

Dear Dr. Blumenthal:

The HIT Policy Committee (Committee) gave the following broad charge to the Governance Workgroup (Workgroup):

Broad Charge for the Governance Workgroup:

The Governance Workgroup is charged with making recommendations to the HIT Policy Committee (HITPC) regarding the mandate in the Health Information Technology for Economic and Clinical Health (HITECH) Act that the Office of the National Coordinator (ONC) establish a governance mechanism for the nationwide health information network (NW-HIN).

Since August 2010, the Workgroup conducted a number of public meetings, held a hearing on Models of Governance, and hosted a series of FACA Blogs regarding governance. On December 13, 2010, the Workgroup reported and discussed its findings with the Committee, which were subsequently approved.

This letter provides recommendations to the Department of Health and Human Services (HHS) on the nationwide health information network governance issue.

Background and Discussion

An important strategic goal of the Office of the National Coordinator (ONC) is to enable a wide range of innovative and complementary approaches that will allow secure and meaningful information exchange within and across states, grounded in a common foundation of standards, technical specifications, and policies. In order to accomplish this, it is important to build public trust for participating in health information technology (IT) and electronic health information exchange, and to provide consumers with the assurance they need regarding network security and the privacy of their information.

The Workgroup's efforts were based on ONC's definition of the Nationwide Health Information Network (NW-HIN) as a set of policies, standards and services that enable the Internet to be used

for secure and meaningful exchange of health information to improve health and health care. The resulting conditions of trust and interoperability (COTIs) encourage the adoption of health information exchange.

The Workgroup presented preliminary suggested recommendations to the HITPC on October 20, 2010, which describe in detail four core functions that need to be addressed for NW-HIN governance.¹ The following recommendations apply to the underlying principles for NW-HIN, a preferred approach including conditions of trust and interoperability, Federal responsibility, a validation mechanism, and governance oversight.

RECOMMENDATIONS

Recommendation 1: Sound Principles for NW-HIN Governance

- 1. Transparency and openness
- 2. Inclusive participation and adequate representation
- 3. Effectiveness and efficiency
- 4. Accountability
- 5. Federated governance and devolution
- 6. Clarity of mission and consistency of actions
- 7. Fairness and due process
- 8. Promote and support innovation
- 9. Evaluation, learning and continuous improvement

Recommendation 2: NW-HIN as a Preferred Approach

The NW-HIN should be an environment of trust and interoperability for exchange based on NW-HIN Conditions of Trust and Interoperability (COTIs):

- Should be the preferred approach for exchange of health information nationwide.
- Should be supported by the federal government with strong incentives to vigorously promote adoption.

Recommendation 3: Federal Leadership and Shared Responsibilities

- Federal leadership
 - The federal government should :
 - Establish fundamental conditions for trust and interoperability and utilize its full range of authorities to assure compliance.
 - Recognize existing state authorities across all relevant domains and facilitate coordination and harmonization with states and other entities as needed.
 - Federal agencies should participate fully and directly in NW-HIN and its governance.

¹ See <u>http://healthit.hhs.gov/Policy#102010</u>

- Federal information exchange should be conditioned upon compliance with NW-HIN requirements.
- Shared responsibilities:
 - Reflecting "governance of governances," other entities should have specific appropriate roles within the framework.

Recommendation 4: NW-HIN Conditions of Trust and Interoperability (NW-HIN COTIs)

- ONC should establish conditions to assure trust and interoperability, optimizing broad stakeholder input, including consumers.
- NW-HIN COTIs should provide a baseline and address need for variability.
 - Some are required and apply across all NW-HIN scenarios.
 - Others may be required in particular circumstances.
- The Governance rule should:
 - Establish an initial set of NW-HIN COTIs.
 - Establish a process for adding and modifying NW-HIN COTIs
 - Should provide maximum flexibility for innovation and adaptation.

Recommendation 5: NW-HIN Validation*

- ONC should establish a mechanism to verify that NW-HIN COTIs are satisfied.
 - Balance assurance with cost and burden of validation.
 - Leverage existing validation methods, processes and entities where appropriate, including currently existing EHR certification.
 - EHR Certification should include applicable NW-HIN COTIs and should be a pathway to NW-HIN validation for those NW-HIN COTIs.
 - Any NW-HIN validation testing method should incorporate EHR validation testing where applicable.
- NW-HIN validation should be required when exchanging in NW-HIN environment and asserting NW-HIN compliance.
- There should be various methods of NW-HIN validation:
 - Appropriate to specific NW-HIN COTIs and the level of assurance needed.

[*NOTE: Validation generally refers to the process of verifying compliance and may include a broad array of possible methods (e.g., self-attestation, testing, certification of systems, accreditation of entities, etc.]

Recommendation 6: NW-HIN Oversight

ONC should oversee NW-HIN governance and assure accountability.

- Coordinate between Federal Agencies, state entities and validation entities.
- Monitor and highlight innovation.
- Address governance barriers.
- Provide ongoing evaluation and continuous improvement.
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We appreciate the opportunity to provide these recommendations on NW-HIN Governance, and look forward to discussing next steps.

Sincerely yours,

/Paul Tang/

Paul Tang Vice Chair, HIT Policy Committee