Final Contract Report

State and Regional Demonstration in Health Information Technology: Delaware

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HEALTH IT

Final Contract Report

State and Regional Demonstration in Health Information Technology: Delaware

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Preface

This project was one of six State and Regional Demonstrations in Health Information Technology (IT) contracts funded by the AHRQ Health IT Portfolio. The goals of the projects were to identify and support data sharing and interoperability activities aimed at improving health care for patients and populations on a discrete State or regional level. These States and their respective health information organizations (HIOs) are as follows:

- Colorado: Colorado Regional Health Information Organization (CORHIO)
- Delaware: Delaware Health Information Network (DHIN)
- Indiana: Indiana Network for Patient Care (INPC)
- Rhode Island: current*care*
- Tennessee: Mid-South e-Health Alliance (MSeHA)
- Utah: Utah Health Information Network (UHIN)

For more information about these projects, including a cross-project summary of lessons learned, please visit http://healthit.ahrq.gov/stateandregionalhie.

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Background and Purpose

In its 2001 report, *Crossing the Quality Chasm*, the Institute of Medicine (IOM) identified health information technology (IT) as one of the most significant tools that could help improve health care quality. Automating and sharing clinical and administrative information among clinicians, patients and other appropriate parties within a secure environment are critical in order to realize the 21st century health care system envisioned by the committee. Further, the IOM, the National Committee on Vital and Health Statistics, and the President's Information Technology Advisory Committee also recommended developing a National Health Information Infrastructure to help improve safety, reduce costs, and enhance the quality of health care.

In October 2004, the Agency for Healthcare Research and Quality (AHRQ) awarded $139 million in contracts and grants to promote health IT by developing networks to share clinical data as well as projects for planning, implementing, and demonstrating the value of health IT. These research projects aimed to do the following:

- Improve patient safety by reducing medical errors.
- Increase health information sharing between providers, laboratories, pharmacies, and patients.
- Help patients transition between health care settings.
- Reduce duplicative and unnecessary testing.
- Increase knowledge and understanding of the clinical, safety, quality, financial, and organizational value and benefits of health IT.

In 2005 the Delaware Health Information Network (DHIN), initially funded through State and private monies, received a 5-year Federal contract from AHRQ to serve as a demonstration project (a 1-year contract extension was approved in 2010). AHRQ's contract provided funding to support patient health data sharing and interoperability activities in the State of Delaware through the DHIN, aimed at supporting the quality, safety, and efficiency of health care for patients and populations on a discrete State or regional level. The project objectives further outlined an expectation that measureable improvements in the quality, safety, efficiency, and/or effectiveness of care would result from data sharing and interoperability measures.

The purpose of this report is to describe the process and outcomes of DHIN's implementation of a statewide Health Information Exchange (HIE), specifically the methods it used to accomplish the project goals and objectives, key deliverables, findings, lessons learned, and opportunities for further research.

Results

On May 1, 2007, the DHIN became the Nation's first live statewide HIE, providing electronic results delivery for four physician practices, three hospital systems, and one major laboratory.

In the years that followed, DHIN grew, connected practices and data senders from throughout the State, and expanded services and functionalities beyond simple results delivery. For example, participating hospitals now send syndromic surveillance data and reportable laboratory results to the Delaware Division of Public Health while providers use the DHIN's query functionality to locate and view a patient's clinical data—by any participating data senders —in a true community health record format.

Today, the eHealth Initiative recognizes the DHIN as a Stage 5[1] HIE. As one of the most advanced HIEs in the Nation, with a level of penetration and adoption unmatched by any other State, the DHIN has the following:

- More than 5,000 providers and staff at 465 Delaware practices live on DHIN (this figure represents approximately 80 percent of providers practicing in Delaware); 168 of these practices receive clinical results/reports exclusively through the DHIN.
- Seventy-five percent of Delaware acute care hospitals participating (BayHealth Medical Center, Beebe Medical Center, Christiana Care Health System, and St. Francis Hospital), which represents 86 percent of all staffed hospital beds and 79 percent of all emergency department visits.
- Seventy-six percent of all outpatient visits in Delaware.
- Five hospital emergency departments and laboratories send data through DHIN to the Delaware Division of Public Health for public health monitoring.
- Three statewide, independent laboratories—Laboratory Corporation of America (LabCorp), Quest Diagnostics, and Doctors Pathology Services—participating.
- Three federally qualified health centers, La Red Health Center, Henrietta Johnson Medical Center, and Westside Family Health, exclusively receiving results via DHIN.
- Four home health agencies, three skilled nursing facilities, two long-term care facilities, one assisted living facility, and three hospice members.
- Three ambulatory electronic health record (EHR) vendors (Allscripts, Varian, STI) that developed interfaces to the DHIN, enabling a practice's EHR to receive data from all data senders rather than having to interface with to each data sender individually. Additionally, 10 EHR vendors have contracted with DHIN to develop such an interface and are in various phases of development.
- Five types of transactions (laboratory results, radiology reports, transcribed reports, pathology results, and hospital admission, discharge, and transfer [ADTs]) delivered via three methods (electronic inbox delivery, fax delivery, and printer delivery).
- More than 7 million clinical results and reports each year.
- More than 1 million unique patients represented in the community master patient index, representing 90 percent of Delaware residents (based on 2010 census figures) as well as patients from nearly every State in the union.
- Also, the DHIN recently achieved two significant milestones. First, as of June 2011, 48 percent of delivered results were sent to practices that made DHIN their only source of information for supported transaction types from participating data senders. Second, in September 2011, the Centers for Medicare & Medicaid Services (CMS) awarded a grant

[1] The eHealth Initiative Stages of Development range begins at Stage 1 (Starting) and progress numerically to Stage 7 (Innovating). Stage 5, an advanced HIE by eHI's standards, is a fully operational health information organization; transmitting data that is being used by health care stakeholders.

to the Delaware Division of Long Term Care Resident Protection to connect all skilled nursing facilities in the State. It is expected that by the fourth quarter of calendar year 2012, all Delaware's skilled nursing facilities will be connected to DHIN.

Looking ahead, the DHIN is currently developing the following additional functionalities and products as it evolves:

- Connectivity to the State immunization registry for query and update of the registry
- Care summary exchange
- Medication history
- Centralized directory services
- Quality reporting data mart
- Patient portal
- Direct (secure messaging protocols for medical content)
- Personal health record (PHR) connectivity
- Administrative functions (e.g., eligibility verification, claims submissions)
- Additional interfaces to EHR systems

Recommendations for Future Research

A Business Model for Wider Information Exchange That Crosses State Boundaries

The DHIN expects to continue to add features and functionality to the DHIN network. Yet, in our mobile society, a statewide HIE, no matter how strongly health IT is adopted and used, still does not achieve the goal of ensuring that the data always follows the patient. As of yet, DHIN has no direct connections to any of the hospitals just across its borders at which many Delaware residents receive care. Nor does DHIN connect to the Veterans Administration Hospital in Wilmington, DE or the laboratory at Dover Air Force Base (though the outpatient clinics at Dover Air Force Base are enrolled in DHIN as data receivers).

DHIN was selected as one of nine HIEs to participate in the Nationwide Health Information Network Trial Implementation project led by the Office of the National Coordinator for Health Information Technology. As such, DHIN is helping to shape the infrastructure and standards for a nationwide HIE. However, to date there has not been a well-defined business model to govern these cross border exchanges of health data. This could be a fruitful area for future research.

Impact of Health IT on Population Health and Chronic Disease

While many anecdotal reports of improved quality of care have surfaced, systematic, population-wide studies of the impact of a statewide HIE on population health are currently lacking. Adoption of the technology must be sufficiently ubiquitous and a large enough percentage of the population must have data discoverable through the HIE before population-wide impacts can be measured. DHIN has achieved these levels within the past year. It will likely be several more years before the impact on the chronic disease burden in the State of Delaware can be systematically assessed. This would be another useful area for further research.

Background, Purpose, and Results

Description of the Purpose and Scope of the Report

In its report, *Crossing the Quality Chasm*, the Institute of Medicine (IOM) identified health information technology (IT) as one of the most significant tools that could help improve health care quality. At that time, the IOM, the National Committee on Vital and Health Statistics, and the President's Information Technology Advisory Committee also recommended developing a National Health Information Infrastructure to help improve safety, reduce costs, and enhance the quality of health care. In July 2004, U.S. Department of Health and Human Services Secretary Tommy G. Thompson announced a Framework for Strategic Action, "The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care." The goals of this 10-year plan were to transform the delivery of health care by building a new health information infrastructure, including electronic health records (EHR) and a new network to link health records nationwide.

The Agency for Healthcare Research and Quality (AHRQ) received more than 1,000 letters of intent, resulting in approximately 600 applications from its request for applications for health IT grants. From this, AHRQ awarded more than 100 grants totaling $96 million in 38 States to help communities, hospitals, providers, and health care systems plan, implement and demonstrate the value of health IT. Planning grants supported communities' efforts to develop IT infrastructure and data sharing capacity among clinical provider organizations, helping those communities compete for future implementation grants. Implementation grants supported community-wide health IT, with emphasis on diverse and rural health care settings. The grants awarded to demonstrate health IT's value focused on how adopting and using health IT would improve patient safety and quality of care.

The research results from contract and grant awardees would provide important information on how health IT could be implemented, its estimated direct and indirect costs, potential benefits and barriers to adoption, and how it could lead to safer and better health for all Americans.

Given the growing interest in health IT, there was considerable interest to promote data exchange at the State level. Many States initiated planning processes that engaged major stakeholders such as the State legislature, public health departments, hospitals, providers, purchasers, and insurers. However, at that time, no State or regional area engaged in demonstration projects examining the impact on patient safety, quality, and efficiency of care. Also at that time, there were many questions about whether the significant upfront costs of large-scale efforts to connect health care entities at a State/regional level would result in long-term cost-savings.

In October 2004, AHRQ awarded $139 million in contracts and grants to promote the use of health IT by developing networks to share clinical data as well as projects for planning, implementing, and demonstrating the value of health IT. An estimated $30 million was awarded to State and Regional Demonstrations (SRD)[2] in Health IT. These research projects aimed to—

[2] SRDs are Health Information Organizations (HIOs) that support state- and regional-level health information exchange (HIE). These HIOs are multi-stakeholder organizations that enable secure HIE, which offers tremendous potential to improve health care quality, reduce medical errors, and lower costs.

- Improve patient safety by reducing medical errors.
- Increase health information sharing between providers, laboratories, pharmacies, and patients.
- Help patients transition between health care settings.
- Reduce duplicative and unnecessary testing.
- Increase knowledge and understanding of the clinical, safety, quality, financial, and organizational value and benefits of health IT.

Contracts for SRDs began in October 2004 for five States: Colorado, Indiana, Rhode Island, Tennessee, and Utah.

AHRQ awarded DHIN a $4.7 million contract with an effective date of contract (EDOC) of September 30, 2005. This report describes the processes and outcomes of DHIN's efforts to implement a statewide HIE, including key deliverables, successes and challenges, lessons learned, and opportunities for further research.

Background on the Project and Local Environment

Formation of the Project

The groundwork for today's Delaware Health Information Network (DHIN) began in 1994. Then, the Delaware Health Care Commission (Commission),[3] issued a Request for Proposals for "A Study Related to the Collection, Analysis and Reporting of Health Care Data." The project was initiated in part because, at the time, the Commission recognized that access to and sound analysis of health data was a critical component to any State-based health reform effort. Subsequently, the Commission contracted with the MEDSTAT Group to assist in developing a strategy to collect, analyze, and disseminate health care information.

To obtain the data it needed, the Commission—

- Conducted a series of interviews to learn how affected groups perceived the State's health care information needs.
- Inventoried all data collected to better understand the strengths and weaknesses of State's data collection efforts.
- Researched other States' activities to assess success stories and mistakes to avoid.
- Identified the most important, realistic, and practical key objectives for the State to pursue.

The Commission also identified seven key objectives:

1. Collect consistent information on the health status of Delawareans, including disease incidence and key public health problems.
2. Reduce administrative costs and improve quality through increased use of electronic data interchange.

[3] The Delaware General Assembly created the Delaware Health Care Commission to function as a policy-setting body. The Commission's mission was "to develop a pathway to basic, affordable health care for all Delawareans."

3. Publish annual reports on health care spending, including information on total spending and across identified subcategories.
4. Disseminate information on the quality and outcomes of treatments by setting and providers of care.
5. Measure patient satisfaction with the health care system.
6. Assess managed care plan.
7. Establish a reference library to serve as a single, easily accessible and widely known location to find information about relevant reports.

The Commission determined that pursuing its identified project objectives in a spirit of public/private partnership would best serve the interests of both State government and private sector partners.

The Commission outlined the following strategies to accomplish its objectives:

1. Publish annual health spending reports.
2. Establish a reference library.
3. Promote use of electronic data interchange.
4. Promote use of the Healthcare Effectiveness Data and Information Set (HEDIS), a tool used by more than 90 percent of America's health plans to measure performance on important dimensions of care and service according to the National Committee for Quality Assurance Web site.
5. Enhance Healthy Delaware 2000 information.
6. Support continued collection, analysis, and publication/dissemination of all current Delaware health information.

Following these strategies, the Commission took the next step and formed a task force to investigate the viability of a Community Health Information Network (CHIN) initiative both in Delaware and the Nation. Included in the task force's mission was, if a CHIN was viable, to recommend a plan to implement a pilot.

Independent of the Commission's efforts, members of the Medical Society of Delaware (MSD) and Blue Cross Blue Shield of Delaware developed an interest to explore electronic information exchange. At the time, many health care stakeholders viewed a "CHIN-like" entity as valuable for administrative uses, such as a means to ease claims and payment processing during managed care's heyday, rather than clinical uses.

With private sector interest in forming an information exchange growing, the MSD spearheaded an effort to create a workgroup comprised of representatives from insurance companies, business, hospitals and, eventually, State government. The workgroup's efforts progressed to the point where they drafted by-laws and planned to form a private non-profit corporation to govern the formation of a health information network, coining the phrase, "Delaware Health Information Network."

Recognizing that both organizations were working toward the same goal, in March 1996 the Commission voted to participate in the DHIN formation efforts. Subsequently, Delaware Secretary of Health & Social Services Carmen Nazario and the Commission corresponded with the MSD to urge greater participation by State officials on a future DHIN Board of Directors.

However, by the fall of 1996, the Delaware Public Integrity Commission (PIC) issued an advisory opinion stating that State officials cannot sit on a private board of directors and serve in their capacity as State officials without violating the State Code of Conduct. The PIC acknowledged that public-private entities existed in the State for the purpose of performing "quasi" or semblance of government services; such entities are formed by statute and not by a completely private action, such as forming a private corporation.

At this juncture it was determined that the best recourse would be to create the DHIN by statute, but care was taken to incorporate much of the language and board composition that had already been developed by this workgroup.

In 1997, the General Assembly passed legislation creating the DHIN as a public instrumentality of the State under the direction and control of the Commission. Culminating 3 years of work and collaboration, Governor Thomas R. Carper signed the legislation into law on July 15, 1997.

The DHIN's purpose was to promote the design, implementation, operation, and maintenance of facilities for public and private use of health care information in Delaware. The statute expressly stated the General Assembly's intent that the DHIN be a public-private partnership for the benefit of all Delaware citizens and granted DHIN the power to do the following:

- Develop a community-based health information network to facilitate communication of patient clinical and financial information.
- Promote more efficient and effective communication among multiple health care providers, including but not limited to hospitals, physicians, payers, employers, pharmacies, laboratories and other health care entities.
- Create efficiencies in health care costs by eliminating redundancy in data capture and storage and reducing administrative billing and data collection costs.
- Create the ability to monitor community health status.
- Provide reliable information to health care consumers and purchasers regarding the quality and cost-effectiveness of health care, health plans and health care providers.

Initially funded through State and private sources, DHIN requested and received from the Agency for Healthcare Research and Quality (AHRQ) a $700,000 planning grant. Following the planning process, DHIN applied for and was awarded a $4.0 million implementation grant in 2005.

Results

Governance

Goals and Objectives

As explained previously, the General Assembly passed and the Governor signed legislation creating the Delaware Health Information Network (DHIN) in 1997. The statute expressly created DHIN as a public instrumentality of the State, stated the Legislature's intent that the DHIN operate as a public-private partnership, and said the DHIN provides an "essential governmental function for the public health and safety."

