FINAL REPORT AND RECOMMENDATIONS OF THE GOVERNANCE DESIGN GRUP

Contributors:

Bruce Adams, JD
Roderick Bremby
Pat Checko, DrPH
Bill Roberts, JD
Jake Star
Lisa Stump, MS, RPh

August 21, 2018

Report prepared for:
Connecticut Health IT Advisory Council

Prepared by:

Jennifer Richmond, ***Connecticut Health IT Program Management Office***
Michael Matthews, ***CedarBridge Group***
Chris Robinson, ***CedarBridge Group***

CedarBridge Group LLC
515 NW Saltzman Rd. #661
Portland, OR 97229
www.cedarbridgegroup.com

CEDARBRIDGE GROUP

Table of Contents

Acknowledgements 3

Executive Summary and Overview of Recommendations 4

Project Structure and Process 6

- Governance Design Group Project Charter 7
- Stakeholder Representation of Governance Design Group Members 7
- Governance Design Group Process 8
- Governance Building Blocks 9

Background 10

- Components of Governance 10
- Models of Data Sharing and Exchange 12
- Trusted Exchange Framework and Common Agreement (TEFCA) 14

Design Group Recommendations and Considerations 19

- Recommendation 1: Mission, Vision, and Values 19
- Recommendation 2: Critical Success Factors 20
- Recommendation 3: Characteristics of Neutral and Trusted Entity 20
- Recommendation 4: Relationship of the State of Connecticut, HIE Entity, Office of Health Strategy, and Health IT Advisory Council 21
- Recommendation 5: Considerations for Designation of Existing Entity vs. Creation of New Entity 26
- Recommendation 6: Data Governance as Component of Corporate Governance 27
- Recommendation 7: Elements of Trust Agreement 28
- Recommendation 8: Table of Contents for Policies and Procedures 29
- Recommendation 9: Conformance with TEFCA 30

Closing Thoughts 31

Appendix 32

- Select National and State Legislation Reviewed by the Design Group 32
- Additional Considerations 33

Acknowledgements

On behalf of the State of Connecticut, the Executive Director of the Office of Health Strategy, and the Health Information Technology Officer express their sincerest gratitude to all those who participated in the Governance Design Group. A sound governance structure and trust framework provide a critical foundation for successful data sharing and health information exchange in the state. Your insights, perspectives, and wisdom were invaluable in the development of these recommendations and are a testament of your desire to help improve the health and wellbeing of the citizens of Connecticut.

Executive Summary and Overview of Recommendations

Recognizing that successful and sustainable data sharing initiatives are built upon solid foundations of governance and trust, the Health IT Advisory Council chartered a Governance Design Group to develop high-level recommendations for how to best establish an overall health information exchange (HIE) governance framework for Connecticut. Such recommendations were prepared over the course of five meetings of the Governance Design Group from May through July of 2018. The recommendations were presented to the Health IT Advisory Council on July 19, 2018. The Council unanimously approved these recommendations and commended the group for its outstanding work.

The implementation of a governance structure for health information exchange and data sharing requires time, effort, and resources beyond the scope of this Design Group. Rather, this Design Group embraced its charge to provide baseline recommendations and principles from which a more detailed action plan could be developed. This *Final Report and Recommendations of the Governance Design Group* represents the fulfillment of this phase of governance construction.

Guidance regarding the governance of HIE in the state was provided in Public Act No. 17-2 (as amended by Public Act No. 18-91), stating the roles of the executive director of the Office of Health Strategy (OHS), the health information technology officer (HITO), and the Health IT Advisory Council. By law, the Secretary of the Office of Policy and Management (OPM), in collaboration with the executive director of OHS, is empowered to establish or incorporate an entity to implement and operate the Statewide HIE program, as defined by statute.

As a result of this legislative directive, the HITO, with the support of the Health IT Advisory Council, specifically requested the Governance Design Group address the following:

1. Relationship of the State of Connecticut, the HIE entity, OHS, and the Health IT Advisory Council;
2. Pros and cons of establishing a new HIE entity or designating an existing entity to oversee HIE operations;
3. Baseline elements of a trust agreement;
4. Table of contents for HIE policies and procedures; and
5. Critical success factors in HIE governance.

The Governance Design Group, with support and facilitation from CedarBridge Group and the Health Information Technology Program Management Office (HIT PMO), produced high-level governance recommendations based on the following objectives:

1. Develop high-level requirements for the Connecticut HIE governance structure;
2. Define attributes of a “neutral and trusted entity”;
3. Review models of governance used successfully by other state HIEs;
4. Review state and national legislation and regulations that should inform HIE governance; and
5. Review existing trust frameworks and trust agreements commonly used for interoperability and HIE initiatives.

Through the detailed discussion of the Governance Design Group, and facilitated exercises designed by CedarBridge Group, recommendations were developed in nine separate categories that are discussed in

more detail throughout this document. The categories of recommendations, considered "building blocks" by the Governance Design Group, are as follows:

- Mission, vision, and values
- Critical success factors
- Characteristics of a neutral and trusted entity
- Relationship of the State of Connecticut, the HIE entity, OHS, and the Health IT Advisory Council
- Considerations for the creation of a new entity or the designation of an existing entity to oversee HIE operations
- Data governance as a component of corporate governance
- Elements of a trust agreement
- Table of contents for policies and procedures
- Conformance with the Trusted Exchange Framework and Common Agreement (TEFCA)

This *Final Report and Recommendations of the Governance Design Group* represents the conclusion of the Governance Design Group's work. However, the Design Group foresees continued refinement of the governance framework, in support of the statewide HIE and the creation or designation of an entity to oversee HIE operations. The work of this Governance Design Group is a positive step forward in achieving the goal of delivering high-value data sharing services that meet the needs of Connecticut's diverse stakeholder community.

Project Structure and Process

The Office of Health Strategy (OHS) is legislatively charged with the planning, design, implementation, and oversight of health information exchange (HIE) services for the State of Connecticut. As prescribed in Public Act No. 16-77[1]:

There shall be established a State-wide Health Information Exchange to empower consumers to make effective health care decisions, promote patient-centered care, improve the quality, safety, and value of health care, reduce waste and duplication of services, support clinical decision-making, keep confidential health information secure and make progress toward the state's public health goals. [Sec. 6, § 17-b-59d (a)]

During special session in June 2017, Public Act No. 17-2[2], was passed, and further amended by Public Act No. 18-91[3] in May 2018, establishing OHS and the following responsibilities:

(1) Developing and implementing a comprehensive and cohesive health care vision for the state, including, but not limited to, a coordinated state health care cost containment strategy;
(2) Promoting effective health planning and the provision of quality health care in the state in a manner that ensures access for all state residents to cost-effective health care services, avoids the duplication of such services, and improves the availability of financial stability of such services throughout the state;
(3) Directing and overseeing the State Innovation Model (SIM) Initiative and related successor initiatives;
(4) (A) Coordinating the state's health information technology initiatives, (B) seeking funding for and overseeing the planning, implementation and development of policies and procedures for the administration of the all-payer claims database (APCD) program, (C) establishing and maintain a consumer health information Internet web site, and (D) designating an unclassified individual from the office to perform the duties of a health information technology officer (HITO);
(5) Directing and overseeing the Health Systems Planning Unit under, and all of its duties and responsibilities as set forth in chapter 368z; and
(6) Convening forums and meetings with state government and external stakeholders, including, but not limited to, the Connecticut Health Insurance Exchange, to discuss health care issues designed to develop effective health care cost and quality strategies.

As a result, the HITO and the HIT PMO formerly under the Office of Healthcare Advocate (OHA) have been reassigned to OHS as of February 1st, 2018.

Guidance regarding the governance of HIE in the state was provided in PA 17-2, as amended by PA 18-91, re-stating the role of the executive director of OHS, the HITO, and the Health IT Advisory Council. In addition, the statute empowers the Secretary of the Office of Policy and Management, in collaboration

[1] https://www.cga.ct.gov/2016/ACT/pa/pdf/2016PA-00077-R00SB-00289-PA.pdf
[2] https://www.cga.ct.gov/2017/act/pa/pdf/2017PA-00002-R00SB-01502SS1-PA.pdf
[3] https://www.cga.ct.gov/2018/act/pa/pdf/2018PA-00091-R00HB-05290-PA.pdf

with the executive director of OHS, to establish or incorporate an entity to implement and operate the State-wide HIE program, as defined in the statute.

