

Montgomery County Health Information Exchange Collaborative



Strategies for a Person-Centric, Inclusive
Maryland Health Information Exchange

February 2009

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Acknowledgements

This work could not have been completed without the enthusiastic and generous contributions of so many individuals and organizations. In spite of extensive and numerous obligations, this group worked together to address the complexities, benefits, and strategic planning necessary to bring the benefits of health information exchange to the people of Maryland. Please refer to the appendix that lists the valued participants for Montgomery County Health Information Exchange Collaborative.

Executive Summary

Introduction

Health Information Exchange (HIE), properly planned, governed, and deployed, has the potential to bring many benefits to the people of Maryland. The structured, inclusive planning approach taken by the state beginning with Senate Bill 251 of the 2005 Maryland General Assembly greatly improves the chances of success compared with failed or stalled efforts elsewhere. The Task Force to Study Electronic Health Records report (December 2007), the Privacy and Security Solutions and Implementation Activities report (September 2008), and the two reports commissioned for the Citizen-Centric Health Information Exchange for Maryland (this report from the Montgomery County HIE Collaborative (MCHIE) and the sister CRISP report) constitute a comprehensive assessment of the national, state and local opportunities and challenges; the identification of critical success factors; and incremental, value driven plans for moving toward a statewide HIE that will benefit every individual

However, a word of caution is in order. The health care sector has traditionally lagged behind virtually all other sectors of the economy in the effective use of information technology to improve quality, lower costs, institute process improvements, and make information more accessible for better decision making. Contributing factors include the fundamental complexity of medical science; the complexity of the U.S. health care delivery system; misaligned reimbursement structures; legal constraints and uncertainties that increase costs and delay implementation; costly, complex, and largely incompatible data systems that further complicate exchanging data; high acquisition and operational costs that stress budgets and inhibit adoption; and difficulty in achieving and demonstrating a positive return on investment.

The highly decentralized health care delivery system is sometimes a contributing factor as well, in that it can be challenging to achieve economies of scale for a one or two provider practice in a way that is both cost effective for the providers and supported in the most efficient manner. In addition to the legal and financial challenges, considerable skills are required not only to deploy and maintain the required technology, but, more importantly, to integrate the tools into the care delivery process. These skills have historically not been available throughout the health care delivery system in a quality and quantity needed for successful adoption and deployment.

To achieve the potentially considerable benefits of a Maryland statewide HIE, governance is a critical, but often neglected activity. For a small practice, community clinic, or individual hospital, the nature of accountability relationships and the requirements to sustain a collaborative framework are a modest to non-existent concern. When creating a statewide exchange, governance must be addressed first. The governance organization must be trusted, representative, transparent, and able to balance the multiple conflicting issues that will inevitably arise in such a venture. Health Information Exchange projects in other states have failed or struggled because of lack of attention to this critical success factor. Effective governance can enhance and accelerate HIE adoption. Poor governance leading to poor adoption and implementation has been shown to lead to failure and a long delay before efforts can be restarted.

Advantages in Maryland

The State of Maryland brings unique strengths that will serve it well in successfully implementing and benefiting from a comprehensive statewide HIE. First, Maryland is well positioned to create an

effective public-private partnership to govern and foster HIE by building on the history and capabilities of the Maryland Health Care Commission (MHCC) and the Health Services Cost Review Commission (HSCRC) in fostering and overseeing statewide multi-stakeholder health care initiatives.

Second, the HSCRC method for financing health care lends itself both to on-going HIE financing and, more importantly, ensuring that HIE costs actually contribute to improved care and lower costs as HIE projects are designed and implemented. (However, the HSCRC funding mechanism may not be adequate or appropriate for large project capital expenditures.)

Third, in making rate adjustments, the HSCRC properly aligns part of the cost burden to payers who benefit the most financially in the projected cost savings.

Fourth, the measured approach to HIT and HIE planning has created a large number of knowledgeable, motivated individuals and organizations that have worked together, shared ideas, understand the benefits that can be achieved, and have thought deeply about the practical challenges that must be faced and how to overcome them. Some of the individuals have participated in all of the above referenced projects (Task Force, Privacy and Security, MCHIE, CRISP). Their commitments transcend local concerns and focus on statewide benefits for higher quality, lower cost, more accessible health care for the people of the state of Maryland. A good example is the degree of consistency between the findings of the MCHIE and CRISP groups, in spite of the community hospital and low income uninsured focus explored by the MCHIE team in contrast to the more urban, large hospital system representation of the CRISP group.

Fifth, the HSCRC already hosts an early form of patient centric HIE based on data reported regularly at the patient level by all hospitals in the state for inpatient and emergency department services. HSCRC and providers have experience with data privacy and security, transmission and access to data, analytical studies to assess and improve health care delivery and cost, and collaborative activities related to health care databases.

Summary of Recommendations

In developing our recommendations, the MCHIE teams worked at two distinct levels simultaneously: (a) the needs and perspectives of patients and health care providers in our local community and (b) positive and negative experience in other states and nationally with respect to HIT and HIE adoption strategies, benefits, costs, inclusiveness, and sustainability. This report addresses key decision elements regarding governance, financing, privacy and security, technical architecture, and community engagement. In reviewing the structure and experience of HIE in other states, we provide a rationale that incorporates the best elements that are appropriate for a state the size and complexity of Maryland. Should MHCC and the legislature choose not to include some of our recommendations, then this report provides the framework of alternative choices from across the country. From this, we have formulated the following key recommendations:

Governance

1. Create an independent statewide public-private HIE governance entity, the Maryland eHealth Collaborative, to ensure consistency, inclusiveness, transparency, focus, and accountability for HIE creation, sustainability, and operational effectiveness.
2. Permit, but not require, the creation of regional health information organizations (RHIOs). For example, the MHA/MedChi report on the Maryland Physician Workforce identified five

3. regions in the state. While such a designation might lend itself to the creation of five RHIOs, we believe that each participating entity should determine how best to connect to the HIE, perhaps independently or as part of a RHIO.
4. Separate HIE governance and technical entities so that a “single point of failure” does not derail the implementation and/or operations of the exchange.
5. Assure compliance with the policies, standards, oversight, consequences, and fiduciary responsibilities of the HIE through legally binding contracts, rather than new legislative directives. We believe that such an approach is more flexible in responding to future changes in the functions, funding, structure, and responsibilities of a HIE.
6. Define and require a single, common, legally appropriate participation agreement for all entities joining an HIE. Legal costs and delays have been the single biggest impediment to the deployment of EHRs and a safety net clinic and patient oriented regional HIE in the Montgomery County/DC area.

Financing and Business Model

7. Implement the HIE incrementally based on specific use cases, beginning with high value, medical data already available in electronic format. Focusing on near term clinical value will foster earlier use by more data users, more data providers, and build an HIE with more perceived and real value more quickly. There is general consensus on the sequencing of use cases and the relative value of different kinds of medical data, allowing for a rapid start-up for the HIE. Note also that some types of medical data may never have sufficient value to be included in an HIE. Psychiatric case notes might be such an example
8. Pursue a three-pronged financial strategy for capital investment leveraging state funding through the HSCRC, federal funding, and a revenue-backed bond issue. Estimated capital costs for the first three years are \$80-\$125M for the HIE, \$25-\$30M for hospitals, and \$8-\$10M for physician offices.
9. Support initial funding to the Maryland eHealth Collaborative through HSCRC seed capital, philanthropy, grant support, and in-kind contribution from stakeholders.
10. Consider re-programming a small percentage of hospital “Community Benefit” dollars to support capital expenditures, expanding functionality, and on-going costs of building and operating a statewide HIE. Hospitals reported over \$812M in community benefits for FY 2007 of which \$11.4 M was listed as financial contributions. A combination of direct financial support and in-kind technical and other services could accelerate and sustain HIE development across the state, especially in communities less well prepared for adoption of new technology. Even a one percent re-direction of community benefit dollars to statewide HIE (\$8M) would generously fund HIE development and operations.
11. Develop a sustainable model that does not require permanent government funding.
12. Develop multiple sources to finance ongoing operations such as set-up fees for initial connection, subscription fees for users, access fees for data requests, payer assessments, HSCRC rate adjustments, etc.

13. Negotiate with vendors on behalf of the HIE to lower costs for stakeholder participants.

Privacy and Security

14. Define clear, enforceable, statewide privacy protection policies that apply to all individuals and organizations accessing health data to ensure maximum participation by all. Failure to do so will lead to significant numbers of people “opting out”, weakening the health care benefits and sustainability of the HIE.
15. Require written consent from the patient before providers and payer organizations can access a patient’s information through an HIE.
16. Do not require affirmative consent for providers to up-load health information to the HIE, provided that the HIE is serving as the data provider’s HIPAA third-party business associate and remains in compliance with state and federal law.
17. Define rules that apply statewide to the exchange of personal health information in a “many-to-many” context, whereby health care providers can reach out to large networks of clinicians and providers. Such rules should not exclude or necessarily apply to “one-to-one” exchanges.
18. Assure compliance by contract rather than by statute. Define clear penalties for breach of agreement, noting that compliance (and penalties) with federal and state regulations remains an obligation in transmitting and accessing personal health information.
19. Do not require the filtering of specific types of sensitive information, with the exception of psychotherapy notes and other types of sensitive data that are subject to specific state and HIPAA requirements.

Technical Architecture

20. Implement a hybrid technical infrastructure solution that will allow for both centralized statewide services and local management and control of databases as appropriate. The goal is to achieve both economies of scale for services needed by everyone who uses the network and flexibility to meet local needs. Based on experiences in other states, it is unlikely that either a fully decentralized architecture or a fully centralized approach would be effective. Existing commercial systems implement the full range of infrastructure models, eliminating or minimizing the need for prototype development.
21. Explore whether a single statewide HIE or local HIEs linked by common standards would be the most cost effective, risk mitigating, quickly deployable model. Smaller states with less health care complexity have been successful with the statewide model. Scalability to a state the size of Maryland is less clear. We believe that an approach based on linking local exchanges to the state HIE is preferred.
22. Conform to federal standards for data representation and exchange, eliminating dependence on single vendor, proprietary products and solutions.
23. The statewide HIE should be designed using a Service Oriented Architecture approach.

24. Implementation of HIE in Maryland should be supported by the development and provision of detailed implementation guides of agreed upon national standards.
25. Consider the relationship and interchange of data with neighboring states where medical service areas overlap and standards for access and privacy may differ. The District of Columbia may pose a particular challenge for MedStar Health as well as Montgomery and Prince Georges County providers. Similar issues will arise with Delaware, Pennsylvania, and Virginia. *Community Engagement*
26. Address the needs of the medically underserved and the health care organizations that support and provide care to them, as an individual health, public health, and ethical imperative. This population has more mobile, fragmented, episodic, and expensive health care. Their health information is typically not available when and where needed. Steps to include these individuals in a structured HIE setting are likely to have major health care prevention, quality, and cost benefits across the state.
27. Encourage local and state public health officers to become early adopters of HIE data to assess, compare, and initiate programs to improve population health in Maryland.
28. Address the challenge of low EHR adoption. In Maryland, as in most states, only ~20% of providers use an EHR for clinical record keeping. The value of an HIE is critically dependent on the amount of clinically significant medical data it contains. Possible solutions include local hospital technical/financial support for physicians with privileges at their institutions and low-cost “EHR-light” applications hosted by the HIE to bring providers more quickly into the HIE setting.
29. Personal health records (PHR) may eventually emerge as a significant component of an HIE, but are probably not essential in the initial implementation. However, the ability of the HIE to send data to a PHR at a patient’s request could be an effective method to involve patients more actively in participating and taking responsibility for their own care.
30. Encourage and support local and regional collaborative efforts centered around community organizations, hospitals, and professional societies to foster HIE and achieve its potential benefits through local activities.

Transformative Change

While HIE can bring new and powerful technology to health care in the state of Maryland, HIE alone is not truly transformative and will not magically result in better, safer, more cost effective, accessible health care for all. The implementation of HIE is not an IT project. Rather, it involves major cultural, clinical, and system changes requiring leadership, innovation, education, communication, transparency, feedback, demonstrated benefit, financial solvency, and earned trust. Success depends on participation by health care providers across the state, by educational organizations, by business, the state legislature, and diverse community organizations. Benefits realization is not an automatic by-product of technology, but requires diligence, insight, and sustained effort. In particular, the presence of an effective HIE will have a profound effect on current health care delivery practices, processes, and business models. Organizations that achieve competitive advantage by sequestering personal health data will require a new business model. Organizations that benefit from unnecessary laboratory tests and imaging studies will suffer. Organizations not conforming to best practices will be more easily identified.

The Transformative Challenge

The transformative challenge that we should pose for ourselves is the following: “Assuming the creation of a successful, widely used Maryland statewide HIE, what are the next steps to truly transform healthcare to achieve the benefits facilitated by HIE?”

Background

The purpose of this project is to engage a broad coalition of healthcare stakeholders in planning the implementation of a successful health information exchange (HIE) among hospitals, providers, clinics, patients, pharmacies, laboratories, and others as a strategy to improve the quality, safety, and efficiency of healthcare in the state of Maryland. This goal supports the strong desire and directives of federal and state government to expand the benefits of HIE. This report explores various components of HIE (governance, financial model, privacy and security, technical architecture, community input), reviews the national landscape of HIE efforts (models, successes, failures), and makes recommendations for how Maryland might proceed.

The Montgomery County Health Information Exchange Collaborative (MCHIE) is built upon the shared vision of a healthcare community in which information exchange is used as a vehicle to expedite and improve the delivery of care, particularly to underserved patients, as well as to serve as a unifying force in a traditionally competitive and non-collaborative environment. Although initially envisioned as limited to Montgomery County, the group expanded to include representation from Prince George's County and regional philanthropic organizations focused on quality health care as a regional challenge. One member also sits on the District of Columbia RHIO Advisory Committee, bringing a broader regional and jurisdictional perspective to our work.

A system of HIEs as envisioned by the Collaborative can serve as a catalyst for changing the delivery of care for all patients particularly when integrated in the Emergency Department setting. For insured patients with a primary care doctor and a detailed medical history, access to this information at the "touch of a button" will expedite care and help to ensure accuracy of medical history, complications, allergies, etc. For uninsured patients, however, it can have an even greater impact by closing the "loopholes" that exist when patients move from one emergency department to the next because they lack a medical home and are not attached to their medical providers. When connected to a medical home, valuable information can be accessed by the same "touch of a button" which results in faster care and better healthcare outcomes. This project envisions making this a reality throughout Montgomery County, with an estimated 125,000 uninsured patients, as well as throughout the state of Maryland.

The nine months of planning that followed the Governor's announcement in May, 2008, as well as almost a year of pre-planning among stakeholders from the public, private and non-profit sectors that took place prior to the award, has culminated in a set of recommendations, observations and "lessons from the field" that are included in this report. The process itself was challenging, not for a lack of commitment, but for the capacity of volunteer stakeholders meet regularly while fulfilling their primary job responsibilities. This is an important lesson and barrier for the development and dissemination of HIE across the state.

Although defined as a final report for the purposes of the planning grant, it is not the ending but rather the beginning of a journey toward interconnectivity for improved healthcare outcomes for all Marylanders. The experience of the Montgomery County Health Information Exchange Collaborative has resulted in a great deal of thought and, ultimately, momentum and excitement for the implementation of HIE in Maryland, as well as in new partnerships. Where there was competition, there is now collaboration. The greatest lesson, perhaps of this planning process, is that HIE is a dynamic process and that the more people who participate in its planning and implementation, the more successful it will be. As the demands on the medical system become more onerous, implementing a system of HIE is not only a logical, but an essential next step.

Montgomery County/Prince Georges County Healthcare Environment

Montgomery County and Prince Georges counties together represent about 32% of the Maryland population. Montgomery County is the most ethnically and linguistically diverse county in the state. Approximately 1/3 of the population is foreign born, with more than 130 languages spoken at home by children in the public school system. Estimates of the low income, uninsured population in Montgomery County range from 80,000 to 125,000¹. Low income and lacking health insurance, they receive medical care at a consortium of safety net clinics partially supported by Montgomery County funds (the “Montgomery Cares” program), in hospital Emergency Departments, or not at all. Five midsize not-for-profit community hospitals provide care to county residents. There are no county owned or operated or university hospitals. Two Federal hospitals, the National Naval Medical Center and the National Institutes of Health Clinical Center are located in Bethesda, but typically only treat specific beneficiaries or provide care under research protocols. Prince Georges County has six small to midsize community hospitals, one military hospital, a large FQHC, a more limited safety net clinic system, and a large Medicaid population.

Study Design and Report Organization

In order to provide a comprehensive analysis of the issues and challenges in building a statewide HIE, the MCHIE participants elected to focus our efforts both locally and nationally. Health care is primarily a local activity, with most people receiving most of their care from doctors and hospitals in their own communities from providers that they know and trust. Most of the remaining care is provided within a short travel distance, and only a small percentage at a significant distance from home. An oft-cited study in the Boston, MA, suburb of Brockton found that 75% of medical care was obtained within the community in spite of the city’s proximity to the massive Boston area university medical campuses.

To meet our twin objectives, we coupled the local health care expertise of Montgomery and Prince Georges county participants with consultants nationally recognized for their contributions to the planning, evaluation, and support of regional, state level, and national RHIO, HIE, and nationwide health information network (NHIN) projects. We believe that this two pronged approach is especially important given the very small number of successful HIEs of any size and the absence of any measurable successes statewide for a state the size and complexity of Maryland. There are a substantial number of state and within-state initiatives in various stages of planning and demonstrations projects. They reflect a remarkable diversity in priorities, funding methods, governance and legal frameworks, use case priorities, and technologies planned or deployed, with no clear evidence to date of confirmed “best practices” or proven optimal strategies for success. As a result, we have chosen to provide extensive discussion and detail in the later chapters of this report that reflect (a) the perspectives, discussions, and decisions of other states, regions, and nationally, (b) the key Decision Points that must be addressed, (c) our recommendation for each Decision Point, and (d) our rationale for our recommendations.

¹ Uninsured persons under 65 years 139,787 (income status unknown)
 Children under 19 years 27,318
 Adults 18-64 years 112,469

Source: 2005 Small Area Health Insurance Estimates (SAHIE), Current Population Survey (CPS), U.S Census Bureau

2000 census data, which is out of date and quite a bit lower—80,000 low-income, uninsured adults

Participants divided themselves into five teams to study what we identified as the five critical areas for achieving a successful statewide HIE for Maryland. The subject areas are Governance, Community Leadership, Privacy and Security, Technical Architecture, and Finance. Initially we convened a separate clinical committee, but found that including clinicians on the five committees above gave us more robust discussions and helped the interdisciplinary learning that will be essential going forward. Meetings averaged twice a month either in person or by conference call. Content driven sessions focused on understanding the key drivers for successful HIE planning and implementation, lessons learned from similar efforts nationally, assessments of what was likely to work or not work in Maryland, assignments for the next meeting, and preparation of evolving draft consensus documents. Four of the five teams were facilitated by our national HIE consultants. The fifth, Community Leadership, was largely self directed, relying on the in depth expertise of its members and their close connections to the community. This team developed survey and focus group tools, conducted community outreach activities, and provided valuable input to the other committees on issues such as the level of public awareness and trust of HIE and the implications for successful implementation. While the MCHIE and CRISP teams worked independently, there was close and open collaboration and regular sharing of findings and ideas, as encouraged by the MHCC/HSCRC RFA and staff. We found this to be both helpful and illuminating for all participants. In terms of membership, the MCHIE group is built around community hospitals and providers, whereas the CRISP group's membership has a heavy representation of large university hospitals and multi-hospital systems. The similarities, especially the relative ranking and value of clinical use cases, is a striking and welcome finding. The exploration of differing perspectives in the two reports will also strengthen and accelerate the effective adoption of HIE throughout the state.

Caveats, Cautions, and Assumptions

While the body of knowledge and experience with HIE is increasing as more states and localities participate, there is still, at best, limited real data about costs, clinical benefits, financial ROI, or best practices. In such a climate, it is necessary to make assumptions about the present and the future in order to move forward, but the assumptions need to be continually assessed as new data and new experiences become available.

As the teams reviewed the estimated costs for various HIE efforts, two features stood out that illustrated the significant challenges associated with deriving valid financial models. The first was the wide variety of cost estimates that did not seem to closely track the number, type, or use cases to be implemented or the time frame for implementation. The second observation is an apparent general tendency to underestimate capital costs, overestimate the availability of Federal and payer funding, and overlook the need for ongoing funding of the governance structure.

Given the population of Maryland; the number, size, and complexity of health care institutions in the state; and the lack of examples of a successful single statewide system in existence elsewhere for comparison, our financial model assumed that there will be five RHIOs within the state along with a statewide system providing core functions to all five RHIOs. This is a conservative model from the technology perspective as permitting multiple RHIOs reduces the risk of failure from a single, statewide technical entity, requires different areas of the state to conform to agreed upon statewide policies and protocols, while they develop the applications most valuable to them, and fosters a diversity of sharable ideas. However, it may be inherently more costly as some services may be duplicated across multiple RHIO instances. The governance and technical challenge is to judiciously select core statewide services to relieve RHIOs of the need to acquire or develop them locally.

For financial cost estimates, the Finance Team did a worst case assessment of the cost of a single local RHIO and multiplied that cost by five to obtain upper limit cost estimates. High cost estimates also reflect the comprehensive and sophisticated HIE model contained in the RFA, well beyond the near term objectives of most other states. A more modest, incremental approach and a smaller number of HIEs would likely reduce costs significantly.

A May, 2008, report from the Congressional Budget Office (Appendix D) concludes that virtually all of the studies purporting to show significant financial benefit from HIE are flawed. This includes studies from the RAND Corporation, the Center for Information Technology Leadership, and other well respected organizations. The report then goes on to discuss EHRs and HIE as a public good and the related benefits that can come from adoption, as well as regulatory barriers, technology barriers, and cost barriers inhibiting more widespread adoption. Important in the context of Maryland, it suggests that benefits realization will require a long term focus on classic process redesign and productivity improvements in all levels of health care. Major savings will not likely be achieved quickly through elimination of redundant test or imaging procedures. This report is well researched and written and an excellent guide to thoughtful and realistic steps toward an effective statewide HIE in Maryland.

Conversely, Mark Frisse, a Professor of Medical Informatics at Vanderbilt University and highly regarded and experienced HIE and EHR implementer, has concluded that substantial benefits will accrue when systems are installed effectively and the focus should be on how to achieve rapid and effective implementation².

The full value of an HIE is ultimately dependent on wide spread use of EHRs, particularly once the first one or two phases of an HIE have been implemented. EHR use hovers around 20% in Maryland, as is true of most states. Various sources estimate that complex, full featured EHRs continue to cost in the range of \$35,000 – 60,000 per physician to implement. Costs may be declining somewhat as web-hosted, reasonably featured EHRs are starting to become available. EHR adoption can also be facilitated and supported by local hospital and health care consortia, which may be preferential in some respects to state HIE supported EHRs. The recently enacted economic stimulus package will further adoption by providing new incentives and support mechanisms for hospital and provider acquisition, implementation and integration of EHRs.

However, it is important to note that, even with modest EHR use, significant benefits can be achieved with much more modest, lower cost data exchanges, especially for safety net patients whose care is typically fragmented among multiple providers. Simply making hospital and ED discharge summaries available to safety net providers and safety net clinic data available to ED physicians electronically (especially lab data) can significantly facilitate care.

We have chosen not to dwell in detail on required features and functions of a statewide HIE that would be self-evident to the reader. Examples include 24 hour per day, 7 day per week access, robust security features, and interoperation with other health care databases locally and statewide.

² J AMMed INFORM Assoc. 2006 May-Jun; 13(3): 365-367
February 19, 2009

Our Vision of Statewide HIE in Maryland in 2012: Three Years into the Future

The Health Care Delivery System

- Hospitals and providers exchanging information in a secure, timely fashion that is consistent with statewide privacy policies and agreed upon standards.
 - *Hospitals*: All Maryland hospitals connected
 - *Providers*: At least 60% of providers and community clinics connected
- Consumers routinely accessing their information to manage their health.
- Automated reporting and analytic capabilities for public health, quality, and research.

The Underlying Health Exchange Infrastructure

- *Heterogeneous exchange environment*: Regional and local exchanges, health record banks, integrated delivery networks
- *Central services*: Core set of services economically provisioned to all participants

Guiding Principles for a Statewide HIE in Maryland

The MHCC/HSCRC RFA enumerated a set of guiding principles around which a Maryland HIE would be created and governed. The MCHIE teams reviewed these precepts, concurred with most, modified several to reflect our perspectives, and added some additional ones. Our revised and extended set of guiding principles for a statewide are:

1. The HIE must have a business model that is sustainable. It considers both who benefits and who bears the cost; and each sector/stakeholder has a well-defined value proposition.
2. Data is appropriately accessible to authorized stakeholders.
3. The HIE is secure and protects patient privacy and confidentiality.
4. The governance structure of the HIE is transparent and inclusive.
5. The HIE includes specific, formal penalties for inappropriate access and misuse of data.
6. Established procedures are in place to permit emergency access to data.
7. The HIE is person-centric (instead of “consumer-centric”, which is only a single class of users)
 - a. It consistently keeps individuals’ interests at the forefront of decision-making;
 - b. Individuals have control over who accesses their data.
8. The implementation of HIE in Maryland will align with nationally-recognized standards to ensure cost-effective implementation and compatibility with efforts in neighboring states. Where gaps in interoperability standards exist, Maryland's HIE efforts will align with emerging standards activities to the greatest extent possible.
9. The primary objective of the statewide interoperable HIE effort is to support high quality, safe, and effective health care for all.

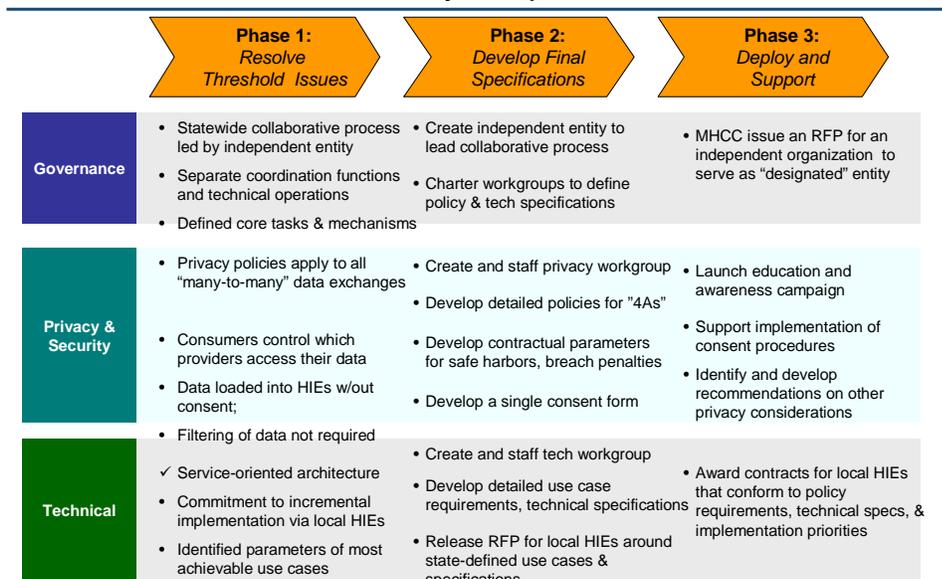
10. A collaborative governance model built on a public-private partnership will guide the planning, development, and implementation of HIE.
11. To the extent practical, HIEs in Maryland must support connectivity to the full range of stakeholders in the community.
12. Maryland’s statewide HIE capabilities must be attuned to and supportive of health care reform efforts.
13. The statewide HIE should be designed using a Service Oriented Architecture approach.
14. Implementation of HIE in Maryland should be supported by the development and provision of detailed implementation guides of agreed upon national standards.

Implementation Approach for a Statewide HIE

Successful implementation requires a sound tactical plan to accelerate benefits realization based on a clearly defined, phased approach; a statewide HIE governance entity; clearly established guidelines governing the collaborative process and accountability among members of the public-private partnership and the state government and its agents; a technical framework for the networks conforming to agreed upon policies, protocols and practices; and a recommended sequencing of use cases.

The following schematic identifies the key steps for moving from the submission of the two planning reports to implementation as a three phase process.

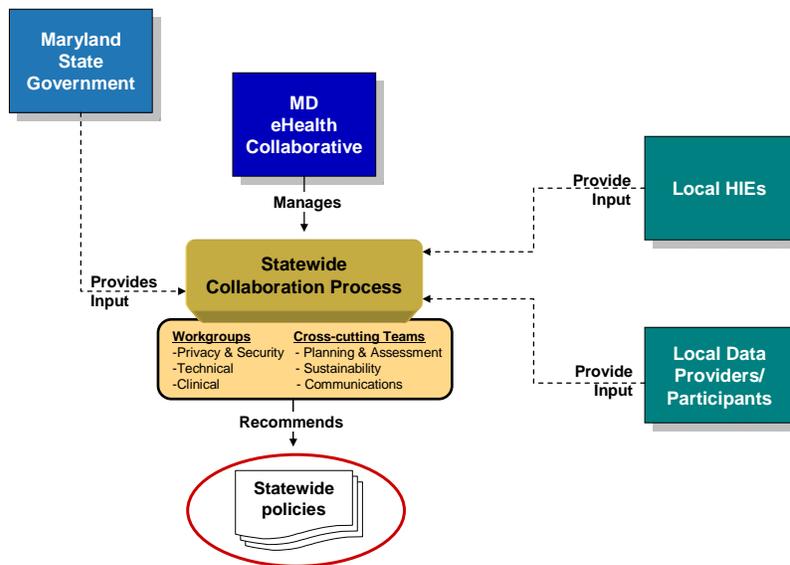
Implementation of Statewide HIE
Key Steps



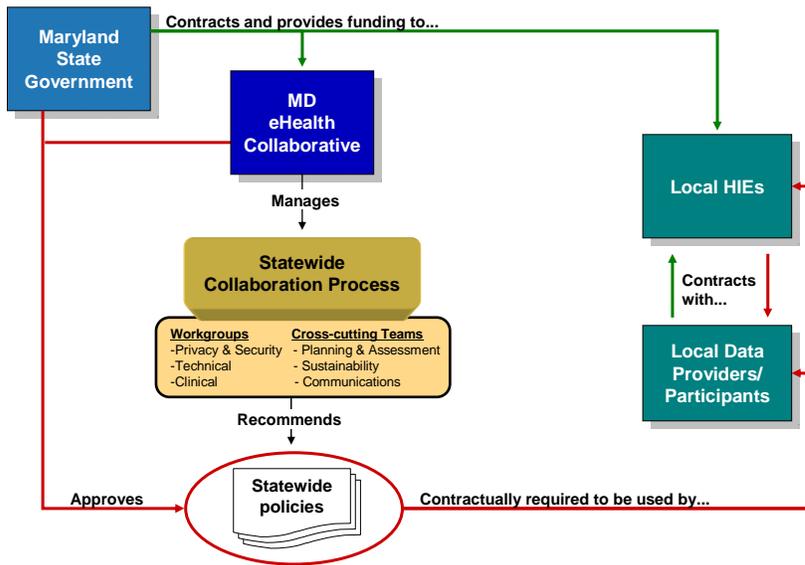
Statewide HIE Participant Relationships

Clearly defining roles, responsibilities, and relationships is an essential component of successful HIE. Failure to address these issues in advance in an open and collaborative environment has been a source of delay, acrimony, and even failure in other HIE efforts. The following two diagrams illustrate the relationships among state government, the MD eHealth Collaborative public-private partnership, local HIE’s, local data providers, and the collaborative teams. The first diagram illustrates the collaborative framework for developing and reaching consensus on statewide policies. The second diagram illustrates accountability flows for contracts, funding, and implementation.

**Implementation of Statewide HIE
Collaborative Framework**



Implementation of Statewide HIE Accountability Flows



Use Case Selection and Priority Sequencing

HIE is only valuable if it is used. HIE will only be used if there is a high probability that relevant data is present and easily and quickly accessible most of the time. For clinicians, this means timely and relevant clinical information, not otherwise easily obtainable. The same characteristics are essential for financial sustainability models. The criteria used to determine the specific use cases and sequence for implementation for a statewide HIE, are based on (a) the clinical value to various participants of different kinds of data, (b) the number of potential users, (c) the number, ease of access, and clinical value of data providers, (d) the technical difficulty of obtaining the data electronically, (e) the availability of vendor products meeting national standards, and (f) the potential for generating revenue from providing specific types of data. A summary of the selected use cases, their rationale for selection, and implementation phasing is shown in the following table.

Implementation of Statewide HIE

Use Case Assessment and Prioritization

Use Case	Demonstrated Value		Ease of Integration	Standards Readiness	Availability of Products	Proposed Phase
	Clinical	Efficiency				
Diagnostic Results Reporting	Moderate	<i>High</i>	<i>High</i>	<i>High</i>	<i>High</i>	1
Medication Management	<i>High</i>	Moderate	Moderate	<i>High</i>	Moderate	1
Transfer of Care	Moderate	Moderate	Difficult	Moderate	Moderate	2
Public Health	<i>High</i>	Moderate	Moderate	Low	Moderate	2
Community Resource Management	Moderate	<i>High</i>	Moderate	Moderate	<i>High</i>	2
Quality Reporting	Moderate	Moderate	Difficult	Moderate	Moderate	3
Consumer Empowerment	Moderate	Unproven	Difficult	Moderate	Low	3
Research	Unproven	Unproven	Difficult	Low	Low	3

Summary of Decision Points, Recommendations, and Rationale

The five team reports that follow this section contain a rich store of information on HIE efforts in other states and regions, as well as an extensive discussion of alternatives, choices, and implications for creating a Maryland statewide HIE. Each report contains a series of key Decision Points followed by the MCHIE recommendations and rationale. The ideal approach is to work through each report in its entirety to gain insight into the reasons behind our recommendations, fully understand the detailed pictorials and flow charts, and appreciate the subtleties of the issues. Recognizing that such an approach is not always possible, we have, with some reluctance, extracted the material here for more rapid access and subsequent use as a quick reference.

Governance Report Decision Points and Recommendations

Decision Point

- Will multiple RHIOs be permitted or prohibited components of statewide HIE?

Recommendation and Rationale

Recommendation: Multiple RHIOs Will Be Permitted

Maryland's implementation of statewide, interoperable HIE may include, but will not require, the creation of independent governance entities to oversee regional or local HIE.

To ensure consistency and lower implementation costs, it is anticipated that all HIEs would conform to agreed-upon statewide policies, standards, and rules.

Rationale: While Maryland has a number of fledgling HIE efforts, there exist no operational RHIOs. MCHIE believes that communities and regions in Maryland should organize in the manner that best suits their local needs and circumstances.

Decision Point

- Should Maryland combine the governance and technical operations into a single entity or split the governance and technical operations into separate entities?

Recommendation and Rationale

Recommendation: Separation of Governance Functions and Technical Operations

MCHIE recommends that the responsibilities of governance be separated from the technical management and operations of the HIE during the initial phases of development.

Rationale: Separation of governance and technical operations allows entities to specialize and focus on their designated roles, and minimizes the risk of a “single-point of failure.”

MCHIE stakeholders indicated that integrating the advisory and coordination functions with the technical entity could skew the alignment of priorities. MCHIE believes that clinical goals, privacy policies, and value propositions should guide implementation. An entity with both governance and technical implementation responsibilities may make decisions based on operational expediency at the expense of the broader policy considerations.

Decision Points

- Should the statewide HIE governance entity exist as an extension of Maryland state government (i.e., an advisory body), a state instrumentality, or an independent organization?
- How should the governance entity be established?

- What will be the sources of authority for the statewide HIE governance entity?

Recommendation and Rationale

Recommendation: Create an Independent Organization

The MCHIE Governance Team recommends the creation of an independent public-private entity, the *Maryland eHealth Collaborative*, to provide the critical convening and statewide policy coordination functions for HIE efforts in Maryland.

In order to expedite the creation of an independent public-private partnership, the MCHIE Governance Team recommends that the MHCC work with key stakeholders to design and construct the *Maryland eHealth Collaborative*.

To ensure consistency with the principles enumerated above and the rapid development of an effective statewide collaborative framework, MCHIE recommends that MHCC allocate seed funding through a contractual mechanism to support the creation and near-term operation of the Maryland eHealth Collaborative and its working groups. The contract with MHCC would also serve as the Maryland eHealth Collaborative's initial source of authority to serve as the designated entity responsible for statewide HIE coordination.

To the extent practical, philanthropic funding and resources should also be sought to support the incubation of the *Maryland eHealth Collaborative*.

Rationale: For continuity and balancing public and private sector interests, many observers believe the ideal structure to support statewide HIE is an independent public-private organization. Also, unlike an advisory body, an independent organization has the ability to negotiate and serve as the contracting agent for statewide services.

In the past, the Maryland General Assembly has used its authority to create a number of instrumentalities (e.g., the Maryland Technology Development Corporation). While the creation of a new instrumentality could be explored, the time required to introduce and pass the necessary legislation for such an entity could delay development of the policies needed to guide and inform HIE implementation.

With respect to the selection of an existing instrumentality or independent organization to serve as the statewide coordinator for HIE, the MCHIE Governance team reviewed likely candidates and determined that no existing public-private partnerships in Maryland could assume the roles and activities of a state-level HIE organization.

MCHIE assessed three options for developing an independent public-private entity: (1) introduce legislation to create such an entity; (2) convene a state-sponsored board to develop a plan for building an independent organization; or (3) identify key stakeholders in the public, nonprofit, and private sector who create the organization.

MCHIE participants indicated that the first option, the introduction of legislation to authorize the creation of an independent entity, could delay the development of the statewide framework

Recommendation: Create an Independent Organization

by as much as two years, jeopardizing the ability of stakeholders to create meaningful statewide policies to guide technical development.

MCHIE participants cautioned that the process for creating a temporary planning board (i.e., chartering, naming representatives, deliberating and making final recommendations) would take time and could also delay the creation of the required statewide policy and technical guides.

The third option, identifying and charging key stakeholders to develop a detailed plan, has been utilized in other states and at the national level for the creation of the American Health Information Community Successor Organization.

MCHIE recommends the third option based on the level of stakeholder readiness in Maryland. Given the inclusive and comprehensive nature of previous statewide advisory committees and planning projects in Maryland, MCHIE believes the key stakeholders are well-informed and poised to act quickly and effectively to create the entity and processes required to support statewide HIE.

Decision Points

- Which stakeholder groups should be represented on the leadership of the state-level HIE organization?

Recommendations and Rationale

During the MCHIE Governance Team meetings, consensus was achieved regarding the recommendations to include the following stakeholder types in the Maryland eHealth Collaborative:

Organization Type	Represented?	Likely Candidates
• Hospitals	Yes	(5) One hospital representative from each of the state’s five regions ³
• Providers	Yes	(4) MedChi provider representative, academic provider representative, mental health provider representative, and a nurse representative
• Clinics	Yes	(1) Mid-Atlantic Association of Community Health Centers (MACHC)
• Long-Term Care Facilities	Yes	(1) TBD
• Local HIEs	??	??
• Payers (public & private)	Yes	(3) State Medicaid, CareFirst, Kaiser
• Purchasers	Yes	(1) TBD
• Public Health...State	Yes	(1) State Dept of Health

³ The five regions in Maryland, as designated by the *Maryland Physician Workforce Study* (April 2008) are the Eastern, Southern, and Western, Central, and Capital regions.

Organization Type	Represented?	Likely Candidates
• Public Health...County/local	Yes	(1) County Health Officer
• Clinical Researchers	Yes	(1) TBD
• Health IT Community	Yes	(1) TBD
• Consumer Organizations	Yes	(1) TBD
• State Government	Yes	(2) MHCC and HSCRC representative
• State Legislature	No	(0)
• Quality Organizations	Yes	(1) Delmarva QIO
• Clinical Laboratories	No	(0)
• Pharmacies	Yes	(1) TBD
• Other(s)	Yes	(1) An academician with expertise in public-private governance
Total		(25)

The MCHIE Governance Team discussed the value of establishing thresholds and the anticipated contributions for the following categories:

- **Hospitals.** With respect to provider settings, the MCHIE Governance Team recommended inclusion of one hospital from each of the five regions in Maryland, in order to reflect the diversity of size, location, and geographic settings across the state. The MCHIE Governance Team indicated that selection of the hospitals could be achieved through a nomination process managed through the Maryland Hospital Association.
- **Long term care facilities.** The MCHIE Governance Team indicated that individuals from long term care facilities would offer valuable perspectives for two use cases in particular: Medication Management and Transfer of Care.
- **Nurses.** As nurses are integral to care teams and have keen insight into the integration of technology workflow considerations in care settings, the MCHIE Governance Team recommended that the Maryland eHealth Collaborative seek a representative from an organization such as the Maryland Nurses Association.
- **Mental health providers.** Because mental health providers and their patients face a unique set of challenges and privacy concerns with regard to the electronic exchange of sensitive personal health information, the MCHIE Governance Team recommended that the Maryland eHealth Collaborative seek a representative from the mental health provider community.
- **Health IT experts.** Given the complexity of health IT and HIE, the MCHIE Governance Team recommended that the Maryland eHealth Collaborative leadership include an individual with experience in managing and implementing health IT who understands and can explain the intricacies of the technical components.
- **Academician with expertise in governance.** Owing to the unique nature of public-private organizations, the MCHIE Governance Team recommended that at least one member of the Maryland eHealth Collaborative leadership group be skilled in facilitation and management of director-level boards in the public and nonprofit sectors.

The MCHIE Governance Team was unable to reach consensus as to whether local HIEs should be included as a component part of the advisory body. Some members thought that participation by local HIEs may lead to the types of challenges and conflict-of-interest described above, while others felt that local HIEs offered unique perspectives and inclusion could help facilitate their buy-in to the statewide policies developed by the governance entity.

Though no recommendations were made, the MCHIE Governance Team also discussed the applicability of adding other groups to the governance leadership, including organizations involved in “pre-hospital care” and pharmacy benefit managers.

Decision Points

- What processes should be used to ensure oversight of the exchange of health information?
- What will be the relationships between key stakeholders?

Recommendations and Rationale

Recommendation: Enforcement through Contracts & Regulations

MCHIE recommends that Maryland require that all participants in statewide HIE abide by the policies, standards, and guidance developed for HIE. Compliance with the agreed-upon statewide policies should be established and enforced through contracts and other incentives for adherence.

For oversight activities related to imposing penalties for breach or other actions harmful to consumers, Maryland state government should continue to exercise its regulatory oversight authorities.

As some entities may forgo state funding and incentives and choose to develop HIE capabilities outside the statewide HIE governance framework, MCHIE recommends that the State government monitor HIEs’ conformance to statewide policies and assess the need for additional enforcement through accreditation and/or regulation.

Rationale: HIEs represent a very early-stage movement for governing the exchange of health information. Information policies governing their oversight need to evolve through participatory public processes and have sufficient flexibility to accommodate innovations and learning from the field..

Utilizing a mix of contractual authority and the state’s existing regulatory authority is likely to enhance the state’s ability to oversee and protect the public’s interests. As practical experience is gained through implementation, the state could, if necessary, create additional enforcement mechanisms through stronger regulations and/or accreditation.

Decision Points

- What variables will be measured?
- When and how should data be collected?
- How frequently should reports be issued?

Recommendations and Rationale

Recommendation: Collect Data, Report on Progress

MCHIE recommends that the Maryland eHealth Collaborative work with local HIEs to collect data and assess the impact of HIE activities in the state during the design, prototype, and implementation phases. As a condition of the receipt of state funding, HIEs would be required to collect and provide data to the Maryland eHealth Collaborative and participate in other state-sponsored evaluation activities.

As a condition of its receipt of state funding, the Maryland eHealth Collaborative would provide an annual report to the public. The report would analyze the previous year’s use and impact data, progress against goals and anticipated milestones, challenges and obstacles encountered, and recommendations for any corrective actions.

Rationale: Given the level of investment and the anticipated breadth and depth of stakeholder involvement, tracking and assessing progress will provide valuable feedback to financiers and stakeholders.

Decision Points

- What will be the primary functions of the collaborative governance process in Maryland?

Recommendation and Rationale

The MCHIE Governance Team recommends that the Maryland eHealth Collaborative perform the tasks identified in the table below.

Tasks	Discussion
1. Develop strategic plan and roadmap	Developing a strategic plan and roadmap provides the foundation for managing implementation and evaluating progress.
2. Develop statewide policies to guide implementation	Oversee the process to develop policy guidance with respect to privacy, security, and technical implementation.
3. Communicate with stakeholders to advance HIE	Provide proactive guidance to policymakers on legislation or regulations that affect HIE initiatives (i.e., white papers, letters of support, etc.). Support and/or organize public efforts to advocate on behalf of policies and legislation that support health IT and statewide HIE.

Tasks	Discussion
4. Coordinate with statewide safety, quality and value efforts	As an enabler of quality and value, HIE efforts should be coordinated with existing quality improvement efforts in Maryland, including the Maryland Patient Safety Council and various healthcare reimbursement reform efforts in the public, private, and nonprofit sectors.
5. Track, evaluate, and report on health IT & HIE progress	The creation and maintenance of a clearinghouse of HIE information and activities occurring within the state helps local exchanges share lessons and track their progress relative to other efforts. Collecting objective information on HIE activities across the state will help decision makers assess the results of HIE investments and the impact of regulations and rule making.
6. Track and engage HIE efforts in neighboring states	Maryland has significant cross-border patient flow and policy coordination considerations that necessitate an ongoing knowledge of other states' efforts (particularly Delaware, the District of Columbia, New Jersey, Pennsylvania, Virginia, and West Virginia).
7. Negotiate on behalf of HIEs with vendors	As candidate services for statewide implementation are identified, a key driver of cost reductions will be the extent to which Maryland can negotiate with vendors for discounts.

Decision Point

- How should the governance functions be staffed, organized, and supported?

Recommendations and Rationale

Recommendation: Initial Collaborative Framework
<p>The MCHIE Governance Team recommends that the statewide collaborative process initially consist of three workgroups:</p> <ul style="list-style-type: none"> • Clinical Workgroup • Technical Architecture and Standards Workgroup • Privacy and Security Workgroup <p>Each workgroup should be chartered to include representatives from the appropriate constituencies and have explicit requirements and timelines for expected deliverables. To support the three initial workgroups, additional teams focused on cross-cutting issues (e.g., planning and assessment, communications, education and outreach, and sustainability) should be considered.</p> <p>Rationale: The proposed workgroups have been modeled after approaches in other states and will provide detailed policies throughout implementation.</p>

Recommendation: Dedicated Funding Source for Collaborative Process

MCHIE Governance Team recommends that the MHCC and HSCRC provide funding through a contract to create and support the initial operation of the Maryland eHealth Collaborative and the statewide collaborative process. Based on estimates from other states, required funding will range from \$1.0 to \$1.5 million annually.

Rationale: Given the importance of creating a forum for stakeholders to develop consistent, statewide policies to guide implementation, adequate support for the convening and coordination function will be a critical determinant of success for statewide HIE.

Community Perspectives Report Decision Points and Recommendations**Decision Point**

- What are the critical factors favoring or inhibiting HIE from the perspective of low income, uninsured, ethnically diverse individuals and how can we influence them?

Recommendations and Rationale**Recommendation: Community Centered Outreach Works But Must be Funded**

Focus group studies found that both patients and their providers described the benefits of HIE as saving time and money for both patients (who take unpaid time from work to receive care) and providers. Patients typically have to go to multiple providers at present to collect their data for specialist and other medical visits.

Patients looked forward to having access to their own health data, particularly for this mobile population, including a desire to be able to take their medical data with them when visiting relatives in other countries.

The primary concerns of the patients are inadequate confidentiality protection, lack of accountability and audit, and fear that employers, peers, family members, or commercial entities will see or use their medical records without authorization. For certain recent African immigrant groups, disease specific stigma may be especially strong.

Interviews with leaders of community-based organizations revealed interest and willingness to provide education to their client populations, and they saw a role for themselves in this area if time and resources were available.

Rationale: Outreach efforts are successful when performed by trusted members of the community. This requires substantial time and effort, but makes the difference between optimistic acceptance vs. fear and withholding of information.

Decision Point

- Can we identify factors that are especially important to patients that will lead to greater support and acceptance?

Recommendations and Rationale**Recommendation: Consider Early Implementation of Simple Patient-Centric Features**

Patients saw great benefit in having electronic access to their medical information. In spite of limited formal education, many are quite computer literate, expressing interest in such things as accessing and controlling their own health information, making on-line appointments, keeping track of medications, understanding and better following their doctor's instructions.

Some assumed that HIE would work like e-mail and on-line banking, especially valuable for a mobile population.

Rationale: Modest, low cost applications have the potential to involve this hard to reach population segment in more active management of their own health care.

The following table summarizes beliefs and attitudes of various community groups. While the sample is small, the findings were consistent. Half the participants favored HIE, with another 20% favorable with suitable privacy protections. In this sample, the least enthusiastic were physicians. More detailed discussion, contained in the Community Perspectives report, gives insight into strategies that community outreach implementation teams might want to consider.

	Yes	Yes, with conditions	No	Unsure	Total
Community-based organizations	8	0	1	0	9
Montgomery Cares (safety-net) clinics	5	8	0	1	14
Montgomery County DHHS	2	2	0	3	7
Physician members of medical society	7	2	5	1	15
Others*	7	0	0	2	9
Total	29 (54%)	12 (22%)	6 (11%)	7 (13%)	54

**"Others" include: leaders of area foundations, a president of a chamber of commerce, a hospital CIO, a representative from the Office of Minority Health*

Privacy and Security Report Decision Points and Recommendations**Decision Point**

- What type of governance process should Maryland adopt to oversee HIE and the development and implementation of Privacy and Security Policies in the state?

Recommendations and Rationale

Recommendation: Creation of Statewide Collaborative Process

MCHIE recommends that Maryland develop a statewide process that involves all interested stakeholders in the creation of a comprehensive privacy and security policy framework for HIE in Maryland.

MCHIE recommends that the statewide collaborative process include issue-specific workgroups. One group should be solely devoted to and responsible for developing the state's privacy and security policies. All work group decisions should be made by consensus.

As a condition of receiving any state funding, HIEs should be required, through contracts, to participate in the statewide process and to comply with the policies, standards, and guidance developed through the process.

Rationale: A single, statewide collaborative process built on a foundation of public-private partnership is the predominant governance model utilized in other states implementing statewide HIE.

Decision Point

- Should new statewide privacy and security policies be applied only to many-to-many HIE occurring through a statewide health information network and not to existing one-to-one exchanges of information?

Recommendations and Rationale

Recommendation: Distinguish Between One-to-One & Many-to-Many Exchanges

MCHIE recommends that Maryland define privacy and security rules that apply statewide to the exchange of personal health information in a "many-to-many" context, whereby health care providers can reach out to large networks of clinicians and providers to obtain health information and use it in patient care. The privacy and security rules for HIE that facilitate "many-to-many" data exchanges, should not, however, apply to one-to-one exchanges.

Further, Maryland should specify that its privacy and security policies represent the minimum standards with which HIEs should comply. Where appropriate, individual HIEs should be free to adopt more stringent policies provided they do not impinge on the liquidity of the statewide health information network.

Rationale: The one-to-one exception is important to avoid significant unintended consequences that could impact a range of electronic results reporting activities that are adequately regulated and do not constitute community-wide or statewide HIE.

As indicated in the comparative analysis, states with advanced statewide privacy and security frameworks recognize this distinction and have structured their policies accordingly.

Decision Point

- Should all participants in statewide HIE be required to abide by the privacy and security policies under development and if so how should Maryland ensure compliance?

Recommendations and Rationale

Recommendation: Require and Enforce Compliance With Policies

MCHIE recommends that Maryland require all participants in statewide HIE to abide by the privacy and security policies developed for HIEs. Maryland should ensure compliance contractually, rather than statutorily. To the extent practical, Maryland should also consider voluntary enforcement models including accreditation.

Rationale: Uniform privacy policy adoption is critical to interoperability of information via statewide HIE infrastructure and ensuring that consumers gain a common understanding of what it means to have their information shared through an HIE.

Recommendation: “Safe Harbor” Provisions

MCHIE recommends that Maryland State government endorse any statewide policies developed as compliant with existing law.

Rationale: Data sharing will not occur if stakeholders have unresolved liability concerns. A safe harbor provision would increase HIEs and stakeholder confidence that they will not face liability in the event they are in compliance with agreed upon HIE policies and applicable federal and Maryland law.

Decision Point(s)

- Should Maryland attempt to amend or pass new state laws or should it draft its privacy and security policies in a manner that complies with existing law?

Recommendations and Rationale

Recommendation: Develop Policy Within Context of Existing Laws

Notwithstanding the need to evaluate certain areas of Maryland law, MCHIE recommends that the State develop its privacy and security policies within existing federal and state legal frameworks and not pursue legislative changes at this time.

MCHIE also recommends that, as Maryland develops its statewide privacy and security policies, it conducts a thorough and ongoing analysis of existing state law related to health records privacy in order to ensure the new privacy and security policies comply with existing laws, as well as any new requirements under the 2009 economic stimulus act.

Recommendation: Develop Policy Within Context of Existing Laws

Rationale: Because creating new or modifying existing privacy laws can be challenging, many states have chosen to develop policies that are consistent with existing laws. This approach allows an opportunity to assess the existing laws impact of HIE based on operational experience, and, if necessary, to pursue legislative corrections at a later date.

Decision Point(s)

- Maryland must decide what constitutes adequate and meaningful patient consent taking into consideration what is required legally, what is appropriate for risk management purposes, what constitutes the best public policy, and what is feasible from an implementation perspective in the state

Recommendations and Rationale

Recommendation: Consent Framework

MCHIE recommends that, with the exception of one-to-one exchanges, the State require affirmative, written consent to be obtained from patients by each provider and payer organization before they are permitted to access a patient's information through an HIE.

Subject to a thorough analysis of state law, MCHIE recommends that Maryland not require affirmative consent for providers to make patient health information available to an HIE provided the HIE is serving as the data provider's HIPAA third-party business associate, is in compliance with applicable state and federal law, and does not make information available to HIE participants until patient consent to access data is obtained.

MCHIE also recommends that the State use a statewide collaborative process to develop granular policies related to consent, including policies to address the durability and revocability of consent, consent for minors, creation of a statewide consent form, enforcement of consent requirements.

Rationale: Within the context of consent, it is important that Maryland balance the need to protect patients' personal health information with the need to facilitate viable HIE within the state by ensuring providers' timely access to complete patient information at the point of care. MCHIE believes this balance can be achieved by requiring that a provider obtain patient consent to access information through an HIE, without requiring consent to make patient information available to an HIE.

Requiring that affirmative, written consent be obtained by each provider or payer organization in order to access a patient's information through an HIE is critical to ensuring that patients have control over who is able to access their personal health information and to building public trust in HIE.

Allowing data to be uploaded to an HIE without consent but under the terms of a HIPAA third-party business associate agreement ensures access to the information in an emergency, supports statutorily-required public health reporting, and guarantees providers' timely access to complete

Recommendation: Consent Framework

patient information at the point of care. The latter point could have potentially significant impacts on the long-term sustainability of statewide HIE, as a lack of readily-available, robust patient data would undermine the perceived value of the HIE and could limit fledgling exchanges' ability to become viable entities.

Decision Point(s)

- Agreement is required as to whether those involved in HIE will be required or allowed to filter certain types of sensitive health.

Recommendations and Rationale**Recommendation: Do Not Require HIEs to Filter Data**

With the exception of psychotherapy notes and other types of sensitive health data that are subject to specific HIPAA requirements, MCHIE recommends that the State not require HIEs to filter specific types of sensitive information (e.g., HIV/AIDS status, mental health, substance abuse and genetic testing).

MCHIE recommends that the State use a statewide collaborative process to develop granular policies related to access, including policies to address authorization, authentication, audits, emergency access, enforcement of access requirements and penalties for breach.

MCHIE also recommends that Maryland monitor the evolution of technology and tools that identify sensitive health information and support increased granularity of patient consent mechanisms; as consent management technologies that allow patients to stratify granular levels of access become available, policies should be modified to grant patients this control.

Further, Maryland should consider allowing (but not requiring) institution-based filtering for certain types of entities, such as mental health institutions or federally-qualified substance abuse centers, that primarily generate sensitive health information and that can be more readily isolated and excluded from the HIE as an information source.

Rationale: It is important that Maryland balance patients' need to have control over their sensitive health information and the ability to fully realize the promise of HIE by having complete patient information available at the point of care. Further, the practical challenges of consistently defining categories of sensitive information and the potential clinical implications of filtering data suggest that current data filtration techniques pose operational challenges and potential risks in a provider's ability to deliver safe and effective care.

Technical Infrastructure Report Decision Points and Recommendations**Decision Points**

- To what extent should the existing principles be modified?
- What additional principles should be added?

Recommendations and Rationale

The table below identifies the MCHIE Technical Team's proposed changes to the principles identified in MHCC's RFA.

Original Principle	Recommended Change/Addition	Rationale
3. Data is appropriately accessible to authorized stakeholders.	<i>Unchanged</i>	
4. The HIE is secure and protects patient privacy and confidentiality.	<i>Unchanged</i>	
7. The HIE uses industry-defined standards.	<i>Change to:</i> The implementation of HIE in Maryland will align with nationally-recognized standards to ensure cost-effective implementation and compatibility with efforts in neighboring states. Where gaps in interoperability standards exist, Maryland's HIE efforts will align with emerging standards activities to the greatest extent possible.	The MCHIE Technical Team believes that adherence to standards is an effective strategy to avoid being locked into vendors' proprietary solutions. This modification addresses the fact that where incompatibility of standards exist, the HIE will need to make choices that maximize the ability of entities to quickly and cost effectively interface to the system.
8. Established procedures are in place to permit emergency access to data.	<i>Unchanged</i>	

The MCHIE Technical Team also recommends that the State consider additional principles described in the table below.

