

SPECIAL REPORT

Building Effective Data Governance Models, Policies and Agreements in a HITECH World

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Indiana Health Information Exchange

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I. Introduction

Data governance is a key component of a successful health information organization (HIO) and is just as important, if not more, than the technology or services offered. Today, providers, hospitals, health systems, and other healthcare stakeholders are actively engaging in the meaningful use, exchange, and reporting of electronic health information to improve healthcare delivery at an individual and population level. As more and more electronic data is stored and collected for use and exchange across interstate and intrastate healthcare networks, diverse configurations of local and regional data-sharing partnerships have emerged to respond to the growing need for health information exchange (HIE). Competing organizations participating in an HIO demand a high level of trust that the HIO will be an effective steward of the shared data. Although HIOs vary in size, technical approach and architecture, business affiliation, and patient population, they share the same objective of exchanging necessary and essential data to facilitate the coordination, safety, efficiency, and quality of care. Critical to achieving this goal is data governance, which consists of policies and procedures necessary for fiduciary management and stewardship of data as it is accessed and exchanged across different environments. A data governance model is dependent upon input from organizations participating in the HIO and establishes vital control, security, and authority measures to promote collaboration and accountability. However, the governance needs of State, Public, and Private HIOs vary in scope, making it difficult to make generalizations let alone develop universal regulations. In recognition of the complexities of governance with a large inter-organizational HIO, this paper will focus on Public HIOs in the context of the current proposed Meaningful Use Stage 2 rule, proposed Health Insurance Portability and Accountability Act (HIPAA) amendments, the Office of the National Coordinator for Health Information Technology's (ONC) Nationwide Health Information Network (NWHIN) Governance Request for Information and State Health Information Exchange Program Information Notice 003 released by ONC.

In the wake of the Health Information Technology for Economic and Clinical Health (HITECH) Act provisions under the American Recovery and Reinvestment Act in 2009, the adoption and implementation of electronic health records (EHRs) and development of HIOs have rapidly proliferated across the United States. In addition to introducing a variety of financial incentives and policy levers to encourage providers to use EHRs and exchange health information, HITECH also provided more than \$300 million in funding to regional and local health information technology (health IT) efforts to support HIE. Although HITECH introduced new regulations and guidance for HIE, many of the data governance requirements and recommendations were already reflected in the models of existing HIOs. However, HITECH stimulated a review and realignment of public and private stakeholder roles by providing specific direction from the federal government regarding state-level efforts. The State Health Information Exchange Cooperative Agreement Program has since created and accelerated HIE capacity within and across states through awards to qualified organizations to build strategic and operational plans according to ONC Program Information Notices (PIN) and guidance regarding business operations, financing, sustainability, technical services, legal and regulatory issues, and governance.

To demonstrate how health IT investments and Meaningful Use of electronic health records (EHR) advance the vision of patient-centered care, while achieving the three-part aim of better health, better care at lower cost, ONC is leading the Beacon Community Cooperative Agreement Program. This program provides \$250 million over three years to 17 selected communities throughout the United States that have already made inroads in the development of secure, private, and accurate systems of EHR adoption and health information exchange. Each of the communities, with its unique population and regional context, is actively pursuing the following areas of focus:

- Building and strengthening the health IT infrastructure and exchange capabilities within communities, positioning each community to pursue a new level of sustainable health care quality and efficiency over the coming years;
- Translating investments in health IT in the short run to measureable improvements in cost, quality and population health; and;
- Developing innovative approaches to performance measurement, technology and care delivery to accelerate evidence generation for new approaches.¹

Today, more than 75% of states are pursuing several models of HIE in return for substantial funding from ONC before the funding period expires in 2014. A number of HIOs have created various structures to assist in the governance and operation of their HIO, usually under both political and social pressures to protect individually identifiable health information; ensure data integrity; and maintain the accuracy and currency of data as it is passed from one entity to another. Following the passage of HITECH, governance models, policies, and agreements were revised and adapted to the new legal framework which closed some of the privacy and security gaps previously created by HIPAA, although additional revisions and adaptations will likely be required once the regulations implementing the HITECH changes to HIPAA are finalized later this Summer. Some of these new requirements included direct application of the HIPAA Security Rule and most of the Privacy Rule to business associates (which includes HIOs), stiffer penalties and potential criminal charges against individuals; the establishment of security and privacy benchmarks and security breach notification.