To develop high-level considerations for how to best establish an overall HIE governance framework and structure in Connecticut, the HITO with the support of Health IT Advisory Council commissioned the formation of a time-limited, multi-stakeholder Governance Design Group.

Governance Design Group Project Charter

Building upon previous planning and analysis, including the Environmental Scan[4] and HIE Use Case Design Group recommendations[5], the HITO and the Health IT Advisory Council formally chartered[6] the formation of the Governance Design Group to address the following:

1. Relationship of the State of Connecticut, the HIE entity, OHS, and the Health IT Advisory Council;
2. Pros and cons of either establishing or designating an entity to oversee HIE operations;
3. Baseline elements of a trust agreement;
4. Table of contents for HIE policies and procedures; and
5. Critical success factors in HIE governance.

By addressing the above topics, Connecticut will have a "starter-set" of governance considerations available that supports the delivery of high-value data sharing services operating within a sound governance and trust framework that meet the needs of Connecticut's diverse stakeholder community.

Stakeholder Representation of Governance Design Group Members

The Governance Design Group was commissioned by the HITO, overseen by the Health IT Advisory Council, and supported by the HIT PMO and CedarBridge Group. The list of Governance Design Group members, and the description of their stakeholder representation, can be seen in Table 1 below.

Table 1: Governance Design Group Members

Name	Role and Stakeholder Representation
Bruce Adams, JD	General Counsel in the Office of the Lieutenant General; represents the perspectives of the state and serves as a legal subject matter expert.
Roderick Bremby	Commissioner of the Department of Social Services; represents the perspectives of the state and the Medicaid population. *Commissioner Bremby was supported by Joe Stanford (DSS) and Polly Bentley (HealthTech Solutions).*
Patricia Checko, DrPH	Co-chair of SIM Consumer Advisory Board and Health IT Advisory Council Member; represents the views and needs of consumers and patients and as an advocate for public health.

[4] https://portal.ct.gov/-/media/OHS/Health-IT-Advisory-Council/Reports/Environmental_Scan_Summary_Findings_FINAL_20170523.pdf?la=en
[5] https://portal.ct.gov/-/media/OHS/Health-IT-Advisory-Council/Design-Groups/HIE/HIE_Use_Case_DG_Final_Report_20171101.pdf?la=en
[6] https://portal.ct.gov/-/media/OHS/Health-IT-Advisory-Council/Design-Groups/Governance/GovernanceDGProjectCharterV10-52118-003.pdf?la=en

Bill Roberts, JD	Partner at Shipman & Goodwin LLP, on assignment to the Office of the Attorney General; represents the perspective of the Office of the Attorney General and serves as a legal subject matter expert, specifically in regard to privacy and security.
Jake Star	Chief Information Officer of VNA Community Healthcare and Health IT Advisory Council Member; represents the perspectives of non-hospital and non-physician stakeholders in the larger healthcare team and advises on the needs and challenges of long-term post-acute care providers.
Lisa Stump, MS, RPh	Senior Vice President and Chief Information Officer of Yale New Haven Health and Health IT Advisory Council Member; represents the perspective of a large health system and advises on the needs of academic medical centers.

Governance Design Group Process

The Governance Design Group consisted of five meetings from May through July of 2018. The first two meetings provided Design Group members with background information and helpful context to establish a common understanding of goals, objectives, terminology, best practices, and relevant information. Over the course of the remaining meetings, CedarBridge Group led Design Group members through nine separate "building block" exercises in which background materials and presentations were used to inform and frame discussions. Each exercise, and the associated outcome, were captured as initial recommendations and considerations and were re-validated amongst Design Group members at the following meeting. The Design Group meeting schedule is detailed in Table 2 below.

Table 2: Design Group Meeting Schedule

Meetings	Topics and Exercises
Meeting 1 *May 23, 2018*	• Background and Overview • Best Practices
Meeting 2 *June 6, 2018*	• Background and Overview • Best Practices • **Building Block Exercise:** Critical success factors
Meeting 3 *June 14, 2018*	• Confirm outcome of exercise from June 6 meeting • **Building Block Exercise:** Characteristics of a neutral and trusted entity • **Building Block Exercise:** Elements of a trust agreement • **Building Block Exercise:** Table of contents for policies and procedures
Meeting 4 *June 20, 2018*	• Confirm outcomes of exercises from June 14 meeting • **Building Block Exercise:** Relationship of the State of Connecticut, the HIE entity, OHS, and the Health IT Advisory Council • **Building Block Exercise:** Data governance as a component of corporate governance • **Building Block Exercise:** Considerations for the creation of a new entity or the designation of an existing entity to oversee HIE operations

Meeting 5 *July 11, 2018*	• Confirm outcomes of exercises from June 20 meeting • **Building Block Exercise:** Mission, vision, and values • **Building Block Exercise:** Conformance with TEFCA • Validation of all recommendations before presentation to Health IT Advisory Council (July 19, 2018)
Health IT Advisory Council Meeting *July 19, 2018*	• Presentation of recommendations *(unanimously approved)*

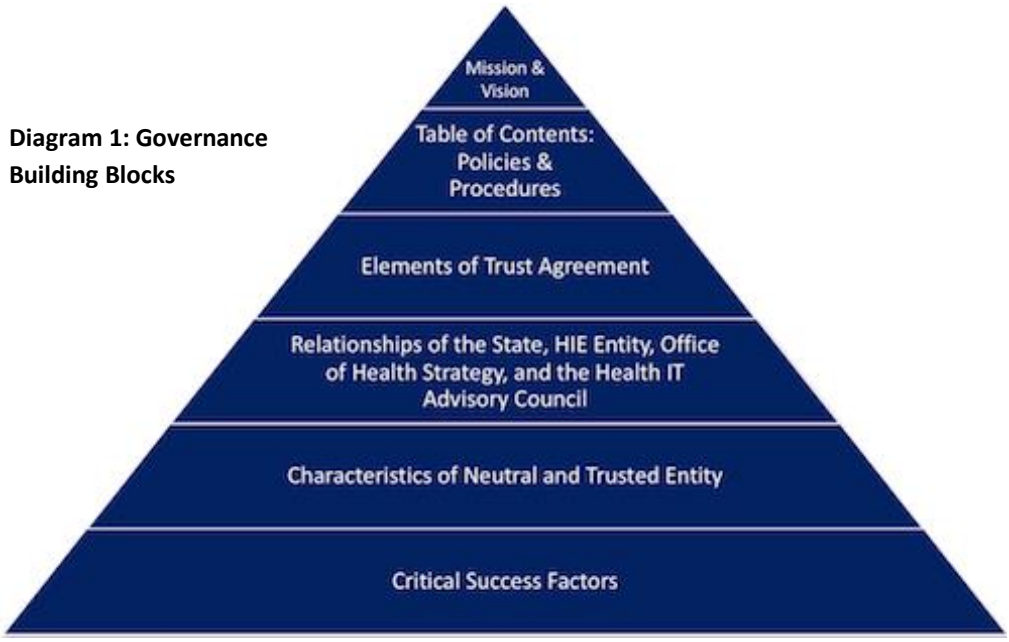
Governance Building Blocks

Recognizing the enormity of the challenge of developing recommendations for governance and trust, a "building block" approach was undertaken by the Design Group to address various aspects of governance. These building blocks would then be melded together into a comprehensive set of recommendations and considerations.

As displayed in Diagram 1, the Governance Design Group considers mission and vision to be of highest consideration in the creation of a governance and trust framework. Likewise, critical success factors must be identified and embraced to ensure the organization responsible for data sharing and health information exchange can bring tangible and sustainable value to Connecticut's diverse stakeholders. In between the mission and vision and the critical success factors building blocks lie important strategic and tactical considerations, such as the characteristics of the HIE entity, elements of the trust agreement that establishes common "rules of the road" for exchange, and robust policies and procedures that guide the organization's day-to-day operations.

Each meeting, the Governance Design Group addressed several building blocks and developed recommendations and considerations for each. These recommendations and considerations are discussed in detail later in the document.

Diagram 1: Governance Building Blocks



Background

Components of Governance

In May of 2013, the Office of the National Coordinator for Health Information Technology (ONC) released the *Governance Framework for Trusted Health Information Exchange.*[7] The intention of this document was to serve as ONC's guiding principles on HIE governance and to provide a "common conceptual foundation applicable to all types of governance models." ONC organized their guiding principles into four overarching categories: organizational principles, trust principles, business principles, and technical principles.