New Principles	Rationale
<p>“The statewide HIE should be designed using a Service Oriented Architecture approach.”</p>	<p>With respect to an architectural design approach, the Maryland Solutions and Implementation Workgroup recommended that Maryland’s statewide HIE infrastructure be developed based on a SOA. SOA is a design approach that guides how the exchange should be built. The purpose is to organize distributed systems into an integrated approach that eliminates information silos. The SOA does not require re-engineering of existing systems. Instead, it supports existing functionality by loosely connecting systems to integrate information across systems. The MCHIE Technical Team supports the recommendation to adopt a SOA approach.</p> <p>Key health IT standards also appear to be migrating to a SOA approach. In September 2008, the HITSP Board voted to establish a working group which will deliver a plan within 90 days to wrap all HITSP work so that it will plug and play with a service oriented architecture.</p>

New Principles	Rationale
<p>“Implementation of HIE in Maryland should be supported by the development and provision of detailed implementation guides of agreed upon national standards.”</p>	<p>In a November 12, 2008 presentation to the American Health Information Community, John Halamka, the Executive Director of the HITSP, claimed that HIE standards are no longer a rate limiting step for HIE implementation. To bolster his claim, Dr. Halamka highlighted the steady progression of completed “use cases:”</p> <ul style="list-style-type: none"> - 2006 - Personal Health Records, Laboratories, Biosurveillance - 2007 - Medications, Quality, Clinical Summaries - 2008 - Medical devices, Referrals, Family History/Genome, Secure messaging, Public Health Reporting, Immunizations <p>While no one questions the need for the HIE to use standards, many observers question whether interoperability standards are sufficiently mature and refined to guide the implementation and product-selection decisions.</p> <p>In its September 2008 recommendations, the Maryland Solutions and Implementation Workgroup also identified the need for implementation guides:</p> <p><i>A statewide HIE should demonstrate a commitment to implementing standards and clearly defining the approach for implementation of those standards. Presently, many systems are incapable of generating standard electronic messages or cannot format data in conformance with national standards. The Workgroup noted that disparate systems will require additional technology to integrate standards in a way that will allow them to interpret data. Identifying which standards and versions should be used by an HIE, and developing guidance on implementing the standards, assures consistent electronic messaging between disparate systems. <u>The Workgroup agreed that stakeholders will require strong guidance to appropriately implement standards.</u></i></p>

Decision Point

- Among the prevailing options for implementing statewide HIE, which approach offers the most feasible, flexible, and cost-effective approach?

Recommendation and Rationale**Recommendation: Statewide interoperability through local HIEs conformance to detailed architectural designs, protocols, and implementation guides**

The MCHIE Technical Team recommends that Maryland develop a statewide HIE approach based on local HIEs that conform to statewide architectural design, protocols, and implementation guides.

The MCHIE Technical Team also recommended that the State conduct a rigorous process to define the minimum services that can be cost-effectively replicated across HIEs.

Rationale: As discussed above, the MCHIE Technical Team believes that an approach based on modular, local HIE deployment offers significant risk mitigation advantages over the alternative approaches. In addition, an infrastructure that includes a layer of local HIEs could reduce costs and implementation burdens on local providers. Because standards and specifications are likely to evolve and change over time, the statewide system will require system maintenance and periodic updates. With a system of local HIEs serving as intermediaries, updates can be done by the local HIEs while participating systems can maintain their legacy systems and focus on the needs of their users instead of devoting resources to address statewide system requirements.

The MCHIE Technical Team also recommends that the State carefully review options for the provision of selected services on a statewide basis. The MCHIE Technical Team recognizes that many states are finding it more difficult than anticipated to identify the common services that would be offered statewide. However, given the pace of technical change and the promise of savings and implementation efficiency, Maryland should establish a process for stakeholders to identify, assess, and develop opportunities for statewide services.

Owing to their technical maturity and readily-available solutions in the marketplace amongst providers and hospitals, three services (medication history via SureScripts-RxHub, laboratory results from national labs, and authentication) were determined to early candidates for a more rigorous analysis regarding their viability and effectiveness as statewide services.

Decision Point

- How should standards conformance be achieved?

Recommendations and Rationale**Recommendation: Enforcement through Contracts & Regulations**

MCHIE recommends that Maryland require all HIE participants abide by the policies, standards, and guidance developed for HIE. Compliance with the agreed-upon statewide policies should be established and enforced through contracts and other incentives for adherence.

As some entities may forgo state funding and incentives and choose to develop HIE capabilities outside the statewide HIE governance framework, MCHIE recommends that State

Recommendation: Enforcement through Contracts & Regulations

government monitor HIEs' conformance to statewide standards and assess the need for additional enforcement through accreditation and/or regulation.⁴

Rationale: HIE represents a very early-stage movement for governing health information exchange, and the information policies governing their oversight need to evolve through participatory public processes and have sufficient flexibility to accommodate innovations and learning from the field.

Decision Point

- From technical perspective, how should use cases be sequenced?

Recommendations and Rationale**Recommendation: Phase 1 Use Cases**

Based on an analysis of the use cases, the MCHIE Technical Team recommended the first phase of implementation include two use cases, diagnostic results reporting and medication management, in addition to the core security, messaging and presentation services.

Other MCHIE teams, particularly the Finance Team, provide additional criteria for selection and sequencing of use cases.

⁴ One organization, the Electronic Healthcare Network Accreditation Commission, recently launched efforts to create a program to accredit HIEs. Additional details are online at http://ehnac.org/pr_2009-0113.html.
February 19, 2009

The table below describes the extent to which each of the eight use cases addresses the two technical criteria identified above.

Use Case	Standards Readiness	Availability of Products & Solutions	Proposed Implementation Sequence	Comments
Diagnostic Results Reporting	High	High	Phase 1	<p>+ Almost all the currently operational HIEs provide this functionality.</p> <p>+ For systems that do not offer electronic exchange, this provides a clinical use case.</p> <p>+ Many lab systems and reference laboratories provide results reporting capabilities.</p> <p>+ In his assessment of standard readiness, the chair of the Health Information Technology Standards Panel, John Halamka, asserted that interoperability standards for lab and radiology orders and results were among the three most ready value cases.⁵</p>
Medication Management	High	Moderate	Phase 1	<p>+ ePrescribing national standards have been established and are being aligned with HITSP.</p> <p>+ In his assessment of standard readiness, the chair of the Health Information Technology Standards Panel, John Halamka, asserted that interoperability standards for electronic prescribing were among the three most ready value cases.⁶</p> <p>- Formulary and benefits decision logic is difficult to implement and varies widely amongst health plans and PBMs.</p>
Transfer of Care	Moderate	Moderate	Phase 2	<p>+ Clinical summary document standards matured significantly over the past year focusing around the Continuity of Care Document, Patient Summary Document Transaction Testing (HITSP C32).</p> <p>- Much of the key information useful to clinicians in a transfer of care scenario may still be paper based resulting in "out-of-band" challenges.</p>

⁵ Halamka, John. "Life as a Healthcare CIO." December 22, 2008. Accessed online February 7, 2009 at <http://geekdoctor.blogspot.com/2008/12/next-steps-for-interoperability.html>.

⁶ Ibid.

Use Case	Standards Readiness	Availability of Products & Solutions	Proposed Implementation Sequence	Comments
Public Health	Low	Moderate	Phase 2	<p>+ Public health specifications look to utilize existing standards to perform biosurveillance and investigation.</p> <p>+ Leverages existing infrastructure and clinical data by applying an analytics layer to existing information.</p> <p>- Challenges federated data storage in that it utilizes cross-patient and cross-facility query logic.</p> <p>- Public health specific queries are not well defined and standard parameters and services have not yet been tested.⁷</p>
Community Resource Management	Moderate	High	Phase 2	<p>+ Leverages existing infrastructure for hospital capacity reporting.</p>
Quality Reporting	Moderate	Moderate	Phase 3	<p>+ Increases value to existing patient-centric data.</p> <p>+ Extends data and technical models of HIEs to applying additional functionality to clinical data exchange.</p> <p>+ Provides opportunity for business model based on payer incentives and pay-for-performance programs.</p> <p>- Requires comprehensive patient record from data that primarily exists in provider EHRs.</p> <p>- Payer organizations have not standardized on a set of quality reports which may present a challenge to organizations looking to reconcile multiple quality parameters and queries.</p>

⁷ Despite the biosurveillance and public health reporting HITSP use cases, there remains significant testing and maturity concerns around the readiness of technology vendors and HIEs to actually support. Especially as HIEs are currently structured to capture transactional clinical messages from participating stakeholders, the HIE capability to support aggregation of data to fulfill the minimum biosurveillance data elements is a concern. Another consideration is the granularity of clinical data and comprehensiveness that is available via HIE. Despite the onset of information exchange, the automation of information actually requested by public health and the processes associated with public health data elements have not yet been determined and implemented at clinical provider source systems. As a first step, significant evaluation of existing minimum dataset and query parameters should be clearly defined to guide implementation activities.

Use Case	Standards Readiness	Availability of Products & Solutions	Proposed Implementation Sequence	Comments
Consumer Empowerment	Moderate	Low	Phase 3	+ Leverages HIE’s patient-centric view of clinical information + Provides opportunities for additional consumer engagement in care processes - May present conflicting sources of information for consent and access.
Research	Low	Low	Phase 3	- Relies heavily on a comprehensive clinical data exchange - Few standards exist around the specific and customized nature of research queries and parameters.

Finance and Sustainable Business Model Report Decision Points and Recommendations

Decision Point

- What principles will guide Maryland’s approach to financing HIE?

Recommendation and Rationale

The table below tracks MCHIE’s proposed changes to the HIE financing-related principles proposed in MHCC’s RFA.

Recommendation: Retain Original Principle as stated

Recommendation: Retain Original Principle as stated

The HIE must have a business model that is sustainable. It considers both who benefits and who bears the cost; and each sector/stakeholder has a well-defined value proposition.

Rationale

A statewide model should be scoped precisely, focusing on the most likely consumers and contributors of patient data

Ongoing operating expenses and the likely near-term expansion to new stakeholders require private sector contributions to combat free rider/moral hazard problems.

Decision Points

- What principles should guide the selection of use cases?
- From a value and financing perspective, how should use cases be sequenced?

Recommendation and Rationale**Recommendation: Phase 1 Use Cases**

From a business case and financing perspective, the MCHIE Finance Team recommends that Maryland use the following criteria for prioritizing implementation of use cases:

- (1) Magnitude of clinical value
- (2) Magnitude of efficiency improvements
- (3) Ease of integrating with existing workflows
- (4) Ability to identify discrete transactions for possible future fee assessment

Based on an analysis of the use cases, the MCHIE Finance Team identified three use cases as candidates for Phase 1 implementation: (1) diagnostic results reporting, (2) medication management, and (3) transfer of care.

Decision Point

- What mechanisms should Maryland utilize for startup capital for HIE in Maryland?
- How can the responsibility for raising the start-up capital be equitably distributed across relevant stakeholders?

Recommendation and Rationale**Recommendation: HSCRC Funding, Bond Issue, Federal Funds, Community Benefit Funds**

Recommendation: HSCRC Funding, Bond Issue, Federal Funds, Community Benefit Funds

For the capital required in the initial 12-24 month period, the MCHIE Finance Team recommends that the State consider four financing strategies:

- An initial State set-aside of \$10 million has already been identified for seed capital.
- Re-programming 1-2% of “Community Benefit” annually
- Approximately \$10-\$15 million from federal sources (including funding for state-level HIE through the recently passed economic stimulus bill).
- The remaining amount, approximately \$55-\$60 million, from a revenue-backed bond issue.

The MCHIE Financing Team also recommends that Maryland pursue philanthropic funding and consider re-programming a small percentage of hospitals’ community benefit dollars to support capital expenditures, expanding functionality, and on-going costs of building and operating a statewide HIE. Hospitals reported over \$812 million in community benefits for Fiscal Year 2007 of which \$11.4 million was listed as financial contributions.⁸ A combination of direct financial support and in-kind technical and other services could accelerate and sustain HIE development across the state, especially in communities less well prepared for adoption of new technology. Even a one percent re-direction of community benefit dollars to statewide HIE (\$8 million dollars) would generously fund HIE development and operations.

Rationale

In undertaking the development of a statewide HIE model, Maryland is implicitly committing to a significant capital outlay. The bulk of capital will be needed in the first 12-24 months of the effort, but the expansion of the HIE model to additional stakeholders and regions of the state will require additional, ongoing capital investment.

In considering the financing needs of statewide HIE development, payment flows should be divided into two broad categories: investment capital and ongoing expenses. For purposes of this analysis and set of recommendations, Maryland should rely primarily on federal and State resources for the “foundational capital” necessary to commence development and deployment.

Providers who participate in the exchange will also have to expend capital to create the interfaces and connectors from their own internal systems to both send and receive patient and provider information into the exchange. For the purposes of this analysis, the MCHIE Finance Team limited its recommendations to what the State should raise to subsidize its own priorities. Subsequent recommendations in this report do suggest that providers will be responsible for providing a bulk of the ongoing operating funds needed to maintain the exchanges, but they are not expected to contribute start-up capital for foundational development.

Decision Point

- What mechanisms should be utilized to support ongoing operations?

Recommendation and Rationale

⁸ Health Services Cost Review Commission. “Maryland Hospital Community Benefits Report FY 2007.” Available online at http://www.hscrc.state.md.us/community_benefits/documents/CBR_FY2007_final_report.pdf

Recommendation: Mixed Approach of Community Benefit Funds, Transaction Fees**Recommendation**

It is highly recommended that Maryland pursue multiple options in developing a sustainable financing model to support ongoing operations and development.

- Re-programming 1-2% of “Community Benefit” annually
- One-time Set-up Fees for Initial Connections
- Subscription Fees for Users.
- Fee for data requests
- Payer Assessments

Rationale

A multi-pronged approach to operational financing eases the burden on any single constituency while giving the State flexibility in setting transaction and subscription fees at modest enough levels to avoid any disincentives for utilization.

Decision Point

- What mechanisms should be used to finance the collaborative governance process?

Recommendation and Rationale**Recommendation: Fund Governance Activities via State Contract**

MCHIE Governance Team recommends that the HSCRC provide funding through a contract to create and support the initial operation of the Maryland eHealth Collaborative and the statewide collaborative process.

Rationale

The MCHIE Finance Team considered three funding sources to support the statewide governance entity and collaborative processes.

The first option is to seek capital and in-kind contributions from stakeholder organizations to launch the organization. Given the current economic conditions, most stakeholders may be unwilling to provide the required funds and/or staff and materials. Moreover, any contributions would need to be structured in such a manner as to ensure the contributors are not granted preferred status in the governance process in exchange for their support.

The second option is to seek support from Maryland-based philanthropic organizations. While this option should be pursued, it may difficult to collect sufficient funding to meet the initial capital needs to create the governance entity and the critical pieces of the collaborative infrastructure.

The third option, funding from the HSCRC seed capital, is attractive because it can be executed more quickly than the alternatives, and it affords the state greater oversight of the governance process to ensure it meets the collective needs of all stakeholders.

Financing Approaches and Cost Estimates for Statewide HIE

As noted in other sections of this report, capital costs and ongoing operational costs are difficult to estimate and highly dependent on the number, complexity, and sequencing of use cases actually implemented. Extrapolating from the few longer term operational HIEs that exist is subject to considerable error as noted in the earlier referenced Congressional Budget Office report.

For purposes of the cost estimates below, we have chosen to err on the high side. We based these estimates on the assumption that there will be five RHIOs within the state (not unreasonable given several nascent RHIO entities in Maryland and multiple RHIOs in similar sized states such as Tennessee), some level of statewide HIE central services, that all eight designated use cases will be implemented (some of them quite complex and not necessarily well defined), that all hospitals in the state will be connected to a RHIO, and that 60% of physicians will be connected to the HIE by 2012.

More gradual implementation starting with high value use cases, more shared services, deferring complex use cases until they are better understood, and the potential to utilize newly evolving technology options may also affect these estimates favorably. However, we believe them to be in line with current findings, particularly for large-state comprehensive HIE models.

Implementation of Statewide HIE Capital Costs

Entity	Capital Costs (for years 1-3)	System Maintenance & Integration Costs (for years 1-3)	Total Costs (for years 1-3)
HIEs	\$4 - \$6 million per HIE <i>(for infrastructure)</i> \$6 - \$10 million per HIE <i>(for functionality)</i>	\$6 - \$9 million per HIE	\$80 - \$125 million (5 HIEs across the state)
Hospitals	\$400 - \$500,000 per hospital	\$100,000 per hospital	\$25 - \$30 million (47 hospitals in the state)
Physician offices and clinics (assuming 60% of sites connect to exchange)	\$30 - \$35,000 per site	\$5,000 - \$7,000 per site	\$8 - \$10 million (~430 sites in the state)

Assumptions/Constraints

- Assumes five operational local HIEs in Maryland
- Deploy and support all 8 use cases

Implementation of Statewide HIE Financing Approaches

Raising Funds to Cover \$80 million in HIE Capital Expense

- HSCRC seed funding... \$10 million
- Federal funding..... \$10-15 million
- Revenue-backed bond.. \$55-60 million

Strategies to Sustain HIEs Ongoing Operations

- Between \$12 - \$15 million for annual maintenance & system expansion.
- Financing strategies to be considered include:
 - One-time set up fee
 - Subscription fee
 - Data request fee
 - Payer assessment

1

Conclusion of MCHIE Study Design and Recommendations Overview

This completes the overview of the study design and summary recommendations from the MCHIE Collaborative, though they can not be fully understood without careful reading of the following five detailed report chapters containing analytical and comparative data.

Montgomery County HIE Collaborative
Governance Considerations for Statewide HIE
Analysis and Recommendations

Montgomery County Health Information Exchange Finance Team,
assisted by Manatt Health Solutions
February 2009

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EXECUTIVE SUMMARY

Effective governance is the foundation to creating and sustaining the interoperable exchange of health information. In developing a governance infrastructure for statewide health information exchange (HIE) in Maryland, the Montgomery County HIE Collaborative (MCHIE) Governance Team considered nine threshold issues:

1. Vision for State-level HIE
2. Role of Regional Health Information Organizations (RHIOs) and Local HIEs
3. Relationship between Governance and Technical Operations
4. Collaborative Governance Structure
5. Composition of Governance Entity
6. Accountability Mechanisms
7. Measuring and Evaluating Progress
8. Key Functions and Tasks
9. Implementation

This document consolidates the analysis of the opportunities, challenges, risks and implications associated with the various governance options. The document consists of three sections.

The first section, *Background on State-Level HIE Governance*, highlights the foundational considerations and influences on state-level HIE efforts. The second section, *Key Decisions for State-Level HIE Governance*, frames the high-level decisions and recommendations for state-level HIE governance in Maryland.

Finally, the document contains a series of attachments including a glossary of key terms and summaries of two leading state's approaches to governance.

I. BACKGROUND: THE NEED FOR STATE SUPPORT OF HIE

Numerous studies have shown that the secure, timely and accurate exchange of health information can improve the quality, safety, and efficiency of healthcare.¹ Recognizing the potential value of HIE to serve as the foundation for healthcare transformation, stakeholders at the national, state, and local levels and across the public, nonprofit and private sectors are working together to advance the interoperable exchange of health information.

A fundamental premise of the MCHIE Collaborative's strategy to advance HIE is that coordinated action, investment, and implementation must occur at the state level in order to ensure HIE is optimally aligned to meet the needs of all stakeholders in Maryland. In the current healthcare landscape, efforts at the federal and local levels are insufficient to develop HIE at the pace or along the parameters to serve Maryland.

At the national level, the federal government has funded policy coordination, privacy and security, technical standards and certification, and demonstration projects. While the federal focus has been on the policy levers to advance health information technology (IT) and HIE, the responsibility of implementation has largely fallen to stakeholders at the state, regional, and local levels.²

In the absence of a federal financing framework, HIEs have grown slowly and have been primarily organized to meet the immediate interests and near-term operational requirements of a limited set of stakeholders.³ For example, the most advanced and sustained clinical HIE efforts, including HealthBridge, THINC RHIO, and the Indiana Health Information Exchange, successfully built systems around the transactional needs of data providers by supporting the automated exchange of clinical results between hospitals, community-based physicians, and independent national laboratories.

These "private exchanges," where organizations with defined business relationships share information to address internal needs, are proliferating and will likely accelerate as healthcare organizations expand their IT capabilities for strategic advantage and marketplace differentiation vis-à-vis their competitors. A recent study of hospitals' support for physician acquisition of EHRs demonstrates the appeal and growth of private exchanges.⁴

Remaining keenly attentive to their paying customers' priorities, the private exchanges aren't designed to address the objectives of the broader healthcare community. As a result, private exchanges often relegate services with less immediate returns (e.g., public health reporting, access for non-referring providers, quality reporting) to second tier priorities. The experiences of health information sharing in Montgomery County corroborate this trend.⁵

¹ A detailed inventory of studies that document the value of HIE is online at <http://www.slhie.org/Docs/Inventory.xls>.

² Pending legislation represents a significant change in federal policy and funding. The Health Information Technology for Economic and Clinical Health (HITECH) Act, included in the federal economic stimulus legislation, currently includes a provision for providing \$300 million in planning and implementation grants to states or "qualified" state-designated nonprofit, multi-stakeholder partnerships to "conduct activities to facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards." Additional details on the HITECH bill are provided in *Attachment B*.

³ Glaser, John, "The Advent of RHIO 2.0," *Journal of Health Information Management*. Summer, 2007.

⁴ Grossman, JM., Bodenheimer, TS, McKenzie, K. "Hospital-Physician Portals: The Role Of Competition In Driving Clinical Data Exchange," *Health Affairs*. November/December 2006.

⁵ Primary Care Coalition. "Metro DC Health Information Exchange (MeDHIX) Program Summary." Submitted to Agency for Healthcare Quality and Research May 2007.

Between the federal strategy and slowly expanding local HIE efforts, states are ideally situated to advance interoperable HIE. In nearly three-quarters of states, policy makers are fostering state-level HIE by providing resources, sponsoring statewide roadmaps for HIE implementation, and codifying state-level HIE functions within legislative, regulatory, and rule-making frameworks.

Serving in a statewide capacity and representing the collective interest of the public, private, and nonprofit sectors, state-level HIEs offer distinct and vital functions:

- ensure that exchange develops beyond narrowly-defined interests.
- serve state public policy interest and consumer protection concerns through a trusted regulatory, legal, and accountability framework.
- identify the boundaries for cooperation and competition and mobilize public and private resources for effective collaboration.
- reduce implementation costs by providing consistent and reliable policies and practices across regions and systems.
- create opportunities for cost-effective, shared investments across stakeholders.

Based on a review of best practices in other states, MCHIE believes that in order for the benefits of health IT to be fully realized in Maryland, a statewide governance infrastructure needs to be designed, created and sustained.

The analysis that follows identifies the options and provides recommendations for the governance infrastructure in Maryland that will engage statewide data-sharing sources and beneficiaries; structure shared accountabilities; and balance needs among consumers, providers, insurers, employers, and state agencies.

II. KEY DECISIONS FOR STATE-LEVEL HIE GOVERNANCE

Effective governance is the foundation to creating and sustaining interoperable HIE. In developing a governance infrastructure for statewide HIE in Maryland, the MCHIE Governance Team considered nine threshold issues outlined in the table below.

Threshold Issue	Key Questions
A. Vision for State-level HIE	<ul style="list-style-type: none"> • What are the principles for guiding development and measuring success?
B. Role of RHIOs and Local HIEs	<ul style="list-style-type: none"> • Will RHIOs be a required or optional component of statewide HIE?
C. Relationship between Governance and Technical Operations	<ul style="list-style-type: none"> • Should the role of governance be separated from the role of technical operations of the HIE?
D. Collaborative Governance Structure	<ul style="list-style-type: none"> • Should a governance entity exist, and if so, should it be an extension of Maryland state government (i.e., an advisory body) or an independent organization? • What will be the sources of authority? • How should the governance entity be created?
E. Composition of Governance Entity	<ul style="list-style-type: none"> • What groups should be represented on the board or decision-making body?
F. Accountability Mechanisms	<ul style="list-style-type: none"> • What processes should be used to ensure oversight of the exchange of health information? • What will be the relationships between key stakeholders?
G. Measuring and Evaluating Progress	<ul style="list-style-type: none"> • What should be measured? • How frequently should reports be issued?
H. Key Functions and Tasks	<ul style="list-style-type: none"> • What are the primary functions of the governance entity?
I. Implementation	<ul style="list-style-type: none"> • How should the statewide governance process be staffed, organized, and supported?

A. Vision for Statewide HIE in Maryland

Background

As a first step, many state-level HIE efforts identify guiding principles. For example, the Minnesota e-Health Initiative, a legislatively-created advisory body, defines its vision as follows:

The vision of the Minnesota e-Health Initiative is to accelerate the use of health information technology to improve healthcare quality, increase patient safety, reduce healthcare costs, and enable individuals and communities to make the best possible health decisions. The Minnesota e-Health Initiative focuses on four areas:

- *Empowering consumers with the information they need to make informed health and medical decisions.*
- *Informing and connecting healthcare providers so they have access to the information they need.*
- *Protecting communities with accessible prevention resources, and rapid detection and response to community health threats.*
- *Enhancing the infrastructure (technical, information, education, privacy and security policies, and financial resources) necessary to fulfill the Minnesota e-Health vision and focus.*

Comparatively, the Vermont Information Technology Leaders, an independent public-private partnership that provides governance and technical functions, identifies its mission as follows:

Our vision is for a healthier Vermont, where shared health information is a critical tool for improving the overall performance of the healthcare system. The healthcare community will work together to achieve new efficiencies through the use of information technology in order to deliver better overall value and care to our citizens.

In 2007, the State-level HIE Consensus Project, a federally sponsored research and advisory effort, conducted a detailed assessment of publicly available mission and vision statements from 21 state-level HIEs initiatives.⁶ The table below highlights the distribution of key principles across the research cohort.

Principles	Percent of States including the principle	Examples
1. Establish clinical goals of quality and value as highest priority	76%	<i>Rhode Island Quality Institute:</i> The Quality Institute will promote coordination and collaborative relationships, increase value to purchasers and improve the overall <u>quality</u> and <u>safety</u> of healthcare in Rhode Island.
2. Emphasize the critical role of interoperability	76%	<i>The Kentucky e-Health Network Board:</i> ...champion the development of a secure, <u>interoperable</u> electronic health network...

⁶ American Health Information Management Association Foundation of Research and Education. "Workbook of Interim Findings: Building Sustainable Health Information Exchange, Roles for State Level Public-Private Partnerships." November 5, 2007.

Principles	Percent of States including the principle	Examples
3. Recognize the need for multi-stakeholder participation	71%	<i>Delaware Health Information Network:</i> To facilitate the design and implementation of an integrated, statewide health data system to support the information needs of <u>consumers, health plans, policymakers, providers, purchasers and research...</u> .
4. Identify its purview as statewide	62%	<i>New York eHealth Collaborative:</i> A public-private partnership that will serve as a focal point for healthcare stakeholders to build consensus on <u>state</u> health IT policy priorities... .
5. Indicate the importance of privacy and security	57%	<i>CalRHIO:</i> A collaborative statewide initiative whose mission is to improve the safety, quality, and efficiency of healthcare through the use of IT and the <u>secure</u> exchange of health information.
6. Articulate a patient-centric focus	33%	<i>Delaware Health Information Network:</i> To facilitate the design and implementation of an integrated, statewide health data system to support the information <u>needs of consumers...</u> .

Through the work of multiple committee and advisory bodies conducted over the course of the last three years, stakeholders in Maryland have developed a series of principles to govern HIE in the state.^{7,8} Based on the results of these deliberations, MHCC identified the following eight principles in its Request for Applications (RFA):

- 1. The HIE must have a business model that is sustainable.**
 - a. It considers both who benefits and who bears the cost; and
 - b. Each sector/stakeholder has a well-defined value proposition.
- 2. The HIE is consumer-centric.**
 - 1) It consistently keeps consumers' best interests at the forefront of decision-making; &
 - 2) Consumers have control over who accesses their data.
- 3. Data is appropriately accessible to authorized stakeholders.**
- 4. The HIE is secure and protects patient privacy and confidentiality.**
- 5. The governance structure of the HIE is transparent and inclusive.**
- 6. The HIE includes specific, formal penalties for inappropriate access and misuse of data.**
- 7. The HIE uses industry-defined standards.**
- 8. Established procedures are in place to permit emergency access to data.**

⁷ "Task Force to Study Electronic Health Records", Maryland Health Care Commission, December 2007. Study conducted under Maryland Senate Bill 251 (2005).

⁸ Maryland Health Care Commission. "Privacy and Security Solutions and Implementation Activities For A Statewide Health Information Exchange." September 2008.

Decision Points

- To what extent should the existing principles be modified?
- What additional principles should be added?

Recommendations and Rationale

The table below tracks MCHIE's proposed changes to the eight principles proposed in MHCC's RFA. Please note that other MCHIE teams will also provide recommendations for modifications and/or additional principles.

Original Principle	Recommended Change/Addition	Rationale
1. The HIE must have a business model that is sustainable. It considers both who benefits and who bears the cost; and each sector/stakeholder has a well-defined value proposition.	<i>Unchanged</i>	
2. The HIE is consumer-centric. a. It consistently keeps consumers best interests at the forefront of decision-making; and b. Consumers have control over who accesses their data.	Change to: The HIE is person-centric. a. It consistently keeps individuals' interests at the forefront of decision-making; and b. Individuals have control over who accesses their data.	Ensures that Maryland's HIE efforts don't discriminate against any particular group (i.e., patients, providers, regulators, payers) all of whom may assume different roles at different times. In addition, being person-centric distinguishes the HIE from efforts that would otherwise be focused on organizations or systems.
3. Data is appropriately accessible to authorized stakeholders.	<i>Unchanged</i>	
4. The HIE is secure and protects patient privacy and confidentiality.	<i>Unchanged</i>	
5. The governance structure of the HIE is transparent and inclusive.	<i>Unchanged</i>	
6. The HIE includes specific, formal penalties for inappropriate access and misuse of data.	<i>Unchanged</i>	
7. The HIE uses industry-defined standards.	Change to: The implementation of HIE in Maryland will align with nationally recognized standards to ensure cost-effective implementation and compatibility with efforts in neighboring states. Where gaps in interoperability standards exist, Maryland's HIE efforts will align with emerging standards activities to the greatest extent possible.	Adherence to standards is an effective strategy to avoid being locked into vendors' proprietary solutions. This modification addresses the fact that where incompatibility of standards exist, the HIE will need to make choices that maximize the ability of entities to quickly and cost effectively interface to the system.
8. Established procedures are in place to permit emergency access to data.	<i>Unchanged</i>	

MCHIE recommends that the state consider additional principles described in the table below.

New Principles	Rationale
<p>“The primary objective of the statewide interoperable HIE effort is to support high quality, safe, and effective healthcare for all.”</p>	<p>HIE should not be considered an end, but rather a means to help stakeholders achieve specific healthcare goals. This new recommendation also ties the statewide HIE to objectives that can be measured and tracked over time.</p>
<p>“A collaborative governance model built on a public-private partnership will guide the planning, development, and implementation of HIE.”</p>	<p>Healthcare delivery and financing involves public, private, and nonprofit sectors. This principle affirms the belief that no one sector can or should lead HIE without the involvement of all healthcare stakeholders.</p>
<p>“To the extent practical, HIEs in Maryland must support connectivity to the full range of stakeholders in the community.”</p>	<p>This recommendation addresses the concern that organizations may seek to use HIEs to leverage or maintain control of data for competitive advantage.</p> <p>MCHIE recommends that Maryland seek to enforce non-discriminatory practices initially through incentive mechanisms (e.g., in order receive state funding and/or data from state-based systems, HIEs would have to meet requirements for inclusiveness).</p> <p>As processes to accredit RHIOs and HIEs mature, the State should consider expanding oversight mechanisms to include self-regulating mechanisms.</p>
<p>“HIEs must be attuned to reform efforts at the federal and regional level that aim to bring about transformational change in the healthcare system.”</p>	<p>This recommendation ensures that HIEs in Maryland evolve as necessary to incorporate and operationalize transformational shifts in the healthcare system that have the potential to bring about reductions in cost and improvements in the quality of care.</p>

B. Role of RHIOs and Local HIEs

Background

State-level HIEs efforts make fundamental choices about the extent to which RHIOs play a role in their implementation approaches.

As an oversight structure, a RHIO describes an arrangement with distinct attributes relating to governance and geography. For purposes of this analysis, a RHIO is defined as a “health information organization that brings together healthcare stakeholders within a defined geographic area and governs HIE among them for the purpose of improving health and care in that community.”⁹ To be considered a RHIO, an organization:

- Must involve data-sharing participants that are separate and distinct legal entities operating within a defined geographic area whose collaboration through the RHIO will cross organizational boundaries.
- Must intend to benefit the population in the community. This requires that stakeholders come from the defined geographic area and that the RHIO provides well-defined and transparent processes to facilitate the interoperable exchange of health information across the range of participating stakeholders.
- Must be inclusive and convene various types of stakeholders in the delineated geographic area who are vested in improving the health of the community.
- Can arrange for the provision of additional technical and operational services supporting its primary purpose. Such services may vary based on stakeholder needs and a range of environmental factors.

In contrast, an HIE is “the electronic movement of health-related information among organizations according to nationally recognized standards.”¹⁰ Unlike a RHIO, an HIE is not bound by geography—it can tie together sources of data from anywhere, whether within a small area or scattered throughout the nation. HIEs can bring together a national network of labs, the network employed by entities representing disease communities, or an organization that facilitates the electronic prescribing of medications, etc. HIEs are typically governed by federal and state data exchange regulations and information sharing agreements, business associate agreements, or other contracts among participants.

A handful of states, most notably Michigan and New York, are pursuing distributive networking strategies based on the implementation of common statewide policies, standards, and protocols managed by RHIOs (details on New York’s approach are provided in *Attachment B*). Such organizations tend to be more stable and are likely to be self-sufficient at the level of the medical trading area (MTA), the natural market within which most referrals, hospitalizations, and other flows of both patients and patient information typically occur. It is an area in which clinicians and healthcare organizations work together to serve a population of consumers, and where working relationships have typically already been established in serving common patients. The MTA is the geographic area in which face-to-face trust can most readily be

⁹ Office of the National Coordinator for Health IT. “Defining Key Health Information Technology Terms.” June 2008. Available online at <http://www.hhs.gov/healthit/resources/reports.html>.

¹⁰ Ibid.

established and within which the bulk of information is currently exchanged (usually on paper) on a daily basis.¹¹

In other states, including California and Minnesota, governance and technical plans call for data providers and users to connect with a single state-level HIE entity.

The table below highlights the advantages and drawbacks of the prevailing approaches.

	States <u>NOT</u> Relying on RHIOs as Key Components of Statewide HIE	States <u>RELYING</u> on RHIOs as Key Components of Statewide HIE
State models	California, Minnesota, Tennessee	Michigan, New York
Advantages	+ Governance and implementation tied to functioning or self-organizing HIEs.	+ Governance can be delegated to local communities, reducing burden on centralized management.
Drawbacks	<ul style="list-style-type: none"> - Concerns regarding scale of oversight and implementation. - Potential for unnecessary duplication of efforts. - Concerns regarding “private” capture of HIE activities for narrowly defined stakeholder interest. 	<ul style="list-style-type: none"> - Costs for creating RHIOs can be high and sustainability remains a challenge. - Potential impact of a region’s inability or unwillingness to sustain a RHIO. - Implementation can be slowed if the pace or distribution of RHIO activity is uneven or if a RHIO proves unworkable in a given geographic region.
Observations	✓ Appears more effective in states without, or with few, operational HIEs or RHIOs.	✓ Significant policy framework and infrastructure required to create and sustain RHIOs.

Maryland’s history with RHIOs is decidedly mixed. Amidst the early successes of the AHRQ-funded MeDHIX project, the Erickson Retirement Communities HIE pilots, the newly announced exchange led by LifeBridge Health, Maryland also experienced the demise of the MD/DC E-Health Initiative.

Decision Point

- Will multiple RHIOs be permitted or prohibited components of statewide HIE?

¹¹ Arizona Health-e Connection Roadmap, http://gita.state.az.us/tech_news/2006/Arizona%20Health-e%20Connection%20Roadmap.pdf, accessed on October 31, 2006.

Recommendation and Rationale***Recommendation: Multiple RHIOs Will Be Permitted***

Maryland's implementation of statewide, interoperable HIE may include, but will not require, the creation of independent governance entities to oversee regional or local HIE.

To ensure consistency and lower implementation costs, it is anticipated that all HIEs would conform with agreed-upon statewide policies, standards, and rules.

Rationale: While Maryland has a number of fledgling HIE efforts, there exist no operational RHIOs. MCHIE believes that communities and regions in Maryland should organize in the manner that best suits their local needs and circumstances.

C. Relationship between Governance and Technical Operations

Background

Previous research has shown that state-level HIE initiatives support two distinct roles:¹²

- **Governance:** A primary role to convene healthcare stakeholders, promote collaboration, develop consensus, coordinate policies and procedures, and lead and oversee statewide HIE.
- **Technical operations:** An optional and variable role to manage and operate the technical infrastructure, services, and/or applications to support statewide HIE.

Role	Governance		Technical Operations
Function	Convene	Coordinate	Operate/Manage
Task	<ul style="list-style-type: none"> • Provide neutral forum for all stakeholders • Educate constituents & inform HIE policy deliberations • Advocate for statewide HIE • Serve as an information resource for local HIE and health IT activities • Track/assess national HIE and health IT efforts • Facilitate consumer input 	<ul style="list-style-type: none"> • Promote consistency and effectiveness of statewide HIE policies and practices • Support integration of HIE efforts with other healthcare goals, objectives, & initiatives • Facilitate alignment of statewide, interstate, & national HIE strategies 	<ul style="list-style-type: none"> • Serve as central hub for statewide or national data sources and shared services • Own or contract with vendor(s) for the hardware, software, and/or services to conduct HIE • Provide administrative support & serve as a technical resource to local HIE efforts

Figure 1: Categorization of State-Level HIE Organizational Roles and Functions

State approaches to organizing these functions vary based on the realities of local, state, and regional healthcare environments. Although many state-level HIE initiatives provide both the governance role and technical operations, a state’s technical roadmap for achieving statewide interoperability may or may not call for some type of centralized state-level technical functions, applications, or services.

Though combining the statewide convening and coordinating elements with the technical operations may have efficiency advantages, some observers believe the combination may limit the ability to engage a full range of stakeholders. As suggested in an evaluation of the MeDHIX project:

The organization controlling the record locator, data aggregation, and display technology may have undue influence over the project plan, policies, and processes compared with

¹² American Health Information Management Association. “State Level Health Information Exchange: Roles in Ensuring Governance and Advancing Interoperability Final Report Part I.” March 10, 2008.

*participants who are simply providing or receiving data. To the extent that use cases or workflow differ, considerable efforts may be required to align the needs of all users with a set of shared objectives and methods.*¹³

The table below summarizes the trade-offs and considerations for states that have combined the governance and technical operations into a single entity and those that have split the governance and technical operations into separate entities.

	Coordination Function & Tech Operations Combined in Single Entity	Coordination Function & Tech Operations in Separate Entities
States	California (CalRHIO), Delaware, Utah, Vermont	Kentucky, Massachusetts, Michigan, Minnesota, New York
Advantages	+ Streamlined policy and implementation decision-making.	+ Separation allows entities to specialize and focus on their designated roles. + Separation reduces the risk that a failure in the technical operations undermines the entire statewide HIE process.
Disadvantages	- Concerns that centralization creates risk of a single point of failure. - Operational challenge in combining both (1) the inclusive decision-making process for collaborative governance and (2) the more narrowly focused framework for implementation and operations.	- Concerns regarding differing pace of policy and technical implementation - Local HIEs have to track and work with two separate entities, consuming more time and resources.

Although consolidating functions within a single organization has been proposed as a means for streamlining coordination efforts, some stakeholders expressed concerns about conferring control of privacy and security issues to entities that also have operational responsibilities.

In its assessment of statewide HIE privacy and security approaches, the Research Triangle Institute found that a governance arrangement in which the HIE oversees all aspects of governance could be interpreted as a conflict of interest because the HIE is responsible for making financial decisions that might conflict with its need to uphold community standards for privacy and security. For example, Vermont noted that it had observed a healthy tension between the Board of Directors of Vermont Information Technology Leaders, the state's HIE, and some of the proposals emerging from the state's Privacy and Security Solutions project work.¹⁴

¹³ Primary Care Coalition. "Metro DC Health Information Exchange (MeDHIX) Program Summary." Submitted to Agency for Healthcare Quality and Research. May 2007.

¹⁴ Dimitropoulos, Linda. *Impact Analysis: Privacy and Security Solutions for Interoperable Health Information Exchange*. December 2007.

http://healthit.ahrq.gov/portal/server.pt/gateway/PTARGS_0_1248_815829_0_0_18/PrivacyandSecuritySolutionsProject_ImpactAnalysis.pdf.

The dichotomy between governance and technical operations may not be a permanent condition. For example, the governance entity in New York, the New York eHealth Collaborative (NYeC), which currently oversees the development of statewide policies and standards, has not ruled out the possibility of offering some statewide technical services in the future.

Decision Point

- Should Maryland combine the governance and technical operations into a single entity or split the governance and technical operations into separate entities?

Recommendation and Rationale

Recommendation: Separation of Governance Functions and Technical Operations

MCHIE recommends that the responsibilities of governance be separated from the technical management and operations of the HIE during the initial phases of development.

Rationale: Separation of governance and technical operations allows entities to specialize and focus on their designated roles, and minimizes the risk of a “single-point of failure.”

MCHIE stakeholders indicated that integrating the advisory and coordination functions with the technical entity could skew the alignment of priorities. MCHIE believes that clinical goals, privacy policies, and value propositions should guide implementation. An entity with both governance and technical implementation responsibilities may make decisions based on operational expediency at the expense of the broader policy considerations.

D. Collaborative Governance Structure

Background

HIE operates most effectively in an environment of trust. Data providers and users must have confidence that the entities participating in data exchange adhere to the financial, technical, and privacy and security underpinnings of exchange.

Though states have various options for configuring their approaches, each governance framework includes three common elements:

1. **Committed participants.** Financing and delivery of healthcare in the United States involves multiple entities in both the private, public, and nonprofit sectors. As such, efforts to create and sustain HIE must include the key stakeholder sectors in the state: state government; private and public healthcare providers, payers, and purchasers; and exchange participants (i.e., physicians, consumers, and caregivers).
2. **Collaborative process.** Stakeholder participation is necessary, but insufficient to achieve the level of orchestration required to implement HIE. States that have moved beyond the planning stages have developed and sustained inclusive, transparent decision-making processes to deliberate, solve problems, and address the complex technical, policy, legal, and financial issues of HIE.¹⁵ States have utilized a variety of mechanisms to enable collaborative deliberations, including legislative hearings, advisory councils, and/or formal independent, organizations.
3. **Statewide policies.** The collaborative decision-making process should yield consistent, enforceable policies that establish the technical, privacy, and financial rules for statewide HIE. Statewide policies can be promulgated through a variety of mechanisms including legislation, rule-making, contracts, or commonly-accepted practices.

The figure below highlights the key collaborative governance elements.

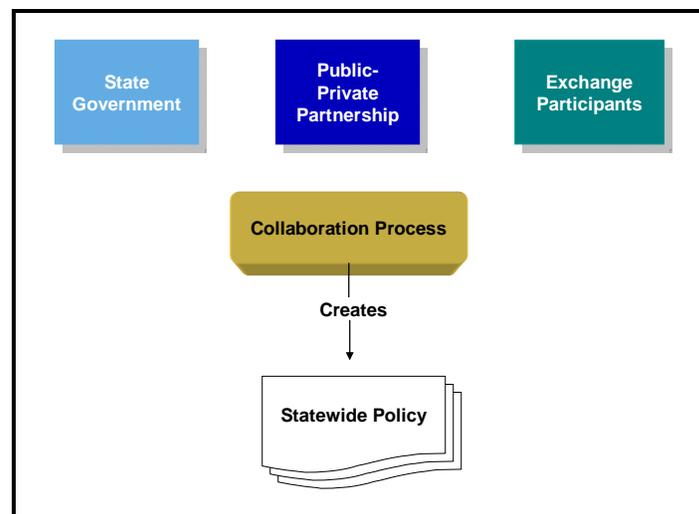


Figure 2: Illustration of State-Level HIE Roles and Functions

¹⁵ The William and Flora Hewlett Foundation. "Collaborative Governance: A Guide for Grantmakers." January 2008. Available online at <http://www.hewlett.org/Publications/collaborativegovernance.htm>.

The entity that oversees the statewide collaborative process can take on one of three forms: (1) a state government sponsored advisory body; (2) an “instrumentality” of state government; or (3) an independent organization.

Though varied across the three models, the role of state government is critical within each. In the advisory body model, state government staffs and oversees the statewide HIE governance body. In the state instrumentality model, the entity exists as a quasi-public agency and consists of both public and private stakeholders.¹⁶ In the case of an independent organization, state government provides input and potentially approves the statewide HIE policies and procedures that are collaboratively developed by the group. Additionally, across all three models, state government sets the goals and monitors the progress of statewide HIE efforts. Additional descriptions of state-level HIE efforts coordinated through an advisory body and an independent organization are provided in *Attachment B*.

While all three models create a framework for public-private partnership, each has distinct advantages and disadvantages as highlighted in the table below.

	Government Advisory Body	State Instrumentality	Independent Organization
States	Minnesota, Tennessee	Delaware	New York
Features	<ul style="list-style-type: none"> State gov’t oversees and staffs the governance infrastructure for statewide HIE activities. 	<ul style="list-style-type: none"> As a quasi-public agency, state instrumentality consists of public and private stakeholders, often defined by legislation. 	<ul style="list-style-type: none"> Independent organization established. Board is multi-stakeholder and includes state gov’t representatives, to the extent permitted under conflicts of interest laws.
Sources of Authority	<ul style="list-style-type: none"> Executive Order, Legislation 	<ul style="list-style-type: none"> Legislation 	<ul style="list-style-type: none"> Stakeholder support, state gov’t contracts
Advantages	<ul style="list-style-type: none"> + Direct government involvement and oversight can mitigate competitive behaviors. + As an agent of state government, easier to obtain state funding. 	<ul style="list-style-type: none"> + As an agent of state government, easier to obtain state funding. + Can contract for services, while at the same time being subject to the same accountability processes as public agencies. 	<ul style="list-style-type: none"> + More operational flexibility than state agencies. + Perceived by many observers to be the most inclusive and balanced mechanism for state-level HIE. + Insulated from changes in political leadership.

¹⁶ “Instrumentalities” denotes entities closely affiliated – generally by government ownership or control – with state or local governments. Whether an entity is an “instrumentality” of a governmental unit is determined based on the following factors: (1) whether it is used for a governmental purpose and performs a governmental function; (2) whether it performs its function on behalf of one or more states or political subdivisions; (3) whether private interests are involved, or whether states or political subdivisions have the powers and interests of an owner; (4) whether control and supervision of the organization is vested in public authority or authorities; (5) whether express or implied statutory or other authority is needed to create and/or use the entity; and (6) the degree of the organization’s financial autonomy and the source of its operating expenses.

	Government Advisory Body	State Instrumentality	Independent Organization
Drawbacks	<ul style="list-style-type: none"> - Non-government stakeholders may view their advisory role as insufficient. - Duration and effectiveness can be subject to state gov't leadership changes. 	<ul style="list-style-type: none"> - Range of functions typically codified in legislation, which limits ability to change and adapt to new circumstances. 	<ul style="list-style-type: none"> - Can be time-consuming to create the organization. - Defining state government role can be a challenge. - Garnering public funds can be more challenging than other models.
Observations	<ul style="list-style-type: none"> ✓ Perceived effectiveness of previous or current advisory bodies in the state a consideration. 	<ul style="list-style-type: none"> ✓ State gov't must have ability to create instrumentalities. 	<ul style="list-style-type: none"> ✓ Ability and willingness to create new organization.

Decision Points

- Should the statewide HIE governance entity exist as an extension of Maryland state government (i.e., an advisory body), a state instrumentality, or an independent organization?
- How should the governance entity be established?
- What will be the sources of authority for the statewide HIE governance entity?

Recommendation and Rationale

Recommendation: Create an Independent Organization

The MCHIE Governance Team recommends the creation of an independent public-private entity, the *Maryland eHealth Collaborative*, to provide the critical convening and statewide policy coordination functions for HIE efforts in Maryland.

In order to expedite the creation of an independent public-private partnership, the MCHIE Governance Team recommends that the MHCC work with key stakeholders to design and construct the *Maryland eHealth Collaborative*.

To ensure consistency with the principles enumerated above and the rapid development of an effective statewide collaborative framework, MCHIE recommends that MHCC allocate seed funding through a contractual mechanism to support the creation and near-term operation of the *Maryland eHealth Collaborative* and its working groups. The contract with MHCC would also serve as the *Maryland eHealth Collaborative's* initial source of authority to serve as the designated entity responsible for statewide HIE coordination.

To the extent practical, philanthropic funding and resources should also be sought to support the incubation of the *Maryland eHealth Collaborative*.

Rationale: For continuity and balancing public and private sector interests, many observers believe the ideal structure to support statewide HIE is an independent public-private

Recommendation: Create an Independent Organization

organization.¹⁷ Also, unlike an advisory body, an independent organization has the ability to negotiate and serve as the contracting agent for statewide services.

In the past, the Maryland General Assembly has used its authority to create a number of instrumentalities (e.g., the Maryland Technology Development Corporation).¹⁸ While the creation of a new instrumentality could be explored, the time required to introduce and pass the necessary legislation for such an entity could delay development of the policies needed to guide and inform HIE implementation.

With respect to the selection of an existing instrumentality or independent organization to serve as the statewide coordinator for HIE, the MCHIE Governance team reviewed likely candidates and determined that no existing public-private partnerships in Maryland could assume the roles and activities of a state-level HIE organization.

MCHIE assessed three options for developing an independent public-private entity: (1) introduce legislation to create such an entity; (2) convene a state-sponsored board to develop a plan for building an independent organization; or (3) identify key stakeholders in the public, nonprofit, and private sector who create the organization.

MCHIE participants indicated that the first option, the introduction of legislation to authorize the creation of an independent entity, could delay the development of the statewide framework by as much as two years, jeopardizing the ability of stakeholders to create meaningful statewide policies to guide technical development.

MCHIE participants cautioned that the process for creating a temporary planning board (i.e., chartering, naming representatives, deliberating and making final recommendations) would take time and could also delay the creation of the required statewide policy and technical guides.

The third option, identifying and charging key stakeholders to develop a detailed plan, has been utilized in other states and at the national level for the creation of the American Health Information Community Successor Organization.

MCHIE recommends the third option based on the level of stakeholder readiness in Maryland. Given the inclusive and comprehensive nature of previous statewide advisory committees and planning projects in Maryland, MCHIE believes the key stakeholders are well-informed and poised to act quickly and effectively to create the entity and processes required to support statewide HIE.

¹⁷ A study of 13 state-level HIE initiatives found that the most effective and desirable legal structure for a state-level HIE governance organization is an independent, non-governmental public-private partnership. Source: American Health Information Management Association. "State Level Health Information Exchange: Roles in Ensuring Governance and Advancing Interoperability Final Report Part I." March 10, 2008. Available online at <http://www.slhie.org/Docs/FinalReportPart1.8.pdf>.

¹⁸ In 1998, the Maryland General Assembly created the Maryland Technology Development Corporation (TEDCO) "as a public instrumentality of the state" and tasked it with funding technology-focused programs and initiatives contributing to Maryland's economic and business development.

E. Composition of Collaborative Governance

Background

State-level HIE entities typically consist of representatives from a wide array of stakeholders including provider organizations, physician, health plans, employers, agencies of state and local government, state legislators, local HIE entities, consumer groups, and privacy advocates.

States experience with the allocation of board seats for state-level HIE organizations varies. In an assessment of 13 state-level HIE efforts, six state-level HIEs required that specific types of organizations participate on the board; seven did not. For those state-level HIE initiatives without allotment requirements, respondents indicated they needed the flexibility to make membership adjustments based on organizational needs.

The table below highlights the range of participants in the decision-making board of six advanced state-level HIE organizations.

	AZ	CA	CO	DE	NY	TN
	<i>AzHeC</i>	<i>CalRHIO</i>	<i>CORHIO</i>	<i>DHIN</i>	<i>NYeC</i>	<i>TN eHealth</i>
Fixed Categories	Yes ¹⁹	No	No	Yes	No	Yes
Board Membership						
• Hospitals	3	3	2	1	3	2
• Providers	2	3	2	1	1	1
• Clinics	0	0	1	0	1	0
• Local HIEs	2	0	0	0	2	2
• Payers (public & private)	5	3	2	2	1	2
• Purchasers	2	1	0	1	0	4
• Public Health...State	0	0	1	1	0	0
• Public Health...County/local	0	0	0	0	2	0
• Researchers	2	1	1	0	0	1
• Consumer Org	0	2	0	0	1	1
• State government rep	3	1	2	3	0	1
• State legislature	0	0	0	0	0	0
• Quality focused orgs	1	2	1	0	0	0
• Clinical Laboratory	1	0	0	0	0	0
• Pharmacy	1	0	0	0	0	0
• Others...	0	1	7	0	2	3
Total	22	22	16	9	13	17

Two groups in particular merit attention: state government and local HIE entities.

The nature of state government involvement in emerging independent state-level HIE initiatives is influenced by the various roles state government plays. While state agencies like the public health department and Medicaid authority have a clear stake regarding the use of statewide systems for sharing health information, state governments' roles as a funder or regulator of HIE can complicate its involvement in state-level HIE initiatives.

¹⁹ Note: Arizona designates permanent members.

With respect to its role as a funder, independent state-level HIE efforts in California, Maine, Massachusetts, and Rhode Island noted that state procurement and conflict-of-interest rules limited the ability of representatives from state government to serve as voting members of organizations that were beneficiaries of state contracts. A number of entities have addressed this issue by having state government officials serve as non-voting board members.

The degree of local HIE involvement in state-level HIE governance structures also varies from state to state. Six state-level HIEs (those in Arizona, California, Florida, Massachusetts, Michigan, New York, and Washington) either currently include, or plan to include, representatives from local HIEs as voting members on their governing boards. Representatives from these state-level HIEs indicated that local HIEs were key stakeholders and their inclusion in the decision-making process was deemed essential.

State-level HIE initiatives that did not have representatives from local HIEs on their boards cited the following reasons for the absence of these entities:

- The state had no local HIEs; therefore, the state-level HIE represented the entire state.
- Key participants from local exchanges were represented on the board and could speak on behalf of both their organization and the local HIE.
- For states with multiple local HIEs, the state-level HIE entity was challenged by choice of allocation of board seats to each local exchange or developing a mechanism to offer seats to a subset of local exchanges.
- The local exchanges in the state had not matured to a point to participate.
- Committees, advisory groups, separate associations, or informal communications were more appropriate mechanisms for involvement by local exchanges.
- To the extent that state-level HIEs provided resources to local exchanges, there may be a perceived conflict of interest regarding local exchanges' participation in the decision-making processes for funding allocation.

Decision Points

- Which stakeholder groups should be represented on the leadership of the state-level HIE organization?

Recommendations and Rationale

During the MCHIE Governance Team meetings, consensus was achieved regarding the recommendations to include the following stakeholder types in the *Maryland eHealth Collaborative*:

Organization Type	Represented?	Likely Candidates
• Hospitals	Yes	(5) One hospital representative from each of the state's five regions ²⁰
• Providers	Yes	(4) MedChi provider representative, academic provider representative, mental health provider representative, and a nurse representative
• Clinics	Yes	(1) Mid-Atlantic Association of Community Health Centers (MACHC)
• Long-Term Care Facilities	Yes	(1) TBD
• Local HIEs	??	??
• Payers (public & private)	Yes	(3) State Medicaid, CareFirst, Kaiser
• Purchasers	Yes	(1) TBD
• Public Health...State	Yes	(1) State Dept of Health
• Public Health...County/local	Yes	(1) County Health Officer
• Clinical Researchers	Yes	(1) TBD
• Health IT Community	Yes	(1) TBD
• Consumer Organizations	Yes	(1) TBD
• State Government	Yes	(2) MHCC and HSCRC representative
• State Legislature	No	(0)
• Quality Organizations	Yes	(1) Delmarva QIO
• Clinical Laboratories	No	(0)
• Pharmacies	Yes	(1) TBD
• Other(s)	Yes	(1) An academician with expertise in public-private governance
Total		(25)

The MCHIE Governance Team discussed the value of establishing thresholds and the anticipated contributions for the following categories:

- **Hospitals.** With respect to provider settings, the MCHIE Governance Team recommended inclusion of one hospital from each of the five regions in Maryland, in order to reflect the diversity of size, location, and geographic settings across the state. The MCHIE Governance Team indicated that selection of the hospitals could be achieved through a nomination process managed through the Maryland Hospital Association.
- **Long term care facilities.** The MCHIE Governance Team indicated that individuals from long term care facilities would offer valuable perspectives for two use cases in particular: Medication Management and Transfer of Care.

²⁰ The five regions in Maryland, as designated by the *Maryland Physician Workforce Study* (April 2008) are the Eastern, Southern, and Western, Central, and Capital regions.

- **Nurses.** As nurses are integral to care teams and have keen insight into the integration of technology workflow considerations in care settings, the MCHIE Governance Team recommended that the *Maryland eHealth Collaborative* seek a representative from an organization such as the Maryland Nurses Association.
- **Mental health providers.** Because mental health providers and their patients face a unique set of challenges and privacy concerns with regard to the electronic exchange of sensitive personal health information, the MCHIE Governance Team recommended that the *Maryland eHealth Collaborative* seek a representative from the mental health provider community.
- **Health IT experts.** Given the complexity of health IT and HIE, the MCHIE Governance Team recommended that the *Maryland eHealth Collaborative* leadership include an individual with experience in managing and implementing health IT who understands and can explain the intricacies of the technical components.
- **Academician with expertise in governance.** Owing to the unique nature of public-private organizations, the MCHIE Governance Team recommended that at least one member of the *Maryland eHealth Collaborative* leadership group be skilled in facilitation and management of director-level boards in the public and nonprofit sectors.

The MCHIE Governance Team was unable to reach consensus as to whether local HIEs should be included as a component part of the advisory body. Some members thought that participation by local HIEs may lead to the types of challenges and conflict-of-interest described above, while others felt that local HIEs offered unique perspectives and inclusion could help facilitate their buy-in to the statewide policies developed by the governance entity.

Though no recommendations were made, the MCHIE Governance Team also discussed the applicability of adding other groups to the governance leadership, including organizations involved in “pre-hospital care” and pharmacy benefit managers.

F. Accountability Mechanisms

Background

Accountability is a critical element of state-level HIE governance. In order to bring interoperable exchange of health information to scale, all stakeholders – state and local governments, providers, payers, and consumers – must have confidence that the entities participating in the exchange serve the public interest and perform the duties expected of them in a transparent manner that earns public trust.

