

I. EXECUTIVE SUMMARY

In the Institute of Medicine's 2006 report, "Patient Safety: Achieving a New Standard for Care," a primary recommendation called for "all health care organizations to provide immediate access to complete patient information and decision support tools." The increasing number of calls locally and nationally to implement health information technology and health information exchange have, at their heart, the goal of putting current and comprehensive patient information in the hands of practitioners at the point of care.

Today, in Michigan, the goal of providing consolidated clinical information to health care practitioners is, as yet, unachieved. Despite progress in the adoption of health information technology within health care organizations, there are no operational health information exchanges providing consolidated clinical records between health care organizations. While Michigan shares many barriers and challenges with other states, it also has unique strengths and opportunities that can be leveraged to ensure success.

The transformation to the electronic exchange of health information across traditional organizational boundaries is inevitable and is driven by many compelling needs, however there are many challenges. First, the U.S. health care system is highly fragmented. Health care data is stored, often in paper form, in "silos", (e.g. hospitals, laboratories, physician offices, ambulatory treatment centers, and pharmacies). Second, public health agencies utilize phone, fax and mail to conduct public health surveillance, detection, management and emergency response. Third, physicians spend 20 – 30 percent of their time searching for information and very often do not find the health care information they need at the time when they need it the most, when with the patient.

In addition, health care professionals and clinical service providers need the capability to exchange health information in order to improve patient care by ensuring that accurate patient data (medications, allergies, chronic conditions, history, etc.) are available at the point of care. Health information exchange (HIE) is a way to electronically move personal health and medical information securely between various health care organizations and providers under current medical privacy and confidentiality standard procedures. The goal of HIE is to facilitate delivery and retrieval of clinical data to provide safe, timely, efficient, effective, and equitable, patient-centered care.

Michigan Governor, Jennifer M. Granholm, has charged the Michigan Department of Community Health (MDCH) and the Michigan Department of Information Technology (MDIT) with bringing together Michigan's health care and business stakeholders to develop a vision and plan for the future of health information technology and exchange in Michigan. In Governor Granholm's 2006 State of the State Address, the goal of extending health information technology to every health care setting was highlighted:

"We will help our health care industry stop depending on your memory and their paper records as databanks. We are going to use technology to vastly improve the system. In the future, you will be able to give your pharmacist, your doctor, or the emergency room immediate access to your information, but you will control who sees *it* and what *it* is used for.."

To support this goal, the Michigan legislature passed legislation (P.A. 137-2006) to create Michigan's first Health Information Technology Commission and appropriated \$9.5 million to fund regional health information exchange projects in FY 2007. Moving forward with the Governor's charge, the Michigan Health Information Network (MiHIN) Conduit to Care project was created to convene Michigan's key stakeholders to define the roles the state can and should play to improve the quality and affordability of health care by advancing the adoption of health information technology and promoting regional HIE. In this report, the state-wide plan is referred to as the "Conduit to Care."

Conduit to Care Methodology

To accomplish the Conduit to Care, a state-wide Steering Committee and six workgroups – clinical, financial, governance, legal, regional and technical were established to address specific issues, foster state-wide involvement and provide recommendations. Overall, 200 health care leaders and experts representing major health care organizations, public health agencies and public and mental health providers, government, providers, health care consumers and payers, information technology, academia, and others contributed their time and expertise to developing this report. Project management and oversight of all the workgroups was provided by a team comprised of Michigan Department of Community Health, Michigan Department of Information Technology, Michigan Public Health Institute, Health Network Services Group and eHealth Initiative. The project team and workgroup leaders met in early April 2006. The workgroups were initiated in May 2006 and conducted research over 180 days with each workgroup meeting for over sixteen hours formally in addition to uncounted hours of work completed independently or in small groups outside of the formal meetings.

Health Information Technology and Health Information Exchange

The Conduit to Care makes a distinction between health information technology (HIT) and health information exchange (HIE). The definitions below state how these two components compliment each other.

HIT is the use of computer software and hardware to process health care information electronically within a health care organization, thereby enabling the storage, retrieval and use of data, information and knowledge for communication and decision making related to patient care delivery. Examples of organizations where HIT is applied include physician offices, commercial laboratories, hospitals and integrated delivery systems. Electronic medical record (EMR) systems, administrative systems (e.g., registration) and clinical information systems (e.g., clinical documentation and computerized physician order entry) are examples of HIT systems.

HIE, within the context of this report, is a technological infrastructure and a set of agreed upon business processes to enable movement of health care information electronically among and between organizations for patient care with primary emphasis in a region or community and ultimately across the State of Michigan and the nation. HIE provides the capability to electronically move clinical information between disparate health care information systems (e.g. hospitals, laboratories, physician offices, ambulatory treatment centers, and pharmacies) while maintaining the integrity and meaning of the

information being exchanged. The goal of HIE is to facilitate delivery access and retrieval of clinical data to provide safe, timely, efficient, effective, equitable, patient-centered care. HIE services are built once and used multiple times by many throughout the evolution of an HIE. The focal point for the organization and delivery of the services is a regional HIE. A central website, provider index, standardized health care terminology translation tools, Master Patient Index (MPI), authentication and authorization infrastructure, data sharing agreements and applications to aggregate information from multiple sources are examples of HIE resources.

Although this report emphasizes the promotion and development of regionally governed and operated HIEs, there are a few crucial parallel efforts that need to be successfully coordinated and implemented in order to support the continuous evolution of the patient record and ultimately, the transformation into safety, quality and efficiency goals. The HIE increases information availability for health professionals and patients, and creates an infrastructure to support other health technologies. Nevertheless, two "last-mile" end-user applications, electronic medical records and electronic prescribing (e-prescribing), are critical to transform improved data availability into improved health outcomes. These two applications play an essential role in making available crucial patient-specific clinical data needed in Phase B and Phase C of the HIE evolution. Therefore, it is essential that the HIE and HIT related (EMR and e-prescribing) incentives be planned and supported together. The Conduit to Care focuses on HIE because it requires community-wide implementation and support, while most HIT is typically implemented and supported by individual organizations. Additionally, HIE emphasizes changes in business processes and behaviors related to the sharing of information. HIT focuses on tools that are necessary, but not sufficient, by themselves to achieve the goals described. Care must be taken, however, to assure that HIE and HIT are compatible and interoperable and that incentives are aligned for the adoption of such technologies.

MiHIN Conduit to Care Guiding Principles

To aid in the Conduit to Care development process, specific guiding principles were endorsed and provided the foundation for a long-term strategy:

Guiding Principle 1: Consumer privacy, security and confidentiality are paramount.

Without consumer trust and acceptance of the process, no matter how well the system or network is designed and executed, it will fail. While there is public support for health information exchange, it is also recognized that Michigan citizens have a strong concern for the privacy and security of their medical health records.

