The HIE Guide for CIOs

NOTE: *For the purposes of this guide, the term health information exchange (HIE) will be used to refer to the underlying technology and associated infrastructure that supports the exchange of information, and the resulting action of exchanging of health information; health information organization (HIO) is used for the organization that manages the exchange of health information.*

Introduction

The exchange of health information will be of significant concern to healthcare providers seeking to qualify for meaningful use payments and to participate in the evolving healthcare environment, which will place a premium on coordination of care through the seamless sharing of healthcare information.

How health information exchange (HIE) is achieved over the next few years is expected to change. This guide is intended to be a starting point for identifying key issues for healthcare executives that are developing a ground-level understanding of how to accomplish health information exchange. As HIE evolves in the coming months, this guide will be further refined to provide ongoing guidance on HIE decisions. In addition, as industry experience with HIE continues to grow, we'll look for and share real-world examples of how healthcare organizations are optimizing the use of HIE to achieve concrete results that could benefit other provider organizations.

Acknowledgements

Chapter 1

Essential Background Knowledge on HIE

In the 1990s, the idea of community health information networks, or CHINs, gained popularity, but with the exception of integrated delivery system formation, these initiatives generally struggled and failed because of their high costs, proprietary network formation and the inability to gain cooperation from competing providers.

While the notion of sharing data hasn't faded, the lofty goals underpinning the CHIN era – the need to exchange patient information among providers to optimize care delivery – have evolved over the last 15 years. In addition, the stakes have been raised through the implementation of recent regulations regarding the meaningful use of electronic health records, which are likely to increasingly require the use of health information exchange (HIE) so providers can qualify for incentive fund payments.

While the meaningful use requirements regarding data exchange during Stage 1 of the incentive program are relatively simple, healthcare providers likely will need to increasingly make use of HIE in subsequent stages of the program. Additionally, reforms being discussed for the healthcare system will put a premium on improving communication between providers and with patients, and will necessitate data sharing capabilities to better coordinate care across the continuum. Proponents say that HIE holds great promise to expedite and improve care, increasing providers' efficiency and saving costs throughout the system.

<u>Legislative and Regulatory Background</u>
The American Recovery and Reinvestment Act (ARRA) became law in 2009. One section of the law (Title XIII of Division A and Title IV of Division B) – the Health Information Technology for Economic and Clinical Health Act (HITECH Act) – provides incentives for the "meaningful use" of electronic health records, providing incentive funding to encourage providers to implement electronic health records and other electronic clinical systems in ways that improve the quality of care.

Through a formal rule-making process, the federal government through the Centers for Medicare & Medicaid Services established 24 objectives for eligible hospitals and critical access hospitals. Of those, 14 are required or core objectives that a provider must meet in order to qualify for stimulus funding; Stage 1 also includes a "menu set" of 10 objectives, five of which must be achieved to qualify for funding (a total of 19 of 24 objectives). (https://www.cms.gov/EHRIncentivePrograms/30_Meaningful_Use.asp).

The final regulations establishing the meaningful use requirements set a core requirement for eligible providers and hospitals to achieve health information exchange. Specifically, this core requirement asks that eligible providers and hospitals have the capability to "exchange clinical information electronically with other providers and patient-authorized entities." In

setting this target for HIE, the rule-writers aimed to make achieving the objective as easy as possible, acknowledging in the final rules that "many areas of the country currently lack the infrastructure to support the electronic exchange of information." To satisfy the objective, eligible providers, eligible hospitals and critical access hospitals "should attempt to identify one other entity with whom to conduct a test of the submission of electronic data. This test must include the transfer of either actual or 'dummy' data to the chosen other entity." In addition, with the development of the Direct Project (http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__direct_project/3338) and supporting technologies, providers have another way to meet this objective.

The ability to exchange health information will be a key function for providers to achieve during Stage 1. An analysis of meaningful use objectives by the Healthcare Information and Management Systems Society (HIMSS) suggests that from six to 10 objectives, depending on individual providers' circumstances imply "some form of HIE. Many of these are likely functions that are already handled electronically, or at least have some form of electronic exchange available (electronic claims, as an example). With that said, it is clear through comments in the Notice of Proposed Rulemaking (NPRM) that HIE is a national strategy. The NPRM clearly provides the impression that Stages 2 and 3 will have many more requirements that will rely on robust HIE availability in the country's communities." (HIE Implications in Meaningful Use Stage 1 Requirements, HIMSS, March 2010).

Additionally, a report this year by the President's Council on Science and Technology (PCAST) offers a variety of suggestions for accelerating and facilitating the exchange of healthcare information, and many of those are being considered for inclusion in future Stages, according to supporting comments from the National Coordinator for Healthcare IT, Dr. Farzad Mostashari. Coincidentally, the Office of the National Coordinator for Health Information Technology (ONC) has active efforts focused on defining the metadata associated with data exchange, as that data is used for routing and location services by and among electronic health records. Several of the provisions in the Advanced Notice for Proposed Rule Making on metadata, released on August 9, are likely to become federal rules, necessitating electronic health records (EHRs) and exchange service harmonization to ensure agnostic health data exchanges on the eventual national health information network.

State-based Approach
Because HIE activities are just getting under way in most areas of the country, the federal government is hoping to jump-start HIE development by offering grants through the State Health Information Exchange Cooperative Agreement Program, funded by ONC. The program "promotes innovative approaches to the secure exchange of health information within and across states and ensures that health care providers and hospitals meet national standards and meaningful use requirements." See http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=1834.

In 2010, ONC awarded 56 grants totaling $548 million to help states (including territories) develop and advance resources to facilitate the exchange of health information. The awards were made to states, or organizations designated by states (known as state designated entities, or SDEs). In their four-year performance periods, "awardees are responsible for increasing connectivity and enabling patient-centric information flow to improve the quality and efficiency of care. Key to this is the continual evolution and advancement of necessary

governance, policies, technical services, business operations, and financing mechanisms for HIE." See http://healthit.hhs.gov/portal/server.pt?open=512&objID=1488&mode=2.

As providers seek to understand the development of HIE capabilities in their states, these grant recipients are their primary points of contact. A states or its state-designated entity may not be the organization that implements or operates the technical services for HIE, but it must serve as the governance entity that ensures that the capability for HIE in each state will be appropriately developed. The state or its designated entity must have a plan in place that makes it likely that, by 2015, HIE requirements for meaningful use will be achievable by hospitals.

As a result of the role the states or their designated entities are required to play in building HIE capabilities within a state, they are key resources for hospital executives seeking to meet HIE requirements to achieve meaningful use. A list of key contacts for each state can be found at http://ciostatenet.org established by CHIME in 2010. CHIME CIO StateNet is a state-by-state network of coordinators who gather and communicate relevant in-state health IT developments. State CIO Coordinators, representing all 50 states and the District of Columbia, are engaged in identifying key developments, communicating them on this website and sharing best practices within and across states in preparation for demonstrating meaningful use of EHRs to improve health and healthcare. Coordinators for CIO StateNet are gathering and updating information on their state's HIE plan, strategic and operational plans for HIE infrastructure; links to ONC-approved state plans; and other related documents. Registration, which is free, is required to access CIO StateNet information.

Another source for assessing existing or developing organizations seeking to provide health information exchange is the annual report by the eHealth Initiative (http://www.ehealthinitiative.org), released in July 2011 during eHI's annual National Forum on Health Information Exchange. The most recent eHI report identified 255 active HIE initiatives across the country.

Some states also are collaborating to create critical mass on the approaches, standards and services necessary to support HIE. For example, the state HIE leaders in California, Colorado, Maine, Massachusetts, New York and Oregon have been collaborating; these states represent 30 percent of the U.S. population.

Resources

- CHIME CIO StateNet: As a result of the role the states or their designated entities are required to play in building HIE capabilities within a state, they are key resources for HIE executives seeking to meet HIE requirements to achieve meaningful use. A list of key contacts for each state can be found on the CIO StateNet website, established by CHIME in 2010. CIO StateNet is a state-by-state network of coordinators for purposes of gathering and communicating relevant in-state health IT developments. State CIO Coordinators, representing all 50 states and the District of Columbia, are engaged in identifying key developments for input into this website and sharing best practices within and across states in preparation for demonstrating meaningful use of EHRs to improve health and healthcare. State CIO coordinators for CIO StateNet are gathering and

updating information on their state's HIE plan, strategic and operational plans for HIE infrastructure; links to ONC-approved state plans; and other related documents. Registration, which is free, is required to access CIO StateNet information. *Link:* http://www.ciostatenet.org/

- eHealth Initiative Annual Report on Health Information Exchange: released in mid-July, this report is a source for assessing existing or developing health information organizations (HIOs). This report identified 255 active health information exchange initiatives across the country. *Link: www.ehealthinitiative.org*

Chapter 2

Assessing Your Local Landscape for HIE

Each healthcare organization's approach to HIE will depend on its own circumstances and the "landscape" in which it operates, the timeframe within which it's working and its strategic priorities for achieving HIE. This chapter looks at key considerations in assessing health information organizations (HIOs), detailing characteristics that HIT executives and their organizations should consider as they compile information in advance of making a selection.