States, acting primarily through the agencies of state government, have three principle means to protect the public's interests and ensure accountability including (1) direct oversight through legislation or regulation of entities; (2) contracts with specific entities; and/or (3) indirect oversight in which the state designates or confers authority to another organization (e.g., an accreditation body) to develop and manage the evaluation of entities in an industry.

With respect to an accountability framework for HIE, regulators, healthcare stakeholders, and policy makers continue to assess the optimal mix of direct and indirect oversight.²¹ While a comprehensive approach has yet to be achieved, each mechanism presents advantages and drawbacks as discussed below.

- **Direct Oversight via Legislation or Regulations.** Studies of accountability mechanisms suggest that legislation or regulation works best in circumstances where participants are vulnerable and require strong consumer protection, and where the industry lacks a dominant professional group with its own mechanisms for professional discipline and has a limited choice of suppliers, which hampers the effectiveness of market forces in ensuring quality.²²

While many contend that direct oversight is the preferred vehicle for certain aspects of HIE, especially privacy and security, others argue that governments are better at developing regulations and guidelines than tracking or measuring them.²³ Critics also note that rules can be difficult to update once codified in laws or regulation. Legislation, which is subject to the political process, can be more even more challenging to adapt effectively.

- **Direct Oversight via Contracts.** If projects are supported with public funding, state government can use contracts to ensure that state funds are used in a way that promotes the policy goals and protects the public's interest. As an accountability mechanism, contractual authority affords the state direct oversight and does not require the creation of new external authorities and processes. Such contracts, however, are limited in duration and do not provide a vehicle for the ongoing monitoring and protecting of the public's interests. Moreover, the contractual terms only bind entities that receive state funds, and entities may be able to circumvent policies by choosing not to receive state funding.

²¹ New York eHealth Collaborative. "Interoperable Health Information Exchange Policy, Governance, and Accountability: Examining the Potential Role for RHIO Accreditation in New York's Health IT Strategy." September 2008. Available online at http://www.nyehealth.org/files/File_Repository16/pdf/NY_RHIO_Accred_Paper.pdf

²² Eleanor D. Kinney, "Private Accreditation As A Substitute For Direct Government Regulation In Public Health Insurance Programs: When Is It Appropriate?" 57 *Law and Contemporary Problems*. 1994.

²³ Institute of Medicine. *Improving the Quality of Long-Term Care*. 2001.

- **Indirect Oversight via Voluntary Accreditation.** In contrast to regulation, accreditation can be more adaptive to market needs. Through research and staying abreast of activities within their profession, accreditation organizations seek to promote use of best practices and continuous process improvement for the entities they accredit.

Accreditation organizations also aim to maintain flexibility in program structure to support innovation as a market evolves. For example, organizations will often specify standards that accredited entities must meet, but will not mandate the means by which an accredited entity must meet them so that innovative practices are given room to develop. When this type of flexibility is made an integral component of program structure, accreditation processes have the potential to improve the organizational efficiencies of nascent entities and to serve as a “roadmap” by which these organizations can plot and assess their development.

On the other hand, critics of accreditation argue that accreditation lacks the sanctioning strength of government and can be too closely aligned with the industry it evaluates.

The use of accreditation as a government oversight mechanism presupposes the existence of a qualified private organization that can effectively serve the government’s interests. While no organizations currently accredit HIEs or RHIOs, Electronic Health Network Accreditation Commission (EHNAC), a national accreditation body for claims clearinghouses and other electronic networks, has recently launched a process to develop criteria for HIE accreditation.²⁴

Decision Points

- What processes should be used to ensure oversight of the exchange of health information?
- What will be the relationships between key stakeholders?

Recommendations and Rationale

Recommendation: Enforcement through Contracts & Regulations

MCHIE recommends that Maryland require that all participants in statewide HIE abide by the policies, standards, and guidance developed for HIE. Compliance with the agreed-upon statewide policies should be established and enforced through contracts and other incentives for adherence.

For oversight activities related to imposing penalties for breach or other actions harmful to consumers, Maryland state government should continue to exercise its regulatory oversight authorities.

As some entities may forgo state funding and incentives and choose to develop HIE capabilities outside the statewide HIE governance framework, MCHIE recommends that the State government monitor HIEs’ conformance to statewide policies and assess the need for additional enforcement through accreditation and/or regulation.

²⁴ The Electronic Healthcare Network Accreditation Commission (EHNAC) is an organization that accredits entities that send or receive HIPAA-regulated transactions. Details on EHNAC’s program to accredit HIE is available online at http://ehnac.org/pr_2009-0113.html.

Recommendation: Enforcement through Contracts & Regulations

Rationale: HIEs represent a very early-stage movement for governing the exchange of health information. Information policies governing their oversight need to evolve through participatory public processes and have sufficient flexibility to accommodate innovations and learning from the field.

Utilizing a mix of contractual authority and the state’s existing regulatory authority is likely to enhance the state’s ability to oversee and protect the public’s interests. As practical experience is gained through implementation, the state could, if necessary, create additional enforcement mechanisms through stronger regulations and/or accreditation.

The figure below illustrates the proposed flow of accountability among the various HIE stakeholders.

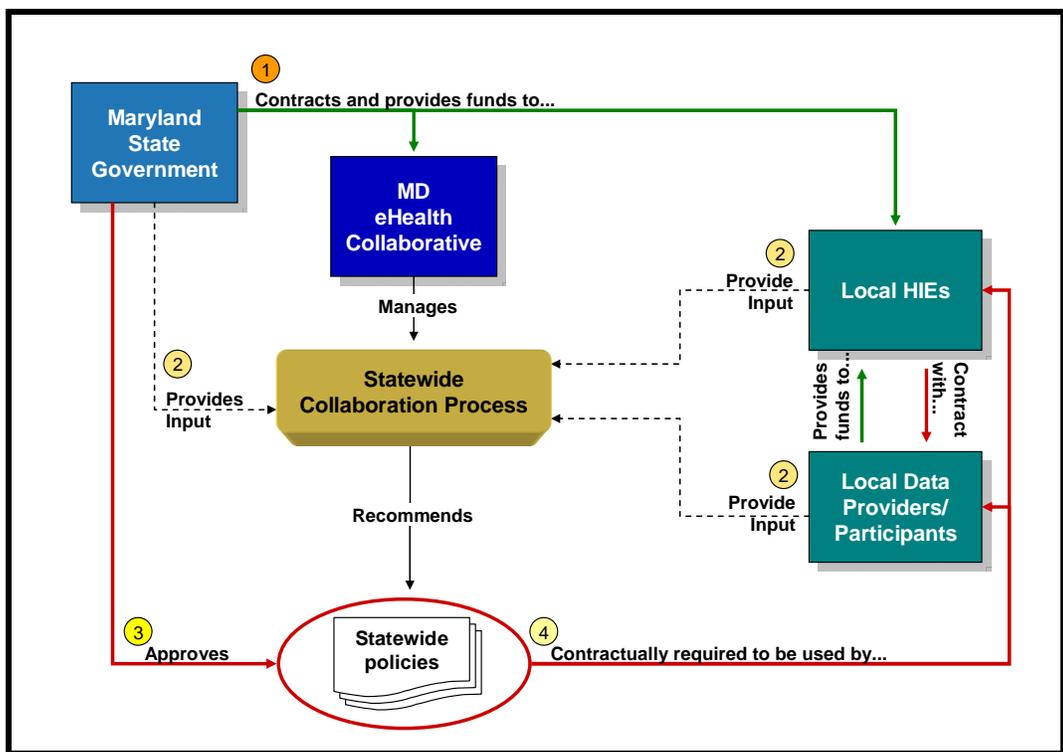


Figure 3: Flow of Accountability Across HIE Stakeholders

In Step 1, the Maryland state government would provide funding through contracts to create the statewide collaborative entity, the *Maryland eHealth Collaborative*, and support local HIEs’ development of selected use cases and capabilities.

The *Maryland eHealth Collaborative* would oversee and manage the statewide collaborative process, which would include working groups drawing input from representatives from all the stakeholder groups (Step 2). The statewide collaborative process would develop and advance recommendations on detailed privacy and security policies, technical specifications, and implementation guides.

Once statewide policies are approved by the *Maryland eHealth Collaborative*, they would be advanced as formal recommendations to the state for its review (Step 3). Local HIEs in Maryland that receive funds would be required to implement any approved statewide policies (Step 4).

G. Measuring and Evaluating Progress

Background

Success of state-level HIEs will be based on their ability to realize their objectives and deliver demonstrable value. As part of their roadmaps and business plans, state-level HIEs have identified objectives and developed mechanisms to gauge progress toward their articulated goals.

In Minnesota, the state-level HIE, the Minnesota eHealth Initiative, calibrates its activities to a staging model developed by the eHealth Initiative as depicted by the illustration below.²⁵

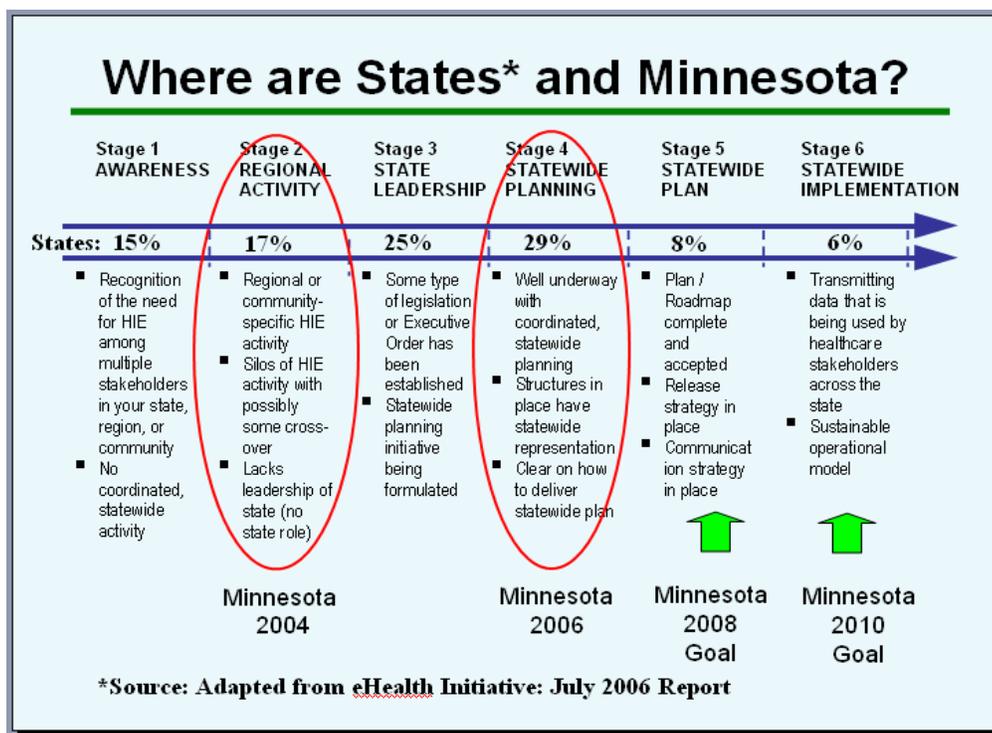


Figure 4: Minnesota’s state-level HIE implementation timeline

Against these broad parameters, a few state-level HIEs have developed more granular objectives and measures. In Oregon, the state-level HIE governance entity, the Health Information Infrastructure Advisory Council (HIIAC), utilizes a logic model built around inputs, processes, and outcomes to identify the activities and delineate milestones and anticipated results for the statewide HIE activities.²⁶

²⁵ Accelerating e-Health in Minnesota: 2007 Minnesota e-Health Initiative Report to the Minnesota Legislature. Minnesota Department of Health (January 29, 2007). Available online at <http://www.health.state.mn.us/e-health/legrpt2007.pdf>.

²⁶ Health Information Infrastructure Advisory Committee (HIIAC) Meeting Notes for Thursday, June 19, 2008. Available online at <http://www.oregon.gov/OHPPR/HIIAC/MeetingMaterials.pdf>.

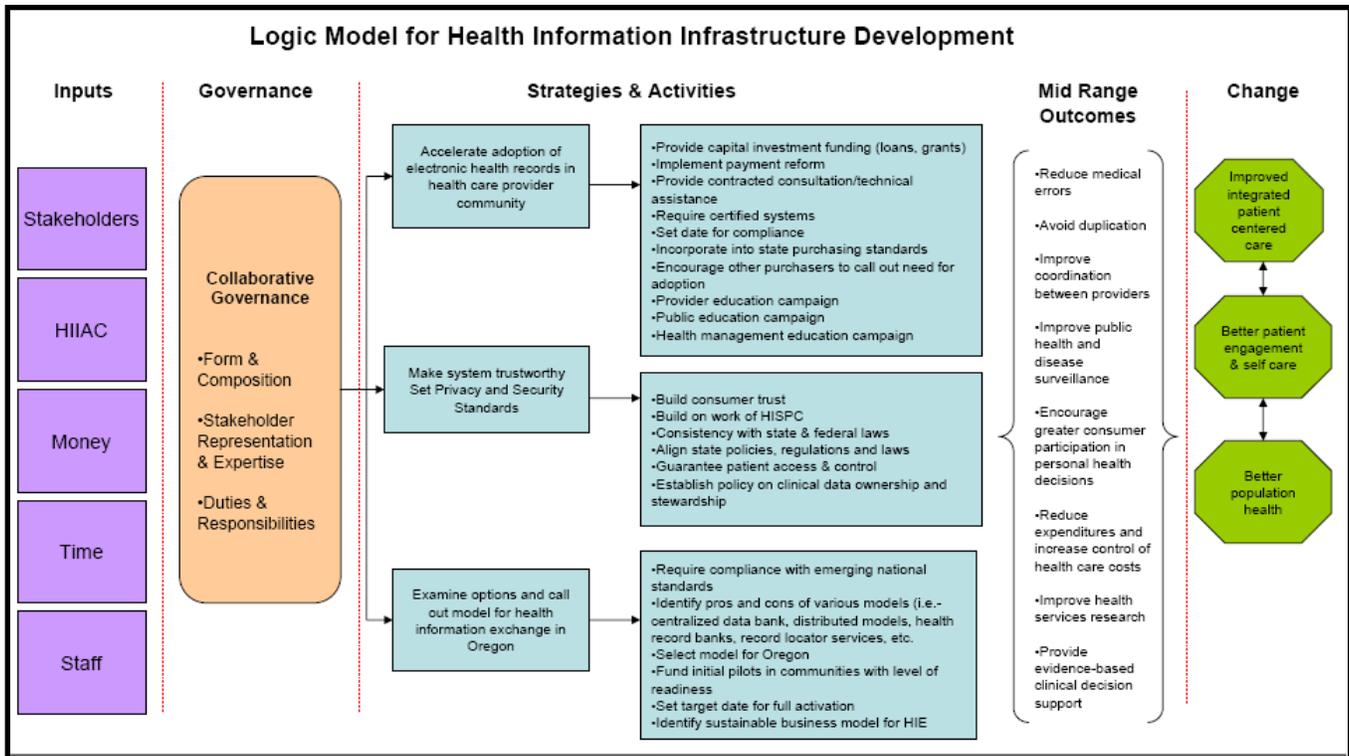


Figure 5: Oregon’s proposed evaluation framework for HIE implementation and health IT adoption

For the handful of states that currently measure HIE progress and health IT adoption, most have focused their efforts on near-term process measures as the table below illustrates.

Measures	Florida	Minnesota	Tennessee
Health IT Adoption: <i>EHR use</i>	✓	✓	
Health IT Adoption: <i>eRx use</i>	✓	✓	✓
Health IT Adoption: <i>Internet access</i>	✓		✓
Data Exchange: <i>Number and types of participants</i>	✓		
Data Exchange: <i>Volume of transactions</i>	✓		

Decision Points

- What variables will be measured?
- When and how should data be collected?
- How frequently should reports be issued?

Recommendations and Rationale

Recommendation: Collect Data, Report on Progress

MCHIE recommends that the *Maryland eHealth Collaborative* work with local HIEs to collect data and assess the impact of HIE activities in the state during the design, prototype, and implementation phases. As a condition of the receipt of state funding, HIEs would be required to collect and provide data to the *Maryland eHealth Collaborative* and participate in other state-sponsored evaluation activities.

As a condition of its receipt of state funding, the *Maryland eHealth Collaborative* would provide an annual report to the public. The report would analyze the previous year's use and impact data, progress against goals and anticipated milestones, challenges and obstacles encountered, and recommendations for any corrective actions.

Rationale: Given the level of investment and the anticipated breadth and depth of stakeholder involvement, tracking and assessing progress will provide valuable feedback to financiers and stakeholders.

The plan to evaluate statewide HIE should be based on the hypotheses that HIEs:

1. Improve the efficiency of care in all care settings, as manifest by:

- Lower rates of testing (expenses per encounter)
- Lower rates of admission

As reported by a variety of researchers, HIE is likely to favorably impact the rate of radiology and laboratory diagnostic/therapeutic testing. However, this research literature provides minimal guidance on the definition of redundant tests. A research team at Vanderbilt assessed redundancy based on the stability characteristics of tests.²⁷ Low stability tests are those whose results could change rapidly such as CBC or EKG. High stability tests are those whose results are unlikely to change rapidly (i.e., if repeated within two weeks) such as HbA1C, HIV or most radiology tests. A test can be categorized as "redundant" if either (a) it is a high stability test that has been repeated too soon, or (b) it is a low stability test that has been normal when last checked.

It is assumed that the availability of data through HIE will greatly impact the duplication of high stability tests. However, if there is no suspicion of an acute process, knowledge of recent normal results may allow the clinician to avoid duplicating an unnecessary low stability test as well.

2. Improve the workflow of the environments in which it is used, by

- Reduce time spent seeking information
- Reduce time spent using computer technology during patient care

A key, long-term expectation of HIE is that this tool will enable care services to be rendered as efficiently as possible. Key determinants of efficiency include, but are not limited to, staff-to-patient ratios, the number and complexity of tests and procedures performed for diagnosis and treatment, and the availability of knowledge about treatment the patient has

²⁷ Vanderbilt University Medical Center. "Evaluation Plan: Tennessee State Regional Demonstration Project." 2006.

received recently at other facilities. Studies of improved workflow should take into consideration the interrelationship between efficiency of information flow during the process of care and the efficiency with which care is rendered overall.

3. Improve the outcomes of specific clinical conditions, as evidenced by

- Increased number of patients receiving preventive screenings and immunizations
- Reduced number of adverse drug events related to errors in medication
- Increased number of patients receiving treatment in accordance with recommended, evidence-based guidelines
- Improved health outcomes for patients with diabetes, cardiovascular disease, hypertension and asthma

HIE has the potential to bring timely and accurate data to the clinical decision-making process and improve the ability for clinicians, patients, and caregivers to coordinate care. Studies that assess these types of impacts take time to develop, can involve complex evaluation methodologies, and require ongoing expertise to monitor, collect, analyze, and report on data. However, as a significant component of the value of Maryland's investment in HIE will be assessed against its ability to improve care, the MCHIE Governance Team recommends that the State allocate resources for these types of evaluation efforts.

The table below highlights potential metrics to assess the levels and types of HIE activities and system usage.²⁸ A more detailed plan should be developed in conjunction with experts in HIE evaluation during the initial design phase of the statewide HIE effort.

Measure	Description	Data Source(s)	Reporting Frequency
Number of facilities	Number of facilities (i.e., hospitals, clinics, provider practices, laboratories, payers, etc) exchanging data.	Implementation records maintained by the local HIE	Monthly
Number of users	Number of individuals (i.e., registrars, physicians, and nurses) who have enrolled, are using, or discontinued use of systems.	Local HIEs and participating entities assess enrollment and access logs	Monthly
Frequency of usage	Number of system accesses over specific time frame.	Access logs	Monthly

²⁸ Candidate measures have been adapted from the following sources: (1) Vanderbilt University Medical Center. "Evaluation Plan: Tennessee State Regional Demonstration Project." 2006; (2) Agency for Healthcare Research and Quality. "Evaluation Toolkit for Data Exchange Projects." 2008; and (3) Florida Agency for Health Care Administration. "Florida's RHIO Initiative: Recycling Lessons Learned into New Strategies for Health Information Exchange." February 2008.

Measure	Description	Data Source(s)	Reporting Frequency
Volume of usage	Volume of use could be further segregated by (1) data or message types for particular use cases, and/or (2) the number of patients for whom the system is queried or tests ordered.	Access logs	Monthly
Data quality	Assess quality of data based on the existence and prevalence of missing data elements, categorization errors, parsing errors or inaccurate assignment of data.	Random sample of HIE data	Quarterly
System performance	Overall productivity of the system, tied to availability, throughput, and response time.	Performance measures collected prospectively from system log data	Quarterly
User satisfaction	Assess clinicians' satisfaction and pair it with data about their system use (site(s) of use, number of months using the system, patients accessed) and their role (e.g., MD, registrar, nurse).	Surveys of end users at participating entities	Annual

H. Key Functions and Tasks

Background

Studies have found that the ability of a state-level HIE initiative to establish and nurture a trusted, independent and collaborative platform for education, negotiation and decision-making among diverse stakeholders, often without a history of collaboration, is an essential element of their obligations and their success.²⁹

An assessment of the relative rank of the elements of convening and coordination functions is provided below. Representatives of 13 state-level HIEs provided an ordinal rank for each task listed based on its importance to the facilitation of HIE. The tasks ranked most important by the 13 state-level HIE representatives received a “1”, the second most important a “2”, etc. The table below provides the average ordinal rank for the tasks to support the convening function.³⁰

Convening Function Task Name and Description	Average Ordinal Rank 1 = Most important 5 = Least important
Advocate on behalf of local stakeholders to advance statewide HIE Provide proactive guidance to policymakers on legislation or regulations that affect HIE initiatives (i.e., white papers, letters of support, etc.). Support and/or organize public efforts to advocate on behalf of policies and legislation that support health IT and statewide HIE.	2.1
Inform policy development to advance statewide HIE Inform development of policy options. Plan and/or carry out public outreach and communication campaigns to educate stakeholders regarding the need for and benefits of HIE.	2.2
Facilitate consumer input Create mechanisms and procedures by which consumers can give input on HIE initiatives.	3.1
Track, assess & distribute information on HIE efforts <i>within the State</i> Track and assess policy and regulations, proposed legislation or regulations, activities, and strategic direction related to HIE issues such as privacy and security (i.e., data access, use, and control) and technology considerations (i.e., standards, tools/applications, services). Survey and maintain an inventory of local HIEs activities. Distribute information to stakeholders.	3.4
Track, assess and distribute information on <i>regional and national</i> HIE efforts Track and assess national policy and regulations, proposed legislation and regulations, funding opportunities, and strategic direction related to HIE issues such as privacy and security (i.e., data access, use, & control), technical considerations (i.e., standards, tools/applications, services), and quality and value efforts. Distribute information to stakeholders.	4.7

²⁹ American Health Information Management Association. “State-Level Health Information Exchange: Roles in Ensuring Governance and Advancing Interoperability Preliminary Report.” September 28, 2007.

³⁰ American Health Information Management Association. “State Level Health Information Exchange: Roles in Ensuring Governance and Advancing Interoperability Final Report Part I.” March 10, 2008. Available online at <http://www.slhie.org/Docs/FinalReportPart1.8.pdf>.

HIE coordination activities foster processes of negotiation and decision-making to clarify participant roles and responsibilities, define obligations and benefits, establish levels of accountability, institute enforcement mechanisms, align efforts and help optimize resource utilization.

As state-level HIE initiatives mature, *governance* activities typically expand from engendering initial stakeholder collaboration to fostering agreements on the HIE policies and practices needed to support interoperability across local and statewide entities, different types of providers, and diverse data sources and data-exchange participants. The table below provides the average ordinal rank for the tasks to support the coordination function.

Coordination Function Task Name and Description	Average Ordinal Rank 1 = Most important 9 = Least important
Technical-Roadmap Develop and maintain technical roadmap for statewide HIE.	2.3
Privacy-Disclosure & Use Policies Coordinate the development of <i>disclosure</i> and <i>use</i> of health information for statewide data exchange.	3.5
Security-Procedures Coordinate the development of security procedures, including authentication, authorization, access control, audit, etc.	3.5
Technical-Interface Requirements Establish interface requirements for entities to participate in statewide data sharing.	4.6
Privacy-Consent Approaches Coordinate the development of <i>consent</i> approaches for statewide data exchange.	4.7
Technical-Standards Conformance Ensure that data providers and local HIEs conform to national standards for health info exchange.	5.6
Technical-Quality of Data Establish and enforce rules for quality (i.e., accuracy, timeliness, etc.) of data exchanged statewide.	5.8
Quality Initiatives Coordinate quality improvement efforts within the state. This would also include newly emerging "value" efforts.	6.4
Transparency Support the development and operation of efforts to publicly release data regarding state providers' performance on various measures.	7.7

Decision Points

- What will be the primary functions of the collaborative governance process in Maryland?

Recommendation and Rationale

The MCHIE Governance Team recommends that the *Maryland eHealth Collaborative* perform the tasks identified in the table below.

Tasks	Discussion
1. Develop strategic plan and roadmap	Developing a strategic plan and roadmap provides the foundation for managing implementation and evaluating progress.
2. Develop statewide policies to guide implementation	Oversee the process to develop policy guidance with respect to privacy, security, and technical implementation.
3. Communicate with stakeholders to advance HIE	Provide proactive guidance to policymakers on legislation or regulations that affect HIE initiatives (i.e., white papers, letters of support, etc.). Support and/or organize public efforts to advocate on behalf of policies and legislation that support health IT and statewide HIE.
4. Coordinate with statewide safety, quality and value efforts	As an enabler of quality and value, HIE efforts should be coordinated with existing quality improvement efforts in Maryland, including the Maryland Patient Safety Council and various healthcare reimbursement reform efforts in the public, private, and nonprofit sectors.
5. Track, evaluate, and report on health IT & HIE progress	The creation and maintenance of a clearinghouse of HIE information and activities occurring within the state helps local exchanges share lessons and track their progress relative to other efforts. Collecting objective information on HIE activities across the state will help decision makers assess the results of HIE investments and the impact of regulations and rule making.
6. Track and engage HIE efforts in neighboring states	Maryland has significant cross-border patient flow and policy coordination considerations that necessitate an ongoing knowledge of other states' efforts (particularly Delaware, the District of Columbia, New Jersey, Pennsylvania, Virginia, and West Virginia).
7. Negotiate on behalf of HIEs with vendors	As candidate services for statewide implementation are identified, a key driver of cost reductions will be the extent to which Maryland can negotiate with vendors for discounts.

I. Implementation

Background

States typically organize their collaborative process around functional workgroups responsible for recommending policies, standards, technical approaches, and services to the statewide oversight body. Despite the differences in form and governance structure, states with separate governance and technical operations have organized similar workgroups as the table below illustrates.

	Arizona <i>AzHeC</i>	Minnesota <i>Minnesota e-Health Initiative Advisory Committee</i>	New York <i>NYeC's Policy and Operations Council</i>
Privacy and Security	Legal Committee	Privacy and Security Advisory Group	Privacy and Security Workgroup
Technical	Clinical/Technical Committee	Standards Workgroup	Protocols and Services Workgroup
Clinical	Clinical/Technical Committee	N/A	Clinical Priorities Workgroup
Health IT Adoption	e-Prescribing Steering Committee	Effective Use of EHRs Workgroup; e-Prescribing Workgroup	EHR Collaborative Workgroup
Education and Outreach	Education and Outreach Committee	Communications Advisory Workgroup	N/A
Consumer	Consumer Advocacy Committee	N/A	N/A
Budget/Finance	Budget/Finance Committee	N/A	N/A
Membership	Membership Committee	N/A	N/A

Typically, the workgroups support the convening and analysis activities and consist of representatives from the provider, consumer, patient advocacy, health insurer, and local HIE communities. The workgroups can be staffed and supported by representatives from the statewide governance entity, state government, and/or subject matter experts retained on contract. For illustration purposes, a description of the roles and responsibilities for participants in New York's statewide collaborative process is highlighted below:

Workgroup Chairs/Vice-Chairs

- Call and facilitate meetings
- Foster consensus among workgroup participants to make decisions
- Resolve issues and disagreements, or if unresolved refer them to the oversight body
- Work with staff consultants to develop agendas and meeting materials
- Work with staff consultants to develop project plans
- Create subgroups to work on specific areas as necessary
- Where appropriate request liaisons from other workgroups
- Arrange to provide liaisons from own workgroup
- Lead workgroup in its review of other workgroup products
- Lead discussion for providing final disposition on public comments

Workgroup Members

- Regularly attend meetings and actively participate in work efforts, including subgroups
- Communicate workgroup activities and decisions back to their organizations
- Represent their organizations; bring issues and feedback forward from their organizations
- Comply with workgroup decisions and fully integrate workgroup products into implementation plans
- Accept and complete action items from chair to advance progress of workgroup
- Represent the opinions of their workgroups at those meetings
- Provide regular progress reports to their workgroups

Workgroup Staff and Consultants

- Develop agendas and meeting materials with Chairs
- Develop and manage project plans, including deliverables, milestones and timelines, in coordination with chairs
- Support meeting facilitation
- Ensure compliance with workgroup policies and procedures
- Draft policies and develop work products
- Keep minutes, record action items and decisions
- Maintain workgroup membership lists
- Submit monthly reports to oversight body on workgroup progress
- Log comments provided during public comment period and document formal disposition

The statewide HIE effort in Maryland will require funding to support the core governance tasks and statewide collaborative process identified in the previous sections. Costs for creating and supporting the ongoing governance capacity for statewide HIE vary.

In Massachusetts, the Massachusetts Health Data Consortium (MHDC) provides convening and coordinating functions for a number of HIE-related activities in Massachusetts. MHDC staff estimate the fully-loaded cost of the share of their convening activities to be approximately \$125,000 per year, spread across multiple individuals. With respect to coordination of privacy and security efforts, MHDC's level of effort to support the work of the HISPC is approximately \$500,000 per year. MHDC supports these governance activities through a combination of contracts, grants, and membership dues.

In New York, the state allocated 5% of its \$105 million health IT investment to support the state-level HIE governance entity, NYeC, the supporting working groups, and subject matter experts in the areas of privacy and security, technical implementation, health IT adoption, and finance. NYeC estimates that it costs approximately \$1 million to support costs for three staff, office space, meeting, travel, and publications. For consulting and advisory services, NYeC utilizes the remaining allocation of state funds (approximately \$1.5 million annually) and additional funding from philanthropies.

Decision Point

- How should the governance functions be staffed, organized, and supported?

Recommendations and Rationales

Recommendation: Initial Collaborative Framework

The MCHIE Governance Team recommends that the statewide collaborative process initially consist of three workgroups:

- Clinical Workgroup
- Technical Architecture and Standards Workgroup
- Privacy and Security Workgroup

Each workgroup should be chartered to include representatives from the appropriate constituencies and have explicit requirements and timelines for expected deliverables. To support the three initial workgroups, additional teams focused on cross-cutting issues (e.g., planning and assessment, communications, education and outreach, and sustainability) should be considered.

Rationale: The proposed workgroups have been modeled after approaches in other states and will provide detailed policies throughout implementation.

Recommendation: Dedicated Funding Source for Collaborative Process

MCHIE Governance Team recommends that the MHCC and HSCRC provide funding through a contract to create and support the initial operation of the *Maryland eHealth Collaborative* and the statewide collaborative process. Based on estimates from other states, required funding will range from \$1.0 to \$1.5 million annually.

Rationale: Given the importance of creating a forum for stakeholders to develop consistent, statewide policies to guide implementation, adequate support for the convening and coordination function will be a critical determinant of success for statewide HIE.

Health Information Exchange: The electronic movement of health-related information among organizations according to nationally recognized standards. (*Source:* US Department of Health and Human Services Office of the National Coordinator for Health IT Reports; <http://www.hhs.gov/healthit/resources/reports.html>).

Interoperability: Interoperability means the ability of health information systems to work together within and across organizational boundaries in order to advance the effective delivery of healthcare for individuals and communities. (*Source:* HIMSS Interoperability Definition; http://www.himss.org/content/files/interoperability_definition_background_060905.pdf).

Office of the National Coordinator for Health Information Technology. Created by an Executive Order in 2001, the Department of Health and Human Services Office of the National Coordinator for Health Information Technology (ONC) had led the federal efforts to advance the adoption of health information technology (IT) and expansion of health information exchange (HIE). ONC built its strategy around four core functional components: (1) policies relating to privacy and security; (2) standards, networking, and interoperability; (3) adoption of technology and information use; and (4) collaborative governance and decision-making.

Public Instrumentalities: Instrumentalities denotes entities closely affiliated – generally by government ownership or control – with state or local governments. Whether an entity is an "instrumentality" of a governmental unit is determined based on the following factors: (1) whether it is used for a governmental purpose and performs a governmental function; (2) whether it performs its function on behalf of one or more states or political subdivisions; (3) whether private interests are involved, or whether states or political subdivisions have the powers and interests of an owner; (4) whether control and supervision of the organization is vested in public authority or authorities; (5) whether express or implied statutory or other authority is needed to create and/or use the entity; and (6) the degree of the organization's financial autonomy and the source of its operating expenses. (*Source:* Internal Revenue Service; <http://www.irs.gov/pub/irs-tege/eotopice90.pdf>.)

Public-Private Partnerships: Public-private partnership (PPP) describes a government service or private business venture which is funded and operated through a partnership of government and one or more private sector companies. (*Source:* Wikipedia; http://en.wikipedia.org/wiki/Public-private_partnership.)

Regional Health Information Organization: A health information organization that brings together healthcare stakeholders within a defined geographic area and governs health information exchange among them for the purpose of improving health and care in that community. (*Source:* US Department of Health and Human Services Office of the National Coordinator for Health IT Reports; <http://www.hhs.gov/healthit/resources/reports.html>.)

State Grants to Promote Health IT (Section 3013)

A. General. The Secretary, acting through the National Coordinator, shall establish a program in accordance with this section to facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards.

B. Planning Grants. The Secretary may award a grant to a State or qualified State designated entity that submits an application to the Secretary at such time, in such manner, and containing such information as the Secretary may specify, for the purpose of planning activities described.

C. Implementation Grants. The Secretary may award a grant to a State or qualified State designated entity that has submitted, and the Secretary has approved, a plan (regardless of whether such plan was prepared using amounts awarded under this paragraph); and submits an application at such time, in such manner, and containing such information as the Secretary may specify.

D. Use of Funds. Amounts received under a grant under subsection shall be used to conduct activities to facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards through activities that include—

- 1) Enhancing broad and varied participation in the authorized and secure nationwide electronic use and exchange of health information;
- 2) Identifying State or local resources available towards a nationwide effort to promote health IT;
- 3) Complementing other Federal grants, programs, and efforts towards the promotion of health IT;
- 4) Providing technical assistance for the development and dissemination of solutions to barriers to the exchange of electronic health information;
- 5) Promoting effective strategies to adopt and utilize health IT in medically underserved communities;
- 6) Assisting patients in utilizing health IT;
- 7) Encouraging clinicians to work with Health Information Technology Regional Extension Centers, to the extent they are available and valuable;
- 8) Supporting public health agencies' authorized use of and access to electronic health information;
- 9) Promoting the use of EHRs for quality improvement including through quality measures reporting; and
- 10) Such other activities as the Secretary may specify.

E. Plan

- 1) General. A plan described in this subsection is a plan that describes the activities to be carried out by a State or by the qualified State-designated entity within such State to facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards and implementation specifications.
- 2) Required Elements. A plan described in paragraph (1) shall—
 - a. be pursued in the public interest;

MCHIE Statewide HIE Plan

ATTACHMENT B: SUMMARY OF PROPOSED HEALTH IT STIMULUS REQUIREMENTS

- b. be consistent with the strategic plan developed by the National Coordinator,
- c. include a description of the ways the State or qualified State-designated entity will carry out the activities; and
- d. contain such elements as the Secretary may require.

F. Qualified State-Designated Entity. For purposes of this section, to be a qualified State-designated entity, with respect to a State, an entity shall—

- 1) be designated by the State as eligible to receive awards under this section;
- 2) be a not-for-profit entity with broad stake-holder representation on its governing board;
- 3) demonstrate that one of its principal goals is to use IT to improve healthcare quality and efficiency through the authorized and secure electronic exchange and use of health information;
- 4) adopt nondiscrimination and conflict of interest policies that demonstrate a commitment to open, fair, and nondiscriminatory participation by stakeholders; and
- 5) conform to such other requirements as the Secretary may establish.

G. Required Consultation. In carrying out activities described, a State or qualified State-designated entity shall consult with and consider the recommendations of—

- 1) healthcare providers (including providers that provide services to low income and underserved populations);
- 2) health plans;
- 3) patient or consumer organizations that represent the population to be served;
- 4) health information technology vendors;
- 5) healthcare purchasers and employers;
- 6) public health agencies;
- 7) health professions schools, universities and colleges;
- 8) clinical researchers;
- 9) other users of health IT such as the support and clerical staff of providers and others involved in the care and care coordination of patients; and
- 10) such other entities, as may be determined appropriate by the Secretary.

H. Continuous Improvement. The Secretary shall annually evaluate the activities conducted and shall, in awarding grants under this section, implement the lessons learned from such evaluation in a manner so that awards made subsequent to each such evaluation are made in a manner that, in the determination of the Secretary, will lead towards the greatest improvement in quality of care, decrease in costs, and the most effective authorized and secure electronic exchange of health information.

I. Required Match

- 1) General. For a fiscal year (beginning with fiscal year 2011), the Secretary may not make a grant under subsection to a State unless the State agrees to make available non-Federal contributions (which may include in-kind contributions) toward the costs of a grant awarded in an amount equal to—
 - a. for fiscal year 2011, not less than \$1 for each \$10 of Federal funds provided under the grant;

MCHIE Statewide HIE Plan

ATTACHMENT B: SUMMARY OF PROPOSED HEALTH IT STIMULUS REQUIREMENTS

- b. for fiscal year 2012, not less than \$1 for each \$7 of Federal funds provided under the grant; and
 - c. for fiscal year 2013 and each subsequent fiscal year, not less than \$1 for each \$3 of Federal funds provided under the grant.
- 2) Authority to Require State Match for Fiscal Years Before Fiscal Year 2011. For any fiscal year during the grant program under this section before fiscal year 2011, the Secretary may determine the extent to which there shall be required a non-Federal contribution from a State receiving a grant under this section.

MCHIE Statewide HIE Plan

ATTACHMENT C: GOVERNANCE APPROACHES IN OTHER STATES

New York

In March 2005, HHS Secretary Mike Leavitt and New York Governor George Pataki announced a reform plan for New York's Medicaid program that would include, among other focus areas, investing in e-Prescribing, EMRs, and RHIO activities. This waiver program is known as the Federal-State Health Reform Partnership and will reinvest \$1.5 billion of savings in federal funding for these and other purposes.

In fall 2005, the New York State Department of Health announced the availability of funds under the Health Care Efficiency and Affordability Law for New Yorkers (HEAL NY) Grant Program. HEAL NY is a multiyear, multiphased program that supports development and investment in health IT initiatives on a regional level. The HEAL NY phase 1 grant process provided \$52 million to 26 grantees for health IT and HIE efforts. HEAL NY phase 5 grants, which will provide an additional \$105 million to support RHIOs, will be released in spring 2008.

In fall 2006, the New York eHealth Collaborative (NYeC) was incorporated as an independent public-private partnership to serve as a leader and point of convergence for healthcare stakeholders across the state to build consensus on health IT policy priorities and to collaborate on implementation efforts.

In January 2007, the Office of Health Information Technology Transformation (OHITT) was created to provide guidance to state and private-sector efforts to improve healthcare quality, accountability, and efficiency through widespread deployment of health IT. OHITT also oversees the HEAL NY grantees.

HIE Activities:

- ***Local HIE Efforts:*** By virtue of significant state funding, there are eight local HIE initiatives in the state of New York.
- ***Chartered Value Exchanges:*** As of February 2008, HHS designated two entities in New York as Chartered Value Exchanges: the New York Quality Alliance and the Niagara Health Quality Coalition.
- ***Statewide Data Activities:*** New York State Department of Health manages the Electronic Medicaid Program of New York State, a database that provides Medicaid eligibility verification to service providers, Medicaid claims payments, and managed care broker enrollment.
- ***State Registries:*** New York State maintains registries for immunization, cancer, and prescription drug monitoring.

MCHIE Statewide HIE Plan
ATTACHMENT C: GOVERNANCE APPROACHES IN OTHER STATES

Organizational Relationships: The proposed organizational relationship of entities is articulated in the New York State Department of Health’s HEAL 5 funding solicitation.³¹

A central strategic focus of New York State’s efforts is to advance interoperability through the development and implementation of a shared health information infrastructure based on a community-driven model available to all providers, payers, and patients. The HIE will evolve in two layers: a *statewide* framework of rules and policies that facilitates exchange between multiple networks at the *local* level. In this two-layer model, NYeC, with state funding, will support the creation and deployment of common policies, technical standards, and protocols, as well as regional bottom-up approaches that allow local communities to structure their own efforts on the basis of clinical and patient priorities.

At the state level, the expectation is that there will not be a single central repository or HIE. Instead, OHITT envisions the evolution of SHIN-NY, which will be responsible for a set of agreed-upon rules, policies, and standards that facilitate the flow of health information across entities.

A portion of the state’s \$105 million HEAL 5 investment will be used to support the state-level activities. First, OHITT will commit \$5 million over two years to the public-private partnership, NYeC, which will serve as a multistakeholder, consensus-driven entity that discusses, analyzes, and makes decisions regarding health information policies and standards for New York.

NYeC	
Annual Budget	Approximately \$1.0 million for staff and costs for meetings, conference calls, travel, and publications
Staff	1 Executive Director 2 program staff members focusing on communications 1 controller 2 administrative assistants

At the local level, RHIOs are being created to serve as the entities that govern HIE in their regions. Funds from HEAL 1 supported the creation (or expansion) of 13 RHIOs across the state. RHIOs will oversee the development of connections between local healthcare providers and ensure they conform to the SHIN-NY policy, privacy, and technical framework.

³¹ NY State Office of Health Information Technology Transformation. *HEAL NY Phase 5 Health IT RGA Section 7.2: Technical Discussion Document: Architectural Framework for New York’s Health Information Infrastructure.*

MCHIE Statewide HIE Plan
ATTACHMENT C: GOVERNANCE APPROACHES IN OTHER STATES

Tennessee

In his inaugural speech in 2003, Governor Phil Bredesen announced his intentions to reform the use of IT in healthcare. In 2004, Tennessee formally began this process when the MidSouth eHealth Alliance (MSeHA), a Memphis-area RHIO, was created with a multiyear grant of \$4.8 million federal from the AHRQ, \$7.2 million in state funding, and in-kind contributions from Vanderbilt University. MSeHA brings clinical patient encounter data from 15 area hospitals, 16 clinics, one university medical group, and one Medicaid managed care organization (MCO) to bear at the point of care. This initiative began in hospital emergency departments and has since expanded to include safety net clinics and hospitalists. MSeHA EHRs include admissions and discharge information, laboratory results, radiology results, transcriptions, and other clinical and demographic encounter information. Actively sharing data since June 2006, MSeHA has 1.35 million records for 950,000 unique patients. Approximately 30,000 records are added daily.

In 2005, Tennessee's Medicaid program, TennCare, contracted with Shared Health to provide clinical health records based on claims data for all TennCare enrollees. Sharing data among practitioners since June 2006, Shared Health has now amassed records for almost 2 million Tennesseans, or one-third of the state's population.

In 2006, Governor Bredesen issued an executive order to form Tennessee's eHealth Advisory Council, supported by the Office of eHealth Initiatives in the Tennessee Department of Finance and Administration. The Council includes public and private stakeholders from across the state, representing payers, employers, providers, and HIEs. Tennessee's eHealth Council has established the following roadmap to guide stepwise progression toward the ultimate goal of having longitudinal EHRs for all Tennesseans.

The Council's goal is to accelerate adoption of EHRs by building in an incremental fashion such that incremental success can build momentum. Initially, the Council's efforts were directed toward building the legal framework to forge trust and establish rules of engagement for HIE in Tennessee. Moving forward, Tennessee's roadmap includes milestones that will continue to strengthen the basic infrastructure hosting the Tennessee eHealth Exchange Zone. The Council collaborates among stakeholders to incubate initiatives, as well as to develop standards for HIE, including best practices, recommended minimum core data set, interoperability, and federated identity management to facilitate secure, single-sign-on capability.

In support of the Council and related projects, the State Office for eHealth Initiatives has a \$650,000 administrative budget to cover four full-time staff members, offices, overhead, meetings, supplies, and all other aspects of council administration.

Tennessee State Office for eHealth Initiatives	
Annual Budget	\$650,000 for staff, overhead, meetings, and supplies
Staff	4 full-time staff members
Services	Support for state and federal grant programs and the Governor's eHealth Council

The Council collaborates among stakeholders to develop standards for HIE including best practices, recommended minimum core data set, interoperability, and federated identity management to facilitate secure single-sign-on capability. They are also incubating initiatives to support ongoing progress and rollout strategies on multiple health IT fronts.

MCHIE Statewide HIE Plan
ATTACHMENT C: GOVERNANCE APPROACHES IN OTHER STATES

In 2007, eHealth Initiatives partnered with the Department of Health and the Community Health Network, using \$1.6 million in state funds and \$364,000 in United States Department of Agriculture funds, to establish the Tennessee TeleHealth Network and provide secure high-speed broadband connectivity to Tennessee's 45 federally qualified health centers. This same team of partners also secured \$1.6 million from HRSA to develop the Middle Tennessee Rural Health Information Network connecting four rural hospitals and a community clinic for data exchange. A similar partnership between eHealth Initiatives, the University of Tennessee Health Sciences Center, and Community Health Network secured nearly \$8 million in Federal Communications Commission (FCC) funding to connect 400 additional nonprofit sites and encourage their use of health IT and TeleHealth. The year 2007 also saw the emergence of more regional initiatives, including CareSpark in upper east Tennessee, a \$2.68 million NHIN trial implementation awardee, and the Innovation Valley Health Information Network in the Knoxville area.

In 2008, eHealth Initiatives is disbursing \$10 million in state funds to physician practices and clinics statewide to drive adoption and use of the Tennessee eHealth Exchange Zone. These grants include connectivity via the state's secure, private broadband network, as well as seed money for eprescribing or EMR applications.

HIE Activities:

- ***Local HIE Efforts:*** Three HIEs are actively exchanging data in Tennessee as of February 2008. MSeHA has 1.35 million records (clinical data) for 950,000 unique patients in the Memphis area. Shared Health has records (claims data) for almost 2 million unique Tennesseans statewide, including the Medicaid population. CareSpark is currently launching a community-based exchange that will serve 17 counties in upper east Tennessee and southwest Virginia. Emerging initiatives are under way in the Nashville area and in the upper Cumberland area of middle Tennessee.
- ***Chartered Value Exchanges:*** As of February 2008, HHS has designated one Chartered Value Exchange in Tennessee: Healthy Memphis Common Table.
- ***Statewide Data Activities:*** Built on the foundation provided by the inclusion of Tennessee's Medicaid population, Shared Health has clinical health records based primarily on claims data for almost 2 million Tennesseans, or one-third of the state's population. The Office of eHealth Initiatives is driving connectivity and eprescribing among healthcare providers statewide by disbursing grants totaling \$10 million in state funds to physician practices and clinics statewide.
- ***State Registries:*** Tennessee maintains registries for immunization, low birth weight, cancer, and controlled substances prescribed.

Organizational Relationships: The eHealth Council serves in an advisory capacity for state policy makers, recommending rules and policies to facilitate secure HIE statewide. State government is supporting the development of sufficient infrastructure to support the growth and use of the Tennessee eHealth Exchange Zone. In addition, state government is working to spur adoption of health IT to build critical mass in the marketplace.

MCHIE Statewide HIE Plan

ATTACHMENT C: GOVERNANCE APPROACHES IN OTHER STATES

Substantial emphasis has been placed on local control of the standards and practices for regional initiatives. The statewide rules and policies for HIE deliberately leave significant room for individual information sources to strike their own data-sharing agreements once they are connected via the common, state-facilitated infrastructure. Market forces are expected to drive further opportunities for progress once the basic infrastructure is in place for the Exchange Zone and a critical mass of users are on the system.

Montgomery County HIE Collaborative
Community Perspectives for Statewide HIE
Analysis and Recommendations

Montgomery County Health Information Exchange Community Leadership Team,
assisted by the Primary Care Coalition of Montgomery County
and
Summit Health Institute for Research and Education

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EXECUTIVE SUMMARY

The purpose of this report is to describe community members' perspectives of the benefits and caveats of health information exchange (HIE), drawing in particular on the opinions of the medically underserved and those who serve them. The report also analyzes beliefs and attitudes in the community which may lead individuals or organizations to support or oppose HIE initiatives, as well as how implementation teams might gain the support and buy-in of various groups. It is intended to inform the larger discussion surrounding the development and implementation of a statewide health information exchange in Maryland.

This report focuses particularly on the medically underserved and those who serve them, and participant groupings are patients, providers, and other stakeholders. Focus group methodology was used to gather the perspectives of uninsured or underinsured patients primarily living in Montgomery and Prince George's Counties. An e-survey was also administered to patients of St. Agnes Hospital in the Baltimore area that were reached by an established community outreach group working with local churches. This report is also based upon the results of fifty-four interviews or surveys with key informants or stakeholders in Montgomery County, which included leaders of community-based organizations, of the county's network of safety-net clinics, and of other kinds of organizations (social service, chamber of commerce, etc.), as well as medical providers. Participants in focus groups and interviews/surveys answered questions about the benefits and utility they perceived in HIE, risks and caveats, desired system features, and why or why not they would support HIE initiatives.

All groups described the primary assets and benefits of HIE to be better coordination and continuity of care, and increased efficiency and cost-effectiveness – both of which they viewed to benefit both providers and patients. Patient focus groups in particular, however, emphasized that they would look forward to having increased access to their own health information. Their primary concern related to the confidentiality of patient data and the security of the system. Some also felt that HIE would exacerbate inconsistency and inaccuracy of data reported, and that measures should be taken to ensure the accountability of those who enter or view patient data. Others discussed how only partial uptake would damage the effectiveness and utility of HIE. And many providers feared the risks of additional burden upon them to implement the system, integrate it into workflow, train staff, take on liability for data security and privacy, and support the costs and paperwork involved.

Although participants discussed a number of concerns, most of them felt that the benefits of increased patient safety and better care coordination outweighed the caveats. A few expressed unconditional support, but most said they would support HIE initiatives if certain conditions were adhered to; patients in focus groups fell primarily within this category. A few (usually providers) opposed HIE outright. It is important to note that most patients—and many stakeholders—had never heard of HIE prior to the focus group, interview, or survey. Significant education and outreach about the purpose and function of HIE would need to accompany its implementation.

Those who answered that they would support HIE conditionally were primarily patients in focus groups, and providers who had some exposure and experience with electronic medical record systems. Patients in focus groups stated that they would support the initiative if they could be assured of the “absolute security and confidentiality” of their information, and if their information were not at risk of release to peers, family members, employers and/or commercial entities (e.g. pharmaceutical companies). Suggestions in this regard included requiring patients' consent before his/her information would be shared, and having a system that could track access to medical records. Those who opposed HIE initiatives reported that they did so because they were unconvinced that it would have a significant, positive impact, they feared that it would place an

inordinate burden on providers, and they felt that the purpose of HIE (and who it would benefit) had not been clearly articulated.

This report recommends that training and education focus not only on system use, but also on patient rights and responsibilities with regard to their medical information. Furthermore, efforts would need to be supported by policy, resources, and incentives; confidentiality and security would need to be clearly demonstrated and secured; HIE implementation would need to be accompanied by standards for recording and classifying medical information in the system; and specific goals should be delineated regarding what HIE is intended to accomplish and for whom.

INTRODUCTION

Background: The Montgomery County Health Information Exchange Collaborative (MCHIE) is a collaboration between Montgomery General Hospital, Holy Cross Hospital, Shady Grove Adventist Hospital, Washington Adventist Hospital, the Montgomery County Department of Health and Human Services, the Prince George's County Health Department, Summit Health Institute for Research and Education (SHIRE), the Primary Care Coalition of Montgomery County, and the Healthcare Initiative Foundation of Montgomery County. Partners in this project were charged with building recommendations that will inform the development of a statewide health information exchange in the near future. Partners contributed their support, guidance, and oversight in this effort. The PCC and SHIRE were charged with assisting to gather opinions from the perspective of the "medically underserved" community as well as peers in the organizations' community-based work. For this purpose, the group convened focus groups with community members and health promoters in the D.C. metropolitan region, as well as interviews and surveys of key informants and stakeholders who were leaders of community-based organizations, health foundations, and chambers of commerce; managers and medical directors of safety-net clinics; employees of the Montgomery County Department of Health and Human Services; physician members of the Montgomery County Medical Society; and a hospital chief information officer.

Objective: To determine citizens' (especially the medically underserved) opinions, concerns, and needs with regard to health information exchange (HIE), as well as attitudes and beliefs that might impact whether individuals or organizations support HIE initiatives.

Methodology:

Patient focus groups

A total of 8 focus groups with a total of 61 participants contribute to this report. For the three groups which the PCC convened, two focus groups consisted of lay health promoters in their communities and churches; one of the groups consisted of 5 Latina women (conducted in Spanish), and the other group consisted of 5 African Americans – 4 women and 1 man. Participants were recruited by flyers through the coordinator of each group. The project team convened one more group with Latinos, primarily uninsured, who were attending a vocational training program at a social services center in Washington, D.C. The group consisted of 8 men and 2 women who reside in the D.C. region, including Montgomery and Prince George's counties. All participants were foreign-born and spoke primarily Spanish, so the group was conducted in Spanish. Unlike the prior groups with health promoters, all participants in this group had little or no experience with the U.S. health care system, or at best, with only the safety-net system of primary care clinics.

SHIRE convened five focus groups in Prince George's County. Two focus groups (4 in one, and 10 in the other) were convened through the St. Agnes Hospital Community Outreach Department, who sent out flyers to recruit residents of its service area who had received services at the hospital.

These two groups were 60% African American, 25% white, and 15% Latino. The three other focus groups (ten, five, and twelve participants each) consisted of all African American participants recruited at a church and two community centers. Brief summaries were provided to inform this report.

Each focus group discussion lasted approximately 1 hour and 15 minutes, and all participants received stipends for their participation. PCC focus groups were categorized, analyzed for key themes, and summarized. Summaries from SHIRE focus groups were used for this report as well. All focus groups were conducted between October and December of 2008. The focus group discussion guides in English and Spanish are also included in the Appendix.

Key informant / stakeholder open-ended surveys

The PCC conducted surveys with 54 stakeholders or key informants, primarily in Montgomery County (questionnaire included in appendix). The PCC sent letters to 67 individuals—primarily peers in the PCC's work with the medically underserved—to invite them to participate in an open-ended survey. After this the project coordinator called each person to set up a time to administer the survey by phone. For 38 of the 54 surveyed, this open-ended questionnaire was administered in an interview format by phone or in person to allow participants the opportunity to share more liberally and ask questions, if necessary. These participants were primarily partners and collaborators with the PCC, and the various groups interviewed are listed in the section above. For the rest of the surveys (primarily those from the Montgomery County Medical Society), participants filled out the surveys in written format and sent them by e-mail for the sake of convenience and time constraints. Many of these were partners of other members of the MCHIE team. To analyze these surveys, responses were categorized by question and then gleaned for salient themes. Quotations and comments were then grouped by theme and weighted according to how often participants mentioned a particular theme. These surveys were conducted in November and December of 2008.

Because two different methodologies were used (focus groups and open-ended questionnaires) which may impact the results' comparability, this report will specify throughout whether the data refers to survey interviews with stakeholders, or to focus groups with patients, if a significant difference exists between the perspectives shared in each.

Patient e-surveys

Additionally, SHIRE conducted an e-survey of patients who had been served at St. Agnes Hospital, primarily from Baltimore and Prince George's Counties. The survey was a 17-question, close-ended questionnaire focused on patients' experiences with transferring medical records, level of support for HIE, and concerns about HIE. The survey was sent out by e-mail through community contacts affiliated with St. Agnes and advocates from Prince George's County; these contacts then sent the survey to over 50 individuals, and 28 people responded. This survey was conducted in November and December of 2008. Respondents were primarily female (71%), African-American (36%) or Caucasian (45%), insured (all but one), and the average age was 67 years old (sd=15). Most had attained a high school education (all but one), and 47% had attained a college education or higher.

Questionnaire development

The PCC developed questions for focus group guides and surveys by (1) evaluating the scientific literature via PubMed of the US National Library of Medicine, including information about the Santa Barbara County Care Data Exchange; (2) evaluating pre-existing HIE questionnaires, such as the Tampa Bay RHIO surveys for institutions, providers, employers, and payers; and recommendation documents—such as the report from the Ohio HIE, “A Strategic Roadmap and Policy Options for the Effective Adoption of Health Information Technology and Exchange in Ohio;” and (3) discussing and reviewing the questionnaires with a panel of partners from the MCHIE Community Leadership Team. The focus group guide was left open-ended so that participants could discuss their perspectives more in depth, whereas the stakeholder survey was more generally directed to issues related to concerns for populations they serve and their potential interest in supporting such an endeavor in the future.

Limitations: These focus groups and surveys are intended to provide guidance and direction for successful future planning, and to comprise one piece of the broader discussion on HIE. They provide a specific set of qualitative information rather than quantitatively precise measures. By and large, participants live in a multicultural, urban/suburban community in the Washington, D.C. metro area, and many of them have some background in public health or health services (with the exception of many focus group participants). Some groups may not be represented in this report, especially residents of rural areas. Furthermore, the differing methods used for different participant groups may limit the comparability of the results.

DETAILED FINDINGS

Perceived assets, benefits, and utility

Understanding how community leaders, health care providers, and patients view the benefits of HIE can indicate the strongest “talking points” for gaining support for this initiative. The following section discusses the benefits that focus group and survey/interview participants identified in HIE.

Participant groups—community leaders, providers, and patients—similarly perceived the primary benefits of HIE to be better coordination of care and increased efficiency – both of which they perceived as supporting the larger goals of increased patient safety, improved quality of care, and better health outcomes. The main difference between participants groups, however, was that patients with little experience of the health care system tended to focus on their own ability to access and control personal health information as a particular benefit to them. Only two physicians mentioned the ability to retrieve data at the population level as a potential benefit of HIE systems.

