



Department of Veterans Affairs

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***Responses to Questions from the Health Information Technology (HIT) Standards Committee
Governance Workgroup
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Submitted by:

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Panelist Questions Process

All panelists were encouraged to submit written comments for any or all of the following questions about their specific governance process.

Questions about VA specific governance implementation.

To assist in framing VA's responses and provide some context a brief discussion of the Nationwide Health Information Network governance structure is provided.

In 2008, as part of the Nationwide Health Information Network Phase II Trial Implementations, a multi-disciplinary team, including VA representatives, was assembled to develop a comprehensive agreement that would create a legal framework using existing law for the electronic exchange of health data. The first version of this agreement, called the Data Use and Reciprocal Support Agreement or DURSA, was executed by a number of Federal agencies and non-Federal organizations (the "Participants") beginning in November 2009. The DURSA is a legal agreement created to promote and establish trust among the Participants. It codifies a common set of trust expectations into an enforceable legal framework, and eliminates the need for point-to-point agreements.

The executed DURSA created a Coordinating Committee and charged it with maintaining this Agreement. The Coordinating Committee provides oversight, facilitation and support for the Participants who transact Message Content with other Participants. Governance mechanisms usually ensure procedural fairness, ensure transparency in proceedings, and ensure standards and consistency in the conduct of business. The Coordinating Committee in essence is a governance mechanism for trust as it develops processes and policies affecting the way the exchange is administered.

[Reference DURSA dated November 18, 2009 and Draft of Amended DUSRA dated August 17, 2010]

a) What are the topics that are decided by the governance process?

VA recommends that topics addressed by governance processes for health information exchange include: 1) Determining processes and structures to ensure trust in health information exchange; 2) examining aspects of governance within the Office of the National Coordinator's (ONC) authority or control, and not within the control of the Government; 3) identifying any mandatory and optional requirements for the preferred approach for health information exchange

Other topics for consideration include who should be included in the governance process, how the structure and function of the governance process should evolve as the HIE space changes, and the rules that govern what can be done with the data and to whom the data belongs.

b) Describe the group of stakeholders that is governed by the governance process.

Nationwide Health Information Network participants.

Federal agencies' participation in governance is governed by PL 104-113, the National Technology Transfer and Advancement Act of 1995, implemented by OMB Circular A-119. This law requires Federal agencies to use technical standards that are developed or adopted by voluntary consensus standards bodies. Thus, it is essential that the governance process developed to govern health information technology using the principles of: 1) voluntary consensus standards bodies of openness; 2) balance of interest; 3) due process; and 4) an appeals process.

c) Describe the group that executes the governance process.

The Nationwide Health Information Network Coordinating Committee, comprised of stakeholder representatives executes the governance process. In VA, the group includes the Office of Information and Technology in conjunction with the Veterans Health Administration's Office of Health Information.

d) How is authority of the governing body established (contract, law, other)?

The authority of the Nationwide Health Information Network Coordinating Committee is established through the DURSA, which is a contract, but also through a very clear understanding and transparency among the members. The governing body is also established through an alignment with the business objectives and a demonstration of reaching these business objectives. Governmental stakeholders are subject to legal requirements that govern their participation in the exchange of health information, such as following standards conformity according to Public Law 104-113 (see section b above).

e) How does the governance approach deal with the parallel needs for a decision-making group that is sufficiently senior to have its decisions carry weight and yet have the participation of specialists to work through technical, economic, or legal issues in preparing an item for decision?

The DURSA was developed by the Coordinating Committee which includes subject matter experts from the stakeholder organizations. In its initial execution the DURSA went through a rigorous vetting process within each organization that included review by appropriate subject matter experts (e.g., lawyers, clinicians, privacy office, identity and access management, health information management, security,

information technology architects, standards architects), to the highest levels of the organization. This process should be repeated when subsequent versions are executed.

f) What is the role of the governance body in interpretation and enforcement of the decisions it makes?

The issue of enforcement needs thorough deliberation by all stakeholders – e.g., health care providers (public/private), health information exchange bodies (public/private), patient/patient advocates. Recommend that the enforcement body be a separate entity than the governance body, and that appropriate conflict-of-interest provisions be included in the regulation-development process.

Questions about Nationwide Health Information Network governance

a) How should organizations be vetted for participation?

Consider an on-boarding process that goes beyond looking at a DURSA signature and conformance of a gateway. It is important to understand that the organization signing the DURSA has a clear set of objectives along with trust from and among its members. At a technical level, it is important to go beyond the gateway and get assurance that the data is real, the patient preferences and policies are real, and that provider use is real. We recommend including accreditation site visits as part of the on-boarding process. For example, a team of individuals representing various stakeholders who participate in the Nationwide Health Information Network would conduct a site analysis after an interested organization has signed the DURSA. The panel would assess the data quality and other technical data elements during the site visit. As the nationwide health information network participation grows, these initial approaches to governance may prove impractical for large scale at a national level. Consideration for transition to other governance structures that can accomplish similar goals in different ways will need to be considered.

b) How should the exchange of information be monitored for appropriateness in a large volume / distributed environment?

The governing body will have to institute a process that will have the capacity to monitor which systems are running and which systems are down and let others know. Today, VA and Kaiser Permanente are communicating directly to notify each other of system downtime. This is not scalable to a large volume of systems. The governing body can help by trying to optimize the system performance. If 99% of the time, the system's response is "I don't know this individual," then maybe we are doing too much of a blind search. This behavior can be optimized. If patients have to provide five authorizations to five different organizations for pieces of their health records to come together as one whole, then maybe that is an easy obstacle to overcome. The governance body will need to identify methods for detecting aberrant data submissions similar to those used by credit card companies or claims processing companies that are able to detect fraudulent behavior.

c) How should information be provided to a consumer regarding who accessed his / her information?

Today, VA answers patient requests for "information disclosure" manually. A Veteran has to submit a request to a VA Medical Center's Release of Information Office. With the Nationwide Health Information Network, each organization has to maintain an audit trail for a report of an accounting of disclosures. At

VA, this “accounting of disclosures” has a user interface available to the Release of Information staff. In the future we need to have an interface for the patient, for example, within VA’s eHealth website, My HealthVet, or another electronic mechanism provided by the governing body to Nationwide Health Information Network participants.

d) How should consumer complaints be investigated?

Consumers’ roles are not well defined at this time within the Nationwide Health Information Network. Of course, patients provide authorization, ask for an accounting of disclosures, and lodge complaints. However, consumers could also serve as “nodes” on the Nationwide Health Information Network through their Personal Health Records. They could request copies of their records, manage their consent directives globally, check the accounting of disclosures, delegate rights, lodge complaints, and request automated decision support services.

The governing body should look to the Department of Health and Human Services (HHS) Office for Civil Rights (OCR) for information and lessons learned regarding the process for investigating complaints since HHS OCR is charged with investigating privacy complaints of individuals arising under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. The governing body may want to consider whether all complaints received regarding the privacy or security of the Nationwide Health Information Network should be forwarded to HHS OCR for investigation.

e) How should “bad actors” be disciplined?

An appropriate response depends on the actions of the “bad actor” and whether such actions violate just the DURSA and policies of the Nationwide Health Information Network or go beyond these instruments. We recommend that “bad actors” be educated on ways to improve processes and come into compliance. We recommend a Table of Penalties be developed and communicated broadly to clearly paint the picture consequences for “bad actor” activities.