In this context, DHIN's fundamental operating principle was that all stakeholders must agree as a group to move forward and with smaller stakeholders having the same voice in the decision making process as large stakeholders.

Identifying Partners and Other Stakeholders

Nearly a decade prior to its contract with the Agency for Healthcare Research and Quality (AHRQ), DHIN identified and engaged every group that could be identified as having a legitimate interest in the activities and decisions of DHIN. These included the following:

- Ancillary services (laboratories and pharmacies)
- Business/Industry
- Consumers/Advocacy Groups
- Education and Research (University of Delaware)
- Delaware State Government
- Delaware congressional delegation
- Hospitals
- Health Plans/Insurers
- Physicians/Clinics

These stakeholders initially provided input regarding data elements that were "must haves" of a complete clinical information sharing utility, the term for the DHIN project contained in the Delaware Health Care Commission's 1994 Request for Proposal. The clinical and operational planning process included a technical requirements definition that was completed in August 2005.

What Is the Governance Structure?

Board structure. DHIN's original 1997 enabling legislation[4] stated that its Board of Directors (Board) consists of at least 13 and not more than 21 members and that "the membership of the [DHIN] Board [of Directors] reasonably reflect the public-private and diverse nature of the DHIN." The legislation explicitly provided that the following rules govern selection of DHIN Board members:

- Three members from Delaware authorized health insurers, HMOs, or medical service Corporations shall be appointed by the Commission.
- Up to three members shall be appointed by the Association of Delaware Hospitals.
- Up to three members shall be appointed by the Medical Society of Delaware.
- One member may be appointed by the Delaware State Chamber of Commerce.
- One member may be appointed by the Secretary of the Department of Technology and Information.
- One member may be appointed by the Director of the Office of Management and Budget.
- One member may be appointed by the Insurance Commissioner.
- One member may be appointed by the Secretary of Health and Social Services.
- One member may be appointed by the Director of Public Health.
- Up to six members shall be appointed by the Commission.

The appointed members served 3-year staggered terms, commencing on January 1 and expiring on December 31. Board membership did not require Delaware State Senate confirmation; members served as volunteers and were eligible for reappointment. A majority of the members elected the Board chairperson.

DHIN's original enabling legislation did not list any qualification guidelines to serve on the DHIN Board of Directors other than the above noted stakeholder representation. However, DHIN's leadership deliberately sought to maintain a balance of individuals and organizations that represent all affected constituencies, including consumers, physicians, hospitals, health plans, employers, and State government.

DHIN's enabling statute also contained several critical legal provisions, including—

- Extending sovereign immunity and liability protection to all members of the Board, DHIN staff and all members of the Commission.
- Declaring that DHIN was not a health care provider and not subject to claims under the Health Care Medical Negligence Insurance and Litigation.
- Shielding DHIN service or information participants or subscribers from liability in any action for damages or costs of any nature, in law or equity, which resulted solely from that person's use or failure to use DHIN information or data.

[4] Refer to Appendix A.

Committee structure. From its inception, DHIN operated with a Board comprised of private and public sector volunteer members. The primary mechanism for receiving stakeholder input was through the Board's committee structure. Committees did most of DHIN's work, with their responsibilities evolving as the system expanded. Original Board committees included the following:

- The Executive Committee—Provided strategic guidance to the Executive Director and acted on behalf of the Board when the Board could not be assembled or as directed by the Board. The Executive Committee met biweekly, had representation from each stakeholder group, and was the organization's primary decisionmaking body.
- The Clinical Advisory Group—Provided a forum for users to give feedback on DHIN policies, made recommendations for system design, features, and applicability to clinical and practice workflow improvements, plus addressed barriers to DHIN adoption. Membership consisted of clinicians and staff from private practices, Federally Qualified Health Centers, and hospitals.
- The Consumer Advisory Committee—Provided the patient's perspective to the DHIN development, planning and implementation. This committee was responsible for engaging consumers and ensuring consumer input on DHIN policies with respect to privacy, security, functionality, and consumer education. Additionally, the group developed marketing and educational materials to promote the DHIN and assisted in design and content selection for consumer materials.
- The Health Information Management (HIM) Committee—Provided guidance and oversight for ensuring the data integrity of information provided through the DHIN. The HIM Committee developed DHIN business processes to ensure consistency of data management and master patient index integrity as well as guidance and input to the Project Management Committee regarding the impact of adding new functionality for existing DHIN data and developing use cases and requirements for testing new data types and data sources.
- The Continuum of Care Workgroup—Focused on long-term care and home health care needs, such as processes to communicate critical patient data at transitions in care. It consisted of representatives from hospitals, home health agencies, long-term care facilities, and regulatory agency leadership.
- The Project Management Committee—Consisted of representatives from all the data senders and had broad responsibility for ensuring that the DHIN scope of work and project plan was achieved on time and accurately. This allowed stakeholders to react to changes in the system, provide feedback on decisions and direction, and reach consensus on any outstanding issues.
- Laboratory Standardization Workgroup—Consisted of the laboratory directors from all DHIN data sending organizations as well as the respective project managers. The group provided guidance on developing a standardized result and ordering compendium, laboratory result trending, and electronic laboratory test ordering. The Workgroup oversaw the Logical Observation Identifiers Names and Codes mapping process as well as defining methodologies for electronic lab ordering through DHIN, including analyzing workflow changes, developing business processes, and defining policies and procedures needed to support new system functions. The Workgroup was also responsible for developing test requirements and was directly involved with testing electronic orders and laboratory result trending functionality.

Management. From 1997 to 2003, the Board worked without the benefit of dedicated project staff. In 2004, the Board decided to hire an outside management company, bringing needed technical experience and project management skills to build on the work done to date and to develop an implementation plan. In 2005 DHIN received its AHRQ State and Regional Demonstration (SRD) contract and leveraged this new funding to focus stakeholders, define measurable goals, and begin the implementation process.

Did Governance Infrastructure Evolve? If So, How?

In 2009, many States, including Delaware faced serious State budget deficits. In response, Delaware Governor Jack Markell proposed numerous State agency consolidations and reorganizations to close these gaps. One proposal in the State's Fiscal Year 2010 Budget Act administratively moved the Delaware Health Care Commission, DHIN's original parent agency, into the Office of the Secretary, Department of Health & Social Services (DHSS). The move removed the Commission's operating budget but did not change its statute or its statutory authority.

Coinciding with this administrative move, DHIN faced criticism from some State legislators. In April 2009, legislation was introduced in the Delaware State Senate that created a new consortium charged with implementing and operating a statewide health information network. In June, this bill was tabled in the Senate. However, the Senate adopted a Resolution requesting that by January 10, 2010, DHIN provide to the Governor and the General Assembly legislation proposing an operational model of governance and financial sustainability.

To meet the requirements of the Senate Resolution, the DHIN Board of Directors established a Governance Workgroup and a Finance Workgroup. The Board charged the Governance Workgroup with exploring different governance options and recommending to the DHIN Board the most appropriate direction for governance and oversight of the DHIN. The Workgroup considered the political, operational, technical, and market climates to ensure that a future model would be able to meet the needs of all stakeholders and constituencies.

The Governance Workgroup reviewed several options, and proposed the following set of guiding principles:

- Maintain certain provisions found in DHIN's original enabling statute such as liability protections and the ability to receive State appropriations.
- Maintain existing DHIN subcommittees' active role in day-to-day operations.
- Structure DHIN in a way that permits it to be capable of anticipating and responding to market changes.
- Amend the original 1997 DHIN statute to remove the DHIN from the control of the Delaware Health Care Commission and establish a public/private corporation, similar in design to other existing State public/private corporations.
- Install a new Board of Directors, appointed by the Governor, that will include, but not be limited to—
    - Five State Agency Representatives (in full voting ex-officio capacity), either the highest ranking officer or their designees from the Department of Technology and Information; the Office of Management and Budget; the Department of Health and Social Services; the Department of Insurance (not appointed by Governor*);* and the Office of the Controller General (not appointed by Governor*)*

    - One consumer of health care in Delaware
    - One business/employer representative
    - Two health insurance representatives
    - Three hospital/health system representatives
    - Three physicians/health care providers
    - Up to four other representatives (e.g., laboratory, radiology, long-term care, home health, and/or pharmacy)
- Allow current Board members to complete their term to provide continuity of oversight as DHIN transitions to its new status.

Working concurrently, the Board charged the Finance Workgroup—comprised of Board members, payers, data senders, medical providers, and the representatives of State government—with developing options to establish a long-term revenue and operational structure. The Finance Workgroup also developed budgeting processes and reporting procedures to monitor DHIN's financial status.

Based on the input provided by DHIN, pursuant to the Senate Resolution, Senate Bill 231[5] was introduced on January 26, 2010. The General Assembly passed and the Governor signed Senate Bill 231 in July 2010, setting in motion DHIN's transition from its position under Delaware Health Care Commission control to a public-private not-for-profit corporation.

Current Board Structure. The new enabling statute called for DHIN to transition fully into a more traditional corporate model on January 1, 2011. Under the new statute, the Board of Directors (Board) consists of 19 members with various business, technology, and health care industry skills:

1. The Director of the Office of Management and Budget or the Director's designee.
2. The Chief Information Officer of the Department of Technology and Information or the Chief Information Officer's designee.
3. The Secretary of the Department of Health and Social Services or the Secretary's designee.
4. The Controller General or the Controller General's designee.
5. Six members, appointed by the Governor, including at least one person who representing the interests of medical consumers and at least three with experience and/or expertise in the health care industry.
6. Three members appointed by the Governor representing hospitals or health systems.
7. Three members appointed by the Governor representing physicians.
8. One member appointed by the Governor representing businesses or employers.
9. Two members appointed by the Governor representing health insurers or health plans.

Board members serving as of January 1, 2011 were allowed to continue to serve until the Governor appointed a successor or designate by the ex-officio members. Additionally, the Board, the Delaware Healthcare Association, the Medical Society of Delaware, Delaware State

[5] Statute found in Appendix B.

Chamber of Commerce, and other interested organizations were permitted to make nonbinding recommendations to the Governor for appointments to the Board.

The new enabling legislation contained several provisions similar to the DHIN's original 1997 enabling statute such as the Chair of the Board was elected by a majority of the Board members; members serve staggered 3-year terms, do not require State Senate confirmation and are unpaid. Also, the State extended sovereign immunity and liability protection for DHIN and its officers and directors as well as DHIN's the ability to receive State appropriations.

Committees. Based on the Finance Workgroup's recommendation, the reconstituted Board created an additional committee, Finance, in addition to the seven original Board committees listed previously. The Finance Committee meets monthly and reviews financial reports regarding DHIN's revenue, expenses (budget and actual), and overall financial health.

Management. The management contract with the outside management company was wound down, and the Board hired a new Executive Director and Chief Information Officer. Today, the relationship between the Executive Director and the Board more closely resembles that of a traditional corporation with all staff now directly employed by DHIN.

Formation and Usefulness of the Technical Advisory Panel

The Delaware Health Information Network Technical Advisory Panel (TAP) began meeting in November 2004—nearly 1 year prior to the AHRQ contract start date. The TAP met at least monthly between November 2004 and January 2006 and included representatives from—

- University of Delaware Center for Applied Demography & Survey Research
- AstraZeneca Pharmaceuticals LP
- Bayhealth Medical Center
- Christiana Care Health System
- Beebe Medical Center
- Delaware Back Pain
- Delaware Department of Technology and Information
- Delaware Healthcare Association
- Delaware Physicians Care
- Happy Harry's (a regional pharmacy)
- LabCorp
- MBNA Technology
- Medical Society of Delaware
- McLeon CG, Inc.
- Office of US Senator Thomas Carper
- Quality Insights of Delaware (now Delaware's Regional Extension Center)
- St. Francis Healthcare Service

Beginning in February 2006, upon selecting Medicity, Inc. and Perot Systems for DHIN system implementation and operation, the TAP narrowed its membership and met weekly in order to emphasize technical system implementation and project management. The TAP was now comprised of participating hospital chief information officers, project managers and

information system staff, LabCorp, DHIN staff, a Board sponsor, State of Delaware Department of Technology and Information project management staff as well as Medicity and Perot Systems representatives. From February 1, 2007, until DHIN system implementation (May 1, 2007), the TAP met daily and included the following members:

- University of Delaware Center for Applied Demography & Survey Research
- Bayhealth Medical Center
- Beebe Medical Center
- Christiana Care Health System
- Delaware Department of Technology & Information
- DHIN Executive Director and staff
- John Snow, Inc (DHIN QA vendor who is no longer active)
- LabCorp
- McLeod CG, Inc. (for Beebe Medical center)
- Medicity
- Perot Systems

As new data sending organizations (hospitals, reference laboratories, radiology facilities) were added to the project, their technical teams became members of the TAP. The TAP became part of the Project Management Committee as the project transitioned from a planning phase to a technical project phase.

Lessons Learned About Governance

It is impossible for every organization with a legitimate interest in the activities of DHIN to have a seat on the Board. As it is, the Board is actually larger than the DHIN employed staff. It is critical to have ways, such as workgroups and advisory groups, to engage stakeholders and interested parties meaningfully, even if they are not on the Board. One example, in addition to the eight standing Board Committees, the DHIN staff meets regularly with the Chief Information Officers of the major Delaware hospitals. As an advisory group, the Chief Information Officers provide the DHIN with technical advice and input. Similarly, DHIN staff meets with smaller non-hospital data senders to hear their perspective on DHIN operations and address issues unique to their business, such as ensuring testing orders from customer practices transmit smoothly via the DHIN. Another example, under DHIN's 2010 enabling statute the Division of Public Health (DPH) no longer sits on the Board but is represented by the Department of Health and Social Services. However, because DPH's technical officer is the State's Health Information Technology Coordinator, the DHIN CIO meets with her weekly for consultation and assistance.

DHIN remains a quasi-government entity, but maturing as an organization and moving from the capital funding stage to the sustaining business operations stage made it appropriate to provide DHIN with the status and prerogatives of a corporation rather than a State controlled entity. To make the transition successful, the board requires strong, high-level appointees supporting and lending expertise to a strong Executive Director.

Conclusions

The DHIN original governance structure was appropriate for a start-up effort that needed significant State capital funding and needed the State to broker relationships between natural competitors for the overall benefit of the citizens of Delaware. But as DHIN matured organizationally and moved into an operational phase rather than start-up phase, it called for a different governance structure. That call was recognized and adopted. The DHIN still has very strong support from the State, both from the General Assembly and the Executive Branch, as well as Members from Delaware's Congressional Delegation. The bottom line is that a governance structure must include representation from all stakeholders, be very transparent and open in its operations, and eventually mature into an entity that operates like a business.

Finance

Goals and Objectives

As described in the Governance Section, a 2009 Delaware State Senate Resolution requested DHIN provide the Governor and General Assembly with legislation proposing a financial sustainability model. To meet this request the DHIN Board of Directors assembled a Finance Workgroup which began its work that September. Through this process, the following financial principles emerged:

- Entities benefiting from DHIN pay for it.
- The amount paid is proportionate to value received.
- Sustainability projects receive high prioritization.

Further, DHIN established that it would not charge its users for the base functionality: results delivery and patient record search. However, providers accessing richer functions providing users with added value, such as medication history or other future functions could result in a paying arrangement.

Initial Sources of Funding

The DHIN initial funding model included Federal, State, and private sources. Under this model, data senders were the source of private funding.