Better coordination and continuity of care

Most primary care physicians (PCPs) surveyed saw particular utility in having access to patients' health records from the hospital emergency department (ED), laboratory tests, and specialty care. Continuity of care from the ED to the primary care home was perceived as a particularly important benefit of HIE. One PCP stated, "On the clinic side, we are missing accurate and clear discharge summaries and recommendations. Like with the neonatal nursery, a patient comes in and to begin with, I have to read the third copy of an NCR paper, if I can read it at all, and that's all I have to go on [for the patient's follow-up care]."

All participants discussed how their clients and patients are involved in multiple systems of care which do not communicate with one another, and both patients and providers expressed strong interest in being able to monitor their patients'—or their own—treatment and progress in these varied systems. They reported that patients would benefit from not having to carry the sole responsibility of transmitting information about their treatment—which they may or may not fully understand—between providers. Leaders of organizations that work with immigrant and refugee communities discussed how their clients often find the U.S. medical system difficult to understand and navigate, and that HIE could be an important mechanism for ensuring patient follow-up and accurate reporting of the often-complex treatment and care provided in different locations. Key informants shared the following comments:

"Often I find that our patients don't distinguish between one clinic and another. They assume there is access to the information they gave to a different provider at a different time...Right now, our HIE is the patient, and they don't necessarily have the language to talk about their care. So much is lost along the way." (Medical director, Montgomery County safety-net clinic)

"Our clients are often frustrated because they don't understand the difference between the places they go to – especially primary care providers versus specialists, or why they have to provide the same information over and over. The system is unfamiliar to them." (Health program manager, refugee service organization)

"Many of our patients who are low-income and uninsured tend to see different physicians and go to different clinics, so it's difficult to get a clear picture of what the patient has been through, what the history is. Maybe they got an x-ray done, and nobody knows about it. They don't tell the meds they are taking, especially traditional treatment – many in our populations use that. Western doctors don't take that seriously, but they need to know what people are taking." (Leader of Asian-American community center)

All participant groups discussed how HIE could enhance patient safety through availability of information about medications, allergies, and diagnoses, especially when the patient may not be able to share this information in the case of an emergency, language barriers, or inability to recall – or when a patient shares various pieces of information in different settings. One nurse mentioned the utility of being able to share information about highly communicable disease for the safety of other patients and medical personnel (as permitted under existing regulations).

Increased efficiency and cost-effectiveness

Survey and focus group participants saw increased efficiency and cost effectiveness as a significant benefit to both patients and providers. Providers reported that having the information at hand would decrease time spent searching for files, calling other providers, and faxing information.

This, too, was seen as enhancing the goal of patient safety by providing more timely care. Patients would reap the benefit of reduced visits, fewer repeated tests, and therefore reduced costs. In the words of a clinic manager, “The provider has to wait until the information [from the ED] is transmitted to us, which could be as quickly as the same day, or we may have to wait a week. In those cases, the patient may have two visits instead of one. I see a big benefit for them.”

Increased patient access to information

By contrast, patients with little or no access to primary care—and even less, to specialty care—hardly discussed the advantage of HIE for coordinating care among providers. Rather, focus group discussions highlighted a particular interest among patients in being able to access and control their personal health information, especially for those who are computer-literate. They felt that this access would be especially useful to keep track of medications and side effects, see doctors’ instructions, monitor progress towards goals, and act on care plans. Some patients in the e-survey reported that they would appreciate using an electronic system to communicate with their physician, schedule appointments, authorize transfer and sharing of health data, review who accessed their record, and to learn more about their health. Some patients assumed that this system would work something like an online bank account or e-mail account which they could access in different locations. This idea held great appeal for those who are highly mobile and receive care in different locations, perhaps even abroad in their countries of birth – as well as for those who fear release of their personal information to immigration authorities. Participants in all groups, however, expressed that they wish to have full access and control over the data included and shared through an HIE system.

Desired features

If a HIE system were put into place, what would make it useful for providers and patients? With confidentiality and HIPAA compliance as a given, participants reported that they would want the system to have the following features:

For providers:

- Ability to access patient information outside the medical office, and outside office hours
- Flags and alerts about drug interactions, side effects, and allergies
- Access to lab results, progress notes, X-ray results, special consultations, medical history, medications, allergies, last visit, and diagnoses
- Ability to scan and view radiographic diagnostics and medical imaging firsthand
- Connections to annual cancer screening results and immunizations provided by other county departments or offices
- Real-time online access and use – more than just a “reporting tool.”
- Transparent referral system – flags and alerts as to whether patient has gone for follow-up
- Ability to track who viewed and entered data into the record, and for what purpose
- Training to use the system
- Computer and IT support

For patients:

- User-friendly and simple format – perhaps a different interface than what clinicians see
- Available in different languages
- Reminders about next health care steps – i.e. need for tests or yearly exams
- Contextualization and explanation of what results mean

- *Provider's comment: "If the labs come to them in the same way as they come to us—that is, 'abnormal, too high'—they might' freak out'. But if we could build some context—for example, it was like this before, and now you're doing better or worse—you know, add some comments about what it means."*
- Ability to see who viewed and entered data into the record, and for what purpose
- Ability to ensure greater privacy of information when needed
- Education and training to understand it
- Ability to ensure different levels of access by different providers/personnel

Risks, caveats, and barriers

By far, the greatest concerns that participants articulated were related to confidentiality. Other significant concerns related to data consistency, uniformity, and meaningfulness; accountability for data entered; lack of buy-in; data security; system reliability and back-up; additional burden on physicians; and limited utility or understandability for patients.

Confidentiality

First of all, patients were concerned about who would be able to view their information. Many patients felt they should be able to designate which providers are granted access to their information, as well as the level of access that each provider or entity would be able to have. For example, some stated that they would want to ensure that front desk staff could not view or search their medical information, and that only "need to know" information be available. Many participants feared loss of control over their information, or worse yet, that their information could be released to employers (or potential employers), peers, or family members; used against them in litigation; or sold to commercial entities.

Many participants—particularly those with less experience of the health care system or the internet—were concerned with who would actually have control over the system and management of the information. In the words of one participant:

"As the patient, how can I be sure that the record would not be seen by someone else? It is all a cloud in my mind. How is the data controlled? Could the doctor or someone else see it without my knowing?"

Other participants articulated that they share certain information with providers with the understanding that it would stay between them and their particular provider whom they trust. They may share more limited information if they feel that it could be disclosed to others with whom they do not have a relationship of trust. One patient reported,

"I don't want doctors or anyone else being able to view it at will. Information such as gynecology and cosmetology wouldn't be pertinent to a doctor treating me for high blood pressure, Paget's disease, G.E.R.D., etc. Some information should be private."

Some patients may not opt-in to HIE at all if they fear that certain information may be released beyond a particular provider. This concern was articulated particularly by leaders who work with immigrant groups from Africa, where stigma for particular diseases or conditions are particularly strong.

Secondly, participants were concerned about the kind of information that may be shared, especially sensitive information about infectious diseases with stigma (e.g. HIV, STDs), mental health or psychiatric treatment information, or incarceration information – especially when there may be

special regulations surrounding the release of this kind of information in the first place. Some providers intimated that medical records may already contain more information about a patient than is necessary or appropriate, and the availability of such information to a wider “audience” may be harmful. One clinic manager stated,

“I think many people, when they write a medical record, they are used to writing everything they know about the patient. I think this HIE requires that we change the paradigm a bit. We need to think about it in terms of, is this something that another provider would need to know?...I read progress notes, and I see that they didn't have to write in there, ‘post-incarceration.’”

Data consistency, accuracy, and meaningfulness

Many participants felt that there would be increased risk for data entry errors, which could lead to problems with patient identification. For example, different forms of Chinese names may lead a patient to have two different records, or for data to be entered in different charts. Multiple last names may lead data entry staff in different locations to enter the information in different ways.

One medical director identified differences in coding and classification as a further barrier to effectiveness of HIE. In his words:

“What about the data? How do we put it together?...As an epi, I'm sensitive to ‘garbage in, garbage out’ – everyone coding and classifying in different ways...How do we know every provider is classifying according to the same CPT code? They don't. So using it for data analyses, you will have a range of error around whatever value you're looking at. I see it as far better to develop standards of coding and classification before you try to combine it all.”

Accountability for data entered and for viewing

Many patients feared that an HIE system posed a high risk of fraudulent information being entered into the system, especially if there were no accountability related to names, date, and time at which a record was viewed or entered. Patients were unsure how inaccurate data could be corrected once it had been entered. And if a breach of confidentiality occurred, what consequences would there be for the individual or entity at fault?

Lack of buy-in

Some community leaders and providers in particular felt that partial uptake of an HIE could be more damaging than not implementing it at all. If only a small percentage of hospitals or PCPs are using it, it would be not be useful. And if the system were implemented in varying stages in different places, it may also inhibit effectiveness due to lack of availability of patient information from some clinics/hospitals.

System security, reliability, and back-up

Patients in particular were concerned about the security of the system, and in focus groups, several referred to the recent theft of laptops in a government facility which contained patient medical information, social security numbers, and other private information. In a survey, one leader of a chamber of commerce stated,

“You can’t trust the government to safeguard data. There are plenty of examples in the past five years alone...We are giving someone to be the custodian of some of our most personal information. Who controls this person? And if the security is breached, what happens?”

Others wondered whether the ability of patients to access the system would lead to decreased system security. One clinic manager said,

“I am not sure if I understand the mechanism through which patients would see their health information. I’m not opposed, I just worry that the protective mechanisms for people seeing others’ health information would be reduced, that the risk of breaching is greater.”

Many patients worried about what would happen if the system were to break down, and whether a paper trail would still be available as a back-up.

Additional burden on physicians

Some providers felt that the burden on them to implement the system, integrate it into workflow, train staff, take on liability for data security and privacy, and the additional costs and paperwork involved would make HIE implementation a “Herculean task.” One physician was particularly skeptical about the prospects for effective HIE:

“I think this would be another fragmented, doomed attempt at pushing EMR into the medical system in which the technology is not yet achieving interoperability between systems and which the physicians cannot afford.”

Utility and understandability for patients

While all groups felt that viewing their personal health information could be a particular benefit for patients, many felt that computer ability, access, and literacy could limit the benefit of this function. Several providers expressed concern that if patients could review results without understanding what they mean—or view sensitive test results which should first be discussed with their physician—patients may panic or worse.

Factors in organizational and individual support of HIE

This section will examine the beliefs and attitudes which may lead organizations or individuals to support HIE or not, or under what conditions they would lend their support to a HIE initiative. Additionally, this section discusses what HIE implementation teams may need to do—or how they may need to frame the initiative—in order to gain buy-in.

All key informants surveyed were asked whether they would support HIE, and the following responses were collected:

	Yes	Yes, with conditions	No	Unsure	Total
Community-based organizations	8	0	1	0	9
Montgomery	5	8	0	1	14

Cares (safety-net) clinics					
Montgomery County DHHS	2	2	0	3	7
Physician members of medical society	7	2	5	1	15
Others*	7	0	0	2	9
Total	29 (54%)	12 (22%)	6 (11%)	7 (13%)	54

**"Others" include: leaders of area foundations, a president of a chamber of commerce, a hospital CIO, a representative from the Office of Minority Health*

For participants in this survey, those from community-based organizations and those not working in the healthcare system (with a few exceptions) were more likely to support HIE initiatives unconditionally than health care providers interviewed. In the patient e-survey, 38% reported that they would support HIE initiatives. Although many of the unconditionally supportive participants did express some of the concerns described above, they felt that the benefits of increased patient safety and better care coordination outweighed these concerns. Interestingly, while many community leaders did voice concerns about confidentiality and security, most seemed more convinced about the ability to keep the system secure than were those who work within the health care system.

Those who answered that they would support HIE conditionally (or "somewhat") were primarily patients in focus groups, and providers with some exposure and experience with electronic medical record systems. Patients in focus groups stated that they would support the initiative if they could be assured of the "absolute security and confidentiality" of their information; if their information were not at risk of release to family members, peers, employers, or commercial entities (e.g. pharmaceutical companies); and if they must give their consent before their information is shared. Patients also noted that ensuring the accountability of those viewing and entering data was important, and some suggested that the system might track who had accessed their records and why. For most participants who fell in this "conditional support" category, assurance of confidentiality was the primary factor that would determine their support. For example, they would want to be assured that immigration status, mental illness, or other particularly sensitive information that is not directly relevant to patient care would not be shared. Secondly, they would want to control what levels of staff or entities could view their information. Some suggested that different levels of access be available to different levels of staff. Other factors discussed by providers that would determine support included widespread implementation and use of the system (beyond Montgomery County), government funding to support implementation in clinics, and clear delineation of what the system would entail.

For those who were unsure of whether they or their organization would support a HIE initiative, their uncertainty usually related to not fully understanding how the system would work or what would be required of them. These participants implied that they might be willing to support the initiative if they knew more about it, or if they could see existing models.

And finally, providers who said they would not support HIE reported the following reasons for their opposition:

Lack of clarity in identifying the purpose of HIE

Some participants felt that HIE was put forward as the panacea for improving patient care and health outcomes, and for providing better coordination of patient care in a system plagued by fragmentation. They doubted that it would be able to achieve the high and multiple goals set for it. One physician commented,

“One thing I’ve heard is that if people are using the same data set, they can all pull up the same records; for example, an ER physician can see what is going on with the patient at the primary care clinic. Another thing I’ve heard is that it will provide an opportunity to pull together vast data sets that could be mined in a variety of ways to collect data on ER visits and the quality of care given. The third purpose is, well, it helps the patients because it puts all their info in one place. All of these are admirable purposes, but there are deficiencies or barriers in each of the three.”

Unconvinced of significant, positive impact

Some physicians stated that they did not think that HIE would have significant, positive impact, or that it would improve patient care. Some reported that they felt the current system was working well enough, and that such initiatives were really nothing new:

“The current system of communication is not so bad. Email, fax, and phone allow pretty good communication already. It’s done every day. I doubt this system will improve on it. Do we really need this?” (Provider)

“I think it’s futile – I heard the same conversation 20 years ago, and they wanted to do something like this, and they are always faced with the same problems. ‘Give them a disk’ – this was the idea back in the seventies. Or give people a universal health ID number. These ideas have been dismissed or forgotten. These are not new ideas – just recasting things that have been talked about in the past. Sure we have new technology, but what’s the quality of information that’s there, and what about all the differences that exist among providers in entering data? Unless there’s someone who can be dictatorial, I don’t see how it will happen.” (Medical director, safety net clinic)

Fear of inordinate burden on providers to implement

Some participants feared that HIE would mean only increased bureaucracy and paperwork, or an effort to force electronic medical records upon already-strained clinics. One physician from a small primary care practice (primarily serving patients with health insurance) mentioned a number of benefits she saw in HIE, but ultimately did not support it because she felt it would be too expensive to implement in her clinic. Many expressed that they would be unable to give their support without a full understanding of what specifically would be required of them.

RECOMMENDATIONS

Gaining Buy-in and Support

Support through policy and allocation of resources will be critical

A few participants indicated that they would support HIE only if policy enforced it. Many felt that the only way to gain widespread usage would be through policy and significant allocation of resources. One participant stated,

“[The barriers] are surmountable if you have someone say ‘this is how it’s gonna be, and here’s the money to make it happen’ -- for example, the state legislature or the state government.”

Another said,

“Endorsement of big shots in charge of systems – state medical societies, etcetera—they really need to be brought into this, not just a few maverick doctors. That won’t help in terms of full integration of the innovation and to take it up. You need incentives, and you need enforcements.”

One clinic manager attributed her support to a certain sense of “inevitability” about HIE. As she put it, “I think it has to happen sooner or later. There’s always reluctance at first, and then you can’t do without it. I worry that it may not be as confidential as it should be, but you know Medicaid is doing it, and the way I see it, it’s going to be out there, so we might as well get started on it.”

Provide specific goals regarding what HIE is intended to accomplish and for whom

Some dissenters felt that HIE was often posed as a “silver bullet” for improved patient care, or for correcting a number of ills in the health care system. Focus on clarifying and specifying the purpose and goals – and describing how it will benefit the intended various “audiences” directly – may help to garner support and better focus the effort. For example, as providers overwhelmingly viewed the primary benefit to them to be improved coordination of care between PCP, specialist, and/or ED, focusing on this goal among providers may enhance support for HIE among this group. Further, providers would need to know that this system would be more than just another “reporting tool,” but rather a real-time mechanism with embedded management functions, such as flags or reminders about needed tests or other appointments, or the capability for patients to use it themselves for health or disease management.

Another participant suggested that focusing on the overarching goal of increasing patient safety and describing how specifically HIE would enhance patient safety may provide a good framework for defining the purpose. In the words of one participant,

“I’d rather not focus on specific feature functionality but rather the general goal of supporting compliance with patient safety oaths – somewhat universal related to hospitals, but allowing us to do better patient reconciliation, have access to community pharmacies and nursing homes...My bias would be to think about the goal of patient safety and better care in our community – whatever features foster that higher goal should be considered.”

Accompany HIE with standards for recording medical information

Interviews suggest that problems already exist with some staff reporting sensitive information that may not be necessary for patient care. It may be helpful to develop guidelines for the kind of information that providers can report in medical records, especially when that information may be shared beyond the medical setting in which the information was first written. Constructing a new paradigm of sharing information on a “need to know” basis only may be important, rather than writing everything in the record that the patient has disclosed.

Furthermore, differences in coding and classification of medical data in different medical settings may also negatively impact the effectiveness of HIE for population health assessment. And if providers cannot rely on HIE for consistent, reliable data, it may be viewed as having limited utility.

Assurances of confidentiality

While in many ways this assurance goes without saying in the development and implementation of a HIE, these data indicate that patients will be more likely to support such initiatives if they have a clear understanding of who is managing the system, who can and cannot access it, and how exactly their data will be kept private and secure. Confidentiality seems to be the most important factor for determining support among all groups but particularly among patients, and if patients do not believe that their information is safely managed, they are unlikely to give their consent.

Need for training and education of patients and system users

The need for training patients and clinic staff on system use is obvious, as well as significant allocation of resources for this purpose. Community-based organizations (who serve low-income, uninsured) in particular were interested and willing to provide education to their client populations, and saw a role for themselves in this area if time and resources were available. They indicated that training would need to be culturally and linguistically appropriate, provide familiarization with the system, involve demonstrations, and state safeguards and ways in which it would benefit them personally.

However, focus group data also suggest that patient education in HIE initiatives may in fact need to go deeper than this. Some participants were unaware of their right to access their medical records at all. This patient education component, therefore, may need to reach beyond even the features and usage of the system itself and also focus on how and why health information is shared at all, how providers use it, and patient rights surrounding use and sharing of health information. If patient education and consent for sharing medical information is to be confined to a dense document that a patient is given to sign prior to receiving care, patients may remain marginal—or opt-out altogether—of HIE.

In the clinical setting, providers who have already begun to use electronic medical records have discussed the importance of providing consent forms in various languages, and of explaining verbally—and in plain language—how their information would be used, why it would be shared, and how their confidentiality would be secured.

CONCLUSIONS

These surveys and focus groups suggest that some foundations of support for HIE exist among the medically underserved and those who work with them. However, the data also make clear that implementation teams will need to respond to the concerns of key stakeholders if support is to be gained. The support of policy and the allocation of resources will be critical, as well as delineation of specific goals, establishment of standards for writing medical records and classifying information, setting up mechanisms to assure confidentiality, and conducting training and education of patients and system users that goes beyond system use and functionality.

APPENDICES:
Data collection instruments

MC- HEALTH INFORMATION EXCHANGE
Focus group discussion guide: English

Focus Groups questions to gather perspectives re HIE from lay community (1st draft)

- Do you know what “Health Information Exchange” is?
- Have you heard anything about current State efforts regarding using a “Health Information Exchange” system?
- Do you have any opinions regarding the implementation of “Health Information Exchange system”?

Statements To Be Read And Provided In A White Card To Each Participant:

- **“HEALTH INFORMATION EXCHANGE” INITIATIVES ARE A WAY TO MAKE YOUR PERSONAL HEALTH INFORMATION AVAILABLE TO YOUR VARIOUS HEALTH CARE PROVIDERS (I.E. FAMILY DOCTOR, PRIMARY CARE PHYSICIAN, HOSPITAL, LABS, ETC.) VIA A SECURE INTERNET CONNECTION.**
- **YOUR INFORMATION CAN ONLY BE VIEWED WITH YOUR AUTHORIZATION, AND ONLY WHAT YOU CHOOSE TO DISCLOSE WOULD BE VIEWABLE.**
- **NATIONAL STATEWIDE AND REGIONAL GROUPS ARE WORKING TO IMPLEMENT THESE SYSTEMS, IN ORDER TO IMPROVE PATIENT SAFETY AND QUALITY OF CARE WHILE REDUCING HEALTH CARE COSTS.**
- **IF THIS “HEALTH INFORMATION EXCHANGE” SYSTEM IS PUT IN PLACE, YOU MAY BE ABLE TO REVIEW YOUR OWN HEALTH INFORMATION.**
- **BASED ON THIS INFORMATION...**
 - **Would you support the implementation of a “Health Information Exchange system”?**
 - **Do you have any potential concerns regarding the implementation of a “Health Information Exchange system”?**
 - **Would you be interested in accessing your own information for health improvement purposes?**
 - **Do you believe there are assets to making your information available to doctors and hospitals?**
 - **Do you believe there are caveats to making your information available to doctors and hospitals?**

- **After this discussion, would you have the same position on supporting the implementation of a “Health Information Exchange system”?**

MC- HEALTH INFORMATION EXCHANGE
Focus group discussion guide: Spanish

Focus Group questions to gather perspectives re HIE from lay community

- **¿Sabén Ustedes lo que es un sistema de “Intercambio electrónico de Información de Salud”?**
- **¿Han escuchado Ustedes sobre algún plan del estado de Maryland para desarrollar un sistema de “Intercambio electrónico de Información de Salud”?**
- **¿Tienen Ustedes alguna opinión sobre los sistemas de “intercambio electrónico de información de salud”?**

DEFINICIONES PARA LEER CON EL GRUPO:

LOS SISTEMAS DE INTERCAMBIO DE INFORMACION ELECTRONICOS SON UNA FORMA DE HACER QUE LA INFORMACION SOBRE LA SALUD ESTE DISPONIBLE -- A TRAVEZ DE UNA CONECCION SEGURA POR MEDIO DEL INTERNET, PARA EL USO E INFORMACION DE SU HOSPITAL, Y/O MEDICO DE FAMILIA Y/O MEDICO ESPECIALISTA.

SU (TU) INFORMACION SOLO PUEDE SER VISTA CON SU (TU) AUTORIZACION, Y SOLO LO QUE UD. ESCOJA COMPARTIR PODRA SER VISTO POR OTROS.

GRUPOS DE LOS DIFERENTES ESTADOS ESTAN TRATANDO DE IMPLEMENTAR ESTOS SISTEMAS DE INTERCAMBIO DE INFORMACION ELECTRONICOS, CON EL OBJETIVO DE MEJORAR LA SEGURIDAD DE LOS PACIENTES Y LA CALIDAD DEL CUIDADO MEDICO MIENTRAS SE REDUCEN LOS COSTOS DE LOS SERVICIOS MEDICOS.

SI ESTOS SISTEMAS DE INTERCAMBIO DE INFORMACION ELECTRONICOS SON IMPLEMENTADOS, UD. (TU) PODRIA REVISAR SU PROPIA INFORMACION DE SALUD Y CUIDADOS MEDICOS.

BASADO EN LA INFORMACION QUE ACABAMOS DE LEER,

- **¿Apoyarían Ustedes [cada una] un sistema de “Intercambio electrónico de Información de Salud”?**
- **¿Tendrían Ustedes alguna inquietud o preocupación sobre información en un sistema de “Intercambio electrónico de Información de Salud”?**
- **¿Querría Usted tener acceso a su propia información para poder mejorar su salud?**
- **¿Cree Usted que hay ventajas en que su medico y los hospitales tuvieran acceso a su información medica?**

- **¿Cree Usted que hay problemas o desventajas de que su médico y los hospitales tengan acceso a su información?**
- **Después de esta plática, ¿tiene Usted la misma opinión relevante a apoyar un sistema de “Intercambio electrónico de Información de Salud”?**

MCHIE Community Perspectives Questionnaire
For community leaders and providers

Please read the following definitions prior to answering questions below:

- "HEALTH INFORMATION EXCHANGE" INITIATIVES ARE A WAY TO MAKE YOUR PERSONAL HEALTH INFORMATION AVAILABLE TO YOUR VARIOUS HEALTH CARE PROVIDERS (I.E. FAMILY DOCTOR, PRIMARY CARE PHYSICIAN, HOSPITAL, LABS, ETC.) VIA A SECURE INTERNET CONNECTION.
- INFORMATION CAN ONLY BE VIEWED WITH YOUR AUTHORIZATION, AND ONLY WHAT A PATIENT CHOOSES TO DISCLOSE WOULD BE VIEWABLE.
- NATIONAL STATEWIDE AND REGIONAL GROUPS ARE WORKING TO IMPLEMENT THESE SYSTEMS IN ORDER TO IMPROVE PATIENT SAFETY AND QUALITY OF CARE WHILE REDUCING HEALTH CARE COSTS.
- IF THIS "HEALTH INFORMATION EXCHANGE" SYSTEM IS PUT IN PLACE, PATIENTS MAY BE ABLE TO REVIEW THEIR OWN HEALTH INFORMATION.

1. Prior to this survey, had you heard about County or State efforts for developing a "Health Information Exchange" as described above? If so, how?

2. Do you think a "Health Information Exchange" system would be useful or meaningful to your clients (and where applicable, your staff)?

- Yes
- No
- I don't know/unsure

Why?

Why not?

3. Do you think your organization/agency would support (be in favor of) the implementation of a Health Information Exchange system?

- Yes
- No
- I don't know/unsure

Why?

Why not?

4. What features would you like to see in a County/State-wide HIE system to make it useful or meaningful to your clients (and where applicable, your staff)?

5. Would you be interested and willing to participate in efforts to educate, train, and do outreach with your clientele related to a County/State-wide HIE system?

6. Do you have any concerns about electronic sharing of patient health information?

No

Yes

If yes, please specify what your concerns are:

Please tell us about your clientele:

7. Can you tell me about the general characteristics of your clientele and what language(s) they generally speak?

8. What percentages of your clients do you think have health insurance, Medicare, or Medicaid?

_____ % private health insurance

_____ % Medicare

_____ % Medicaid

_____ % uninsured

_____ I don't know/not sure

9. Additional comments:

Consumer Survey (used as e-survey)

QUESTIONNAIRE

{intro here}

1. What is your country of birth? _____

2. What is your home zip code? _____

3. How would you describe yourself? (Mark all that apply)

- African American or Black
- Asian
- Caucasian or White
- Hispanic or Latino
- Native American or American Indian
- Pacific Islander
- Prefer not to answer
- Other, specify: _____

4. How long have you lived in the U.S.? _____

5. How old are you? _____

6. What is your gender? Male Female

7. What level of schooling have you completed?

- None
- Elementary School
- Junior-High/Middle School
- High School or GED
- University/college
- Masters / Professional level and above

8. In general, what language do you speak?

- Only a language other than English
- Another language better than English
- Both equally
- English better than another language
- Only English

10. How often do you need help from someone else to read written materials in a hospital or clinic?

- Never need help
- Rarely need help
- Sometimes need help
- Usually need help
- Always need help

11. Do you have health insurance, Medicare, or Medicaid? (Mark all that apply)

- Yes, I have health insurance
- Yes, I have Medicare
- Yes, I have Medicaid
- No, I do not have health insurance
- I don't know/not sure

12. Have you heard about county or state efforts to develop a “Health Information Exchange”?

- Yes No Unsure

13a. Have you ever tried to send your or your family’s medical records (paper copies) from one provider to another?

- Yes No Unsure

{IF NO, SKIP TO 14a.}

13b. Were you successful in sending those records (paper copies) from one provider to another?

- Yes Partial success No Unsure/don't know

13c. How easy or difficult would you say it was to share your health information between healthcare providers? Would you say that it was...[read options]

- Very easy
- Easy
- Neither easy nor difficult
- Difficult
- Very difficult

13d. How did you send that information (e.g. doctor faxed it, I took it with me, etc.)? _____

14a. Have you ever tried to see or get a copy of your medical records?

- Yes No Unsure/don't know

{IF NO, SKIP TO 15}

14b. Were you successful in getting a copy of your medical records?

- Yes Partial success No Unsure/don't know

14c. How easy or difficult would you say it was to obtain a copy of your or your family members’ medical records? Would you say that it was...[read options]

- Very easy
- Easy
- Neither easy nor difficult
- Difficult
- Very difficult

15. [Please read the following]:

- "HEALTH INFORMATION EXCHANGE" INITIATIVES ARE A WAY TO MAKE YOUR PERSONAL HEALTH INFORMATION AVAILABLE TO YOUR VARIOUS HEALTH CARE PROVIDERS (I.E. FAMILY DOCTOR, PRIMARY CARE PHYSICIAN, HOSPITAL, LABS, ETC.) VIA A SECURE INTERNET CONNECTION.
- YOUR INFORMATION CAN ONLY BE VIEWED WITH YOUR AUTHORIZATION, AND ONLY WHAT YOU CHOOSE TO DISCLOSE WOULD BE VIEWABLE.
- NATIONAL STATEWIDE AND REGIONAL GROUPS ARE WORKING TO IMPLEMENT THESE SYSTEMS IN ORDER TO IMPROVE PATIENT SAFETY AND QUALITY OF CARE WHILE REDUCING HEALTH CARE COSTS.
- IF THIS "HEALTH INFORMATION EXCHANGE" SYSTEM IS PUT IN PLACE, YOU MAY BE ABLE TO REVIEW YOUR OWN HEALTH INFORMATION.

Based on the information above, would you be in favor of a Health Information Exchange system?

Yes, definitely Somewhat No Don't know/unsure

16. Do you have any concerns about electronic sharing of patient health information?

No
 Yes, specify: _____

16. How well can you use a computer?

Not at all [If not, if there someone who can use the computer for you? Yes
 No] {If no,

end

survey here}

A little
 Sufficiently
 Very well
 Proficient

17. Would you be interested in using a computer (or having someone help you use a computer) to:

	Yes	No	Don't know	Need more info
Review your health data and information about health status				

Add information on you or a family member's health status				
Communicate electronically with physicians and other providers				
Review appointment history and make appointments				
Review progress for chronic diseases				
Authorize transfer and sharing of health data with other providers				
Review who accessed your healthcare information				
Access educational information on health and healthcare				
Be reminded of tests or screenings that may be due for me				
To learn more about medications and/or side effects				

Montgomery County HIE Collaborative
Privacy and Security Considerations for Statewide HIE
Analysis and Recommendations

Montgomery County Health Information Exchange Finance Team,
assisted by Manatt Health Solutions
February 2009

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EXECUTIVE SUMMARY AND PURPOSE OF DOCUMENT

The success of Maryland's health information exchange (HIE) effort will be determined not only by its clinical and technical achievements, but also its ability to protect the privacy and confidentiality of patients' health information.

This document makes specific recommendations to advance a privacy and security framework for Maryland's statewide HIE effort, and it provides the basis for the Montgomery County HIE Collaborative's (MCHIE) final report to the Maryland Health Care Commission (MHCC).

Specifically, this document makes recommendations on six threshold issues upon which agreement is necessary before the State proceeds with implementation and the development of detailed privacy and security policies. These threshold issues include:

- **Governance** – Should Maryland establish a statewide governance body that is charged with the development of granular statewide privacy and security policies?
- **Scope** – Will all participants in statewide HIE be required to abide by the statewide privacy and security policies under development? Should an enforcement mechanism exist to ensure compliance?
- **Policy Interoperability and Enforcement** – Should Maryland distinguish between “one-to-one” and “many-to-many” exchanges for the purposes of applying any statewide privacy and security policies? If so, what rules should apply to each type of exchange?
- **Seek Changes or Conformance With Existing Law** – Should Maryland change or pass new laws to govern HIE or should it develop policies that are consistent with existing law?
- **Baseline Consent Principles** – Should Maryland develop a statewide approach to consent? If so, what should be the statewide approach for consent requirements?
- **Data Filtering** – Should Maryland require that HIEs allow patients to limit provider access to certain types of data contained in, or available through, the exchange?

Upon the convening of an appropriate statewide governance entity, these threshold issues should be ratified and a working group of stakeholders from throughout the state convened to address the specific privacy and security policy issues that flow from these threshold decisions. These issues include:

- | | | |
|------------------------------|-------------------------|----------------------------------|
| • Affirmative Consent | • Sensitive Health Info | • Audits/Transparency |
| • Uses of Health Information | • Consent for Minors | • Breach |
| • Consent Forms | • Access Requirements | • Converting Data |
| • Durability & Revocability | • Emergency Access | • Consumer Engagement and Access |
| • Sanctions/Penalties | • Authorization | |
| • Enforcement Mechanisms | • Authentication | |

We believe that once the statewide group is assembled, and if it is adequately staffed and funded, ratification of the key threshold issues and establishment of a Privacy and Security Workgroup to develop granular privacy and security policies and procedures could be accomplished within a three month period.

I. BACKGROUND ON STATE-LEVEL HIE PRIVACY & SECURITY

Strong policies that protect the privacy and security of health information are crucial to achieving interoperable health information exchange (HIE). Current federal and state laws governing HIE and the resulting business practices of healthcare providers were developed in the context of a paper-based healthcare environment where decisions on what to communicate, how, and to whom were generally made on a “one-to-one” basis by clinicians.

Current laws attempt to serve the patients’ privacy interests by restricting what can and cannot be shared and the terms on which sharing takes place. Human judgment and personal relationships play a major role, as clinicians attempt to act as guardians of their patients’ information.

Moving from a paper to an electronic health system changes the information-sharing dynamic. An interoperable health system facilitates a “many-to-many” relationship, enabling different information technology systems and software applications to exchange information accurately, effectively, and consistently. This offers new opportunities to promote patient access to and control over healthcare information, as well as to facilitate the safety, quality, and efficiency of healthcare.

However, it also demands new approaches for protecting privacy and security, including policies addressing the disclosure and use of healthcare information, and technologies that address consumer identification, authentication, record location, identity management, and storage of special classes of information.

A key lesson from other states’ experiences in developing privacy and security policies is the need for phased implementation that (1) identifies and resolves the threshold issues (which are more fully defined in the section below), (2) establishes a mechanism to collaboratively engage stakeholders to build consensus around granular privacy policies and procedures, and (3) manages an ongoing, iterative deliberation process that continues to generate the policies necessary to govern an evolving HIE market.

The three phases for building a privacy and security framework are highlighted in the figure below.

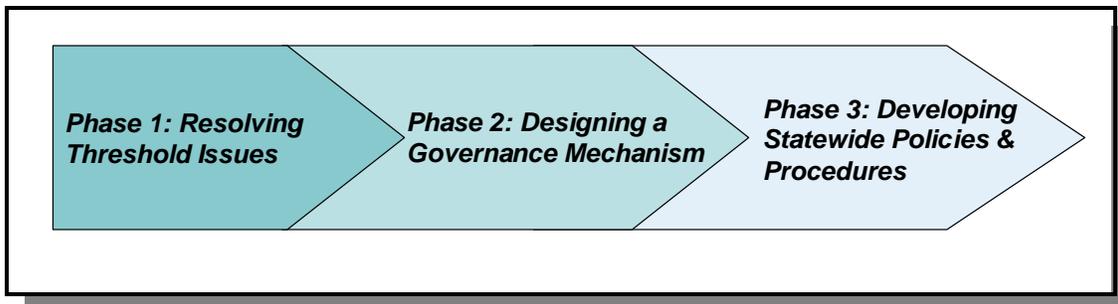


Figure 1. Illustration of State-Level HIE Governance Phases

II. THRESHOLD ISSUES FOR STATE-LEVEL HIE PRIVACY & SECURITY

The MCHIE Privacy Team has identified and offered recommendations for six threshold issues that require resolution to advance a privacy and security framework for HIE in Maryland. Each issue and key decision points are summarized below.

- A. *Governance.*** Privacy and security policies must be informed by the viewpoints and experiences of all of those who will be subject to their regulation. Agreement is required regarding the need for, structure of, and authority for a collaborative governance process involving broad stakeholder representation to resolve issues.
- B. *Scope of Privacy and Security Policies.*** Health information exchange occurs in two principal forms: one-to-one or many-to-many. While HIPAA does not require consent for treatment and other specific uses of health information, it is important to remember that HIPAA was written in the context of a one-to-one health information exchange environment. An interoperable health system facilitates a many-to-many information exchange relationship that, some believe, may demand new approaches for protecting privacy and security. Agreement is required as to whether or not any new statewide privacy and security policies should be applied only to many-to-many HIE occurring through a statewide health information network and not to existing one-to-one exchanges of information.
- C. *Policy Interoperability and Enforcement.*** Statewide policies are necessary to obtain patient trust and ensure interoperability. Agreement is required as to (1) whether all participants in statewide HIE will be required to abide by the privacy and security policies under development and (2) whether a statewide enforcement mechanism will be in place to ensure compliance.
- D. *Seeking Changes to or Conforming with Existing Laws.*** Agreement is required as to whether new statewide privacy and security policies will be aided by changes in law or whether policies should be adopted in compliance with existing law.
- E. *Baseline Consent Principles.*** Maryland must decide what constitutes adequate and meaningful patient consent, taking into consideration what is required legally, what is appropriate for risk management purposes, what constitutes the best public policy, and what is feasible from an implementation perspective in the state.
- F. *Data Filtering.*** Maryland must decide whether authorized users may access all Protected Health Information about a patient or whether certain types of sensitive health information (e.g., HIV/AIDS status, mental health, substance abuse, and genetic testing) will be required or permitted to be kept out of the exchange.

A. Governance

Background

In order to be successful, Maryland’s HIE framework must support the fluid and automated exchange of health information among authorized users. The key to generating liquidity in any exchange is the belief on the part of stakeholders that using the exchange will be successful and beneficial and that, in rare cases where problems exist, the stakeholders will be protected and problems will be solved. Data providers and users must have confidence that the entities participating in data exchange adhere to its financial, technical, and privacy and security underpinnings.

This is as much a function of trust as technology or clinical participation, and is achieved through policy and governance. Though states have various options for configuring their governance approaches, each framework includes three common elements:

- **Committed participants.** Financing and delivery of healthcare involves multiple entities in both the private, public, and nonprofit sectors. As such, efforts to create and sustain a statewide HIE must include the key stakeholders: state government; private and public healthcare providers, payers, and purchasers; and exchange participants (i.e., physicians, consumers, and caregivers).
- **Collaborative process.** Stakeholder participation is necessary, but insufficient to achieve the level of orchestration required to implement HIE. States that have moved beyond the planning stages have developed and sustained inclusive, transparent decision-making models to address the complex technical, policy, legal, and financial issues. To enable collaborative deliberations, states utilize a variety of mechanisms, including legislative hearings, advisory councils, and/or formal independent, public-private organizations.
- **Statewide policies.** The collaborative decision-making process should yield consistent, enforceable policies that establish the technical, privacy, and financial rules for a statewide HIE. Statewide policies can be promulgated in a variety of ways, including legislation, rule-making, contracts, or commonly accepted practices.

The figure below highlights the key elements and participants in the governance framework for a statewide HIE.

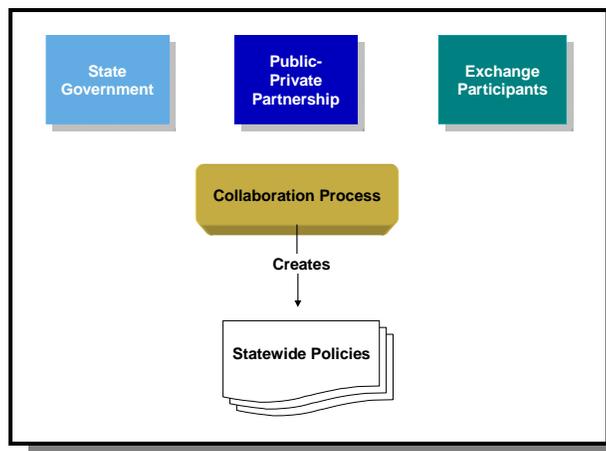


Figure 2. Illustration of State-Level HIE Governance Elements

Based on the experiences of HIE in other states, state government will play a pivotal role in the governance process and in relationship with the collaborative public-private partnership that guides implementation. A study of 13 statewide HIE efforts found that in order to advance statewide HIE, state governments must provide the necessary level of empowerment through designation of authority and financial and nonfinancial support, including facilitating coordination and participation across agencies and executive branch policies and practices.¹ Moreover, state governments establish and enforce the fundamental accountabilities related to state policy goals, fiduciary responsibilities, and statutory requirements to ensure consumer protection.

Decision Point

- What type of governance process should Maryland adopt to oversee HIE and the development and implementation of privacy and security policies in the state?

Recommendation and Rationale

Recommendation: Creation of Statewide Collaborative Process

MCHIE recommends that Maryland develop a statewide process that involves all interested stakeholders in the creation of a comprehensive privacy and security policy framework for HIE in Maryland.

MCHIE recommends that the statewide collaborative process include issue-specific workgroups. One group should be solely devoted to and responsible for developing the state's privacy and security policies. All workgroup decisions should be made by consensus.

As a condition of receiving any state funding, HIEs should be required, through contracts, to participate in the statewide process and to comply with the policies, standards, and guidance developed through the process.

Rationale: A single, statewide collaborative process built on a foundation of public-private partnership is the predominant governance model utilized in other states implementing statewide HIE.

¹ American Health Information Management Association. "State-Level Health Information Exchange: Roles in Ensuring Governance and Advancing Interoperability Final Report Part I." March 2008. Available online at <http://www.sihie.org/Docs/FinalReportPart1.8.pdf>.

B. Scope of Privacy and Security Policies

Background

Interoperable health information exchange represents a paradigm shift in the way information is transmitted among a consumer's healthcare providers. In today's largely paper-based world, exchange of health information between providers generally is managed by the consumer. In order for Provider A to obtain health information from Provider B, the consumer must tell Provider A that he or she is receiving care from Provider B and would like his or her health information to be shared. The consumer in effect is the gatekeeper of a "one-to-one" relationship among various providers who are responsible for his or her care.

A one-to-one exchange is a disclosure of health information by one of the patient's providers to one or more other healthcare providers treating the patient with the patient's knowledge and implicit permission. The exchange is limited to the records of the providers jointly caring for the patient; other records maintained by the RHIO are not accessible. Common examples of one-to-one exchanges include physician referrals, a discharge summary being sent by a treating hospital to the admitting physician, or the delivery of lab results to the clinician who ordered the test. Each one-to-one exchange is understood and predictable to the patient, and limited in scope to the providers coordinating the delivery of healthcare services with the patient's knowledge and implicit or explicit permission.

HIEs usher in a new world by enabling the free flow of information, and fundamentally change the one-to-one paradigm that exists in a paper-based world. Entities that support HIE allow providers for the first time to reach out to large networks of clinicians and providers independent of the consumer to see what information is available and to use it to aid in the provision of care. This brings obvious benefits to the consumer – eliminating the burden of gathering and transporting paper records, avoiding duplicative tests and procedures, and ensuring providers have the best information available to make medical decisions and coordinate care. It also, however, takes away a measure of consumer control, and for some brings a heightened sense of vulnerability related to the transmission of identifiable health information across networks of providers in electronic form.

Decision Point

- Should new statewide privacy and security policies be applied only to many-to-many HIE occurring through a statewide health information network and not to existing one-to-one exchanges of information?

Recommendations and Rationale

Recommendation: Distinguish Between One-to-One and Many-to-Many Exchanges

MCHIE recommends that Maryland define privacy and security rules that apply statewide to the exchange of personal health information in a "many-to-many" context, whereby healthcare providers can reach out to large networks of clinicians and providers to obtain health information and use it in patient care. The privacy and security rules for HIE that facilitate "many-to-many" data exchanges should not, however, apply to one-to-one exchanges.

Further, Maryland should specify that its privacy and security policies represent the minimum standards with which HIEs should comply. Where appropriate, individual HIEs should be free to adopt more stringent policies, provided they do not impinge on the liquidity of the statewide health information network.

Recommendation: Distinguish Between One-to-One and Many-to-Many Exchanges

Rationale: The one-to-one exception is important to avoid significant unintended consequences that could impact a range of electronic results reporting activities that are adequately regulated and do not constitute communitywide or statewide HIE.

As indicated in the comparative analysis in Attachment C, states with advanced statewide privacy and security frameworks recognize this distinction and have structured their policies accordingly.

C. Policy Interoperability and Enforcement

Background

One of the main goals of the policies advanced in this document is to promote uniform adoption of privacy policies across HIEs in Maryland. Policy interoperability is critical to facilitating informed consumer consent and to ensuring that patient information is truly portable through a chain of trust that exists among the multiple networks comprising the statewide HIE infrastructure. The creation of a single statewide consent form exemplifies the value of interoperable HIE policies. Rather than the proliferation of multiple, potentially inconsistent consent forms, a single statewide form allows consumers to better understand and monitor how their information is used through the HIE, enables the state to create a cost-effective education campaign around the consent form, and reduces the technical and practical difficulties that would result from allowing the use of varying consent documents.

Statewide accountability and enforcement mechanisms are critical to ensure statewide interoperability. In order to bring interoperable exchange of health information to scale, all stakeholders – state and local governments, providers, payers, and consumers – must have confidence that the entities participating in the exchange serve the public interest and perform the duties expected of them in a transparent manner that earns public trust.

States, acting primarily through the agencies of state government, have three principal means to protect the public's interests and ensure accountability of HIEs in the state: (1) direct oversight through legislation or regulation of entities, (2) contracts with specific entities, and/or (3) indirect oversight in which the state designates or confers authority to another organization (e.g., an accreditation body) to develop and manage the evaluation of entities in an industry.

- **Legislation and Regulation:** Studies of accountability mechanisms suggest that legislation or regulation works best in circumstances where participants are vulnerable and require strong consumer protection, and where the industry lacks a dominant professional group with its own mechanisms for professional discipline and a choice of suppliers, which limits the effectiveness of market forces in ensuring quality.² While many contend that direct oversight is the preferred vehicle for certain aspects of HIE, especially privacy and security, others argue that governments are better at developing regulations and guidelines than tracking or measuring them.³ Critics also note that rules can be difficult to update once codified in laws or regulation. Legislation, which is subject to the political process, can be even more challenging to adapt.
- **Contracting:** If projects are supported with public funding, state government can use contracts to ensure that state funds are used in a way that promotes the policy goals and protects the public's interest. As an accountability mechanism, contractual authority affords the state direct oversight and does not require the creation of new external authorities and processes. Such contracts, however, tend to have limited duration. Moreover, the contractual terms bind only entities that receive grant funds and would be difficult to use for other entities that may want to participate in the statewide HIE.
- **Accreditation:** In contrast to regulation and contracting, accreditation can be more adaptive to market needs. Through research and staying abreast of activities within their profession, accreditation organizations seek to promote use of best practices and

² Eleanor D. Kinney, "Private Accreditation As A Substitute For Direct Government Regulation In Public Health Insurance Programs: When Is It Appropriate?" 57 *Law and Contemporary Problems*, 47, 51. 1994.

³ Institute of Medicine. *Improving the Quality of Long-Term Care*. 2001.

continuous process improvement for the entities they accredit. Accreditation organizations also aim to maintain flexibility in program structure to support innovation as a market evolves. For example, organizations will often specify standards that accredited entities must meet, but will not mandate the means by which an accredited entity must meet them so that innovative practices are given room to develop. On the other hand, critics of accreditation argue that accreditation lacks the sanctioning strength of government and can be too closely aligned with the industry it evaluates.

The use of accreditation as a government oversight mechanism presupposes the existence of a qualified private organization that can effectively serve the government's interests. While no organizations currently accredit HIEs or Regional Health Information Organizations (RHIOs), a few accreditation bodies are exploring options for creating an accreditation framework for entities that support HIE.⁴

Decision Point

- Should all participants in statewide HIE be required to abide by the privacy and security policies under development and, if so, how should Maryland ensure compliance?

Recommendations and Rationale

Recommendation: Require and Enforce Compliance With Policies

MCHIE recommends that Maryland require all participants in statewide HIE to abide by the privacy and security policies developed for HIEs. Maryland should ensure compliance contractually, rather than statutorily. To the extent practical, Maryland should also consider voluntary enforcement models, including accreditation.

Rationale: Uniform privacy policy adoption is critical to interoperability of information via statewide HIE infrastructure and in ensuring that consumers gain a common understanding of what it means to have their information shared through an HIE.

Recommendation: "Safe Harbor" Provisions

MCHIE recommends that Maryland state government endorse any statewide policies developed as compliant with existing law.

Rationale: Data sharing will not occur if stakeholders have unresolved liability concerns. A safe harbor provision would increase HIE and stakeholder confidence that they will not face liability in the event that they are in compliance with agreed upon HIE policies and applicable federal and Maryland law.

⁴ The Electronic Healthcare Network Accreditation Commission (EHNAC) is an organization that accredits entities that send or receive HIPAA-regulated transactions. EHNAC accredits electronic health care networks, payers, clearinghouses, transactions processors, value-added networks, real-time networks, financial institutions, and provider management organizations. Working with a range of stakeholders, including MHCC, EHNAC is developing a new program to accredit clinical health information exchanges.

D. Seeking Changes to or Conforming With Existing Laws

Background

Interpretation of existing federal and state laws influences the development of HIE privacy and security policies. Federal and state laws may, for instance, require that special protections be granted to certain classes of information (e.g., laws requiring consent for disclosure of records of federally assisted substance abuse centers).

Two states with advanced statewide HIE privacy frameworks, New York and Minnesota, offer contrasting approaches regarding whether to frame privacy and security policies within existing laws or to seek legislative changes.

In New York, state law requires that hospitals, physicians, other healthcare providers, and HMOs obtain patient consent before disclosing Protected Health Information (PHI) for nonemergency treatment. Unlike the Health Information Portability and Accountability Act (HIPAA), New York state law provides no exception to this requirement for treatment, payment or healthcare operations. While consent may be verbal or even implied for most types of health information, this is not the case for certain classes of specially protected healthcare information, including information related to HIV status, mental health and genetic testing, the disclosure of which requires written consent.

These laws reflect a desire to ensure that patients are protected from unauthorized use of PHI and are provided both a legal and normative guidepost for development of consent policies for HIE in New York. As a result of its interpretation of these laws, New York chose to require that each provider and payer participating in an HIE obtain an affirmative consent from the patient before accessing their PHI through the state's statewide HIE.

On the other hand, stakeholders in Minnesota chose to pass new legislation to govern the practice of HIE. In 2007, the Minnesota legislature amended the existing Minnesota Health Records Act, which was originally passed in 1977. The updated law defines key terms and components of HIE (including a Record Locator Service) and clarifies consent-related requirements for the electronic exchange of information.

In Maryland, healthcare providers are subject to the Maryland Confidentiality of Medical Records Act (MCMRA), which was enacted in 1991.⁵ The MCMRA addresses many of the same issues as HIPAA. In 2003, a study commissioned by the State of Maryland found the MCMRA to be more stringent than HIPAA in two key areas:⁶

- MCMRA establishes a special category for mental health records, which are subject to different disclosure rules (HIPAA has similar provisions for psychotherapy notes); and
- MCMRA prohibits all redisclosures, unless specifically authorized by the patient or otherwise permitted.

Additional details on Maryland's analysis of MCMRA are provided in *Attachment B*.

⁵ Office of the Attorney General, Maryland Health Care Commission, Department of Health and Mental Hygiene, the State Advisory Council on Medical Privacy and Confidentiality, with assistance from the Maryland State Bar Association Health Law Section, HIPAA Subcommittee, *Maryland Confidentiality of Medical Records Act Compared with HIPAA*. Department of Health and Mental Hygiene, *Privacy Statute & Regulation*. March 2003. Available online at <http://www.dhmd.state.md.us/sacmpc/pdf/compchart.pdf>.

⁶ Maryland Health Care Commission. *An Assessment of Privacy and Security Policies and Business Practices*. November 2007. Available online at http://mhcc.maryland.gov/electronichealth/assess_privacy_security.pdf.

Decision Point

- Should Maryland attempt to amend or pass new state laws, or should it draft its privacy and security policies in a manner that complies with existing law?

Recommendations and Rationale**Recommendation: Develop Policy Within Context of Existing Laws**

Notwithstanding the need to evaluate certain areas of Maryland law, MCHIE recommends that the state develop its privacy and security policies within existing federal and state legal frameworks and not pursue legislative changes at this time.

MCHIE also recommends that, as Maryland develops its statewide privacy and security policies, it conduct a thorough and ongoing analysis of existing state law related to health records privacy in order to ensure that the new privacy and security policies comply with existing laws.⁷

Rationale: Because creating new or modifying existing privacy laws can be challenging, many states have chosen to develop policies that are consistent with existing laws. This approach allows an opportunity to assess the existing laws' impact on HIE based on operational experience, and, if necessary, to pursue legislative corrections at a later date.

⁷ Ongoing assessment of health privacy policies will be important if, as anticipated, Congress approves the privacy provisions in the current versions of the economic stimulus package, the American Recovery and Reinvestment Act of 2009. The Bill proposes to expand current federal privacy and security protections for health information by: (1) extending the reach of HIPAA to a broader range of organizations handling such information; (2) mandating notification to individuals and government agencies in the event of security breaches; (3) expanding individual rights currently afforded under HIPAA; and (4) increasing civil penalties for HIPAA violations.

E. Baseline Consent Principles

Background

Informed patient consent is key to ensuring patient trust in HIE. Diverse consent policies are a barrier to interoperability and prohibit consistent privacy and security protections. When setting standardized consent policies, states must take into consideration what is (1) required under existing law; (2) appropriate for risk management purposes; (3) effective public policy; and (4) feasible operationally.

New York state law, for instance, requires that hospitals, physicians, other healthcare providers, and HMOs obtain patient consent before disclosing PHI for nonemergency treatment. Unlike HIPAA, New York state law provides no exception to this requirement for treatment, payment or healthcare operations. While consent may be verbal or even implied for most types of health information, this is not the case for certain classes of specially protected healthcare information, including information related to HIV status, mental health and genetic testing, the disclosure of which requires written consent.

As a result of this and other considerations, New York chose to require that each provider and payer participating in an HIE obtain a written affirmative consent from the patient before accessing their PHI through the HIE.

Because New York law does not require patient consent for the storage or management of data by technology vendors acting on behalf of healthcare providers,⁸ New York healthcare providers are free to convert or upload information to an HIE as long as the HIE does not make the information accessible to providers unless they have obtained an affirmative written consent, as described above. This reflects the fact that healthcare providers routinely enter into data storage and management arrangements with electronic medical record hosting vendors, outsourced data centers and other technology companies. Indeed, many facets of a provider's routine operations may be carried out by independent contractors who have access to identifiable consumer information, and this occurs without consumer consent.

Another approach is for HIEs to require patient consent in order for providers to upload information to an HIE. In Massachusetts, for example, the three HIE pilot projects led by the Massachusetts eHealth Collaborative (MAeHC) have taken such an approach, owing primarily to their interpretation of state law regarding disclosures of health information. In practice, the MAeHC has found that over 90 percent of patients consent to uploading their data to an HIE. The pilot sites do not require patient consent for a provider to access the information once it has been converted or uploaded to the HIE.

Decision Point

- Maryland must decide what constitutes adequate and meaningful patient consent, taking into consideration what is required legally, what is appropriate for risk management purposes, what constitutes the best public policy, and what is feasible from an implementation perspective in the state.

⁸ If a vendor holds consumer data solely as a custodian of the provider and does not make the data available to other entities, the storage arrangement is not treated as a "disclosure" to a third party, requiring consent under New York law.

Recommendations and Rationale**Recommendation: Consent Framework**

MCHIE recommends that, with the exception of one-to-one exchanges, the state require affirmative, written consent to be obtained from patients by each provider and payer organization before they are permitted to access a patient's information through an HIE.

Subject to a thorough analysis of state law, MCHIE recommends that Maryland not require affirmative consent for providers to make patient health information available to an HIE, provided the HIE is serving as the data provider's HIPAA third-party business associate, is in compliance with applicable state and federal law, and does not make information available to HIE participants until patient consent to access data is obtained.

MCHIE also recommends that the state use a statewide collaborative process to develop granular policies related to consent, including policies to address the durability and revocability of consent, consent for minors, creation of a statewide consent form, and enforcement of consent requirements.

Rationale: Within the context of consent, it is important that Maryland balance the need to protect patients' PHI with the need to facilitate viable HIE within the state by ensuring providers' timely access to complete patient information at the point of care. MCHIE believes this balance can be achieved by requiring that a provider obtain patient consent to access information through an HIE, without requiring consent to make patient information available to an HIE.

Requiring that affirmative, written consent be obtained by each provider or payer organization in order to access a patient's information through an HIE is critical to ensuring that patients have control over who is able to access their PHI and to building public trust in HIE.

Allowing data to be uploaded to an HIE without consent but under the terms of a HIPAA third-party business associate agreement ensures access to the information in an emergency, supports statutorily required public health reporting, and guarantees providers' timely access to complete patient information at the point of care. The latter point could have potentially significant impacts on the long-term sustainability of statewide HIE, as a lack of readily available, robust patient data would undermine the perceived value of the HIE and could limit fledgling exchanges' ability to become viable entities.

F. Data Filtering

Background

Owing to the sensitive nature of certain types of PHI (e.g., HIV/AIDS status, mental health, substance abuse, genetic testing), some HIEs choose to filter such information. It is important to note that considerations for the availability of and access to sensitive health data are interrelated to approaches for consent. For example, data filtering can be accomplished by requiring HIEs to gain patients' consent to share data from particular providers, data pertaining to particular conditions, or even discrete data fields within their health records.

At the national level, significant attention has been focused on the issue of filtering or "sequestering" sensitive health information. The National Committee on Vital and Health Statistics (NCVHS) has deliberated extensively about how best to ensure that appropriate privacy protections are included in the emerging HIE frameworks. Based on more than a year of hearings and analysis, NCVHS recommended in February 2008 that HIEs allow individuals to sequester sensitive information based on predefined categories of information.⁹ According to the NCVHS recommendation, if an individual designates a category for sequestering, then healthcare providers accessing the individual's data via an HIE would not see any information in the selected categories; the individual would have the further option of providing consent to a healthcare provider to access the sequestered information. Recognizing that "sequestration of sensitive health information by category represents a new model of clinical care," NCVHS also called for pilot projects and studies of the consequences of sequestration of sensitive health information.¹⁰

At an implementation level, a number of HIEs have found the process to develop and deploy consistent and uniform filtering approaches to be a challenge, especially when weighed against the potential impact on care. In 2005, an exchange in Massachusetts conducted a pilot study that provided ED physicians with patient summaries built from health plan and PBM data.¹¹ The HIE pilot initially chose to establish a sensitive drug list of more than 150 medications that could indicate the treatment of HIV/AIDS, mental health disorders, or substance abuse. The resulting drug filter to prevent the display of sensitive drug information varied by health plan. Some of the statutes apply to specific insurers or products, and the statutes were interpreted differently by the health plans. Though a single filtered drug list had been a goal, the project team believed it would have resulted in defining a large "lowest common denominator" list, preventing the release of medication history that would be clinically useful.