Guiding Principle 2: Clinical data will only be utilized for *the* clinical care process.

Health care information disclosed for one purpose may not be used for another purpose without informed consent, unless otherwise permitted by law. Patients understand their personal health data is being used for diagnosis, treatment, and operational activities as defined in the Health Insurance Portability and Accountability Act (HIPAA) regulations. This specific Guiding Principle will facilitate the early adoption of HIE and build trust. Clinical data must only be utilized for clinical care processes during the formative

stages of HIE development in MI. **As** HIE in the State of Michigan evolves, this decision and Guiding Principle may be revisited.

Guiding Principle 3: The delivery of health care is local; therefore, health information initiatives at the regional level are critical.

By adopting this view of the health care system it is a natural extension that data be shared amongst a naturally occurring and commerce defined community of providers. Patients seek services on a regionalized basis therefore the model of greatest economical efficiency is one where a patient's data is available throughout the region to participating entities.

Guiding Principle 4: Multi-stakeholder collaboration is needed to implement achievable and measurable initiatives in order to show *early* progress and value.

Cooperation and collaboration on the implementation of health information exchange will drive innovation and change within regional HIE efforts as well as across the various stakeholders in the state. It is on this front in a local health care market where the average citizen will see the greatest administrative relief and impact. Multi-stakeholder involvement is needed to ensure the patient's health information is robust and to foster the sustainability and financial solvency of regional HIE efforts.

Why a Regional Focus?

The trend of state-wide efforts to create an interconnected, electronic health care system has been driven by needed improvements in health care quality and effectiveness and the need to reduce the cost of health care. Today, state leaders are recognizing that HIT and HIE can address many health care challenges. However, the development of HIE has been, for the most part, driven by local and grassroots efforts since health care services and patient health care experiences are primarily local or regional.

Physicians, clinical service providers and patients live with the realities of highly fragmented, inaccessible and expensive patient-specific clinical information delivery and retrieval every day. Since the early application of information systems in health care (some **40** years ago), where the hospital was the primary repository for most clinical information, much has changed. Now the vast majority of clinical information and patient encounter data reside outside the hospital in fragmented silos based on where health care delivery occurs, such as the physician office.

Patients tend to seek care locally, or at most, regionally. Therefore, a regional focus is needed. Solving the problems inherent in the transition to interoperable interconnected electronic health information requires the development of ever increasing trust and further collaboration in order to move through the stages of the electronic medical record and HIE evolution. Thus, the focus of the Conduit to Care was the development of a plan to encourage, facilitate, incent and organize regional health information exchanges to:

- Free clinical data from their silos, transform it and deliver it securely, rapidly and reliably to the patient's caregiver;

- Aggregate and organize clinical data to inform physicians and other caregivers about the patient's complete history and treatment thereby enhancing quality and patient safety; and
- Empower patients to manage their health care data through personal health records for quality improvement and care management.

Conduit to Care Recommendations

The Steering Committee and workgroups determined various recommendations that have regional and state-wide impact. The Conduit to Care discusses these recommendations in the following two sections:

1. Evolution of the patient health record
2. Role of the State of Michigan government

Evolution of the Patient Health Record

Advancement of the electronic patient health record is an incremental process that begins by making data available in a systematic way to reduce "silos" and evolve toward the aggregation of data specifically for patient quality and safety. The logical steps to accomplish this include: assembling patient records from multiple sources for viewing more complete patient histories, and eventually empowering Michigan citizens through the creation of a portable personal health record. This approach should take into special consideration the rural and underserved areas which will not necessarily have as many resources to acquire, support, or maintain health information technologies to more fully enable participation in HIE efforts.

An essential characteristic of the recommendations from the **MiHIN** Conduit to Care project is the focus on the patient, their clinical data and its electronic transformation into ever improving completeness, communication, organization and presentation to **serve** the needs of the patient, their **physician(s)** and others involved in their care and health. The three phases (A, **B** and C) outlined below provide a schematic focal point of the Conduit to Care demonstrating the developmental building blocks/evolutionary phases comprising for the foundation and development of Michigan's health information exchange initiatives.

Diagram A: Evolution of the Electronic Patient Health Record

Phase A
Making the Patient's
Data Available



Tomorrow:
Move healthcare data
out of distributed "silos"
to authorized users and
exchange patient healthcare
data in a systematic way

Phase B
Aggregating Each
Patient's Data for Care,
Quality & Patient Safety



Future:
Assembling patient records
from multiple sources for
viewing patient history

Phase C
Empowering
Michigan Citizens



Goal:
"My personal health record."
PHR is part of the overall
network of information
resources

The phases present a logical sequence based on the current organization and availability of patient information as well as economic feasibility; however, this does not preclude regional HIEs from starting at any point within these phases. All three phases are described below.

Phase A: Making Patient Data Available

- "Freeing" the data from silos by creating secure, robust information delivery pipelines.
- Moving from paper to electronic transactions to facilitate the delivery, completeness, security, privacy, reliability, timeliness of information delivery, and implement other value added services to patients, physicians and other care givers. In short, technologically improving today's complex, fragmented, poorly functioning information delivery systems in preparation for Phase B.

Phase B: Aggregating Each Patient's Data for Care, Quality and Patient Safety

- Assembling an electronic clinical data summary of each patient from across many sources of care, for use by their clinicians and other authorized care givers to facilitate and improve, real-time clinical decision making.

Phase C: Empowering Michigan Citizens

- Mobilizing the patient's clinical data to other tools and systems of their choosing in order to improve patient-clinician collaboration (e.g. Personal Health Record Systems, disease and chronic care management programs, drug interactions, mental health facilities, and research programs).

Privacy and Security

In any phase, one of the greatest potential barriers to the electronic sharing of clinical information is the difficulty in establishing privacy and security credibility with the public and participating stakeholders. Because of the sensitive nature of patient-related data, and the potentially devastating consequences of

an inappropriate disclosure, security and privacy concerns must be met in order to achieve success. While there are detailed privacy and security recommendations from the workgroups, emphasis is noted on:

- Creating a documented consensus on legal opinion regarding all security and privacy requirements and recommended approaches.
- Clarifying legislation to provide clear direction for the use of electronic clinical data and define clear penalties for misuse of clinical data.
- Educating providers and consumers on this new process and their rights regarding the use of their clinical information.

As HIE implementations grow across Michigan, the State of Michigan government will have a specific role in health information exchange. That role will continue to be defined as each of the initiatives delineates the specific process and products of their HIE, and more detailed legal issues need to be addressed. Additionally Michigan recently received federal funding to complete the Health Information Security and Privacy Collaboration (HISPC) work. The HISPC project's main task is to identify barriers and solutions to security and privacy of health information exchange. These findings will be beneficial in supporting HIE efforts in Michigan as the recommendations are implemented.