As a result of the opportunities presented by HITECH, many providers and other health care entities have been restarting their discussions on how to build effective exchanges that securely share patient data. An organization considering joining an HIO or starting one, should carefully consider key data access and management points that will impact the governance model, policies and agreements that are needed to operate an effective HIO. These points relate to data discovery, data reuse, data sharing, data entity harmonization and interoperability. Thinking through these points can help organizations determine policy and system requirements to ensure that the HIO meets the needs of its participants

¹ Website of the Office of the National Coordinator for Health Information Technology, Beacon Community Program overview:
http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_onc_beacon_community_program_improving_health_through_health_it/1805

and stakeholders; adheres to HITECH regulatory requirements, and offers safe data exchanges that add value to care delivery.

This white paper will demonstrate how to develop and implement effective data governance models, policies and agreements under HITECH by examining the following:

- Understanding the key elements for effective data governance, such as consistent application of HIO policies, practices and interoperability standards
- Knowing the key success factors for data governance, such as aligning incentives for participation across communities
- Best practices for developing appropriate contract structures for sustainability and services
- How to use a contracting structure for accountability within the HIO

II. Common Components of Data Governance Agreements, Policies and Contracts

The governance of information technology (IT) has been an established discipline for a number of years, as it entails the leadership and organizational processes that extends IT to meet the strategies and objectives of the organization. However, despite being a mature process that has been implemented across many organizations, the focus of IT governance is usually on the applications rather than on the data flows. This type of model does not consider the data that is driving the applications; it is typically managed in how it is serving a particular application, rather than the broad benefit it might have to the entire organization. However, in the area of HIE, the organizations that are overseeing these efforts are aligning the data within the exchange with their business processes in order to add value and create sustainability over time. The success of an HIO is dependent upon its ability to send and receive clinical data to a multitude of entities at specific points in time in order to understand the current needs of a patient or population. Therefore, in order to get the most value out of this data, an HIO needs to establish a governance structure that focuses on the data itself and how to manage it as an asset.

Data governance refers to the overall management of the availability, usability, integrity, and security of the data employed in an enterprise². A sound data governance program includes a governing body or council, a defined set of procedures, and a plan to execute those procedures. This type of data governance is essential regardless of the type of HIO model that is being used, which could include:

- State-run HIO – An HIO that is overseen and managed by a state or local government unity or entity controlled by a state or local governmental unity to advance interoperability through a multi-stakeholder, public-private partnership as a governance structure. For example, the Illinois Health Information Exchange Authority.
- Private (Intra-organizational) HIO – An HIO entity that facilitates electronic exchange within a single legal entity or among a group of legally affiliated or related entities; generally concentrated in a community and the surrounding area, it is typically sponsored by a local healthcare organization from the private sector that raises or provides capital to implement a

² Data Governance Institute, 2012

narrow set of services. For example, a large integrated delivery network using HIE software to exchange information between two EHRs used by different units within the IDN.

- Public (Inter-organizational) HIO – An HIO entity that facilitates electronic exchange among entities that are not otherwise legally affiliated or related; generally an effort among two or more organizations that shape, develop and manage a common infrastructure. For example, the Indiana Health Information Exchange and Greater Cincinnati HealthBridge.

Each of these entities has a different organization structure and may have varied technical approaches, but they are all dependent upon data for their success. Therefore, there is a need for strong data governance agreements, policies and contracts to manage this data as an asset. In this manner, data can be shared and reused across numerous applications and systems, business processes and users. As shown in Table 1, even with the various HIO approaches, a stable data governance agreement has the following six attributes:

Table 1: Key Attributes of Data Governance

Attribute	Description
Availability	The data must be available to the applications of all HIE users when needed
Accessibility	The agreement must ensure that the data is accessible, regardless of the application used
Interoperability	The data must be both semantically and syntactically interoperable across systems
Auditability	There must be a trail of the data from its source to its destination
Quality	The data must be accurate and complete
Security	The data must be kept secure

