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HIE Governance: Organizational Model and Policies Adopted by NYS
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New York State Health IT Organizational and Governance Model

Summary: Since 2006 New York State has committed approximately \$400 million to improve health care through broad adoption and use of health IT. This investment has resulted in the creation of more than 8 vibrant regional health information exchanges that are the center piece for many important initiatives to improve the quality and efficiency of health care services. A collaborative statewide governance model is a key building block for NY's statewide health IT strategy and is the secret sauce that has enabled regional efforts throughout the State to be bound together by a common technical and policy infrastructure.

From the beginning, New York elected to pursue its health IT strategy through a public-private partnership. The Partnership consists of the following critical components:

- The NYS Department of Health which provides funding and strategic policy direction;
- The New York eHealth Collaborative, a not for profit corporation with a multi-stakeholder Board of Directors, which convenes stakeholders (through a process known as the Statewide Collaboration Process) and manages development of protocols, standards and policies (known as Statewide Policy Guidance) that govern participation in New York's health information exchange network; and
- The Policy and Operations Council, comprised of all of the projects receiving state funds which are required to comply with state policies developed through NYeC, with NYS DOH input.
- Regional Health Information Organizations which establish community level governance that binds participants to Statewide Policy Guidance and determine how information will be shared within the community to improve patient care and population health, based on specific resources and priorities established at the community level. This is an important forum for health plans, providers, and consumers to decide together how information will be used across the health care system in a given community.

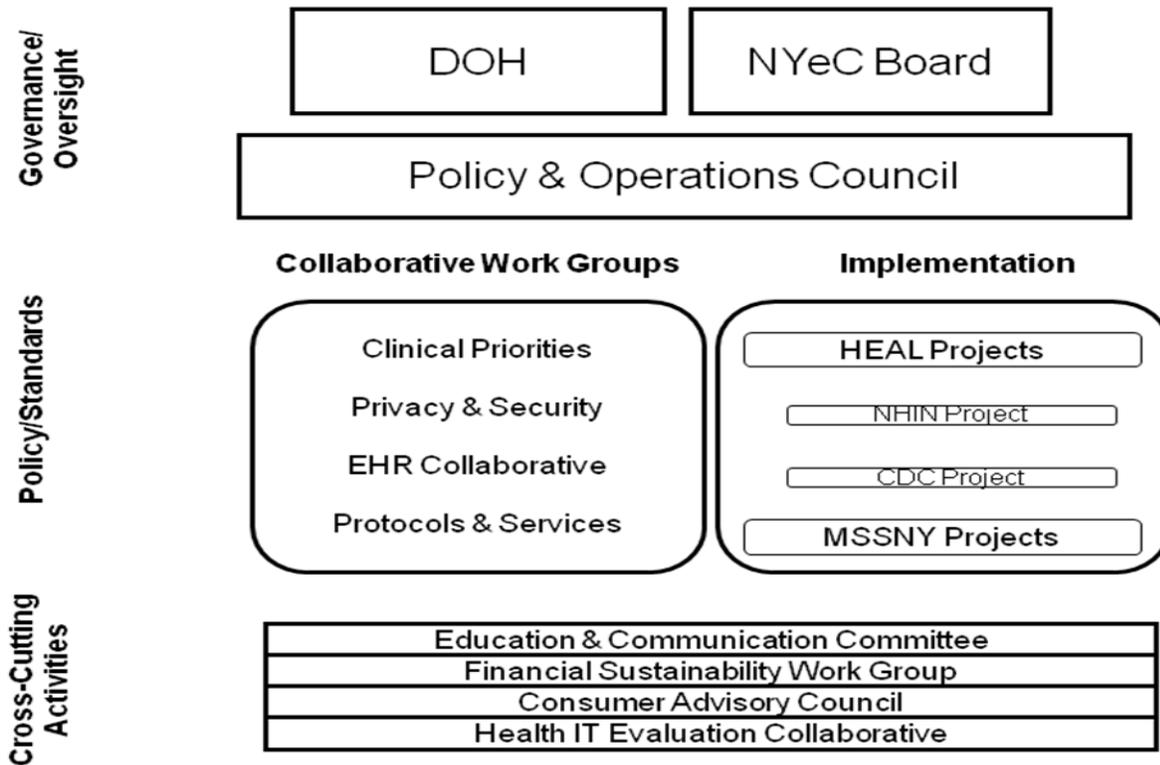
New York's governance structure is dedicated to developing and operating the State Health Information Network of New York (SHIN-NY). The SHIN-NY is a network of networks, which through common protocols, standards and policies, utilizes the Internet to facilitate information exchange between and among health care stakeholders in a private and secure manner. The governance process is the glue that makes sure the participants in the network have real input into how the SHIN-NY develops.