In parallel to the HISPC work the MiHIN initiative conducted a Legal Workgroup. Included in this report, is a summary of the Legal Workgroup initial discussions which will require integration into the outcomes of the HISPC to ensure that laws are accurately and consistently interpreted throughout the process of planning and implementation. A variety of federal and state statutes and regulations affect the formation of any health information exchange in Michigan. Implementation of the Conduit to Care requires that consistent and meticulous legal interpretation of laws that are applicable to HIT and HIE be performed to gain long-term success. These can include federal and state laws on electronic medical record confidentiality and privacy, security, consumer rights, electronic medication prescribing, fraud, abuse, and antitrust. The resolution of many of the legal challenges will depend greatly on how a health information exchange is structured, the types of health care information being exchanged, the types of participants in the exchange, and the purposes for which the exchange is accessed by the participants.

Role of State of Michigan Government

Over the last year there has been a significant increase in the amount of activity at the national, state and regional levels to create a more interconnected, electronic health care system. Increasingly, decisions regarding the scope and the direction of HIT and HIE initiatives will be made at the regional level where healthcare is delivered. However, state-level coordination is required and should be focused on those functions that add clear value when performed at the state level. Recommended functions that can be implemented at the state level to support the MiHIN vision and Michigan's regional HIE initiatives include the following:

Legal Interpretation and Consensus

- 1 Reduce legal and regulatory barriers for the sharing of electronic health data

2. Establish or strengthen state laws to protect consumers against privacy and security breaches
3. Facilitate state-wide consensus of legal opinion

Standard Setting and Technical Support

1. Advocate for the use of national standards (e.g., for interoperability)
2. Provide a forum for regional input to national standard setting bodies
3. Promote the development of state-wide master patient and provider indices and a record locator service (RLS)
4. Identify and develop HIT and HIE solutions for medically under-served areas, technology challenged areas or areas falling between naturally occurring regional HIEs

State-wide Coordination

1. Establish the MiHIN Resource Center
2. Leverage MiHIN Resource Center workgroup structure for HIE & HIT advisory needs
3. Provide resources to Michigan's HIT Commission
4. Encourage regional HIEs to move toward the exchange and interoperability of clinical data
5. Conduct state-wide medical trading area analysis

Fundraising and Administration of State-wide Funding

1. Set criteria and align incentives for HIE recognition, support, and funding

Education and Marketing

1. Encourage collaboration and communication amongst stakeholders regarding Conduit to Care

The state, along with foundational regional efforts, can play an important role in transforming the way that health care is delivered to patients in Michigan. It is important to note that the Conduit to Care provides a blueprint and a set of recommended strategies to foster HIE. For the goals outlined to be achieved, however, leadership at all levels is required in order to continue this dialogue and facilitate the activities needed in Michigan to create an interconnected health care system.

Conclusion

There is an expansion of Michigan HIT and HIE initiatives currently in operation or in the planning stages. Now is the time to take action to ensure these initiatives are coordinated across the state and do not develop into "islands of information." This report has been designed to capture and provide an overall view of health information exchange in Michigan, focused primarily on the development of healthcare information exchange to create the basis for state-wide connectivity. The Conduit to Care delivers a strategy for future development of HIEs and incorporates the discussions, recommendations and admonitions of the workgroups and participants. Additionally, this report initiates an incremental approach for building a strong foundation upon which leadership in the State of Michigan can transform health care.

In order to maintain the momentum established over the past several months and to transition the *Conduit to Care*, there are immediate activities to be performed. First and foremost, is the establishment of the state-wide coordinating structure (MiHIN Resource Center) and the need to orient the HIT Commission to the recommendations and the details provided in the *Conduit to Care*. Other immediate actions that can be performed by the MiHIN Resource Center include:

- Development of a marketing and education plan for the *Conduit to Care*
- Creation of a consumer brochure providing information about the *Conduit to Care* and HIE
- Continuation of **the** development of the Reference Guide and tools for regional HIEs
- Develop a Request for Proposal process for regional HIE funding

The *Conduit to Care* provides the structure and tools to implement the recommendations and deliver success. Success can be defined many ways; however it can be summarized as the long-term tangible improvements in health care quality, safety, and costs through focused, collaborative incremental efforts. Achieving success will be possible with the collaborative contributions and efforts of many Michigan public and private partners, each with a sense of urgency and commitment to advance health information exchange.

II. INTRODUCTION

Background

In early 2005, the State of Michigan government, through the leadership of Governor Jennifer M. Granholm and the Departments of Community Health (MDCH) and Information Technology (MDIT), placed a priority on using information technology to drive quality improvements and efficiency in the health care system. Leadership in State of Michigan government recognized that planning for advancing the use of health information technology in Michigan's health care system would involve the challenge of leveraging existing health IT investments throughout the state, as well as aligning HIEs with national initiatives.

In the spring of 2005, the Directors of MDCH, Janet Olszewski, and MDIT, Teri Takai, met with Dr. David Brailer, former chief of the Office of the National Coordinator for Health Information Technology within the U.S. Department of Health and Human Services, to discuss a state-wide Michigan Health Information Network (MiHIN) and to learn more about national health information technology activity.

In the summer of 2005, MDIT and MDCH convened seven stakeholder forums, facilitated by Public Sector Consultants, Lansing, Michigan, to hear the perspectives of key health care stakeholders on the role of state government in health information technology policy. Participants in the forums were representatives from automobile manufacturers, state agencies, unions, health systems, insurers / health plans, physicians, pharmacists, nurses, researchers and health care consumers. Throughout each of these seven forums, each with a diverse set of stakeholder perspectives and opinions, two common threads emerged. First, all groups felt strongly that any innovation in the health care system must be driven by quality improvements and should be patient-centered as opposed to driven by efficiency or cost-reduction. Second, each group found that the State of Michigan government was in the best position to convene stakeholders to facilitate and coordinate activity. It was recommended that MDCH and MDIT should bring stakeholders together to develop a common vision and plan for advancing health information technology in Michigan.

From the stakeholder forum outcomes, in December 2005, Michigan held a MiHIN kick-off conference, sponsored by CyberMichigan. Over 300 stakeholders from across the state attended this event. The MiHIN kickoff began with presentations from local, regional and national experts on health information activities and initiatives that were currently underway or being planned. At this kick-off, volunteers were self-assigned to MiHIN workgroups. Following that event, on January 24, 2006, Governor Granholm announced the long term direction of health information exchange and health information technology in Michigan during her 2006 State of the State Address.