Two Options for Pursuing Meaningful Use of HIE

Organizations may pursue two separate courses of action in attempting to achieve the meaningful use of HIE, and thus, in the short term, qualify for incentive fund payments under the HITECH Act.

1. **Connectivity via an outside entity**. First, eligible providers and hospitals may be looking to an outside entity that will help facilitate HIE by providing the connectivity to other providers in an area, region or state. By selecting the right HIO – one which can successfully achieve connectivity in an area, offer a growth plan to offer increasingly complex HIE in the future, and which offers the right governance model and financial stability over time – providers can increase the likelihood that they'll meet objectives for current and future stages of meaningful use.

2. **Connectivity via an enterprise network connecting entities within an organization**. Integrated health delivery networks can satisfy the requirement to "exchange clinical information electronically with other providers and patient-authorized entities" by sharing patient data among the providers within their network through Enterprise Health Information Exchange (EHIE). For example, Baylor Health Care System in Dallas expects to use enterprise HIE to meet its data exchange needs with a variety of its provider sites, which include a partially owned group of hospitals; an affiliated but not owned cancer center group; and outsourced rehabilitation services. EHIE also will help with data exchange for Baylor's physician group, which uses at least three different ambulatory records systems, and for which there are no current plans to create direct interfaces to the hospitals' records system.

Thus, enterprise wide HIE may be a logical first step for some organizations that face issues of timing, control, risk concerns and solution availability. In fact, a survey (for press release, see http://www.klasresearch.com/News/PressRoom/2011/HIE which also contains a link to the report, which is available for purchase) released in July 2011 by KLAS, an HIT research organization, found 161 private-sector HIOs were in operation this year, compared with 52 private sector HIOs in 2010. By contrast, only 67 public HIOs were functioning in

2011, KLAS said. Chapter 3 of this guide discusses key considerations for organizations heading in this direction.

Key Considerations in Selecting an HIO

For HIT executives tasked with selecting an HIO, the first step involves gathering key information that will be needed in making a decision. Some information will be at one's fingertips; other data points will be more difficult to gather. A panel of CHIME members versed in HIE considers learning and understanding the HIT leadership in one's State to be an essential base for making an educated choice of an HIO partner.

- **State HIT Oversight:** HIT executives should know the HIT Coordinator who is responsible for each state's HIE oversight. In some states, that individual is appointed by the governor. The HIT leader may be a designee in the state's department of health or in a public organization that has been established by the state. In some cases, a hybrid approach may be used; for example, in New York, there is an appointed deputy commissioner for health information transformation at the department of health, who works in tandem with an executive director of the New York eHealth Collaborative, a public organization that was specifically established to execute the state's HIT plan. The eHealth Initiative offers a directory of HIT Coordinators and organizations at http://www.ehealthinitiative.org/issues/health-information-exchange-hie.html.

- **HIT Committee Contacts:** It's also important to identify the individuals who may sit on committees or task forces that work on various elements of HIT. To find the person in charge for your state, please consult CHIME CIO StateNet by visiting http://ciostatenet.org and, after registering, consult the information for your state. Some states have technology committees, and the chairs of those committees may hold other roles or have connections to statewide HIOs or other HIOs in the state.

- **State Statutes and Laws:** Beyond knowing people in key roles within a state, CIOs need to understand state statutes or laws that may have an impact on HIE. Other state variations are important to know, such as whether a state has separate privacy or security regulations that differ from those contained in federal HIPAA regulations.

Additional concerns:
- States are using different approaches to structuring HIE plans, and HIT executives must understand either the state approach or that of any other organizations that have received HIE funding within a state.

- Understanding the HIE landscape in a state is important because most HIE initiatives are at a very early stage in their development.

A Checklist of Topics to Consider

Understanding HIE within your context is multifaceted, and to make the best decision, HIT executives should evaluate the following topics and questions.

Governance

- How is the HIO to be operated?
- Does a separate entity own and operate it, or will it be owned and operated in a shared fashion, by its members?
- Is there an overall state model for governance or oversight? Does the governance or oversight team include clinicians from different member organizations?
- What will be the intersection of efforts within the state by an HIO with national efforts, such as the Direct Project and CONNECT software? See http://healthit.hhs.gov/portal/server.pt/community/nhin_direct_project_and_connect_software/3340/home/21289.

Finance

- How will the HIO operate as a business?
- What is the source of its startup capital?
- How long are startup funds expected to last?
- What funding options will sustain the HIO's operation after startup funds are exhausted?
- Will participants be at risk for covering shortfalls in operational expenses?

Technical infrastructure

- What is the underlying architecture (central data repository, federated or hybrid)?
- How will data be exchanged? If exchanges will involve proprietary approaches, connections are typically more difficult.
- Will interfaces be available for the hospital's current clinical system, or will data exchange mechanisms need to be developed on a customized basis?
- What data standards will be used? Will those standards be sustainable for the long term?
- Will the HIO be able to easily connect to the Nationwide Health Information Network (NwHIN)?
- Will it be able to exchange data to meet Medicaid and public health requirements?
- If the HIO is to be owned by a vendor, has it integrated products from multiple health information system vendors?
- A healthcare organization's vendor also may be able to shed light on integration capabilities with a particular HIO. Approaches to the HIO role continue to evolve as states examine models to determine how they might connect to the state or national health information network, or how the HIO might play a pivotal role in being the infrastructure for the NwHIN by delivering services for a region or state, such as EHR-to-EHR routing of CCDs, management of EHR-produced epidemiologic reporting, and other such services.
- What interface and vocabulary standards are supported?
- What service level agreements (SLAs) are in place for the repository and provider portal, as well as transaction throughput?
- What approach is used for master patient indexing?
- Are there considerations for feeds into patient electronic health record systems, such as Microsoft HealthVault?

Legal policy and confidentiality

- How will data be protected?
- Will patients be able to opt out of participation, or will a more restrictive "opt-in" approach be used, which may limit the number of patients choosing to participate?
- Are appropriate policies and legal agreements in place to guide the technical services?
- Upon close examination, are privacy and security policies logical and effective, and are they being followed?
- Are various meetings, such as for the technical or privacy-security discussions, open for providers to join in and participate?
- A state's HIT Director should be able to provide background on many of these policies and procedures.

Resources and Tips

- CHIME CIO StateNet and its coordinators for each state should know state-specific information about HIE efforts within a state.
- CIOs need to do their own research and speak to their peers to confirm information that HIOs are publishing.
- State websites for HIT should contain official state information related to HIE initiatives and approaches, but some CHIME members warn that these state websites may not always include the latest, updated information.
- Public meetings on HIE are helpful, as are conferences or presentations that are sponsored by the state.
- State HIMSS chapters may have information on HIE initiatives within the state.
- HIE initiatives will probably have their own websites, but some HIT executives warn that these websites are not always up-to-date.
- Also see the following:
  - ➢ The eHealth Initiative HIE Toolkit: http://www.ehealthinitiative.org/issues/health-information-exchange-hie/hie-toolkit.html
  - ➢ eHealth Initiative Interactive Map of all HIEs: http://www.ehealthinitiative.org/directories/hie-map.html
  - ➢ eHealth Initiative Market Analysis on HIE and List of HIE Vendors
  - ➢ HIE Market Analysis Report: http://www.chilmarkresearchstore.com/hiemareja20.html
  - ➢ eHealth Initiative Governance Models for HIE
  - ➢ ONC: Acceptable HIE Governance Structure, *Source: Nevada Department of Health and Human Services*

Chapter 3

Meeting Meaningful Use Requirements by Forming an Enterprise Health Information Organization

For more than 20 years, healthcare IT visionaries have had the dream of exchanging healthcare information within a community, region, state and even at the national level to improve the flow of information and, thus, the quality of care.

Whether the vehicle was intended to be a community health information network (CHIN), a regional health information organization (RHIO) or health information organization (HIO), success has proven elusive. For whatever reason – high startup or operational costs, governance issues or technology difficulties – relatively few such organizations are currently exchanging data among providers in a community or region.

But providers are feeling the pressure to take initial steps toward developing the capacity to exchange health information. As a result, HIOs are expected to play an increasingly critical role in helping healthcare providers achieve the meaningful use of electronic health records and thus qualify for incentive funding, particularly in Stages 2 and 3 (the current objective for Stage 1 only requires successful completion of a test to demonstrate interoperability). So it's not surprising that some healthcare organizations are deciding to first develop information exchange capabilities within their own enterprises.

<u>Growth in Private Sector HIOs</u>
A survey released in July 2011 by KLAS, an HIT research organization, found 161 private-sector HIOs were in operation this year, compared with 52 private-sector HIOs in 2010. By contrast, only 67 public HIOs were functioning in 2011, KLAS reported.