In addition, there must be policies that conform to the governance of the data in order to form a consistent and effective framework. As shown in Table 2, even though different types of HIOs may have various structures, the policies that govern data also have a number of key attributes:

Table 2: Key Components of Data Governance Policies

Component	Description
Standards	All data definitions, structures, formants and taxonomies must be included within a policy in order to facilitate interoperability
Organization	The roles and responsibilities of each individual within the data governance program must be defined
Processes	Process must be defined around the creation, development and management of data, including business rules as well as access and monitoring mechanisms

Issue Management

There must also be policies in place that guide data prioritization and remediation

These common practices reflect the degrees in which HIO stakeholders understand the relationship between the data and the business needs for the exchange. In the beginning phase of an HIO, there are few formal governance process that support data management as the infrastructure is put into place and the immediate needs of the stakeholders are still being defined. However, as the organization matures, the business requirements are defined into documented practices and compliance is integrated into the HIO process. The use of formal contracting agreements provides controls for the stakeholders that oversee governance to ensure the data is used appropriately within the HIO. While the type of HIO will determine the breadth and detail of each contract, there are a number of common elements, as shown in Table 3:

Table 3: Common Elements of Data Governance Contracts

Contract Element	Description
Data Requirements	The data used within an HIO is mapped to a specific requirement with rules established to measure compliance
Data Management	Data policies are defined and documented for common data sets within the HIO
Data Validation	Validation methods are embedded into each of the defined business processes
Alerts and Remediation	Processes for prioritizing data issues and methods of remediation and the responsibilities of each of the stakeholders are defined

Data governance must focus on how the applications that compose the HIO handle data; how the data is transferred from one entity to another; how the data can be used appropriately and how the data will be kept secure. It also must ensure a mechanism for monitoring compliance with the policies and contractual obligations of each entity as well as maintaining consistency of data use across the exchange. The need of an HIO to provide accurate, comprehensive and essential information to a provider when needed is essential in fulfilling its objective to improve care for patients. For this reason, the use of data governance, policies and agreements are critical to its success.

III. Why Data Governance, Policies and Agreement are Critical

Implementing an HIO to collect and share information across disparate organizations can fundamentally alter the way that providers coordinate their work activities and collaborate to deliver care. Sharing information has become an essential element in the new era of healthcare reform, as health information exchange can assist with the coordination of care for accountable care models, create efficiencies to reduce medical errors and improve clinical outcomes, and provide a robust data set for better and more effective population care management. However, these benefits become difficult to

realize without a stable and comprehensive data governance framework, which requires an examination of various models and policies to determine the most reasonable way to achieve data stakeholder participation. Additionally, the development of an appropriate contracting structure runs parallel to data governance as they define the terms and conditions for how data is shared, reused and harmonized between various entities, and must include both the functions of the HIO and its organizational model.

HIOs have generally coalesced into a series of key functions and key organizational models that provide either data governance or data governance combined with technical operations. The most significant driver to these models in ensuring effective governance is convening and coordinating functions that are required for effective collaborative data-sharing practices. While state governments can use their statutory and regulatory rule-making authority for the sharing of individual patient data and consumer protection, the type of governance used for HIOs involves the facilitation of compliance with prevailing laws and regulations in addition to sound data management practices across diverse interests and organizations.

The HIO governing body must serve as a neutral and skilled resource for convening diverse stakeholders and leading and coordinating consensus-based efforts to develop and implement a road map for both data sharing and exchange between various entities. This road map represents the strategies, timelines and goals for achieving connectivity across the particular characteristics of a community or region.

IV. Key Policies and Success Factors for Data Governance

From within these models, several key elements and policies are essential for effective data governance:

Consistent Application of HIE Policies, Practices and Interoperability Standards: Given the wide range of entity types that will participate in HIE, consistent application of the policies that govern the exchange and use of data from within the network is necessary. To accomplish this, an HIO needs to establish a structured collaborative process to develop and select options for an accountability structure that incorporates the roles and contributions of HIO participants at various levels, including the governance entity. Part of this process must include a set of guidelines for maintaining accountability for key HIO functions (such as exchanging medication information) and organizational roles (such as technical operations). In this manner, the policies developed around data governance are applied to each entity participating in the HIO, regardless of its type. Because each HIO participant may utilize different data standards, it is also essential to develop a policy and timeline for the integration of consensus-based standards that accommodate the various stages of development of the participants within the HIO.