While most states do not impose statewide requirements for data filtering, they do permit varying degrees of allowances for data suppliers to sequester data from HIEs.

In New York, patients may limit which providers access their health information, but they cannot limit or "filter" the types of data to which health providers have access. Data suppliers, however, can seek patient consent before making sensitive health information available to an exchange. For example, an HIV clinic may request patient consent before it uploads clinical data to the HIEs in which it participates.

Like New York, the three most advanced local HIEs in Massachusetts do not offer an option for patients to filter sensitive health data from the information they consent to exchange. For

⁹ National Committee on Vital and Health Statistics. *Recommendation letter regarding individual control of sensitive health information accessible via the Nationwide Health Information Network for purposes of treatment*. February 20, 2008. Available online at <http://www.ncvhs.hhs.gov/080220lt.pdf>.

¹⁰ Ibid.

¹¹ Gottlieb, L.; Stone, E.; Stone, D.; Dunbrack, L; and Calladine, J. "Regulatory And Policy Barriers To Effective Clinical Data Exchange: Lessons Learned From MedsInfo-ED." *Health Affairs*. October 2005.

individuals in these three communities, it is a blanket consent in which the individual consents to disclose all of his or her health data. In addition, Massachusetts law requires consent to disclose each HIV and genetic test result. As these tests have relatively well-defined sets of data codes that are practical to sequester from the exchange, the three pilot communities have chosen to filter these specific tests.

Though Maryland does not have a statewide approach for data filtering, one HIE in Maryland, MeDHIX, has chosen to filter various data associated with mental health, HIV and drug rehabilitation. Medications, labs and problem lists associated with these health issues are not displayed to providers.

The MeDHIX eChart contains a disclaimer reminding physicians that medications for mental health, drug rehabilitation, and HIV medications are not displayed and that lack of inclusion does not imply that the medications are not currently prescribed to the patient. In addition, there is no alert that some health information has been censored, as that warning itself would violate a patient's privacy by identifying that the patient may have a mental health, drug rehabilitation, or HIV condition.

Decision Point

- Agreement is required as to whether those involved in HIE will be required or allowed to filter certain types of sensitive health data.

Recommendations and Rationale

Recommendation: Do Not Require HIEs to Filter Data

With the exception of psychotherapy notes and other types of sensitive health data that are subject to specific HIPAA requirements, MCHIE recommends that the state not require HIEs to filter specific types of sensitive information (e.g., HIV/AIDS status, mental health, substance abuse and genetic testing).

MCHIE recommends that the state use a statewide collaborative process to develop granular policies related to access, including policies to address authorization, authentication, audits, emergency access, enforcement of access requirements and penalties for breach.

MCHIE also recommends that Maryland monitor the evolution of technology and tools that identify sensitive health information and support increased granularity of patient consent mechanisms; as consent management technologies that allow patients to stratify granular levels of access become available, policies should be modified to grant patients this control.

Further, Maryland should consider allowing (but not requiring) institution-based filtering for certain types of entities, such as mental health institutions or federally qualified substance abuse centers, that primarily generate sensitive health information and that can be more readily isolated and excluded from the HIE as an information source.

Rationale: It is important that Maryland balance patients' need to have control over their sensitive health information and the ability to fully realize the promise of HIE by having complete patient information available at the point of care. Further, the practical challenges of consistently defining categories of sensitive information and the potential clinical implications of filtering data suggest that current data filtration techniques pose operational challenges and potential risks in a provider's ability to deliver safe and effective care.

Affirmative Consent: The consent of a patient obtained through the patient's execution of an approved consent form.

Authorized User: An individual who has been authorized by a participant or an HIE to access patient information via the statewide HIE infrastructure.

Business Associate Agreement: A written signed agreement meeting the HIPAA requirements of 45 CFR § 164.504(e).

Confidentiality: Material existing within the system will only be disclosed to those authorized to have it, and who need it for treatment, payment, operations, or other authorized purposes. (Source: Markle Foundation; *Connecting for Health: Linking Health Care Information: Proposed Methods For Improving Care And Protecting Privacy*).

Demographic Information: Patient's name, gender, address, date of birth and other identifying information, but shall not include any information regarding a patient's health or medical treatment or the names of any data suppliers that maintain medical records about such patient.

Health Information Exchange (HIE): The electronic movement of health-related information among organizations according to nationally recognized standards. (Source: US Department of Health and Human Services Office of the National Coordinator for Health IT Reports; <http://www.hhs.gov/healthit/resources/reports.html>).

Interoperability: Interoperability means the ability of health information systems to work together within and across organizational boundaries in order to advance the effective delivery of healthcare for individuals and communities. (Source: HIMSS Interoperability Definition; http://www.himss.org/content/files/interoperability_definition_background_060905.pdf).

National Committee for Vital and Health Statistics (NCVHS): The NCVHS serves as the statutory public advisory body to the Secretary of Health and Human Services in the area of health data and statistics. In that capacity, the Committee provides advice and assistance to the Department and serves as a forum for interaction with interested private sector groups on a variety of key health data issues. The Committee is composed of 18 individuals from the private sector who have distinguished themselves in the fields of health statistics, electronic interchange of healthcare information, privacy and security of electronic information, population-based public health, purchasing or financing healthcare services, integrated computerized health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services.

One-to-One Exchange: A disclosure of protected health information by one of the patient's providers to one or more other providers treating the patient with the patient's knowledge and implicit or explicit consent where no records other than those of the participants jointly providing healthcare services to the patient are exchanged.

Payer Organization: An insurance company, health maintenance organization, employee health benefit plan established under ERISA or any other entity that is legally authorized to provide health insurance coverage.

MCHIE Statewide HIE Plan
ATTACHMENT A: GLOSSARY

Privacy: An individual's interest in protecting his or her individually identifiable health information and the corresponding obligation of those persons and entities, that participate in a network for the purposes of electronic exchange of such information, to respect those interests through fair information practices. (Source: US Department of Health and Human Services Office of the National Coordinator for Health IT, "Nationwide Privacy and Security Framework For Electronic Exchange of Individually Identifiable Health Information." December 15, 2008; http://www.hhs.gov/healthit/documents/NationwidePS_Framework.pdf)

Protected Health Information (PHI): Under the HIPAA Privacy Rule, all "individually identifiable health information" held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral must be protected. The Privacy Rule calls this information "protected health information (PHI), including demographic data, that relates to: the individual's past, present or future physical or mental health or condition, the provision of healthcare to the individual, or the past, present, or future payment for the provision of healthcare to the individual, and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual. Individually identifiable health information includes many common identifiers (e.g., name, address, birth date, Social Security Number).

Provider Organization: An entity such as a hospital, nursing home, home health agency or professional corporation legally authorized to provide healthcare services.

Public-Private Partnerships: Public-private partnership describes a government service or private business venture which is funded and operated through a partnership of government and one or more private sector companies. (Source: Wikipedia; http://en.wikipedia.org/wiki/Public-private_partnership)

Regional Health Information Organization (RHIO): A health information organization that brings together healthcare stakeholders within a defined geographic area and governs health information exchange among them for the purpose of improving health and care in that community. (Source: US Department of Health and Human Services Office of the National Coordinator for Health IT Reports; <http://www.hhs.gov/healthit/resources/reports.html>.)

Security: The physical, technological, and administrative safeguards used to protect individually identifiable health information. (Source: US Department of Health and Human Services Office of the National Coordinator for Health IT, "Nationwide Privacy and Security Framework For Electronic Exchange of Individually Identifiable Health Information." December 15, 2008; http://www.hhs.gov/healthit/documents/NationwidePS_Framework.pdf)

Sensitive Health Information: Any information subject to special privacy protection under state or federal law, including but not limited to, HIV/AIDS, mental health, alcohol and substance abuse, reproductive health, sexually transmitted diseases, and genetic testing information.

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ATTACHMENT B: STATE OF MARYLAND'S COMPARISON OF MCRA AND HIPAA

In an effort to identify and understand discrepancies between the federal and state statutes, the State prepared a detailed, comparative analysis of MCMRA and HIPAA in 2003.¹² In summary, the State found that both MCMRA and HIPAA: (1) address information shared in verbal, written, and electronic format; (2) share broad similarities in permitting disclosure of patient identifiable information for treatment, payment, and healthcare operations; and (3) allow for disclosure without consent in emergency circumstances.

MCMRA and HIPAA laws were found to differ in the following areas:

Definition of identifying information and de-identification criteria: HIPAA refers to protected health information as “individually identifiable health information maintained or transmitted in any form or medium.” The MCMRA uses the term “medical record,” defining it as “any oral, written or other transmission in any form which is entered into the record of and relates to the healthcare of the patient and which identifies or can readily be associated with the patient.”

Although the terms are similar, the meaning by which individual identification is addressed differs, with HIPAA being more clearly defined. For example, to de-identify personal health data to be used for research, the identifiers for individuals, their relatives, employers, and household members are removed. However, exceptions can be made based if approved by an Institutional Review Board, which adheres to federal guidelines. Some examples of information that must be removed to de-identify data include: names; all geographical subdivisions smaller than a state; all elements of dates (except year) for dates directly related to an individual; telephone numbers; fax numbers; email addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; and other identifiers.¹³

Rules of confidentiality for uses of information in treatment, payment, and healthcare operations: Although the rules for HIPAA and MCMRA are similar, HIPAA rules require more explicit notification to patients regarding **healthcare** information disclosures and privacy protections.¹⁴ These HIPAA provisions place additional administrative burdens on providers.

Disclosures Requiring Authorization: Although HIPAA and MCMRA rules regarding disclosure are similar, HIPAA requires that a patient be consulted about preferences regarding what information may be given out about their medical condition (i.e., Jane Doe is in stable condition), while MCMRA permits such disclosure unless the patient declines in writing.¹⁵

Permissive Disclosures without Authorization: HIPAA and MCMRA both allow for the disclosure of health information by covered entities for certain purposes. Most HIPAA provisions are permissive, while disclosure under MCMRA or other state laws are often mandatory, such as for disclosures related to abuse and neglect, or other legally-compelled activities.

¹² Ibid.

¹³ University of South Florida. (2007). *Use and Disclosure of De-Identified Data For Research Purposes*. Tampa, FL. Available at: http://www.research.usf.edu/cs/hipaa_forms/sopdeidentified.doc.

¹⁴ Maryland Department of Health and Mental Hygiene. (March, 2003). *Maryland Confidentiality of Medical Records Act Compared with HIPAA Privacy Statute & Regulations*.

¹⁵ Ibid.

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Patient Remedies: HIPAA violations can result in administrative fines, while persons violating MCMRA laws may be sued in state court for actual damages. No comparable private right of action exists under HIPAA. Additionally, MCMRA grants broad immunity from suit to healthcare providers who disclose or fail to disclose a medical record if acting in good faith. HIPAA contains a somewhat less generous exculpatory clause that prohibits imposition of a civil penalty if the person, acting with reasonable diligence, did not know that the action violated federal law.¹⁶

Un-emancipated Minor Disclosure Rights: HIPAA defers to state law in regard to disclosure rights for un-emancipated minors. In Maryland, these rights are tied to a minor's capacity to consent to treatment. Maryland law allows a minor the right to consent to treatment for drug abuse, alcoholism, venereal disease, pregnancy, contraception, injuries from rape or sexual offense, and initial media screening of the minor into a detention center.¹⁷ Older minors (at least 16 year of age) may also consent to treatment for mental or emotional disorders.

With regard to mental health and abortion services, physician judgment plays a key role in whether disclosure is made to parents. The issue in including personal health information in a school record is that information protected by HIPAA would become visible by parents and guardians as part of the (unprotected) school record.

Overview of Administrative Procedures and Forms: HIPAA supersedes MCMRA regarding administrative requirements. These include designation of the entity, designation of a privacy official, and training of personnel. The entity also must have appropriate administrative, technical, and physical safeguards in place to protect personal health information security and sanctions for violators.

Subsequent to passage of the MCMRA, the Maryland legislature worked to balance the protection of personal health information with the use of information sharing to benefit individual, State and public health needs. For example, Senate Bill 690 (2005) clarified the compulsory process and procedures for authorized disclosures of specified health records under specific circumstances. This statute specifically addresses disclosure of a medical record without the patient's authorization, if that disclosure is a result of being served with a subpoena or other court order.¹⁸

In areas related to HIE and patient safety, the Maryland General Assembly has also focused on monitoring and identifying the misuse of controlled prescription drugs. Maryland has passed a series of laws that address the contents of prescription orders, monitor for Schedule II controlled substances, and define specifications for transferring and outsourcing prescriptions.¹⁹

The Code of Maryland Regulations (COMAR) 10.19.03.071 states that all prescriptions for drugs listed under Schedule II of the Controlled Substances Act must, among other

¹⁶ Ibid.

¹⁷ Ibid.

¹⁸ Maryland General Assembly (2005). Senate Bill 690.

¹⁹ Maryland Health Care Commission. *Maryland Laws Pertaining to Prescriptions*. Available on the Maryland Health Care Commission website: <http://mhcc.maryland.gov>.

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requirements, be written with ink, indelible pencil, typewriter, or computer and shall be manually signed by the practitioner.²⁰

In addition, COMAR 10.19.03.08 specifically states that a prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy by facsimile equipment, if the original written, signed prescription is presented to the pharmacist for review before the actual dispensing of a controlled substance.

²⁰ Department of Health and Mental Hygiene. Title 10 Department of Health and Mental Hygiene Subtitle 19 Dangerous Devices and Substances Chapter 03 Controlled Dangerous Substances.

1. GOVERNANCE

- ***Does the state have a statewide governance body in place that is tasked with the development of statewide privacy and security policies?***

NEW YORK

Yes. New York has created a statewide governance body tasked with developing privacy and security policies that HIEs receiving state grant monies must follow; this governance body includes a Privacy and Security Committee.

New York has developed a statewide governance body that is tasked with developing privacy and security policies for the state. The governance body facilitates a Statewide Collaboration Process (SCP) involving all interested stakeholders in the creation of a comprehensive policy framework to govern New York’s Statewide Health Information Network (SHIN-NY), which is being built with state funds from the HEAL NY Phase 5 Program. As a condition of receiving state funding, RHIOs are required, through contracts, to participate in the SCP and to comply with Statewide Policy Guidance developed through the SCP.

The New York eHealth Collaborative (NYeC) oversees the SCP, which consists of four workgroups: (1) Clinical Priorities, (2) Privacy and Security, (3) Technical Protocols and Services, and (4) EHR Collaborative. The SCP consists of representatives from RHIOs, providers, consumers, patient advocacy, health insurers, and other groups. The workgroups recommend policies, standards, technical approaches, and services to the NYeC Policy and Operations Council, the NYeC Board and the New York State Department of Health.

The Privacy and Security Committee is tasked with developing privacy and security policies and procedures to govern the electronic exchange of information within the state. The Privacy and Security Committee consists of three subgroups: (1) Authorization, Authentication, Access, and Auditing (i.e., the 4As); (2) Consumer Consent; and (3) Contractual & Regulatory Solutions.

New York has committed \$5 million to NYeC to manage the entire SCP over a period of two years.

MASSACHUSETTS

No. Massachusetts does not currently have a statewide governance body in place tasked with developing privacy and security policies.

Massachusetts has not developed a statewide governance body that is tasked with developing privacy and security policies for the state. Instead, in Massachusetts oversight and operations of health information exchange are spread across three overlapping entities:

- (1) Massachusetts Health Data Consortium (MHDC), formed in 1978, leads the development of a comprehensive health data system to address the health information needs. MHDC leads Massachusetts HISPC activities.
- (2) MA-SHARE, created in 2003, is the state’s “clinical grid,” providing utility services that support secure clinical data exchange.

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- (3) Massachusetts e-Health Collaborative (MAeHC), launched in 2004 with \$50 million from Blue Cross Blue Shield, is supporting physician adoption of EHRs and HIE efforts as pilot projects in three communities.

With respect to governance of statewide HIE, MAeHC operational guidance for its three pilot communities is envisioned as a potential model for the state; if designated and funded, MAeHC will reconstitute its statewide committees. With respect to the creation of statewide privacy and security policies and procedures, no statewide deliberative process for privacy and security exists in Massachusetts at this time beyond the MHDC-supported HISPC activities.

MINNESOTA

No. Minnesota does not currently have a statewide governance body in place tasked with developing privacy and security policies; however, an e-Health Advisory Committee exists and includes two workgroups which advise the Committee as privacy-related issues arise.

While Minnesota has developed a statewide e-Health advisory body, this entity is empowered only to advise the Commissioner of Health on issues related to the electronic exchange of health information and is not empowered to create enforceable policies to govern HIE within the state. This advisory body, the Minnesota e-Health Initiative (MN e-Health) Advisory Committee, was established by the Minnesota Department of Health in 2005, and is a public-private collaborative consisting of 26 appointed members.

Beginning in 2005, MN e-Health launched a comprehensive statewide analysis of the privacy and security considerations for HIE. MN e-Health has two subcommittees focused on privacy and security: the Patient Consent Subgroup and the Authorization, Authentication, Access Control and Auditing Subgroup (4A Subgroup).

Currently, the MN e-Health Privacy and Security Work Group serves as a standing body to review policies and offer guidance to emerging HIEs in Minnesota regarding privacy and security. This Work Group serves in a reactive capacity as an advisory group that responds to HISPC-related questions and that gives feedback to the MN e-Health (and other workgroups) as privacy-related issues arise. However, the workgroup has not been tasked with proactively creating statewide privacy and security policies and procedures.

TENNESSEE

No. Tennessee does not currently have a statewide governance body in place tasked with developing privacy and security policies.

Tennessee has not developed a statewide governance body tasked with developing privacy and security policies for the state. Tennessee has created an "eHealth Coordinating Council" that is charged with coordinating across local HIE initiatives in order to ensure interoperability, facilitate the definition of uniform standards, eliminate duplication of effort and reduce competition for resources. However, this entity serves only in an advisory capacity and is not empowered to develop statewide policies to govern the electronic exchange of health information within the state. While the Coordinating Council has occasionally generated ad hoc issue-based committees, none of these committees have been permanent and none have produced final recommendations or reports.

2. SCOPE OF PRIVACY AND SECURITY POLICIES

- ***Does the state distinguish between “one-to-one” and “many-to-many” exchanges for the purpose of applying any statewide or other privacy and security policies?***

- ***What rules apply to one-to-one exchanges? To many-to-many exchanges?***

NEW YORK
Yes. New York distinguishes between one-to-one and many-to-many exchanges; one-to-one exchanges are governed by existing federal and state regulations and excluded from the statewide privacy and security policies developed for many-to-many exchanges.

New York makes a distinction between “one-to-one” and “many-to-many” exchanges of health information and excludes one-to-one exchanges, including those conducted via the SHIN-NY, from its privacy and security policies governing statewide information exchange.

New York defines one-to-one exchanges as a disclosure of PHI by one of the patient’s providers to one or more other providers treating the patient where no records other than those of the Participants jointly providing healthcare services to the patient are exchanged. A one-to-one exchange is an electronic transfer of information that mirrors a paper-based exchange.

While one-to-on exchanges are excluded from New York’s Privacy and Security Policies and Procedures, they remain subject to all applicable federal and state laws. However, providers are not obligated to obtain the new RHIO-specific consent required of the Policies & Procedures, nor abide by the access policies included therein within the context of one-to-one exchanges.

MASSACHUSETTS
Yes. Local exchanges in Massachusetts distinguish between one-to-one and many-to-many exchanges; one-to-one exchanges are governed by existing federal and state regulations and excluded from privacy and security policies developed for many-to-many exchanges.

In the MAeHC pilots, the projects distinguish between “one-to-one” and “many-to-many” exchanges.

One-to-one exchange is allowed without consent for treatment, payment and operations (TPO) under HIPAA. In the context of a one-to-one exchange, two distinct entities can exchange information electronically (such as the exchange of results, ordering of tests, etc.) without consent. This would be considered TPO and would be covered by HIPAA regulations.

MINNESOTA
Yes. Minnesota distinguishes between one-to-one and many-to-many exchanges; one-to-one exchanges are governed by existing federal and state regulations and excluded from privacy and security policies developed for many-to-many exchanges.

The Minnesota Health Records Act (see below) makes a distinction between “one-to-one” and “many-to-many” exchanges of health information. Within a health system or for uses where data exchange isn’t facilitated through a Record Locator Service (RLS), authorized participants can exchange information in compliance with federal and state laws.

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For “many-to-many” exchanges, i.e., data exchange enabled through a RLS, participants must comply with applicable HIE consent requirements and policies.

TENNESSEE

No. Tennessee does not explicitly distinguish between one-to-one and many-to-many exchanges; both types of exchange are governed by existing federal and state regulations.
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Tennessee has not made a distinction between “one-to-one” and “many-to-many” exchanges of health information. The same federal and state laws that govern the “one-to-one” exchange of health information apply to “many-to-many” exchanges.

Because the state does not have any laws in place that are more stringent than HIPAA, these rules govern both types of exchange within the state.

3. POLICY INTEROPERABILITY AND ENFORCEMENT

- ***Are all participants in statewide HIE required to abide by privacy and security policies under development?***

- ***Does a statewide enforcement mechanism exist to ensure compliance?***

NEW YORK
Yes. New York is attempting to ensure statewide policy interoperability by requiring that HIEs receiving state contracts abide by the privacy and security policies developed through the state governance body.

New York requires that participants in HIE abide by privacy and security policies developed through the SCP. New York is building its Health Information Infrastructure, called the SHIN-NY, by means of contracts with awardees who receive funding under the HEAL NY Phase 5 Program. Participant accountability is ensured by requiring awardees to participate in the SCP under the direction of NYeC and to adopt and abide by the policies and procedures, known as the Statewide Policy Guidance, developed through the SCP.

This Statewide Policy Guidance is the vehicle through which New York State has developed, and is requiring compliance, with common policies including those related to privacy and security.

New York State's initial Statewide Policy Guidance Package, called HEAL 5 Version 1.0 Requirements, includes RHIO Privacy and Security Policies and Procedures which set out the official privacy and security policy requirements that RHIOs receiving HEAL 5 grant monies must follow as they exchange information through the SHIN-NY.

The Policies and Procedures set forth minimum policies that RHIOs must follow to protect privacy, strengthen security, ensure affirmative and informed consent, and support the right of New Yorkers to have greater control over and access to their personal health information.

MASSACHUSETTS
No. Massachusetts does not require that participants in HIE abide by uniform statewide privacy and security policies; privacy policies vary among local exchanges.

Because Massachusetts has not developed statewide privacy and security policies to regulate the electronic exchange of health information, participants in HIE are not required to abide by a specific set of policies and procedures. All three pilot communities within MAeHC have privacy and security workgroups which have developed their own community-specific privacy policies and procedures.

At the state level, a statewide, collaborative privacy and security advisory workgroup existed in the past and has now become the state's HISPC group. This statewide workgroup has helped standardize privacy approaches across the three local exchanges when significant discrepancies in community-specific privacy policies or procedures have occurred.

For example, the North Adams community wanted a global consent model (RHIO-wide consent) instead of requiring a patient to give consent on an entity-by-entity basis (which was favored by

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the other two exchanges). The statewide workgroup mediated this difference between the two groups by coming up with a scenario/specific set of rules where global consent would/could be allowed.

Therefore, variation does exist across the communities; in North Adams, patients have a global consent model, while in the other two systems, consent is required on an entity-by-entity basis.

MINNESOTA
Yes. Minnesota does require that participants in HIE abide by the privacy and security policies promulgated via state statute; however, specific privacy policies and procedures vary among local exchanges.

Minnesota requires that participants in HIE abide by the rules for electronic exchange laid out in the Health Records Act. However, local exchanges (such as the Wynona RHIO, Southwest MN RHIO, Northwest MN RHIO) have all developed their own unique consent forms and detailed consent processes to meet state statutory requirements (and applicable federal requirements) around privacy.

The Minnesota DOH does not directly regulate how HIEs set up the specifics of their consent policies and related consent forms outside of the requirement that whatever they create must comply with relevant laws.

Further, while the Minnesota DOH provides guidance, information, and technical assistance to assist local exchanges in complying with statutory requirements, it does not confirm or certify that the processes they implement are in compliance.

TENNESSEE
No. Tennessee does not require that participants in HIE abide by uniform statewide privacy and security policies; privacy policies vary among local exchanges.

Because Tennessee has not developed statewide privacy and security policies to regulate the electronic exchange of health information, participants in HIE are not required to abide by a specific set of policies and procedures. Accordingly, privacy and security policies vary across local RHIOs and all of these local initiatives have developed unique privacy policies and procedures as well as requirements around consent.

Further, because state law in Tennessee is more stringent than HIPAA only with respect to patients' mental health data, local participants predict that if statewide policies were to be created for HIE, they likely would be primarily created to account for this specific category of data.

However, despite the fact that adherence to uniform policies is not required, local participants have observed consistency in privacy policies across local exchanges. Participants surmise that this is because state privacy laws lack complexity and generally mirror HIPAA requirements, making similarities in privacy policies more likely.

4. SEEKING CHANGES TO OR CONFORMING WITH EXISTING LAWS

- *Did the state change or pass new laws to govern HIE or did it develop its policies such that they are consistent with existing law?*

NEW YORK
No. New York did not change/pass new laws. New York’s statewide privacy and security policies have been developed in compliance with existing law.

New York agreed early on that changes to state law would be difficult, time-consuming, and potentially too rigid of a mechanism to allow for the flexibility required by a still-evolving HIE market. As such, stakeholders agreed that the state’s privacy framework should be designed to comply with existing state law.

New York state law requires that hospitals, physicians, other healthcare providers, and HMOs obtain patient consent before disclosing Protected Health Information for nonemergency treatment. Unlike HIPAA, New York state law provides no exception to this requirement for treatment, payment or healthcare operations. While consent may be verbal or even implied for most types of health information, this is not the case for certain classes of specially protected healthcare information, including information related to HIV status, mental health and genetic testing, the disclosure of which requires written consent.

These laws reflect a desire to ensure that patients are protected from unauthorized uses of Protected Health Information and have provided both a legal and normative guidepost for the development of consent policies for information exchange by RHIOs via the SHIN-NY.

As a result, New York chose to require, consistent with existing New York law as described above, that each provider and payer participating in a RHIO obtain an affirmative consent from the patient before accessing their Protected Health Information through the SHIN-NY (see below).

MASSACHUSETTS
No. Massachusetts did not change/pass new laws. Massachusetts’ privacy and security policies have been developed in compliance with existing law.

Massachusetts has not passed new laws to govern the electronic exchange of health information. Instead, HIE in the state is regulated by existing federal and state laws. State law in Massachusetts is more stringent than HIPAA; it requires written consent to share medical data, and it requires a second informed written consent for the sharing of sensitive data (including mental health information, substance abuse information, HIV information and genetic information). Both types of consent are required whether the transfer of clinical information is by paper or electronic means.

Further, the second informed consent for sensitive data is necessary for each subsequent disclosure (described as “per instance” consent). The protection follows the medical record.

As such, local exchanges in Massachusetts have interpreted relevant state and federal law to require written consent before data can be uploaded to the exchange, and to require a second consent to upload/disclose sensitive data to the exchange (see below).

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MINNESOTA

Yes. Minnesota has passed new laws to govern HIE in the state.

Minnesota has passed new legislation to govern the electronic exchange of health information. The Minnesota Health Records Act (Minnesota Statutes §§ 144.291–.298), first passed in 1977, requires patient consent for the disclosure of patient information. This law was recodified in 2007 so that it would specifically address the electronic exchange of health information.

Like New York, Minnesota law requires written consent even for purposes of treatment, with exceptions existing only for medical emergencies and for disclosures among facilities within an integrated care system. Patient consent generally expires within one year.

When the state legislature revised the Minnesota Health Records Act in 2007, it defined requirements for new and existing terms and concepts in order to account for the electronic exchange of health information. These terms included:

- Health record
- Medical emergency
- Health information exchange
- Record locator service
- Authorized “representation of consent”

Developing privacy policies through the 2007 statute served several purposes: in the original Health Records Act, terms were not well-defined; consent-related requirements were not readily applied to the electronic exchange of information; and a need existed to update and recodify the Act in order to facilitate electronic exchange.

TENNESSEE

No. Tennessee did not change/pass new laws. Tennessee’s privacy and security policies have been developed in compliance with existing law.

Tennessee has not passed new laws to govern the electronic exchange of health information. Instead, local participants in HIE are required to develop privacy and security procedures that are in compliance with existing federal and state laws regarding the exchange of health information.

Unlike the other states included here, Tennessee law does not have stronger requirements than HIPAA.

Accordingly, consent is not required for treatment, payment, or operations (and, as HIE is considered TPO under HIPAA, it also does not require patient consent). Written consent is only required for the disclosure of mental health data.

5. BASELINE CONSENT PRINCIPLES

- *Does a statewide approach to consent exist?*
- *Is affirmative consent required for data suppliers to make available (i.e., upload) patient data, demographic or clinical, to the exchange?*
- *Is affirmative consent required for providers to access patient data, demographic or clinical, that has been made available to the exchange?*
- *Do patients have a right to entirely exclude their data from the exchange?*

NEW YORK

New York requires affirmative consent for a provider or payer to access patient information contained in the exchange. However, New York does not require affirmative consent for data suppliers to make available (i.e., disclose/upload) patient information to the exchange. Patients cannot exclude their data from the exchange.

Per the Privacy and Security Policies and Procedures developed through the SCP, New York requires that affirmative consent be obtained by each provider and payer organization participating in a RHIO before they are permitted to access a patient's Protected Health Information through the SHIN-NY.

Consent may be obtained at a provider or payer organization level (e.g., medical practice, hospital) and need not be at the individual clinician level. Once a provider or payer organization obtains consumer consent, it may access the information of all RHIO data suppliers unless the RHIO has voluntarily established additional restrictions on disclosures as indicated below in Baseline Access Principles.

In order to ensure that health information about a patient is available after a provider obtains affirmative consent to access the information, New York allows providers to convert/upload a patient's Protected Health Information to a RHIO without patient consent if the RHIO is serving as the provider's business associate and the RHIO does not make the information accessible to other RHIO participants until patient consent to access the data is obtained.

Although patient consent is required to make uploaded or converted data maintained by a RHIO accessible to other participants, it is recognized that, in connection with attempting to identify consumers in a record locator service or other comparable directory, RHIO participants may, on an occasional basis, inadvertently view limited demographic information about the wrong consumer contained in such service or directory. These incidental disclosures of consumer information are not treated as privacy or security breaches by New York state government.

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MASSACHUSETTS

Exchanges in Massachusetts do not require affirmative consent to access patient information contained in the exchange. However, affirmative consent is required for data suppliers to *make available* (i.e., disclose/upload) patient information to the exchange.

Patients can exclude their data from the exchange by denying consent to disclose/upload data to the exchange.

While there are no current statewide consent policies, all three communities participating in the MAeHC pilot operate under an affirmative consent model in which consent is required to upload information to the exchange. No affirmative consent is required for the provider to access the information once a patient has consented to having his or her data uploaded to the exchange, and any authorized user can access patient data after it is uploaded.

In fact, the only specific requirements that could be viewed as governing access to the information after it has been uploaded are the set of qualifications a provider must meet upon joining the exchange in order to be deemed an authorized user.

The only information that is available at the point of access is a patient summary. The patient summary includes patient demographics, medications, allergies, problem, diagnoses, procedures, radiology summary, and laboratories.

MINNESOTA

Exchanges in Minnesota require affirmative consent for a provider to access both patient-identifying and clinical data from the exchange. Affirmative consent is not required to *make available* (i.e., disclose/upload) patient information to the exchange. Patients can, however, actively choose to exclude their data from the exchange.

Like New York, consent is not required to make data available to the exchange, but is instead required to access information that has been uploaded to the exchange.

Per the requirements set forth in the Health Records Act, no affirmative consent is required to disclose (or upload) patient-identifying information to a RLS. This means that payers and providers can populate the RLS (out of their own Master Patient Indexes, MPIs) without patient consent, so that anyone who has a record at a participating institution and has not specifically opted to exclude their data from the exchange may potentially already have data within the RLS.

With regard to consent to access data that has been uploaded to the exchange, two separate forms of affirmative consent are required for access: providers must obtain consent to access both the patient-identifying information contained in the RLS, and to retrieve a patient's clinical data (after locating it through the RLS). Both types of affirmative patient consent (to access the RLS and to retrieve a patient's information) are included on the same patient consent form (same form but two different, specific types of consent).

An additional important element of Minnesota's consent framework is the "representation of consent." If a provider who is requesting data states they have obtained consent, the releasing provider can rely on the "representation of consent" from the requesting provider and can release the data without fear of liability.

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Finally, the Health Records Act requires that every HIE have an option in place for patients to exclude their data from the exchange. This means that while consent is not required to prepare and upload data to the exchange (i.e., data suppliers can do so without fear of liability), the HIE must have the policy and technical capacity to remove all patient data from the HIE if the patient requests that it do so. The methods by which RHIOs in the state will operationalize these requirements are still unclear.

TENNESSEE

Exchanges in Tennessee do not require affirmative consent for a provider to access patient information, nor is affirmative consent required to *make available* (i.e., disclose/upload) patient information to the exchange. Within some local exchanges, however, patients can actively choose to exclude their data from the exchange.

Unlike the other states included in this analysis, Tennessee does not require affirmative consent for a provider to access patient information or for a provider to upload patient data to the exchange. This is because no statewide laws or policies have been developed to govern the exchange of health information outside of existing federal and state laws, and stakeholders within the state have interpreted these laws to not require consent to access, nor to upload, patient data.

Accordingly, the electronic exchange of information is treated as TPO under HIPAA, HIEs are treated as third party business associates of HIPAA-covered entities, and consent is not required to exchange information between the two types of entities. Based on state law, the only exception to this is related to mental health data; written consent is required to disclose mental health data whether exchanged via traditional paper-based methods or electronically through an HIE.

However, some local exchanges have voluntarily chosen to require that providers notify patients that their data will be disclosed to the HIE. For example, CareSpark requires that providers provide written notification to patients that their data will be disclosed to the HIE and accessible by providers using the HIE (i.e., notification, but not consent, is required).

Participants in CareSpark have two options for notifying patients: a “passive enrollment” model in which patients are informed via a separate piece of paper that their data will be disclosed to and accessible through the exchange, or an “active enrollment” model in which the provider obtains a patient’s written authorization to participate in HIE. Providers can choose either of the two options and are obligated to verify to the HIE that one of the two has been performed for each patient whose data is included in the exchange.

Though consent is not required to disclose or access data, patients participating in the CareSpark HIE have the right to exclude their data from the exchange. In order to do so, they need only request that the HIE remove their information and that their providers no longer disclose their information to the exchange.

6. DATA FILTERING

- *Does the state allow HIEs to limit provider access to certain types of data?*

NEW YORK
<p>No. In New York, patients may not limit the types of data to which providers have access. Data Suppliers, however, are free to request patient consent before making sensitive health information available to an exchange.</p>

New York chose an “all or nothing” approach to health information exchange through the SHIN-NY, meaning that upon obtaining an affirmative consent from the patient, RHIO participants may access **all** Protected Health Information about the patient, including Sensitive Health Information.

Sensitive Health Information means any information subject to special privacy protection under state or federal law, including, but not limited to, HIV/AIDS, mental health, alcohol and substance abuse, reproductive health, sexually transmitted disease, and genetic testing information.

Recognizing that providers of sensitive health services (e.g., family planning and HIV clinics) and other organizations may have heightened concerns about permitting RHIO participants to access their information based on a consent signed by a patient at another provider or payer organization, however, New York allows providers to withhold their data (or “filter” it) unless/until a patient signs a consent permitting the organization to share the information through the RHIO. This, however, is not required.

MASSACHUSETTS
<p>No. Exchanges in Massachusetts are not required to allow for patients to limit the types of data to which providers have access; however, due to existing law, affirmative consent is required to disclose certain types of sensitive health data.</p>

No statewide policy exists that requires patients to have the ability to limit the types of data to which providers have access. Thus far, local exchanges have chosen to not allow patients to filter certain types of data.

For example, MAeHC does not offer an option for patients to filter sensitive health data from the information they consent to exchange. It is a blanket consent in which a patient consents to disclose all data: if a patient opts in, all of their data is available. Exchanges make sure that patients know this by specifically stating in the consent form that the exchange does not have the ability to filter sensitive data.

However, for specific types of tests results (those related to HIV and genetic testing), consent is required to disclose each specific test result. So there is some filtering in the three communities, but only from a consent perspective, and only because it is required by law.

MCHIE Statewide HIE Plan
ATTACHMENT C: APPROACHES IN LEADING STATES

MINNESOTA

No. Exchanges in Minnesota are not required to allow for patients to limit the types of data to which providers have access.

No statewide policy exists that allows patients to limit the types of data to which providers have access. Thus far, local exchanges in Minnesota have chosen an “all or nothing” approach to health information exchange through an HIE and do not allow patients to filter certain types of data. When patients consent to allow a provider to access data contained in the exchange, the provider has access to all available data.

At this time there are no efforts to mask, filter or allow patients to choose specific components of information that physicians can see.

TENNESSEE

No. Exchanges in Tennessee are not required to allow for patients to limit the types of data to which providers have access. However, some local exchanges in Tennessee allow for the filtering of sensitive data on a provider-specific basis.

No statewide policy exists that allows patients to limit the types of data to which providers have access.

However, some local exchanges allow patients to choose whether to disclose their data on a provider-specific basis. For example, patient participants in CareSpark have control over which providers they allow to upload data to the exchange (so they can choose to upload data from one provider, but can ask that data from another provider not be uploaded/included in the exchange).

Further, patients can also choose to exclude data from a specific office visit with a provider, even if they allow for data from other office visits with that provider to be disclosed to the exchange. This works by having the providers simply not upload data from the office visit at issue to the exchange; if the office visit data is inadvertently disclosed, the patient can ask that CareSpark remove data from that particular office visit. Once the data has been disclosed, patients do not have control over which providers see the data.

Montgomery County HIE Collaborative
Technical Considerations for Statewide HIE
Analysis and Recommendations

Montgomery County Health Information Exchange Finance Team,
assisted by Manatt Health Solutions
February 2009

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EXECUTIVE SUMMARY AND PURPOSE OF DOCUMENT

The technical implementation of Maryland's health information exchange (HIE) effort will be driven by the clinical priorities, value proposition, privacy and security requirements, and financing parameters.

In developing its overall technical approach, the Montgomery County HIE Collaborative (MCHIE) Technical Team assessed four threshold issues:

- **Technical Design Principles** – What principles should guide the technical design and implementation of statewide HIE?
- **Implementation Approach** – Which is the most feasible, flexible, and least costly approach for achieving statewide HIE in Maryland?
- **Interoperability Standards** – How should standards conformance be achieved?
- **Use Case Sequencing** – Of the portfolio of existing use cases, how should implementation be sequenced to ensure cost-effectiveness, maximize flexibility, and minimize risk?

This document consolidates the analysis of the opportunities, challenges, risks and implications associated with the various technical approaches for statewide HIE, and it provides the basis for the MCHIE final report to the Maryland Health Care Commission (MHCC).

I. MHCC RFA REQUIREMENTS FOR TECHNICAL FEATURES

The MHCC Request for Applications requires each of the awarded planning projects to address a series of technical architecture considerations. The RFA requirements are provided below; elements directly related to the technical architecture are highlighted in *italics*.

“Core” Functions

1. *A substantive health record for participating consumers*
2. *Information source identification*
3. *Consumer controls access to their information*
4. Voluntary participation
5. A process for consumers to correct errors and incomplete information
6. A consumer and public education component
7. *A clear process for consumers to authorize access and electronic transfer of information*
8. *Strong authentication procedures*
9. *Audit trails and access reporting to consumers*
10. *Incorporate appropriate standards as they become recognized national standards*
11. *Adherence to state and federal laws – HIPAA, MD’s Confidentiality of Medical Records Act, etc.*
12. *System availability 24/7*
13. *Accommodation of existing technology infrastructures*
14. *Clinical decision support priorities*
 - a. *Medication history and reconciliation*
 - b. *Diagnostic results reporting*
 - c. *Continuity of care records*
 - d. *Longitudinal health records*

“Expansion” Functions

1. *Public health priorities*
 - a. *Immunization tracking*
 - b. *Bioterrorism alerts*
 - c. *Disease incidence monitoring*
2. *Quality and patient safety standards*
 - a. *Tracking national and regional best practices*
 - b. *Benchmark regional performance against national standards*
3. *Personal health record management*
 - a. *Define Elements of a PHR*
 - b. *Relevant integrated data set*
 - c. *Provisions for self-reported data*
 - d. *Include value-added services*
 - e. *Multiple modality access*

Infrastructure/data management

1. *Data architecture*
2. *Security and privacy*
3. *Standards (both national and community-based)*
4. *Infrastructure assessment (including gap analysis)*
5. *Analytics, including:*
 - a. *Population health*
 - b. *Disease/health management*
 - c. *Patient safety*
 - d. *Resource management*

II. BACKGROUND ON STATE-LEVEL HIE TECHNICAL APPROACHES¹

A functional statewide HIE is a “system of systems,” in other words, a collection of parts that work together to achieve a common purpose or carry out a specific goal within a defined architecture.

In the architecture of a network, the “parts” are generally subsystems and interfaces. The “subsystems” of a statewide architecture in Maryland will be the networks and applications that support four broad classes of entities:

- Care delivery organizations that use electronic health records (EHRs), disease management, clinical decision support and other clinical applications;
- Organizations that operate personal health records (PHRs) and support other consumer applications;
- HIEs that serve multi-stakeholder entities and enable the movement of health-related data; and
- Specialized participants that operate for specific purposes including, but not limited to laboratories, radiology centers, public health, research, and quality assessment.²

Many of these organizations have their own health IT systems and networks. The statewide HIE is not intended to supplant these networks. At any point in time the organizational networks will be in different stages of their life cycles, will be built on many different technologies, and have differing priorities regarding the data they collect and transmit.

A. Technical Components and Key Considerations

Technical architectures for the exchange of health information are typically segmented into three geographic units of organization: (1) nationwide standards and protocols; (2) regional or sub network HIEs; and (3) enterprise or organization information exchange components.

Across and within these geographic constructs, HIE implementation is built on a “stack” of seven layers:

1. Source System Data, Interfaces, and Service Components
2. Source System Integration, Messaging, and Service Components
3. Business Processes
4. Presentation
5. Security
6. Non-functional Requirements
7. Technology Governance

¹ Background information adapted from two sources: (1) National Committee on Vital and Health Statistics. “Letter on Functional Requirements for a NHIN.” October 30, 2006; and (2) Gartner. “Summary of the NHIN Prototype Architecture Contracts.” May 31, 2007.

² The specialized nature of these organizations means that they may require only a subset of the shared architecture (standards, services and requirements), processes and procedures used by the other participants.

The layers are based on the sequence of events to enable the core functional services starting with a discussion of clinical information sources and acquisition, integration patterns, business processes as services, and presentation layer implications. With separation between presentation layer, business logic, and data, a multi-tier approach better ensures application scalability and security.

A discussion of the key functions and implementation considerations for each of the seven layers of the statewide HIE architecture in Maryland is provided below.

Layer 1. Source System Data, Interfaces, and Service Components

The foundation and basic premise of HIE is enabling the exchange of healthcare data from source systems. When considering the relationship between a local physician and HIE at a enterprise, local, regional, or state level, it is helpful to examine the source systems that make up the health records of patients.

Typical data sources include some that may be nationwide such as records from Pharmacy Benefit Managers (PBMs) or retail pharmacy chains, regional organizations such as hospitals or delivery networks, and some that are highly localized such as individual provider offices. Each organization may contain components of a patient's records. Due to the differing size and scope of data sources, these enterprise organizations may be able to facilitate all or some of the HIE services as part of their enterprise. For this architectural layer, the primary consideration is the ability of the data sources to either send data to an external network or serve as a node on the network where direct queries and responses can be made.

Within this framework, data sources contribute to record locators, respond to queries, and deliver data to authorized requests. Additionally the infrastructure to manage information exchange may be present even as a part of the data source, in which case, the set of source systems may be able to act as network of their own. Examples of these include SureScripts-RxHub's service-based capabilities where formulary, eligibility and medication history data can be made available to enterprises or to HIEs without requiring replicated storage of data in a HIE specific repository.

On the other hand, for data sources can only "push" information, it may be necessary to establish a separate data repository that replicates the data already stored by the data source system. These are frequently described as federated edge servers which then handle the aggregation and transport of records for a data source system.

2. Source System Integration, Messaging, and Service Components

Once data sources and approaches to data acquisition are established, the next step is to consider how enterprise or local systems can be connected and which protocols the source systems are capable of providing. Due to the local nodes requiring proprietary or non-standards based interfaces, the requirements of HIE integration can change, particularly as new systems are implemented or existing systems are replaced.

Once the question of where responsibility for data acquisition exists is addressed, the next step is to determine (1) how interfaces are handled, (2) what transformations are needed to enable clinical data interoperability, and (3) what service components are needed to securely route messages to service requesters or endpoints such as a presentation layer or clinical decision support service.

Service-oriented Architecture (SOA) using an Enterprise Service Bus (ESB) paradigm is the accepted practice for messaging standards based exchange and is the common integration model targeted for the application, enterprise, region and statewide. SOA is especially useful for loosely coupled, network applications that are typical of many HIE implementations. As a baseline, the ESB is a common pattern used for connectivity, transport, security, and messaging management. In addition to messaging, the ESB paradigm instantiates information exchange services such as identity management, data standards, normalization, retrieval, and consent. Services and their definitions are stored in a Universal Description Discovery and Integration (UDDI) registry which can be searched and invoked as part of a service discovery function and applied at run-time based on defined business processes.

Core architectural considerations to consider are the protocols that make up the services stack hosted by a service bus, segmentation of the service bus based on functions, service registration, invocation and connectivity to enterprise systems. Key architectural decisions for the ESB include defining the protocol stack and the scope of its implementation both for a local HIE, as well as statewide.

Layer 3. Business Processes

In a SOA approach, business processes and use cases serve as the foundation for determining an implementation framework to enable the functional requirements that define and constrain the system. As described above, services, once defined to support a business process, typically exist as part of either a local HIE service stack or a statewide one in which case it is meant to be implemented uniformly across all local HIEs. To the extent that a statewide bus is the primary vehicle, then implementation to local nodes or enterprises such as physician organizations or hospitals may be made directly to a statewide utility. This would enable developing HIEs or information exchange nodes to be able to more rapidly adopt and implement services as they matured through conformance to the defined structure of the HIE service. Additionally, hospital systems or services compliant would be able to connect to these services more rapidly through existing HIEs or, if authenticated and policy allows, directly to a statewide service bus.

To establish business processes as services, major functional requirements must first be elucidated. For example, medication history and reconciliation could potentially form a set of sub-services. Based on the functional requirements around medication management, use cases are typically formed which identify the actors and decompose the overall interactions and workflows in order to form the set of web services and definitions which will enable message definitions.

Important cost considerations in this layer include determining and prioritizing the set of functional services and the need for distributed implementation of these services as they require instantiation of both uniform interfaces to any network requesting services. Each HIE would need to implement, at a minimum, the bootstrapping process to access the statewide ESB as well as all infrastructure requirements such as "core" services including authorization, authentication, access, consent, and audit controls.

Layer 4. Presentation

The presentation layer consists of the suite of applications that end-users such as clinicians, administrators, support staff, and consumers utilize to interact and perform the actual business processes. One of the goals of a SOA is to provide standardized interfaces to existing presentation layers as well as providing interface mechanisms for the business users.

It is helpful for each service component to describe standards for implementation at the presentation layer in order to tie functional requirements and use cases to the interactions by which end users utilize the system. Portals are commonly utilized by HIEs as they can act as the intermediary between users and the services.

Additionally, portals are customizable and can be further segmented using a services approach by defining specific web service portlets which can be used to directly invoke and process web services. As services are enabled, it is possible for existing systems or legacy systems to integrate service functions into the existing clients to perform the specified functions.

In all three state models, the primary presentation layers consist of provider EMRs (pushing messages to them to support specific use cases) and portals made available via the HIE.

Layer 5. Security

Based on the messaging architecture paradigm being adopted and utilized for health information exchange (SOA-ESB), security policies should be defined and adopted by MCHIE as part of the initial architecture process. Security policies are usually described as ensuring data confidentiality according to privacy policies, protection data, and making it available in a timely manner.

As a starting point, Healthcare Information Technology Standards Panel (HITSP) provides a set of security and privacy technical constructs consisting of:

- Entity Identity assertion (C19)
- Nonrepudiation of origin (C26)
- Collect and communicate audit trail (T15)
- Consistent time (T16)
- Secured communication channel (T17)
- Manage sharing of documents (TP13)
- Access control (TP20)
- Manage consent directives (TP30)

The set of HITSP-provided security constructs bring forth best practices such as WS-Interoperability and WS-Security for securing web services and acknowledges the lack of healthcare specific standards for activities such as patient consent directives and assertions.

In addition to adopting the messaging standards, HITSP standards for security are considered as starting points for statewide HIE capabilities. These standards cover:

- Attachments: MTOM for encoding of message payloads
- Security: WS-Security
- Authorization Assertions: SAML
- WS-I Basic security profile
- Identification Controls – digital certifications, security assertions, LDAP and Kerberos
- Audit – Audit tracking and node authentication (ATNA) including authentications, audit trails and trail transport primarily via BSD syslog.

Specific considerations in terms of security include:

- Implementing security protocols and parameters into HIE nodes
- Determining security and implementation requirements for end points

- Internet connectivity requirements
- System availability requirements
- Firewall / DMZ partitioning
- Protecting web services
- XML message scanning
- XML and WSDL validation
- WSDL interface definitions
- Disaster recovery
- Consistent time – Network Time Protocol RFC 1305
- Securing nodes
- X.509 digital certificates

Layer 6. Non-functional Requirements

Below is a proposed list of categories that include system qualities or “non-functional” requirements. The expectation is that categories of non-functional requirements will only be designated where the property has a substantial impact on the architecture and capabilities of the state’s health information infrastructure.

- Accuracy: A measure of the application service quality from the customer’s perspective, the precision with which responses are provided to customer inquiries.
- Availability: Specifies a system’s capabilities with respect performance expectations (e.g., 24/7 availability) during operations.
- Business Rules: Policy driven dynamic requirements that may change during the operation of the system, requiring that the system adapt to the change without major rework.
- Performance: A measure of the degree to which an entity satisfies its intended purpose.
- Robustness: A measure of the ability of system to adjust to unanticipated conditions (i.e., the ability of a system to adjust to unanticipated conditions without losing its endurance and level of quality).
- Scalability: A measure of the ability of system to adjust or extend to changing demands (user load, data load).

To a large degree, detailed specification of the non-functional requirements will be driven by the outcomes of the statewide collaborative process defined by the MCHIE Governance Team.

Layer 7. Technology Governance

Technology governance, in a SOA approach, becomes highly linked to policy as organizations and systems need to align across specific implementation of business processes. An approach to validate, certify and monitor existing processes as well as provisions to sunset and introduce additional services is required.

Part of the cost of being flexible is that there must be mechanisms to accommodate changes. In addition to establishing policies, procedures and operational teams to make services level and business process decisions, enforcing governance rules and policies at run-time via the technology architecture is paramount to ensuring ongoing SOA development and maturity.

B. Use Case Definitions

Background

The development of information technology systems historically has relied on the identification and description of use cases. Use cases are the series of events that outline what a system (or systems) needs to do to achieve a specific mission or stakeholder goals. Use cases define relevant stakeholders, information flows, issues, and systems needs that apply to the multiple organizations participating in these specified data exchanges.

With respect to health IT, use cases have guided the development of HIE efforts at the national, state, and local levels. At the national level, the American Health Information Community defined and the HHS Secretary accepted a series of use cases to advance standards harmonization, define architecture specification, inform certification consideration, and provide the framework for detailed policy discussions to advance the national health IT agenda.

MHCC's Request for Applications identified four core functions (described as "clinical decision support priorities"):

- Medication history and reconciliation
- Diagnostic results reporting
- Continuity of care records
- Longitudinal health records

The Request for Applications also identifies three additional "expansion" functions:

- Public health reporting, tracking and monitoring
- Quality and patient safety
- Personal health record management

Clarity regarding the parameters of these use cases is essential for building the technical framework, assessing system costs and integration considerations, and ascertain financing options. Accordingly, MCHIE expanded MHCC's definitions, identified key functionalities, and documented quantified benefits along eight use cases:

1. Diagnostic Results Reporting
2. Medication Management
3. Transfer of Care
4. Quality Reporting
5. Research
6. Public Health
7. Community Resource Management
8. Consumer Empowerment

The table below provides a high-level summary of the functional parameters of each use case.

Use Case	Details
1. Diagnostic Results Reporting	<p>Definition: Allow a clinician to electronically obtain diagnostic results (including laboratory test results, radiology reports, and pathology reports) that he or she has ordered and to electronically obtain relevant test results for the purpose of the clinical care of a patient.</p> <p>Functionality: The delivery of diagnostic results for the initial phases of implementation is on a “push” basis to a targeted set of recipients (e.g., the requesting physician).</p>
2. Medication Management	<p>Definition: Medication Management Services typically provide medication history retrieval and aggregation from multiple sources, Medicaid and insurance eligibility checks, formulary queries, and e-prescribing functionality.</p> <p>Functionality: Via an EHR or portal, authorized clinicians will be able to (1) determine patient eligibility; (2) download the appropriate formulary file for patient’s coverage plan; and (3) search for patient’s medication history across multiple records and aggregate into a single view, providing clinician additional patient medication information including allergy, drug sensitivity, and condition information.</p>
3. Transfer of Care	<p>Definition: Defined by the AHIC in March 2008, the Transfer of Care use case describes the information flows, issues and system capabilities that apply to a provider requesting a transfer of care for a patient and the receiving facility admitting the patient.</p> <p>Functionality: This use case focuses on providing patient information needed by clinicians to accomplish a transition in care from one care setting to another. The focus is on transitions between acute, long-term care, nursing facility, rehabilitation facility, home healthcare, and other inter-organizational transitions rather than transfers within a given care setting.</p> <p>The transferring setting can transmit a core set of clinical information to the receiving setting to assist in the coordination and management of patient care and may also send relevant information to the patient’s personally controlled health records.</p>
4. Quality Reporting	<p>Definition: The technical capacity and functionality needed to measure and report on hospital and clinician quality and use quality measures to support clinical decision making.</p> <p>Functionality: Quality Reporting supports the capture and reporting of quality, performance, and accountability measures to which providers, facilities, delivery systems, and communities are held accountable including measures related to process, outcomes, and/or costs of care, may be used in ‘pay for performance’ monitoring and adherence to best practice guidelines.</p>

Use Case	Details
5. Research	<p>Definition: Query either a centralized repository or multiple data sources to produce a de-identified report for an approved research project.</p> <p>Functionality: Access to aggregated patient care data provides an opportunity to improve clinical research, recruitment for clinical trials, and comparative effectiveness efforts.</p>
6. Public Health	<p>Definition: Transmit essential ambulatory care and emergency department visit, utilization, and lab result data from in standard and anonymized format to authorized public health agencies.</p> <p>Functionality: This use case can support reportable disease investigation, influenza surveillance, etc.</p>
7. Community Resource Management	<p>Definition: The ability for hospitals to transmit capacity and availability data (including institution, unit-level census, and facility utilization data) to Public Health Agencies.</p>
8. Consumer Empowerment	<p>Definition: According to HITSP, The Consumer Empowerment and Access to Clinical Information via Networks Interoperability Specification defines specific standards needed to assist patients in making decisions regarding care and healthy lifestyles (i.e., registration information, medication history, lab results, current and previous health conditions, allergies, summaries of healthcare encounters and diagnoses).</p> <p>Functionality: Includes the capabilities to: (1) share information with designated entities; (2) patient care management tools; and (3) conduct routine health scheduling and administrative functions (e.g., pre-registration).</p>

III. THRESHOLD TECHNICAL DECISIONS FOR MARYLAND STATEWIDE HIE

A. Technical Design and Implementation Principles

Background

Through the work of multiple committee and advisory bodies conducted over the course of the last three years, stakeholders in Maryland have developed a series of principles to govern HIE in the state.^{3,4} Based on the results of these deliberations, MHCC identified the following eight principles in its Request for Applications:

- 1. The HIE must have a business model that is sustainable.**
 - a. It considers both who benefits and who bears the cost; and
 - b. Each sector/stakeholder has a well-defined value proposition.
- 2. The HIE is consumer-centric.**
 - a. It consistently keeps consumers best interests at the forefront of decision-making; &
 - b. Consumers have control over who accesses their data.
- 3. Data is appropriately accessible to authorized stakeholders.**
- 4. The HIE is secure and protects patient privacy and confidentiality.**
- 5. The governance structure of the HIE is transparent and inclusive.**
- 6. The HIE includes specific, formal penalties for inappropriate access and misuse of data.**
- 7. The HIE uses industry-defined standards.**
- 8. Established procedures are in place to permit emergency access to data.**

Decision Points

- To what extent should the existing principles be modified?
- What additional principles should be added?

³ "Task Force to Study Electronic Health Records", Maryland Health Care Commission, December 2007. Study conducted under Maryland Senate Bill 251 (2005).

⁴ Maryland Health Care Commission. "Privacy and Security Solutions and Implementation Activities For A Statewide Health Information Exchange." September 2008.

Recommendations and Rationale

The table below identifies the MCHIE Technical Team's proposed changes to the principles identified in MHCC's RFA.