Many integrated health delivery networks have grown quickly, and their provider sites are using disparate information systems. New funding models, such as those using accountable care principles for reimbursement, will cause new organizations to be formed or existing organizations to be re-formed. The exchange of data in an efficient manner will be vital to their success for both clinical and administrative reasons. Enterprise wide HIE (EHIE) can help these healthcare delivery systems operate in an integrated manner. EHIEs that connect both eligible providers and eligible hospitals can satisfy the meaningful use objective for Stage 1 that requires organizations to "exchange clinical information electronically with other providers and patient-authorized entities" by sharing patient data among the providers within their network. However, the regulation contains an exclusion that notes that "information must be sent between different legal entities with distinct certified EHR or other system that can accept the information."

Healthcare IT executives face a variety of different decisions as they consider whether to pursue forming an EHIE. In part, a healthcare organization's decision on whether to pursue the development of an EHIE hinges on whether that effort will best help it meet strategic goals cost-effectively. Additionally, it's helpful to establish guidelines for what the organization defines as cost-effectiveness.

To help organizations evaluate the decision about whether to create an EHIE, this guide offers a series of questions to consider. The following points were developed with David Muntz, FCHIME, CHCIO, senior vice president and CIO at Dallas-based Baylor Health Care System.

<u>Decision Factors in Considering Enterprise Health Information Exchange</u>

- What are the factors impacting your decision to consider an enterprise HIO)?
  - Disparate data sources in the areas where you as a CIO have responsibilities, which are too challenging or too costly to interface via traditional means.
  - Too many challenges interfacing in areas where you do not have responsibilities as a CIO.
  - Other factors. For example, economic pressures in the healthcare environment are creating new business relationships at an accelerating pace. The ability for new "partners" to exchange data will put significant pressure on integration teams. HIEs can offer a less challenging approach than using traditional interface engines.
  - Evolving federal and/or state regulations or guidelines or requirements governing all aspects of data transactions and access.
- Will you host the HIO? Physicians are naturally cautious about putting data into repositories controlled by entities that they believe might use the physician's data to learn more about them. If the host of the HIO is a hospital or payer, physicians will need to be convinced that their data will be protected. Although the hosting entity might offer to segregate data, suspicions can remain. Finding a "Switzerland" to host the data can eliminate this concern. While this is a common fear, it can be overcome with the correct governance structure, implemented security policies, and rules – collectively agreed upon – for gaining access to clinical data.
- Will your vendor host the HIO?
- If you are not hosting the HIO, will you be using an edge server?
  - If so, how long will you retain data on the edge server?
- If you don't use an edge server, will you feed data to another repository hosted by the HIO vendor?
  - If so, how long will you retain data there?
- What data types will you exchange? Does that include images?
- Will you be able to incorporate data (including images) from the exchange into your records, and, if so, how?
- How will you address consents?
- What kind of security agreements will you put into place?
- How will you authorize users?
- How will you audit activities? The audit activity should focus not only on the customers of the exchange, but the HIO that is managing the exchange.
  - How long will you keep audit trails?

- o Will you be able to track what data was presented to the user?
- o If so, how long will you retain it?
- o How will the HIO address accounting for disclosures?
- o Is the HIO HITRUST certified? If not, is the HIO SAS-70 certified? If neither, will you be allowed to perform an unannounced audit?
- Who will educate and train your users?
  - o Initially
  - o Over time
- How will you support users (for example, answering calls, making field service visits and the like)?
- How will the organization populate the master patient index (MPI) initially?
  - o What patient matching criteria will be used?
  - o What happens when patients' information is merged in your organization? For example, a new baby is born with the name "Baby Jones." The baby's name is later changed to a new name. What processes will your organization have in place to check and ensure that merges are performed correctly?
- On what conditions will you push data to the edge or the repository?
- How will you manage downtime, recovery and business continuity?
- If you are forming an ACO, does this technology give you a means to solve a business problem?
  - o If so, will you require members to participate?
  - o The ability to reproduce the data that was presented is of particular concern to physicians. Suppose that an HIO, any HIO, has been operating for more than two years. Suppose, also, that a physician on your staff is called to court to answer charges that treatment harmed a patient. The physician claims that his or her action was a result of information that was presented by the HIO; of that, the physician is certain. Suppose that the physician's action was evidence-based, but that the data presented was later modified by a source on the HIO that is no longer available, and that the changed data contraindicates the action that was taken. If the doctor acted on the original data (or chose not to act) and harm resulted based on data that is no longer available, what is the likely outcome of the court case?
  - o If not, how will you manage risk without an HIO? How will you measure and manage quality?
- Who is responsible for the quality of the data posted on the HIO?
- When an error is discovered, is there a clear process for correcting the error?
- How will data corrections be audited?
- How will your organization influence the changes to the HIO portal or solution? As an example, suppose that serious issues are discovered during unit testing of microbiology results. Do you exclude microbiology results from the list of data sent to the HIO, or do you work with the HIO to get the issue corrected? Structural changes to the way HIE solutions present data take a long time to complete, as the solution must be vetted with all member organizations.
- How does this enterprise HIO interact with a personal health record?
  - o Does the HIO have its own personal health record solution?
  - o If yes, does the HIO allow patients to directly contact physicians from your organization?

- What policies and procedures does your organization have in place to handle patient-provider relations, from both a clinical and billing standpoint?
- If the patient collects clinical information in the PHR, does the HIO permit the push of such information back to the HIO solution from the PHR? If so, how do physicians in your organization feel about the quality of such data, and is it differentiated from other clinical data?

Chapter 4

Selecting an HIO

In considering how to achieve the exchange of health information, providers nationwide will face a variety of choices among several variable decision points. Some areas will have no specific HIOs from which to choose; others may have only a developing state option; while other provider organizations may be courted by more than one HIO and be facing a decision on which one to choose.

In the latter case, providers will need to carefully consider their options before making a decision. Gathering key information can be accomplished by looking to several resources within a state.

Finding the Facts

Some sources of information on HIOs can include:
* A state's hospital association.
* The state HIT Coordinator (in some states, such as Minnesota, HIOs need to be certified by the state, which authorizes entities to conduct health information exchange).
* Participants in the CHIME CIO StateNet group within a state.
* Other HIT executives in a state that may have had experience with an HIO. Existing participants in an HIO often are excellent resources for sharing both good and bad experiences with health information exchange.

How to Base a Decision

* A key in any decision on an HIO is analyzing its proof of concept. Ideally, the organization should be up-and-running and demonstrate a viable model for financial sustainability.

* In addition, HIOs must be able to demonstrate that their services, either current or projected, offer enough value for participating healthcare organizations to be able to make a business decision to affiliate with the HIO. According to a recent report from the National eHealth Collaborative (the successor to the American Health Information Community, which was established prior to the HITECH Act), "Reduced data distribution costs and increased staff productivity are the major reasons why participants are willing to pay for the services offered by these HIOs."

* Engendering a sense of trust among participants in an HIO is also a key in assessing likelihood of success of an HIO, according to this same report. "The culture, policies and procedures of the HIE regarding data usage must assure participants that no

stakeholder will gain a competitive advantage at the expense of others," said the report, which was funded by ONC.

- Assessing the worthiness of an HIO for selection also requires examination of the governance model for the HIO and predicting how comfortable the HIT executive's organization will be in working with the HIO. Background information crucial to this decision includes:

  - The HIO's steering committee and its membership
  - The HIO's vision and mission
  - Sources of early funding
  - Plans for financial sustainability and services growth (particularly in areas that will provide value to offset costs)
  - The commitment of the membership or founding members to financially support the HIO
  - The organization's strategic plan
  - The governance model
  - Privacy protection capabilities
  - Technological approaches
    - o Product and solution maturity
    - o Vendor presence in the market

Counting the Cost

Because of the financial commitment required to build and maintain connections to an HIO over time, it's crucial for a healthcare organization to have a thorough understanding of the cost implications of a decision. A CIO needs to understand the HIO's pricing approach and how fees or charges will be assessed, to justify projected charges against potential savings or increased revenue (a return on investment calculation), and to weigh "hard" savings against potential "soft" savings from the exchange of health information.

State laws and regulations may affect cost as well. States may have some indirect involvement in the charges HIOs can levy because each state is responsible for creating a "financial sustainability" model for health information exchange. Under this approach, the state may "certify" an HIO according to standards related to technical infrastructure, governance, privacy/security policies, sustainability, and so on. "Certified" HIOs may be regulated regarding what they can charge.

Beyond subscription costs or ongoing transaction expenses to the HIO, a healthcare organization will need to take into account other one-time and ongoing expenses for participation in HIE. For example, a federated model HIO (see architecture discussion in Chapter 6) generally will require that organizations purchase and operate edge servers that hold patient information that can be accessed. Overall, federated approaches tend to be more expensive to cover hardware costs, but they are easier technically to implement.