Consensus-Based Approaches for Data Sharing: The term “data sharing” has a wide range of interpretations that need to be carefully analyzed to determine the appropriate procedures and system requirements. This includes answering the following questions:

- What data are being shared?
- How will it be shared?
- When, or under what circumstances, will it be shared?

In order to approach consensus, it is equally essential to develop a business case for sharing data and how it ties into the overall objective of the HIO. Successful efforts have found that starting small and broadening the data sharing over time as the scope of the HIO expands generally increase participation. For example, in Massachusetts, the New England Health Exchange Network (NEHEN) started with eligibility and benefits checking and then became the infrastructure for an e-Prescribing solution called MA-Share.³

No Constraint by Political Variables or Governmental Budgetary Constraints: Even in states where the government currently plays a key sponsorship role for early HIE efforts, it is most viable for any HIO governance organization to be an independent entity that engages, but is outside of state government. In this manner, the entity can be an unbiased and objective arbiter of the data issues and practices that occur between the numerous entities that comprise a network. This allows the governance entity to maintain an allegiance to the operation of the HIO achieving its goals to benefit all stakeholders, not simply to a government entity that may have initially sponsored the HIO.⁴

Understanding Confidentiality, Consumer Empowerment and Accountability - These three issues with respect to data access, use and control are growing public concerns, particularly in managing secure and effective HIE practices. Data governance practices must include policies that clearly describe who owns and controls the patient data, and specify how relationships between participants will be formed, implemented and ultimately managed. Since there is a wide range of data access and sharing, the complexity of privacy and security requirements increases as more data is available and as users are able to do more with the data than simply view it. The HIO governance entity must possess the appropriate expertise to coordinate and oversee the development of consistent data management practices. One method to accomplish this is to develop explicit systems that define and measure the accountabilities.⁵

Steady and important progress can be achieved by HIOs as they incorporate the key elements into their governance model. However, it still becomes critical to understand how to identify and evaluate success factors to determine if data governance is leading to better accountability, sustainability and interoperability among those participating in the HIO. Pragmatic and incremental strategies to engage data-sharing partners in order to build and expand the HIO have demonstrated both value and effectiveness in early HIO development. However, an examination of a number of data governance practices points to several key success factors that will lead to longer range sustainability.

- Avoiding Competition - Successful data governance is contingent on clear ownership of the process. Without it, the effort will be adrift with no clear purpose or compass. However, if one organization alone owns the effort, then other stakeholders may feel that the data governance initiative does not address their needs, and may create their own model as a result. A data governance committee is needed that is comprised of representatives from each of the business

³ Rhoads, Jared, "HITECH's Impact on Health Information Exchange: Key Decision Points for Privacy and Security," 2010, www.csc.gov

⁴ Griffin, Jane, "Four Critical Principles of Data Governance Success," *Information Management Magazine*, January 2, 2010.

⁵ Dierker, Lynn, "State-level Efforts in Health Information Exchange," www.ahima.org

units and stakeholders involved within the HIO. In this manner, any type of competition between these organizations is removed as the committee will set data policies, procedures and standards that will collectively benefit the participants. Additionally, incentives should also be created that are aligned across each of the stakeholders and encourage participation in both the HIO and the committee.