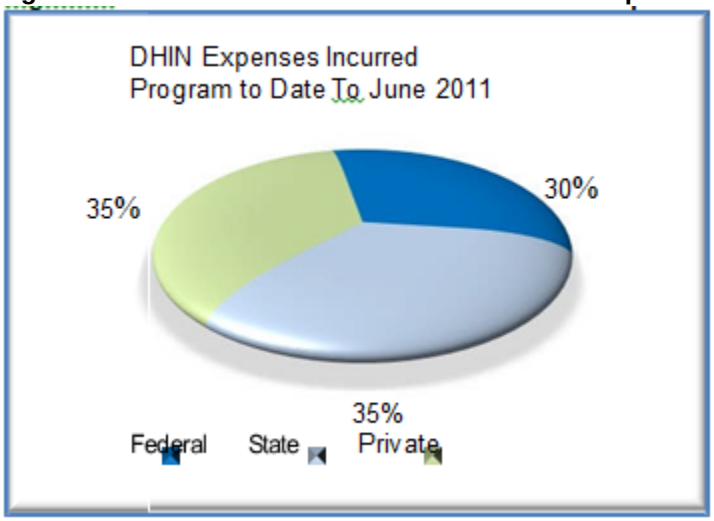
Providers were not asked to pay, under the principle that they expect to receive results for test they have ordered and the financial burden of providing those results fell to the laboratory or hospital doing the test. In September 2005, Agency for Healthcare Research and Quality (AHRQ) funding began. In July 2006, the State of Delaware, through the General Assembly's Joint Committee on Capital Improvement (Bond Bill Committee) provided funding, and DHIN secured matching funds from three hospital systems and LabCorp. In 2009, two more laboratories, Quest and Doctor's Pathology Services, began funding DHIN. In addition, DHIN has received supplementary funding from Blue Cross Blue Shield of Delaware. DHIN also successfully earned Nationwide Health Information Network (NwHIN) funding during fiscal year 2008, and was awarded funding in 2010 from the HIE Cooperative Agreement. Table 1 summarizes the above history.

Table 1. Delaware Health Information Network expense history (accrual basis)

	AHRQ	NwHIN	HIE Cooperative Agreement	Private	State (Bond)	TOTAL
FY 2006	$538,188	$0	$0	$0	$0	$538,188
FY 2007	$897,225	$0	$0	$1,110,929	$1,102,713	$3,110,867
FY 2008	$707,300	$867,506	$0	$1,820,482	$1,752,234	$5,147,522
FY 2009	$282,762	$1,173,788	$0	$1,981.080	$1,934,080	$5,371,711
FY 2010	$1,273,764	$209,747	$0	$1,662,286	$1,631,352	$4,777,150
FY 2011	$519,268	$33,613	$706,770	$1,959,730	$2,026,613	$5,245,994
Total Expenses	$4,218,508	$2,284,655	$706,770	$8,534,507	$8,446,991	$24,191,431

Since DHIN funding began, expenses incurred through Fiscal Year 2011 (ending 6/30/2011) show a strong distribution amongst the three, as indicated in Figure 1.

Figure 1. Delaware Health Information Network expenses since funding began



Developing and Implementing the Sustainability Plan

As noted previously, the DHIN's Finance Workgroup developed three principles to support a sustainability plan. Each stakeholder—data senders, payers, and providers—function is structured uniquely because of the different value it receives from DHIN relative to their counterparts.

Data Senders—Hospitals and Laboratories

Assumptions. Hospitals and Laboratories that use DHIN to distribute reports and results gain value from reducing and eventually eliminating paper-based processes, faxes, and the administrative costs associated with these manual processes. Furthermore, the ability to use DHIN to interface with physician practice electronic health record (EHR) systems eliminates the work to build and maintain interfaces with each practice that wants one.

The benefit of DHIN as a clinical results/reports distribution method is enhanced by expanding the types of transactions delivered through DHIN (e.g., transcribed reports, cardiology reports, radiology images) and the volume of transactions that (1) reach a DHIN user and (2) reach a DHIN user who has signed-off and receives their results only through DHIN.

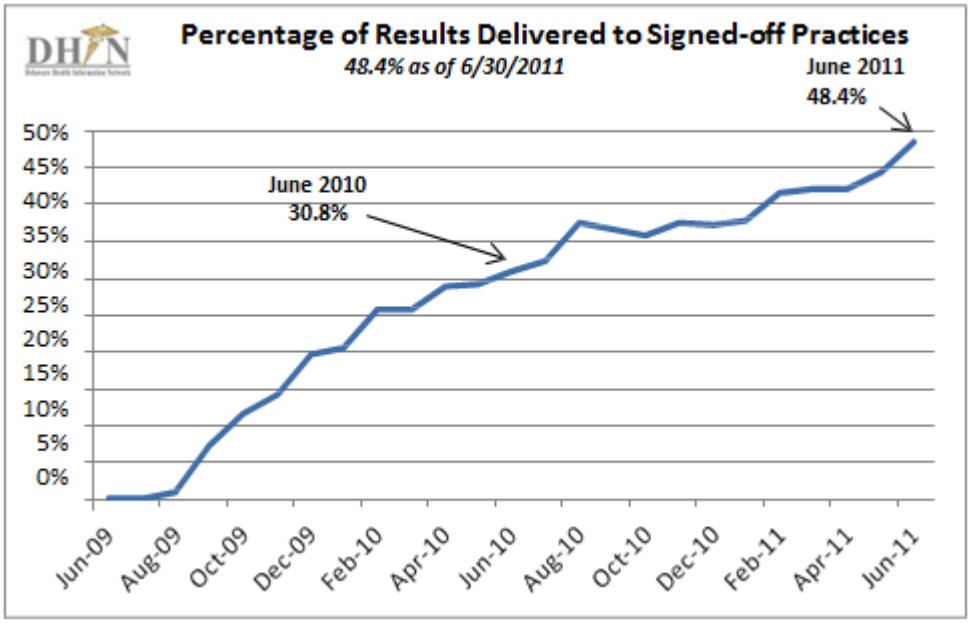
Pricing structure. Hospitals and Laboratories currently pay volume-based fees. In FY11, the data senders agreed to move to this model based on the value they derive from each transaction. The tiers are as follows:

- Tier 1: Includes any results/reports sent to DHIN but for which the recipient of the result is not a DHIN user. The assumption is that there is value from sending the result to DHIN because it is available for query and saves the data sender from having to send copies of the result to a provider who needs it. The cost for such results/reports is $0.02 per transaction sent to DHIN and available for query.
- Tier 2: Includes results/reports that are sent to DHIN and were delivered to a DHIN user who has not yet "signed-off" to exclusively receive results/reports through DHIN. The cost for such results/reports transactions is $0.10 per transaction sent to a DHIN user.
- Tier 3: Includes results/reports that are delivered by DHIN to a signed-off practice for which DHIN is the only way that practice receives results/reports from the participating data sender. The cost for such results/reports transactions is $0.25 per transaction sent to a DHIN user who has "signed-off" on DHIN.

DHIN continues to work with the major nonparticipating hospitals as well as the smaller radiology and laboratory facilities to gauge interest and enroll them as DHIN data senders in order to increase the robustness of DHIN's data and to aid in financial sustainability.

Challenges. As of June 2011, 48 percent of delivered results go to signed-off practices. As indicated in Figure 2, DHIN has moved quickly up the curve.

Figure 2. Percentage of results delivered to signed-off practices



The tiered approach, key for financial sustainability, assumes that 75 percent of deliveries are sent to a signed-off DHIN user by 2015. DHIN must continue to execute flawlessly in order to maintain the strong word of mouth reputation that it enjoys within the Delaware health care community in order to maintain its rate of sign-off growth.

Payers—Health Plans

Assumptions. Insurance companies should pay on a fair share principle because they too receive value. DHIN's query/patient search functionality benefits health plans by lowering their costs by reducing duplicative patient testing, supporting disease management, monitoring quality, and supporting clinical decisions. Also, health plans could benefit by reducing complications from duplicative therapies, which could lead to fewer patient emergency department visits, hospital re-admissions, and further testing and treatments.

It is assumed that health plans will pay a nominal fee to support the DHIN because of its potential for savings and improved patient care/quality. In addition, payers can achieve operational savings which result in better case management, thereby lowering claims, by having access to its corresponding members' data. DHIN expects to provide hospital discharge summary and Admission, Discharge and Transfer report information to payers which will allow the payers to effectively manage care at earlier stages as they have previous claim information available to them. DHIN also plans to provide the ability to query its own members in order to improve anticipatory care (reminders for appointments, etc.) and provide improved case management abilities when a patient is admitted by having clinical data available to them.

Although the State of Delaware will no longer pay operating expenses for DHIN from the Bond Bill, this revenue model includes the State as a purchaser of DHIN services as a health care payer for Medicaid and for State employees, retirees and potentially other populations, such as the incarcerated. Medicaid will pay on the same basis as other health plans and other State

agencies will pay on the same basis as their private counterparts.

Pricing structure. DHIN has proposed a per member per month fee to the three major payers Medicaid, Blue Cross Blue Shield, and Aetna, to support the HIE.

Challenges. Gaining commitment from all health plans is a challenge. Value to payers derives from both administrative savings due to efficiencies and eliminating duplicate test orders and procedures, as well as potentially from improved tools for population health management and outreach. Thus, payers' value is proportional to the number of covered lives and they will be asked to pay on that basis.

With regard to giving health plans access to data, DHIN must continue to work with the health plans and Consumer Advisory Committee to allay consumer fears that health plans could inappropriately use the data. DHIN continues to work with both constituencies to develop a working data use agreement that addresses concerns while meeting the data needs of the health plan.

To date, Medicaid has obtained Centers for Medicare & Medicaid Services approval to participate. Private health plans are looking toward Medicaid to determine their commitment and initial conversations have begun with most of Delaware's private payers. While this is part of DHIN's business plan, to date no payers have agreed to participate on this basis.

Other Potential Revenue Sources. The sustainable revenue model may adjust over time as HIEs become operational across the country and various pricing structures could become acceptable as standard practices.

The following are options for future revenue sources. These are not included in the current revenue plan or pro forma financial projections. They are alternatives being considered by other State and Regional HIEs and are not being ruled out by DHIN for future consideration. First, many other State and regional HIEs are building a revenue stream from providers into their financial sustainability plans. Currently, DHIN offers Providers the current set of functionality to be "Core Services"—results delivery and query functionality—free of charge. There may be value added services that are added in the future that will result in revenue from providers. Also, as a combination of contingency planning and fair share philosophy, the following pricing structure has been proposed.

It would be assumed that practices that have EHR that are connected to DHIN receive an added benefit in terms of workflow efficiency, administrative cost savings, and incentive payments for meaningful use. These benefits are derived from four primary areas:

- Support provided by DHIN for interfacing DHIN with their EHR.
- Direct delivery of clinical results and reports into the electronic patient chart.
- Improved quality reporting capabilities.
- Ability to share data from the EHR with other DHIN users.

Practices without EHRs receive less benefit from the use of DHIN. However, when fully integrated into the practice's workflow, DHIN provides value in terms of operating efficiencies and administrative savings.

While DHIN policy has established that DHIN users will not be charged for the base functionality of results delivery and patient record search, providers accessing the medication

history function as well as future functions (e.g., electronic order entry and electronic referrals and consultations) may be of added value to users. These services could result in a subscription fee.

Fees for providers/users will be based upon the value derived from the service, such as—

- Interface Connectivity. A one-time interface connectivity fee may be charged to each practice to support the DHIN. This includes setting up the practice to receive results/reports into their electronic health record (EHR), installing the DHIN application at the practice, coordinating the interface go-live with the EHR vendor, facilitating the validation process and upon practice sign-off, assuring that the data senders cease old delivery methods.
- Annual Subscription Fee. EHR practices may be charged a nominal annual subscription fee. For non-EHR practices this may be a tiered subscription fee based on the type of information they send or receive.

The challenge DHIN faces is that providers do not want to pay for services, and this could impede further DHIN adoption. There needs to be a tie to Federal incentive payments, meaningful use and/or enhanced reimbursement rates in order to implement this option. The social value[6] of DHIN is diminished if providers elect not to use some or all of the services DHIN provides.

A second option is annual hospital subscription fee. Hospitals may pay for a menu of value added services, such as medication history, electronic orders, and referrals and consultations. The fee structure would be based on the number of users from each hospital.

The challenge here would be that participating hospitals may believe or not understand that they receive value from DHIN as a data sender (from their laboratory and radiology departments) and as a user (from their provider and emergency department areas). As a result, they may believe that they are being overcharged for participation in the HIE. DHIN must continue to work with hospitals at an enterprise level to explain the benefits received for each of the two different functions.

Third, it is assumed that employers will benefit from future functionality to include those that are consumer focused. In the future, when security issues have been adequately resolved, patients will have the opportunity to enroll in the patient portal and direct their clinical information from DHIN to a personal health record (PHR) of their choice. Additionally, they can sign-up for reminders to inform them of preventive services based on nationally recommended protocols, medication refill reminders and other alerts. The challenge to be overcome with this option is that Employee Retirement Income Security Act (ERISA) laws prevent the ability for third party administrators to pass through DHIN charges to the self-insured employers.

Finally, an All Payer Assessment would most directly tie the value to the beneficiary. It is also the only existing mechanism for Medicare to pay its share, which is substantial considering most of the health care expenses are from the Medicare population. Because health plans act as the patient agent and every patient covered by a health plan benefits from HIE, a surcharge on

[6] DHIN's social value is a function by the number of health care entities contributing, the type of information, utilization of the information, and the impact it has on the patient's care.

health care insurance claims may be assessed.

The Vermont HIE (Vermont Information Technology Leaders) is a case study for all payer fees. Since Oct. 1, 2008, each health insurer operating in Vermont has paid a quarterly fee into a fund. Insurers choose between paying 0.199 percent of all health care claims paid for their Vermont members in the previous quarter, or a fee based on the insurer's proportion of overall claims in the past year.

Assessing a fee would require an act by the legislature to require that all health plans doing business in Delaware pay the claims assessment. This could be challenging considering the legislative and/or economic climate may or may not support this option and if it is passed, payers will likely pass the fee on to patients or employers through increased premiums. Additionally, ERISA plans fall out of the State's jurisdiction and therefore, cannot be directly assessed. A possible means to address this is for an ERISA plan's third party health plan to be assessed, passing the assessment cost back to the ERISA covered entity.

Lessons Learned About Finance and Sustainability

1. Quantify value and benefits—DHIN has attempted to develop a value-based model for each of its stakeholder groups. The tiered data sender transaction model was received by its constituents because the value was clear. As for the payers, the value is understood, but until recently, benefits were not able to be well-quantified. Given recently published studies regarding payer benefits from HIEs, DHIN now has more quantifiable support to justify its proposed fees.

2. Dedicated finance staff—Since its inception in 1997, the DHIN had been a public instrumentality of the State under the direction and control of the Delaware Health Care Commission (Commission). Upon its creation, a nonappropriated special funds account under the Commission budget was established in order for the DHIN to receive gifts and donations. While the State of Delaware provided capital financial support for DHIN since its inception, DHIN recognized the importance of a resource dedicated to incorporating financial management into its leadership structure and decision making process. As a result, DHIN's first financial manager was hired in February 2009 to provide formalized budgeting, reporting, analytical support and fiscal management to the organization.

3. Transferring finance streams can take longer than expected—As mentioned above in the governance section, the State's Fiscal Year 2010 Budget Act administratively moved the Commission, and consequently the DHIN, into the Department of Health & Social Services (DHSS) Office of the Secretary. In June 2010 the Delaware General Assembly passed, and the Governor subsequently signed into law, Senate Bill 231, which establishes a permanent governance structure for the DHIN by removing it from the organizational structure of the Commission/DHSS and creating a more traditional public/private corporation model of governance. This bill went into effect January 1, 2011.

Since DHIN's financial inception, access to Federal, private, and State DHIN funds resided with the State of Delaware. A finance workgroup, comprised of State and DHIN stakeholders, was formed to determine how DHIN funds should be accessed and managed after January 1, 2011. The workgroup determined that the State would continue to act as the DHIN's fiscal agent through June 30, 2011, with the DHIN assuming financial management responsibility after that point.

While the procedures and milestones for the funding streams were created and recognized, actually getting the Federal funds pointed to the DHIN from the State proved challenging. For AHRQ, DHIN was required to complete a Novation process in order to transfer the contract from the State to DHIN. This process took much longer than expected. As the Novation process is rare, there was a lack of knowledge within DHIN and within AHRQ contract management on exactly how to accomplish this. As a result, the process spanned more than 6 months, much longer than expected.

Also, DHIN's HIE Cooperative Agreement funds both State and DHIN projects. As a result, DHIN and the State determined that both parties needed access to the Federal Payment Management System (PMS) in order for each party's corresponding financial payment processes to operate efficiently. As a result, DHIN's Employer Identification Number (EIN) needed to be added to the Federal PMS, a process that took much longer than expected, like AHRQ, because the situation was uncommon and there was a lack of knowledge on how to best to approach it.