Other indirect costs also must be accounted for, such as:

- Personnel time in developing interfaces and ensuring network connectivity

- Time required by personnel to implement new processes
- Workflow interruptions
- Other staffing costs related directly or indirectly to an organization's involvement in data exchange
    - Pre- and post-live validation by the data generators at your organization. For example, laboratory technologists need to validate the data sent to the HIO from their laboratory system, and radiology staff need to perform a similar validation.

Other Factors to Consider

IT staffing commitment is required for any organization that seeks to exchange patient information through HIE. Regardless of the HIO vendor chosen by the provider, each participating organization has to anticipate additional cost in managing their own data with the HIO as well as the cost of complying with all security requirements.

The sustainability of an HIO is a continuing concern for providers. HIOs are generally funded by private or public money. Members that participate in data exchanges also may pay a fee or assessment. But the development of a viable business model that scales sufficiently to support data exchanges with current technology for inter-operational data exchange is a challenge. Thus, a given HIO's level of technological advancement becomes an important factor in choosing an HIO.

As a result, exchanges will rely on financial goodwill or look to a time when service technologies will evolve to a manageable state that enables scaling solutions that may provide significant reach. This already has occurred with organizations such as the Surescripts-RxHub exchange for e-prescribing. Many industry leaders believe that health information exchange will become a commodity – in a sense, a utility – given the basic importance of the function, and appreciating the basic nature of a mature structured medical vocabulary-based summary of care exchange, which may occur in Stage 3 of Meaningful Use objectives.

Chapter 5

Technical Requirements for HIE

While there are many decisions to be made about how to achieve health information exchange, the technical requirements for actually accomplishing the exchange of data is not likely to require the hands-on participation of an organization's top HIT executive. However, a basic understanding of how information will be exchanged with the HIO, and the impact it will have on a healthcare organization, is necessary.

The technical requirements for a healthcare organization will greatly depend on the type of HIO with which it's working, the HIO's capabilities for exchanging information, the healthcare organization's ability to generate a standard message, and how soon the organization plans to implement HIE, including whether it plans to implement an enterprise health information organization.

Currently, meaningful use requirements for exchanging healthcare information are fairly simple. One of the core objectives for eligible hospitals is the ability to "exchange clinical information electronically with other providers and patient-authorized entities." Because rule-makers recognized the early stages of HIE capability in this country, providers can satisfy the objective by attempting "to identify one other entity with whom to conduct a test of the submission of electronic data. This test must include the transfer of either actual or 'dummy' data to the chosen other entity," according to the meaningful use requirements. The rules don't consider the transfer of data via a thumb drive or other removable media to be a valid test.

However, later stages of meaningful use are likely to require more sophisticated and wide-ranging capabilities for exchanging patient information. Although proposed meaningful use requirements for Stage 2 aren't expected to be released until later in 2011, HIT executives should concurrently be planning for the technical challenges of more advanced data exchange expected in the future.

Beyond that, it's apparent that new forces affecting healthcare, particularly payment reform approaches and increasing business and care delivery coordination, will place a premium on better, more advanced healthcare information exchange.

<u>**Early Requirements**</u>

In the early stages of the program, exchanges of patients' healthcare information can be accomplished through the Continuity of Care Document (CCD), which is based on the Health Level 7 Clinical Document Architecture elements. The CCD was formed through a joint collaboration between Health Level Seven International (HL7) and ASTM International, and it's used to share summary information about a patient. The CCD is the

more difficult and advanced of the interfaces. Patient demographics (ADT) and lab results (ORU) or transcribed reports are easier to generate.

The Continuity of Care Record (CCR) also is a viable option for enabling the exchange of patient information; the Office of the National Coordinator also recognizes the CCR as a valid approach to exchange data. The CCR, a standard promulgated by ASTM International and several other health groups and vendors, is used by a large segment of the HIT industry, and some consider it easier, faster and less resource-intensive to implement than the CCD. However, the CCD is considered better for document exchange and is emerging as the preferred standard for HIE.

Certified EHR software that healthcare organizations are using as electronic health records must be able to produce a CCD as a requirement to be certified. How exactly a vendor's product generates a CCD varies, said William Sorrells, executive director of the Alaska eHealth Network and a member of CHIME. Some vendors' applications require someone to manually request that a CCD be created, while others automatically generate a CCD each time a new instance of care delivery is recorded in a patient's electronic record.

The CCD is compatible with any document or standard that uses HL7's Reference Information Model (RIM-based) for databases. The CCD uses a detailed set of constraints (templates) to contain various types of patient information. The templates define how to use elements to communicate clinical data. Templates include the header, purpose, problems, procedures, family and social history, payers, advance directives and various other medical information, and plans of care.

Data Storage

Health information exchange will take on different forms depending on the type of HIO through which a healthcare organization plans to exchange information and the data storage approach that's envisioned by the HIO.
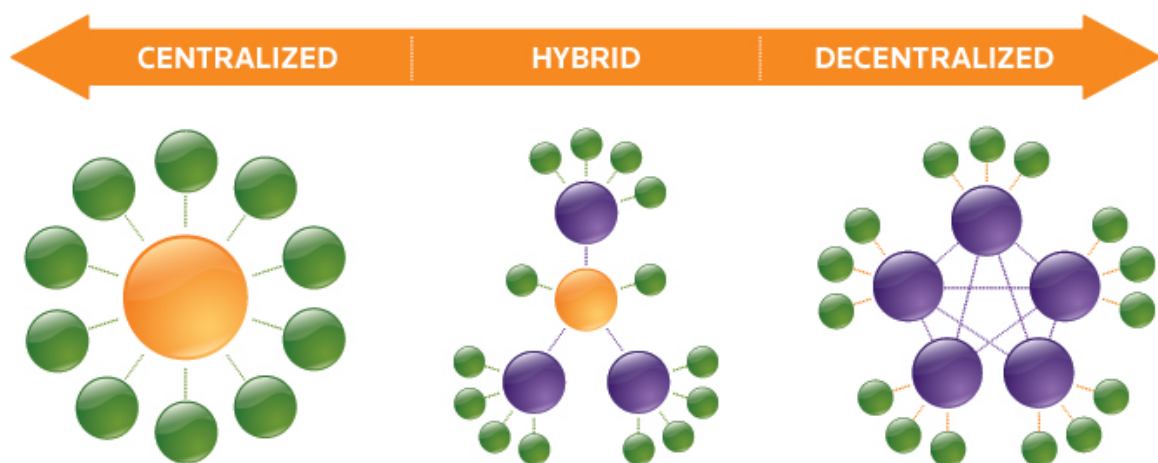
Source: eHealth Initiative

- With HIOs using a **centralized approach**, one repository is used to collect all clinical information. The centralized entity manages and performs the exchange of clinical and administrative data among all the participants in the exchange. Master patient indexing and record locator services are located at the HIE level, and all matching services are performed by the exchange; registries and repositories also are handled centrally. The central data repository also may collect and disseminate electronic prescriptions, lab results and other digital healthcare information.

  There are economies of scale available in a centralized approach; for example, data backup and user auditing can be done centrally rather than at each site where data is stored. Costs also can be more closely monitored and controlled. Most of the concerns surrounding a centralized approach have to do with data ownership and privacy worries of providers who are concerned that sensitive patient data is under the control of an outside entity, thus limiting their direct control of security procedures in place at the HIO.

- With a **decentralized (federated) approach**, the HIO acts mostly as a coordinator and collaboration facilitator to enable the exchange of information; no actual data is held by the entity serving as the HIO. Healthcare organizations make copies of their clinical information on patients available, storing them on edge servers that are accessible to other organizations but protected by firewalls to prevent access to their core data storage systems. The decentralized HIO does other important connection tasks, including linkages to the NwHIN, and it ensures that all data that's shared is accurate and standardized, while all stakeholders are properly secure and validated.

  Federated approaches are considered the easiest to implement but are more complex to maintain. Limitations of the federated approach include the challenge of coordinating many separate stakeholders on the use of set standards and procedures for exchange, and the need for many disparate systems to work together at any given time. For example, New York state initially provided grant funding for more than 30 HIOs – through business attrition, that number has dropped to fewer than 15 during the past three years (not all of which were related to the data storage model they used). HIOs in New York continue to make efforts to demonstrate financial sustainability while the state reshapes its HIT strategy to a services approach that intends to centralize and scale select exchange transactions.

  The federated model presents performance issues that vendors must overcome, and participating providers should be aware of current limitations. For example, it is important to inform providers that they may have to wait a few more seconds while their information is being retrieved from all participating members.