Diagram 2: ONC Governance Principles

These ONC principles were reviewed as part of the Governance Design Group process in order to provide background and context regarding the federal government's perspective of HIE governance, and the key principles that should be considered when establishing a governance framework. The following ONC principles were reviewed with Design Group members:

Organizational Principles: *The entity that sets HIE policy plays a central role in the success of an electronic HIE initiative. It has a primary responsibility to instill confidence among governed organizations, their users, and other exchange partners regarding the way in which electronic exchange is conducted. With respect to the way in which an entity sets HIE policy performs its duties, ONC believes that it should:*

- Operate with transparency and openness.
- Establish mechanisms to ensure that the entity's policies and practices and applicable federal and state laws and regulations are adhered to.
- Promote inclusive participation and adequate stakeholder representation (especially among patients and patient advocates) in the development of policies and practices.
- Ensure oversight is consistent and equitable.
- Provide due process to the stakeholders to which the organization provides oversight.

Trust Principles: *Trust is a prerequisite for electronic HIE and starts with patients. Without trust, the ultimate success of an electronic HIE initiative could be jeopardized. With respect to trust, ONC believes an entity that sets HIE policy is responsible for creating an environment in which patients should:*

- Be able to publicly access, in lay person terms, a "Notice of Data Practices." Such notice would explain the purpose(s) for which personally identifiable and de-identified data, consistent with applicable laws, would or could be electronically exchanged.

[7] https://www.healthit.gov/sites/default/files/GovernanceFrameworkTrustedEHIE_Final.pdf

- Receive a simple explanation of the privacy and security policies and practices that are in place to protect their personally identifiable information when it is electronically exchanges and who is permitted to access and use electronic HIE services.
- Consistent with applicable laws, be provided with meaningful choice as to whether their personally identifiable information can be electronically exchanged.
- Consistent with applicable laws, be able to request data exchange limits based on data type or source.
- Consistent with applicable laws, be able to electronically access and request corrections to their personally identifiable information.
- Be assured that their personally identifiable information is consistently and accurately matched when electronically exchanged.

Business Principles: *Successful electronic HIE requires cooperation among all parties. Responsible financial and operational HIE policy is vital to improving care coordination, improving the efficiency of health care delivery, and mitigating behaviors that could result in proprietary networks and resistance to exchanging information even when it could enhance patient care. With respect to how an entity that sets HIE policy ensures electronic exchange occurs with the patient's best interests in mind, ONC believes that it should:*

- Set standards of participation that promote collaboration and avoid instances where (even when permitted by law) differences in fees, policies, services, or contracts would prevent patients' health information from being electronically exchanged.
- Provide open access to exchange services that would enable local, regional, and nationwide partners to identify who they can electronically exchange information with and how such exchange could be completed under applicable laws and regulations.
- Publish statistics describing their electronic exchange capacity, including, for example: number of users, the types of standards implemented, number of patient lives covered, and transaction volume.
- Maintain and disseminate up-to-date information about: compliance with relevant statutory and regulatory requirements; available standards; potential security vulnerabilities; and best practices developed for HIE.

Technical Principles: *Electronic HIE requires technical conformance at multiple levels and the consistent implementation of highly specified and rigorously tested implementation specification. With respect to the expectations of technical conformance and use of standards an entity that sets HIE policy promotes, ONC believes that it should:*

- Ensure that technology is implemented to support the Trust and Business Principles.
- Prioritize, where available, the exclusive use of federal vocabulary, content, transport, and security standards and associated implementation specification adopted to support HIE.
- Encourage the use of vocabulary, content, transport, and security standards, and associated implementation specifications developed by voluntary consensus standards organizations (VCSOs) when equivalent federal standards have not been adopted.
- Lead engagement in VCSOs and national efforts to accelerate standards development and consensus on the adoption of standards as well as the improvement of existing standards.

- Work with VCSOs to develop standards for specific use cases and volunteer to pilot and use new standards when no such standards exist.
- Take an active role in the development and implementation of conformance assessment and testing methods for HIE and utilization (or promote the use of) testing methods developed to assess compliance with federal standards.

Models of Data Sharing and Exchange

As Connecticut is embarking on the mission for a statewide HIE, it is important to recognize, study, and build upon the lessons learned and successes of other regional, state, and national HIE initiatives. In advance of the Governance Design Group, OHS and the HIT PMO conducted extensive background research on trust frameworks and models of data sharing and exchange used by existing data sharing initiatives. A matrix displaying this trust framework analysis was produced by OHS and distributed to Design Group members as a supplemental resource. This matrix analyzed the trust framework for the following organizations and initiatives:

- The eHealth Exchange (The Sequoia Project)
- Carequality (The Sequoia Project)
- CommonWell Health Alliance
- Michigan Health Information Network Shared Services (MiHIN)
- Massachusetts Health Information HIway (Mass HIway)
- CurrentCare (Rhode Island Quality Institute)
- State Health Information Network of New York (SHIN-NY) and the New York eHealth Collaborative (NYeC)
- HealthInfoNet (Independent, non-profit organization and Maine's State Designated Entity)
- Delaware Health Information Network (DHIN)
- Chesapeake Regional Information System for our Patients (CRISP)
- ConnectVirginia HIE
- California Association of Health Information Exchanges (CAHIE)

The trust framework analysis matrix was organized into the categories and sub-categories listed in Table 3 below. Analyses identified common elements shared across these agreements and similarities and differences within the elements. In addition to the analysis on trust frameworks, the matrix included an analysis of the Trusted Exchange Framework and Common Agreement (TEFCA), the Health Insurance Portability and Accountability Act (HIPAA), Connecticut statutes, a list of associated resources available from the above organizations and initiatives, and a list of relevant definitions.

Table 3: Trust Framework Analysis Matrix Categories

Purpose & Scope	Allocation of Liability and Risk	Permitted Uses	Permitted Participants
• HIE / Network Entity • Goal • Scope of Services • Signed National Agreements • Approach to Establishing Trust • Governance Structure • Operational Policies / Procedures	• Liability and Limitation of Liability • Indemnification	• Permitted Purposes • Retention and Re-use	• Permitted Participants
Identity Proofing and Authentication	**Technical Approach and Infrastructure**	**Cooperation and Non-Discrimination**	**Accountability**
• Identity Proofing and Authentication	• Architecture • Standards	• Cooperation and Non-discrimination	• Technical • Network Flow-down • Enforcement • Dispute Resolution
Consent Model	**Transparency**	**Privacy & Security**	**Access**
• Consent Model • Opt-out	• Fees	• HIPAA and National Institute of Standards and Technology (NIST) Cybersecurity Standards • Breach Notification	• Identity (Patient) Access

As part of the Governance Design Group meetings, members were presented with a high-level review of specific documents from existing entities and organizations, in order to inform the associated building block exercises. The reviewed documentation was provided to Design Group members as a reading assignment between meetings to further inform exercises. The following documents were reviewed by the Design Group:

- ConnectVirginia Policy and Procedure Manual[8] – *dated December 2014*
- CRISP Policies and Procedures[9] - *v8 dated February 3, 2016*
- SHIN-NY Privacy and Security Policies and Procedures for Qualified Entities and their Participants in New York State under NYCRR § 300.3(b)(1)[10] – *v3.5 dated January 2018*
- ConnectVirginia EXCHANGE Trust Agreement[11] – *dated October 8, 2014*
- CRISP HIE Participation Agreement[12] – *dated July 2014*

[8] https://www.connectvirginia.org/wp-content/uploads/2014/12/ConnectVirginia-Policy-and-Procedure-Manual-12-2014.pdf
[9] https://www.crisphealth.org/wp-content/uploads/2016/08/CRISP-Policies-and-Procedures-v8-Feb-3-2016.pdf
[10] https://www.health.ny.gov/technology/regulations/shin-ny/docs/privacy_and_security_policies.pdf
[11] https://www.connectvirginia.org/wp-content/uploads/2015/03/ConnectVirginia-REVISED-Exchange-Trust-Agreement-10-08-14.pdf
[12] https://www.crisphealth.org/wp-content/uploads/2016/08/CRISP-DC-Participation-Agreement-July-2014.pdf

- eHealth Exchange Restatement I of the Data Use and Reciprocal Support Agreement (DURSA)[13] – *dated September 30, 2014*

In addition to the above documentation, the Design Group members received an in-depth presentation[14] from Jeff Livesay, Senior Executive Vice President of MiHIN and its subsidiary, Velatura, regarding the MiHIN trust framework and legal agreements, including the Qualified Data Sharing Organization Agreement (QDSOA), Data Sharing Agreement, Master Use Case Agreement, and Use Case Exhibits.