To ensure the smooth transfer of funding streams from the State to DHIN, the DHIN's Finance Committee and Board developed and approved financial policies and procedures. Prior to the transition, DHIN used the State's Data Universal Numbering System (DUNS) and EIN numbers. As a result of transition from the State, DHIN was required to create its own DUNS and EIN numbers. DHIN quickly learned that obtaining bank accounts and access to credit lines for operational items such as leases and utilities, and credit cards posed challenges due to a lack of credit history, as the EIN number was unable to be used until the transition date of July 1, 2011.

In addition, DHIN needed to establish policies and procedures prior to the transition as a prerequisite to obtain bank accounts and to ensure compliance with an annual audit. All of these items needed to be approved by a Finance Committee and Board of Directors, comprised of volunteers who held full time positions, which drove additional time and availability constraints.

4. Use private sector financial tools—The move from an entity controlled by the State to a more traditional, private governance structure, as directed by Senate Bill 231, led to a more sustainable business model, both financially and operationally. To execute this model successfully and achieve sustainability, the DHIN now uses commonly accepted private sector financial tools, budgeting and reporting procedures and a business plan. With this sustainability plan DHIN now aligns its financial support structure with the value received from stakeholders. In FY 2011, more than 50 percent of DHIN's revenue came from fees for services. These fees will account for nearly 100 percent of revenue in FY2013. Federal grants are not required for sustainability, but may be pursued in the future. Management and processes are in place to ensure that DHIN is able to respond to the dynamic health care market in a way that continues to support the financial sustainability of the organization.

Conclusions

DHIN's unique placement relative to the State and its transition to an instrumentality of the State presented special challenges and provided unique learning experiences.

First, the DHIN could only get financial support from stakeholders who were willing to act on the presumption of value. Someone had to go first. The DHIN saw elements of this in each

new service or function it offered. Someone had to be willing to come in, almost as an act of faith, before quantifiable studies were available proving value. The DHIN witnessed this with the leadership demonstrated by Delaware hospitals who served as DHIN's first private sector source of "venture capital" and who are now realizing rewards. Conversely, payers−who are critical to DHIN's sustainability plans and who currently receive benefit from the DHIN−have expressed reluctance to commit financially in the absence of hard data documenting a return on investment.

Second, DHIN has achieved significant success in establishing financial management practices and analytical reporting, while working with stakeholders to develop a clear sustainability path. In addition, DHIN has successfully realized significant cost savings both with its technical provider, as well as generating cost savings for it constituents. As DHIN continues refine its business plan, its opportunity to expand its revenue streams will increase as well.

Third, one of the more significant conclusions DHIN reached was the importance of adhering to the three principles it developed as it continues its transition from State control. Maintaining this discipline and following its business plan now allows the DHIN to demonstrate its value to stakeholders and contributes to sustainability.

Technical Infrastructure

Goals and Objectives

DHIN's approach−consistently throughout its design and implementation processes−has been that it only has one chance to get it right. The presumption is that providers are busy, have very low fault tolerance, and would be unlikely to give DHIN a second chance if it failed to execute on its promise. In this environment, DHIN adheres to national standards for data reporting and security. Additionally, DHIN's approach to building a HIE infrastructure is that it must be reliable, available, and scalable to ensure participants' needs are met.

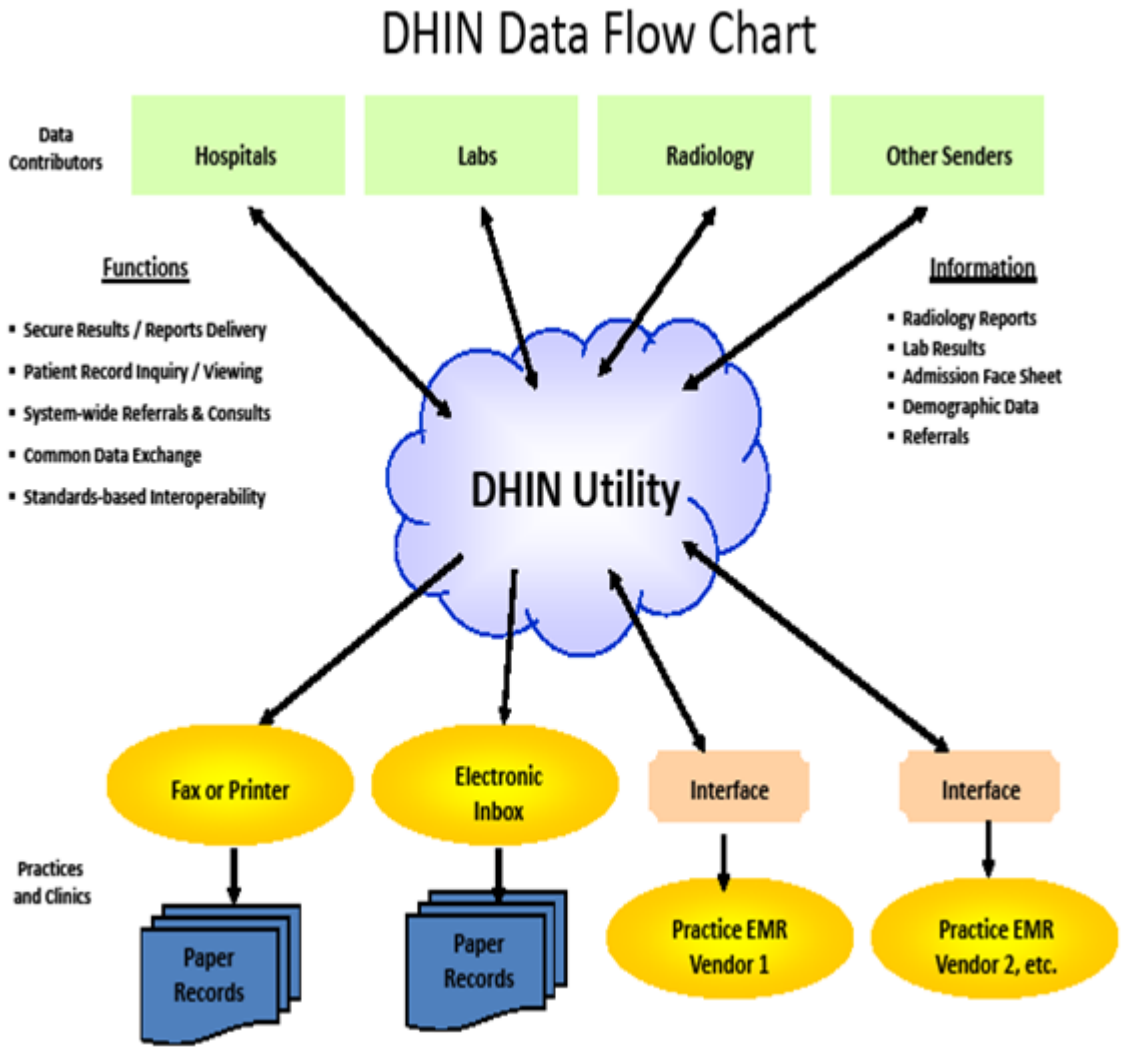
From the beginning, DHIN adopted a neutral posture toward hardware and software vendors already used by stakeholders when they sought to interface with DHIN. Using widely adopted industry standards, such as HL7, enables health care organizations to participate in the exchange of health care information as standards continue to evolve. From the requirements definition process forward, DHIN has determined to leverage the standards-based approach that it currently has in place to stay current with evolving national standards.

Selecting Technical Infrastructure Design

Role of stakeholder preferences/opinions. After examining existing technological architecture options−centralized, federated, and hybrid—and receiving feedback from its key stakeholders, the DHIN determined that a hybrid (or confederated) model was the best solution for DHIN's current and long-term goals. Under this model, each data sender's data is housed in a segregated data environment, which accommodates their desire not to comingle information in a centralized repository. The alternative centralized approach is more often seen in closed hospital and health system environments and in rural HIE environments where participants are not particularly competitive. A hybrid model also meets DHIN's approach to adhere to national security standards and meets its objective to be scalable and flexible.

To meet diverse user needs and configure to physicians' office practice workflow, the DHIN (Figure 3) offers three options for receiving clinical results and reports: (1) a Web-based Clinical Inbox for providers and their office staff for viewing clinical results— typically the Clinical Inbox is utilized by office staff members to retrieve results and reports available in the DHIN, (2) an automated interface with an electronic medical records system to allow for automated delivery of result and reports into physician-based electronic health records (EHR), eliminating the practice's need for scanning paper results/reports into their EHR, and (3) helpful printing options for paper-based practices that allow for the DHIN Clinical Inbox to be set to auto-print results and reports in a standard report format—creating efficiencies for those practices.

Figure 3. DHIN Data Flow Chart



The DHIN also provides a Web-based community health record that enables authorized health care providers to search for a patient for whom they are providing care. This patient search function affords the user a longitudinal view of all patient data available in the DHIN

statewide.

New data senders such as hospitals, radiology facilities, and laboratories can readily become members of the DHIN because of its highly scalable technology platform and environment. Maintaining the technological ability to incorporate new data senders easily reinforces the DHIN's objectives and by incorporating more data senders, demonstrates value to medical providers accessing data via the DHIN.

Selecting a Vendor

In 2005, the State of Delaware commissioned an Environmental Scan of Health Care and Policy Issues (environmental scan) that addressed a health information exchange's needs in Delaware. Delaware Technical & Community College conducted the environmental scan, gathering feedback from 80 individuals representing 30 organizations (e.g., physicians, hospitals, radiology facilities, consumers, laboratories, and State government).

For clinical applications, the environmental scan highlighted the following clinical opportunities:

- Key ways to obtain critical mass in priority order:
  - Electronic results delivery, especially laboratory data.
  - View capability.
  - Referrals (interest of private practices).

From the providers' perspective, the environmental scan identified the following needs:

- Electronic results delivery (especially laboratory data).
- Ability to view key information across organizations.
- Streamline referrals between doctors and services.
- Deliver results and reports directly into their electronic medical record systems.

The final component in the environment scan included what "data senders" (hospitals and laboratories) identified as needs:

- A system that allows them to send results and reports to providers in a faster, safer, and more cost-effective way.
- A better way to receive and share data.
- A level playing field for all hospitals and laboratories.
- A system that does not require large investments and changes in internal systems.
- A system that all practices can use, regardless of their level of technology (paper vs. electronic).

Requirements Definition. In 2005-2006, the State of Delaware contracted with a consulting firm, Health Care Information Consultants (HCIC), to prepare a functional/technical planning document, a system requirements definition, a cost-benefit analysis, and a preliminary operations and sustainability plan. The planning report included specific information on volume estimates, data receiver architecture, interface approach, data migration and translation approach,

performance standards, and a technical architecture overview. Through a strategic planning process, DHIN stakeholders expressed their discomfort with a centralized data repository for data storage resulting in the requirement for a confederated data exchange model.

From the HCIC report, the high-level functional and technical requirements that were defined and included in a Request for Proposals (RFP)[7] for a Health Information Exchange Clinical Utility are provided in Table 2.

Table 2. Functional and technical requirements

Functional	Technical
Benefit Eligibility and Claims Processing	Application Server Management
Chronic Care Management	Audit & Reporting Processing
Clinical Referrals and Consults	Charge Capture and Billing
Data Transport	Data Collection Management
Data Warehouse	Data Store Management
Electronic Orders	Data Warehouse Configuration and Management
Electronic Prescription	Inbox Management
Electronic Signature	Information Senders and Receivers Management
Inbox Management	Inquiry/Viewing Processing
Inquiry/Viewing of Patient-Centric Data	Master Person Index
Interfaces to Physician Office Management Information System (POMIS) and EMR Systems	Report Processing
Medication History	Results/Report Delivery Processing
User Enrollment and Audit	Security and Access Controls Processing
Patient Portal and Personal Health Record	
Population Health	
Practitioner Workflow Prep for Patient Inquiry	
Secure Results/Reports Delivery	
Security and Access Controls	

[7] The State of Delaware issued the RFP on March 9, 2006, with responses due on April 21, 2006.

Eight vendors responded to the RFP. During the vendor evaluation process, DHIN invited all stakeholders to participate and included representatives from—

- University of DE Center for Applied Demography & Survey Research
- AstraZeneca Pharmaceuticals LP
- Bayhealth Medical Center
- Christiana Care Health System
- Beebe Medical Center
- Delaware Back Pain
- Delaware Department of Technology and Information
- Delaware Healthcare Association
- Delaware Physicians Care
- Happy Harry's (a regional pharmacy)
- LabCorp
- MBNA Technology
- Medical Society of Delaware
- McLeon CG, Inc.
- Office of US Senator Thomas Carper
- Quality Insights of Delaware
- St. Francis Healthcare Service

DHIN and its stakeholders evaluated vendor's proposals for application functionality, an installed base, a prototype demonstration, the vendor's ability to develop, implement and enhance the product, the vendor's ability to provide ongoing systems maintenance and support, provide data center capabilities, and meet business requirements.

The DHIN invited three vendors to participate in the second phase of the evaluation process. These vendors were given 2 weeks to prepare a product demonstration using DHIN data, administrative, and clinical test scripts. The administrative script focused on patient identification and results management (e.g., results forwarding). The clinical script focused on reports exchange (e.g., delivery of laboratory and pathology results, radiology imaging studies, and admission face sheets). DHIN also required these vendors to conduct a live Web services call, during which vendors conducted a real-time query for patient information from a DHIN-affiliated health plan.

Contracted vendor deliverables. On September 15, 2006, the State of Delaware signed a 6-year contract, with 4 additional option years, with Medicity and Perot Systems to provide a statewide health information exchange.

Medicity is a health care information technology vendor supplying commercial off the shelf software solutions designed specifically to support health information exchange and clinical interoperability. As is industry standard, all solutions are owned intellectual property of Medicity; all data contributed to DHIN belongs to the appropriate contributing data sender (hospitals, laboratories, etc.) and is not the property of Medicity or the DHIN. The DHIN does not have an ownership stake in any of Medicity's intellectual property.

The DHIN went live on May 1, 2007. Since that time, the DHIN has added data senders, data receivers and receiver options, and functionality. Table 3 lists the progression of features and functionality provided through the DHIN by year.

Table 3. DHIN Features and Functionality

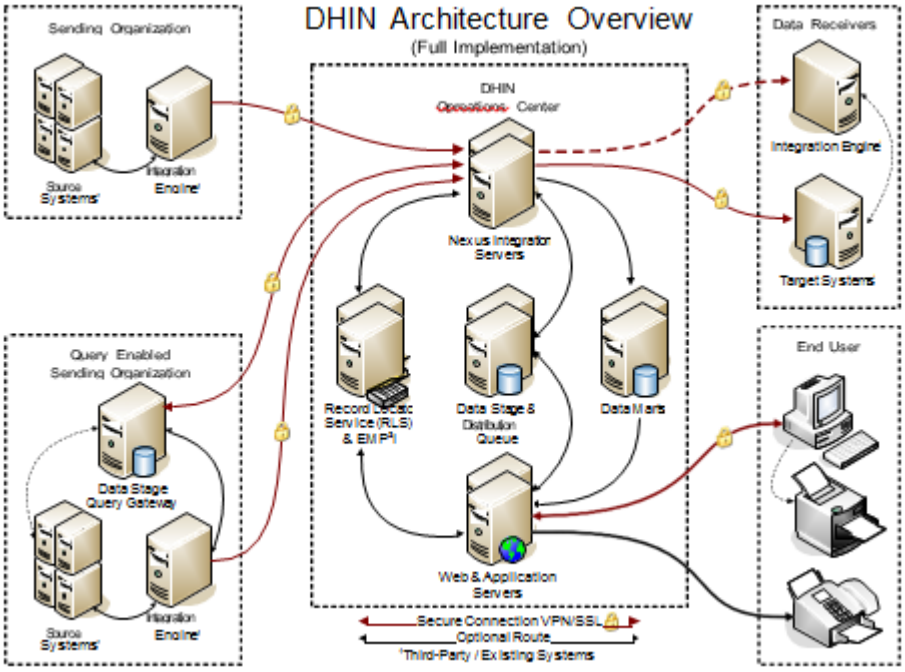
Functionality	FY2007	FY2008	FY2009	FY2010/2011
Adding Participants	Implementation of Secure Results and Reports Delivery from 3 hospital systems (5 hospitals) and national laboratory (LabCorp)		Adding additional national laboratory (Quest) and regional pathology firm (DPS)	Adding St. Francis Hospital as the fourth hospital sender organization in DHIN
Adding Features	Delivery of Laboratory Results Delivery of Pathology Results Delivery of Radiology Reports Delivery of Admission Face Sheets	Two-Tiered, delegated master patient index Provision for Record Locator Service Delivery of real- time automated public health biosurveillance reporting	Patient Centric Community Health Record Provision of Patient Search	Delivery of Transcribed reports Provision for Medication History Search Radiology Image Viewing Delivery of Laboratory Order Entry from EHR (In Planning Phase) Delivery of Clinical Summary Document (In Planning Phase)
Interfacing with EHR Vendor Systems		Interfaces to physician office electronic health records (EHR) systems Negotiated with EHR vendors for discounts of 75% off of EHR vendor charges passed onto the doctor	Additional EHR Connections	Additional EHR Connections
Adding Functionality	Flexible User Preferences Security and Access Controls (user authentication, log-in management, and audit logging and reporting)	Business Process Mapping	Enhanced Security Protocols NHIN Connectivity	

Deployment of Technical Infrastructure Design

The DHIN was established with multiple delivery mechanisms—fax, auto print, Clinical Inbox, and EHR). Delivering results through an EHR gateway provided connectivity from DHIN through EHR vendors to the practices in a standard format for laboratory results, radiology reports, and pathology results. When the DHIN expanded functionality to include transcribed reports or bidirectional functionality for items such as electronic orders laboratory orders or continuity of care documents (CCDs), the EHR gateway could not handle it.