- In a **hybrid approach**, elements of both the centralized and decentralized models are combined. Services such as a master patient index, record locator service and consent management may be handled centrally by one or more HIOs in an area. Often, the hybrid approach takes the form of a central repository of information with "edge servers" utilized for data storage. These edge servers can be located at stakeholder sites or within the central repository, but are notable for the control that providers maintain over their data. Because stakeholders' data is not comingled, each

entity can maintain control and ownership of their data. Some security and other advantages of the hybrid model include:

- o Data is stored both locally and centrally and accessed only when needed for exchange
- o There is no conflict over who owns the data
- o Centralized access is tight and limited
- o Data is more current
- o Failure of a single system does not cripple the entire system
- o More repositories provide compartmentalization, meaning a smaller amount of data is available to potential hackers who may be able to penetrate a single system

Standards Enable Data and Information Exchange

There are various types of standards that need to be considered as HIOs develop technical infrastructure: terminology standards, messaging standards and document standards. An understanding of these standards is vitally important to HIT executives whose organizations plan to participate in clinical information exchange. HIOs tend to relax their requirement to receive data in standardized fashion just to get the data. It is important to recognize that HIOs that insist on data standards are more mature in their approach and tend to provide higher quality data results.

- **Terminology standards** ensure that stakeholders across the entire spectrum of a health information exchange are speaking the same language. Medical terms, laboratory results, specific diagnoses, and procedures are shared across the HIE, but without terminology standards, these results remain as institution-specific internal codes, only useful to those providers who input the data. Terminology standards enable widespread use and understanding of medical results to be utilized in the delivery of care or in outcomes management, and facilitate clinical decision support.

  There are limitations to the widespread use of terminology standards. One significant challenge is adoption. If certain organizations are slow to adopt the generally accepted terminology standard, their data cannot easily be consumed or shared at the HIE level. Providers also may implement and use standardized terminology at different levels of specificity for documentation and delivery to the HIE. Finally, local variations of the national standard do exist, and some new diagnoses, procedures or medications may not have an assigned code or term.

  Another challenge with terminology standards lies in the details of translation. Who will translate local codes for lab results or diagnoses into the proper standard format? Is this done at the user level, or after information has been sent to the HIO? Some HIOs have struggled to attain this level of data integration. Normalization across organizations is a complex, and extremely challenging task; it is dependent on the terminology, the EHR functionality and having processes in place to accomplish it.

- **Messaging standards** are used to send and receive messages easily and efficiently. These standards enable the structuring of messages in such a way that all stakeholders across an HIO can easily decipher their meaning and content.

Messaging standards make it possible for different computer systems to pull out the same messages across the spectrum, regardless of local specification.

However, there are challenges regarding the use of messaging standards. These standards continue to develop and evolve, and confusion around exact specifications for some of these standards can still be a challenge. In the case of National Council for Prescription Drug Programs (NCPDP), the lack of adoption of consistent units and standards of measurement has proven to be a challenge. However, some of the standards around which consensus has grown include:

- HL7 –Standards framework for the exchange of health information
- Web Services
- Secure transport and encryption protocols such as HTTPS, SFTP, VPN and PHINMS (a government standard)
- XDS – Integrating the Healthcare Enterprise (IHE) Cross-Enterprise Document Sharing specification, for the exchange of healthcare documents across different enterprise stakeholders, typically used for storing in a document repository
- PIX/PDQ – IHE interoperability specification for Patient Identifier Cross Reference Manager and Patient Demographics Query, respectively. Use of these standards enables EHRs and other applications to query HIOs for patient demographics and patient identifier information.

- **Document standards** across an HIO ensure that organizations are sharing relevant patient data organized in a useable and readable manner. By standardizing the documents shared across the HIO, providers can be sure they are receiving accurately recorded and organized patient summary data (as with the CCR or CCD), laboratory images and results, or any other formalized communication. Also, by using document standards, electronic health records can accurately extract patient data, interpret the information, and place data into the appropriate location within the user's EHR.

  Widely recognized document standards and specifications include the following:
  - ADT (patient demographics, known as admission/discharge/transfer)
  - ORU (lab results)
  - VXU (Vaccination Record Update)
  - CCD – The Continuity of Care Document is a patient summary containing pertinent clinical and administrative information
  - CCR – The Continuity of Care Record is a summary of a patient's health status at a certain point in their continuum of care
  - DICOM – Radiology image sharing and workflow management
  - XML – (Extensible Markup Language) An Internet standard that supports the ability to represent structured data and hierarchical data as stored in relational databases; it's used for encoding documents and data into a form that can be read by machines
  - NCPDP SCRIPT – (National Council on Prescription Drug Programs) Data interchange standard for exchange of prescription data between pharmacies,

prescribers, payers, and intermediaries (e.g. Surescripts). NCPCP also leads development of a formulary and benefit standard.

- **Data Translation and Mapping:** As provider organizations deliver care and record diagnoses, medications and any other medical data into an EHR system, vendor-specific or localized methodologies are used to document the information. For medical data to be shared for population reporting and analytics across a state, region or nationwide, data must be converted to the appropriate standard. Data still can be useful if it isn't normalized. If one practice uses one term for heart attack, and another practice uses another term, a provider should still be able to understand a clinical note. This can be a resource-intensive undertaking, but some proponents believe that, by prioritizing the most commonly used codes and terms, some of the difficulties inherent in data mapping and translation can be mitigated.

  There are multiple standards for similar types of information. Data transformation can occur at numerous levels in the health information exchange process. The HIO can perform the transformation at its centralized location within the exchange community, or organizations can be required to transform and properly map their data prior to distribution. As such, data transformation is a value-added service provided by some HIOs. Additionally, the federal HIT Standards Committee recommended standards in their August meeting, suggesting that SNOMED and LOINC be used wherever possible, to increase standardization of vocabulary and to facilitate data mapping during health information exchange between healthcare organizations.

- **Data Presentation:** As HIOs receive information, they also provide ways for users to download information. In some cases, the information is downloaded as a CCD. The CCD file usually contains translation instructions in the form of a link to an XSL file, which tells the browser how to format the content of the CCD in HTML for viewing. Each system vendor provides standard transformation instructions for their CCDs.

Other Infrastructure Considerations

- Make sure your HIE data facility is SAS 70 Type II certified. This certification covers nine specific areas, including network monitoring, customer service, data backup, change management, deployment and physical security (battering rams, bulletproof glass, and so on), in its core managed services business.

- Be sure to check on disaster recovery specifications, including hot site, clustering, mirror configuration between the PDC and SDC, among key issues.

- Another consideration is to ensure that there is robust wired and wireless connectivity. Related topics include bandwidth costs; the mix of fiber and T-lines for redundancy; and how many buildings are connected to the community cloud.

- An HIO should be able to provide reliable hardware support. It must support continuous refresh to make sure practices are up to spec. It is a major time investment to ensure that practice PCs have the right power, memory, level of operating system and encryption to participate in the exchange of data through the HIO.

- There should be ample capacity at the HIO for throughput and storage. This includes provisions for servers, SANs, backups and logging. This requires another level of expertise in the area of database administration, storage engineering, and wide area network planning.

- Use of an experienced integration partner that has already worked on HIE connectivity projects is recommended by many CIOs.

Chapter 6

Assessing Service Offerings from an HIO

Healthcare organizations will face a variety of choices in selecting HIE services, depending on the technical infrastructure of the health information organization that offers data exchange services, as well as policies involving consent, sender MPI data quality and other factors.

In some cases, these services will be "have to haves" that will be necessary for participation in an HIO. Others will be optional "add-ons" from which healthcare organizations can make choices.

<u>Typical Core Services</u>

Master Patient (Person) Index
The master patient index is a database containing a unique identifier for all patients under the domain of an HIO. Hospitals, health systems, labs and other entities may have their own identifiers for patients, and as a result, there will be multiple identifying codes in use among participants in an HIO that can refer to one patient. When a provider queries the HIO for a patient's information, the MPI uses the patient's demographic information to match all appropriate records in the numerous disparate systems that are linked to the HIO.

The Master Patient Index uses several matching algorithms to find all of a given patient's records across disparate systems and match these records to the correct patient. These algorithms typically use the patient's name, date of birth, sex, mailing address, telephone number, and a combination of additional data elements, such as insurance or family information that promote accuracy. The more data elements incorporated into the matching process, the more accurate the process becomes. Still, human intervention in the matching process is sometimes necessary to ensure the accuracy of the records being associated with an individual.

Trust Broker
At its base, the trust broker is a list of all participating stakeholders in the HIO. That list also includes the specific provisions that each stakeholder has approved for the exchange of health information.

A related component is the **provider directory**, a comprehensive list of all providers with an NPI in the service area of an HIO. Because the nature of health information exchange involves both the "push" of healthcare information to other organizations or the "pull" exemplified by requests for patient information, it's critical that HIOs provide protections to all by verifying the credentials of each associated stakeholder or provider. In fact, the HIT Policy Committee's Information Exchange Work Group (established by ONC under the

HITECH Act) suggests that a provider directory also should include other healthcare organizations (health plans and public health agencies); health information organizations (such as regional HIE operators and health information service providers); and other organizations involved in the exchange of health information (such as business associates and clearinghouses). As another example, in Vermont, the provider directory in the HIO will be a subset of the statewide provider directory that encompasses the superset of providers.

Beyond ascertaining a provider's identity and verifying rights to have access to healthcare information, provider authentication is verified on an ongoing basis through the use of a combination of a user ID and password.