- Flexibility – The proliferation of multiple HIO entities within a region and a state, each of which is at a different stage of development, demonstrates that HIOs evolve based upon a number of circumstances: financing, value proposition and stakeholder involvement. However, it is crucial for each entity that wants to participate in the HIO be allowed to do so, provided participation is consistent with the overall value proposition and sustainability of the HIO. Furthermore, these entities must be able to ensure high data quality in order for the benefits of an HIO to be realized in addition to trusting the source from which the data originated. Access mechanisms into the HIO must be flexible enough for a participant to join, regardless of their level of technical acumen, so that individual entities can become part of the exchange and also part of the committee that governs it.
- Broad Stakeholders – Inevitably some participants will contribute more to the HIO effort than others, however, the data governance committee must consist of a broad group of stakeholders in which all of the needs of each participant are expressed, and their input is considered. A data governance model that only includes a small set of stakeholders runs the risk of developing policies and standards that are not uniform across the HIO and would not be updated or modified through consensus of each of the participants. As a result, a regional HIO effort may splinter off into smaller exchanges; there will less accountability for each of the entities that participate; and the long-term viability and sustainability of the HIO is called into question without broad stakeholder support.
- Quick Victories - For an HIO to advance, it urgently needs to define its value proposition and related sustainability models that will foster and maintain desired levels of success. In order to underscore the need for a collaborative governance model that will nurture the HIO towards ongoing success, it is important to identify areas where quick victories can be achieved. Examples of quick victories that highlight the viability of the HIO and its associated data governance model include:
 - Utilization of agreed-upon data standards to exchange needed information, such as laboratory data
 - Consensus approach to authorization and use of data for purposes other than a clinical encounter
 - Creation of a data reuse plan
- Stay focused - As HIOs continue to grow and develop across the country, it is critical that each organization avoid overextending its mission, reach, and services to meet the various requirements and future demands of participating HIO customers. By adopting an incremental, phased approach that emphasizes specific, value-driven steps, HIOs can better align short-term success with more cost-efficient preparations for longer-term sustainability.

V. Data Governance and Contracting Structures

The growing interdependence among the collections of stakeholders, business processes and their corresponding applications within an HIO exposes the amplified risks associated with the absence of best practices for data management. Even if an organization develops an HIO governance model that incorporates a number of key principles as well as success metrics, the desire for formal data management oversight begins with an appropriate contracting structure. In the enthusiasm to institute formal data governance, a number of the organizations that comprise the HIO will take the first step of establishing a data governance committee populated with key stakeholders. Although this formal structure is a critical component to exercising control over the data and information used throughout the HIO, there is still a risk of creating a data governance gap.⁶

A gap occurs when a formal organizational structure for data governance is created before there is a clear definition of the roles and responsibilities associated with each of the stakeholders participating in the HIO as well as those serving on the data governance committee. An established and structured collaborative process is needed to develop and vet options for an accountability structure. Assigning roles and responsibilities to organizations and individuals before a contracting agreement defining data principles, policies and practices is in place could lead to an increased risk of confusion and fear with how the data is being managed and who is accountable for adhering to the policies.

Without a means for defining and documenting data policies as well as establishing methods for monitoring accountability of the role and performance of each entity, there are no tools for enforcing the data governance policies of the HIO. A contracting structure must be put into place that maintains accountability and oversight for key HIO functions and organizational roles. The contract must have time frames and approaches for implementing the mechanism for data management oversight, and the data governance entity must continue to support expanded dialogue and consensus building among each of the entities that comprise the HIO.

In order to use the contracting structure to foster greater accountability and sustainability for HIOs, these efforts need to be linked to national HIE governance, such as the governance mechanism framework for the Nationwide Health Information Network (NwHIN) proposed by ONC this Spring. While the proposal is currently only a request for information to influence potential future rule making, a number of elements within the initial draft should be considered when developing a data governance contract, such as:

- Clearly defining the parameters on how individually identifiable health data can be used; how the entities that are exchanging the data can be authenticated; and the rights of an individual with respect to how their data can be shared and viewed.
- The specific data standards that must be employed both in the exchange and protection of data.

⁶ Loshin, David, "Operationalizing Data Governance through Data Policy Management," Knowledge Integrity, Inc. knowledge-integrity.com

- The preconditions an entity must adhere to in order to participate within the HIO; specifically around data use and reuse.
- The business practices that justify the use of data exchange.

Additionally, the contract should specifically align both its privacy and security policies with the changes in HIPAA that have occurred under HITECH. Prior to the passage of this legislation, there were strict rules regarding the release of protected health information (PHI) among covered entities, such as providers, health plans and health care clearinghouses. Business associates that were contracted under these organizations to perform certain functions had to abide by contract provisions written by the covered entity with respect to PHI. However, under HITECH, the definition of business associates has been expanded to include:

- Patient safety organizations, e-prescribing gateways, vendors offering a personal health record to individual on behalf of a covered entity, and health information organizations.
- “Downstream Entities,” such as subcontractors, are now considered business associates if they have access to PHI on behalf of a covered entity or business associate.