On April 3, 2006, the MiHIN officially began the Conduit to Care 180-day project which was created to convene Michigan's health care stakeholders to speed the adoption of health information technology and promote health information exchange in order to improve access to clinical data to provide safe, efficient, effective, and equitable, patient-centered care. As an output from the stakeholder forums held in the

summer of 2005, the *Conduit to Care* approach was to utilize information technology with a clear focus on improving the delivery of high quality, safe health care.

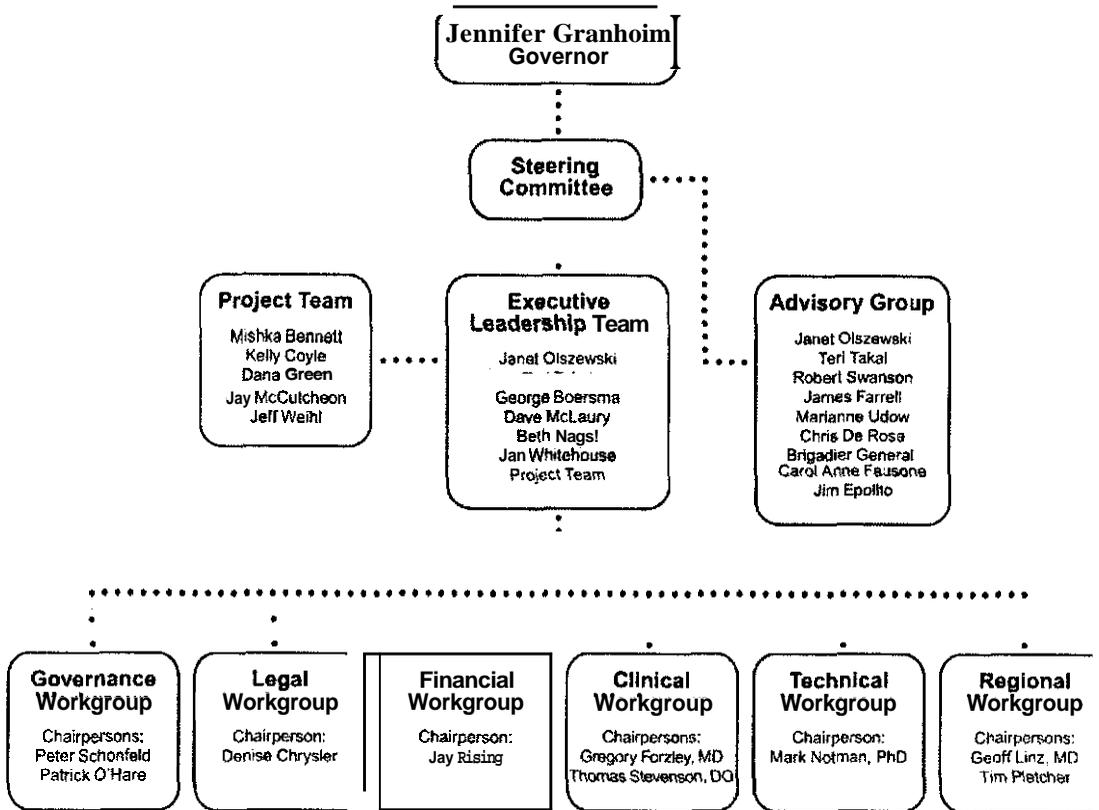
While the *Conduit to Care* Steering Committee and Workgroups met at least once a month, multiple other meetings with staff and leadership also aided in facilitating progress. Michigan continued to demonstrate leadership in May 2006, when Governor Granholm signed legislation introduced by Representative Gary Newell and passed by the Michigan legislature that created a Health Information Technology Commission within MDCH. This 13 member HIT Committee will use the *MiHIN Conduit to Care* to advise the State of Michigan in its ongoing efforts to promote and support the exchange of health information technology. The HIT Commission was appointed on Monday, August 7, 2006 and is scheduled to meet for the first time in October, 2006.

Finally, in May 2006, Michigan was awarded a contract from the Research Triangle Institute and the National Governor's Association Center for Best Practices. Under this contract, worth \$350,000, Michigan will participate in the Health Information Security and Privacy Collaboration (HISPC), which will implement a process addressing organization-level business policies and state laws that affect privacy and security practices and may pose challenges to interoperable health information exchange. This contract will end in April 2007 and will assist efforts in the privacy and security work of *MiHIN*.

Project Structure

As Diagram B illustrates, the *MiHIN Conduit to Care* operated through a Steering Committee and six workgroups to efficiently produce a plan exploring methods that mobilize information in support of patient care and focusing on the creation of an interconnected, electronic health system. An Executive Leadership Team, Workgroup Leadership Team, Advisory Group and a Project Management team supported this process. A listing of all *Conduit to Care* participants is available in Appendix A.

Diagram B: MiHIN Conduit to Care Organization Chart



The Steering Committee was charged with comprehensively reviewing issues surrounding the creation of an e-health infrastructure in Michigan and to develop guidance for the users of such infrastructure. There were 22 members seated on the Steering Committee including two Co-Chairs – Janet Olszewski, Director of the Michigan Department of Community Health and Teri Takai, Director of the Michigan Department of Information Technology. The Steering Committee included membership from a diverse and comprehensive of state-wide representation of Michigan health care stakeholders. See Appendix A for the listing of organizations and stakeholder groups that were represented on the Steering Committee.

Workgroups were created to assist the Steering Committee and to provide specific recommendations for Steering Committee consideration. The six Workgroups established were clinical, financial, governance, legal, regional, and technical. All Workgroups were formed on a voluntary basis and all meetings were open to the public. This open and inclusive makeup of Workgroup membership provided a channel for all interested individuals and organizations to be represented and heard. There were approximately 200 people who volunteered their time to participate in the Conduit to Care workgroups. See Appendix A for the listing of Workgroup Chairpersons and volunteers.

Each Workgroup was led by at least one Chairperson, who also participated in the Steering Committee meetings. Also, nationally based subject matter experts were assigned to some of the Workgroups through the assistance of the eHealth Initiative (www.ehealthinitiative.org). Health Network Services (HNS) also contributed to the overall coordination of the project. Further, several Workgroups were assigned staff members to assist with activities through sponsorship agreements with the following associations: Michigan State Medical Society (Clinical Workgroup), Michigan Hospital Association (Governance Workgroup), Michigan State University (Technical Workgroup) and Central Michigan University (Regional Workgroup). See Appendix B for a detailed description of each Workgroup. From April to September 2006, key activities were achieved to develop the *MiHIN Conduit to Care*:

- Workgroups made recommendations
- Steering Committee reviewed recommendations
- Executive Leadership and Project Management Teams synthesized recommendations into a cohesive document
- Draft report was presented to the Steering Committee and Advisory Group for review and approval
- Once approved, the final report will be received by the Governor
- Upon the Governor's approval, the plan will be implemented in a phased approach

The sections in this report are structured around concepts and recommendations, not around the specific recommendations from each of the Workgroups. This structure helps to present the cohesive and interrelated nature of the process and output of the Workgroups. Many of the recommendations discussed in the following pages were echoed in more than one Workgroup.