The Governance Design Group reviewed the concept of a "network of networks" and a diagram adapted from MiHIN. This diagram, provided below as Diagram 3, illustrates a model in which a common statewide service utility connects various Connecticut, federal, and private stakeholder networks and individual participants (providers, clinics, hospitals, etc.) under uniform contract terms and "rules of the road" that are applied to all participants and flow down to exchange partners of participants.

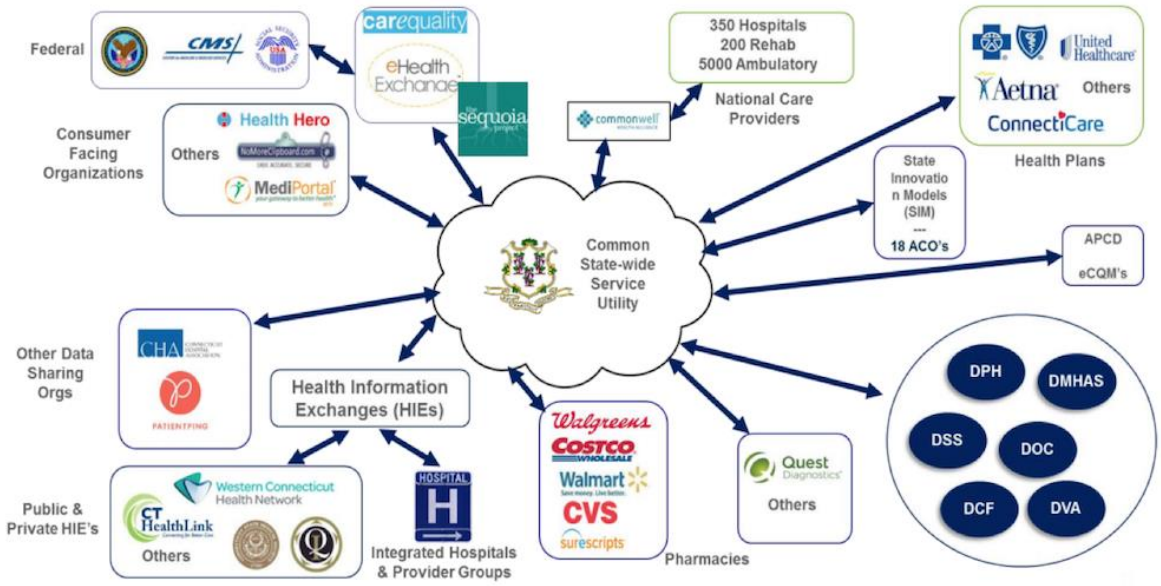


Diagram 3: Connecticut Network of Networks

Trusted Exchange Framework and Common Agreement (TEFCA)

As summarized by the Healthcare Information and Management Systems Society (HIMSS), the "21st Century Cures Act,[15] signed December 13, 2016, by President Barack Obama, promotes and funds the acceleration of research into preventing and curing serious illnesses; accelerates drug and medical device development; attempts to address the opioid abuse crisis; and tries to improve mental health

[13] https://sequoiaproject.org/wp-content/uploads/2017/01/Restatement_I_of_the_DURSA_9.30.14_final.pdf
[14] https://portal.ct.gov/-/media/OHS/Health-IT-Advisory-Council/Design-Groups/Governance/Meeting-5/GovernanceDesignGroup_Session5_Presentation_201800711.pdf?la=en
[15] https://docs.house.gov/billsthisweek/20161128/CPRT-114-HPRT-RU00-SAHR34.pdf

service delivery. The Act includes a number of provisions that push for greater interoperability, adoption of electronic health records (EHRs) and support for human services programs."[16]

Of particular relevance for the Governance Design Group were the aspects related to interoperability, specifically the mandate for ONC to create a trusted exchange framework, including a common agreement among health information networks (HINs) nationally. The central premise of ONC's approach to the TEFCA is that much success has been realized in the sharing of health information, but such sharing is still not ubiquitous and the effort to conduct sharing is too burdensome. A draft framework was published by ONC on January 5, 2018 and listening sessions and a public comment period resulted in significant feedback that is now under ONC review and consideration.

It was expected that the final version of the TEFCA would be published during the course of Governance Design Group discussions. However, the draft framework was still of interest and relevance to the considerations of the Governance Design Group and a review and discussion occurred over the course of the Design Group. A few highlights of the TEFCA information reviewed by the Design Group include:[17]

- In the current environment, there is a proliferation of agreements in which many organizations have to join multiple HINs, and the HINs do not share data with each other. ONC's visualization of today's current network complexity is seen in Diagram 4.
- ONC outlined principles of Trusted Exchange, including:
    - **Standardization:** Adhere to industry and federally recognized standards, policies, best practices, and procedures.
    - **Transparency:** Conduct all exchange openly and transparently.
    - **Cooperation and Non-Discrimination:** Collaborate with stakeholders across the continuum of care to exchange electronic health information, even when a stakeholder may be a business competitor.
    - **Security and Patient Safety:** Exchange electronic health information securely and in a manner that promotes patient safety and ensures data integrity.

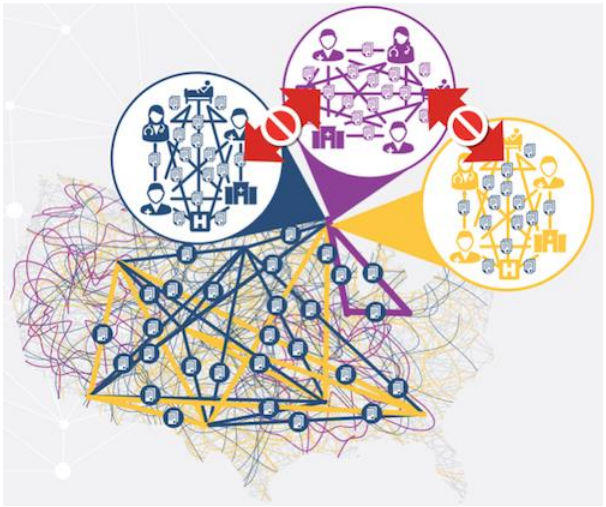


Diagram 4: ONC visualization of network complexity

    - **Access:** Ensure that patients and their caregivers have easy access to the electronic health information.
    - **Data-driven Accountability:** Exchange multiple records at one time to enable identification and trending of data to lower the cost of care and improve the health of the population.
- ONC outlined the goals of the draft Trusted Exchange Framework:
    - **Goal 1:** Build on an extend existing work done by the industry

[16] https://www.himss.org/news/21st-century-cures-act-summary
[17] https://www.healthit.gov/sites/default/files/draft-guide.pdf

    - **Goal 2:** Provide a single "on-ramp" to interoperability for all
    - **Goal 3:** Be scalable to support the entire nation
    - **Goal 4:** Build a competitive market allowing all to compete on data services
    - **Goal 5:** Achieve long-term sustainability
- ONC outlined the stakeholders who will be able to use the Trusted Exchange Framework:
    - **Health Information Networks**
    - **Federal Agencies:** Federal, state, tribal and local governments
    - **Individuals:** Patients, caregivers, authorized representatives, and family members serving in a non-professional role
    - **Providers:** Professional care providers who deliver care across the continuum, not limited to but including ambulatory, long-term and post-acute care (LTPAC), emergency medical services (EMS), behavioral health, and home and community-based services
    - **Public Health:** Public and private organizations and agencies working collectively to prevent, promote, and protect the health of communities by supporting efforts around essential public health services
    - **Payers:** Private payers, employers, and public payers that pay for programs like Medicare, Medicaid, and TRICARE.
    - **Technology Developers:** Organizations that provide health IT capabilities, including but not limited to EHRs, HIE technology, analytics products, laboratory information systems, personal health records, Qualified Clinical Data Registries (QCDRs), registries, pharmacy systems, mobile technology, and other technology that provides health IT capabilities and services.
- ONC outlined how the Trusted Exchange Framework will work, as seen in Diagram 5, including draft definitions for HINs, Qualified Health Information Networks (QHINs), the Recognized Coordinating Entity (RCE), Connectivity Brokers, Participants, and End Users:
    - **HINs** are an Individual or Entity that:
        - Determines, oversees, or administers policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities;
        - Provides, manages, or controls any technology or service that enables or facilitates the exchange of electronic health information between or among two or more unaffiliated individuals or entities; or
        - Exercises substantial influence or control with respect to the access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities.
    - **QHINs** (or Qualified HINs) must meet all of the requirements of a HIN (outlined above). In addition, it must also:
        - Be able to locate and transmit electronic protected health information (ePHI) between multiple persons and/or entities electronically;
        - Have mechanisms in place to impose Minimum Core Obligations and to audit Participants' compliance;
        - Have controls and utilize a Connectivity Broker service;