Original Principle	Recommended Change/Addition	Rationale
3. Data is appropriately accessible to authorized stakeholders.	Unchanged	
4. The HIE is secure and protects patient privacy and confidentiality.	Unchanged	
7. The HIE uses industry-defined standards.	Change to: The implementation of HIE in Maryland will align with nationally-recognized standards to ensure cost-effective implementation and compatibility with efforts in neighboring states. Where gaps in interoperability standards exist, Maryland's HIE efforts will align with emerging standards activities to the greatest extent possible.	The MCHIE Technical Team believes that adherence to standards is an effective strategy to avoid being locked into vendors' proprietary solutions. This modification addresses the fact that where incompatibility of standards exist, the HIE will need to make choices that maximize the ability of entities to quickly and cost effectively interface to the system.
8. Established procedures are in place to permit emergency access to data.	Unchanged	

The MCHIE Technical Team also recommends that the State consider additional principles described in the table below.

New Principles	Rationale
"The statewide HIE should be designed using a Service Oriented Architecture approach."	<p>With respect to an architectural design approach, the Maryland Solutions and Implementation Workgroup recommended that Maryland's statewide HIE infrastructure be developed based on a SOA.⁵ SOA is a design approach that guides how the exchange should be built. The purpose is to organize distributed systems into an integrated approach that eliminates information silos. The SOA does not require re-engineering of existing systems. Instead, it supports existing functionality by loosely connecting systems to integrate information across systems. The MCHIE Technical Team supports the recommendation to adopt a SOA approach.</p> <p>Key health IT standards also appear to be migrating to a SOA approach. In September 2008, the HITSP Board voted to establish a working group which will deliver a plan within 90 days to wrap all HITSP work so that it will plug and play with a service oriented architecture.</p>

⁵ Ibid.

New Principles	Rationale
<p>“Implementation of HIE in Maryland should be supported by the development and provision of detailed implementation guides of agreed upon national standards.”</p>	<p>In a November 12, 2008 presentation to the American Health Information Community, John Halamka, the Executive Director of the HITSP, claimed that HIE standards are no longer a rate limiting step for HIE implementation. To bolster his claim, Dr. Halamka highlighted the steady progression of completed “use cases:”</p> <ul style="list-style-type: none"> - 2006 - Personal Health Records, Laboratories, Biosurveillance - 2007 - Medications, Quality, Clinical Summaries - 2008 - Medical devices, Referrals, Family History/Genome, Secure messaging, Public Health Reporting, Immunizations <p>While no one questions the need for the HIE to use standards, many observers question whether interoperability standards are sufficiently mature and refined to guide the implementation and product-selection decisions.</p> <p>In its September 2008 recommendations, the Maryland Solutions and Implementation Workgroup also identified the need for implementation guides:</p> <p><i>A statewide HIE should demonstrate a commitment to implementing standards and clearly defining the approach for implementation of those standards. Presently, many systems are incapable of generating standard electronic messages or cannot format data in conformance with national standards. The Workgroup noted that disparate systems will require additional technology to integrate standards in a way that will allow them to interpret data. Identifying which standards and versions should be used by an HIE, and developing guidance on implementing the standards, assures consistent electronic messaging between disparate systems. <u>The Workgroup agreed that stakeholders will require strong guidance to appropriately implement standards.</u></i></p>

B. Implementation Approach

Background

While the promise of shared services is widely embraced, the options for bringing full interoperability to scale vary and are influenced by the configurations of healthcare providers, purchasers, payers and supporting organizations, which can vary significantly from state to state. Moreover, state-level HIEs must navigate the differing technical implementations, business cases, and operational scale from a range of existing and emerging data networks including local exchanges, integrated delivery networks, aggregators of data for public health and quality purposes, clearinghouses, disease registries, regional and national data processors.

In these complex environments, state-level HIEs struggle to array resources and prioritize technical implementation. Though approaches continue to evolve and adapt to changing conditions, three alternatives are emerging to achieve statewide interoperability.

- (1) a single, statewide technical utility that provides a few core services that works in coordination with sub-networks in the state.
- (2) a decentralized statewide model in which HIEs provide services to local stakeholders and connect with other HIEs through agreed upon policies, standards, and protocols;
- (3) a network of “health record banks” through which patients’ directly control access to their health information.

A comparative analysis of the characteristics, advantages, and challenges for the three approaches is provided below. It is important to note that while some state-level HIEs can be categorized into one of the three approaches, others are blending elements of all three and adapting the models to suite their specific circumstances.

Model 1. Core services managed centrally to connect healthcare entities. A number of state-level HIEs are developing centralized technical approaches designed to create a common infrastructure that minimizes the number of interfaces for data providers and users, and thereby may reduce overall development costs for statewide interoperability.

In this model, entities and local HIEs connect the statewide utility through specified interfaces and protocols. The technical architecture of the individual entities or smaller HIEs do not need to be the same as that of the statewide utility, because many of the statewide architecture components would not be needed at the local level.

In California, the California Regional Health Information Organization (CalRHIO) is developing a statewide utility based on a service-oriented architecture, through which authorized and authenticated providers can query the network and receive patient-centric information. In its initial phase, CalRHIO will facilitate the delivery of medication histories and laboratory results to Emergency Departments to facilities across the state.

A schemata of CalRHIO’s proposed approach is provided in Figure 1.

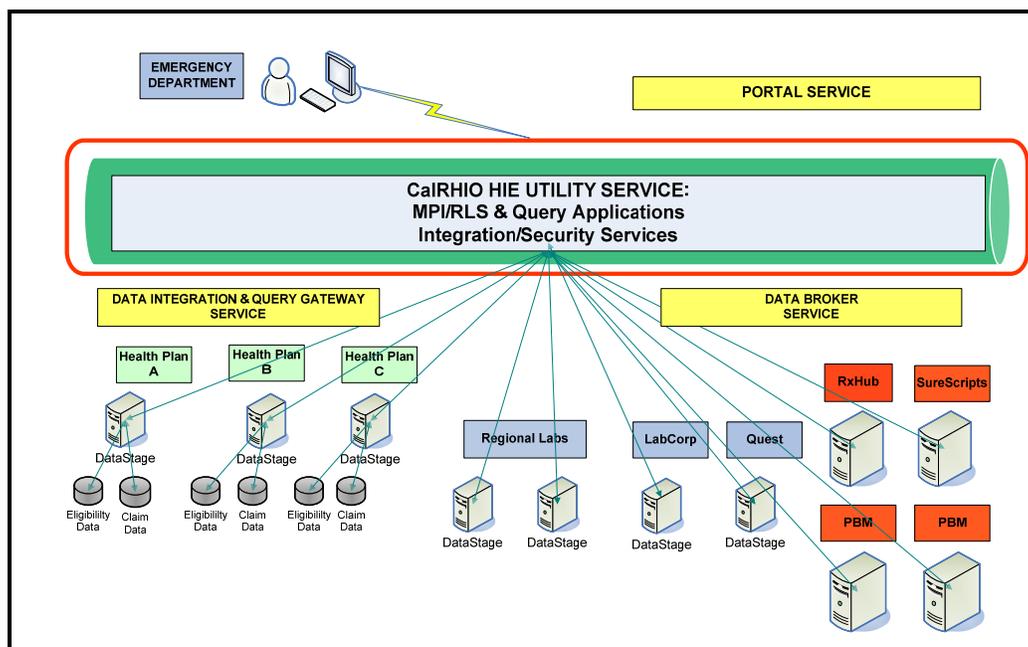


Figure 1. Illustration of CaIRHIO's Proposed Technical Architecture
(Source: CaIRHIO CMS eRx Presentation, October 2008)

In Tennessee, an eHealth Exchange Zone is being built that will allow physicians to securely access a range of applications including electronic prescribing, licensing services, immunization registries, and longitudinal patient health records.⁶

In 2008, the State of Tennessee awarded a 10 year contract worth between \$20 and \$30 million to expand the capabilities of the existing statewide broadband network, the Tennessee Information Infrastructure, for healthcare providers. Through the Tennessee Information Infrastructure, health practitioners can access broadband capabilities, security protocols and performance level guarantees at State negotiated rates.

The Tennessee Information Infrastructure also provides the foundation for a secure, statewide portal for authorized healthcare providers called the Tennessee eHealth Exchange Zone. The eHealth Exchange Zone will allow authorized healthcare providers to access aggregated patient health information from private and public insurers, renew licenses, and submit data to the state immunization registry. With guidance from the eHealth Advisory Council, the statewide public-private advisory board, the eHealth Exchange Zone will gradually expand to include additional services and functionality for healthcare professionals.

⁶ 2009 eHealth Progress Report and Analysis. Tennessee eHealth Advisory Council (June 2008). Available online at <http://www.tennesseeanytime.org/ehealth/documents/2008ProgressReport6-04-08.pdf>.

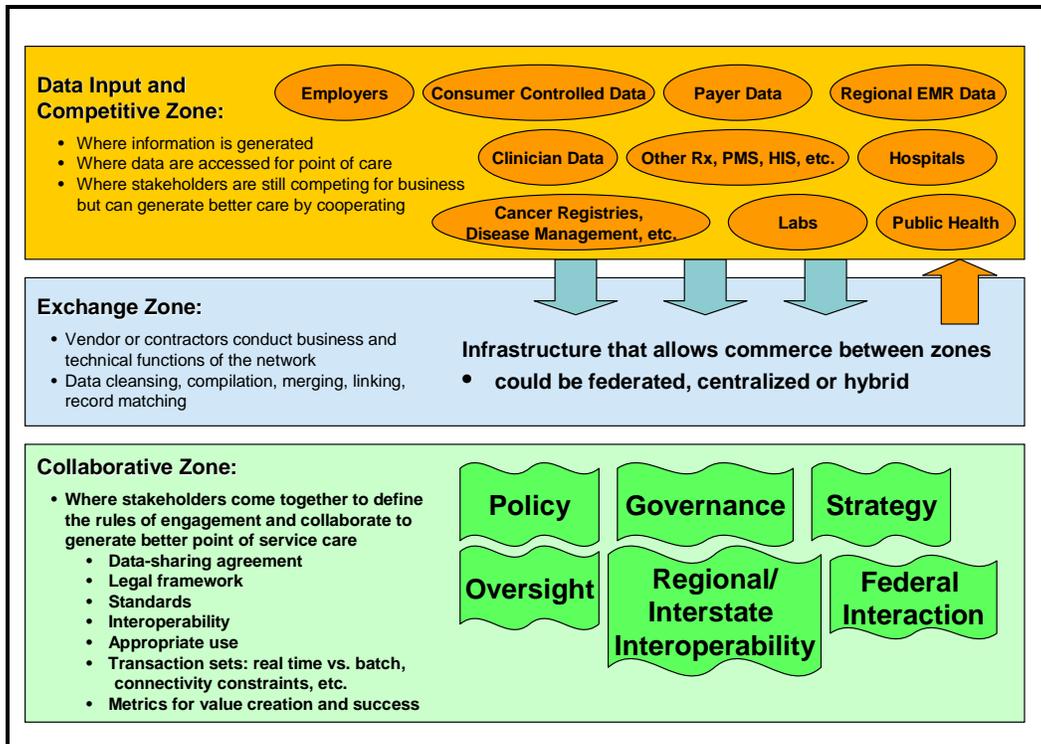


Figure 2. Illustration of Tennessee's Statewide eHealth Exchange Zone
 (Source: State of TN, Office of eHealth Initiatives, October 2008)

As the figure below illustrates, Tennessee's statewide architecture takes specific components of the healthcare services and looks to instantiate those on a statewide bus in a piecemeal basis—starting with authentication and identity services.

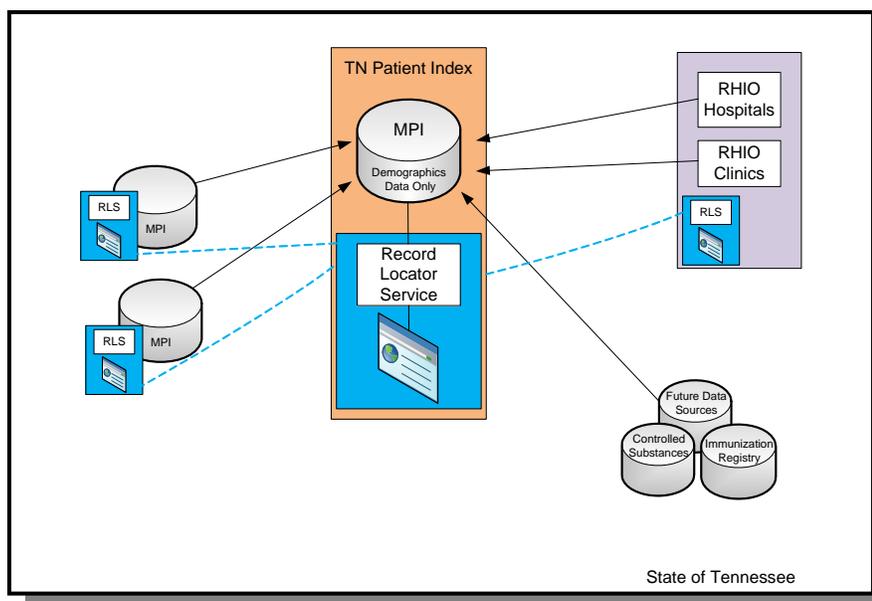


Figure 3. Illustration of Tennessee's State-Level HIE Architecture
 (Source: State of TN, Office of eHealth Initiatives, January 2009)

2. Statewide interoperability through local HIEs and shared services. Instead of achieving interoperability by linking all entities directly with a single state-level HIE utility, Michigan and New York are pursuing distributive networking strategies based on local HIEs deploying technical architecture and services that conform with common statewide policies, standards, and protocols.

In this model, smaller, more localized HIEs may develop within networked organizations within the state, such as a hospital network for its local service area. This architecture recognizes that smaller HIEs could function, and would be able to interoperate with the other networks as long as they comply with the agreed upon standards through compliant interfaces.

This model is predicated on the ability of local HIEs to develop and support connectivity for stakeholders in their respective regions. The local HIEs tend to represent medical trading area (MTA), the natural market within which most referrals, hospitalizations, and other flows of both patients and patient information typically occur. It is an area in which clinicians and healthcare organizations work together to serve a population of consumers, and where working relationships have typically already been established in serving common patients. The MTA is the geographic area in which face-to-face trust can most readily be established and within which the bulk of information is currently exchanged (usually on paper) on a daily basis.⁷

In New York, stakeholders are working collaboratively through the New York eHealth Initiative to identify commonly-used “shared” services and avoid the costly proliferation of redundant and incompatible services.⁸ The State-wide Health Information Network (SHIN-NY) will provide the technical health information infrastructure that supports New York’s broader healthcare goals to improve the quality and efficiency of healthcare. The SHIN-NY will be comprised of standardized regional sub-networks or HIEs governed by Regional Health Information Organizations (RHIOs) through contracts with health information service providers and vendors.

The SHIN-NY will also include state-level services through which the regional HIEs communicate and share services, governed by RHIOs and NYeC. The regional sub-networks or HIEs and the state-level services will communicate through a service-oriented architecture using web services and common health information exchange protocols.

ESB platforms will be utilized as state-level services to facilitate a public registry of SHIN-NY services not unlike the Domain Name System servers for the Internet with additional capabilities. ESB platforms will also be utilized at the regional sub-network or HIE level to support communication with the public registry among many possible providers and consumers of services and data. Candidates for core services currently under consideration include authentication, master person index (MPI), and medication management.⁹

⁷ Arizona Health-e Connection Roadmap, http://gita.state.az.us/tech_news/2006/Arizona%20Health-e%20Connection%20Roadmap.pdf, accessed on October 31, 2006.

⁸ New York Department of Health. “Architectural Framework for New York’s Health Information Infrastructure.” Available online at http://www.health.state.ny.us/technology/projects/docs/technical_discussion_document.pdf.

⁹ Statewide Health Information Network for New York (SHIN-NY) Technical Architecture Overview V1.0 – DRAFT. November 3, 2008. Available online at http://www.nyehhealth.org/files/File_Repository16/pdf/SHIN-NY_TechArch_20081125.pdf.

An illustration of New York’s shared services approach is provided in the figure below.

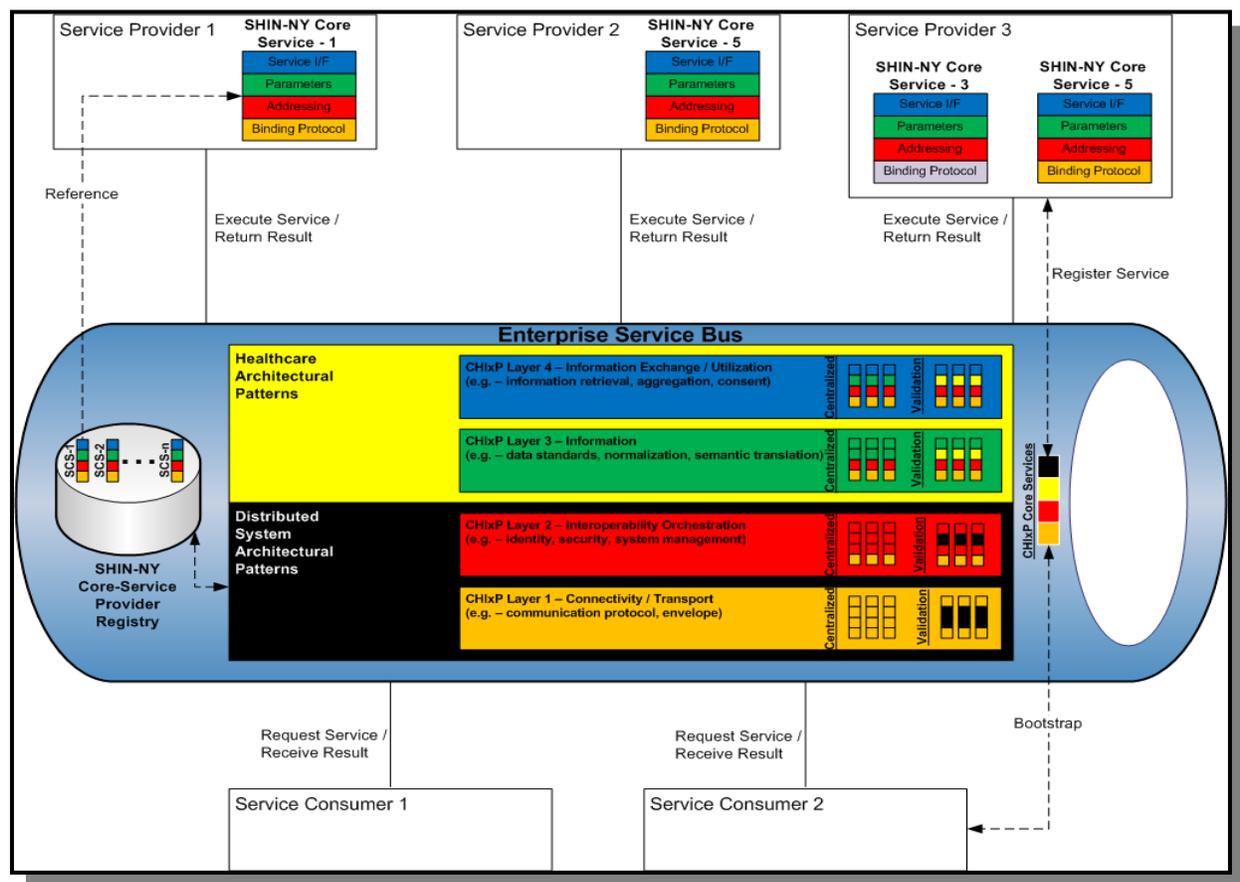


Figure 3. Illustration of New York’s State-Level HIE Architecture
 (Source: New York eHealth Collaborative, September 2008)

The New York’s architecture consists of HIEs interacting with centralized SHIN-NY ESB nodes that act as service providers or consumers and will all communicate in the prescribed manner. The New York protocol stack consists of four layers to handle both distributed systems patterns (i.e., connectivity, transport, security, and management) and healthcare architecture patterns (e.g., data standards, normalization, retrieval, consent). Connections to local nodes (or enterprises) are to RHIO HIEs as well as any local functionality. This allows for the statewide bus to focus on defining a common protocol stack and allows for a layer of abstraction between enterprise applications to the statewide bus through local HIEs.

Statewide interoperability based on local HIEs can reduce operational risk. In a “network of networks” approach, HIEs can be build modularly and take advantage of lessons learned from other exchanges. In addition, failure of one of the HIEs in a regional approach can be localized and addressed, whereas failure in system reliant on a single statewide utility can bring down exchange statewide.

Statewide interoperability built on local HIEs has disadvantages. Costs are higher relative to single statewide utilities. By relying on multiple regional efforts, the state-level HIE must deal with multiple, independent *but* interdependent, moving pieces. Implementation can be slowed if

the pace or distribution of HIE activity is uneven or if a HIE proves unworkable in a given geographic region.

Model 3. Interoperability through Health Record Banks. In Washington and Oregon, state-level HIE efforts are building the governance, technical, and business frameworks to create and sustain a system of health record banks. Health record banks would serve as designated repositories of consumers' health information, and consumers would grant permission for authorized health providers to deposit data to or access their health records.¹⁰

While pilot demonstrations have just begun in Washington, stakeholders in both states continue to explore the implications and considerations of a state model based on health record banks. In December 2006, a state-legislated advisory body, the Washington Health Information Infrastructure Advisory Board submitted its final report, *Washington State Health Care Authority Health Information Infrastructure: Final Report and Roadmap for State Action* that recommended the creation of a network of Health Record Banks (HRBs).

According to this model, HRBs serve as entities where consumers may choose to store their health records. A central account locator service will ultimately be established to keep track of which HRB holds the record for each consumer. When the record is needed for care, the consumer provides access information for the record (i.e., the name of his or her bank and account number). The consumer record is then obtained directly from the applicable HRB. When the care is completed, a copy of the information is sent directly to the consumer's HRB for aggregation with the existing health record.

With respect to the governance infrastructure, the HCA is considering the creation of an entity that would serve as a utility commission and have the authority (either from legislation or rule making) to:

- Serve as a consumer ombudsman
- Accredite HRBs
- Review conformance to privacy, security, technical, and standards policies
- Provide for sanctions and penalties for misuse of the system
- Enforce rules

In August 2008, the Washington Health Care Authority awarded a total of \$1.7 million to three health record bank pilot projects to test the feasibility and usefulness of online health record bank accounts to see if they offer a useful way for consumers to maintain, track and use their personal health information.

¹⁰ Additional details on Washington's and Oregon's support of health record banks are available online through the *AccessMyHealth* (<http://www.accessmyhealth.org/>) and the Health Information Infrastructure Advisory Committee (<http://www.oregon.gov/OHPPR/HIAC.shtml>) respectively.

Decision Point

- Among the prevailing options for implementing statewide HIE, which approach offers the most feasible, flexible, and cost-effective approach?

Recommendation and Rationale

Recommendation: Statewide interoperability through local HIEs conformance to detailed architectural designs, protocols, and implementation guides

The MCHIE Technical Team recommends that Maryland develop a statewide HIE approach based on local HIEs that conform to statewide architectural design, protocols, and implementation guides.

The MCHIE Technical Team also recommended that the State conduct a rigorous process to define the minimum services that can be cost-effectively replicated across HIEs.

Rationale: As discussed above, the MCHIE Technical Team believes that an approach based on modular, local HIE deployment offers significant risk mitigation advantages over the alternative approaches. In addition, an infrastructure that includes a layer of local HIEs could reduce costs and implementation burdens on local providers. Because standards and specifications are likely to evolve and change over time, the statewide system will require system maintenance and periodic updates. With a system of local HIEs serving as intermediaries, updates can be done by the local HIEs while participating systems can maintain their legacy systems and focus on the needs of their users instead of devoting resources to address statewide system requirements.

The MCHIE Technical Team also recommended that the State carefully review options for the provision of selected services on a statewide basis. The MCHIE Technical Team recognizes that many states are finding it more difficult than anticipated to identify the common services that would be offered statewide. However, given the pace of technical change and the promise of savings and implementation efficiency, Maryland should establish a process for stakeholders to identify, assess, and develop opportunities for statewide services.

Owing to their technical maturity and readily-available solutions in the marketplace amongst providers and hospitals, three services (medication history via SureScripts-RxHub, laboratory results from national labs, and authentication) were determined to early candidates for a more rigorous analysis regarding their viability and effectiveness as statewide services.

C. Interoperability Standards

Background

Regardless of the approach chosen, identification, selection, ongoing maintenance of the standards will be a critical element to ensure fully interoperable exchange of health information.

The Health Level 7 (HL7) organization defines interoperability in three contexts:

1. **Technical interoperability** focuses on the physical transmission and receipt of health data, its transport between participating systems. Much of the work here is on message formats and reliable, secure message transport.
2. **Semantic interoperability** focuses on ensuring shared meaning between sending and receiving partners – ensuring that the meaning of what was sent is consistent with the understanding of what was received. Much of the work in this area is focused on medical terminology which can be referenced consistently by all parties.
3. **Process interoperability** focuses on higher-order workflow concepts that make data sharing a richer and more valuable experience. Work in this area tries to understand how shared health data supports the specific activities and workflow of the organizations that use it and the integration of health data into the work setting.

In many cases technical standards for healthcare information systems are not fully mature. Indeed, most healthcare organizations use standards in one way or another for the interchange of information between disparate systems both within and outside of their organizations. Generalized standards are often not fully effective within healthcare organizations' operational systems because they may not be sufficiently detailed enough to document or describe all healthcare episodes or transactions required by an organization, or are otherwise poorly structured for this purpose.

States take differing approaches to advancing interoperability of health systems and networks. In some states, including Vermont, conformance to interoperability standards is achieved through regulatory mechanisms. Under Vermont law (18 V.S.A. § 9440b, 22 V.S.A. § 903), the Vermont Health Information Technology Plan serves as the framework within which certificate of need applications for the purchase or lease of healthcare information technology that are subject to regulation. Certificates of need may not be granted or approved by the Vermont Commissioner unless they are consistent with the State's plan.

The State of New York, on the other hand, has adopted a contractual approach to ensure conformance to standards. Local HIEs that receive state funding are required to develop systems that conform to agreed upon standards, protocols, policies and implementation guides. The standards and protocols are approved through a statewide collaborative process in which all stakeholders participate to help identify national standards and refine the implementation guides.

Decision Point

- How should standards conformance be achieved?

Recommendations and Rationale

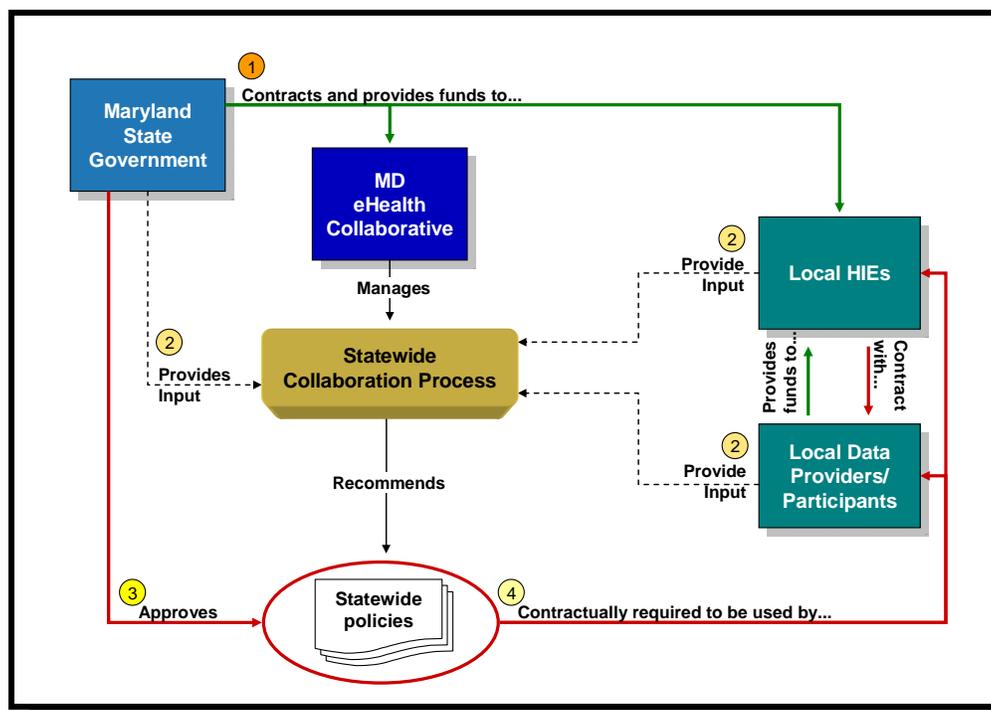
Recommendation: Enforcement through Contracts & Regulations

MCHIE recommends that Maryland require all HIE participants abide by the policies, standards, and guidance developed for HIE. Compliance with the agreed-upon statewide policies should be established and enforced through contracts and other incentives for adherence.

As some entities may forgo state funding and incentives and choose to develop HIE capabilities outside the statewide HIE governance framework, MCHIE recommends that State government monitor HIEs' conformance to statewide standards and assess the need for additional enforcement through accreditation and/or regulation.¹¹

Rationale: HIE represents a very early-stage movement for governing health information exchange, and the information policies governing their oversight need to evolve through participatory public processes and have sufficient flexibility to accommodate innovations and learning from the field.

The figure below illustrates the proposed flow of accountability among the various HIE stakeholders.



¹¹ One organization, the Electronic Healthcare Network Accreditation Commission, recently launched efforts to create a program to accredit HIEs. Additional details are online at http://ehnac.org/pr_2009-0113.html.

In Step 1, the Maryland State government would provide funding through contracts to create the statewide collaborative entity, the *Maryland eHealth Collaborative*, and support local HIEs' development of selected use cases and capabilities.

The *Maryland eHealth Collaborative* would oversee and manage the statewide collaborative process, which would include working groups drawing input from representatives from all the stakeholder groups (Step 2). The statewide collaborative process would develop and advance recommendations on detailed privacy and security policies, technical specifications, and implementation guides.

Once statewide policies are approved by the *Maryland eHealth Collaborative*, they would be advanced as formal recommendations to the State for its review (Step 3). Local HIEs in Maryland that receive funds would be required to implement any approved statewide policies and conform to agreed upon standards, protocols and implementation guides (Step 4).

IV. Use Case Sequencing

Background

In determining the sequence of implementation, state-level HIEs typically assess candidate services and use cases across the following criteria: (1) the clinical value generated, (2) the degree of competition for the service, (3) the breadth and depth of potential clients, (4) anticipated net revenue and return on investment, (5) technical difficulty; and (6) vendor interest, capabilities, and costs for service provision.

To determine the implementation sequence of the various use cases, the MCHIE Technical Team evaluated each use case based on two factors:

- (1) the “readiness” of standards (i.e., the extent to which the underlying standards are being used by vendors and integrated into their products).
- (2) the current availability of products and solutions to meet the required functions.

The goal is eventually to have every healthcare organization abide by minimum interoperability standards such that all can take advantage of the statewide HIE architecture. In evaluating the deployment of the HIE technology, it is important to consider the readiness levels for organizations engaged in the exchange to support the core HIE services. With the tremendous push by HITSP to harmonize health information exchange standards, many HIE vendors are investing heavily in strengthening and incorporating these standards into their products.

However, many challenges still exist in the readiness of the underlying clinical source systems and there still persists a large amount of “out-of-band” clinical processes that do not utilize any underlying information technology. For example, despite establishing a clear set of minimum biosurveillance data elements, a survey of the types of transactional clinical data elements that are currently being exchanged indicates that public health surveillance will still require additional time for there to be additional data integration of sources.

Even for use cases such as results delivery and medication management where there seems to be a high level of implementation of the underlying systems, there are readiness challenges in that few systems currently map to already established terminology codes for laboratory results and medications in the core systems resulting in significant cost and effort to reach semantic interoperability.

In order to align readiness of key components to the use cases, the MCHIE Technical Team focused on the availability of HIE standards and technologies that implemented those standards. It is recognized that there is significant planning, design and implementation required for any participating healthcare provider or clinical source system to engage in information exchange.

The table below highlights the use case implementation strategies for the more advanced statewide HIEs.

State	State-level HIE Initiative	Proposed Use Cases and HIE services
California	CalRHIO	<ul style="list-style-type: none"> • Phase 1: Medication history and diagnostic results delivery to Emergency Departments
Delaware	Delaware Health Information Network	<ul style="list-style-type: none"> • Phase 1: Clinical results/reports delivery; public health reporting • Phase 2: Med and patient histories, eOrders, patient portal, enhanced Public Health reporting • Phase 3: Physician workflow management and administrative functions
Maine	HealthInfoNet	<ul style="list-style-type: none"> • Phase 1: Patient ID & demographics, encounter histories, lab and radiology results, patient consent management via secure, Internet-based portal • Phase 2: Adverse reactions/allergies, medication history, diagnosis/conditions/problems, dictated/transcribed documents
Minnesota	Minnesota HIE	<ul style="list-style-type: none"> • Phase 1: Medication history view • Phase 2: Eligibility checking
Rhode Island	Rhode Island Quality Institute	<ul style="list-style-type: none"> • Phase 1: Medication and lab histories via secure, Internet-based portal • Phase 2: TBD
Utah	Utah Health Information Network	<ul style="list-style-type: none"> • Phase 1: Administrative data delivery • Phase 2: Clinical results delivery
Vermont	Vermont Information Technology Leaders	<ul style="list-style-type: none"> • Phase 1: Medication histories to Emergency Departments • Phase 2: Chronic Disease Management

Decision Points

- From technical perspective, how should use cases be sequenced?

Recommendations and Rationale

Recommendation: Phase 1 Use Cases

Based on an analysis of the use cases, the MCHIE Technical Team recommended the first phase of implementation include two use cases, diagnostic results reporting and medication management, in addition to the core security, messaging and presentation services.

Please note that other MCHIE teams, particularly the Finance Team, will provide additional criteria for selection and sequencing of use cases.

The table below describes the extent to which each of the eight use cases addresses the two technical criteria identified above.

Use Case	Standards Readiness	Availability of Products & Solutions	Proposed Implementation Sequence	Comments
Diagnostic Results Reporting	High	High	Phase 1	<p>+ Almost all the currently operational HIEs provide this functionality.</p> <p>+ For systems that do not offer electronic exchange, this provides a clinical use case.</p> <p>+ Many lab systems and reference laboratories provide results reporting capabilities.</p> <p>+ In his assessment of standard readiness, the chair of the Health Information Technology Standards Panel, John Halamka, asserted that interoperability standards for lab and radiology orders and results were among the three most ready value cases.¹²</p>
Medication Management	High	Moderate	Phase 1	<p>+ ePrescribing national standards have been established and are being aligned with HITSP.</p> <p>+ In his assessment of standard readiness, the chair of the Health Information Technology Standards Panel, John Halamka, asserted that interoperability standards for electronic prescribing were among the three most ready value cases.¹³</p> <p>- Formulary and benefits decision logic is difficult to implement and varies widely amongst health plans and PBMs.</p>

¹² Halamka, John. "Life as a Healthcare CIO." December 22, 2008. Accessed online February 7, 2009 at <http://geekdoctor.blogspot.com/2008/12/next-steps-for-interoperability.html>.

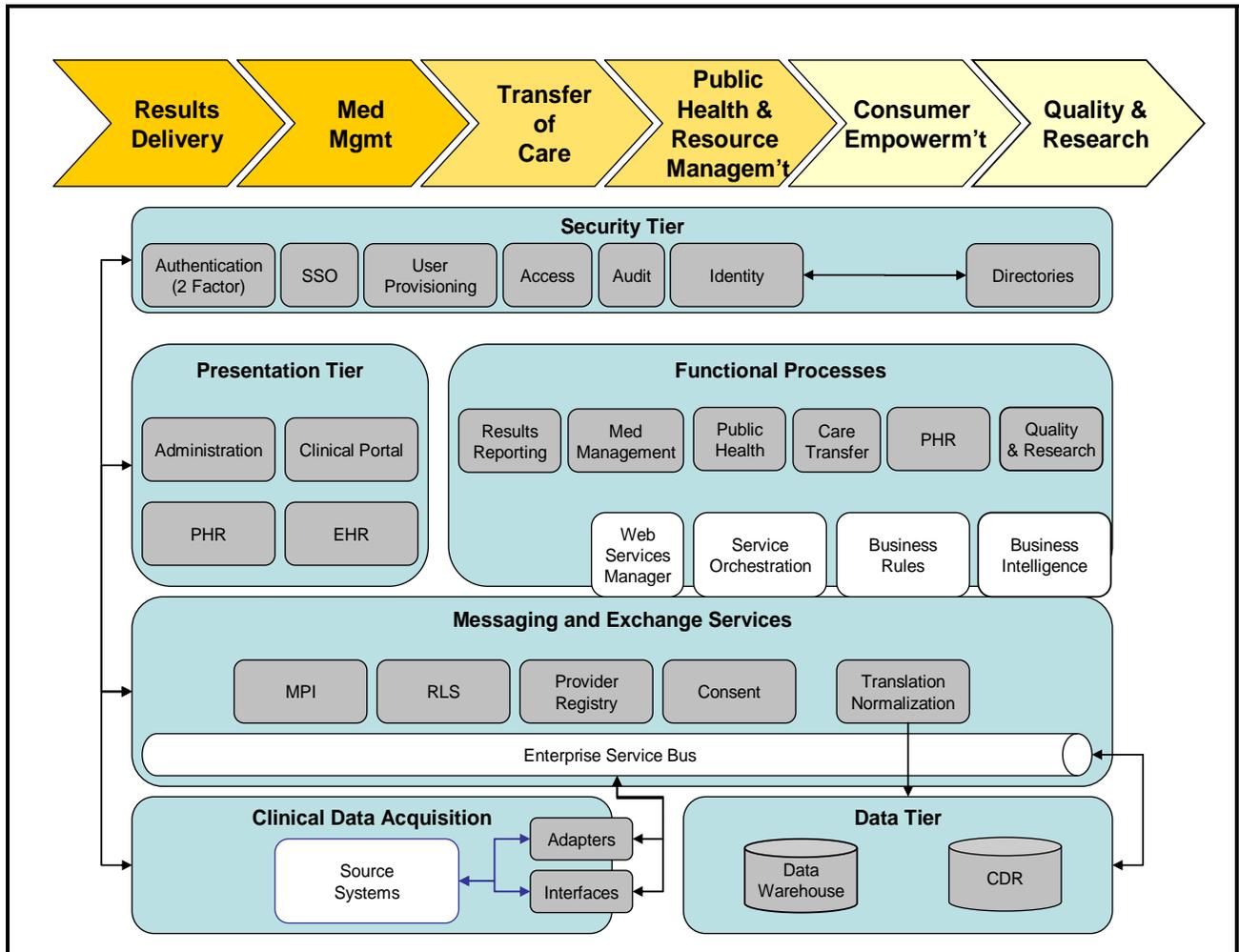
¹³ Ibid.

Use Case	Standards Readiness	Availability of Products & Solutions	Proposed Implementation Sequence	Comments
Transfer of Care	Moderate	Moderate	Phase 2	<p>+ Clinical summary document standards matured significantly over the past year focusing around the Continuity of Care Document, Patient Summary Document Transaction Testing (HITSP C32).</p> <p>- Much of the key information useful to clinicians in a transfer of care scenario may still be paper based resulting in “out-of-band” challenges.</p>
Public Health	Low	Moderate	Phase 2	<p>+ Public health specifications look to utilize existing standards to perform biosurveillance and investigation.</p> <p>+ Leverages existing infrastructure and clinical data by applying an analytics layer to existing information.</p> <p>- Challenges federated data storage in that it utilizes cross-patient and cross-facility query logic.</p> <p>- Public health specific queries are not well defined and standard parameters and services have not yet been tested.¹⁴</p>
Community Resource Management	Moderate	High	Phase 2	<p>+ Leverages existing infrastructure for hospital capacity reporting.</p>

¹⁴ Despite the biosurveillance and public health reporting HITSP use cases, there remains significant testing and maturity concerns around the readiness of technology vendors and HIEs to actually support. Especially as HIEs are currently structured to capture transactional clinical messages from participating stakeholders, the HIE capability to support aggregation of data to fulfill the minimum biosurveillance data elements is a concern. Another consideration is the granularity of clinical data and comprehensiveness that is available via HIE. Despite the onset of information exchange, the automation of information actually requested by public health and the processes associated with public health data elements have not yet been determined and implemented at clinical provider source systems. As a first step, significant evaluation of existing minimum dataset and query parameters should be clearly defined to guide implementation activities.

Use Case	Standards Readiness	Availability of Products & Solutions	Proposed Implementation Sequence	Comments
Quality Reporting	Moderate	Moderate	Phase 3	<ul style="list-style-type: none"> + Increases value to existing patient-centric data. + Extends data and technical models of HIEs to applying additional functionality to clinical data exchange. + Provides opportunity for business model based on payer incentives and pay-for-performance programs. - Requires comprehensive patient record from data that primarily exists in provider EHRs. - Payer organizations have not standardized on a set of quality reports which may present a challenge to organizations looking to reconcile multiple quality parameters and queries.
Consumer Empowerment	Moderate	Low	Phase 3	<ul style="list-style-type: none"> + Leverages HIE's patient-centric view of clinical information + Provides opportunities for additional consumer engagement in care processes - May present conflicting sources of information for consent and access.
Research	Low	Low	Phase 3	<ul style="list-style-type: none"> - Relies heavily on a comprehensive clinical data exchange - Few standards exist around the specific and customized nature of research queries and parameters.

An illustration of the sequencing phases and HIE components are provided in the figure below.



V. Cost Modeling

Based on recommendations from the MCHIE Governance team regarding statewide HIE implementation being based on a heterogeneous mix of local HIEs, Health Record Banks, and RHIOs conforming to statewide standards, the MCHIE Technical Team developed a cost model around the costs required to bring up an HIEs to support each of five regions.

The MCHIE Technical Team developed its cost model based on the following scenario:

- Five HIEs would be implemented and fully operational within three years connecting all the hospitals and 60% of the provider and clinic sites in their regions.
- Each of the five HIEs would support the core services and all eight use cases identified in this analysis.

Costs were determined using the following assumptions:

- Prices are industry averages for “best-of-breed” applications and do not reflect potential cost savings for bulk license or “bundled service” discounts nor any savings associated with using open source alternatives.
- Maintenance and implementation costs are incurred in equal increments over three years, and begin in year 1.
- Initial “start-up capital” would be front-loaded for expenditure.
- No borrowing costs have been included in the financing assumptions.
- Functionality – and additional software development/integration – were limited to that identified in the use cases.

A. Costs for Local HIEs

The MCHIE Technical Team’s model for the cost of building local HIEs is predicated on the following assumptions regarding core components:

Enterprise Service Bus

- HIE Sizing: 500 messages per minute, based on the number of message throughput and request/response times

MPI

- HIE Sizing: 2 million patient records, based on the number of identities and patient demographic records per data source

Provider Registry

- HIE Sizing: 2000 providers, based on the number of provider records

Record Locator Service (RLS)

- HIE Sizing: IHE Document Registry and Repository, considered a scalable component deployed with ESB

Clinical Data Repository

- HIE Sizing: Results and Medication repository, assumed to be deployable on edge, variable costs deal with extending repository

Translation/Normalization

- HIE Sizing: Translation for one use case type e.g., lab results across hospital systems, variable costs deal with extending data types

The table below illustrates software license costs to support the core services, component infrastructure layers, and use cases requirements. The costs represent the average of the ranges described in *Attachment C*.

Layer	Component	Cost	Comments
Clinical Data Acquisition	Interfaces	\$0	This cost is not factored into the license charge for this model.
	Adapters	\$300,000	Assumes 10 adapters.
Messaging & Exchange Services	Enterprise Service Bus	\$250,000	Statewide bus assumed to be 4 times to enable high performance clustered & failover capacity.
	MPI	\$400,000	MPI for approximately 2 million lives.
	Provider Registry	\$100,000	
	Record Locator Service	\$100,000	
	Clinical Data Repository	\$200,000	
	Translation-Normalization	\$150,000	
Functional Processes	Web Services Deployment	\$0	This cost is not factored into the license charge for this model.
	Services Orchestration	\$100,000	
	Business Rule Engine	\$125,000	
	Diagnostic Results Reporting	\$100,000	Results reporting scaled to 4 times to account for increase in smaller reference labs that exists when moving outside specific regions.
	Medication Management	\$200,000	
	ESSENCE expansion	TBD	Additional details regarding ESSENCE capabilities and costs required before a determination can be made regarding this cost.
	Consent Service	\$125,000	
	Clinical Decision Support	\$300,000	Decision support increased to recognize increased complexity in scaling reporting systems to meet multiple incentive programs.
	Personal Health Record	\$200,000	Increased to recognize complexity of scaling to meet multiple PHRs.
	Business Intelligence	\$300,000	Business activity monitoring, dashboard utilities and business intelligence query tools.

Layer	Component	Cost	Comments
Presentation	Clinical Portal	\$200,000	
	Administration Modules	\$100,000	
Security	Authentication	\$200,000	Scaled to account for increase in complexity for authentication to multiple systems.
	Single Sign-on	\$200,000	Scaled to account for increase in complexity for authentication to multiple systems.
	2nd Factor Token	\$250,000	Scaled to account for increase in complexity for authentication to multiple systems.
	User Provisioning	\$75,000	Scaled to account for increase in complexity for authentication to multiple systems.
	Access Management	\$100,000	
	Directories (e.g., LDAP)	\$100,000	
	Identity Administration	\$125,000	
	Auditing	\$125,000	
Non-functional	Monitoring tools	\$125,000	
	Backup	\$200,000	Increased to recognize system scale
	Hosting and Connectivity	\$100,000	
Governance	Service Provisioning	\$0	This cost is not factored into the license charge for this model.

Based on the best available estimates, and working under the assumption that there will be a minimum of five HIEs developed across the State, Maryland should expect to spend between \$20 million and \$30 million for the purchase of the necessary hardware, software and interfaces for the HIEs, and another \$30 million to \$50 million over three years for implementation and maintenance.

To build the interfaces and functionality required to support all eight of the use cases specified in this report range will require an additional \$30 million and \$45 million. Hence, the total development costs for the State should range between \$80 million and \$125 million over a three year period, with the bulk of those expenses likely incurred in the final two years of this window.

B. Costs for Hospitals and Providers to Connect to Local HIEs

These estimates provided above did not include the costs borne by hospitals, providers, payers, pharmacies or diagnostic centers to tap into the exchanges.

Hospital Costs. Presuming that most hospitals will have the data necessary to inform the functionality defined by the use cases, hospitals will need to spend between \$400,000 and \$500,000 apiece for interface development.

Layer	Component	Capital Costs	Ongoing Costs
Clinical Data Sources	Interfaces and adapters	\$400,000	\$88,000
Security	Authentication	\$97,500	\$21,450
Presentation	Portal	\$15,000	\$3,300
Non-functional	Connectivity and hardware	\$13,000	\$2,860

Assumptions:

- 47 hospitals in Maryland
- 10 interfaces and two adapters per hospital to connect with exchange
- Authentication for 1,500 individuals
- Portal for 150 users

Provider Costs: It will cost approximately \$30,000 to \$35,000 to connect the average independent physician office or clinic to the exchange.

Layer	Component	Capital Costs	Ongoing Costs
Clinical Data Sources	Interfaces	\$30,000	\$6,600
Security	Authentication	\$200	\$44
Non-functional	Connectivity & hardware	\$2,500	\$550

Assumptions:

- 412 Practices and 14 FQHCs (at 50 sites) in Maryland, 60% of which would connect to state-sponsored exchanges by the third year of implementation
- Two adapters per hospital to connect with exchange
- Authentication for 10 users per site

C. Total Costs

The total cost for the developing and supporting the five HIEs and connectivity among hospitals and providers is outlined in the table below.

Entity	Capital Costs (for years 1-3)	System Maintenance & Integration Costs (for years 1-3)	Total Costs (for years 1-3)
HIEs	\$4 - \$6 million per HIE <i>(for infrastructure)</i> \$6 - \$10 million per HIE <i>(for functionality)</i>	\$6 - \$9 million per HIE	\$80 - \$125 million (5 HIEs across the state)
Hospitals	\$400 - \$500,000 per hospital	\$100,000 per hospital	\$25 - \$30 million (47 hospitals in the state)
Physician offices and clinics (assuming 60% of sites connect to exchange)	\$30 - \$35,000 per site	\$5,000 - \$7,000 per site	\$8 - \$10 million (~430 sites in the state)

ATTACHMENT A: GLOSSARY

Electronic Prescribing (eRx) – A type of computer technology whereby physicians use handheld or personal computer devices to review drug and formulary coverage and to transmit prescriptions to a printer or to a local pharmacy. E-prescribing software can be integrated into existing clinical information systems to allow physician access to patient-specific information to screen for drug interactions and allergies.

Enterprise Architecture – A strategic resource that aligns business and technology, leverages shared assets, builds internal and external partnerships, and optimizes the value of information technology services.

Health Information Exchange – The electronic movement of health-related information among organizations according to nationally recognized standards.

Healthcare Information Technology Standards Panel (HITSP) – A multi-stakeholder coordinating body designed to provide the process within which stakeholders identify, select, and harmonize standards for communicating and encouraging broad deployment and exchange of healthcare information throughout the healthcare spectrum. The Panel's processes are business process and use-case driven, with decision making based on the needs of all NHIN stakeholders. The Panel's activities are led by the American National Standards Institute (ANSI), a not-for-profit organization that has been coordinating the U.S. voluntary standardization system since 1918.

Interface – A means of interaction between two devices or systems that handle data.

Interoperability – Interoperability means the ability of health information systems to work together within and across organizational boundaries in order to advance the effective delivery of healthcare for individuals and communities.

Medical Trading Area (MTA) – The natural market within which most referrals, hospitalizations, and other flows of both patients and patient information typically occur. Another term for this is a medical referral area.

Nationwide Health Information Network (NHIN) – A national effort to establish a network to improve the quality and safety of care, reduce errors, increase the speed and accuracy of treatment, improve efficiency, and reduce healthcare costs.

Office of the National Coordinator for Health Information Technology – Created by an Executive Order in 2001, the Department of Health and Human Services Office of the National Coordinator for Health Information Technology (ONC) had led the federal efforts to advance the adoption of health information technology (IT) and expansion of health information exchange (HIE). ONC built its strategy around four core functional components: (1) policies relating to privacy and security; (2) standards, networking, and interoperability; (3) adoption of technology and information use; and (4) collaborative governance and decision-making.

Regional Health Information Organization – A health information organization that brings together healthcare stakeholders within a defined geographic area and governs health information exchange among them for the purpose of improving health and care in that community.

ATTACHMENT B: USE CASE DETAILS

1. Diagnostic Results Reporting Use Case

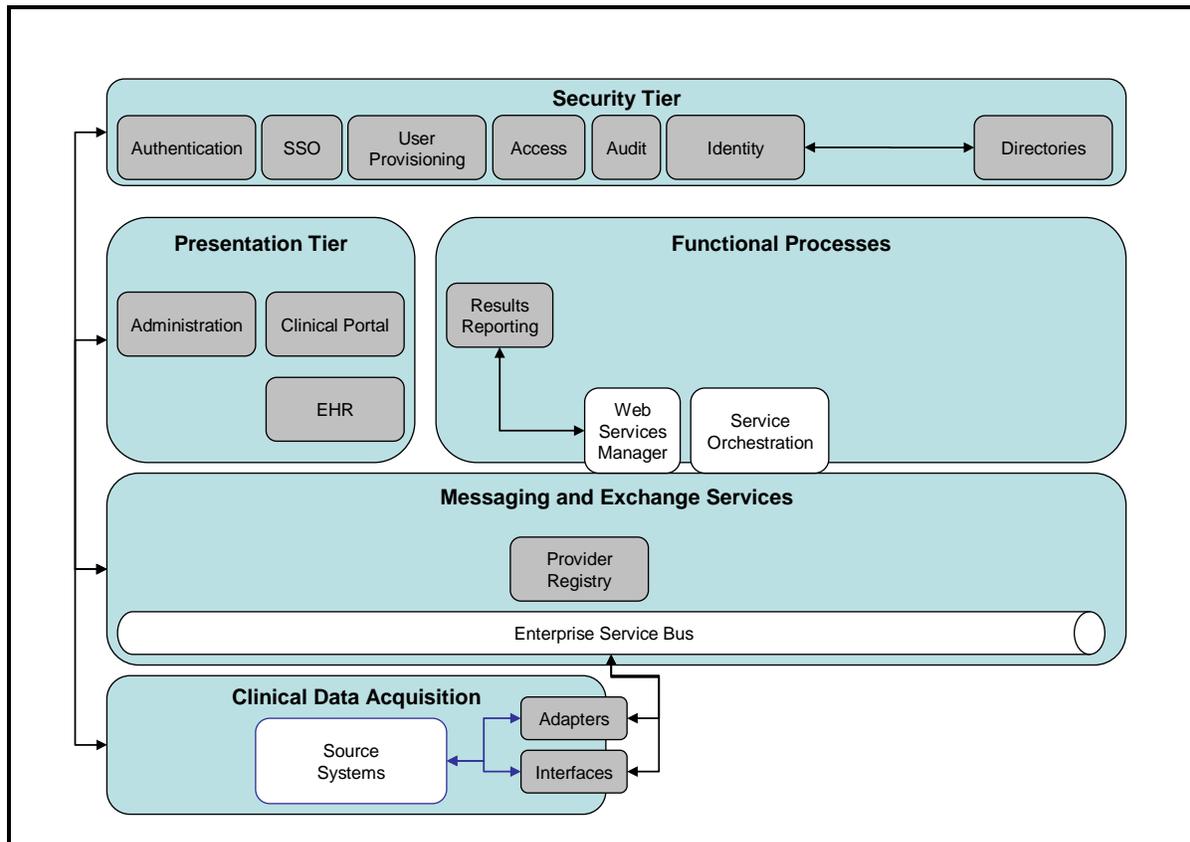
Diagnostic results reporting allow a clinician to electronically obtain test results (e.g., laboratory, radiology, pathology) that he or she has ordered. An extension of this use case would allow non-ordering providers to electronically obtain relevant test results for the purpose of the clinical care of a patient.

Functionality: The delivery of diagnostic results on a “push” basis to a targeted set of recipients (e.g., the requesting physician). An extension of this use case would allow non-ordering providers to electronically obtain relevant test results on a “pull” basis.

Technical Elements:

<p><u>Interfaces by Source Systems</u></p> <ul style="list-style-type: none"> • ADT • CPOE • Electronic Medical Records • PACS • Reference labs (Quest, Labcorp) • Clinical Repositories 	<p><u>Data Users</u></p> <ul style="list-style-type: none"> - Ordering clinicians <p><u>Data Sources</u></p> <ul style="list-style-type: none"> - Hospitals - Diagnostic centers
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Visual Representation of Technical Layers:



ATTACHMENT B: USE CASE DETAILS

Applicable Standards:

- HITSP Electronic Health Record (EHR) Laboratory Results (IS 01):
http://www.hitsp.org/InteroperabilitySet_Details.aspx?MasterIS=true&InteroperabilityId=44&PrefixAlpha=1&APrefix=IS&PrefixNumeric=01

Health Information Exchanges Deployed or Deploying Use Case (within next 6 months):

- Delaware Health Information Network (DE)
- HealthBridge (IN, KY, OH)
- HealthInfoNet (ME)
- Indiana Health Information Exchange (IN)
- Long Beach Network for Health (CA)
- MedVirginia (VA)
- Quality Health Network (CO)
- Taconic Health Information Network Community (NY)
- Utah Health Information Network (UT)
- Vermont Information Technology Leaders (VT)
- Western Medical Associates (CA)

ATTACHMENT B: USE CASE DETAILS

2. Medication Management Use Case

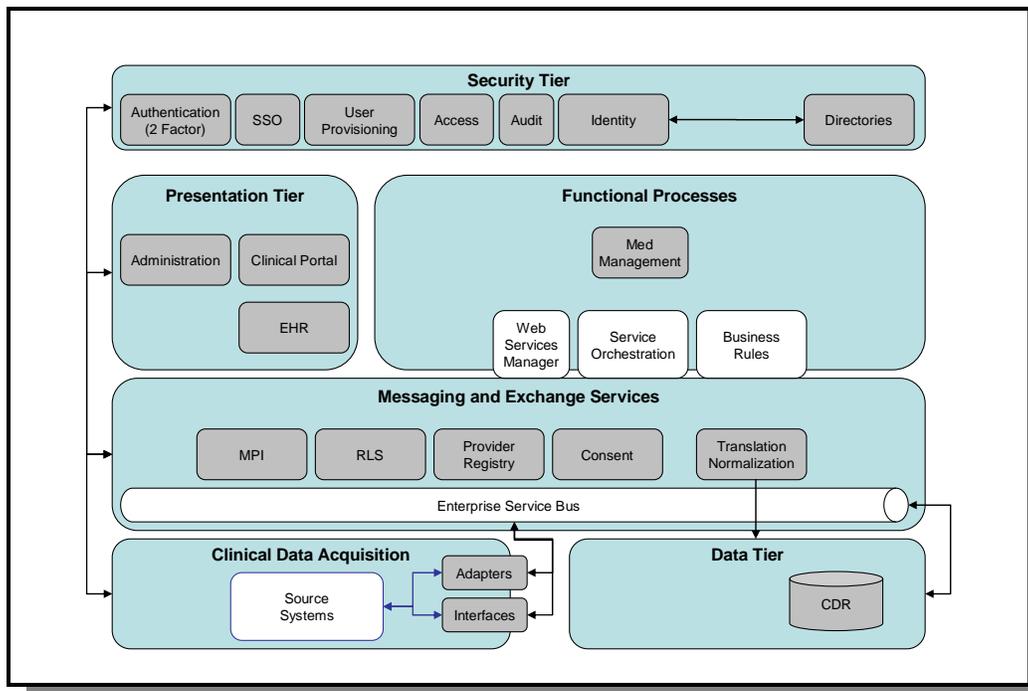
Medication management services typically provide medication history retrieval and aggregation from multiple sources, Medicaid and insurance eligibility checks, formulary queries, and e-prescribing functionality.

Functionality: Via an EHR or portal, authorized clinicians will be able to (1) determine patient eligibility; (2) download the appropriate formulary file for patient's coverage plan; and (3) search for patient's medication history across multiple records and aggregate into a single view, providing clinician additional patient medication information including Allergy/Drug Sensitivity, Condition Information.