III. STATE OF HEALTH INFORMATION TECHNOLOGY AND HEALTH INFORMATION EXCHANGE IN MICHIGAN

Health Information Technology and Health Information Exchange

This report makes a distinction between HIT and HIE. The recommendations listed try to clarify the affiliation between the various components and analyze the approaches necessary for implementation. Health information technology (HIT) is the use of computer software and hardware to process health care information electronically, thereby allowing for the storage, retrieval, sharing and use of the information, data and knowledge for communication and decision making related to health care delivery. The main function of HIT resides within physician offices, laboratories, hospitals, mental health centers or large hospital systems. Electronic medical record (EMR) systems, administrative systems (e.g., registration and billing) and clinical information systems (e.g., clinical documentation and computerized physician order entry) are examples of HIT systems.

Health information exchange (HIE) is an infrastructure to enable movement of health care information electronically across organizations within a region or community. It must also have agreed-upon business relationships and processes to facilitate information sharing across organizational boundaries. HIE provides the capability to electronically move clinical information between disparate health care information systems while maintaining the meaning of the information being exchanged. The goal of HIE is to facilitate access to and retrieval of clinical data to provide safe, timely, efficient, effective, equitable, patient-centered care. HIE services facilitate a one to many connection between clinical service providers and clinicians/patients instead of the many to many connection today. A central website, health care terminology translation tools, a Master Patient Index (MPI), authentication and authorization infrastructure, and applications to aggregate information from multiple sources are examples of HIE resources.

The difference between HIE and HIT is that HIE consists of communicating across multiple organizations in a region, the state and between regions, hospitals and physician offices while HIT is the support infrastructure that enforces HIE, provides information movement in a health care organization and makes each document readable and informative. Electronic Medical Records and e-Prescribing tools, both HIT, are two of the most referenced tools that will change healthcare.

1. Electronic Medical Records

Electronic medical records (EMRs) are an important part of the overall vision of the *Conduit to Care*. An EMR is an electronic record containing information about a patient with the ability to communicate with other applications within a health enterprise (hospital, clinic, physician practice). EMRs are very important to health care as they can provide cost savings as well as improve the efficiency and safety of health care. Health care technology can provide alerts and reminders to the clinician warning of possible injury or missed opportunities for prevention. They can also enable continuous 24/7 access to records as well as simultaneous access to a single record by multiple users. Additionally, they can reduce the cost of record management over time, when compared to paper records.

An EMR is only as useful as the clinical information it contains, and the task of getting information into an EMR is still daunting. Information is constantly arriving at the physician's office from the many different clinical service providers involved with a patient's care (laboratories, pharmacies, imaging centers, mental health centers, therapists and, of course, the patient and his or her caregivers). Information about medications, tests and procedures performed by other providers is also needed for clinical-decision making. In today's marketplace, the lack of standardization causes hand-transcription, scanning paper-based documents into the EMR and other practices that do not facilitate a holistic view of the patient or enable automated alerts and reminders. Another solution is to create different interfaces for each EMR, in order to import data from every provider, which rapidly becomes cost-prohibitive. Thus, electronic health information exchange actually becomes a prerequisite for the cost-effective implementation and full benefit of EMRs in many, if not most, physician practice settings. It is therefore impractical to wait to initiate clinical information exchange pending the widespread installation of EMRs.

On the other hand, much information of value that might flow through health information exchanges could potentially originate with EMRs. In order for this to occur most efficiently, the EMRs should be equipped in an interoperable fashion. The implementation of non-standardized EMRs in this fashion complicates, rather than aids, the development of effective information exchange. For this reason, EMR implementations should only be encouraged and incentivized if they meet minimum interoperability standards, including Certification Commission on Health Information Technology (CCHIT) certified products, and those meeting **Hi**HIN interoperability standards as well.

2. Electronic Prescribing (e-Prescribing)

Many have proposed e-Prescribing, referring to the electronic transmission of prescriptions, with the possible addition of a variety of other applications, as a promising early implementation for electronic information exchange. Indeed, the potential to reduce transcription errors, improve formulary-based prescribing, detect drug-drug and drug-allergy interactions, reduce the costs of paper transactions and records are all important goals of the Conduit to Care.

With e-Prescribing implementation, the information produced should be structured in such a way as to contribute to the HIE. If they are developed in silos within disparate health care systems, this would be problematic. Therefore, the technology used by the clinicians and clinical service providers should allow integration of the information. Specifically, e-Prescribing decision-support should incorporate information from other sources and standards for user-identity, patient-identity, data transmission and vocabulary. The vocabulary used in e-Prescribing should be the same as vocabulary used in HIE. If this does not occur, new impediments to exchange and new obstacles to efficient workflow will be created. As described in the Health Care Industry Laws and Regulations section, in addition to the above challenges, changes in federal law will be required to fully implement e-prescribing.

Current State - Michigan *HIT* and *HIE* Activity

Michigan shares many barriers and challenges with other states, but it also has unique strengths and experiences that can be built upon to help ensure success. The state continues to provide vision, leadership and direction on health IT - telemedicine, vital records, immunization registry, disease surveillance, Medicaid management, pharmaceutical pricing and others. Specifically, the Michigan Care Improvement Registry (formerly the Michigan Childhood Immunization Registry) (MCIR) is an award winning, state-of -the-art electronic, state-wide immunization tracking system for all Michigan citizens who receive, or are offered, immunizations anywhere in the state of Michigan. Other unique factors about Michigan follow below and are further detailed in Appendix C.

1. Vision, Leadership, Landmark Policy and Program Alignment
2. Critical Mass of Stakeholders
3. National Caliber IT Capabilities and Foundation of Experience
4. Historic Economic Pressures and Restructuring Serve as Challenges and Drivers
5. Geographic, Service Scope and Diversity Call for Regional Solutions

Specific to HIT, according to a report commissioned by Blue Cross Blue Shield of Michigan and the Partnership for Michigan's Health (comprised of the Michigan Health & Hospital Association, the Michigan State Medical Society, and the Michigan Osteopathic Association), many of Michigan's health care providers have had widespread success in implementing electronic medical systems, but less than one-third of the state's acute care hospitals have comprehensive systems¹. According to the report, Michigan is also outpacing most states in adopting computerized forms of physician order entry. The report also pinpointed barriers to adopting a state-wide system, which include inconsistent coding systems between providers, a lack of promotion, and computer systems that vary between hospitals. For an inventory of the many HIT projects underway in Michigan see Appendix D.