Detailed Description:

State governance: The state-level governance for health IT and HIE is based on a public-private partnership model comprised of the New York State Department of Health (NYSDOH) and the New York eHealth Collaborative (NYeC). NYSDOH provides high-level strategic and policy direction and funding support for the statewide strategy; more than \$350 million in grants has been awarded to a variety of organizations to support health IT adoption and HIE at the local or regional level. The state's strategic and policy interests for health care improvement through health IT have focused specifically on strengthening provider, consumer and community capabilities for care management and population health improvement. Fostering a robust health IT infrastructure is also essential to improve the operation and outcomes of the state's \$46 billion Medicaid program as well as other public and private health insurance programs.

NYeC is an independent, statewide, non-profit corporation established in 2006 by a diverse group of health care leaders to promote policies and conduct educational activities to expand health IT adoption and use. NYSDOH contracts with NYeC to manage the statewide collaboration process (SCP) to develop policies and implementation specifications in a manner that is open, transparent, and inclusive of a broad range of stakeholder interests. The SCP is further supported by a structured mechanism called the Policy and Operations Council (POC) for stakeholder participation in health IT policy development and implementation support to advance the statewide interoperable health IT infrastructure.

Agreement on common policies, and establishing mechanisms to enforce them, are essential to ensure public support and trust in health IT and HIE efforts. These policies – known as statewide policy guidance (SPG) – are formally approved by these stakeholders, by the NYeC board, and ultimately adopted by NYSDOH. Initially, the SCP and SPG focused on successful implementation of activities supported through state grant funding; as a result, the POC membership is currently comprised of representatives from all of the funded projects. In the future, the structure, process, and policies will be broadened to advance effective implementation of emerging federal and state policies governing health IT and HIE. The following diagram illustrates the organizational structure and process described above.



Regional: NYS has provided policy and funding support for the development of regional governance and HIE technical services through regional health information organizations (RHIOs). The definition and specification of roles and responsibilities for RHIOs is based mainly on the state’s grant funding and related contract requirements. The operation of the statewide health IT infrastructure – known as the statewide health information network for New York or SHIN-NY – is based on implementation of common policies and standards governing technical implementation and uses of health information. RHIOs currently serve as the primary governance and operational structure through which the SHIN-NY is implemented. This is commonly referred to as a federated model for HIE.

In NYS, RHIOs are defined as non-profit corporations which have adopted a mission of advancing interoperable health IT to improve health care quality and safety and reduce costs. To fulfill this mission, RHIOs require commitment from multiple health care stakeholders in a geographic region, including providers across the continuum of care, patients, payers, purchasers and government. RHIOs are responsible for enabling interoperability through which these stakeholders are linked together – both organizationally and technically – in a coordinated manner for health information exchange and quality and population health reporting. They are responsible for providing services to advancing interoperability including but not limited to governance and policy implementation. RHIOs are not vendors – rather they contract for technical services in a manner that ensures clinical goals are achieved, and open health information exchange protocols and services are implemented and available to all providers and payers.

RHIOs must adhere to policies and standards developed through the SCP in 5 domain areas:

- Organizational (e.g., corporate structure, staffing, board composition, maintenance of data exchange agreements)
- Clinical (e.g., clinician participation in governance and implementation, identification of clinical priorities, focus on HIE adoption)
- Technical (e.g., technical services for HIE based on common protocols and standards)
- Financial (e.g., maintain financial systems, business plans)
- Privacy and security (e.g., policies and procedures, informed consent, rules governing access to and use of information)

A more detailed description of the requirements can be found at

<http://www.health.state.ny.us/funding/rfa/0708160258/0708160258.zip>

Ensuring trust in use of interoperable health IT

The operation of the SCP, and the issues addressed through statewide policy guidance adopted by NYeC and NYSDOH, are specifically designed to establish trust and maximize the value of interoperable health IT. The broad policy domains for interoperable health IT include (1) clinical requirements, (2) privacy and security, (3) technical standards and specifications for HIE, and (4) policy and technical requirements for EHRs. Many of these policies and standards have specific applicability to the activities funded through the state grant program and therefore reflect contractual obligations for those projects, but some of the policies were designed to ensure broad adoption and use of health IT, particularly those relating to privacy and security.