Technical Elements:

<p><u>Interfaces by Source Systems</u></p> <ul style="list-style-type: none"> • ADT • CPOE • Electronic Medical Records • Emergency Department systems • Clinical systems • SureScripts-RxHub • Medicaid 	<p><u>Data Users</u></p> <ul style="list-style-type: none"> - Providers (ERs, clinics, practices) <p><u>Data Sources</u></p> <ul style="list-style-type: none"> - Health plans, PBMs (RxHub) - Hospitals, providers - Pharmacies (SureScripts)
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Visual Representation of Technical Layers:



ATTACHMENT B: USE CASE DETAILS

Applicable Standards:

- HITSP Medication Management Interoperability Specification (IS 07):
http://www.hitsp.org/InteroperabilitySet_Details.aspx?MasterIS=true&InteroperabilityId=54&PrefixAlpha=1&APrefix=IS&PrefixNumeric=07

Health Information Exchanges Deployed or Deploying Use Case (within next 6 months):

- CareSpark (TN, VA)
- Indiana Health Information Exchange (IN)
- Minnesota Health Information Exchange (MN)
- Regional Health Information Exchanges in New York State
- Rhode Island Quality Institute (RI)

ATTACHMENT B: USE CASE DETAILS

3. Transfer of Care Use Case

Defined by the AHIC in March 2008, the Transfer of Care use case describes the information flows, issues and system capabilities that apply to a provider requesting a transfer of care for a patient and the receiving facility admitting the patient.

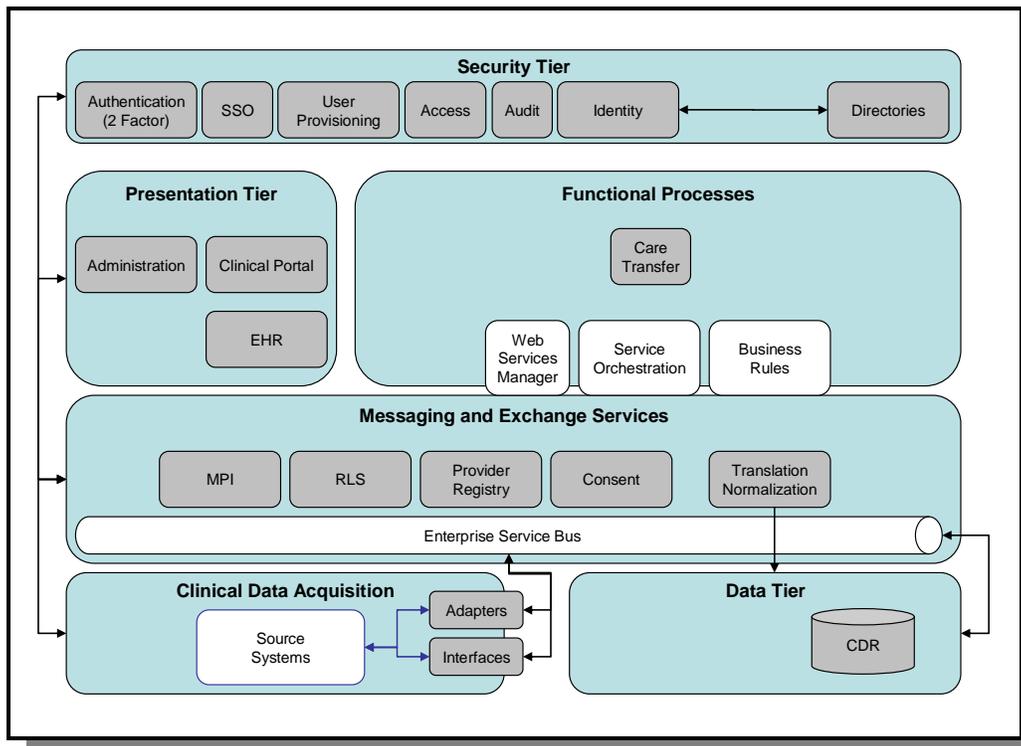
Functionality: This use case focuses on providing patient information needed by clinicians to accomplish a transition in care from one care setting to another. The focus is on transitions between acute, long-term care, nursing facility, rehabilitation facility, home healthcare, and other inter-organizational transitions rather than transfers within a given care setting.

The transferring setting can transmit a core set of clinical information to the receiving setting to assist in the coordination and management of patient care and may also send relevant information to the patient’s personally controlled health records.

Technical Elements:

<p>Interfaces by Source Systems</p> <ul style="list-style-type: none"> • ADT • Electronic Medical Records • Emergency Department systems • CPOE systems • Clinical systems 	<p>Data Users</p> <ul style="list-style-type: none"> - Requesting clinician - Receiving care setting <p>Data Sources</p> <ul style="list-style-type: none"> - Consulting clinician - Discharge/transfer setting
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Visual Representation of Technical Layers:



ATTACHMENT B: USE CASE DETAILS

Applicable Standards:

- HITSP Consultations and Transfers of Care (IS 09):
http://www.hitsp.org/InteroperabilitySet_Details.aspx?MasterIS=true&InteroperabilityId=362&PrefixAlpha=1&APrefix=IS&PrefixNumeric=09

Health Information Exchanges Deployed or Deploying Use Case (within next 6 months):

- MedVirginia (VA)

ATTACHMENT B: USE CASE DETAILS

4. Quality Reporting Use Case

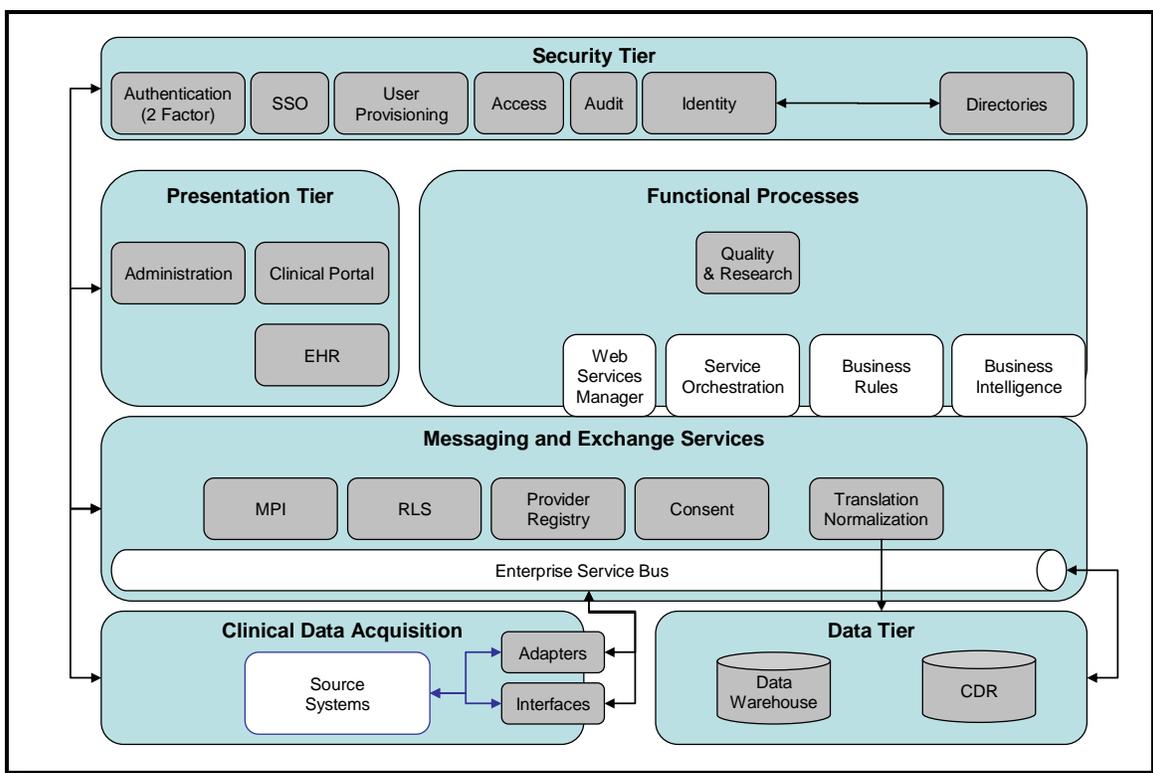
The technical capacity and functionality needed to measure and report on hospital and clinician quality and use quality measures to support clinical decision making.

Functionality: Pay-for-Performance/Quality Data Reporting supports the capture and reporting of quality, performance, and accountability measures to which providers, facilities, delivery systems, and communities are held accountable including measures related to process, outcomes, and/or costs of care, may be used in 'pay for performance' monitoring and adherence to best practice guidelines.

Technical Elements:

<p>Data Elements</p> <ul style="list-style-type: none"> Agreed upon quality measure sets <p>Interfaces by Source Systems</p> <ul style="list-style-type: none"> Data repositories 	<p>Data Users</p> <ul style="list-style-type: none"> Quality reporting entities Health plans Hospitals, providers <p>Data Sources</p> <ul style="list-style-type: none"> Hospitals, providers Health plans
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Visual Representation of Technical Layers:



ATTACHMENT B: USE CASE DETAILS

Applicable Standards:

- HITSP Quality (IS 06):
http://www.hitsp.org/InteroperabilitySet_Details.aspx?MasterIS=true&InteroperabilityId=53&PrefixAlpha=1&APrefix=IS&PrefixNumeric=06

Health Information Exchanges Deployed or Deploying Use Case (within next 6 months):

- HealthBridge (IN, KY, OH)
- Indiana Health Information Exchange
- Long Beach Network for Health (CA)
- Regional Health Information Exchanges in New York State

ATTACHMENT B: USE CASE DETAILS

5. Research Use Case

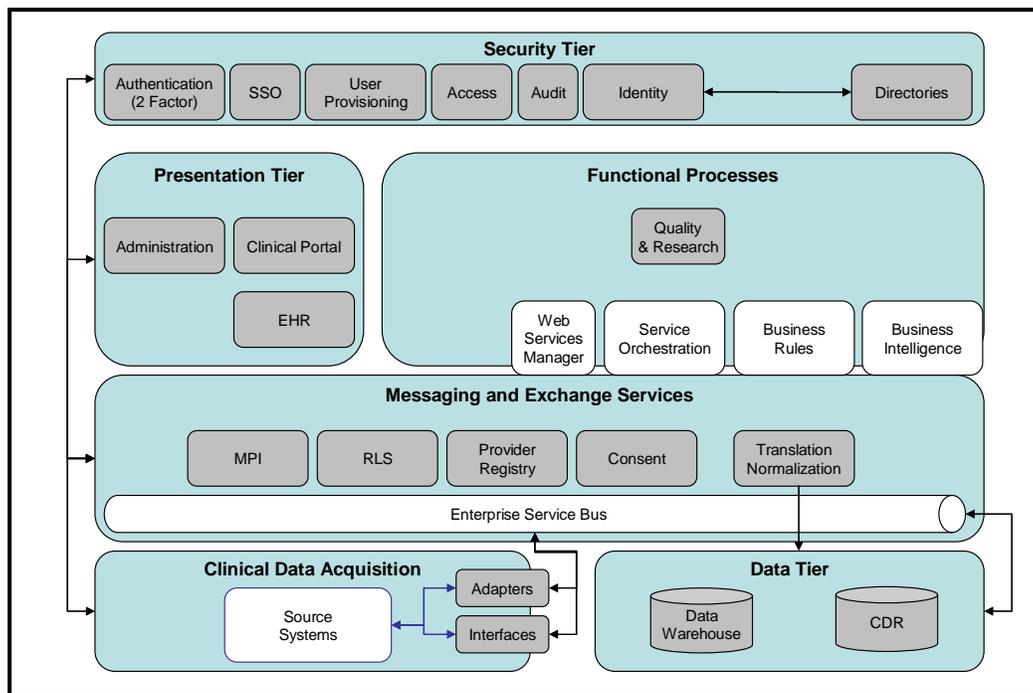
Query either a centralized repository or multiple data sources to produce a de-identified report for an approved research project.

Functionality: Access to individual patient care data and the ability to query across large numbers of patients provide opportunities to improve clinical research, recruitment for clinical trials, and comparative effectiveness efforts.

Technical Elements:

<p>Interfaces by Source Systems</p> <ul style="list-style-type: none"> Data repositories 	<p>Data Users</p> <ul style="list-style-type: none"> Quality reporting entities Health plans Hospitals, providers <p>Data Sources</p> <ul style="list-style-type: none"> Hospitals, providers Health plans
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Visual Representation of Technical Layers:



Applicable Standards:

- In development, none approved by HITSP as of publication of this analysis.

Health Information Exchanges Deployed or Deploying Use Case (within next 6 months):

- Indiana Health Information Exchange

ATTACHMENT B: USE CASE DETAILS

6. Public Health Use Case

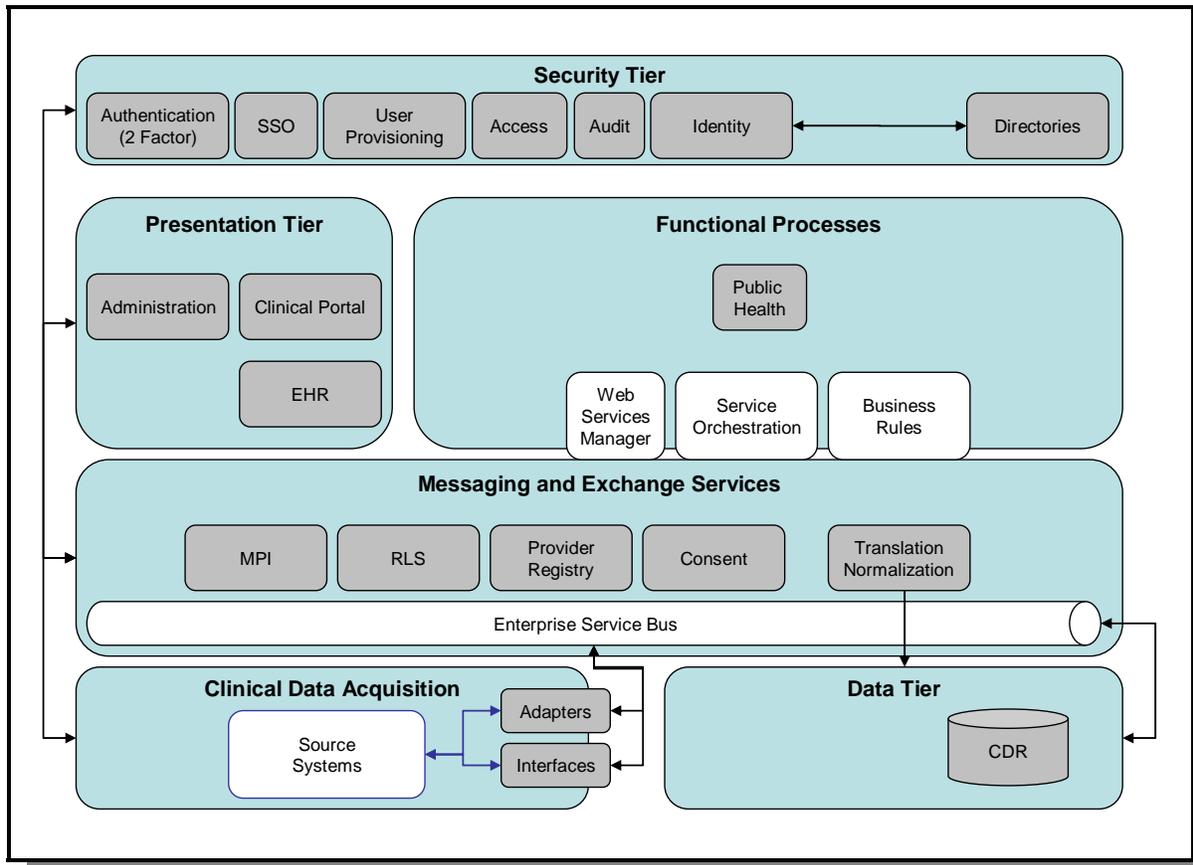
Transmit essential ambulatory care and emergency department visit, utilization, and lab result data from in standard and anonymized format to authorized Public Health Agencies.

Functionality: This use case can support reportable disease investigation, influenza surveillance, etc.

Technical Elements:

<p>Data Elements</p> <ul style="list-style-type: none"> Limited patient demographics Inpatient clinical data (diagnosis, chief complaints) Lab & radiology test orders & results Outpatient clinical data Pharmacy data (med order number, name, route) <p>Interfaces by Source Systems</p> <ul style="list-style-type: none"> Data repositories 	<p>Data Users</p> <ul style="list-style-type: none"> Public health agencies <p>Data Sources</p> <ul style="list-style-type: none"> Hospitals, providers Laboratories Pharmacies
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Visual Representation of Technical Layers:



ATTACHMENT B: USE CASE DETAILS

Applicable Standards:

- HITSP Immunizations and Response Management (IS 10):
http://www.hitsp.org/InteroperabilitySet_Details.aspx?MasterIS=true&InteroperabilityId=363&PrefixAlpha=1&APrefix=IS&PrefixNumeric=10
- HITSP Public Health Case Reporting (IS 11):
http://www.hitsp.org/InteroperabilitySet_Details.aspx?MasterIS=true&InteroperabilityId=364&PrefixAlpha=1&APrefix=IS&PrefixNumeric=11

Health Information Exchanges Deployed or Deploying Use Case (within next 6 months):

- Delaware Health Information Network (DHIN)
- Indiana Health Information Exchange (IN)
- Inland Northwest Health Services (WA)
- Regional Health Information Exchanges in New York State

ATTACHMENT B: USE CASE DETAILS

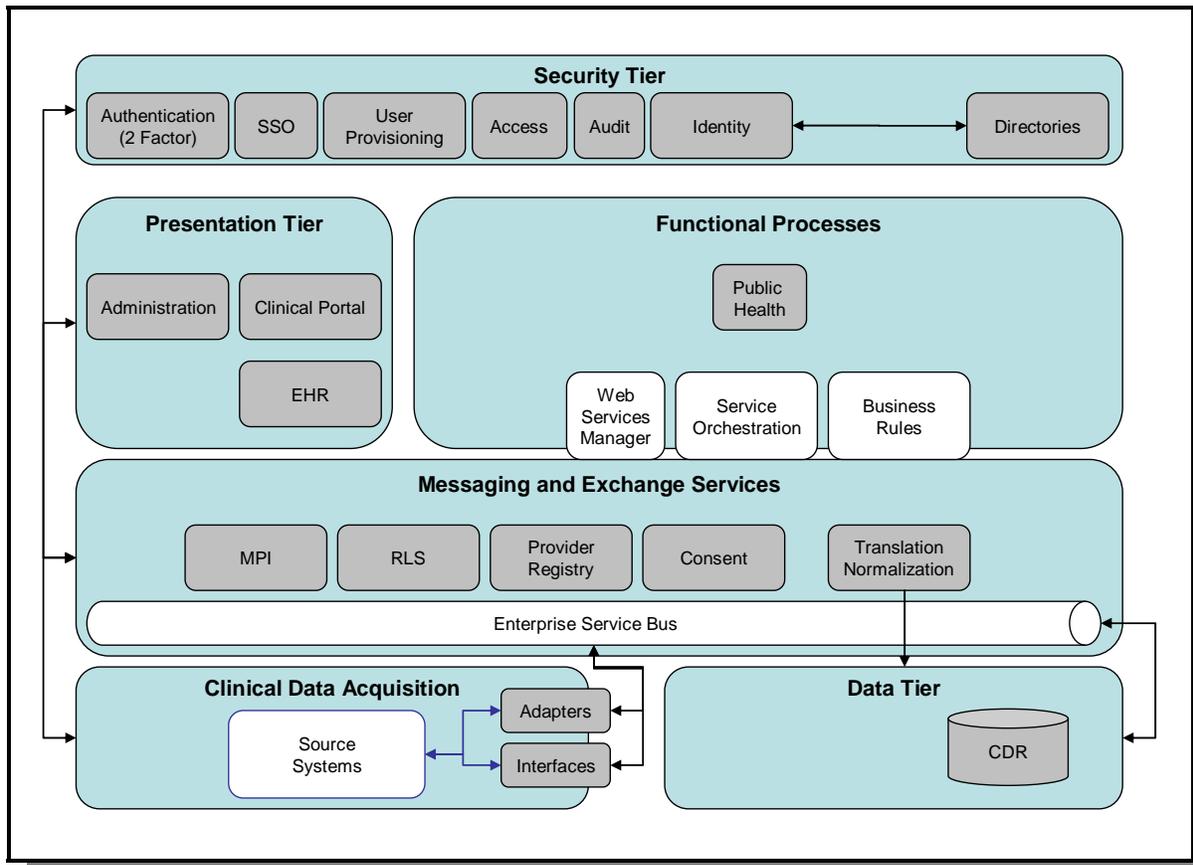
7. Community Resource Management Use Case

The ability for hospitals to transmit capacity and availability data (including institution, unit-level census, and facility utilization data) to Public Health Agencies.

Technical Elements:

<p>Data Elements</p> <ul style="list-style-type: none"> • Institution data • Unit-level census data • Facility utilization data <p>Interfaces by Source Systems</p> <ul style="list-style-type: none"> • Data repositories 	<p>Data Users</p> <ul style="list-style-type: none"> - Public health facilities <p>Data Sources</p> <ul style="list-style-type: none"> - Hospitals
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Visual Representation of Technical Layers:



Applicable Standards:

- In development, none approved by HITSP as of publication of this analysis.

Health Information Exchanges Deployed or Deploying Use Case (within next 6 months):

- Regional Health Information Exchanges in New York State

ATTACHMENT B: USE CASE DETAILS

8. Consumer Empowerment Use Case

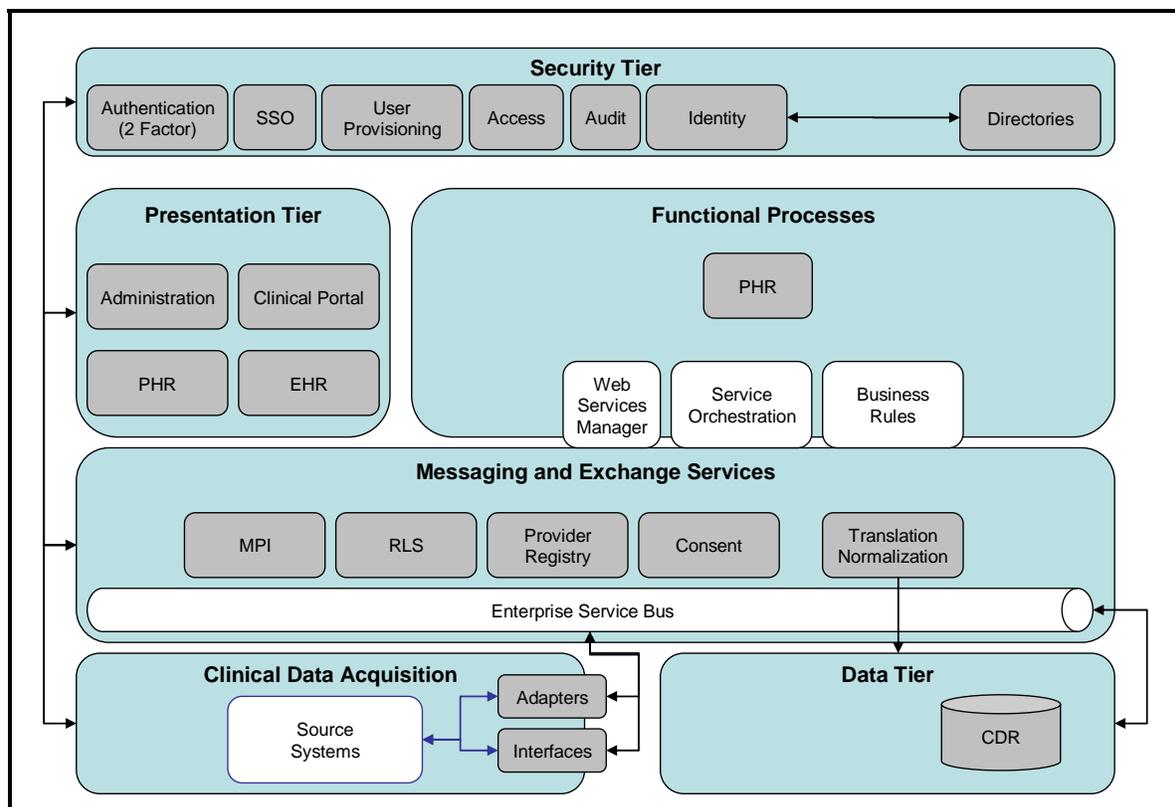
According to HITSP, The Consumer Empowerment and Access to Clinical Information via Networks Interoperability Specification defines specific standards needed to assist patients in making decisions regarding care and healthy lifestyles (i.e., registration information, medication history, lab results, current and previous health conditions, allergies, summaries of healthcare encounters and diagnoses).

Functionality: Includes the capabilities to: (1) share information with designated entities; (2) patient care management tools; and (3) conduct routine health scheduling and administrative functions (e.g., pre-registration).

Technical Elements:

<p>Data Elements</p> <ul style="list-style-type: none"> Varied <p>Interfaces by Source Systems</p> <ul style="list-style-type: none"> Patient Centric HIE 	<p>Data Users</p> <ul style="list-style-type: none"> Patients, consumers Designated care givers <p>Data Sources</p> <ul style="list-style-type: none"> Health plans, PBMs (RxHub) Hospitals, providers
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Visual Representation of Technical Layers:



ATTACHMENT B: USE CASE DETAILS

Applicable Standards:

- HITSP Consumer Empowerment (IS 03):
http://www.hitsp.org/InteroperabilitySet_Details.aspx?MasterIS=true&InteroperabilityId=50&PrefixAlpha=1&APrefix=IS&PrefixNumeric=03

Health Information Exchanges Deployed or Deploying Use Case (within next 6 months):

- CareSpark (TN, VA)
- Regional Health Information Exchanges in New York State

ATTACHMENT B: MARYLAND HEALTH IT CAPABILITIES

Below are data on the known capabilities of health IT systems and HIE capabilities that will be used to assess the viability of various technical approaches and ascertain the overall system cost parameters. Maryland's healthcare system consists of 47 hospitals, 25,098 physicians, and two large health plans (CareFirst Blue Cross/Blue Shield and United Health Group).

Montgomery County Health IT and HIE Capabilities

As described in MCHIE's application, below are the organizational entities and key system features that would participate in a local and/or statewide exchange of health information.

Provider	Clinical-EMR	Radiology	Labs	Registration	Emergency	Pharmacy	Other
Holy Cross ¹⁵	GE QS	McKesson Star Radiology Carestream PACS	SoftCom puter Soft Lab	McKesson Star Patient Care	McKesson Horizon Emergency	McKesson Star Pharmacy	RES Q for Windows (OR)
Montgomery General Hospital	Siemens Clinician View (INVISION OAS Gold)	McKesson Horizon Medical Imaging, Siemens Novius Radiology	Siemens Novius Lab	Siemens Clinician View (INVISION OAS Gold)	Allscripts (A4 Health) EMSTAT	Siemens Pharmacy	Centricity Perioperative System
Shady Grove Adventist Hospital	Siemens Invision	McKesson PACS, Cerner Quadris	Misys	Siemens Invision	Allscripts (A4 Health) EMSTAT	Siemens Invision	Centricity ORMIS
Washington Adventist Hospital	Siemens Invision	McKesson PACS, Cerner Quadris	Misys	Siemens Invision	Allscripts (A4 Health) EMSTAT	Siemens Invision	Centricity ORMIS

The Holy Cross Health Center. The Holy Cross Health Center supported by Holy Cross Hospital for the care of safety net patients will be using the Cerner EMR.

Mary's Center. Mary's Center, a Washington DC-based FQHC recently open a branch in Montgomery County to provide care to low income uninsured patients. As part of the Washington DC Primary Care Associate EMR initiative, Mary's Center installed eClinicalWorks EMR which they will also be using in Montgomery County.

Primary Care Coalitions' CHLCare. CHLCare is an open source, safety net oriented basic EHR that helps the safety net clinics manage patients. It has extensive appointment making and registration capability tailored to safety nets, the ability to record clinical information, problem lists, ICD and CPT codes, lab and radiology results, etc. While not a comprehensive EHR, it serves the clinics well at their stage of operations. CHLCare is used by 11 Montgomery County clinics, one District of Columbia clinic, one Prince Georges County clinic, and two Northern Virginia clinics. CHLCare represents what is sometimes referred to as a "subnetwork organization or SNO," as it is a shared database used by eight independent safety net clinic organizations containing the records of 80,000 patients, covering more than 350,000 visits for patients treated at over 50 clinic sites.

Primary Care Coalitions' Metro DC Health Information Exchange (MeDHIX). MeDHIX is a demonstration project that links the EHR systems of the Metro DC region's safety-net clinics with each other, with the region's hospitals, and with other mainstream healthcare providers, to improve patient safety, care quality, and efficiency for the region's uninsured populations. The initial planning for MeDHIX was funded by a "Transforming Healthcare Quality through Information Technology" planning grant from the Agency for Healthcare Research and Quality

¹⁵ Holy Cross recently migrated many of its systems to Cerner.

ATTACHMENT B: MARYLAND HEALTH IT CAPABILITIES

that was awarded to the Primary Care Coalition. A subsequent three-year implementation grant from AHRQ, along with matching funds from community partners, has been awarded to fund the implementation of MeDHIX.

Non-profit associations (initially Primary Care Coalition of Montgomery County and District of Columbia Primary Care Association), safety net clinics, hospitals and local governments have formed a regional community of interest for MeDHIX that is focused on the specific needs of the uninsured and the safety-net environment. MeDHIX facilitates point of care access to a patient's complete medication information, allergies, problem/diagnosis lists, assessments, and lab results from the disparate systems of safety-net clinics, hospital emergency departments (EDs), specialty providers, and other mainstream healthcare providers. Initial participants in MeDHIX will be safety-net clinics and Hospital EDs. The workflow process for is being implemented as follows:

- A patient obtains an ID card that contains the medical record number (MRN) associated with the patient in the CHLCare EHR. This information is stored in the health system registration system as an additional patient ID.
- An ADT message automatically updates the MeDHIX MPI upon completion of ED registration, thus linking the hospital MRN to the safety net clinic MRN facilitating future data exchanges using either of the linked IDs.
- All data provided by the hospital will contain this MRN and the process for identifying the relationship between the MRNs of the health systems would reside in the MeDHIX MPI.
- If a physician or RN wishes to access the browser view of MeDHIX, they identify their patient request utilizing their own health system MRN, simplifying internal processes and reducing the risk of errors and misidentified patient records.

ATTACHMENT B: MARYLAND HEALTH IT CAPABILITIES

Health IT and HIE Capabilities of Other Providers in Maryland

Erickson Retirement Communities.¹⁶ Erickson has deployed GE's Centricity Ambulatory Electronic Medical Record to all 19 community medical centers. Erickson Retirement Communities has also recently launched a collaborative project with St. Agnes Hospital which established instant patient data exchange between the Electronic Medical Records systems of Erickson and St. Agnes. This is the first time in the United States that such a system has been developed between a hospital and a continuing care retirement provider.

Frederick Memorial Healthcare System.¹⁷ Frederick Memorial Healthcare System (FMH) founded the Frederick Medical Services Organization (FredMed) in 1998, to bring providers and the hospital together for the exchange of patient information. The initiative is largely funded by FMH, and is governed by a Board of Directors that consists of three elected physician members and two hospital representatives. FredMed offers physicians a cost-effective way to connect to FMH for purposes of information exchange. Approximately 165 physicians use the system to gain access to FMH. The technology is available to physicians on a wide area network that provides high speed connection to FMH, allowing access to Meditech and other FMH applications. FredMed participants also have access to a practice management system from Misys, from whom FredMed has recently agreed to purchase an electronic medical record system. FMH also has a physician portal that allows physicians to access lab results from any location, and includes a Picture Archiving and Communication System for viewing x-rays.

Johns Hopkins Medicine.¹⁸ The Johns Hopkins Hospital is creating an Enterprise Patient Record (EPR) system. Eclipsys' Sunrise Clinical Manager (SCM) will be used as its primary clinical system in all settings. Johns Hopkins Bayview Medical Center and Howard County General Hospital will continue to use the Meditech product for their primary clinical system. Johns Hopkins Community Physicians will continue to use the GE Centricity product for its primary clinical system. Across Johns Hopkins Medicine, an Enterprise Longitudinal Repository will be implemented. Microsoft's Azyxxi product will serve as the enterprise's longitudinal clinical repository, aggregating information from Eclipsys, Meditech and Centricity, for purposes of patient care, and clinical research, replacing the existing EPR application.

MedStar Health.¹⁹ MedStar Health has implemented a diverse suite of applications to support its eight hospitals and other health related businesses. In the MedStar hospitals, patients are registered, orders written, results are managed through the Siemens Invision system. The laboratory and pharmacy systems are currently being replaced with an integrated and standardized Cerner solution. Nursing documentation is also being automated through the Cerner product suite. Department-specific EMRs are utilized in Obstetrics (E&C IProB) and Oncology (Varian Aria). All discharged patient records are scanned and stored in McKesson Document Imaging, which is the official patient record for MedStar. In practices owned by MedStar, patients are registered, scheduled and billed through GE/IDX or Medical Manager. MedStar is currently implementing the GE Centricity product as its ambulatory electronic

¹⁶ Chesapeake Regional Information System for our Patients (CRISP). "Application for Statewide HIE Planning Grant." March 2008.

¹⁷ Task Force to Study Electronic Health Records. "Infrastructure Management & Policy Development Workgroup's Health Information Exchange Report." September 11, 2006. Available online at <http://mhcc.maryland.gov/electronichealth/presentations/hlthinfxexchange.pdf>

¹⁸ Chesapeake Regional Information System for our Patients (CRISP). "Application for Statewide HIE Planning Grant." March 2008.

¹⁹ Ibid.

ATTACHMENT B: MARYLAND HEALTH IT CAPABILITIES

medical record. The Microsoft Amalga product provides a centralized clinical data repository, which integrates data across all venues of care.

Peninsula Regional Medical Center.²⁰ Since 1996, Peninsula Regional Medical Center has invested nearly \$130 million on state-of-the-art clinical, surgical, medication dispensing, pharmaceutical and information technologies. About a decade ago, the hospital recognized the value of building information technology to support the growing infrastructure of the hospital. Peninsula Regional Medical Center uses McKesson's Physician Portal to allow physicians to obtain patient information from hospital records. Physicians have access to the medical record, and radiology and cardiac images. More than 100 physicians currently have access to the system.

University of Maryland Medical System.²¹ The University of Maryland Medical System is a regional provider of healthcare services to the citizens of Maryland. The Medical System is a not-for-profit healthcare corporation which operates seven hospitals in Maryland and also has a 50/50 venture with Johns Hopkins Medicine on another. In partnership with the Medical Center, The University of Maryland School of Medicine and its affiliated practices are closely aligned in services and technologies on the combined campus. Like most emerging Integrated Delivery Systems, the computing environment at UMMS is diverse and complex. Multiple commercially available systems have been implemented over the years with no specific integration in mind. Patient identifiers; such as the medical record number are unique from hospital to hospital and practice to practice. Each hospital organization has managed applications and information technology at a local level for many years. Hospital specific clinical data is captured and maintained at the local hospital level on its own computing environment. Data transfer between hospitals is generally paper-based or verbally from provider to provider.

During the next few years the University of Maryland Medical System will create a progressive and comprehensive integrated approach to clinical computing. This approach specifically relies on a more central strategy to clinical computing while maximizing local investments of its member hospitals. This new computing environment relies on three cornerstone technologies. The first is the implementation of an enterprise patient master patient index which acts as the index for all patient identifiers across the Medical System. The second is an enterprise integration engine which provides the system to system and entity to entity transfer of patient clinical data. The third is the creation of the enterprise electronic medical record which provides both the repository of clinical information; but also serves as the clinical workflow engine. The workflow engine begins in the ambulatory centers and moves to inpatient and acute care settings over-time.

Washington County Health System.²² Washington County Health System (WCHS) currently uses about eight different electronic health record products throughout its health system, which includes Washington County Hospital and Antietam Health Services. Their major inpatient vendor system is Meditech, which has been in place for about 14 years. Meditech accounts for around 95 percent of all transactions. However, since most medical practices in the area use

²⁰ Task Force to Study Electronic Health Records. "Infrastructure Management & Policy Development Workgroup's Health Information Exchange Report." September 11, 2006.

²¹ Chesapeake Regional Information System for our Patients (CRISP). "Application for Statewide HIE Planning Grant." March 2008.

²² Task Force to Study Electronic Health Records. "Infrastructure Management & Policy Development Workgroup's Health Information Exchange Report." September 11, 2006.

ATTACHMENT B: MARYLAND HEALTH IT CAPABILITIES

Misys, WCHS is developing technology that will enable these systems to interoperate in a virtual mode. The technology, which is in a testing stage, is intended to function as a locator of patient information. Once the information is located, it is merged together and displayed on the desktop of the requestor.

Public Health Systems

The Johns Hopkins University Applied Physics Laboratory in Laurel, Md., has received a \$4-million, three-year grant from the Centers for Disease Control and Prevention (CDC) to establish a Center for Excellence in Public Health Informatics. APL's Center will be one of five funded by CDC to conduct research leading to major scientific advances in public health informatics. Public health informatics is a relatively new field that refers to the science that deals with health information, its structure, acquisition and use to promote health. In recent years, APL has become a leader in developing computer applications to automate several aspects of disease surveillance.

In 1998, the Special Applications Branch of the Lab's National Security Technology Department began work on an automated disease surveillance system, now known as the Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE), which compiles data such as emergency room visits and over-the-counter drug sales to look for early recognition of patterns that could indicate the outbreak of a disease. Currently the system is being used in the National Capitol Region, composed of the District of Columbia (D.C.), Maryland, Virginia and the seven counties surrounding D.C.²³ By 2003, ESSENCE surveyed 12 counties in Maryland and Virginia, plus the District and Baltimore, and the number of data sources has grown steadily.²⁴

²³ <http://www.jhuapl.edu/newscenter/pressreleases/2006/061201.asp>

²⁴ <http://www.ph.ucla.edu/epi/bioter/strategictrackingsniffles.html>

ATTACHMENT C: PRODUCT CATEGORIES, VENDORS, PRICE RANGES

Infrastructure Components	Description	Industry Vendors	Component Price Range
Access Control	Supports identity and access management across web services as well as for specific applications.	Oracle, Sun	\$150,000 (20000 Users)
Authentication	To positively verify the identity of a user, device, or other entity in a computer system, often as a prerequisite to allowing access to resources in a system	Oracle, Sun	\$200,000 (Consideration for multi-factor authentication for 10,000 users)
Business Activity Monitoring / Business Intelligence	Tools to analyze aggregate and centralized data	Oracle, Sun, InterSystems	\$250,000 (Per Server)
Clinical Viewer Software	Software that provides a view of is a front facing application and runs on web servers.	Sun, Orion	\$100,000 to \$250,000 (5,000 physicians)
Data Warehouse	Tool to gather and store aggregate or centralized data according to a particular schema for applying analytics without interrupting operational data store.	Oracle, Sun, InterSystems	\$350,000
Database	A database is a collection of data that is organized so that its contents can easily be accessed, managed, and updated. The most prevalent type of database is the relational database, a tabular database in which data is defined so that it can be reorganized and accessed in a number of different ways. A distributed database is one that can be dispersed or replicated among different points in a network. An object-oriented programming database is one that is congruent with the data defined in object classes and subclasses.	Oracle, InterSystems, Microsoft, HP, Sun	\$200,000 to \$400,000 (Based on number of servers supporting underlying messages to data layer)
Enterprise Service Bus	The Enterprise Service Bus (ESB) is utilized for exchange of messages between services and nodes on a network.	IBM, Oracle, Sun, Tibco, Cape Clear, Microsoft, Glassfish	\$200,000 - \$400,000 (Processor-based pricing)

ATTACHMENT C: PRODUCT CATEGORIES, VENDORS, PRICE RANGES

Infrastructure Components	Description	Industry Vendors	Component Price Range
Integration Engine	Software and hardware which is run by a set of complex business rules to ensure that data is communicated from one system to another in a meaningful way.	Quovadx, InterSystems, Oracle, IBM, Orion Rhapsody, Sun Systems, OpenLink	\$100,000 to \$250,000 (Per server based on 1000 messages per minute)
Master Person Index (MPI)	MPI is an enterprise tool to assure vital clinical & demographic information can be cross-referenced between different facilities in a healthcare system	Axolotl, Initiate, InterSystems, SUN	\$300,000 to \$500,000 for approximately 2 million lives.
Record Locator Service (RLS)	An information service that locates patient records across systems that subscribe to the service.	Intel SOAE, InterSystems, Oracle, and SUN	\$100,000; note: many of these are sold as a comment / access layer to the clinical data repository.
Servers	Servers operate as computer systems which provide services to other computers. To that end, servers are typically defined based on the ability of the hardware and software to support multiple requests from clients operating on a network.	HP, Dell, IBM	\$9,000 to \$20,000 ea
Systems Auditing	Tools that allow monitoring based on security policy. System auditing and host-based intrusion detection type functions.	InterSystems, Oracle, Sun Systems	\$250,000 (Structured reporting, data layer, and auditing application)
Terminology Translation	Most health information exchanges provide simple table to table level mapping of master data values to terminology standards. Additional 3rd party products are also made available to assist in mapping and rules to support clinical interoperability.	Sun, Oracle, InterSystems, Apelon	250,000 (Per license and terminology set)

**Montgomery County HIE Collaborative
Statewide HIE Financing and Business Case
Analysis and Recommendations**

Montgomery County Health Information Exchange Finance Team,
assisted by Manatt Health Solutions
February 2009

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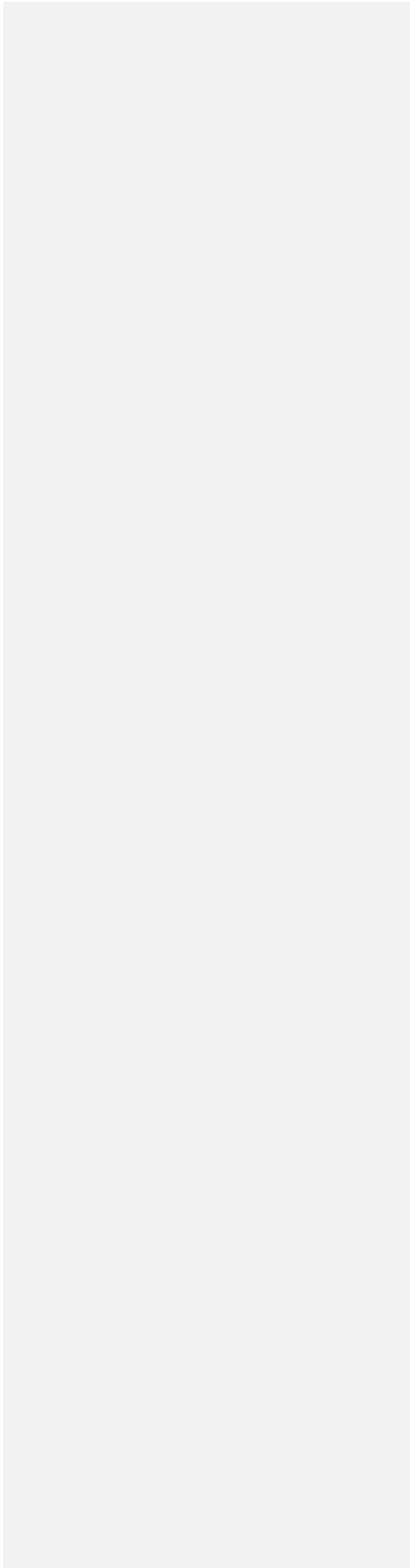
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EXECUTIVE SUMMARY AND PURPOSE OF DOCUMENT

Maryland's ability to advance health information exchange (HIE) will depend on its ability to both *build* and *sustain* the policy infrastructure and technology components. With respect to building the statewide HIE capacity, the most pressing challenge is identifying and securing startup capital. Of equal importance is the need for Maryland to distinguish capital needs from ongoing funding required to support HIE operations.

Developed through deliberations of the Montgomery County HIE Collaborative (MCHIE) Finance Team, this document assesses the business drivers and financing options and provides the basis for the Montgomery County HIE Collaborative's final report to the Maryland Health Care Commission (MHCC).

This report provides recommendations for building sustainable HIE in Maryland for five threshold issues:

- **Principles to Guide Financing of Statewide HIE**
- **Use Case Selection**
- **Startup Capital**
- **Ongoing Operating Expense**
- **Financing for Governance Process**

Based on the analysis of these issues, the MCHIE Finance Team recommends the creation of a "Maryland eHealth Fund" using seed capital from the Health Services Cost Review Commission (HSCRC) hospital rate setting authority, a revenue-backed bond, and available federal funding sources. Administered by Maryland State government, the Maryland eHealth Fund would provide the initial capital investments to build a statewide collaborative governance process and develop the technical capabilities to support high-value use cases.

With respect to supporting the ongoing operations of Maryland's HIE infrastructure, the MCHIE Finance Team recommends that the State diffuse costs across stakeholders by using multiple mechanisms, including: (1) incentive programs for eRx and electronic health records (EHRs), (2) start-up, subscription and transaction fees; (3) payer rate adjustments; (4) consulting fees; and (5) quality-focused reimbursement mechanisms (e.g., pay-for-performance, medical homes) that will increase demand for HIE services.

I. BACKGROUND ON STATE-LEVEL HIE FINANCING

Designing, piloting and implementing interoperable HIE is a complex, multi-year process that extends beyond most organizations’ annual operating and budgeting cycles. Like other long term investments, decisions on when and what to fund are determined largely through return on investment analysis.

As depicted in the figure below, financing of HIE involves a complex array of funding sources, mechanisms, recipients, and revenue sources for financing state-level HIE.

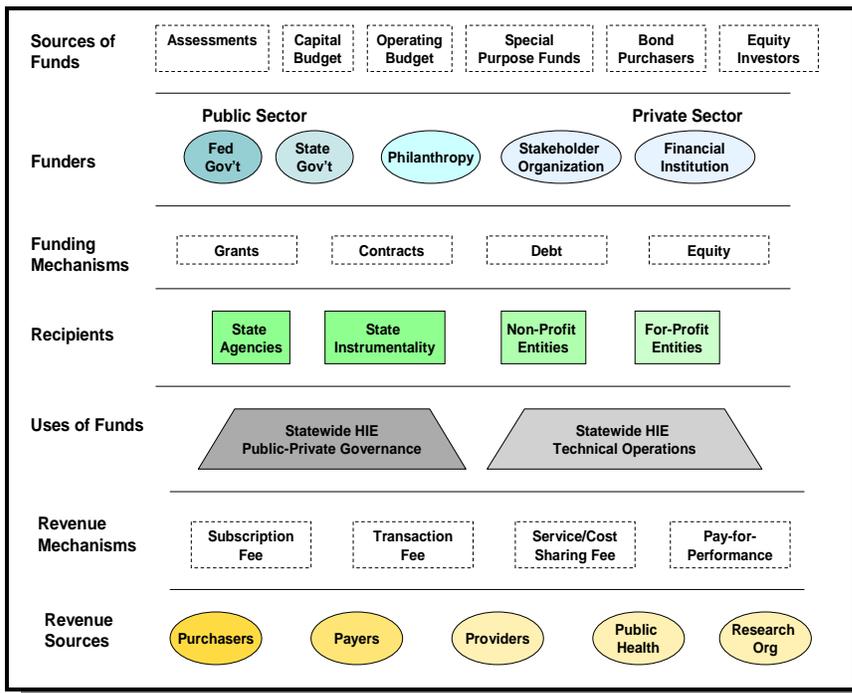


Figure 1: State-level HIE Financing Analytic Framework

Making informed decisions regarding the timing and focus of investments in state-level HIE requires understanding of the start-up and ongoing costs of implementation and the anticipated returns in savings or revenue generation based on the services offered.

Whether building a single statewide technical infrastructure or relying on local HIEs or health record banks as the locus of implementation, states face similar obstacles in (1) securing the financial capital to build infrastructure capabilities and (2) developing ongoing revenue streams to maintain operations.

As discussed below, the challenges for sustaining HIEs stem largely from the public good characteristics of HIE and existing incentive structures within the healthcare system.

A. Public Good Characteristics of Interoperable HIE

Like other network systems, interoperable HIE exhibits a key characteristic of a “public good” in that it is “non-rivalrous.” This means that consumption of the HIE by one individual does not reduce availability for others.¹ Moreover, the value of information doesn’t diminish with use, in contrast to most assets which depreciate the more they are used.²

While increased access to information spurred through interoperability translates into broad societal benefits, it also raises the specter of the “free-rider effect” that leads to suboptimal production of the public good. In the fragmented health market, no single entity dominates the system. In this environment, any individual stakeholder’s investment in HIE generates benefits not only for its constituents, but those of its competitors as well. Faced with the prospect of their economic benefits “leaking” to others, stakeholders have little incentive to make the significant investments required to establish and participate in interoperable HIE.

B. Impact of Healthcare Structure and Incentives

The current healthcare system, particularly the reimbursement structure for health provision, can influence efforts to advance health IT adoption and the expansion of interoperable HIE. Reinforced by a complex array of regulations and laws, the system has evolved into a patchwork of administrative processes that creates barriers to the collaboration needed to support quality care.

By providing patient information in a complete, accurate and timely fashion, interoperable HIE has the potential to increase efficiency by reducing the need for duplicate or redundant testing. However, in a fee-for-service reimbursement system, physicians and hospitals have significant financial incentives to *increase* testing and other procedures.

Moreover, health providers’ costs for participating in HIE are not commensurate with their benefits. While healthcare providers shoulder health IT acquisition expenses, near-term productivity losses, and implementation risks, more than 80% of the value accrues to third party, fiscal intermediaries (i.e., those who hold the risk for the cost of care, whether it be health plans, employers, or providers themselves who bear risk through capitation arrangements).³

Although payers and purchasers are expected to derive most of the benefits from widespread exchange of health information, they remain reluctant to invest in shared HIE frameworks owing to the speculative nature of anticipated returns on investment and the challenge of capturing the value that does accrue.

¹ Varian, H. *Microeconomic Analysis*. W. W. Norton & Co., New York, 1992.

² Vogel, L. “Finding Value from IT Investments: Exploring the Elusive ROI in Healthcare.” *Journal of Healthcare Information Management*. Fall 2003.

³ *The Value of Healthcare Information Exchange and Interoperability*. Center for Information Technology Leadership. 2005.

II. THRESHOLD ISSUES FOR STATE-LEVEL HIE FINANCING

The MCHIE Finance Team identified five issues that will frame the recommendations for financing statewide HIE in Maryland. Each issue and key questions are outlined below.

Threshold Issue	Key Questions
A. Guiding Principles for Financing Statewide HIE	<ul style="list-style-type: none"> • What are the principles that will guide the financing of statewide HIE in Maryland?
B. Use Case Selection	<ul style="list-style-type: none"> • What criteria should guide the assessment and sequencing of use cases?
C. Startup Capital	<ul style="list-style-type: none"> • What is the range of capital required to create an interoperable statewide HIE infrastructure? • What funding mechanism should be used to generate capital?
D. Financing of Ongoing Operating Expenses	<ul style="list-style-type: none"> • What mechanisms should be utilized to support ongoing operations?
E. Financing For Governance Bodies And Processes	<ul style="list-style-type: none"> • What amount of investments are needed to create and sustain the collaborative governance process? • What mechanisms should be used to finance the collaborative governance process?

A. Principles to Guide Financing of Statewide HIE

Background

Through the work of multiple committee and advisory bodies conducted over the course of the last three years, stakeholders in Maryland have developed principles to govern HIE.^{4,5} Based on the results of these deliberations, MHCC identified the following eight principles in its Request for Applications (RFA):

- 1. The HIE must have a business model that is sustainable.**
 - a. It considers both who benefits and who bears the cost.
 - b. Each sector/stakeholder has a well-defined value proposition.
- 2. The HIE is consumer-centric.**
 - a. It consistently keeps consumers best interests at the forefront of decision-making;
 - b. Consumers have control over who accesses their data.

⁴ "Task Force to Study Electronic Health Records", Maryland Health Care Commission, December 2007. Study conducted under Maryland Senate Bill 251 (2005).

⁵ Maryland Health Care Commission. "Privacy and Security Solutions and Implementation Activities For A Statewide Health Information Exchange." September 2008.

3. Data is appropriately accessible to authorized stakeholders.
4. The HIE is secure and protects patient privacy and confidentiality.
5. The governance structure of the HIE is transparent and inclusive.
6. The HIE includes specific, formal penalties for inappropriate access and misuse of data.
7. The HIE uses industry-defined standards.
8. Established procedures are in place to permit emergency access to data.

Decision Point

- What principles will guide Maryland's approach to financing HIE?

Recommendation and Rationale

The table below tracks MCHIE's proposed changes to the HIE financing-related principles proposed in MHCC's RFA.

Original Principle	Recommended Change	Rationale
1. The HIE must have a business model that is sustainable. It considers both who benefits and who bears the cost; and each sector/stakeholder has a well-defined value proposition.	<i>Unchanged</i>	<p>A statewide model should be scoped precisely, focusing on the most likely consumers and contributors of patient data</p> <p>Ongoing operating expenses and the likely near-term expansion to new stakeholders require private sector contributions to combat free rider/moral hazard challenges.</p>

B. Use Case Selection

Background

Network designers typically utilize use cases to guide IT system development. Use cases describe what a system (or systems) needs to do to achieve a specific mission or stakeholder goals. Use cases identify relevant stakeholders, information flows, issues, and systems needs that apply to the multiple organizations participating in these specified data exchanges.

With respect to health IT, use cases have guided the development of HIE efforts at the national, state, and local levels. At the national level, the American Health Information Community defined and the HHS Secretary accepted a series of use cases that would be supported by the Nationwide Health Information Network.⁶ The federal government utilizes the approved use cases to advance standards harmonization, define architecture specification, inform certification consideration, and provide the framework for detailed policy discussions to advance the national health IT agenda.

MHCC's RFA identified four core functions (described as "clinical decision support priorities"):

- Medication history and reconciliation
- Diagnostic results reporting
- Continuity of care records
- Longitudinal health records

The RFA also identified three additional "expansion" functions:

- Public health reporting, tracking and monitoring
- Quality and patient safety
- Personal health record management

Clarity regarding the parameters of these use cases is essential for building the technical framework, assessing system costs and integration considerations, and ascertain financing options. Accordingly, MCHIE expanded MHCC's definitions, identified key functionalities, and documented quantified benefits along eight use cases. The table on the following page provides a summary of MCHIE's analysis.

⁶ Additional details on the Nationwide Health Information Network are available online at <http://www.hhs.gov/healthit/healthnetwork/background/>.

Use Case	Details
1. Diagnostic Results Reporting	<p>Definition: Allow a clinician to electronically obtain diagnostic results (including laboratory test results, radiology reports, and pathology reports) that he or she has ordered and to electronically obtain relevant test results for the purpose of the clinical care of a patient.</p> <p>Functionality: The delivery of diagnostic results on a “push” basis to a targeted set of recipients (e.g., the requesting physician).</p> <p>General Benefits:</p> <ul style="list-style-type: none"> • Workflow efficiency for providers as they can go to a single location to retrieve clinical messages from multiple sources/systems. • Reduce costs for delivering results over traditional methods (e.g., fax, mail, courier). • Allow hospitals to eliminate redundant clinical results delivery services. • Reduce unnecessary testing. • Serve as a platform to enable the push of other types of information to physicians (e.g., public health alerts).
2. Medication Management	<p>Definition: Medication Management Services provide medication history retrieval and aggregation from multiple sources, Medicaid and insurance eligibility checks, formulary queries, and e-prescribing functionality.</p> <p>Functionality: Via an EHR or portal, authorized clinicians will be able to (1) determine patient eligibility; (2) download the appropriate formulary file for patient's coverage plan; and (3) search for patient's medication history across multiple records and aggregate into a single view, providing clinician additional patient medication information including Allergy/Drug Sensitivity, Condition Information.</p> <p>General Benefits:</p> <ul style="list-style-type: none"> • Reduce adverse events due to med errors and related hospitalizations. • Reduce narcotics fraud and medication seeking. • Reduce unnecessary hospitalizations. • Increase formulary compliance. • Increase administrative efficiencies by reducing calls for clarification, renewal, and eligibility. • Increase generic substitution.

Use Case	Details
3. Transfer of Care	<p>Definition: Defined by the American Health Information Community in March 2008, the Transfer of Care use case describes the information flows, issues and system capabilities that apply to a provider requesting a transfer of care for a patient and the receiving facility admitting the patient.</p> <p>Functionality: This use case focuses on providing patient information needed by clinicians to accomplish a transition in care from one care setting to another. The focus is on transitions between acute, long-term care, nursing facility, rehabilitation facility, home healthcare, and other inter-organizational transitions rather than transfers within a given care setting.</p> <p>The transferring setting can transmit a core set of clinical information to the receiving setting to assist in the coordination and management of patient care and may also send relevant information to the patient's personally controlled health records.</p> <p>General Benefits:</p> <ul style="list-style-type: none"> • Clinicians benefit from more comprehensive and usable health information with which to coordinate and improve care, minimize medical errors and costs, and maximize efficiency. • Patients benefit from greater continuity and quality of care during consultations with providers and transitions between care settings.
4. Quality Reporting	<p>Definition: The technical capacity and functionality needed to measure and report on hospital and clinician quality and use quality measures to support clinical decision making.</p> <p>Functionality: Quality Reporting supports the capture and reporting of quality, performance, and accountability measures to which providers, facilities, delivery systems, and communities are held accountable including measures related to process, outcomes, and/or costs of care, may be used in 'pay for performance' monitoring and adherence to best practice guidelines.</p> <p>General Benefits:</p> <ul style="list-style-type: none"> • Greater efficiency and cost savings associate with submitting, collecting, and analyzing data. • Reduce delays in the provision of performance data to physicians.
5. Research	<p>Definition: Query either a centralized repository or multiple data sources to produce a de-identified report for an approved research project.</p> <p>Functionality: Access to aggregated patient care data provides an opportunity to improve clinical research, recruitment for clinical trials, and comparative effectiveness efforts.</p> <p>General Benefits:</p> <ul style="list-style-type: none"> • Enables better identification of previously undetected patterns of safety events and/or co-morbidities. • Improves timeliness and effectiveness of post-market surveillance of drugs and medical devices.