Medicity had a product called the Grid®, a proprietary product which is part of the iNexx platform. The DHIN found that this infrastructure allowed for bidirectional functionality and was much more configurable for DHIN practices. This meets DHIN's objective that its technical infrastructure must be reliable, available, and scalable. In the coming months, DHIN will evolve into a fully bidirectional exchange of data between data senders and providers (Figure 4).

Figure 4. DHIN Architecture Overview



Security Policy and Practices

State law[8] is explicit pertaining to privacy and protection of information:

- "The DHIN shall by rule or regulation ensure that patient specific health information be disclosed only in accordance with the patient's consent or best interest to those having a need to know."
- "The health information and data of the DHIN shall not be subject to the Freedom of Information Act, Chapter 100 of Title 29, nor to subpoena by any court. Such information may only be disclosed by consent of the patient or in accordance with the DHIN's rules, regulations or orders."
- "Any violation of the DHIN's rules or regulations regarding access or misuse of the DHIN health information or data shall be reported to the office of the Attorney General, and subject to prosecution and penalties under the Delaware Criminal Code or federal law."

To meet the privacy and security laws written into DHIN's enabling statute, DHIN developed a privacy policy, which is publicly available on its Website. In March 2009, the DHIN implemented its Access to Individually Identifiable Health Information Policy.[9] The purpose of this policy is to (1) provide information about patients'/consumers' rights regarding the use and disclosure of their personal health information and (2) maintain an appropriate level of security to protect patient data from unauthorized access and disclosure. This policy defines the access controls and parameters necessary to achieve this protection and to ensure the secure and reliable operation of the DHIN.

Lessons learned about technical infrastructure. Choosing the proper architecture is vital. DHIN participants found that hybrid architecture is the most appropriate. In building the DHIN, it was important not to let technology become a hurdle to building and maintaining solid relationships between stakeholders, users, and data senders. The hybrid architecture—both extensible and scalable—provides the DHIN with a platform where competitive health care organizations can come together for the common cause of sharing information.

Conclusions. When dealing with disparate stakeholders, who are business competitors, it is important to build and maintain the relationships, gain their buy-in on the HIE's mission, and not to let the technology get in the way.

[8] 16 Delaware Code, Section 103.

[9] The full policy is located in Appendix C.

Business and Technical Operations

Goals and Objectives

The DHIN community of stakeholders believed that doing fewer things very well would yield higher adoption rates more quickly than attempting more ambitious initial functionality and failing to execute at a level of quality that is acceptable to demanding and busy providers.

Developing Partnerships and Programmatic Linkages

Delaware's small geographic size plus its small population facilitates an expectation that all stakeholders will be brought together to seek solutions to public policy issues or advance a cause. The following are the partnerships and linkages important to DHIN:

1. Medical Society of Delaware—The Medical Society of Delaware (MSD) has been actively involved with the DHIN, helping to advance the DHIN's creation in the 1990's. Since then, both organizations maintain solid, working relationships. DHIN's original 1997 enabling statute permitted MSD to appoint up to three DHIN Board members; DHIN's 2010 enabling statute permits MSD to make nonbinding recommendations to the Governor regarding DHIN Board member appointments. Today, DHIN and the MSD continue to support each other's organizational mission. For example, DHIN's new Executive Director is a member of the MSD while the MSD encourages its members to use EHR vendors that are compatible with DHIN.

2. Quality Insights of Delaware—The Delaware Health Information Network has a two-fold relationship with Quality Insights of Delaware (QID). First, QID serves as Delaware's Regional Extension Center. DHIN also contracts with QID as the REC for practices that don't qualify for assistance from the REC under the terms of Health Information Technology for Economic and Clinical Health. DHIN pays QID to help practices connect their EHR to the DHIN.

3. State Government—With the exception of the Delaware Department of Correction (DOC) and the Department of Services for Children Youth and Their Families (DSCYF), most large State programs are represented on the DHIN Board of Directors and have input into DHIN's plans.

The Governor's Stimulus Committee has created a subcommittee on health IT. The subcommittee is comprised of representatives from the Governor's Office, Delaware Department of Technology and Information Medicaid, DSCYF, DOC, and DHIN. Additionally, this subcommittee is coordinating efforts for application of the HIE grant and therefore, DHIN is working with the remaining affected State agencies to ensure collaboration and ultimately connectivity to provider efficiencies for these agencies whose client populations overlap with one another as well as the private sector.

The State Health Information Exchange Cooperative Agreement Program was established under the American Recovery and Reinvestment Act of 2009. Governor Markell specifically named DHIN as the State Designated Entity for the State of Delaware, making the DHIN the authorized applicant for the State Health Information Exchange Cooperative Agreement Program grant. DHIN has received $4.7 million over 4 years (2010–2014) under this program. Under this agreement, the following deliverables are required over the next 4 years:

- Electronic clinical laboratory ordering and results delivery
- Electronic eligibility and claims transactions
- Electronic prescribing and refill requests
- Electronic public health reporting
- Quality reporting
- Prescription fill status and/or medication fill history
- Clinical summary exchange for care coordination and patient engagement.

4. Centers for Medicaid & Medicare Services (CMS)—Recently, CMS and the Delaware Division of Medicaid and Medical Assistance agreed to participate in DHIN. As noted in the Finance portion of this report, Medicaid's involvement will provide DHIN with an additional revenue stream, as a direct payer and, hopefully, as a catalyst for private payers to participate.

Role of Stakeholder Preferences/Opinions on Business and Technical Operations

In 2005, DHIN conducted an environmental analysis surveying hospitals, practices, laboratories, radiology facilities, specialty groups, consumers, and government agencies about the type of information that would be valuable to them. Results showed that all parties wanted a way to increase the portability of health information and to deliver clinical results, especially laboratory results more quickly and securely. The original DHIN core data elements planned for exchange were extensive. The following functional and technical requirements were included in DHIN's original RFP for the Delaware Health Information Network Clinical Information Exchange Utility services issued in March 2006 (see Table 4).

Table 4. Functional and technical requirements issued in DHIN's original RFP

Functional	Technical
Benefit Eligibility and Claims Processing	Application Server Management
Chronic Care Management	Audit & Reporting Processing
Clinical Referrals and Consults	Charge Capture and Billing
Data Transport	Data Collection Management
Data Warehouse	Data Store Management
Electronic Orders	Data Warehouse Configuration and
Electronic Prescription	Management
Electronic Signature	Inbox Management
Inbox Management	Information Senders and Receivers
Incentive and Outcomes Management	Management
Inquiry/Viewing of Patient-Centric Data	Inquiry/Viewing Processing
Interfaces to Physician Office Management	Master Person Index
Information System (POMIS) and EMR	Report Processing
Systems	Results/Report Delivery Processing
Medication History	Security and Access Controls Processing
User Enrollment and Audit	
Patient Portal and Personal Health Record	
Population Health	
Practitioner Workflow Prep for Patient Inquiry	
Secure Results/Reports Delivery	
Security and Access Controls	

Identifying Data Elements for Sharing

The initial focus on results delivery was based upon the needs and preferences expressed by hospitals and laboratories that were willing to fund the system in order to streamline their paper-based methods of results delivery. DHIN prioritized results delivery in ambulatory clinics because of the high rate of EHR usage (30 percent of ambulatory providers) in the State. DHIN believed that establishing data exchange among ambulatory providers was critical to affecting health care quality and cost in Delaware.

Once implemented, DHIN turned its focus on expanding its base of users and to implementing the patient search functionality. To accomplish this, DHIN took an initial list of 15 core data elements, and grouped them into to five data types: (1) patient identification/ demographics, (2) admission, discharge, and transfer information, (3) laboratory results, (4) radiology reports, and (5) medication history. The reason for this was based on priority and ability to implement given the current technology.

One opportunity identified in the previously outlined environmental scan that has not yet been implemented is referrals. The reason is that when DHIN approached its Clinical Advisory Committee (CAC) for input, the CAC members believed that this function did not add value beyond the existing functionality that they were willing to pay to sustain. As a result, DHIN has altered its priorities for implementation, but not abandoned referrals as a functionality to be offered eventually.

Implementing Data Sharing

DHIN chose a phased approach to system implementation, beginning with a core group of health care providers, data sets, and building upon them to eventually include all health care providers and additional services to improve patient safety and quality of care.

Exchange capabilities currently include results delivery, transcribed reports, patient record inquiry to view the last 3 years of patient information, public health reporting to the Division of Public Health's Delaware Electronic Reporting and Surveillance System and admission face sheets.

For results delivery, the EHR interface is configured to pull directly from the DHIN. DHIN acts as the clinical messaging solution for its providers, which is seamless to the EHR users.

The DHIN has implemented Medicity's commercial product with minimum DHIN-specific customization and maintains a close partnership with Medicity to inform and collaborate on

future product capabilities. The DHIN plans to include a patient portal, personal health record, decision support tools, images, notes, and aggregate data for biomedical research.

Maintenance of Technical Infrastructure

A major system upgrade relating to patient inquiry functionality in early 2009 led to a temporary hold on implementation of new practices for several months and required extensive retraining of more than 600 providers.

Introducing new functionalities, such as the record locator service which enables query functionality, led to a dramatic uptick in rate of new provider enrollments. In the span of 6 months, from January to June 2009, DHIN's penetration rate increased from 27 percent of Delaware providers to 64 percent. Further illustrating the dramatic increase during this period, DHIN enrollment and use more than doubled over that achieved in the entire previous 2 years in which the only functionality was results delivery. This would appear to verify the self-evident premise that value-added features and functions will draw in new users. Results delivery was something providers already had, and the nominal value of getting those results faster in near real time was not a sufficient draw to bring in providers in large numbers, even though the service was provided to them at no charge.

Another major system upgrade is currently in progress for implementation in late 2011. This new software version will introduce functionality intended to support the requirements of Meaningful Use. Data feeds to Delaware Division of Public Health will be enriched to render the data more useful. Clinical summary (CCD exchange) will be enabled, though hospitals and practices will still have to install and implement a new interface to take advantage of this functionality.

Impact on Sustainability Plan

The earliest functionality provided by DHIN was clinical results delivery. DHIN was in essence the post office. Recipients of the "mail," the providers, received results at no charge. The data senders were assessed a proportional share, based on volume, of the required private

funding (the State required dollar for dollar private matching commitment before DHIN was permitted to draw down State funds). Data receivers did not pay.

As DHIN began the transition from development and capitalization to operations, the funding model has also transitioned from cost sharing to fixed fees. Beginning with Fiscal Year 2012, data senders pay pursuant to a three tiered model as described in the Finance Section.

It is also critical to the DHIN's sustainability plan that health plans and insurers participate as paying contributors to the DHIN. Initial approaches have been met with hesitation. The proposed funding level of $0.75 per member per month has been met with reluctance, based on competitive concerns and also lack of hard data quantifying a return on investment (ROI) that is commensurate with that level of funding. Arguably, the health plans have already begun to see value from the improved efficiencies and cost containment that DHIN has made possible, and we expect the results of the project evaluation, as outlined in the AHRQ contract and performed by Maestro, to validate that. With the emergence of a few significant studies on ROI of HIEs and the willingness of Medicaid to lead the way this year, followed by required participation of the health plans covering Delaware State employees and retirees, we hope that the private health plans and self-insured employers will gain the confidence to join the DHIN at the fee structure determined necessary for DHIN to truly be self-sustaining once the Federal grants and State capital funding are no longer available.

Lessons Learned About Business and Technical Operations

1. In retrospect, the introduction of query functionality may have been the point at which providers could have been asked to take a share in the cost of providing services through DHIN. Clearly, this was a service that did not duplicate anything currently available to them through other sources, and the upsurge in adoption following introduction of this capability verified that providers valued it. At the time, however, the decision was made to continue to allow providers to join the DHIN at no charge, focusing on increasing adoption and utilization among providers, and allowing the data senders to bear the full load of private sources of funding of the DHIN.

2. The availability of additional grant funding through the HIE Cooperative Agreement has resulted in reprioritizing and reordering the development of the DHIN's planned functionality to remain in step with the national agenda for stimulating the adoption and meaningful use of health information technology. A concern is that markets are local, and we may be devoting time and energy to functionality desired in the national agenda at the expense of functionality of more immediate value and demand for the Delaware market.

3. Following the next major system upgrade, the burden of retraining will be significantly higher than previously experienced, given that over 80 percent of Delaware providers are now enrolled in DHIN. The number of data senders has also grown since the last major system upgrade, and acceptance testing must verify data integrity in the feeds from all of them, and accurate consumption of those data over the seven EHR interfaces currently certified or in beta testing. The growth in numbers and diversity of the DHIN community creates some definite challenges in ongoing maintenance and ability to introduce new features and functions.

4. There were two possible approaches to aggregate data: probabilistic and deterministic. The DHIN chose the deterministic approach. Since dealing directly with health care data, the consequences would be serious if there were any mistakes. As noted earlier, the DHIN approach

was, and is, to execute on its promise correctly the first time because any loss of confidence in the DHIN would be detrimental. Proceeding with a deterministic algorithmic approach to data has been supported by the tremendous efforts of participating hospitals. Because this algorithm requires a high degree of certainty in the data, there were a large number of unmatched results that needed to be reconciled. Participating hospitals—as data senders—undertook a massive reconciliation process address the large number of unmatched results, leading to a threshold of no more than 3 percent of their data list unmatched.

5. The DHIN is challenged with competing initiatives and priorities from its many stakeholders, partners and funding sources. As the DHIN has matured, so has the opportunity for project initiatives outside of its core mission. The DHIN has had to be very selective and diligent about managing its portfolio of projects. Stakeholders have their own key initiatives that sometimes compete for DHIN project implementation and testing resources. The DHIN has had to incorporate these competing initiatives into its own project timeline, sometimes adjusting its timeline to accommodate the stakeholder's available resources or the technology vendor's project timeline.

6. As the DHIN has continued to advance its portfolio of projects, it came to the realization that certain initiatives may be outside of the stakeholders', partners', and/or technology vendor's ability to successfully implement the initiative. For example, the DHIN has attempted to advance its electronic laboratory orders initiative with partnering laboratories and pharmacies. It has faced hurdles such as using nonstandardized lab compendiums across data senders, challenges across its data sender partners to map to Logical Observation Identifiers Names and Codes, and poorly defined contractual arrangements limiting EHR vendors' ability to devote additional development resources to new functionality without significant changes to contractual terms.

7. Other challenges have focused on the implementation of new functionality where the benefits do not appear to match the initial or ongoing costs. For example, in 2010 the DHIN implemented a pilot medication history initiative with its technology vendor and a third-party aggregator. Although the pilot proved successful in providing this functionality, it was halted because of problems due to data integrity and network latency. The problems were corrected and the functionality is ready to be rolled out. The DHIN, however, is now challenged with implementing this functionality at a considerable cost to users who believe that it should be provided as core functionality at no cost.