- Be participant neutral; and
- Have participants that are actively exchanging the data included in the U.S. Core Data for Interoperability (USCDI)[18] in a live clinical environment.
- Structure of a QHIN:
    - A **Connectivity Broker** is a service provided by a QHIN that provides all of the following functions with respect to all Permitted Purposes: Master Patient Index (federated or centralized); Record Locator Service; Broadcast and Directed Queries, and electronic health information return to an authorized requesting QHIN.
    - A **Participant** is a person or entity that participates in the QHIN. Participants connect to each other through the QHIN, and they access organizations not included in their QHIN through QHIN-to-QHIN connectivity. Participants can be HINs, EHR vendors, and other types of organizations.
    - An **End User** is an individual or organization that use the services of a participant to send and/or receive electronic health information.

- **Recognized Coordinating Entity (RCE):**
    - Entity selected by ONC that will enter into agreements with HINs that qualify and elect to become QHINs in order to impose, at a minimum, the requirements of the Common Agreement on the QHINs and administer such requirements on an ongoing basis.
    - The RCE will act as a governing body that will operationalize the Trusted Exchange Framework by incorporating it into a single, all-encompassing Common Agreement to which QHINs will agree to abide.
    - The RCE, in its capacity as a governing body, will be expected to monitor QHINs with the final TEFCA and take actions to remediate non-conformity and non-compliance.
    - The RCE will be expected to work collaboratively with stakeholders from across the industry to build and implement new use cases that can use the final TEFCA as their foundation, and appropriately update the TECA over time to account for new technologies, policies, and use cases.

[18] https://www.healthit.gov/sites/default/files/draft-uscdi.pdf

Diagram 5: ONC visualization of how the Trusted Exchange Framework will work

- ONC outlined the draft Permitted Purposes, including:
  - Public Health
  - Treatments
  - Benefits Determination
  - Payment
  - Individual Access
  - Healthcare Operations
- ONC outlined a draft timeline for the implementation of TEFCA, as seen in Diagram 6. This timeline was discussed by the Design Group members and it was recognized that it is likely this timeline will be delayed, based on currently available information.

Diagram 6: ONC's draft timeline for TEFCA implementation

Design Group Recommendations and Considerations

Recommendation 1: Mission, Vision, and Values

As a building block exercise, the Governance Design Group reviewed the concepts and elements of mission and vision statements. The Design Group members were tasked with developing high-level considerations that could be used to inform the development of a mission statement and vision statement by the HIE entity in the future, once such entity is established or designated. Design Group members were not asked to draft the actual language of mission and vision statements for the HIE entity.

As part of this exercise, the following definitions were presented to Design Group members to inform and frame their considerations:

- A **Mission Statement** defines the company's business, its objectives and its approach to reach those objectives. A **Vision Statement** describes the desired future position of the company. Elements of Mission and Vision Statements are often combined to provide a statement of the company's purpose, goals, and values. However, sometimes the two terms are used interchangeably.[19]
- At its core, a **company's purpose** is a bold affirmation of its reason for being in business. It conveys what the organization stands for in historical, ethical, emotional, and practical terms. No matter how it's communicated to employees and customers, a company's purpose is the driving force that enables a company to define its true brand and create its desired culture.[20]

In addition, Simon Sinek's concept of "Start with Why[21]" was reviewed by Design Group members. This concept puts "why" in the center of the "The Golden Circle" for organizations. Sinek says, "Every organization on the planet knows WHAT they do. These are the products and services they offer. Some organizations know HOW they do it. These are the things that make them special or set them apart from their competition. Very few organizations know WHY they do what they do. WHY is not about making money. That's a result. WHY is a purpose, cause, or belief. It's the very reason your organization exists."

As a starting point for mission, vision, and value considerations, the Design Group were presented with the recommendations from the May 23, 2017 Environmental Scan report, *Assessing Connecticut's Health Information Technology & Health Information Exchange Services: Summary Findings or Current State, Future Needs, and Recommendations for Action*[22]. Following a review of these Environmental Scan recommendations, the following considerations were developed by the Governance Design Group:

The mission, vision, and values of the HIE entity should be informed by the Environmental Scan recommendations approved by the Health IT Advisory Council in May 2017, and expanded to include the following:

[19] https://hbr.org/2014/09/your-companys-purpose-is-not-its-vision-mission-or-values
[20] https://news.gallup.com/businessjournal/184376/company-purpose-lot-words.aspx
[21] Sinek, S. (2009). *Start with why: How great leaders inspire everyone to take action*. New York, N.Y.: Portfolio.
[22] https://portal.ct.gov/-/media/OHS/Health-IT-AdvisoryCouncil/Reports/Environmental_Scan_Summary_Findings_FINAL_20170523.pdf?la=en

- Keep patients and consumers as the most important stakeholder group and a primary focus in all efforts to improve health IT and HIE (patient as the "North Star");
- Leverage existing national and state-based interoperability initiatives;
- Implement core technology, such as identity services, that complements and interoperates with systems currently in place;
- Build trust by implementing common "rules of the road" that provide a sound policy framework;
- Support value-based care initiatives such as Accountable Care Organizations (ACOs) and Clinically Integrated Networks (CINs);
- Ensure all stakeholders can participate in standards-based data sharing;
- Implement workflow tools that improve efficiency and effectiveness; and
- Ensure data are meaningful and create tangible value for stakeholders.

Recommendation 2: Critical Success Factors

As part of the Governance Design Group's building block exercises, members developed a list of recommended critical success factors for the future HIE entity. The development of the recommended critical success factors was the first building block exercise conducted by the Design Group and helped to frame subsequent exercises. The concept of success and its contributing factors can be highly subjective; Design Group members were encouraged to bring forth personal and professional perspectives, as well as the view of represented stakeholders as part of the discussion. The Governance Design Group recommendations for critical success factors are as follows:

Factors critical to the success of the HIE entity should be identified, adopted, and used to underpin governance, strategy, and operations. Initial considerations should be given to the following:

- Alignment with Connecticut statutes
- Alignment with Federal statutes
- Compatibility with national interoperability initiatives, including TEFCA
    - Note that this may require alignment of Connecticut statutes
- Stakeholder engagement, support, and participation
- Sustainability supported by stakeholder buy-in and aligned financial incentives
- Foundation for trust
- Reliable, accessible, and secure technology
- Tangible value to stakeholders
- Neutrality, i.e. no competitive advantage to any one stakeholder or segment
- Consumer confidence in the security, confidentiality, and use of their data
- Clear roadmap for HIE development and use case implementation that fosters early participation and ongoing support for those who participate in later use cases
- Remain flexible in order to adapt to a dynamic market

Recommendation 3: Characteristics of Neutral and Trusted Entity

Connecticut Public Act 17-2, as amended by Public Act 18-91, stated that one of the purposes of the program to expedite the development of the statewide HIE shall be to "assist the State-wide Health Information Exchange in establishing and maintaining itself as a neutral and trusted entity that serves

the public good for the benefit of all Connecticut residents." Building on this legislative directive, the Environmental Scan of May 2017 put forth the recommendation that "Connecticut should establish, or designate, a neutral, trusted, organization representing public and private interests to operate agreed-to statewide health information exchange services. The organization should adhere to best practices in health information governance."