While the previous privacy regulations had business associates only indirectly contractually obligated to comply with HIPAA; the new regulations under HITECH will require that these entities are now directly subject to HIPAA’s security obligations and certain privacy obligations. Thus, the implementation of the HITECH Act will extend the reach of HIPAA to more organizations. In addition, HITECH also created new privacy restrictions; created new enforcement mechanisms and established a new federal breach notification requirement. This requires a comprehensive and detailed contract that outlines how each of the entities that comprise the HIO are affected by HIPAA; what the penalties are for data breaches; and a response plan that can be implemented immediately if a data breach occurs. Additionally, state law requirements must be considered and addressed. Many states’ laws were drafted prior to the proliferation of electronic information exchange and, as a result, are antiquated and ambiguous. Further, some states are drafting laws to address electronic information exchange that are inconsistent with or more stringent than HIPAA. This results in a patchwork of state laws that add a layer of complexity to HIE.

VI. Conclusion

Data governance and its associated policies and contracting structures have taken on greater significance in this new world of health reform. With the passage of the Patient Protection and Affordable Care Act (ACA), the focus of health care will shift to improved patient outcomes, better cost efficiencies and provider accountability. New care delivery systems such as accountable care models and patient-centered medical homes rely on the timely and accurate exchange of data to coordinate care among various providers and to ensure the appropriate care is provided during the clinical encounter. In order to realize the benefits of these models, states must engage with numerous partners within various communities that provide care to their patient population. By creating effective data governance policies and procedures, states and other entities can assist in automating manual processes; view real-time patient data at the point of care; and increase patient engagement in their

care. These are all potential values that can come from an effective HIO that is associated with the patient care priorities that are coming from healthcare reform.

By aligning practices and standards across both state and federal levels, there is greater accountability among each of the entities that participate in the HIO. Additionally, clear contractual documentation allows for an understanding of the types of data that will be exchanged and for what purpose, thus underscoring the value proposition in terms of services provided to participants. The structure of a new data governance model in the era of HITECH would be pragmatic and ensure compliance with data policies linked to the achievement of the HIO business objectives. This can be accomplished by focusing on the following strategies to engage data-sharing partners and build up the exchange:

- A process for collecting and documenting data that maps to the expectations of each HIO participant.
- A process for defining and agreeing upon data policies that directly correspond to the business objectives of the HIO.
- Procedures for alerting key individuals to either HIPAA or HITECH concerns.
- A process for prioritizing and remediating data issues.
- A framework and process for monitoring performance with respect to data policy compliance.

Additionally, a data governance organization can utilize the following methods to better understand and reduce risks associated with the use and disclosure of PHI:

- Understanding HIPAA status - Most covered entities are aware of their HIPAA status, but it is important that all business associates of these organizations, and their potential subcontractors, understand they are subject to the same rules and penalties as any other covered entity under HIPAA.
- Understanding data flows - The key to compliance is understanding how data flows within, into and out of the HIO. Governance of the data must address who is collecting the data; where the data is stored; who is authorized to use the data; and who is authorized to disclose the data.
- Learning from mistakes – It is important to learn from the mistakes of organizations that comprise the HIO as well as those of the data governance organization. This allows time to update policies and procedures to prevent similar problems in the future.
- Preparing for breaches – Both the data governance organization and the participants in the HIO should develop and implement practical breach response plans that detail what will happen when a data incident occurs.

By aligning practices and understanding the impact of HITECH and other federal requirements, an HIO is able to develop a strong governance model and supporting policies that are necessary to engage providers, build sustainability and leverage the functionality of an HIO. These must be developed in a collaborative manner, in which the needs of each of the participants and stakeholders are recognized and the value proposition is clearly defined. An appropriate contracting structure is needed that aligns with the overall objectives of the model and policies as well as aligning with national governance efforts, in order to ensure sustainability and accountability within the HIO. Effective and operational HIOs,

whether at the state, regional or local level, are vital to the success of healthcare providers and payors in the future of healthcare in the United States.

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