Conclusions

The introduction of valued features and functions will draw in new users and new stakeholder groups. Yet asking them to share in the cost of funding DHIN requires either a very nominal fee or else the ability to demonstrate a monetary ROI to offset that cost to them. Given the State of the industry at this time, studies validating such an ROI are few in number and often difficult to generalize the results. It is difficult to judge the ideal time or price point to bring in new sources of funding. Too soon or too high a price represents a barrier to adoption, but waiting too long or setting the initial price point too low means that some constituencies will receive value in excess of their financial participation, and getting them to subsequently participate at the price point that is realistic for the value provided will be seen as asking them to pay for something they were previously getting for free or at a very low cost. If the DHIN and other statewide HIEs are to become truly sustainable, there must be a funding stream based on revenue

generated by products and services that users value enough to pay the true cost of providing them, plus a margin to allow for future growth. Pressure from the State for the DHIN to reach true sustainability this fiscal year is great. It remains to be seen whether the DHIN is seen as so valuable to the health care community of Delaware that allowing it to fold is unthinkable, and if existing and new data senders, payers, and providers will pay into DHIN at the levels required to maintain it after capital funding by the federal and State government ends.

Legal/Policy

Goals and Objectives

DHIN is a public/private partnership created to facilitate the electronic exchange of health information between health care entities. DHIN provides fast, secure and reliable exchange of health information among health care facilities and clinicians across the State. DHIN is not a medical database or an electronic medical record. DHIN's mission is "To facilitate the design, implementation and operations of an integrated, statewide health data system to support the information needs of consumers, health plans, policymakers, providers, purchasers and researchers to improve the quality and efficiency of health care services in Delaware."

To succeed and be sustainable in its mission, public and stakeholder confidence in the DHIN operating a statewide HIE is critical. The DHIN, both under the direction of the Delaware Health Care Commission and now as an independent public instrumentality of the State, developed operational policies—both internally focused and user-focused—designed to protect and safeguard personal health information through individual choice in participation, proper use, data quality, safeguards, and accountability.

Developing Policies: How Many? On What Topics? How They Were Implemented

Because DHIN is involved with the movement and delivery of patient health information, it and DHIN participants are subject to standards and requirements of the Health Insurance Portability and Accountability Act (HIPAA). Additionally, the DHIN's original 1997 enabling legislation expressly stated additional confidentiality standards as well as operational requirements for the DHIN participants.

As mentioned previously, for more than a decade, the Delaware Health Care Commission (Commission) served as DHIN's parent agency. Statute permitted the DHIN Board of Directors (Board) to propose the adoption of rules or regulations to the Commission for implementing and operating the DHIN to meet these legal requirements.

The Commission/DHIN maintained business associate agreements with the DHIN data senders for the purpose of satisfying HIPAA standards and requirements regarding protected health information and permitted uses of data. The DHIN, through contractual arrangement with all connected EHR vendors, maintains HIPAA Business Associate Agreements for the purpose of satisfying HIPAA standards and requirements and to define the rights and obligations of each entity.

Administratively housed in a State commission, the DHIN followed existing State policies as it related to the State's Administrative Procedures Act, Freedom of Information Act (FOIA) requirements, budgeting, personnel, procurement, and promulgating regulations.

The DHIN did promulgate regulations that clarified the obligations, requirements, permitted use and privacy of data that pertained to Clinical Laboratory Improvement Amendments. Additionally, DHIN maintained the following specific policies:

- Information Security Incident Policy and Procedures—which provided guidelines and established procedures for reporting, defining, determining, and responding to information security incidents and appropriate handling of confirmed breaches in the confidentiality of the DHIN data.
- User Access and Rights—to maintain an appropriate level of security to protect patient data from unauthorized access and disclosure. This policy defined the access controls and parameters necessary to achieve this protection and to ensure the secure and reliable operation of the DHIN.
- Break Glass Access Level—to define the access controls associated with the "break glass" function in the DHIN in order to maintain an appropriate level of security to protect patient data from unauthorized access and disclosure.
- Technical criteria for the DHIN participation that established matching rules and minimum data sets that must be collected from new data senders and other mandatory criteria.

As a result of Senate Bill 231, the DHIN became an independent public instrumentality of the State in 2011. One provision of that legislation required that "all rules and regulations relating to the DHIN promulgated by the Health Care Commission shall remain in full force and effect until amended by the DHIN." As such, these existing promulgated regulations and policies listed previously carried forward.

Senate Bill 231 did free the DHIN from some State policies governing procurement and hiring. Because it is a public instrumentality of the State, it still follows existing public notice and FOIA requirements. For example, the DHIN posts meeting notices on its website at least one week in advance for Board or committee meetings where a binding vote will be held. Those meetings are open to the public and offer the public an opportunity to comment.

During the transition period, members of the DHIN's Board worked with DHIN staff to identify policies that needed to be modified or created for when the DHIN became independent. In 2011, the DHIN Board approved the following policies:

- Access to Individually Identifiable Health Information which (1) provides information about patients'/consumers' rights regarding the use and disclosure of their personal health information, (2) maintains an appropriate level of security to protect patient data from unauthorized access and disclosure, and 3) defines the access controls and parameters necessary to achieve this protection and to ensure the secure and reliable operation of DHIN.
- Financial Policies Manual that (1) provides information on relevant financial policies, (2) establishes a set of rules, checks, and balances on the financial operations of DHIN, and (3) provides greater reporting consistency and greater transparency of the DHIN's true financial condition.

- Human Resources policies that provide an explanation to employees of paid time off, insurance coverage, and other benefits.

Role of Legal Counsel

A Deputy Attorney General within the Office of the Delaware Attorney General serves as DHIN's in-house legal counsel. The Deputy Attorney General advises on application of Federal and State law to DHIN activities, reviews all contracts and memoranda of agreement, as well as advises management and the Board of Directors on conflicts of interest and FOIA requirements.

Specific Discussion of the Following (including role of stakeholder preferences/opinions)

Developing data sharing agreements. The DHIN maintains Memoranda of Understanding (MOU) with the DHIN data senders to define their responsibilities and expectations. The data senders must agree to provide technical resources and expertise, space, power, hardware, software, and maintain DHIN participation.[10] DHIN agrees to manage and oversee project planning, development and implementation processes, funding and facilitate coordination among DHIN, its contractors and project partners.

The DHIN also maintains a MOU with the Delaware Division of Public Health (DPH), which defines collaboration between the DHIN and DPH's Delaware Electronic Reporting and Surveillance System (DERSS). DERSS receives data through the DHIN in one standard, real-time interface from the DHIN participating hospitals. This data includes laboratory results and emergency room chief complaints for the purpose of monitoring patterns of disease/symptoms, alerting public health officials of possible communicable disease outbreaks or bioterrorism events.

Developing privacy policy. The DHIN prepares and maintains Business Associate Agreements with all connected EHR vendors and data senders to satisfy the standards and requirements of the Health Insurance Portability and Accountability Act (HIPAA) regarding protected health information and permitted uses of data. Providers sign an End-User Licensing Agreement.

Patients can opt out at any point in time. DHIN maintains a hybrid opt-out policy for patient participation, which means patients may opt-out of DHIN's query functionality through their physicians, but patients cannot opt-out of the results delivery functionality. Providers and data senders include in their HIPAA-required privacy policies a disclosure that the patient's clinical data is sent into the DHIN, and also at that time offers the patient the choice to opt-out. To date, very few patients have chosen to opt out.

The DHIN is currently working with Medicity, its technology vendor, on more granular opt-out options rather than the current purely binary (in or out) approach. This will be a critical foundation to expanding DHIN services to include more mental and behavioral health organizations, State administrative oversight organizations, and a patient portal which will foster

[10] The MOU with data senders includes a provision stating that either the DHIN or the data sender may, upon 90-days notice, terminate the agreement.

consumer engagement (but through which legally protected information on children and adolescents must be shielded from disclosure to their parent or guardian without permission).

Developing liability policy. As noted in the Governance Section, both the DHIN's enabling statutes included a number of critical legal provisions regarding liability, including extending sovereign immunity and liability protections, declaring DHIN was not a health care provider, and shielding DHIN participants and subscribers from liability over use, or non-use, of DHIN data.

Lessons Learned About Legal/Policy Development

Federal and State laws and regulations can impact HIE policies. For example, the DHIN created policies around the rules governing permission to disclose personal health information established in the HIPAA Privacy Rule, and expanded under the American Recovery and Reinvestment Act, as well as in response to Federal regulations promulgated under the Clinical Laboratory Improvement Amendments.

In addition, Delaware State laws explicitly required the DHIN to establish rules and policies to protect personal health information and data. Creating internal operating procedures and policies cannot be neglected either. External stakeholders have an interest to see the organization operate as a business, especially with financial controls in place and other internal policies.

Conclusions

To succeed and be sustainable in its mission, public and stakeholder confidence in the DHIN operating a statewide HIE is critical. It is important to have in place a process to develop and keep current appropriate and policies to address Federal and State laws as well as business operations.

Evaluation

Developing the Evaluation Plan

As a part of its contract with the Agency for Healthcare Research and Quality (AHRQ), DHIN) was required to conduct a rigorous evaluation of the data exchange program and provide documentation of this evaluation to AHRQ. The purpose of the evaluation was to assess the nature and extent to which HIE has had an impact on important patient safety, quality processes, and outcomes within the State. In addition, the evaluation was expected to examine costs associated with DHIN to establish statewide implementation and interoperability and lessons learned regarding implementation, especially those that would be helpful to other HIEs.

The Evaluation Report, submitted separately, was the result of the rigorous evaluation of the DHIN, conducted by Maestro Strategies, LLC, a national strategy consulting firm and a recognized thought leader in return on investment and benefits realization from health IT.

A rigorous evaluation of the data exchange program offered by the DHIN was conducted to assess the nature and extent to which the HIE has had an impact on important patient safety, quality processes and outcomes within the State of Delaware. Where feasible and appropriate, AHRQ identified the following potential benefits to consider for measurement:

- Advances in care processes, improved patient outcomes, improvements in safety and quality, and better monitoring of diseases and other health risks.
- Organizational benefits such as improved organization effectiveness as evidenced in work and quality improvement processes; communication among individuals, groups, and organizations; satisfaction of needs and expectations of patients, providers, and other stakeholders; and organization risk mitigation.
- Financial benefits such as cost reduction, revenue enhancement, and productivity gains.

After initial analysis of available data, functionality provided by the DHIN, and relationship of the DHIN to potential benefits, eight measures were identified for inclusion in this analysis. These measures, which reflect a combination of formative, cost reduction, and care process efficiency and effectiveness, include the following:

- Formative Measures
  - Adoption rate: Evaluates the growth in the use of the system both in terms of number of users and transactions by user.
  - Number of unique patients: Evaluates the growth of data in the DHIN over time and as compared to the population of Delaware.
  - Privacy and security: Protection of Data: Reviews the process for ensuring the privacy and safety of patient data.

- Cost Reduction
  - Reduction in results delivery costs for data senders: Evaluates cost savings of using the DHIN for delivery of results as compared to traditional, paper-based methods.
  - Reduction in interface costs to ambulatory electronic medical records: Compares the cost of providers, hospitals, reference labs, and other public agencies directly connecting to individual ambulatory electronic health records (EHR) versus utilizing the DHIN as the central point of contact. Includes an analysis of payback period for DHIN standup costs.

- Care Process Effectiveness and Efficiency
  - Request for information outside provider's normal access: Reviews provider use of the DHIN for patients where an established relationship between patient and provider did not exist prior to seeking services to understand how providers and their extenders (nurses, medical assistants) use the DHIN to support care delivery.
  - Reduction in duplicate high cost and volume tests: Analyzes a select group of common tests to determine the reduction in the test results sent from an initial period of data availability in the DHIN to the recent activity.
  - Process improvement in practices: Utilizes feedback from end users, advisory groups, and standing committee of the DHIN to identify the impact DHIN has had on provider processes.

Internal evaluation is ongoing and accomplished through the three workgroups which make up DHIN's primary customer base. They are data sender, data receivers and consumers. Internal

evaluation is further accomplished through surveys and system monitoring, which make up DHIN's primary customer base. The DHIN became operational in May 2007 with a limited number of participants and minimum functionality. Up until recent months, a formal outside evaluation would not have yielded enough results to base an assessment.

Implementing the Evaluation Plan

The DHIN requested several contract modifications to allow extension of the deadlines around the evaluation requirement. It was felt that evaluation objectives needed to be tied to both a sustainability plan and to planned new functionality. The DHIN requested a contract modification to permit an extension from March 31, 2009, to September 30, 2010, for submission of the final evaluation plan. The DHIN developed a request for proposals to obtain a neutral third party evaluator and entered into a contract with John Snow, Inc. to develop a 2-year plan for a formal independent evaluation to assess such factors as quality, costs, patient outcomes, efficiencies and effectiveness of the DHIN. The DHIN received the report and the Evaluation Steering Committee reviewed it and prioritized the potential evaluation processes.

As a result of analysis of the market penetration of resulting validity of the evaluation, it was determined that two factors were needed before the DHIN could begin a valid evaluation of efficiency and cost savings derived from the system. First, 70 percent of the provider population must be using the DHIN, and second, the majority of data sources must be participating in the DHIN.

Another contract modification request was made in April 2010. At that time, more than 60 percent of Delaware providers were enrolled and active users of the DHIN, and a fourth hospital was expected to go live as a data sender within a few months. Per the contract modification request, the DHIN intended to issue a request for proposals and begin formal evaluation in September, 2010 and submit evaluation findings in September 2011.

The turnover of the Board of Directors under the provisions of SB231 transitioning to an independent organization in January 2011 resulted in a loss of momentum in evaluating responses to the RFP and selecting a vendor. A meeting was held at the DHIN office in May 2011 with members of the Maestro evaluation team to discuss the history and achievements of DHIN and determine what data sources were available and viable given the very compressed timeframe left to complete the evaluation. Internal DHIN data sources were identified and made available, interviews were arranged with the DHIN staff and representatives of providers, office staff, data senders, and miscellaneous others, and Medicity assisted with some directed analytics from their database. The first draft of the evaluation was due to the DHIN the first week of September 2011, and the final report was due to AHRQ by September 29, 2011.

DHIN identified that there are challenges in collecting data for evaluation of benefits realization when a sparsely staffed organization is focused with start-up and daily operational issues. In this environment, with staff efforts directed to executing an implementation plan, collecting data consistently and reliably is relegated to second-level status.

For each measure, the background, aims of measurement, method of evaluation, details of the analysis, and conclusions are outlined in the next pages in detail.

The methodology used for the assessment included both qualitative and quantitative evaluation. All qualitative assessment was completed through interviews and discussions with

four unique stakeholder groups. This included two DHIN standing committees, the Consumer Advisory Committee and the Clinical Advisory Group. End user interviews were conducted with physician representatives to understand the impact on care delivery and office practice managers to determine workflow improvements. Both end user interview groups were limited to nine or less individuals to comply with the Paperwork Reduction Act of 1995.

Detailed data at the transactional level was limited to the period of July 1, 2009, to present. For the purposes of the analysis, a cutoff date of June 30, 2011, was used to create analysis across fiscal years (DHIN's fiscal year is July 1 through June 30).

Results

Since the initial four physician practices first accessed data from the three data senders in May 2007, DHIN has steadily worked toward achieving its mission. The DHIN has worked to build the required infrastructure, engage hospitals and reference labs to establish a critical mass of patients, and connect providers across the State to this data. This work has provided the foundation for the DHIN to begin to achieve the goals established with AHRQ when DHIN was selected to serve as a demonstration project.

The Evaluation Report, submitted separately, provides the findings of the rigorous evaluation conducted to determine the extent DHIN has achieved the measures established with AHRQ. The results indicated DHIN has made progress toward all measures as outlined below:

- Advances in care processes, improved patient outcomes, improvements in safety and quality, and better monitoring of diseases and other health risks. The improvements identified are qualitatively based and demonstrated that access to information can have a positive impact on outcomes, patient safety, and quality. Examples of reduction in laboratory and radiology tests were identified as were trends indicating providers were accessing the DHIN as their initial source of information outside their practice.
- Organizational benefits such as improved organization effectiveness as evidenced in work and quality improvement processes; communication among individuals, groups, and organizations; satisfaction of needs and expectations of patients, providers, and other stakeholders; and organization risk mitigation. Both qualitative and quantitative data indicated end users have integrated use of the DHIN into their workflow and are receiving benefits. "DHIN-ing the patient" and "did you DHIN the patient" have become common practice terminology for many of the providers interviewed, demonstrating this adoption into the workflow.
- Financial benefits such as cost reduction, revenue enhancement and productivity gains. The analysis identified two significant, quantifiable financial benefits of the DHIN. By sending results through the DHIN, a savings of approximately $2.03 million dollars has been generated for the data senders. By utilizing the DHIN to connect to provider practice's Ambulatory Electronic Health Record (EHR) to hospitals and others, a single provider can save between $18,500 and $28,500 in initial implementation costs. The estimated total savings for all providers in the DHIN to connect their EHR via the DHIN is $7.5 million one-time and $1.5 million annually.