Providing Wider Connectivity
As states begin connecting to health information exchanges and unite stakeholders across a wide spectrum, integration with the state Medicaid platform becomes a key consideration. Coordination between state Medicaid plans and HIE efforts is a requirement for the approval of a state's strategic and operational plans.

State HIOs can leverage Medicaid resources and infrastructure to strengthen exchange capability and pre-populate or bolster the information coffers of the HIO with data. Additionally, coordination between the state Medicaid agency and HIOs empower providers to achieve Meaningful Use of EHRs, as outlined by the CMS Incentive Programs.

Many states are aligning efforts to build health information exchange capacity with the process of upgrading or replacing the existing Medicaid Management Information System (MMIS) with a new system. CMS provides the basic framework for an information system to manage Medicaid claims processing and provider procurement of patient Medicaid information. State Medicaid agencies then build on this framework to create a customized MMIS to be used statewide. This framework, known as the Medicaid Information Technology Architecture (MITA), has evolved over the years, and states are eager to employ the most current set of principles, MITA 2.0. The new foundational elements in MITA 2.0 focus on business processes to promote interoperability and workflow optimization. States upgrading or replacing existing MMIS infrastructures may choose to employ a Service Oriented Architecture (SOA) as the capacity for interoperability between numerous systems within a given state continues to grow.

As such, HIOs may eventually be able to provide continued access to states' MMIS as they evolve and provide increased functionality and information exchange capabilities. This is not likely in the near term, because HIOs and MMIS serve different "customers" and have different sources of data.

Other Clinical Data Services

Other information exchange possibilities may include:
- **Immunization Registries:** Providers may be able to interact with state immunization registries to submit and receive/retrieve immunization data. Utilizing regular batch feeds, real-time HL7 interfaces or real-time Web-based queries, HIOs can send and receive patient immunization data that can be presented to authorized providers at the point of care. Gateways facilitate the documentation and exchange

of immunization data between the connected EHR/EMR and local or state registry systems through the HIO. Depending on the capability and form of the HIO, immunization data can be first aggregated or entered directly, and then transmitted to the registry system in various formats, depending on the requirements of the specific system.

- **Public Health Reporting:** Interfaces also may be available to transfer data to reporting systems or government agencies, such as public health departments. These interfaces, which should be configured to de-identify protected health information as required, enable community-wide scanning and reporting on conditions and provide a number of benefits with regard to tracking community health, corresponding care treatment methods, and the effectiveness of these treatments. Using reporting and analytics tools, this interface may be extended to enable automated reporting on conditions and syndromic surveillance and alerts for configured public health conditions.

- **Medication Management:** HIOs should be able to exchange information through SureScripts-RxHub. These interfaces provide various functionality for medication management, including e-delivery of prescriptions to pharmacies, automated receipt of refill requests, query for medication fill history, and query for pharmacy benefits eligibility. These interfaces are integrated and can manage both inbound and outbound medication data from appropriately interfaced EMR systems.

Integrating with Payers

Payer incentives are closely aligned to those of health information exchanges. As care coordination and management is enhanced through HIE, and outcomes improve with appropriate delivery of care, payers are seeking to determine the impact to reimbursement.

Payer contributions to HIE include sharing claims data to add to the existing repository of health information or providing basic summaries of care for a significant number of patients. A health plan's participation in an HIO fosters communication with providers regarding administrative data, such as coverage and payment information. As a result, some payers are funding EHR implementations for practices and helping them connect to appropriate health information exchanges.

Health plans have a growing interest in participating in HIOs and have the ability to contribute funding to help HIOs achieve financial sustainability. A small but growing number of HIOs are finding creative ways for health plans to participate in their organizations. For example, the Indiana Health Information Exchange operates the Quality Health First program, which utilizes claims data from health plans and clinical data from providers, to generate quality outcome reports for physicians. HEALTHeLINK, in Buffalo, generates admission/discharge/transfer alerts for health plans when a patient is admitted, discharged, or transferred from the hospital. This alerts the health plan's care management team to a change in care several weeks earlier than if they solely relied on claims information.

Providers looking to select an HIO should question which major payers are participating, the extent of their collaboration and how their participation could grow over time.

Chapter 7

Types of Services that HIOs Could Provide or Facilitate

Even though many health information organizations are only beginning operations, they already offer – or plan to offer – a wide range of services to healthcare organizations. What types of services are available become a meaningful discussion points as providers seek to make contracting decisions based on expected values from an HIO's services.

What follows is a list of service areas, followed by a range of specific services that HIOs might offer to providers. These lists become important "shopping guides" which can help CIOs direct questions to HIOs, as well as guide internal discussions about which data exchange capabilities could add the most strategic value to an organization.

General areas of HIO services:
- Secure access to patient-specific healthcare interventions via associated data
- Aggregation of administrative transactions
- Billing services
- Charges for providing access to provider and provider related databases
- Credentialing services
- Distribution services, such as distributing reports to physicians
- Electronic medical record hosting or EHR-Lite
- Hosting Nationwide Health Information Network (NwHIN) Gateway/Connecting EHRs to NwHIN
- Patient identity management reports
- Performing analytics for stakeholders
- Printing services
- Provider directory services
- Providing access to clinical trial database
- Providing services that reduce interfaces for EHR vendors (for example, delivering laboratory or other types of information directly into the provider's EHR system)
- Quality reporting
- Routing services for personal health records
- Services to assist with data loads into EHRs
- Telecom management services

Specific services that HIOs may provide

Alerts to providers
Alerts to providers-drug-to-allergy
Alerts to providers-drug-to-drug
Alerts to providers-drug-to-food allergy
Ambulatory order entry

Analytics
Claims or eligibility checking
Clinical decision support
Clinical documentation
Connectivity to electronic health records
Connectivity to other HIOs, IDNs, RHIOs, etc
Consultation/referral
Disease or chronic care management
Disease registries
Electronic prescribing
Electronic referral processing
Emergency Medical Services (EMS) connectivity
Health summaries for continuity of care
Home monitoring
Image exchange
Immunization registry
Master Patient Index (MPI)
Medical device interoperability
Medication reconciliation
Patient access to information through the exchange/patient portal
Patient-provider clinical data exchange
Patient-provider communication - other
Patient-provider email
Populate PHRs
Provider directory
Public health: case management
Public health: electronic laboratory reporting
Public health: syndromatic surveillance reporting
Public health alerts
Quality improvement reporting for clinicians
Quality performance reporting for purchasers or payers
Record Locator Service (RLS)
Reminders
Results delivery (e.g. laboratory or diagnostic study results)
VA connectivity
Visiting nurses accessibility

Advance directives
Allergy information
Cardiology
Care summaries (demographics, encounter history, medications, etc.)
Claims: pharmacy, medical, and/or hospital
Dictation / transcription
Elder care information
Emergency Department episodes/discharge summaries
Enrollment / eligibility
Gastroenterology
Inpatient diagnoses and procedures
Inpatient discharge summaries
Laboratory results

Laboratory ordering
Medication data (including outpatient prescriptions)
Outpatient episodes
Outpatient laboratory results
Pathology
Patient-reported data
Physician notes
Pulmonary
Radiology images
Radiology results
Retail pharmacy
VA data
Coordinating financial incentives within the market
Dissemination of best practices and research
Group purchasing
Hosting a support hotline for providers
Liaison between public and private health IT efforts in service area
Providing implementation guides for health information exchange
Provide patient or provider data management services
Recommendations for specific vendors
Supporting quality improvement or performance reporting for purchasers and/or payers
Technical assistance for implementation in hospitals
Technical assistance for implementation with clinicians
Vendor-neutral advice on purchasing decisions
Workflow modification guidance for clinicians
Workflow modification guidance for hospitals

Many of the capabilities previously outlined may be provided by an EHR system and its associated or extended elements. Thus, if the HIO is not the primary services bureau to provide the EHR, the services may be viewed as unnecessary or redundant by potential member organizations. As EHR vendors mature their abilities to create their own health information exchanges amongst others that share their products exclusively, or in the case of direct exchanges, agnostically, more HIO services will be challenged by competitors. HIOs will need to have high competency-based services and capabilities that make them desireable and viable to members.

Chapter 8

Ensuring Privacy and Confidentiality

The increasing use of electronic health records enables providers to send a patient's personal health information wherever it's needed, both easily and quickly. With the capabilities of health information exchange, all aspects of patient information can be widely disseminated, if necessary.

That's both the blessing and the curse of digital information and the various modes available to share it. From a patient privacy and confidentiality standpoint, this mobility of information creates new risks and concerns in safeguarding personal health information.

Weighing Connectivity Vs. Privacy Concerns

Provider organizations and their HIT executives face several levels of concern. First and foremost, they are responsible for protecting information within their organization and complying with all federal privacy requirements, particularly the Health Insurance Portability and Accountability Act (HIPAA) as well as state laws.

The success of health information exchange is dependent on many factors, including the trust that patients and providers have in the accuracy of health information made accessible through HIE, and the confidence that the health information organization is facilitating appropriately authorized and authenticated access to the health information in accordance with the patient's consent.

The passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act provisions, within ARRA, represented a significant change in the applicability of HIPAA to HIE. Under the HITECH Act, HIOs will be directly obligated to comply with the HIPAA regulations as HIPAA "business associates" of healthcare providers. Up until HITECH, HIOs were subject to privacy and security rules only indirectly through their contracts with providers. As Business Associates, HIOs will need to have extensive policies and procedures in place to comply with the HIPAA Privacy and Security regulations, and will have to have contracts in place with their subcontractors that receive health information. HIOs are required to demonstrate the same rigor required of healthcare provider organizations. They will need to have policies that control how the HIOs use and disclose health information and how they will protect patient rights.

HIOs will be required to notify their participating healthcare providers of data breaches. Also, HIOs will be required to comply with state privacy regulations, particularly in those states where laws are more stringent on patient privacy.

As new federal HIPAA rules raise requirements for HIOs, healthcare organizations that are participating in HIE can expect them to be well versed in their privacy and confidentiality obligations. However, because of the potential damage that could result from being even tangentially related to a release of patients' personal health information, healthcare organizations must be extremely careful in entering into partnerships with HIOs, ensuring that they have clear privacy and security policies for accountability, transparency, consent, access, and use and disclosure of personal health information.

The Importance of Protecting Patient Privacy in Health Information Exchange

To ensure trust in the HIO, among both providers and patients, the HIO must demonstrate it will take the protection of patient privacy seriously. The protection of privacy, as part of the mission of the HIO, makes it clear to all stakeholders that the clinical or administrative value of HIE and the protection of health information are irrevocably linked by all participants. A clear statement of privacy and security principles and information about privacy and security policies, communicated in terms that patients understand and available in multiple mediums to facilitate patient access, will underscore the importance of patient privacy and the patient-centeredness of HIE.

Consent models

There are two models for gaining consent from patients to have their data shared via an HIE:

- "Opt-in consent" usually requires affirmative authorization from the patient, often through signing a standardized consent form, before a patient's health information may be exchanged through the network.
- "Opt-out consent" may include, but does not require, that an organization gives notice, via a mailing, brochures or posted notice, at which point the patient can object to having his or her health information exchanged through the network.
- Hybrid models of consent are available as well, such as allowing patients to opt out of health information flowing to the HIO, but requiring opt-in consent to take health information out of the HIO.

The decision about which consent model to adopt is complicated and involves several factors, including:

- The education and outreach to patients about their options for consent, to facilitate informed decision making
- State law

HIOs' Approaches for Communicating with Patients

Many HIOs are seeking to achieve best practices in communicating their privacy and security policies with other entities in the care delivery network and patients, to seek a market advantage and achieve competitive advantage, as well as offering the highest potential assurance to those involved with HIE.

The Health Information Security and Privacy Collaboration (HISPC/2007-2009) brought stakeholders from several states together to address and make recommendations on the privacy and security challenges in HIE, with the goal of identifying replicable steps that can

build patient understanding and trust in HIE. Many communities have taken the recommendations and customized them to address the particular needs of their states to inform patients about HIE privacy, security and confidentiality policies, how complaints will be handled, how individuals will be informed of a violation and existing remedies available to them.

A review of several HIE specific materials identified key themes:
- Make the principles available in plain language
- Make the policies available in multiple mediums – print brochures, websites with information including self-directed tutorials
- Develop FAQs and a glossary of terms
- Utilize media to amplify the message to the larger public – posters, print ads, PSAs, videos
- Consider the literacy levels and languages spoken by the patients receiving the information
- Develop a process to measure and improve on the effectiveness of patient education about privacy and security policies

Healthcare organizations looking to contract with an HIO should determine their degree of commitment to following good security and privacy practices and their effectiveness in communicating that information to patients.

Resources

- Patient Consent Models: http://www.ehealthinitiative.org/protecting-patient-privacy/consent-models.html

- Sample privacy documents for HIOs: http://www.ehealthinitiative.org/protecting-patient-privacy/sample-privacy-documents.html

Chapter 9

Fitting HIE Into a National Context

There are ambitious plans for health information exchange in the U.S. As envisioned by those building a national network for HIE, the eventual goal for the country is to move health information anywhere, whenever it's needed.

The ultimate product is the Nationwide Health Information Network (NwHIN), which is being called "a critical part of the national health IT agenda" by federal agencies tasked with achieving the digital transformation of healthcare.

The Nationwide Health Information Network

Over the past several years, the NwHIN "is being developed to provide a secure, nationwide, interoperable health information infrastructure that will connect providers, consumers and others involved in supporting health and healthcare." See http://www.hhs.gov/healthit/healthnetwork/background/ . Through the NwHIN, a patient's clinical information can be accessed anywhere in the country.

The NwHIN will make use of a set of standards, services and policies that enable secure health information exchange over the Internet, one of the goals of the HITECH Act.

In 2010, two workgroups under the federal Health IT Policy Committee began essential work intended to result in the formation of the NwHIN. A Governance Work Group prepared recommendations for governance of the NwHIN; and the Nationwide Health Information Network Work Group offered recommendations on how best to use standards, services and policies to enable the sharing of health data.

Work began on the NwHIN by developing prototype architectures to perform a number of key functions, which include:
- Developing capabilities to find and retrieve healthcare information inside of health information exchanges and between health information exchanges.
- Delivering new data to appropriate recipients.
- Offering key consumer services, such as control over who can access a personal health record, data searching, and the ability to choose not to use a network service.
- Proofing, authenticating and authorizing user identities.
- Identifying methods for matching patients to their data without the use of a national patient identifier.
- Accessing control and other security protections.
- Offering specialized network functions.
- Investigating the feasibility of large-scale deployment.

The second phase of the project involved using prototype architectures to securely exchange data between nine HIOs, providers and several federal agencies. Exchanging patient information through a "network of networks" approach is a key strategy to support the NwHIN because the NwHIN isn't a physical network running on servers supplied by the federal government nor does it enable a central depository for storing records. Thus, as it is envisioned, the NwHIN will be highly dependent on the development of HIE initiatives nationwide to enable the exchange of health information. As such, the NwHIN exists as a long-term goal with which all current and future HIOs are expected to interact.

In assessing HIOs, providers should expect potential candidates to employ NwHIN standards and to have a plan to connect with other HIOs through the NwHIN.

The Direct Project
While the ultimate goal is to use a network of HIOs to achieve information exchange on a national scale, HIE efforts are only just beginning in several areas of the country, and it will take time to build up information exchange on a national scale.

As a result, based on recommendations from the Nationwide Health Information Network Work Group, the Direct Project was launched in early 2010 to develop a simple, secure, scalable, standards-based approach for participants to send authenticated, encrypted health information directly to known and trusted recipients over the Internet. Secure messaging enables simple transfer of information through email client software.

A number of electronic health record and personal health record vendors, integrated delivery systems, HIOs and states have committed to implementing Direct Project approaches to exchanging information. The Direct Project web site includes commitments to participate by 20 ONC-approved state plans, as of mid-August 2011. To view the web site, see http://directproject.org/home.php

Nine pilot projects are currently under way or planned. For example, in Minneapolis, Hennepin County Medical Center has been successfully sending immunization records to the Minnesota Department of Health. In New York state, MedAllies, a Health Information Service Provider or HISP, will launch a pilot project to demonstrate the delivery of critical clinical information across transition of care settings in a "push" fashion that supports existing clinical workflows in the Hudson Valley of New York. MedAllies will implement the full Direct Project infrastructure, including both the required SMTP backbone, as well as support for the Cross-Enterprise Document Reliable Interchange (XDR) elective protocol. Albany Medical Center participated in this Direct pilot project and demonstrated Allscripts Enterprise and Siemens Clinicals CCD-based patient data exchanges between it and other participating pilot organizations. According to George Hickman, executive vice president and CIO at Albany Medical, efforts are continuing to build a production-state exchange with its key vendor partners and MedAllies in an effort to demonstrate the viability of this approach while supporting the needs of its community physician constituents.

CONNECT – A Standardized Way to Exchange Patient Data
CONNECT is billed as an open-source software solution that supports health information exchange, both locally and at the national level. It is intended to promote interoperability in the U.S. healthcare system.

The CONNECT solution was developed by federal agencies that needed to share their health data, not only amongst themselves but also with other levels of the government and the private sector using the NwHIN. Rather than developing individual gateway solutions, the federal agencies banded together through the Federal Health Architecture to build CONNECT.

The government then released the CONNECT gateway to the private sector at no cost, and envisions that it will be further developed and supported by a community of users, which is expected to grow over the next several years.

"Though federal agencies delivered the initial versions of CONNECT, the long-term vision is for a broad community of organizations building upon the CONNECT software to collaboratively define and implement its future direction," according to the CONNECT website. "The CONNECT team has started this move by opening the development process beyond the initial development team, enabling other stakeholders to contribute to features important to them. The program will go further, implementing a true community governance structure as the stakeholder community matures and the options can be explored collaboratively."