To further demonstrate Michigan's uniqueness, **MiHIN's** Regional Workgroup interviewed eight current health information exchange (HIE) initiatives (self-identified) in various stages across Michigan. These eight HIE initiatives are:

- Capital Area RHIO
- Greater Flint Health Coalition
- Holland Regional Effort
- Michigan Health Infrastructure – Grand Rapids area
- Michigan Health Information Alliance – Central Michigan area
- Michigan Upper Peninsula Health Information Technology Network
- Southeast Michigan Health Information Exchange
- Thumb Rural Health Network

¹ <http://www.detnews.com/apps/pbcs.dll/article?AID=/20060322/BIZ/603220390/1040>

We recognize there may be additional initiatives across the state that the Regional Workgroup did not interview. Interviews were conducted by a subset of Regional Workgroup members to gather information on the status of these initiatives as well as to discover what a state-wide effort could do to assist them in their endeavors. Information gathered was considered by the Regional Workgroup and assisted in making decisions regarding recommendations for the *Conduitto* Care report. Specifically, the interviews assisted with understanding the expectations that each self-identified regional initiative had for a state-wide effort and how it could facilitate their efforts. The interview template and summaries of each interview are in Appendix E.

It became apparent during the interviews, there is not only interest around the state to develop such exchanges, but also that there is an understood role necessary at a state-wide level. Besides assistance with funding, the initiatives listed other specific support needed:

- Provide standards/ guidelines for exchange of information within and between regional HIE activities
- Provide a "starter guide" (e.g. reference guide/tool kit) for regional HIE initiatives
- Act as an umbrella to connect regional initiatives
- Identify and facilitate the availability of subject matter experts to assist with planning and helping regional efforts get started
- Provide recommendations on key legal issues relevant to data sharing
- Foster the promotion and adoption of standards
- Facilitate the development of a state-wide master patient index

Regional health information exchanges have been classified, in an annual survey, by eHealth Initiative into stages showing their progress in the HIE evolution. Listed below are the definitions used by eHealth Initiative for each stage. A majority of the initiatives in Michigan are in the first three stages of HIE development. It is anticipated that Michigan may have several HIEs in the later stages of development by the next survey.

Stage 1: Described as the recognition of the need for HIE among multiple stakeholders in the region.

Stage 2: Getting organized. In this stage regional initiatives are defining their shared visions, goals and objectives. They are identifying funding sources and setting up legal and governance structures.

Stage 3: In this stage initiatives are transferring vision, goals and objectives to tactics and business plan. They are defining the needs and requirements and securing funding.

Stage 4: Well under way with the implementation of the health information exchange. This includes technical, legal and financial aspects.

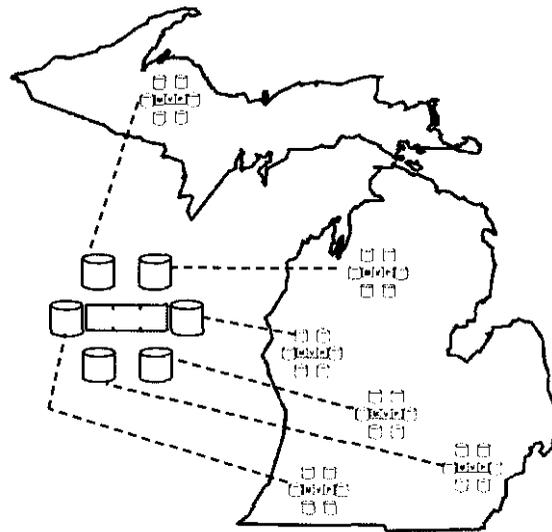
Stage 5: In this stage the regional HIE is fully operational. They are transmitting data that is being used by health care stakeholders. A sustainable business model has been established.

Stage 6: In this stage the regional HIE is demonstrating the expansion of the organization to encompass a broader coalition of stakeholders than present in the initial operational model.

Future State – Michigan HIE

The trend of state-wide HIE efforts is to closely integrate regional initiatives with the state-wide HIE initiative. Large and complex states like Michigan are not starting with a statewide HIE approach; therefore, a regional emphasis is a critical aspect of any Michigan HIE approach. The number of stakeholders who are needed to participate in order to gain a critical mass, are far too numerous at a state level. However, it has been seen that by working within regions (or Medical Trading Areas (MTAs) as they are referred to in this document) there is a greater impact and success rate. Therefore a decision was made to view Michigan as being comprised of multiple regional HIE initiatives that may have different architectures and capabilities. A state-wide organization will be necessary to facilitate the exchange of data between the regional HIEs.

Diagram C: Future State – Regional and State-wide Approach



In order to facilitate HIE initiatives, with the highest probability of sustainability and effectiveness, there are certain characteristics necessary to ensure that these regional HIEs are adequately prepared to participate in HIE within the State. The Regional Workgroup developed these characteristics and recommends they be used in the future when defining a regional HIE in Michigan.

1. Goals include improving the quality, patient safety, access and cost-effective delivery of care as a result of using technology which facilitates the collective ability of the involved organizations to exchange, share and integrate health information
2. Governed by a multi-stakeholder group representing organizations involved in the exchange of administrative and clinical information. The kinds of stakeholders would include but not be limited to: practicing clinicians; hospitals; laboratories; health plans; major employers; the State; public health; patient groups; purchasers; quality improvement organizations; hospital associations; and medical societies

3. Follow a common (or when completed, nationally-endorsed) set of principles and standards for the technology and policy aspects of health information exchange
4. Develops and implements a technical infrastructure based on national standards to facilitate interoperability
5. Develops and maintains a model for sustainability that aligns costs with benefits
6. Designs and implements metrics to measure performance from the perspectives of patient care, public health, provider value, and economic value

Regional HIE's need to develop trust and a framework for collaboration among the stakeholders before they can evolve to higher levels of data sharing and sustainability. From the Workgroup discussions, it became apparent that an incremental approach to building HIEs and electronic health records for patients would be needed. This type of incremental approach allows the HIE to show early progress, value, create momentum and to focus on mid-term and long-term activities prioritized by criteria such as urgency and feasibility. Thus, the focus of the Conduit to Cafe is the development of recommendations to encourage, facilitate, incent and organize health information exchange at the regional and the state-wide level, to provide the services needed to support regional HIEs (e.g., gain economies of scale, provide funding) and remove barriers for the regional HIEs that individually they can not overcome.

To assist with painting the future of MiHIN, the Governance Workgroup drafted a vision statement and goals. These two items are important to focus on while implementing many of the recommendations listed.