The Evaluation Report also provides a summary of lessons learned with a focus of the revelations most closely related to measuring and delivering value from the health information

exchange (HIE). These lessons include measurement processes, data standardization, and submission processes.

The DHIN has been successful in laying a foundation and establishing initial benefits for all stakeholders. Throughout, the Evaluation Report also identified opportunities for the DHIN to expand the value it provides. This included expanding the type of data provided through the DHIN, expanding both the number of providers and data senders, and gaining agreement from early DHIN provider members to accept results from the DHIN as the primary source of results delivery.

These findings lead to one significant, overall conclusion. The DHIN has reached the point where care givers are actively "pulling" data from the HIE (using results and reports available as a part of their workflow) and data is being "pushed" to the end users and made available for use. The full value of any HIE is realized when the pull exceeds the push. It is at this point users are utilizing the information as a part of the care delivery process, effectiveness and efficiency are improved, and cost savings are realized. Both the quantitative and qualitative measures demonstrated the DHIN has reached this point and users are realizing the benefits.

Additionally, the DHIN continually seeks feedback from its stakeholders, including consumers, providers, hospitals, health plans, and State government to evaluate the value of its services. It recently began an electronic satisfaction survey following a practice going live on DHIN. Responses from the survey indicate the DHIN's value in a physician practice as follows:

- Eighty percent of respondents believe that DHIN will improve the practice's efficiency.
- Eighty-four percent believe that using DHIN will improve patient care.

Additionally, DHIN has received anecdotal information from providers who have been able to redirect clinical staff away from administrative activities to focus on clinical care due to the efficiencies they gain from connecting the DHIN to their electronic health record system.

> We recently had a patient who was referred to our office for [prenatal] counseling and a level II ultrasound due to a family history of a congenital anomaly. In her appointment, the patient stated that her OB/GYN office called her that morning and stated that her AFP tetra screen, a screening test for Down syndrome, came back indicating that her pregnancy was an increased risk for Down syndrome. Her OB/GYN had not faxed over these records to our office prior to her appointment. With the DHIN, we were able to access her results within minutes, appropriately counsel her regarding her risks, answer all of her questions, and offer her the appropriate follow-up testing. Kim McGreevey, MS, CGC Lead Genetic Counselor, Delaware Center for Maternal Fetal Medicine, Newark, DE.

> I believe the benefits of the DHIN are most evident in the field of emergency medicine. Christiana Care emergency departments are receiving sites for patients from the entire State and surrounding region. Many patients are incapacitated and unable to provide vital medical information. Where in the past emergency physicians were working blindly without this information, DHIN gives us real- time access to critical data that will save lives. Dr. Tim

Shiuh, Attending Emergency Physician Christiana Care Health Systems, Associate EMS Medical Director, New Castle County, DE.

At Saint Francis ER, we cared for a patient who was complaining of abdominal pain as a result of a condition named diverticulitis. According to the patient, this condition had been diagnosed by "Cat Scan" at another Delaware facility just few days prior. We used the DHIN to obtain the results of the test. We found that in fact the patient had the test more than once at different facilities and the results were negative for diverticulitis. We also learned that the patient had multiple ER visits for the same complaint all over the State of Delaware. Thanks to the DHIN we were able to avoid unnecessary testing and prevent further exposure to radiation and risk of complications for this patient. Dr. Jaime Roques ER Physician, St. Francis Hospital Wilmington, DE

Having recently converted to an electronic medical record, the DHIN automatically places the patient's test results in their file and notifies the physician test results have arrived. It even posts the results that are out of range in red so the physician can prioritize his/her work, focusing attention on the patients who are sicker and in need of treatment more urgently. Adrian Scipione, JD, MBA Executive Director—Pulmonary Associates.

Recommendations for Future Research

The DHIN has achieved much in a few years, but many challenges remain and could serve as fruitful areas of future research.

The DHIN is currently challenged by the following:

- Long-term care and home health care u research and explore opportunities to expand the DHIN across the continuum of care.
- Medication History —medication (including over-the-counter) history obtained from numerous sources make it nearly impossible to capture a complete medication history. In 2010, DHIN undertook a pilot with medication history derived from aggregated pharmacy data. There is a cost to DHIN for each medication history search. The DHIN must therefore determine the value and usefulness of the data before permanently implementing. The pilot revealed that the data is extremely valuable, particularly in the emergency setting, but incorporation of the capability into sound workflow is critical for user acceptance. As a result of feedback from the pilot, Medicity has made modifications in this capability that will be made available at the next major system upgrade in November 2011. However, it still remains to be seen whether the perceived value of this functionality will draw users in at the price point that will be required to sustain it.
- While the national movement is to adopt EHRs and health information exchange as a vehicle to improve health outcomes, there are many practices that are very ill-prepared for the move to very different tools and in some cases, very different workflow demanded by adoption of health IT. Further research into how tech-savvy and tech-averse users can coexist on the same network and technology platform would be useful.

Appendix A: 1997 Enabling Statute

TITLE 16
Health and Safety
Delaware Health Care Commission
CHAPTER 99. DELAWARE HEALTH CARE COMMISSION
Subchapter IV. Delaware Health Information Network

§ 9920. Purpose.

(a) The purpose of this subchapter is to create a public instrumentality of this State known as the Delaware Health Information Network ("DHIN") under the direction and control of the Delaware Health Care Commission ("Commission") to promote the design, implementation, operation and maintenance of facilities for public and private use of health care information in the State.

(b) It is intended that the DHIN be a public-private partnership for the benefit of all of the citizens of this State.

(c) The DHIN shall ensure the privacy of patient health care information.

§ 9921. Creation of Delaware Health Information Network.

(a) There is hereby established the Delaware Health Information Network, which will be managed and operated by a Board of Directors consisting of at least 13 and not more than 21 members. It is intended that the membership of the Board reasonably reflect the public-private and diverse nature of the DHIN. Up to 6 members of the Board shall be appointed by the Commission to serve at its pleasure for a term to be determined by the Commission. The Chairperson of the Board shall be elected by a majority of the members appointed to the Board.

(b) The remaining membership of the DHIN Board shall be appointed as follows: The Commission will appoint an additional 3 members from Delaware authorized health insurers, HMOs or medical service corporations; the Association of Delaware Hospitals and the Medical Society of Delaware or their successor entities may each appoint up to 3 members; the Delaware State Chamber of Commerce, the Secretary of the Department of Technology and Information, the Director of the Office of Management and Budget, the Insurance Commissioner, the Secretary of Health and Social Services and the Director of Public Health, or their successor entities, may each appoint 1 member.

(c) The Commission and other appointing authorities are authorized to appoint State

officers and employees and other individuals to the Board, and no State officer or employee appointed to the Board or serving in any other capacity for the Board shall be construed to have resigned from public office or employment by reason of such appointment or service.

(d) The Board is authorized to conduct its business by a majority of a quorum. A quorum is a simple majority of the members appointed.

(e) The Board may propose the adoption or amendment of rules or regulations to the Commission for implementing and operating the DHIN, including, but not limited to, the establishment of staggered terms for the Board Chairperson and members.

§ 9922. Powers and duties.

(a) In furtherance of the purposes of this subchapter, the DHIN shall have the following powers and duties:

(1) Develop a community-based health information network to facilitate communication of patient clinical and financial information, designed to:

a. Promote more efficient and effective communication among multiple health care providers, including, but not limited to, hospitals, physicians, payers, employers, pharmacies, laboratories and other health care entities;

b. Create efficiencies in health care costs by eliminating redundancy in data capture and storage and reducing administrative, billing and data collection costs;

c. Create the ability to monitor community health status; and

d. Provide reliable information to health care consumers and purchasers regarding the quality and cost-effectiveness of health care, health plans and health care providers;

(2) Develop or design other initiatives in furtherance of its purpose;

(3) Report and make recommendations to the Commission; and

(4) Perform any and all other activities in furtherance of the above or as directed by the Commission.

(b) To carry out the above duties, the DHIN is granted all incidental powers, including contracting with others to perform its duties and employing sufficient staff. The DHIN is authorized to establish a nonappropriated special funds account in the Commission’s budget

in order to receive gifts and donations. All of the above are subject to the Commission's approval and control.

§ 9923. Immunity from suit; limitation of liability.

(a) All members of the Board of Directors of the DHIN and all members of the Commission, whether temporary or permanent, shall not be subject to and shall be immune from claim, suit, liability, damages or any other recourse, civil or criminal, arising from any act or proceeding, decision or determination undertaken, performed or reached in good faith and without malice by any such member or members acting individually or jointly in carrying out the responsibilities, authority, duties, powers and privileges of the offices conferred by law upon them under this chapter, or any other State law, or duly adopted rules and regulations of the aforementioned committees, good faith being presumed until proven otherwise, with malice required to be shown by a complainant. All employees and staff of the DHIN and the Commission, whether temporary or permanent, shall enjoy the same rights and privileges concerning immunity from suit otherwise enjoyed by State employees pursuant to the Constitution of this State and
§§ 4001 through 4005 of Title 10.

(b) The DHIN is not a health care provider and is not subject to claims under Chapter 68 of Title 18. No person who participates or subscribes to the services or information provided by the DHIN shall be liable in any action for damages or costs of any nature, in law or equity, which result solely from that person's use or failure to use DHIN information or data that was imputed or retrieved in accordance with the rules or regulations of the DHIN as approved by the Commission. In addition, no person shall be subject to antitrust or unfair competition liability based on membership or participation in the DHIN, which provides an essential governmental function for the public health and safety.

§ 9924. Property rights.

(a) All persons providing information and data to the DHIN shall retain a property right in that information or data, but grant to the other participants or subscribers a nonexclusive license to retrieve and use that information or data in accordance with the rules or regulation promulgated by the Commission.

(b) All processes or software developed, designed or purchased by the DHIN shall remain its property subject to use by participants or subscribers in accordance with the rules or regulations promulgated by the Commission.

§ 9925. Regulations; resolution of disputes.

(a) The Commission is hereby authorized to promulgate rules and regulations under and pursuant to subchapter II of Chapter 101 of Title 29 to carry out the objectives of this subchapter.

(b) To resolve disputes under this subchapter or the rules and regulations promulgated herein among participants, subscribers or the public, the Commission is hereby authorized to hear and determine case decisions under and pursuant to subchapter III of Chapter 101 of Title 29.

(c) Any person aggrieved by the unlawfulness of any rule or regulation of the Commission herein, or any person against whom a case decision has been decided, may appeal to the Superior Court in accordance with subchapter V of Chapter 101 of Title 29.

§ 9926. Privacy; protection of information.

(a) The Commission shall by rule or regulation ensure that patient specific health information be disclosed only in accordance with the patient's consent or best interest to those having a need to know.

(b) The health information and data of the DHIN shall not be subject to the Freedom of Information Act, Chapter 100 of Title 29, nor to subpoena by any court. Such information may only be disclosed by consent of the patient or in accordance with the Commission's rules, regulations or orders.

(c) Any violation of the Commission's rules or regulations regarding access or misuse of the DHIN health information or data shall be reported to the office of the Attorney General, and subject to prosecution and penalties under the Delaware Criminal Code or federal law.

§ 9927. No pledge of state credit; no assumption of liability by State.

The DHIN shall have no power, except where expressly granted by separate act of the General Assembly, to pledge the credit or to create any debt or liability of the State or of any other agency or of any political subdivision of the State, and the State shall not assume or be deemed to have assumed any debt or liability of the DHIN as a result of any actions by the DHIN.

Appendix B: 2010 Enabling Statute

TITLE 16
Health and Safety
Delaware Health Information Network
CHAPTER 103. DELAWARE HEALTH INFORMATION NETWORK

§ 10301. Purpose.

(a) The purpose of this subchapter is to create a public instrumentality of this State known as the Delaware Health Information Network ("DHIN") which is a not-for-profit body both politic and corporate, which shall have the rights, obligations, privileges and purpose to promote the design, implementation, operation and maintenance of facilities for public and private use of health care information in the State. The DHIN shall be the State's sanctioned provider of health information exchange services.

(b) It is intended that the DHIN be a public-private partnership for the benefit of all of the citizens of this State.

(c) The DHIN shall ensure the privacy of patient health care information.

§ 10302. Creation of Delaware Health Information Network.

(a) There is hereby established the Delaware Health Information Network, which will be managed and operated by a Board of Directors consisting of 19 members. It is intended that the membership of the Board include individuals with various business, technology and healthcare industry skills committed to managing the Corporation in an efficient, effective and competitive manner. The Board shall be comprised of the following members:

(1) The Director of the Office of Management and Budget or the Director's designee;

(2) The Chief Information Officer of the Department of Technology and Information or the Chief Information Officer's designee;

(3) The Secretary of the Department of Health and Social Services or the Secretary's designee;

(4) The Controller General or the Controller General's designee;

(5) Six members, appointed by the Governor, including at least 1 person who shall represent the interests of medical consumers and at least 3 with experience and/or expertise in the healthcare industry;

(6) Three members appointed by the Governor representing hospitals or health systems;

(7) Three members appointed by the Governor representing physicians;

(8) One member appointed by the Governor representing businesses or employers; and

(9) Two members appointed by the Governor representing health insurers or health plans. The Chair of the Board shall be elected from among its members by a majority of the

Directors and shall serve a 3-year term. Each member shall serve a 3-year term, with such initial terms being staggered as set by the Governor and each member continuing to serve beyond such term until a successor is appointed. Any member absent without adequate reason for 3 consecutive meetings, or who fails to attend at least half of all regular business meetings during any calendar year, may be removed from the Board with the approval of the Governor upon a recommendation from the Board. The Board, the Delaware Healthcare Association, the Medical Society of Delaware, Delaware State Chamber of Commerce, and other interested organizations may make nonbinding recommendations to the Governor for appointments to the Board.

(b) No state officer or employee appointed to the Board or serving in any other capacity for the Board shall be deemed to have resigned from public office or employment by reason of such appointment or service. Members of the Board who are serving on January 1, 2011, shall continue to serve until a successor is appointed by the Governor or otherwise designated by the ex officio members.

(c) The Board is authorized to conduct its business by a majority of a quorum. A quorum is a simple majority of the members appointed.

§ 10303. Powers and duties.

(a) In furtherance of the purposes of this subchapter, the DHIN shall have the following powers and duties:

(1) Develop and maintain a community-based health information network to facilitate communication of patient clinical and financial information, designed to:

a. Promote more efficient and effective communication among multiple health care providers, including, but not limited to, hospitals, physicians, payers, employers, pharmacies, laboratories and other health care entities;

b. Create efficiencies in health care costs by eliminating redundancy in data capture and storage and reducing administrative, billing and data collection costs;

c. Create the ability to monitor community health status; and

d. Provide reliable information to health care consumers and purchasers regarding the quality and cost-effectiveness of health care, health plans and health care providers;

(2) Develop or design other initiatives in furtherance of its purpose;

(3) Report and make recommendations to the Governor and General Assembly;

(4) Adopt bylaws to govern the conduct of its affairs and to carry out and discharge its powers, duties and functions and to adopt policies as appropriate to carry out and discharge its powers, duties, and functions, and to sue, but not be sued, to enter into contracts and agreements and to plan, control facilities and such real and personal property as it may deem necessary, convenient or desirable without applications of the provisions of Chapters 59, 69, or 70 of Title 29;

(5) All prior regulations and rules promulgated by the Delaware Health Care Commission regarding the DHIN shall remain in full force and effect until the DHIN replaces the aforementioned regulations and rules with bylaws and/or policies;

(6) The bylaws shall include a provision pertaining to conflicts of interest and that Board members, staff, committee members and others conducting business or associated with the DHIN shall be required to sign conflict of interest statements;

(7) To have and exercise any and all powers available to a corporation organized pursuant to Chapter 1 of Title 8, the Delaware General Corporation Law;

(8) To employ such personnel and provide such benefits as necessary to carry out its functions and to retain by contract engineers, advisors, and other providers of advice, counsel and services which it deems advisable or necessary in the exercise of its purposes and powers and upon such terms as it deems appropriate;

(9) To exercise all of the power and the authority with respect to the operation, development and maintenance of the DHIN;

(10) To do all acts and things necessary or convenient to carry out its functions, including without limitation, the authority to open and operate separate bank accounts in the name of the DHIN;

(11) To collect, receive, hold and disburse funds in accordance with the needs of the DHIN, including user fees set by the DHIN;

(12) Implement and operate a statewide integrated health information network to enable communication of clinical and financial health information, and other information and other related functions as deemed necessary by the Board;

(13) Promote efficient and effective communication among Delaware healthcare providers and stakeholders including hospitals, physicians, state agencies, payers, employers, and laboratories;

(14) Promote efficiencies in the healthcare delivery system;

(15) Provide a reliable health information exchange to authorized users;

(16) Work with governments and other states to integrate into or with the DHIN and/or assist them in providing regional integrated health information systems;

(17) Work towards improving the quality of health care and the ability to monitor community health status and facilitate health promotions by providing immediate and current outcome, treatment and cost data and related information so that patients, providers and payers can make informed and timely decisions about health care;

(18) The DHIN shall make annual reports to the Governor and members of the General Assembly setting forth in detail its operations and transactions, which shall include annual audits of the books and accounts of the DHIN made by a firm of independent certified public accountants mutually agreed to by the Auditor of Accounts and the Director of the Office of Management and Budget; and

(19) Perform any and all other activities in furtherance of the above.