More information about CONNECT can be found at http://www.connectopensource.org/.

The CONNECT community has conducted a variety of events to spread information about the application, and the latest iteration of CONNECT, version 3.2, was released in mid-June 2011.

In addition to the federal agencies, several vendors, HIOs and provider groups are in the process of pilot-testing the application.

Chapter 10

Key Elements to Consider in a Contract with an HIO

CIOs are used to dealing with a vast variety of contracts for widely differing products and services. In that regard, reaching a binding agreement with a health information organization will require similar due diligence and legal assistance for review of contract language.

However, contracts with HIOs will require specific features, particularly in light of expected changes and refinements of regulations regarding patients' personal health information (PHI).

HIOs are considered business associates of the HIPAA-covered providers who contract for their services. Before passage of the HITECH Act in 2009, they were not directly subject to enforcement by the federal government. However, HITECH expands jurisdiction to the government to regulate the privacy and security of PHI to business associates. HIOs continue to be business associates of the covered entity providers who contract with them. A summer 2011 Notice of Proposed Rulemaking to adjust the HIPAA Privacy Rule for accounting of disclosures of PHI proposed an expansion of business associate requirements and penalties for business associate contracts that release PHI.

HIOs offer standardized contracts, typically termed participation agreements. The following information on contractual elements and guidance on what should be included is intended to assist healthcare IT executives in taking necessary contractual precautions to help protect the interests of their organizations. As always, legal counsel should review all documents that bind an organization into a contractual relationship.

- **Grant of right to use services:** These provisions give providers the right to access and use a system, based on certain restrictions. Verbiage in this section can discuss changes and terminations, and responsibilities regarding third-party software for licensing and installation.

- **Access to the system:** Provisions outline permitted and prohibited uses, and perhaps delineates what other types of organizations may be granted access to the system. Rights of authorized users may be spelled out, and discipline and termination steps may be outlined.

- **Purpose of the system:** Very simply, the contract permits sharing of patient health information among all participants in the HIO. However, the contract also should spell out which information should be shared and which is not to be shared over the

network, particularly individuals' information if they have opted to exclude their information from sharing over the network.

- **Business Associate acknowledgement:** The contract should spell out that the HIO acknowledges its role as a business associate and that it agrees to the terms and conditions of the HIPAA Business Associate Agreement.

- **Audit provisions:** The contract should provide opportunities for HIO participants to audit system performance as it relates to the agreement.

- **Computer systems implications:** The contract should spell out responsibilities for installing hardware, software and communication systems infrastructure, and how the HIE participant can contract with the HIO for services.

- **Policies and procedures:** The contract should spell out the HIO's role in developing these rules of operations, and procedures that will be followed if the HIO changes them, and time requirements for implementing changes.

- **Fees and charges:** Of course, the contract will explain the basis on which participant fees are based, when payments are expected, and responsibility for taxes and other charges. Prices likely will vary depending on type of provider and/or size of organization.

- **Confidentiality provisions:** The contract outlines the need for parties to protect each other's confidential information and not to disclose it to third parties.

- **Other typical contract language:** Standard contract language that protects both the HIO and the provider signing the contract in areas such as warranty, disclaimers, limitation of liability, dispute resolution, term modification, indemnification and more.

- **Additional detail:** A contract should describe the HIO's system, with vendors and products, and how the components will provide which services to participants.

Other Considerations

Many state HIT leaders have strongly positioned contractual elements that also must be included, such as privacy and security expectations, consent for the exchange of information, including special concerns for HIV, behavioral health and minors; and the content and technology standards about which exchanges must be built to connect to statewide and, eventually, national health information networks.

There are also a host of contractual elements that address uniqueness and liability concerns. For example, patient health data moves from a provider across the exchange and may be found to require modification due to error. The responsibility of individual physician providers to review and consider exchanged data and its implications – even when the data may create some level of ambiguity – is a debated legal consideration. Systems must provide clear audit trail reports to help resolve questions about data integrity. HIOs also must display

the source organization of the data if any questions arise among end users of the information. Further, HIOs may disclaim data in the same manner that EHR vendors do, requiring clinical providers to own their decisions despite the data that the solutions present. These and other similar issues will continue to find a place of equilibrium as HIOs mature.

Appendix

HIE Resources

General

- 2011 eHealth Initiative Annual Report on Health Information Exchange
  Source: eHealth Initiative

- HIE Cover Story
  Source: Hospitals & Health Networks

- HIE Market Report Analysis & Trends
  Source: Chillmark Research

Governance

- Establishing Governance: Focus on Sustainability and Community
  Source: The Center for Community Health Leadership

- Governance Models for HIE
  Source: eHealth Initiative

- ONC -Acceptable HIE Governance Structure
  Source: Nevada Department of Health and Human Services

HIE and ACOs

- ACOs Will Depend on HIEs, With an Assist From Plans
  Source: Managed Care Magazine

Liability

- HIE Liability Issues
  Source: Legal Health Information Exchange

- Liability Coverage for Regional Health Information Organizations
  Source: Agency for Healthcare Research and Quality: Health IT

Policy

- [Health Information Exchange Challenge Program Supplemental Funding Opportunity to the State Health Information Exchange Cooperative Agreement Program](#)
  Source: [eHealth Initiative](#)

- [ONC Original Funding Announcement for the State HIE Cooperative Agreement Program](#)
  Source: [eHealth Initiative](#)

- [Program Information Notice: Change in annual financial reporting submission requirements](#)
  Source: [Office of National Coordinator: Health Information Technology](#)

- [Program Information Notice: Requirements and Recommendations for the State Health Information Exchange Cooperative Agreement Program](#)
  Source: [Office of National Coordinator: Health Information Technology](#)

Privacy/Security

- [Markle Foundation's Security and Systems Requirements](#)
  Source: [Markle](#) Foundation

- [Markle Foundation's Technology Overview for Security](#)
  Source: [Markle](#) Foundation

- [Security Architecture Design Process for Health Information Exchanges](#)
  Source: [Computer Security Division](#)

State HIE Toolkit

- [ONC State HIE Cooperative Agreement Toolkit](#)
  Source: [State Health Information Exchange Program](#)

Sustainability

- [Formula for Long-term HIE Sustainability, Better Health Care - The HIE Gateway Model, Part II: Return Model for HIE Value-Add Advanced Analytics Services](#)
  Source: [Chilmark Research](#)

- [Health Information Exchange Economic Sustainability Panel: Final Report](#)
  Source: [Office of National Coordinator: Health Information Technology](#)

- [Public Governance Models For A Sustainable Health Information Exchange Industry](#)
  Source: [National Governors Association](#)

- [Staying Alive: Determinants of HIE Sustainability](#)
  Source: eHealth Initiative

- [White Paper: HIE Sustainability](#)
  Source: eHealth Initiative

Technical Architecture

- [The Common Framework: Technical Issues and Requirements for Implementation](#)
  Source: Markle Foundation

- [Markle Foundation's HIE: Architecture Implementation Guide](#)
  Source: Markle Foundation

Interviews with Top HIE Leaders

- [Scott Afzal, Director-HIE, Chesapeake Regional Information System for Our Patients (CRISP), Maryland SDE](#)
  Source: eHealth Initiative

- [Deb Bass, Executive Director, Nebraska Health Information Initiative (NeHII)](#)
  Source: eHealth Initiative

- [Bill Beighe, CIO, Santa Cruz Health Information Exchange](#)
  Source: eHealth Initiative

- [David Cochran, MD, President and CEO of Vermont Information Technology Leaders Inc.](#)
  Source: eHealth Initiative

- [Carladenise Edwards, CEO & President, Cal eConnect](#)
  Source: eHealth Initiative

- [Tom Fritz, CEO, Inland Northwest Health Services](#)
  Source: eHealth Initiative

- [Christina Galanis, Executive Director, Southern Tier HealthLink New York](#)
  Source: eHealth Initiative

- [LaDonna Larson, Executive Director, Idaho Health Data Exchange, the State Designated Entity for Idaho](#)
  Source: eHealth Initiative

- [Jerry Malone, Vice President, Sandlot, LLC](#)
  Source: eHealth Initiative

- [Robert Mayer, State HIT Coordinator, New Mexico Department of Information Technology](#)
  Source: [eHealth Initiative](#)

- [Joyce Peters, Director of HealthLink Client Services, Western Connecticut Healthcare](#)
  Source: [eHealth Initiative](#)

- [J. Marc Overhage, PhD, CEO, Indiana Health Information Exchange](#)
  Source: [eHealth Initiative](#)

- [Will Ross, Project Manager, Redwood MedNet](#)
  Source: [eHealth Initiative](#)

- [Robert Steffel, CEO, HealthBridge](#)
  Source: [eHealth Initiative](#)

- [Jamie Welch, CIO, Louisiana Rural HIE](#)
  Source: [eHealth Initiative](#)