MiHIN Vision:

"The MiHIN will foster development of HIE that will reduce the overall cost of care while at the same time increasing the quality of care and patient safety."

MiHIN Goals:

- Improve the quality and efficiency of health care delivery for Michigan citizens by accelerating the adoption and use of a collaborative model including health information technology (HIT) and health information exchange (HIE)
 - Minimize redundant data capture and storage, inappropriate care, incomplete information and administrative, billing and data collection costs
- Promote evidence-based medical care to improve patient safety and quality.
- Encourage patient-centered care: Connect health care providers – clinicians and facilities to ensure continuity of care for every patient
 - Increase patient understanding and involvement in their care

- Enhance communication between patients, health care organizations and clinicians
- Promote national standards to guide the sharing of information and electronic data interoperability
- Safeguard privacy and security of personal health information
- Leverage existing health information systems
- Create a business model that balances cost and risk
 - Implementing organizations must see sufficient value to justify their investment
 - Regional HIEs need to be self sustainable

The specific mission for the 180 day MiHIN Conduit to Care process was to articulate a path to develop a health information network connecting the State of Michigan, with an infrastructure and governance model for long-term sustainability through public-private partnerships.

Health Care Industry Laws and Regulations Impacting Health *Information* Organizations

All workgroup volunteers articulated and understood the importance of laws and regulations in the health care industry, especially in protecting patient's rights. Therefore the Conduit to Care specifically reviewed those laws and regulations that impact health information organizations and the sharing of information. The laws discussed below are those which are likely to have the most extensive and pervasive impact on HIE, however, this list is not exhaustive. Appendix F includes a more extensive list of Michigan laws, with citations, that are relevant to HIE.

Working within a highly regulated industry, health care providers and health-related information are subject to a myriad of laws at both the state and the federal level. "Law" includes both statutes passed by Congress or the State legislature, regulations adopted by governmental agencies as promulgated pursuant to statute and court rulings (common law). Laws that impact HIE include:

- A. **Privacy and Confidentiality Laws.** Federal, state and common law create minimum protections regarding the privacy and confidentiality of identifiable health and personal information in electronic, written, verbal, and any other form. These include the federal privacy regulations under the Health Insurance Portability and Accountability Act (HIPAA), federal Alcohol and Other Drug (AOD) confidentiality regulations, Michigan's Public Health and Mental Health Codes, and Michigan's Social Security Number Privacy Act. These laws, and Michigan's Medical Records Access Act, establish patients' rights regarding access to their health information. Patients' rights include the right to inspect and obtain copies of their own health information, to request restrictions on disclosure of health information, seek amendments for inaccuracies, and obtain an accounting of certain disclosures.
- B. **Security Laws.** Federal security regulations under HIPAA, although technology neutral, require implementation of appropriate security safeguards to protect certain electronic health care information that may be at risk while permitting appropriate access, availability and integrity and use of that

information. Covered entities must conduct an assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the entity. Also, they must implement sufficient administrative, physical, and technical safeguards (considering their size, funding and ability) to protect information that the covered entity creates, receives, maintains, or transmits. The regulations contain standards for each type of safeguards, and implementation specifications for each standard. See Appendix G for a matrix of standards and implementation specifications for administrative, physical, and technical safeguards, which was included as an appendix to the federal security regulations.

The requirements in the security regulations are designed to be technology neutral to accommodate changes in technology. This flexibility also allows clinical service providers to choose technologies to best meet their specific needs, taking into account size, capabilities, the costs of the specific security measures, and the operational impact. This means that specific security measures adopted by clinical service providers may comply with the security regulations yet impede interoperability and health information exchange.

C. Health Care Fraud and Abuse Laws. These laws are intended to prevent fraud and abuse by regulating the relationships between physicians and other health care entities.

- a. **Physician Self-Referral (Stark Laws).** The federal Stark Law prohibits a physician from making referrals for certain "designated health services" (**DHS**) payable by Medicare to an entity with which the physician has a financial relationship, unless an exception applies. The law also prohibits the entity from submitting claims to Medicare or anyone else for Medicare DHS that are furnished as a result of a prohibited referral. The Stark Law is enforced by the Centers for Medicare and Medicaid Services (CMS). Violations of the statute are punishable by denial of payment for all DHS claims, refund of amounts collected for DHS claims, and civil money penalties for knowing violations of the prohibition.

Michigan law incorporates the federal Stark Law as it existed on June 3, 2002, prohibiting a physician from making referrals for certain "designated health services" regardless of source of payment. This means that federal exceptions to the Stark Law adopted after June 3, 2002, such as the recently adopted exception for certain electronic prescribing and electronic health records arrangements, described below, have not been incorporated in Michigan law.

- b. **Anti-kickback Laws.** The federal anti-kickback statute provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward the referral of business reimbursable under any of the federal health care programs. Remuneration may be direct or indirect. Prohibited conduct includes not only the payment of remuneration intended to induce or reward referrals of patients, but also the payment of remuneration intended to induce or reward the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by any federal health care program. Violations of

the anti-kickback statute may also result in the imposition of civil money penalties, exclusion from federal health programs, and liability under the False Claims Act.

The U.S. Department of Health and Human Services, Office of Inspector General (OIG) enforces the federal anti-kickback statute. Congress required that OIG adopt regulations providing "safe harbors" to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial or innocuous arrangements. These "safe harbor" provisions specify various payment and business practices that would not be treated as criminal offenses under the anti-kickback statute, even though they may potentially be capable of inducing referrals of business under the federal health care programs.

Implications under Stark and anti-kickback provisions are similar. For example, a hospital may provide equipment, services or other incentives to participating physicians to participate in an HIE. Stark and anti-kickback laws may be triggered if the physician then refers a patient to the hospital that has provided these technologies. Thus, the Stark and anti-kickback laws must be considered in structuring an HIE, providing incentives and benefits to participating physicians to minimize liability.

CMS recently adopted an "exception" from Stark for certain electronic prescribing and electronic health records arrangements. Likewise, OIG adopted a "safe harbor" from the anti-trust statute for certain electronic prescribing and electronic health records arrangements. Both of these take effect October 10, 2006 and may be found at <http://www.oighhs.gov/fraud/safeharborregulations.html>. This exception (safe harbor) as well as other exceptions (safe harbors), need to be evaluated to choose the most advantageous structure, while minimizing risk for violations. Michigan law incorporates the federal Stark Law, and licensing action can be taken against a physician for violation; however, Michigan has not updated its provisions to remain consistent with the federal law. This mismatch between federal and state law needs to be corrected.