(b) To carry out the above duties, the DHIN is granted all incidental powers, without limitation, including the following:

(1) To contract with sufficient third parties and/or employ nonstate employees, without applications of the provisions of Chapters 59, 69, or 70 of Title 29 respectively;

(2) To establish a nonappropriated special funds account in its budget in order to receive gifts and donations;

(3) To establish reasonable fees or charges for provision of its services to nonparticipant third parties; and

(4) To sell or license any copyrighted or patented intellectual property.

§ 10304. Immunity from suit; limitation of liability.

(a) All members of the Board of Directors of the DHIN, whether temporary or permanent, shall not be subject to and shall be immune from claim, suit, liability, damages or any other recourse, civil or criminal, arising from any act or proceeding, decision or determination undertaken, performed or reached in good faith and without malice by any such member or members acting individually or jointly in carrying out the responsibilities, authority, duties, powers and privileges of the offices conferred by law upon them under this chapter, or any other State law, or duly adopted rules and regulations of the DHIN, good faith being presumed until proven otherwise, with malice required to be shown by a complainant. All employees and staff of the DHIN, whether temporary or permanent, shall enjoy the same rights and privileges concerning immunity from suit otherwise enjoyed by State employees pursuant to the Constitution of this State and §§ 4001 through 4005 of Title 10.

(b) The DHIN is not a health care provider and is not subject to claims under Chapter 68 of Title 18. No person or entity who participates or subscribes to the services or information provided by the DHIN shall be liable in any action for damages or costs of any nature, in law or equity, which result solely from that person's use or failure to use DHIN information or data that was imputed or retrieved in accordance with the rules or regulations of the DHIN. In addition, no person shall be subject to antitrust or unfair competition liability based on membership or participation in the DHIN as the State's sanctioned provider of health information services that are deemed to be essential to governmental function for the public health and safety.

§ 10305. Property rights.

(a) All persons providing information and data to the DHIN shall retain a property right in that information or data, but grant to the other participants or subscribers a nonexclusive license to retrieve and use that information or data in accordance with the rules or regulation promulgated by the DHIN.

(b) All processes or software developed, designed or purchased by the DHIN shall remain its property subject to use by participants or subscribers in accordance with the rules or regulations promulgated by the DHIN.

§ 10306. Regulations; resolution of disputes.

(a) The DHIN is hereby authorized to promulgate rules and regulations under and pursuant to subchapter II of Chapter 101 of Title 29 to carry out the objectives of this subchapter. All prior regulations and rules promulgated by the Delaware Health Care Commission in regards to the DHIN shall remain in full force and effect until amended or repealed by the DHIN.

(b) To resolve disputes under this subchapter or the rules and regulations promulgated herein among participants, subscribers or the public, the DHIN is hereby authorized to hear and determine case decisions under and pursuant to subchapter III of Chapter 101 of Title 29.

(c) Any person aggrieved by the unlawfulness of any rule or regulation of the DHIN herein, or any person against whom a case decision has been decided, may appeal to the Superior Court in accordance with subchapter V of Chapter 101 of Title 29.

§ 10307. Privacy; protection of information.

(a) The DHIN shall by rule or regulation ensure that patient specific health information be disclosed only in accordance with the patient's consent or best interest to those having a need to know.

(b) The health information and data of the DHIN shall not be subject to the Freedom of Information Act, Chapter 100 of Title 29, nor to subpoena by any court. Such information may only be disclosed by consent of the patient or in accordance with the DHIN's rules, regulations or orders.

(c) Any violation of the DHIN's rules or regulations regarding access or misuse of the DHIN health information or data shall be reported to the office of the Attorney General, and subject to prosecution and penalties under the Delaware Criminal Code or federal law.

§ 10308. No pledge of state credit; no assumption of liability by State.

The DHIN shall have no power, except where expressly granted by separate act of the General Assembly, to pledge the credit or to create any debt or liability of the State or of any other agency or of any political subdivision of the State, and the State shall not assume or be deemed to have assumed any debt or liability of the DHIN as a result of any actions by the DHIN.

Appendix C: DHIN Privacy Policy

The Delaware Health Information Network (DHIN) provides fast and secure exchange of test results and reports among hospitals, labs, x-ray facilities, and doctors statewide. DHIN is *not* a complete record of your health history. It is simply a way for health care providers to access patient medical information that they need to provide you with the best care possible.

Non-Participation:

Patients who do not want their medical information to be accessible to authorized health care providers through DHIN may choose not to participate. If you choose not to participate, health care providers will not be able to look for your records in DHIN.

Choosing not to participate means emergency room (ER) doctors will not be able to get information that could help them give you better care or save your life in an emergency.

Also, some providers may decide not to see patients that do not participate in DHIN because they won't have access to medical information that would help them give patients the best care possible.

If you do not want to participate in DHIN, you must complete the Non-Participation Form below. If you have filled out a Non-participation form and have decided to participate in DHIN, please complete the Cancellation of Non-Participation Request Form below.

For your protection, DHIN requires that you verify your identity in one of two ways: have the form signed by a health care provider licensed in Delaware, or have the form signed by a notary public.

Access to Individually Identifiable Health Information Policy

In March 2009, the DHIN implemented the following Access to Individually Identifiable Health Information Policy:

A. Background

1. The Delaware Health Information Network, (DHIN) is a public/private partnership created to facilitate the electronic exchange of health information between health care entities. DHIN provides fast, secure and reliable exchange of health information among health care facilities and clinicians across the state. DHIN is *not* a medical database or an electronic medical record. It is a mechanism to facilitate the movement and delivery of patient health information among those with a need to know. The design and implementation of DHIN include state-of-the-art security precautions to safeguard personal health information.

B. Purpose

1. The purpose of this policy is to:

    a. Provide information about patients'/consumers' rights regarding the use and disclosure of their personal health information.

    b. Maintain an appropriate level of security to protect patient data from unauthorized access and disclosure. This policy defines the access controls and parameters necessary to achieve this protection and to ensure the secure and reliable operation of DHIN.

C. ***Scope*** This policy is applicable to all users and member organizations of DHIN. All users of DHIN, senders and receivers of data, have signed and agreed to the DHIN Data Use Agreement and Business Associate Agreement. This policy does not supersede or replace any Health Insurance Portability and Accountability Act (HIPAA) privacy and security policies in use by individual DHIN users and member organizations.

1. All participating DHIN hospitals' privacy policies have been reviewed and are inclusive of electronic exchange of health information. This applies to delivery and query of information through DHIN for the purposes of treatment, payment or operations/administrative actions.

D. Definitions

1. *Access Controls*—system level security that grants authorization to view personal health information in DHIN.
2. *Auditing*—the logging and monitoring of all system activity, including: user log-in identification, user name, user organization, date and time, patient account that was accessed, and type of records viewed by user.
3. *Health Care Provider*—health professionals licensed in Delaware with the authority to order or prescribe clinical tests and diagnostics, including physicians as defined by

Title 18, Section 1861(r) of the Social Security Act, and clinical medical professionals who are licensed to diagnose and treat patients under the supervision of such physicians.

4. *Data Contributing Organizations*—those health care facilities that send clinical data (e.g., lab results) to health care providers/clinicians through DHIN.
5. *Users*—those who enroll in DHIN to receive clinical results and reports. DHIN users are clinicians and their designated staff, who must agree to maintain the privacy and security of the information they obtain from DHIN. DHIN users receive clinical results and reports free of charge and, when available, may also query DHIN for clinical history.
6. *Member Organizations*—those who are sending data into the health information exchange as well as those who benefit from the system, such as health plans and employers. Member Organizations have a responsibility to DHIN both financially as well as to ensure accurate delivery of data into the system for consumption by DHIN users for the delivery of clinical care.
7. *User Roles*—rules defined by DHIN and assigned to users, determining an individuals' level of access to personal health information through DHIN.
8. *User Authentication*—requirements for users to gain authorized access to the DHIN application.
9. *Query*—allows an authorized user who has an established relationship with a patient to search for clinical information for that patient available through DHIN on a need to know basis.
10. *Expanded Query Access*—allows a user to temporarily extend their access rights under defined parameters to view clinical information available through DHIN on a need to know basis.
11. *Need to Know*—in order to safeguard patient/consumer privacy, DHIN users shall receive access only to the minimum functions and privileges required for performing their jobs.
12. *Individually Identifiable Health Information*—a subset of health information, including demographic data and past, present, or future health condition information collected from an individual that is created or received by a health care provider participating in DHIN.
13. *HIPAA* — the Health Insurance Portability and Accountability Act (HIPAA) designed to help protect privacy of a patient/consumer's protected health information

E. Patient/Consumer Privacy

1. Notice to Patient/Consumers Regarding DHIN

a. Patient/consumer privacy is of critical importance. DHIN complies with state and federal laws, including HIPAA, as applicable. With the assistance of Delaware's privacy officers, hospitals, legal counsel and the DHIN consumer advisory committee, DHIN has established a policy that considers the patients' rights and expectations while balancing the need for health care providers to have information that enables them to make informed decisions and ultimately provide better quality health care services.

b. DHIN users shall implement appropriate procedures to (1) inform patients that they use DHIN, and (2) inform patients of their right to non-participation in DHIN.

c. DHIN shall make available to users tools necessary to respond to patient inquiries about DHIN.

2. Uses and Disclosures of Individually Identifiable Health Information

a. Disclosure of Individually Identifiable Health Information. DHIN patient/consumer information is not sold or disclosed for any activity that may support marketing to the individual nor is individual information provided and/or used for mailing lists.

b. Query Access. Only users enrolled in DHIN who have an established relationship with a patient will have access to that patient's information available through DHIN. Emergency care personnel will have access to DHIN whereby they can access patient records in emergency care situations on a need to know basis.

c. Expanded Query Access. Users may expand their access to patient information by requesting to establish a relationship with a patient in DHIN. Users are required to log a reason for the relationship and set a defined time period for access, not to exceed six (6) months. Refer to the Expanded Query Access (Section F.6) for specific details related to this function.

d. Audit Reporting. Patients/consumers are provided the means and opportunity to request an audit report that identifies which DHIN user(s) has accessed their individually identifiable health information through DHIN. Audit reports will not contain any personal health information. Specific procedures shall be established to respond to requests for audit reports.

e. Compliance with Law. All disclosures of individually identifiable health information through DHIN and the use of such information obtained from users of DHIN shall be consistent with all applicable federal and state laws and regulations and shall not be used for any unlawful discriminatory purpose. Violations of privacy are subject to immediate termination of access to DHIN up to and including legal action in accordance with DHIN's privacy policy and with all applicable federal and state laws and regulations. Pursuant to the DHIN

Statute, inappropriate access is a criminal offense that could be a Class D felony punishable by eight (8) years imprisonment, fines and penalties for each offense.

3. **Patient/Consumer Non-Participation**

a. Patients/consumers may decide not to participate in DHIN.

b. Non-participation will result in personally identifiable health information not being available to users (including emergency personnel) upon a query or expanded query.

c. Patients/consumers may choose to participate in the system again at any time.

d. DHIN will develop specific procedures to process non-participation requests, as well as requests to begin participating again.

e. Users should adopt procedures for notifying DHIN of requests from patients/consumers not to participate. DHIN shall respond in a timely manner and according to the procedures that are established.

4. Amendment of Data

a. In accordance with HIPAA, patients/consumers are provided the means to challenge and amend their individually identifiable health information. Requests to amend data shall be made to the data contributing organizations; DHIN does not have the authority or access to amend individually identifiable health information.

F. Information Security

1. **Access Controls**

a. Only authorized users are granted access to DHIN, and users are limited to specifically defined, documented and approved levels of access rights.

b. Access control to DHIN is achieved via identifiers that are unique to each user and provide individual accountability and enable tracking.

c. Access rights are based on user roles and job responsibilities. The health care provider enrolled in DHIN is responsible for creating staff accounts and assigning user roles to those who work for them. Users should be granted access to information on a need to know basis. That is, users should only receive access to the minimum functions and privileges required for performing their jobs.

d. Users will be required to acknowledge and accept the Terms and Conditions of Use statement prior to logging into the application.

e. Users will be held responsible for all actions conducted under their sign-on.

f. Any user accessing the DHIN application must be authenticated. The level of authentication will correspond appropriately to the designated access rights.

g. When a user is inactive for a period of time, defined by DHIN and consistent with HIPAA, the application will automatically time-out. Users will then be required to log on again to continue usage. This minimizes the opportunity for unauthorized users to assume the privileges of the intended user during the authorized user's absence.

2. **User Authentication**

a. To obtain access to the DHIN application, an authorized user must enter his/her unique user identification and supply an individual user password.

b. To obtain a new password from DHIN, users must be able to provide the answers to unique questions selected and answered by the user at the time of set-up.

c. All users will be required and prompted to change their passwords at a time interval defined by DHIN and consistent with HIPAA.

d. Passwords must be promptly changed if it is suspected of being disclosed to unauthorized parties.

e. At the time a user is no longer associated with or employed by a member organization, the member organization is required to terminate the user's access to DHIN.

3. **User Roles**

a. DHIN will define, document and maintain user roles created in the application and establish a process for periodic review.

4. Access Rights

a. Users will be defaulted to have access only to their organization's data. Only pre-defined and approved users will be allowed to obtain expanded access to individually identifiable health information through DHIN.

b. Expanded Query Access is an access level that enables a user to temporarily expand their standard security rights to view patient information available through DHIN on a need to know basis. Refer to Section F.6 "Expanded Query Access" for information specific to this function.

5. Audit Controls

a. DHIN logs and monitors all system activity, including: user log-in identification, user name, user organization, date and time, patient account that

was accessed, and type of records viewed by user. Audit reports do not contain personal health information.

b. DHIN shall audit access to individually identifiable health information on a regular and scheduled basis to ensure appropriate use of the system. Procedures shall be established to define this process.

c. Patients/consumers are provided the means and opportunity to request an audit report of who has accessed their health information through DHIN. DHIN shall establish specific procedures to respond to patient requests for audit reports in a timely manner.

6. Expanded Query Access

a. User Requirements

1. The right of a user to obtain expanded query access is established by the DHIN user roles.
2. If expanded query is utilized, the user must indicate a reason, from a pre-populated list of options, as to why they have expanded their access rights.
3. Each time expanded query is utilized, the user must also indicate the period of time in which they need to have access to the patient's data, from one time to a period of time not to exceed six (6) months.

b. Auditing

1. DHIN logs and monitors all expanded query access activity, including: user log-in identification, user name, user organization, date and time, patient account that was accessed, the reason the user utilized expanded query, time period for which access was established, and the type of records viewed by user.
2. Patients/consumers are provided the means and opportunity to request an audit report of who has accessed their health information through DHIN, including utilization of expanded query. Audit reports do not contain personal health information. DHIN shall establish specific procedures to respond to patient requests for audit reports in a timely manner.