As a result of this statutory and advisory precedent, the concepts of neutrality and trust were central tenants of the Governance Design Group's process and discussions. Governance Design Group members were tasked with developing a list of characteristics to be adopted by the future HIE entity to ensure that neutrality is established and maintained, and that such entity successfully builds trust amongst the diverse stakeholder groups of Connecticut. The Governance Design Group recommendations for the characteristics of a neutral and trusted entity are as follows:

The HIE entity, serving as the corporate home for the exchange of health information, should be neutral and trusted. The following are suggested attributes and values for the HIE entity:

- **To be neutral, the entity should:**
  - Serve the public good and be of benefit for all Connecticut residents
  - Provide no competitive advantage for any group of stakeholders
  - Be owned and governed by a party or parties other than the state
  - Be governed by an engaged board of directors representing private and public-sector leaders with decision-making authority in the organizations that they represent
  - Make business decisions based on value-creation, leading to financial sustainability
  - Balance value creation across stakeholder groups

- **To be trusted, the entity should:**
  - Provide a trust framework that establishes clear "rules of the road" including enforcement authority related to compliance
  - Be accountable and transparent to stakeholders
  - Conduct business based on sound policies and procedures
  - Employ a consensus-driven approach for decision-making
  - Have transparent contracting and purchasing practices
  - Obtain external certification or audit from an information security perspective

Recommendation 4: Relationship of the State of Connecticut, HIE Entity, Office of Health Strategy, and Health IT Advisory Council

The State of Connecticut, OHS, the Health IT Advisory Council, and the HIE entity, once established or designated, will have relationships with numerous touch-points and intersections. Many aspects of these relationships are currently defined in statute, including the requirement for the HIE entity to fulfill the purposes of OHS. As part of the Governance Design Group, members reviewed relevant legislation pertaining to these relationships and were tasked with confirming the current structure or developing

additional considerations or recommendations. In particular, members reviewed relevant provisions from Connecticut Public Act 17-2, as amended by Public Act 18-91, including:

- **Section 1a:** There is established an Office of Health Strategy, which shall be within the Department of Public Health for administrative purposes only. The department head of said office shall be the executive director of the Office of Health Strategy, who shall be appointed by the Governor in accordance with the provisions of sections 4-5 to 4-8, inclusive, as amended by PA 18-91, with the powers and duties therein prescribed.
- **Section 1b:** OHS shall be responsible for the following:
    - (1) Developing and implementing a comprehensive and cohesive health care vision for the state, including, but not limited to, a coordinated state health care cost containment strategy;
    - (2) Promoting effective health planning and the provision of quality health care in the state in a manner that ensures access for all state residents to cost-effective health care services, avoids the duplication of such services, and improves the availability and financial sustainability of such services throughout the state;
    - (3) Directing and overseeing SIM and related successor initiatives;
    - (4) (A) Coordinating the state's health information technology initiatives, (B) seeking funding for and overseeing the planning, implementation, and development of policies and procedures for the administration of the APCD program established under section 19a-775a, as amended by PA 18-91, (C) establishing and maintaining a consumer health information internet web site under section 19a-755b, as amended by PA 18-91, and (D) designating an unclassified individual from the office to perform the duties of HITO, as set forth in sections 17b-59f and 17b-59g, as amended by PA 18-91;
    - (5) Directing and overseeing the Health Systems Planning Unit established under section 19a-612, as amended by PA 18-91, and all of its duties and responsibilities as set forth in chapter 368z; and
    - (6) Convening forums and meetings with state government and external stakeholders, including, but not limited to, the Connecticut HIE, to discuss health care issues designed to develop effective health care cost and quality strategies.
- **Section 4b (1):** There is established an APCD program. OHS shall:
    - (A) Oversee the planning, implementation, and administration of the APCD program for the purpose of collecting, accessing, and reporting health care information relating to safety, quality and cost-effectiveness, access, and efficiency for all levels of health care;
    - (B) Ensure that data received is securely collected, compiled, and stored, in accordance with state and federal law;
    - (C) Conduct audits of data submitted by reporting entities in order to verify its accuracy; and
    - (D) In consultation with the Health Information Technology Advisory Council established under section 17b-59f, as amended by PA 18-91, maintain written procedures for the administration of such APCD. Any such written procedures shall include (i) reporting

requirements for reporting entities, and (ii) requirements for providing notice to a reporting entity regarding any alleged failure on the part of such reporting entity to comply with such reporting requirements.

- **Section 4b (5):** The executive director of OHS shall:
  - (A) Utilize data in the APCD base to provide health care consumers in the state with information concerning cost and quality of health care services for the purpose of allowing such consumers to make economically sound and medically appropriate health care decisions; and
  - (B) Make data in the APCD available to any state agency, insurer, health care provider, consumer of health care services, or researcher for the purposes of allowing such person or entity to review such data as it relates to health care utilization, costs, or quality of health care services. The executive director of OHS may set a fee to be charged to each person or entity requesting access to data stored in the APCD.
- **Section 11a:** There shall be a State Health Information Technology Advisory Council to advise the executive director of OHS and the HITO in developing priorities and policy recommendations for advancing the state's health IT and HIE efforts and goals and to advise the executive director and HITO in the development and implementation of the state-wide health IT plan and standards for the state-wide HIE. The advisory council shall also advise the executive director and HITO regarding the development of appropriate governance, oversight, and accountability measures to ensure success in achieving the state's health IT and exchange goals.
- **Section 11b:** The council shall consist of the following members:
  - (1) One member appointed by the executive director of OHS, who shall be expert in state health care reform initiatives;
  - (2) The HITO, or their designee;
  - (3) The Commissioners of Social Services, Mental Health and Addiction Services, Children and Families, Correction, Public Health, and Developmental Services, or the Commissioners' designees;
  - (4) The chief information officer of the state, or their designee;
  - (5) The CEO of the Connecticut Health Insurance Exchange, or their designee;
  - (6) The chief information officer of the University of Connecticut Health Center, or their designee;
  - (7) The Healthcare Advocate, or their designee;
  - (8) The Comptroller, or their designee;
  - (9) Five members appointed by the Governor, one each who shall be (A) a representative of a health system that includes more than one hospital, (B) a representative of the health insurance industry, (C) an expert in health IT, (D) a health care consumer or consumer advocate, and (E) a current or former employee or trustee of a plan established pursuant to subdivision (5) of subsection (c) of 29 USC 186;
  - (10) Three members appointed by the president pro tempore of the Senate, one each who shall be (A) a representative of a federally qualified health center (FQHC), (B) a provider of behavioral health services, and (C) a physician licensed under chapter 370;

- (11) Three members appointed by the speaker of the House of Representatives, one each who shall be (A) a technology expert who represents a hospital system, as defined in section 19a-486i, as amended by PA 18-91, (B) a provider of home health care services, and (C) a health care consumer or a health care consumer advocate;
- (12) One member appointed by the majority leader of the Senate, who shall be a representative of an independent community hospital;
- (13) One member appointed by the majority leader of the House of Representatives, who shall be a physician who provides services in a multispecialty group and who is not employed by a hospital;
- (14) One member appointed by the minority leader of the Senate, who shall be a primary care physician who provides services in a small independent practice;
- (15) One member appointed by the minority leader of the House of Representatives, who shall be an expert in health care analytics and quality analysis;
- (16) The president pro tempore of the Senate, or their designee;
- (17) The speaker of the House of Representatives, or their designee;
- (18) The minority leader of the Senate, or their designee; and
- (19) The minority leader of the House of Representatives, or their designee.

- **Section 11d (1):** The HITO shall serve as chairperson of the Health IT Advisory Council. The council shall elect the second chairperson from among its members, who shall not be a state official. The chairpersons of the council may establish subcommittees and working groups and may appoint individuals other than members of the council to serve as members of the subcommittees or working groups.
  - (2) The chairpersons of the council may appoint up to four additional members to the council, who shall serve at the pleasure of the chairpersons.
- **Section 11e (1):** The council shall establish a working group to be known as the All-Payer Claims Database Advisory Group. Said group shall include, but not be limited to, (A) the Secretary of OPM, the Comptroller, the Commissioners of Public Health, Social Services, and Mental Health and Addiction Services, the Insurance Commissioner, the Healthcare Advocate, and the Chief Information Officer, or their designees; (B) a representative of the Connecticut State Medical Society; and (C) representatives of health insurance companies, health insurance purchasers, hospitals, consumer advocates, and health care providers. The HITO may appoint additional members to said group.
- **Section 12a:** The state, acting by and through the Secretary of OPM, in collaboration with the executive director of the OHS, shall establish a program to expedite the development of the State-wide HIE to assist the state, health care providers, insurance carriers, physicians, and all stakeholder in empowering consumers to make effective health care decisions, promote patient-centered care, improve the quality, safety, and value of health care, reduce waste and duplication of services, support clinical decision-making, keep confidential health information secure, and progress toward the state's public health goals. The purposes of the program shall be to:

  - (1) Assist the State-wide Health Information Exchange in establishing and maintaining itself as a neutral and trusted entity that serves the public good for the benefit of all Connecticut residents;
  - (2) Perform, on behalf of the state, the role of intermediary between public and private stakeholders and customers of the State-wide HIE; and
  - (3) Fulfill responsibilities of OHS, as described in Section 19a-754a, as amended by PA 18-91.
- **Section 12b:** The executive director of OHS, in consultation with the HITO, shall design, and the Secretary of OPM, in collaboration with said executive director, may establish or incorporate an entity to implement the program established under subsection (a). Such entity shall, without limitation, be owned and governed, in whole or in part, by a party or parties other than the state and may be organized as a nonprofit entity.
- **Section 12c:** Any entity established or incorporated pursuant to subsection (b) shall have its powers vested in and exercised by a board of directors. The board of directors shall be comprised of the following members who shall each serve for a term of two years:
  - (1) One member who shall have expertise as an advocate for consumers of health care (appointed by the Governor);
  - (2) One member who shall have expertise as a clinical medical doctor (appointed by the president pro tempore of the Senate);
  - (3) One member who shall have expertise in the area of hospital administration (appointed by the speaker of the House of Representatives);
  - (4) One member who shall have expertise in the area of corporate law or finance (appointed by the minority leader of the Senate);
  - (5) One member who shall have expertise in group health insurance coverage (appointed by the minority leader of the House of Representatives);
  - (6) The Chief Information Office and the Secretary of OPM, or their designees, who shall serve as ex -officio, voting members of the board; and
  - (7) The HITO, who shall serve as chairperson of the board.
- **Section 12e:** Any entity established or incorporated under subsection (b) may:
  - (1) Employ a staff and fix their duties, qualifications, and compensation;
  - (2) Solicit, receive, and accept aid or contributions, including money, property, labor, and other things of value from any source;
  - (3) Receive, and manage on behalf of the state, funding from the federal government, and other public sources or private sources to cover costs associated with the planning, implementation, and administration of the State-wide HIE;
  - (4) Collect and remit fees set by the HITO charged to persons or entities for access to or interaction with said HIE;
  - (5) Retain outside consultants and technical experts;
  - (6) Maintain an office in the state at such place or places as such entity may designate;
  - (7) Procure insurance against loss in connection with such entity's property and other assets in such amounts and from such insurers as such entity deems desirable;

- (8) Sue and be sued and plead and be impleaded;
- (9) Borrow money for the purpose of obtaining working capital; and
- (1) Subject to the powers and restrictions of sections 17b-59a, 17b-59d, and 17b-59f, as amended by PA 18-91, do all things necessary and convenient to carry out the purposes of this section and section 19a-754a, as amended by PA 18-91.

Following the review of the relevant legislative references, the Design Group members confirmed the existing relationship structure of these key entities, as detailed by Diagram 7 below.

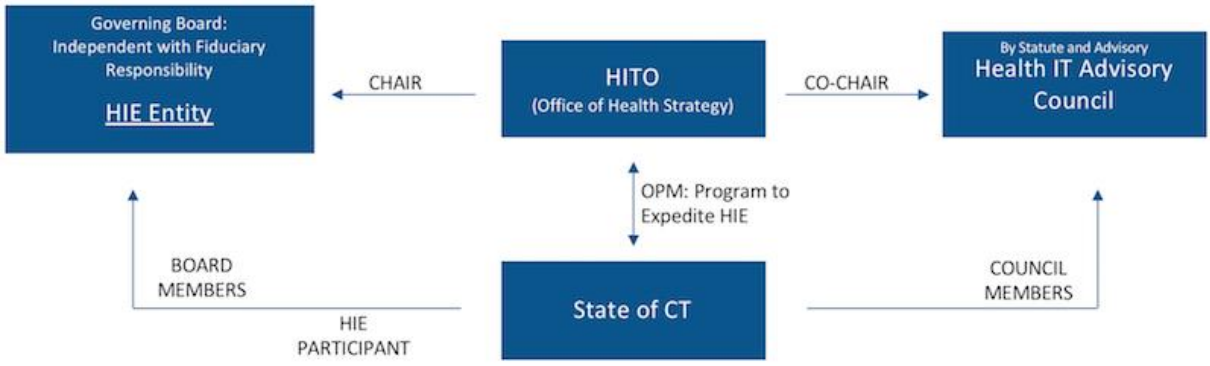


Diagram 7: Relationship of Key Parties

Recommendation 5: Considerations for Designation of Existing Entity vs. Creation of New Entity

Public Act 17-2, as amended by Public Act 18-91, provides flexibility for the corporate home of the HIE entity in that it may be created as a new entity or through the designation of an existing entity. In either case, the HIE entity may be structured as a nonprofit entity.

The Governance Design Group engaged in thoughtful discussion about the pros and cons of creating a new entity versus the designation of an existing entity. Consistent with the Project Charter, the Design Group stopped short of a specific recommendation regarding these options. However, considerations for the designation of an existing entity vs. the creation of a new entity to oversee HIE operations were developed to support such a decision. The Governance Design Group considerations are as follows:

A new not-for-profit entity should be strongly considered as the corporate home for HIE services and activities, though only after a thorough review of other options (i.e., designation of an existing entity); such review should be undertaken as soon as practicable. Such review should include consideration of the following advantages of each option:

- **Creation of a New Entity:**
  - No pre-existing perceptions of the organization
  - Ability to more efficiently effectuate statutory intent
  - Clear focus and intent of the organization (vs. competing interests of other lines of business)

- **Designation of an Existing Entity:**
  - Ability to leverage existing infrastructure
  - Leadership and staff already in place
  - Tax-exempt status already in place
  - Economies of scale

Recommendation 6: Data Governance as Component of Corporate Governance

Data governance was another topic discussed in-depth by Governance Design Group members as part of the building block exercises. To frame the discussion, members were presented with some background information from the Data Governance Institute (DGI), including a definition of the term:

- "Data Governance is a system of decision rights and accountabilities for information-related processes executed according to agreed-upon models which describe who can take what actions, with what information, and when, under what circumstances, using what methods."[23]

Design Group members also reviewed DGI's guiding principles for data governance, including:

- Integrity
- Transparency
- Auditability
- Accountability
- Stewardship
- Checks-and-Balances
- Standardization
- Change Management

Following this background information, members reviewed the model in which data governance serves as a component of the larger corporate governance structure and provides information services to other key governance areas, such as IT governance financial governance, and human resources governance. This model can be seen in Diagram 8. Design Group members were asked to either confirm the data governance definition, guiding principles, and model as a recommendation, or to provide comments and additional considerations and build upon / adapt the presented information. The Design Group members confirmed the presented information and model as a recommendation.

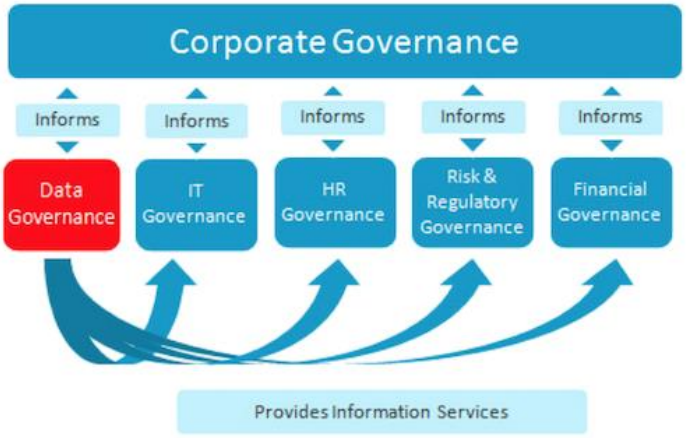


Diagram 8: Data Governance as a Component of Corporate Governance

[23] http://www.datagovernance.com/wp-content/uploads/2014/11/dgi_framework.pdf

Recommendation 7: Elements of Trust Agreement

As discussed previously, the Design Group members were provided with documents from existing organizations and entities to inform their understanding of commonly included components within trust agreements and data sharing agreements. This review included the ConnectVirginia Trust Agreement, the CRISP HIE Participation Agreement, and the eHealth Exchange DURSA. The common differences between trust agreements were also presented, including consent models, time requirements of breach notifications, participant testing, certification, and onboarding, permitted purposes, use cases, and the types of policies and procedures that accompany agreements.