- D. **Antitrust.** Federal antitrust laws include the Sherman Antitrust Act, the Clayton Act and the Federal Trade Commission Act. These laws are intended to promote competition, prohibit collusion and regulate other business practices that unfairly reduce competition. Generally, clinical service providers are competitors in the marketplace. Thus, when competitors join together in a cooperative venture, such as an HIE, questions may arise regarding activities that unfairly control development or access to HIE technology or contractual terms that exclude certain providers from participating. Thus these laws must be considered in structuring an HIE and defining terms of participation.
- E. **Federal Tax laws.** Parties that join together to form a HIE may include one or more tax-exempt entities. Tax-exempt organizations are prohibited from providing improper financial or other benefits to a private individual or entity. Since HIE contemplates the interchange of information

between tax exempt entities and private or for-profit entities, these laws must be addressed in structuring an HIE and defining terms of participation.

- F. **Intellectual Property.** "Intellectual property" is a product of the intellect that has commercial value, such as trademarks, patents, copyrights, and trade secrets. Legal concerns will need to be addressed in developing an HIE including the ownership of the system that electronically transmits health information and its components. Software licensing and ownership issues will need to be resolved regarding each element and process that make up the HIE (e.g. data formats, data layouts, interfaces, security measures, process to standardize data, creation of an aggregate health record, record locator system, etc.) Additionally, in connecting to the HIE, and building interoperability with their current systems, clinical service providers may encounter legal issues related to current software licensing agreements, these will also need to be resolved.
- G. **Laws Regulating Prescribing Practices.** Prescribing practices are highly regulated to ensure appropriate use and distribution of controlled and non-controlled substances.

Controlled substances are regulated on the federal level by the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA) and at the state level by the Public Health Code and the Michigan Board of Pharmacy Rules regarding controlled substances. At this time, DEA regulations require that prescriptions for controlled substances be hand-signed. The DEA is currently developing standards to permit electronic transmission of prescriptions for controlled substances (see Electronic Prescriptions for Controlled Substances, Anticipated Standard for DEA Electronic Transmission of Prescriptions for Controlled Substances System, available at <http://www.dea/diversion.usdoj.gov/ecommerce/standard.htm>) and anticipates that any system that meets technological, security and audit standards described at the website listed above may be used to process electronic prescriptions. However, the standards are not yet final. According to the DEA this electronic system is in addition to and not a replacement of, the existing paper-based prescription system.

The Michigan Board of Pharmacy Rules regarding controlled substances already allow e-prescribing at the option of the patient, provided there would be no conflict with federal law.

Prescriptions of non-controlled medications are primarily controlled at the state level. There are e-prescribing systems operating in Michigan, although e-prescribing is not specifically addressed under the Public Health Code or current Michigan Board of Pharmacy Rules. This is in the process of changing. In December 2005, the Board of Pharmacy filed draft rules that specifically address electronic prescribing of non-controlled substances, establishing standards for e-prescribing systems to protect the public. More recently, HB 6323 was introduced into the legislature on August 9, 2006 and would amend the Public Health Code regarding e-prescribing for non-controlled and controlled substances to the extent allowed by federal law. Both HB 6323 and the Board of Pharmacy's proposed rules require that the patient "opt-in", providing that

prescriptions may be transmitted electronically only at the request (option) of the patient from the prescriber to the pharmacy of the patient's choice.

IV. MIHIN CONDUIT TO CARE GUIDING PRINCIPLES

The context of the recommendations within the Conduit to Care are based on the following core principles, which the MiHIN Conduit to Care participants widely viewed as the building blocks for a state-wide health information exchange.

Guiding Principle 1: Consumer privacy, security and confidentiality are paramount

The Conduit to Care acknowledges that safeguarding consumer privacy, security and confidentiality, within the limits imposed by law, is a critical key to success in advancing the use of health information technologies and exchanges. From the beginning of Governor Jennifer Granholm's charge for Michigan's health care to move into the 21st century by utilizing health information technology - it is clear that consumer needs and interests are of the utmost importance.

"In the future, you will be able to give your pharmacist, your doctor, or the emergency room ***immediate access to your information, but you will control who sees it and what it is used for.***" – Governor Jennifer M. Granholm. 2006 State of the State Address.

It has been Michigan's mission from the beginning that consumers must be in control of their health information and as this state moves to support sustainable HIE efforts, legal compliance and patient health information protections must be a central focus. The Conduit to Care is based on the premise that with any improvement to Michigan's health care system, privacy and security of health information must be maintained in compliance with local, state and federal statutes.

Michigan's health care stakeholders agree with this mission and during stakeholder forums commissioned by the State of Michigan in the summer of 2005, a patient-centered and collaborative approach to health information technology was a common vision shared throughout a diverse set of stakeholders. This group of employers, unions, insurers, providers and consumers agreed that quality benefits and maintaining appropriate access to personal health data were essential to facilitating health IT initiatives. Further, Michigan's health care stakeholders support the need for patient privacy in the **use** of personal health data.¹

Throughout each phase of MiHIN's efforts to help build health information exchanges, the standard of consumer privacy, security and confidentiality will be paramount within the limits imposed by law. The Conduit to Care promotes the development of technology, policy and legal solutions that allow for the greatest patient control, access and ownership to personal health information as well as effective security and privacy assurances.

² Health Information Technology in Michigan: Stakeholder Forums, October 2005

Guiding Principle 2: Clinical data will only be initially utilized for the clinical care process.

Health care information disclosed for one purpose may not be used for another purpose without informed consent, unless otherwise permitted by law. Patients must know their personal data is being used for diagnosis, treatment, and operational activities as defined in HIPAA regulations, unless they have given explicit permission for their information to be shared for other purposes (e.g. disease surveillance, research, etc.).

In order to gain commitment and understanding from key stakeholders involved in HIEs around the State of Michigan, the Conduit to Care team realized that other specified uses of a person's clinical data would be needed. Therefore, the consensus of the Workgroups was that in the beginning of HIE across the State of Michigan, clinical data will only be utilized for clinical purposes. Potential future uses will follow naturally, based on stakeholder interest, agreement and support.

Guiding Principle 3: The delivery of health care is local; therefore, health information initiatives at the regional level are critical.

By adopting this view of the health care system it is a natural extension that data be shared amongst a naturally occurring and commerce defined community of providers. Patients are seen as seeking service on a regionalized basis therefore the model of greatest economical efficiency is one where a patient's data is available throughout the region to participating entities.

Guiding Principle 4: Multi-stakeholder collaboration is needed to implement achievable and measurable initiatives in order to show early progress and value.

Cooperation and collaboration on the implementation of health information exchange will drive innovation and change within regional HIE efforts as well as across the various stakeholders in the state. It is on this front in a local health care market where the average citizen will see the greatest administrative relief and impact. Multi-stakeholder involvement is needed to ensure the patient's health information is robust and to foster the sustainability and financial solvency of regional HIE efforts.