Clinical: New York's health IT strategy is designed to ensure clinical involvement in governance as well as health IT design and implementation. Clinicians have an important perspective relating to trust in HIE. Having a common set of policies encourages trust by all HIE participants including clinicians. Clinicians also want to have access to a comprehensive set of information for as many patients as possible, so the broad availability of information also engenders trust in use of HIE. Because we require transparent, community oriented governance, clinicians know how the rules of the road are set in their community, which means they will have a better understanding of health plan, hospital and consumer input into the process. In short, clinicians will know who has access to patient information and how their use of the information is being regulated at the local level.

Privacy and security: Policies and standards governing privacy and security are essential to maintain trust in the use of interoperable health IT. NYS has developed policies and procedures through the SCP that address patient consent as well as security requirements which address authentication, access, authorization, audit and breach. The SCP also developed model consent forms which are being used or adapted by the RHIOs; NYS DOH approves all RHIO consent forms. The initial focus was consent for access by an individual provider organization or all of the providers caring for a patient to information for purposes of treatment and quality

improvement; subsequent policies and procedures have been developed governing health plan access and use. Additional policies and procedures for research uses of information will be developed. The consent forms have been translated into multiple languages and are available on the NYeC website (www.nyehealth.org).

Technical standards and specifications for HIE and EHRs: Trust is also engendered through the use of common, nationally published standards and specifications for HIE and EHRs. These standards help to ensure that data is represented in a consistent fashion, and in a manner that can interoperate with a variety of EHR systems. Standards and protocols facilitate broad participation in and access to information through HIE services, and ensuring more information availability will also engender trust. Stakeholders play an important role in selecting standards and designing implementation guidance through the SCP which ensures openness and transparency in the selection process.

Accountability, oversight and enforcement

As noted above, NYS has a coordinated approach to ensure accountability and provide oversight and enforcement for HIE policies. Common policies and standards have been developed through a statewide collaborative process that includes representation from RHIOs, which in turn provide local governance and operational support for policy implementation, including enforcement. RHIOs develop and oversee participation agreements for their stakeholders; they manage the consent process including provision of information to consumers about privacy and security protections, and how consumers can review information disclosures and make inquiries or complaints.

NYS DOH oversees these activities through its contracts with the NY eHealth Collaborative (which manages the SCP) and the projects receiving state grants. With regard to the projects, NYS DOH reviews participation agreements, monitors governance and technical activities, approves patient consent forms, and generally oversees policy implementation at the regional level. If specific contract requirements are not met, the state may withhold funding, establish corrective action plans; if the issues are not resolved, the contract may be terminated and the project sponsor may be excluded from receiving future state grants.

Within the state policy framework, RHIOs develop their own specific procedures to address privacy and security requirements (e.g., implementation of breach disclosure policies) as well as mechanisms to handle consumer or provider complaints or to discipline individual participants who violate RHIO policies and procedures. While they are subject to state requirements and oversight, the RHIOs are self-governing independent entities accountable to their boards of directors and stakeholders for the operation of HIE services in their community.

New York State has also linked adherence to the SPG explicitly as a requirement for certificate of need review for institutional health IT projects over a specified dollar threshold. The goal is to further align health IT policy and implementation at the community level as new health IT projects move forward.

In the near future, NYS DOH will advance a more formalized regulatory model for HIE which will include (1) criteria for RHIOs to access and work with Medicaid claims data and (2) establishing requirements for HIE that will transcend the limited grant funding and contractual

context described above. Specifically, in 2010, legislative language was enacted which provides the commissioner of health broad regulatory authority regarding HIE, including such measures as may be necessary to ensure compliance with federal rules and policies. In addition, NYS DOH has provided funding and specified additional contract deliverables for NYeC to develop recommendations for RHIO or HIE accreditation.

Considerations for ONC

From a state perspective, the future governance model for HIE needs to consider the multiple regulatory and policy roles that states play, and which will need to be aligned from an organizational and policy perspective.

- Many state programs (e.g., Medicaid and public health) are subject to a variety of federal and state requirements, and many states have specific laws governing privacy and confidentiality of health information. In the absence of a comprehensive federal regulatory framework that applies broadly to the health care system and preempts state law, it would make sense to leverage the existing state level regulatory framework and create a federal-state partnership to oversee HIE policy implementation pursuant to national standards.
- The policy committee recently adopted recommendations relating to consumer enrollment in health programs. States also operate a variety of disparate systems for provider enrollment and accountability. The policy committee should convene a workgroup for the purpose of developing national standards for these systems and processes which could both streamline state policies and procedures for provider enrollment, and provide a mechanism to implement standards more broadly.
- A national accreditation program for qualified HIE entities might also be desirable, so long as the development of standards and the implementation of such a program would be conducted in some manner through a multi-stakeholder governance model.