Design Group members were also provided with the trust framework analysis matrix, developed by the HIT PMO, which reviewed various categories of trust agreements across a selection of state, regional, and national interoperability initiatives, as detailed in Table 3.

Design Group members were presented with an initial list of trust agreement elements and engaged in thoughtful discussion in order to expand and adapt the list based on industry expertise and factors specific to the Connecticut environment. The Design Group recommendations are as follows:

Trust agreements should be developed and implemented that codify "rules of the road" for data sharing and data usage, consistent with Federal and State statutes and regulations in conformance with TEFCA. Elements of the trust agreement should include the following:

- Purpose and Scope
  - Scope of Exchange
  - Approach to Establishing Trust
  - Governance Structure
- Operational Policies and Procedures
- Permitted Purposes
- Permitted Participants
- Identity Proofing and Authentication
- Technical Approach and Infrastructure
  - Standards Used
- Cooperation and Non-discrimination
- Allocation of Liability and Risk
- Accountability
- Technical
  - Network Flow-down
  - Enforcement
  - Dispute Resolution
- Consent Model
- Transparency
- Privacy and Security
  - Breach Notifications
- Access
- Amendment Process
- "Boilerplate" Provisions
  - Governing Law
  - Venue
  - Severability / Savings
  - Force Majeure
  - Assignment
  - Amendment
  - Independent Contractors / Relationship
  - HIE's Relationship to the State
  - Entire Agreement
  - Survival
  - Waiver
  - Priority (between other documents)
  - Counterparts
  - No Third-party Beneficiaries
  - Mediation of HIE-related Disputes Between Participants

Recommendation 8: Table of Contents for Policies and Procedures

The Governance Design Group were provided with documents from existing organizations and entities to inform their understanding of commonly included components within HIE policies and procedures. This review included the ConnectVirginia Policy and Procedure Manual, the CRISP Policies and Procedures, and the SHIN-NY Privacy and Security Policies and Procedures for Qualified Entities and their Participants in New York State.

Design Group members were presented with an initial list of policies and procedures, separated into three categories: privacy and security, technical and operational, and organizational. The Design Group engaged in a thoughtful discussion in order to expand and adapt the list based on industry expertise and factors specific to the Connecticut environment. The Design Group recommendations are as follows:

Governance practices should be supported by a robust set of policies and procedures that ensure fiduciary responsibilities and oversight of activities are fulfilled. Policies should be adopted by the board of directors and procedures should be developed by management for the following:*

Privacy and Security:

- Consent
- Authorization
- Authentication
- Access
- Audit
- Breach
- Compliance
- Sanctions and Enforcement
- Cybersecurity
- Specially Protected Information
- Individual's Access and Rights
  - HIE Entity
  - HIE Participants
- Participant Subcontractor Requirements
- Permitted Purposes
  - Permitted Uses
  - Permitted Disclosures

Technical and Operational:**

- System Requirements
- Standards
- Testing and Onboarding
- Auditing and Monitoring
- Identity Management
- Data Quality and Integrity
- Service Level Agreements (SLA)
- Training
- Help Desk

Organizational:

- Openness and Transparency
- Node Eligibility
- Insurance and Liability
- Flow-down Requirements
- Suspension
- Dispute Resolution
- Non-discrimination
- Information Blocking
- Fees
- Application Review Process

**Note that standard corporate policies and procedures, such as those related to finance, were not addressed in these recommendations.*

*** Note that these are policies and procedures that should be developed for Technical and Operation. In some cases, standards will be adopted for those as well.*

Recommendation 9: Conformance with TEFCA

As referenced previously in the Background Section, the 21st Century Cures Act contained provisions related to interoperability, specifically the mandate for ONC to create a trusted exchange framework, including a common agreement among health information networks nationally. It was expected that the final version of the Trusted Exchange Framework would be published during the course of Governance Design Group discussions. However, the draft framework was still of interest and relevance to the considerations of the Governance Design Group.

Overall, the Design Group recognizes value in aligning its technology, services, and trust framework with ONC's current effort (and eventually that of the Recognized Coordinating Entity). It was determined by the Design Group that an absolute endorsement of TEFCA was not appropriate, given that neither the Trusted Exchange Framework nor the Common Agreement have been finalized. This led to the Design Group's recommendation that governance of health information exchange be aligned with TEFCA, while also recommending ongoing monitoring of development of TEFCA by the HITO.

The exact recommendations related to TEFCA are as follows:

Governance of health information exchange and data sharing within the State of CT should be conformant with the Trusted Exchange Framework and Common Agreement (TEFCA) currently under development by the Office of the National Coordinator for Health Information Technology (ONC) pursuant to the 21st Century Cures Act.

- The HITO should closely monitor ongoing development of TEFCA to ensure alignment and conformance with CT governance and trust framework; strategic opportunities for participation as either a HIN or QHIN should be identified and assessed.
- The Principles of Trusted Exchange should be endorsed:
    - Standardization
    - Transparency
    - Cooperation and non-discrimination
    - Security and patient safety
    - Access
    - Data-driven accountability
- The final Common Agreement of TEFCA should be taken into consideration in the development of a Trust Agreement by the HIE entity.

Closing Thoughts

While much remains to be done in the construction of an effective governance structure and trust framework for Connecticut, the Governance Design Group strived to provide recommendations that can serve as useful guideposts for the work that lies ahead. Future milestones such as establishing the HIE entity, constructing the board of directors of the HIE entity, adopting a sound set of policies and procedures, developing and executing trust agreements that codify common “rules of the road”, and implementing effective management and operations infrastructure will all be realized in the coming months, and will benefit from the thoughtful recommendations and considerations of the Governance Design Group.

Appendix

Select National and State Legislation Reviewed by the Design Group

Federal Laws:

- Health Insurance Portability and Accountability Act (HIPAA), Public Law 104-191, Stat. 1936. enacted August 21, 1996
- Privacy Act of 1974, 5 U.S.C. § 552a
- Freedom of Information Act (FOIA), 5 U.S.C. § 552
- Family Education Rights and Privacy Act (FERPA), 20 U.S.C. § 1232g; 34 C.F.R. Part 99
- Federal Torts Claims Act, August 2, 1946, ch.646, Title IV, 60 Stat. 812, "28 U.S.C. Pt.VI Ch.171" and 28 U.S.C. § 1346(b)
- Federal Information Security Management Act, 44 U.S.C. § 3541
- Confidentiality of Substance Use Disorder Patient Records, 42 U.S.C. § 290dd-2; 42 C.F.R. Part 2

Connecticut Statutes:

- Disclosure of personally identifiable information by state agencies to the Connecticut Health Information Network – C.G.S. § 19a-25f
- Availability of patient information to certain agencies – C.G.S. § 17b-225
- APCD – § 38a-1091 of the 2018 supplement of the general statutes, as amended by PA 18-91
- Data submission requirements - C.G.S. § 19a-654, as amended by PA 18-91
- Data submission requirements for the Office of Health Care Access (OHCA) – C.G.S § 19a-654, as amended by PA 18-91
- Establishment of the Office of Health Strategy and associated responsibilities, C.G.S § 19a-754a, as amended by PA 18-91
- Establishment of All-Payer Claims Database Program and associated OHS responsibilities, C.G.S § 19a-755a, as amended by PA 18-91
- Establishment of State-wide Health Information Technology Advisory Council, Advisory Council membership and chairpersons, and establishment of All-Payer Claims Database Advisory Group, C.G.S § 17b-59f, as amended by PA 18-91
- Establishment of State-wide Health Information Exchange Program, the incorporation or establishment of an HIE entity, the definition of the HIE entity board of directors, and the description of HIE entity characteristics, C.G.S § 17b-59g, as amended by PA 18-91

Additional Considerations

The below additional considerations are not formal recommendations from the Governance Design Group. These additional considerations brought forth by Design Group members were captured as potential future discussion topics for the HIE entity, once designated or established:

- Once established or designated, the HIE entity should make recommendations based on the below activities:
    - Review existing state privacy laws for HIE adaptation to align with TEFCA and the needs and requirements for statewide data sharing.
    - Conduct ongoing monitoring of legislation and market research to ensure policy and strategy alignment.
    - Engage in ongoing governance review, including monitoring the composition and size of the HIE entity board of directors.