Use Case	Details
6. Public Health	<p>Definition: Transmit essential ambulatory care and emergency department visit, utilization, and lab result data from in standard and anonymized format to authorized public health agencies.</p> <p>Functionality: This use case can support reportable disease investigation, influenza surveillance, etc.</p> <p>General Benefits:</p> <ul style="list-style-type: none"> • Improves ability to identify and respond to public health threats. • Improves timeliness and completeness of automated reporting vs. paper-based methods.
7. Community Resource Management	<p>Definition: The ability for hospitals to transmit capacity and availability data (including institution, unit-level census, and facility utilization data) to Public Health Agencies.</p> <p>General Benefits:</p> <ul style="list-style-type: none"> • Reduces cost of resource management. • Builds on existing disaster management applications.
8. Consumer Empowerment	<p>Definition: According to the Health Information Technology Standards Panel, the Consumer Empowerment and Access to Clinical Information via Networks Interoperability Specification defines specific standards needed to assist patients in making decisions regarding care and healthy lifestyles (i.e., registration information, medication history, lab results, current and previous health conditions, allergies, summaries of healthcare encounters and diagnoses).</p> <p>Functionality: Includes the capabilities to: (1) share information with designated entities; (2) patient care management tools; and (3) conduct routine health scheduling and administrative functions (e.g., pre-registration).</p> <p>General Benefits:</p> <ul style="list-style-type: none"> • To the extent the patient shares his/her views of their data with providers, increases quality, safety, and effectiveness likely to ensue. • Heightened patient engagement in care. • Complementary tool for improved chronic disease management. • Administrative efficiencies in accessing care (e.g., scheduling and registration).

For any use case, the cumulative benefits depends upon the value generated for various stakeholders. Stakeholders or potential customers who derive value from state-level HIE services include:

- Physicians (small, medium, and large general and specialty practices)
- Hospitals (emergency department and in-patient facilities)
- Clinical service providers (laboratories and pharmacies)
- Payers (health insurance companies and federal/state government)
- Employers (public/private firms that purchase healthcare for their employees)
- Researchers (public health authorities, academia, and pharmaceutical companies)
- Consumers (patients and care-givers)

The grid on the following page illustrates anticipated benefits for a range of potential state-level HIE applications across stakeholder groups.

		Benefit Potential						
Service Stakeholder	Diagnostic Results Delivery	Medication Management	Transfer of Care	Quality Reporting	Research	Public Health	Community Resource Managem't	Consumer Empowrm't
Physicians	High	High	High	High	Medium	Low	Medium	Medium
Hospitals	High	High	High	High	Medium	Medium	Medium	Low
Laboratories	High	Low	Low	Low	Medium	Low	Low	Low
Pharmacies	Medium	Low	Low	Low	Low	Low	Low	Low
Payers	Low	High	High	Low	Low	Medium	Medium	Medium
Employers	Low	Low	Medium	Medium	Low	Low	Low	Medium
Researchers	Low	Low	Low	Medium	High	High	Low	Low
Consumers	Low	Medium	Medium	Medium	Low	Low	Medium	Medium

ANTICIPATED MAGNITUDE OF BENEFITS OF EACH SERVICE FOR STAKEHOLDER GROUPS⁷



⁷ Adapted from *Massachusetts eHealth Collaborative* Presentation at AHRQ's 2007 Annual Meeting, September 26, 2007. Available online at <http://www.ahrq.gov/about/annualmtg07/0926slides/tripathi/Tripathi.ppt>.

In determining the sequence of implementation, state-level HIEs typically assess candidate services and use cases across the following criteria: (1) the clinical value generated, (2) the degree of competition for the service, (3) the breadth and depth of potential clients, (4) anticipated net revenue and return on investment, (5) technical difficulty; and (6) vendor interest, capabilities, and costs for service provision.

The table below highlights the use case implementation strategies for the more advanced statewide HIEs.

State	State-level HIE Initiative	Proposed Use Cases and HIE services
California	CalRHIO	<ul style="list-style-type: none"> • Phase 1: Medication history and diagnostic results delivery to Emergency Departments
Delaware	Delaware Health Information Network	<ul style="list-style-type: none"> • Phase 1: Clinical results/reports delivery; public health reporting • Phase 2: Med and patient histories, eOrders, patient portal, enhanced Public Health reporting • Phase 3: Physician workflow management and administrative functions
Maine	HealthInfoNet	<ul style="list-style-type: none"> • Phase 1: Patient ID & demographics, encounter histories, lab and radiology results, patient consent management via secure, Internet-based portal • Phase 2: Adverse reactions/allergies, medication history, diagnosis/conditions/problems, dictated/transcribed Documents
Minnesota	Minnesota HIE	<ul style="list-style-type: none"> • Phase 1: Medication history view • Phase 2: Eligibility checking
Rhode Island	Rhode Island Quality Institute	<ul style="list-style-type: none"> • Phase 1: Medication and lab histories via secure, Internet-based portal • Phase 2: TBD
Utah	Utah Health Information Network	<ul style="list-style-type: none"> • Phase 1: Administrative data delivery • Phase 2: Clinical results delivery
Vermont	Vermont Information Technology Leaders	<ul style="list-style-type: none"> • Phase 1: Medication histories to Emergency Departments • Phase 2: Chronic Disease Management

Decision Points

- What principles should guide the selection of use cases?
- From a value and financing perspective, how should use cases be sequenced?

Recommendation: Phase 1 Use Cases

From a business case and financing perspective, the MCHIE Finance Team recommends that Maryland use the following criteria for prioritizing implementation of use cases:

- (1) Magnitude of clinical value
- (2) Magnitude of efficiency improvements
- (3) Ability to identify discrete transactions for possible future fee assessment
- (4) Ease of integrating with existing workflows

Based on an analysis of the use cases, the MCHIE Finance Team identified three use cases as candidates for Phase 1 implementation: (1) diagnostic results reporting, (2) medication management, and (3) transfer of care.

Please note that other MCHIE teams, particularly the Technical Team, will provide additional criteria for selection and sequencing of use cases.

The table below describes the extent to which each of the eight use cases addresses the four business case and financing criteria identified above.

Use Case	Improvements		Discrete Transactions	Integration Ease	Comments
	Clinical Value	Efficiency			
Diagnostic Results Reporting	Low	High	High	High	+ Proven business case amongst operational HIEs + Higher ease of adoption within provider community relative to other use cases - Clinical value lower than other use cases ⁸
Medication Management	High	Moderate	High	Moderate	+ Proven clinical and administrative benefits + Included in early phases of many HIEs + Links to existing incentives for eRx adoption + Potential to leverage this use case to satisfy facilities' medication reconciliation requirements

⁸ If the Diagnostic Results Reporting use case is expanded to provision results to non-ordering clinicians, its clinical value would increase.

Use Case	Improvements		Discrete Transactions	Integration Ease	Comments
	Clinical Value	Efficiency			
Transfer of Care	Moderate	Moderate	High	Low	<ul style="list-style-type: none"> + Significant potential for both clinical and administrative efficiencies - Requires significant workflow modifications - Many long term care facilities, a key stakeholder for realizing clinical value and efficiency, lack the capabilities to accept and exchange data and participate fully in this use case.
Public Health	High	Moderate	Moderate	Moderate	<ul style="list-style-type: none"> + Ability to leverage ongoing and future federal/state investments in public health. - Adoption slowed by public health's reliance on mandates (vs. incentives) to support reporting. - While the benefits of automated reporting have been demonstrated, public health departments will require significant investments in business intelligence tools to organize and analyze data quickly and effectively.
Community Resource Management	Moderate	High	Moderate	Moderate	<ul style="list-style-type: none"> + Ability to leverage ongoing and future federal/state investments in biosurveillance. + Compatibility with existing ED diversion efforts in Maryland. - Adoption stymied by public health's reliance on mandates to support reporting as opposed to incentives.
Quality Reporting	Moderate	Moderate	Low	Low	<ul style="list-style-type: none"> + Quality reporting requirements will be a growing feature of healthcare reimbursement - In ability of providers to obtain timely feedback remains significant hindrance for integration into clinical workflows.

Use Case	Improvements		Discrete Transactions	Integration Ease	Comments
	Clinical Value	Efficiency			
Consumer Empowerment	Moderate	Unproven	Low	Low	<ul style="list-style-type: none"> - Business case for consumer empowerment remains elusive. - Poses significant challenges for workflow integration for healthcare providers.
Research	Unproven	Unproven	Low	Low	<ul style="list-style-type: none"> + Maryland, with the presence of prominent national research facilities, has opportunity to stimulate interest in this use case. - While academic institutions and IDNs continue to build data sets for research, there have been few studies proving the clinical value of heterogeneous data sets for research. - Monetization of clinical data based on HIEs has not been achieved. - Requires high degree of data availability in order to yield value.

C. Startup Capital

Background

While funding for pilot projects and initial planning have generally been available, bringing interoperability to scale is an iterative, developmental process that requires reliable and sustained funding. Facing challenging economic conditions and misaligned incentive structures, state-level HIEs have had a difficult time accessing adequate capital.

No single financing strategy has emerged that works across all settings and circumstances. Instead each state-level HIE effort must understand the opportunities, constraints and limitations inherent to the various funding sources and optimize its strategy based on the characteristics of its healthcare market.

Frameworks to assess the viability and applicability of financing approaches address three fundamental questions:

- (1) Who are the funders?
- (2) What are their sources of funds?
- (3) How do funders collect and disbursing their funds?

The diagram below illustrates the financing components arrayed across the public, non-profit and private sectors. A glossary is provided in *Attachment A*.

	Public Sector			Private Sector	
Funders	Federal Gov't	State Gov't	Philanthropy	Stakeholder Organizations ⁹	Financial Institutions
Funding Sources	<ul style="list-style-type: none"> o Operating budget o Capital budget o Assessment o Special purpose funds 		<ul style="list-style-type: none"> o Operating budget o Capital budget 	<ul style="list-style-type: none"> o Operating budget o Capital budget 	<ul style="list-style-type: none"> o Equity investors o Bond purchasers

The public sector, through state and federal grants and contracts, has provided the largest proportion of funding for state-level HIE planning and capacity building. To a lesser extent, philanthropies and providers, largely through matching contributions, have also supported state-level HIE capacity building.

At the national level, the federal government has funded policy coordination, privacy and security, technical standards and certification, and demonstration projects. While the federal focus has been on the policy levers to advance health IT and HIE, the responsibility of implementation has largely fell to stakeholders at the state, regional, and local levels.¹⁰

⁹ Stakeholder organizations includes providers, payers, and employers.

¹⁰ Pending legislation represents a significant change in federal policy and funding. The Health Information Technology for Economic and Clinical Health (HITECH) Act, included in the federal economic stimulus legislation, currently includes a provision for providing \$300 million in planning and implementation grants to states or "qualified" state-designated non-profit, multi-stakeholder partnerships to "conduct activities to facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards."

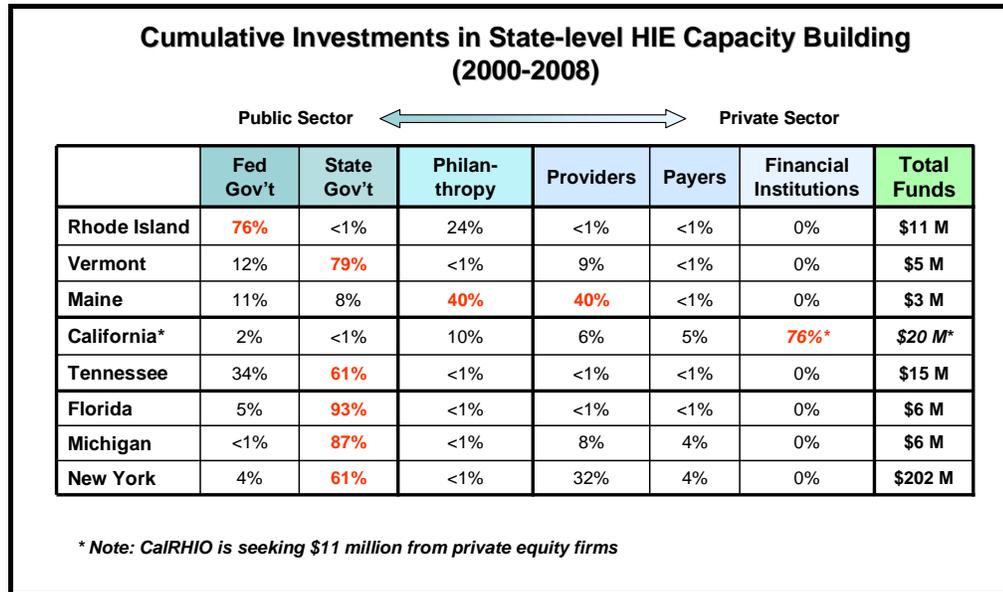


Figure 2: Distribution of funding sources for state-level HIE

Attachment B provides additional details on the challenges, opportunities and considerations associated with each funder and the funding sources.

Anticipated Start-up Capital Needs for Statewide HIE in Maryland

Based on the best available estimates, and working under the assumption that there will be a minimum of five HIEs developed across the State, Maryland should expect to spend between \$20 million and \$30 million for the purchase of the necessary hardware, software and interfaces for the HIEs, and another \$30 million to \$50 million over three years for implementation and maintenance.¹¹ To build the interfaces and functionality required to support all eight of the use cases specified in this report range will require an additional \$30 million and \$45 million.

Hence, the total development costs for the State should range between \$80 million and \$125 million over a three year period, with the bulk of those expenses likely incurred in the final two years of this window.

These estimates do not include the costs borne by hospitals, providers, payers, pharmacies or diagnostic centers to tap into the exchanges. Presuming that most hospitals will have the data necessary to inform the functionality defined by the use cases, hospitals will need to spend between \$400,000 and \$500,000 apiece for interface development.

Moreover, it will cost approximately \$30,000 to \$35,000 to connect the average independent physician office or clinic to the exchange. The total costs for developing and supporting

¹¹ Costs were derived from an analysis conducted by the MCHIE Technical Team. For additional details, see the *Montgomery County HIE Collaborative Analysis and Recommendations: Technical Considerations for Statewide HIE*.

statewide HIE through five local HIEs and connectivity among Maryland hospitals and providers is outlined in the table below.

Entity	Capital Costs (for years 1-3)	System Maintenance & Integration Costs (for years 1-3)	Total Costs (for years 1-3)
HIEs	\$4 - \$6 million per HIE <i>(for infrastructure)</i> \$6 - \$10 million per HIE <i>(for functionality)</i>	\$6 - \$9 million per HIE	\$80 - \$125 million (5 HIEs across the state)
Hospitals	\$400 - \$500,000 per hospital	\$100,000 per hospital	\$25 - \$30 million (47 hospitals in the state)
Physician offices and clinics <small>(assuming 60% of sites connect to exchange)</small>	\$30 - \$35,000 per site	\$5,000 - \$7,000 per site	\$8 - \$10 million (~430 sites in the state)

Decision Point

- What mechanisms should Maryland utilize for startup capital for HIE in Maryland?
- How can the responsibility for raising the start-up capital be equitably distributed across relevant stakeholders?

Recommendation and Rationale

<p>Recommendation: HSCRC Funding, Bonds, Federal Funds, Community Benefit Funds</p>
<p>For the estimated \$80 million capital requirement during the initial three year period, the MCHIE Finance Team recommends that the State pursue a three-pronged financing strategy:</p> <ul style="list-style-type: none"> • An initial State set-aside of \$10 million that has already been identified for seed capital. • Re-programming 1-2% of "Community Benefit" annually • Approximately \$10-\$15 million from federal sources (including funding for state-level HIE through the recently passed economic stimulus bill). • The remaining amount, approximately \$55-\$60 million, from a revenue-backed bond issue. <p>The MCHIE Financing Team also recommends that Maryland pursue philanthropic funding and consider re-programming a small percentage of hospitals' community benefit dollars to support capital expenditures, expanding functionality, and on-going costs of building and</p>

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Recommendation: HSCRC Funding, Bonds, Federal Funds, Community Benefit Funds

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operating a statewide HIE. Hospitals reported over \$812 million in community benefits for Fiscal Year 2007 of which \$11.4 million was listed as financial contributions.¹² A combination of direct financial support and in-kind technical and other services could accelerate and sustain HIE development across the state, especially in communities less well prepared for adoption of new technology. Even a one percent re-direction of community benefit dollars to statewide HIE (\$8 million dollars) would generously fund HIE development and operations.

Rationale

In undertaking the development of a statewide HIE model, Maryland is implicitly committing to a significant capital outlay. The bulk of capital will be needed in the first 12-24 months of the effort, but the expansion of the HIE model to additional stakeholders and regions of the state will require additional, ongoing capital investment.

In considering the financing needs of statewide HIE development, payment flows should be divided into two broad categories: investment capital and ongoing expenses. For purposes of this analysis and set of recommendations, Maryland should rely primarily on federal and State resources for the “foundational capital” necessary to commence development and deployment.

Providers who participate in the exchange will also have to expend capital to create the interfaces and connectors from their own internal systems to both send and receive patient and provider information into the exchange. For the purposes of this analysis, the MCHIE Finance Team limited its recommendations to what the State should raise to subsidize its own priorities. Subsequent recommendations in this report do suggest that providers will be responsible for providing a bulk of the ongoing operating funds needed to maintain the exchanges, but they are not expected to contribute start-up capital for foundational development.

The “value chain” illustrated below depicts the anticipated flow of benefits and funds for a local HIE.

¹² Health Services Cost Review Commission. “Maryland Hospital Community Benefits Report FY 2007.” Available online at http://www.hscrc.state.md.us/community_benefits/documents/CBR_FY2007_final_report.pdf

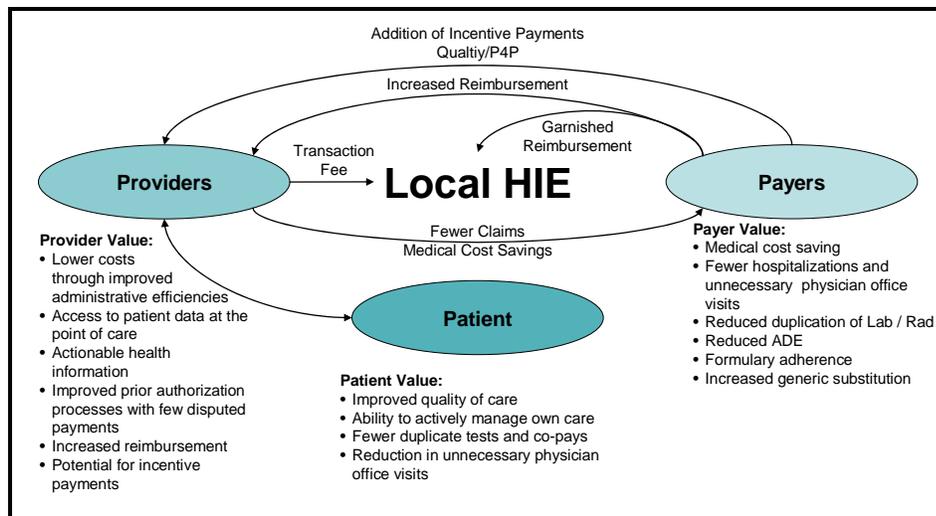


Figure 3: Value chain for local HIEs in Maryland

Two principles have guided the options and recommendations set forth below:

- **The reliability of the recommended start-up funding sources.** As noted above, States are capable of financing some capital projects through the annual/biannual appropriations process, such funding is by nature discrete, time-delimited, and unpredictable. The vagaries of the State budgeting process, and the State economy in general, inhibit long-term planning and consistency in developing capital spending plans.
- **Keep the capital funding options endogenous to the healthcare system.** Options presented expand beyond healthcare transactions, but the universality of the healthcare system and the sheer volume of transactions suggest that revenue can be generated on a reliable and substantial basis.

This is not to suggest that other sources – including philanthropy, payers and large employers – are unwilling to contribute to the start-up costs of the exchanges. Research indicates, however, that in most states that have successfully funded their HIE investments, such third-party, private sources have played very small roles.

Given the pre-existing nature of the State’s commitment of the \$10 million in seed capital, the following analysis will focus on the second two items listed above.

Revenue-backed State Bond Issue. Increasingly, states have pursued have pursued dedicated bond issues in recent years to finance HIE capital development. The recent contraction of the credit markets notwithstanding, such an approach still represents the most predictable and reliable way to raise substantial capital funds over an extended period of time.

Several states have pursued this route, notably New York and Rhode Island. New York’s HEAL program represents perhaps the most comprehensive state bond-backed program in the country. The HEAL program has allocated \$160 million in funding to the development of a

state-wide health information architecture, while another \$240 million in funds augment the state grants through private matching funds and other Federal and state programs. The HEAL bonds, however, are not backed by a dedicated revenue stream, and represent only a portion of all monies allocated under New York's plan.

MCHIE Finance Team proposes a tighter and more explicit relationship between funding streams and a prospective Maryland bond issue, with dedicated revenue streams to service the bonds.

- **The all-payor mechanism.** Leveraging Maryland's all-payor hospital rate system (APHS) makes sense, at first blush, given its long-term presence as a major factor in the Maryland healthcare economy, the marginal changes needed to it that could raise significant capital over time, and its placement of the primary financial burden on payers themselves, who stand to reap the greatest gains from interoperability and commensurate gains in quality of care.

Political factors suggest this is a difficult route to go. The APHS exists under a renewable CMS waiver, and is currently operating at the ceiling of the cap. The HSCRC could conceivably seek additional waivers from CMS to raise the cap, but the process would be arduous. Moreover, the Maryland Hospital Association has been pressuring rates down during recent rate-setting cycles and is likely to resist unplanned increases.

The APRHS mechanism remains a point of discussion, and one that should be addressed early in the State's discussions of possible revenue mechanisms.

- **Excise taxes/sales taxes.** Strictly speaking, excise taxes are levied on the producer of a good as a flat amount, while sales taxes are paid directly by consumers as a percentage of sales price. In either case, consumers ultimately bear much of the costs.

Such levies often are used as a method of re-capturing for the State the additional costs incurred as a result of consumption, e.g., gas taxes to pay the costs of road construction and maintenance, "sin" taxes for alcohol and cigarettes to offset increased healthcare costs. Such uses maintain a sense of the endogenous relationship sought in financing the start-up capital for Maryland's HIE endeavor – the use (and future use) of relatively fixed assets (roads, hospitals) are financed by activities that contribute to future use.

As a predictable source of financing for revenue-backed bonds, such dedicated, item-specific taxes also benefit from a relative degree of predictability. The more inelastic the demand for such goods, the more reliable the revenue stream.

Political challenges confront the traditional consumption levies as well. The cigarette tax in Maryland – \$2.00 per pack – is the fourth highest in the nation, the gasoline tax the 17th highest. Maryland levies a relatively low tax on wine, beer and distilled spirits, though some geographic variance exists at the county level.

All three categories of products demonstrate relative inelasticity of demand; absent external price or regulatory shocks (e.g., an oil embargo, the direct regulation of nicotine under the FDA), state revenue experts are likely to be able to estimate revenue flows from additional levies with some degree of accuracy and reliability.

Available Federal Funding Initiatives. The federal government is likely to make available over the next five years significant federal resources for states pursuing data exchange. Efforts since 2004 have been modest, largely limited to demonstration projects. The recently approved economic stimulus legislation, however, includes a federal commitment to HIE funding in the range of \$2 billion, with an express focus on States and/or State-chartered entities eligible for assistance. By seeking to identify and establish its HIE opportunities and plans at this point, Maryland is well-positioned to capitalize on some of this funding when it becomes available, mostly likely in 2010.

Provider Collaboration on Raising Capital. The HealthBridge example in the greater Cincinnati region is a provocative one to consider as a supplement to State-led efforts on capital development. Funded almost entirely by an ad hoc coalition of hospitals, HealthBridge has managed to avoid virtually all public funding sources in developing, deploying, and operating its exchange. Granted, HealthBridge has a scope of ambition and geographic reach much more limited than the vision outlined for the State of Maryland, as well as dominant health systems that facilitate collaboration across relatively few actors.

Depending on the level of local autonomy the State affords the chartered HIEs, such provider collaboration can provide a significant component to HIE capital development. Such collaboration, however, is unlikely to arise organically if other regions are primarily capitalized by State-backed bonds. As Maryland continues to refine the parameters of HIE governance and finance, it is advised to examine the option of requiring such collaboration across health systems to exist as a precondition for an HIE to receive any State funding.

D. Ongoing Operating Expense

Background

The goal of achieving statewide interoperability does not end with implementation. State-level HIEs must also develop business plans to address the ongoing challenges of sustaining the infrastructure for interoperability.

In order to remain viable entities beyond their initial deployment stage, state-level HIEs must deliver value to their customers in one of two ways: by reducing costs or creating revenue generation opportunities. In a dynamic marketplace characterized by structural disincentives for HIE, emerging alternatives and competitive challenges, rapidly evolving technologies, and wide cost variation, developing workable business models continues to be a significant challenge.

While a handful of local HIE efforts have developed successful models based on transactional efficiencies for participating providers, state-level HIE initiatives continue to assess the viability of shared infrastructure, applications, and services for generating the revenues needed to sustain operations and/or repay interest on debt instruments.

Development of the basic building blocks and “on-ramps” for the HIEs largely falls on the State, but the HIEs will have ongoing costs to maintain, improve and extend their reach and value over time. While it is certainly possible that the State Legislature will fund these ongoing cash needs through annual appropriations, this section examines more market-based mechanisms to generate the payment flow to cover these costs.

As with the identification of capital mechanisms in the previous section, some principles guide the analysis that follows. First, specific points of transaction were sought. Transactions are easily identified, discrete, and in the context of HIE, represent a burden on the network that entails marginal costs. Second, payment burdens for financing the ongoing maintenance and improvement of the HIEs should be borne across the full range of customers, with no single constituency of an HIE forced to bear a disproportionate share of the costs. Finally, there is an effort to recapture a portion of any savings derived from the use of the exchange. Ultimately, meeting this final criterion depends on the actual costs assessed per transaction.

Best estimates based on current conception of the state-wide HIE suggest that Maryland should expect to pay between \$12 million and \$15 million annually for ongoing maintenance and system expansion.

Financing options include:

- ***One-time Set-up Fees for Initial Connections.*** Authenticated users who opt into HIE participation place a modest burden on the infrastructure of the HIE. While scalability is not necessarily a linear equation in such systems, marginal users will entail marginal costs.
- ***Subscription Fees for Users.*** The principle of a subscription fee is similar to the one-time set-up fee described above – an attempt to cover the marginal costs of adding marginal users to the network. Such a mechanism may be less desirable in some situations – especially for those constituencies who will be both data suppliers as well as data consumers of the exchange.

Subscription fees can also be set at variable levels, as certain constituencies will be heavier users of exchange functionality than others – and therefore, generators of more marginal costs.

- **Data Requests.** One of the components of the value proposition of HIE is the efficiency that can be gained in speed, time, paper reduction, courier fees, and ultimately, clerical support needed for various clinical settings to accrue relevant and comprehensive patient information. In most instances, specific data sets – such as medication history, lab results, or discharge orders – will be requested, not a complete patient record.

The use cases delimit several common data requests that are anticipated in an HIE. The focus herein addresses two of those use cases, as each represents discrete transactions with relatively easily-identified benefits.

- **Diagnostic results.** The cornerstone of HealthBridge, one of the few functioning HIEs in existence, diagnostic results represent the core clinical value of HIE for many clinicians in an HIE. HealthBridge relies on both “pull” and “push” mechanisms to deliver the results, an approach advocated here as well. In these instances, a fee for data requests is most appropriate for “pull” requests – a transaction instigated by a clinician of a hospital-based or independent diagnostic facility.
- **Medication records.** Medication records are another anticipated popular request for HIE-participating clinicians. Fees on such requests, however, should be considered carefully and if implemented, set at relatively low levels. While patients have an imperfect knowledge of their own medication regimens and histories, many clinicians are able to obtain sufficient histories from their own querying of patients. Setting a transaction fee at too high a point may discourage utilization altogether, as clinicians turn to payers, pharmacy benefit managers, and SureScripts-RxHub services to compile histories independent of HIE functionality.
- **Payer Assessments.** Most analysts agree that payers likely stand to reap the greatest benefit from HIE deployments; the improvements in care coordination are expected to produce greater preventive care, lower cost of treating the chronically ill, and increases in quality that will produce lower costs for payers. Adjusting the all-payer mechanism is one mechanism already discussed; the political environment and waiver challenges within CMS may make that a difficult route to pursue.

A second option may be to charge payers upon the request of patient data by providers through the exchange. It is a discrete and regular transaction that seeks to recapture some of the benefit from the beneficiary, without appropriating it entirely. Moreover, per-transaction assessments on payers for access to their data helps to avoid a clear “free rider” problem – where payers benefit the most from the exchange, yet do not have to contribute to its ongoing maintenance. CalRHIO, as described in *Attachment C*, is pursuing such an approach.

Decision Point

- What mechanisms should be utilized to support ongoing operations?

Recommendation**Recommendation: Mixed Approach**

It is highly recommended that Maryland pursue multiple options in developing a sustainable financing model to support ongoing operations and development.

Rationale: A multi-pronged approach to operational financing eases the burden on any single constituency while giving the State flexibility in setting transaction and subscription fees at modest enough levels to avoid any disincentives for utilization.

E. Financing for Governance Process

Background

Success of Maryland's statewide HIE effort will depend on the existence of a viable and robust governance mechanism and statewide collaborative process. The MCHIE Governance Team recommended that the statewide HIE effort be supported by a independent public-private partnership, the *Maryland eHealth Collaborative*, that oversees a statewide collaborative process initially consist of three workgroups:

- Privacy and Security Workgroup
- Clinical Workgroup
- Technical Architecture and Standards Workgroup

Each workgroup should be chartered to include representatives from the appropriate constituencies and have explicit requirements and timelines for expected deliverables. The MCHIE Governance Team also recommended that additional teams focused on cross-cutting issues (e.g., planning and assessment, communications, education and outreach, and sustainability) be created to support the three initial workgroups

Based on estimates from other states, approximately \$1.0 million annually will be required to support the staff, travel, education and outreach, communications, planning and operational overhead needs for the *Maryland eHealth Collaborative*. To provide subject matter expertise and logistical support for each of the workgroups noted above, states typically budget between \$100,000 and \$200,000 per workgroup per year.

In most cases, state funds support statewide HIE convening and coordinating functions. In Michigan and New York, for example, the independent state-level HIE initiatives receive substantial funding from state government. In the case of Michigan, MiHIN received a grant of nearly \$1 million from the state to support its operations. In New York, the State Department of Health allocated \$5 million over two years to fund the New York eHealth Collaborative's operations and support for HIE activity.

In some states, foundations have provided critical funding to incubate the planning and governance functions of state-level HIE initiatives. In Arizona, the St. Luke's and the BHHS Legacy Foundation funded the development of the statewide Arizona Health-e Connections roadmap. In New York, the United Hospital Fund provided funds and essential in-kind support to the statewide collaborative NYeC. In California, CalRHIO has received nearly \$2.5 million in total from the Blue Cross of California Foundation, the Blue Shield of California Foundation, the California HealthCare Foundation, and the Blue Shield Foundation of California.

Decision Point

- What mechanisms should be used to finance the collaborative governance process?

Recommendation and Rationale**Recommendation: Fund Governance Activities via State Contract**

MCHIE Governance Team recommends that the HSCRC provide funding through a contract to create and support the initial operation of the *Maryland eHealth Collaborative* and the statewide collaborative process.

Rationale: The MCHIE Finance Team considered three funding sources to support the statewide governance entity and collaborative processes.

The first option is to seek capital and in-kind contributions from stakeholder organizations to launch the organization. Given the current economic conditions, most stakeholders may be unwilling to provide the required funds and/or staff and materials. Moreover, any contributions would need to be structured in such a manner as to ensure the contributors are not granted preferred status in the governance process in exchange for their support.

The second option is to seek support from Maryland-based philanthropic organizations. While this option should be pursued, it may difficult to collect sufficient funding to meet the initial capital needs to create the governance entity and the critical pieces of the collaborative infrastructure.

The third option, funding from the HSCRC seed capital, is attractive because it can be executed quicker than the alternatives, and it affords the state greater oversight of the governance process to ensure it meets the collective needs of all stakeholders.

ATTACHMENT A: GLOSSARY

Electronic Health Record: An electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be created, managed, and consulted by authorized clinicians and staff across more than one healthcare organization. (Source: US Department of Health and Human Services Office of the National Coordinator for Health IT Reports; <http://www.hhs.gov/healthit/resources/reports.html>).

Health Information Exchange: The electronic movement of health-related information among organizations according to nationally recognized standards. (Source: US Department of Health and Human Services Office of the National Coordinator for Health IT Reports; <http://www.hhs.gov/healthit/resources/reports.html>).

Interoperability: Interoperability means the ability of health information systems to work together within and across organizational boundaries in order to advance the effective delivery of healthcare for individuals and communities. (Source: HIMSS Interoperability Definition; http://www.himss.org/content/files/interoperability_definition_background_060905.pdf).

Public Good: In economics, a public good is a good that is non-rival and non-excludable. This means, respectively, that consumption of the good by one individual does not reduce availability of the good for consumption by others; and that no one can be effectively excluded from using the good. Non-rivalness and non-excludability may cause problems for the production of such goods. Specifically, some economists have argued that they may lead to instances of market failure, where uncoordinated markets are unable to provide these goods in desired quantities. These issues are known as public goods and are related to the broader issue of externalities. (Source: Varian, H. *Microeconomic Analysis*. W. W. Norton & Co., New York, 1992.)

Public Instrumentalities: Instrumentalities denotes entities closely affiliated – generally by government ownership or control – with state or local governments. Whether an entity is an "instrumentality" of a governmental unit is determined based on the following factors: (1) whether it is used for a governmental purpose and performs a governmental function; (2) whether it performs its function on behalf of one or more states or political subdivisions; (3) whether private interests are involved, or whether states or political subdivisions have the powers and interests of an owner; (4) whether control and supervision of the organization is vested in public authority or authorities; (5) whether express or implied statutory or other authority is needed to create and/or use the entity; and (6) the degree of the organization's financial autonomy and the source of its operating expenses. (Source: Internal Revenue Service; <http://www.irs.gov/pub/irs-tege/eotopice90.pdf>.)

Public-Private Partnerships: Public-private partnership describes a government service or private business venture which is funded and operated through a partnership of government and one or more private sector companies. (Source: Wikipedia; http://en.wikipedia.org/wiki/Public-private_partnership.)

Regional Health Information Organization: A health information organization that brings together healthcare stakeholders within a defined geographic area and governs health information exchange among them for the purpose of improving health and care in that community. (Source: US Department of Health and Human Services Office of the National Coordinator for Health IT Reports; <http://www.hhs.gov/healthit/resources/reports.html>.)

ATTACHMENT A: GLOSSARY

State Assessments: The primary objective of the special assessment, as in the case of taxes, is some common benefit and they are compulsory. Unlike taxes, which are paid without reference to specific individual benefits, special assessments are based on an anticipated benefit for a specific activity. In other words, whereas taxes are levied for general expenses, special assessment is for a definite purpose, which typically adds to the capital account of the government. (*Source:* A Planner's Guide to Financing Public Improvements; <http://ceres.ca.gov/planning/financing/chap3.html>.)

State Capital Budget: A state's capital budget provides for the acquisition or construction of major capital items, including land, buildings, structures, and equipment and requires multiple years for completion. Money for these projects is typically appropriated from funds whose revenue comes from bond sales. (*Sources:* State of Ohio, Office of Management and Budget; <http://www.obm.ohio.gov/budget/capital/> and President's Commission to Study Capital Budgeting; http://clinton4.nara.gov/pcscb/staf_states.html.)

State Operating Budget: State's operating budgets are the annual/biennial budgets proposed by the governor and ratified by the state legislature. State operating budgets fund state agencies and programs during an agreed upon appropriations cycle. (*Source:* State of Minnesota, Office of Management and Budget; <http://www.finance.state.mn.us/budget/operating/index.html>.)

State Special Purpose Funds: Special purpose funds are used in this report to describe funding sources that are not subject to the traditional legislative appropriation process. Examples of special purpose funds include tobacco settlement funds and federal Medicaid waivers.

1. DIAGNOSTIC RESULTS REPORTING

Overview

The diagnostic results reporting use case attempts to delimit the scope of the functionality and anticipated benefits from the implementation of data sharing capabilities of laboratory and radiology results with relevant clinicians, institutions and payers.

The ability to share laboratory and radiology results electronically rests at the core of a functioning and value-added health information exchange (HIE). To the extent that HIEs have gone into production, the bulk of data transmitted consists of such results. Diagnostic data can often be thought of as the independent variables in clinical decision-making, determining the medication orders, treatment plans, and diagnoses that ensue once results have been reviewed by clinicians. Hence, it follows that the anticipated increase in timeliness and decision-making that results from electronic exchange of such data will accelerate and improve the delivery of care.

Definition of the Use Case

In the planning of Maryland's HIE efforts, it is imperative to define as precisely as possible the scope of functionality, data to be exchanged, and suppliers and consumers of the data to provide the most practical roadmap for eventual development efforts. For the purposes of this use case, we define diagnostic results exchange under the following assumptions:

- **Data.** Initial design, development and deployment plans should focus on laboratory results, pathology reports, radiology reports, and radiologist notes. For the purposes of these use case and near-term development objectives, we are not advising the inclusion of radiology images or the actual orders.

Data will be patient-centric, per Maryland's stated preferences, but such centrality will create some complexities during technical implementation, as noted later in this report.

- **Data Suppliers.** The use case assumes that the lab and radiology departments of hospitals will be expected to supply data to the exchange, as well as independent, freestanding lab and radiology centers. In certain instances, patients will have to provide permission to clinicians to enable access; this permission should be included in the results delivered.
- **Technology.** We envision a hybrid approach of "push" and "pull" technologies being developed. Different clinicians will have different needs and urgencies; as the use case demonstrates below, the vastly different workflows of primary care physicians, radiologists, and ER physicians dictate that an effective solution incorporate multiple access options to the results.
- **Financing.** To the extent possible, the use case has been designed to identify transaction points that can be leveraged as potential points of financing, i.e., the charging of transactional fees and/or subscription fees to help finance the ongoing budgetary needs of the information exchange.

ATTACHMENT B: DETAILED ANALYSIS OF HIGH-PRIORITY USE CASES

It is anticipated that the key actors in this exchange of data will be:

- Freestanding diagnostic centers, serving as the primary suppliers of data to the exchange(s).
- Physicians, whose adoption of the new functionality will be critical to delivering the potential benefits.
- Hospital lab and radiology departments, which will be secondary sources of data as well as a primary venue by which data will be accessed by hospital-based physicians, pathologists, and radiologists.
- Payers, which will need to provide patient eligibility and provider identification information.

Anticipated Clinical and Administrative Benefits

Such functionality should produce some notable benefits to the healthcare system, though the preponderance of benefits will likely accrue to physician offices. Anticipated administrative benefits include:

- Reduction in costs associated with physical document delivery.
- Reduction in duplicate tests.
- Faster turnaround times on results delivery.
- Reduction in administrative costs through reduced phone calls between physician offices and hospitals/diagnostic centers.

Anticipated clinical benefits include:

- Greater speed of clinical decision-making at the point of care.
- A more complete picture of patient history and condition at the time of treatment.
- Reduction in unnecessary tests.
- Assistance in public health surveillance.

The clinical benefits accruing under this use case are difficult to quantify; better-informed decision-making, in a more timely fashion, by clinicians is undoubtedly valuable and likely to contribute to more precise and accurate treatment regimens. It is difficult, however, to pinpoint specific decisions or outcomes that are likely to change as a result of this accelerated information delivery.

ATTACHMENT B: DETAILED ANALYSIS OF HIGH-PRIORITY USE CASES

Anticipated Workflow Impacts: Physicians

Physicians will face the most dramatic shifts to their workflow under this use case, but the impact will vary by specialty and setting. Under this use case, the following impact is anticipated:

- **Primary Care Physicians.** Primary care physicians would receive all lab results, pathology reports, and radiology reports for their patients on a “push” basis, according to permissions granted by their patients. There is less urgency to the workflow needs of primary care physicians; in order to ensure they have timely access to the data, the exchange will likely have to send the results proactively to the physician’s inbox.

Orders submitted by the primary care physician will be the easiest to identify for delivery; the unique patient and provider identifiers will serve to ensure that the results corresponding to the patient arrive at the right physician’s inbox.

The delivery of results to primary care physicians that are associated with the orders of specialist and referral physicians becomes trickier. In this scenario, there are two straightforward mechanisms by which a patient’s primary care giver will receive these results:

- Most managed care payers can provide the cross-check necessary for the results to be delivered accurately to the identified primary care physician.
- In the absence of an identified primary care gatekeeper, patients will likely have to identify, proactively, the physicians to whom they want data “pushed” at the diagnostic center itself.

This latter scenario shifts a great deal of the burden of accurate routing to the patients’ shoulders. Through an electronic personal health record (PHR), patients should find an easier time of it, by the inclusion of unique physician identifiers and the explicit granting of permission for records downloaded to the PHR to be forwarded to identified physicians.

The patient-centricity of the data will complicate the ability of primary care physicians to receive access to referral physician-based results. Other exchanges across the country – notably HealthBridge in the Cincinnati region – have adapted a physician-centric approach to data organization that simplifies the problem and eliminates some of the cross-indexing complexities.

Office-based physicians should also be provided the opportunity to download exchange-based data into their own ambulatory EMRs if they prefer.

- **Hospital-Based Physicians.** This scenario addresses the needs of emergency room physicians and consulting physicians for diagnostic results developed independent of the specific episode of care. Such results should produce near-term historic context for physicians as they make decisions. The context should:
 - Reduce duplicate test orders
 - Prevent unnecessary orders by revealing chronic and existing conditions
 - Better inform clinician decision making

ATTACHMENT B: DETAILED ANALYSIS OF HIGH-PRIORITY USE CASES

Because the end users (hospital-based physicians) and context are unpredictable and in many cases urgent, physicians will need to “pull” the data – make specific requests to the exchange to compile a view of the patient’s history and results. From a bedside or ED-based terminal, the physician would log in and make a request based on the patient’s unique identifier that should be included as part of the admission process. The request should be time delimited, e.g., all results in the last 30/60/90 days.

The request would then go to the exchange, compiling and organizing lab and radiology reports from all hospitals participating in the network, as well as freestanding diagnostic centers

- **Radiologists and Pathologists.** Radiologists and pathologists will primarily be consumers of data from the exchange, referencing historic results on specific patients in order to calibrate their own testing. It is expected that they should “pull” the data from the exchange in advance of the executing against the current order.

They will also serve as suppliers to the exchange, with their results and accompanying reports uploaded to the exchange for distribution to the ordering physician and the patient.

Anticipated Workflow Impacts: Freestanding Diagnostic Centers

There should be little anticipated disruption to the workflows of freestanding diagnostic centers. As the primary suppliers of data to the exchange, such centers will post results and reports in a standardized format that will identify the patient, payer, primary care physician, and the ordering physician.

Standardized, posted results reports will include the ordering physician’s and patient’s unique identifiers; they will then be automatically sent to the exchange inbox of the physicians registered on the exchange, and in the case of patients with online PHRs, made available for their download.

The initial rollout of the data exchange should be limited to results and reports. Given the multiple and disparate media used to transmit orders – electronic, paper, fax, etc. – to the centers, the early versions of the exchange should not create new burdens in standardizing orders for inclusion in the exchange.

It is also not anticipated that the exchange will include digital images, at least not in the initial stages of rollout. Hospitals increasingly provide access to their own digital images through physician portals, with sufficient resolution to be used for consultations but not diagnoses. The inconsistent adoption of computer-based technologies in physician offices suggests that an investment in providing online access to digital images would have limited value to the physician community and is unwarranted at this point.

Anticipated Workflow Impacts: Hospital-Based Diagnostic Centers. An almost identical set of implications for the use case is present for hospital-based diagnostic functions. As a data supplier to the exchange, hospital departments will largely serve office-based physicians with the results obtained for their patients’ inpatient stays.

In this scenario, both admitting and ordering physicians would be identified as intended recipients of “pushed” data upon the uploading of the results. Consulting and hospital-based

ATTACHMENT B: DETAILED ANALYSIS OF HIGH-PRIORITY USE CASES

physicians would have access to the results through the normal clinical information systems (CIS).

The standards used for the exchange must be flexible to account for the myriad inpatient clinical systems that will be sharing this data as well. The challenge for hospitals with relatively sophisticated CIS' in place already will be to minimize the amount of work required to edit the native data into the separate, standardized format for the exchange. The governance process will have to weigh these considerations as it seeks to establish standards for the flow of laboratory and radiology data.

Barriers to Achieving Buy-in and Adoption

The use case presents no dramatic changes to clinical workflow that so often inhibit the adoption of IT functionality. Since the use case presents no needs or requirements of physician electronic data entry, resistance is likely to be minimal. Physician resistance, to the extent it exists, will likely rest largely on the lack of Internet access in the office setting.

Diagnostic center adoption – either freestanding or hospital-based – should also be relatively easy to achieve. Some marginal economic incentives exist that should modestly encourage adoption, as administrative costs associated with greater efficiencies (e.g., reduced copies, paper delivery, and calls from physician offices) should encourage participation.

One potential barrier will be the possible need to re-model results and report data to incorporate into the exchange; given that hospitals have invested much in their own, largely proprietary clinical information systems, the expense of retrofitting the results for a different, standards-based model may be a deterrent. Moreover, health systems and diagnostic centers will likely have to develop web interfaces to support connections to physician offices.

Financing Options

The HealthBridge experience – serving roughly two million patients, 5,000 physicians, and 18 hospitals suggests that upfront capital costs and ongoing expenses for such functionality should be manageable.

HealthBridge was initially funded through loans made by the region's primary health insurers and health systems, and its annual operating budget is roughly \$3 million. Hospital members pay annual dues; extending participation and dues to freestanding centers in the Maryland endeavor can augment this revenue stream.

Additional financing options include:

- The reselling of ISP services by the HIE to physician offices, for a monthly fee to support connectivity with the data.
- Adjustments to the all-payor mechanism to compensate hospitals for tests performed by their lab, pathology, and radiology departments. As payers are collateral beneficiaries from such functionality – based on the reductions in duplicate tests – there is a business case to be made for their participation in the financing mechanism.
- As similar beneficiaries in anticipating reduced administrative costs, the regional HIE and/or the State could assess freestanding diagnostic centers for a portion of the costs of operating the exchange.

2. MEDICATION MANAGEMENT

Overview

Adverse drug events cost the nation \$177 billion annually. Studies indicate that 400,000 preventable drug-related injuries occur each year in hospitals. Another 800,000 occur in long-term care settings, and roughly 530,000 occur just among Medicare recipients in outpatient clinics.

Medication History pilot programs are underway in several states. Horizon Blue Cross Blue Shield of New Jersey announced in July that they will be assisting select hospitals with the cost of implementing medication history technology. Additionally, Vermont Information Technology Leaders (VITL) is undertaking a similar program in two hospital emergency rooms and is able to access medication histories on 70% of the emergency patients.

Definition of the Use Case

The medication management services use case includes medication history retrieval and aggregation from multiple sources, Medicaid and insurance eligibility checks, formulary queries, and e-prescribing (eRx) functionality for providers.

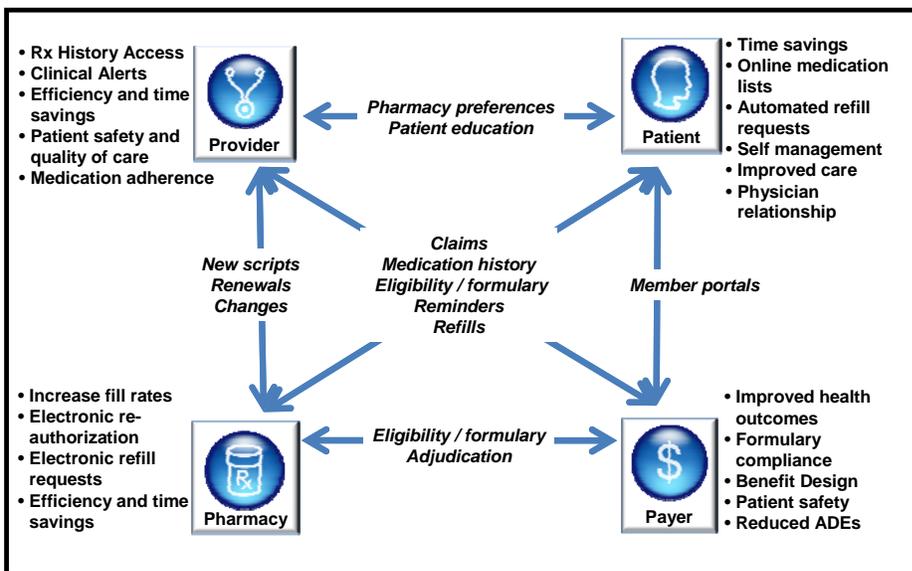


Illustration of Medication Management Use Case¹³

¹³ Adapted from Prematics, Inc. July, 2008 presentation.

ATTACHMENT B: DETAILED ANALYSIS OF HIGH-PRIORITY USE CASES

Key actors in this use case include:

- Providers (physicians and nurses) in multiple care settings (e.g., office, clinic, hospital, ER, Hospital Admitting, SNF);
- Pharmacy (e.g., hospital, chain, independent);
- Payers;
- pharmacy benefits managers (PBMs);
- SureScripts-RxHub;
- Patients;
- Pharmaceutical companies.

Pharmaceutical companies will be approached to participate in the development of the system to assist them, physicians and the State to control the distribution of free samples.

The scope of data to be included in the use case includes:

- Current medications: drug, dose, route, frequency and prescribing physician;
- Medication history: drug, dose, route, frequency and prescribing physician;
- Fills;
- Known allergies;
- Formularies; and
- Eligibility.

Information retrieval and aggregation of current medications, medication history and fills will be primarily focused primarily on data from PBMs and payers. Provider organizations with electronic medication history may be considered as a secondary source of data.

MCHIE will leverage the use of existing and available technologies for eRx for this use case including SureScripts-RxHub connectivity and developing a short list of SureScripts-RxHub certified eRx applications. In addition, interfaces will be developed to access data from PBMs and Payers.

Anticipated Clinical and Administrative Benefits

This use case has the benefit of both improving quality and reducing cost simultaneously. The anticipated clinical benefits associated with this use case include:

- Reduce adverse events (ADEs) and related hospitalizations due to med errors and medication compliance;
- Administrative efficiencies: Clarification calls, renewal calls, eligibility calls;
- Increase formulary compliance;
- Increased generic substitution; and
- Reduce narcotics fraud / med seeking.

Medication management and the increase e-prescribing could reduce federal health expenditures by up to \$29 billion over the next decade and help physicians to prevent nearly 1.9 million adverse drug events (ADE's) over the same time period, where individuals otherwise would have been sickened, hospitalized, or killed by serious medication errors. Approximately 70 percent of the safety and savings advantages of e-prescribing result from doctors being given immediate access to patient medication histories, safety alerts, preferred drug options,

ATTACHMENT B: DETAILED ANALYSIS OF HIGH-PRIORITY USE CASES

and pharmacy options so that they can better counsel patients on safe and affordable choices before prescriptions are transmitted to the pharmacy.¹⁴

Measuring the reduction of ADEs is difficult if not impossible due most of them not being reported as an ADE but as the condition caused by drug to drug interaction or the drug/allergy warnings. Harvard researchers have shown that ADEs can be prevented at an average rate of 8.8% per physician per year in an ambulatory environment that has installed ePrescribing with sufficient levels of decision support.

The Henry Ford Health System (HFHS) that serves over 1 million residents in SE Michigan monitored the use of the system and analyzed claims before and after the rollout of eRx and found:

- 420,000 prescriptions were changed due to drug to drug interaction warnings.
- 31,000 prescriptions were changed due to drug/allergy warnings.
- Comparing the pre/post, there was a 24% reduction in the incidence of patients with prescription claims for severely contraindicated medications (warfarin and erythromycin, insulin and propranolol, lithium and thiazides, etc.)

There was also a 48% reduction in the incidence of pregnant women who had prescription claims for severely contraindicated medications during pregnancy (coumadin, heparin, oral diabetic agents, etc.)

While avoiding ADEs has very strong clinical quality benefits, it also results in large cost savings associated with avoidance of ER visits, hospitalizations and follow-up physician visits. Similarly, medication non-compliance is dangerous to the health of patients and is unknown to physicians. It is estimated that approximately 20% of prescriptions go unfulfilled by patients every year.¹⁵ This medication non-compliance increases the likelihood hospitalizations, complications and increased costs.¹⁶

Medication management also provides additional cost savings to payers related to formulary compliance and generic substitution.¹⁷

The majority of the financial benefits of medication management flow to payers. Physicians, after overcoming the initial workflow inefficiencies, are also able to realize some administrative efficiencies related to renewals and clarification calls. Having formulary information available at the time a prescription is written can help prevent customer service problems between the physician and the patient by 21% to 33% under moderately and highly restrictive formularies.¹⁸

¹⁴ Gorman Health Group. "Options to Increase E-Prescribing in Medicare: Reducing Medication Errors and Generating Up to \$29 Billion in Savings For the Federal Government."

¹⁵ Boston Consulting Group. "The Hidden Epidemic: Finding a Cure for Unfilled Prescriptions and Missed Doses." December 2003.

¹⁶ Dunbar-Jacob J, Mortimer-Stephens MK. "Treatment adherence in chronic disease," *Journal of Clinical Epidemiology* 54 (suppl 1): s57-s60, (2001). Ellis S, Shumaker S, Sieber W, Rand C. "Adherence to pharmacological interventions: Current trends and future directions," *Controlled Clinical Trials* 21(Suppl): 218-225, (2000) Jackevicius CA, Mamdani M, Tu JV).

¹⁷ Note: CareFirst Blue Cross and Blue Shield of Maryland reported a threefold return on its e-prescribing investment through lower drug costs since launching its pilot program in 2004. CareFirst lent access for about 300 physicians to DrFirst's Web-based e-prescribing tool or a PDA. Formulary compliance increased by 4%, which the health plan considered significant, said Pete Stoessel, director of administration, medical systems and business development at CareFirst. (Source: Vesley, Rebecca. "The Riches of e-Prescribing." *ModernHealthcare*. February 18, 2008.)

¹⁸ Milliman Report. "Potential Impact of Electronic Prescribing on Medicare Prescription Drug Spend."

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Anticipated Workflow Impacts

Physicians

Physicians in an ambulatory setting will use the system much like any stand-alone eRx system. The difference will be in the amount of available information for each patient. Physicians will have access to a patient’s current medications and medication history, receive warnings of potential drug to drug interactions, allergy warnings and formulary checks, ability to electronically create and send a prescriptions to a preferred pharmacy or a patient designated pharmacy, and the ability to quickly and electronically authorize refills.

The impact to the workflows of physician depends upon the level of existing technology use in the physician practice or clinic. Offices with existing eRx system will be able to continue to use their existing systems connected to the statewide network without an impact to workflow. However, they will need to have the appropriate interfaces built and implemented.

Physician offices without any eRx or and EHR system will have a significant impact to their workflows. Typical timeframes to overcome workflow impacts vary but can be as quick as a few months and as long as a year or more (based on Manatt experience with CCRMC and HFHS).

Physician offices and clinics with existing EHRs but without eRx functionality will be more used to accessing and updating patient information electronically and will have a modest impact to their workflow as long as the eRx functionality can be implemented within their existing systems and providers are not required to go to an additional system.

Entity	Key Transactions	Workflow Change
Physician Office or Clinic with eRx implemented (physicians and nurses)	<ul style="list-style-type: none"> • Current Med & History Check • Eligibility Check • Formulary Check • Drug Interaction Check • Send Rx to Pharmacy • Authorize Refills 	Low
Physician Office or Clinic with EHR but without eRx activated (physicians and nurses)	<ul style="list-style-type: none"> • Current Med & History Check • Eligibility Check • Formulary Check • Drug Interaction Check • Send Rx to Pharmacy • Authorize Refills 	Med
Physician Office or Clinic without eRx or EHR (physicians and nurses)	<ul style="list-style-type: none"> • Current Med & History Check • Eligibility Check • Formulary Check • Drug Interaction Check • Send Rx to Pharmacy • Authorize Refills 	High

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Hospitals

Hospitals will be able to use data available through medication management use case to assist with medication reconciliation processes in addition to the other prescribing process done in either an inpatient or outpatient setting. Nurses will be able to access current medication lists and medication history for admissions while physicians will be able to update that with any medication changes or additions from the patient stay.

Prescriptions will be able to be automatically routed to the hospital pharmacy for both inpatient needs as well as from outpatient clinics. Hospital pharmacist will also have the information necessary to assist physicians with medication reconciliation upon discharge.

Entity	Key Transactions	Workflow Change
Hospital (physicians and nurses)	<ul style="list-style-type: none"> • Current Med & History Check • Eligibility Check • Formulary Check • Drug Interaction Check • Send Rx to Pharmacy • Authorize Refills 	High – Med
Emergency Department (physician, nurses, ED admission)	<ul style="list-style-type: none"> • Current Med & History Check • Eligibility Check • Formulary Check • Drug Interaction Check • Send Rx to Pharmacy • Authorize Refills 	Med
Pharmacy – Hospital	<ul style="list-style-type: none"> • Receive Rx • Send Refill Requests • Assist with medication reconciliation 	Med – Low
Skilled Nursing Facility (physician, nurses)	<ul style="list-style-type: none"> • Current Med & History Check • Eligibility Check • Formulary Check • Drug Interaction Check • Send Rx to Pharmacy • Authorize Refills 	Med

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Payers and PBMs

Payers and PBMs do not have workflow impacts directly because their role is to provide data to the system. PBMs provide fill data and payers provide medication claim history as well as formulary data and eligibility information.

RxHub, which is now part of SureScripts, already receives formulary, eligibility and medication history information from PBMs and Payers (representing about 200 million lives nationally). The SureScripts Pharmacy Health Information Exchange can be leveraged by Maryland for their efforts.

Entity	Key Transactions	Workflow Change
Payer	• Provide medication claims data	None
Pharmacy Benefits Manager (PBM)	• Provide fill data	None
SureScripts-RxHub	• Facilitates eRx between Providers, Pharmacies, Payers and PBMS	None

Pharmacies

Only 3% of chain pharmacies are not currently connected to SureScripts-RxHub and able to receive electronic prescriptions and send electronic refill requests. However, 73% of independent pharmacies are not yet connected although the majority of them have certified systems to allow connection.¹⁹

The impact of medication management to pharmacy workflows is very low – however, their may be technical barriers for independent pharmacies. The largest impact to a pharmacy that is new to accepting electronic prescriptions is remembering to check their electronic in box for new prescriptions.

Entity	Key Transactions	Workflow Change
Pharmacy – Chain	• Receive Rx • Send Refill Requests	Med – Low
Pharmacy – Independent	• Receive Rx • Send Refill Requests	High – Low
Pharmacy – Hospital	• Receive Rx • Send Refill Requests • Assist with medication reconciliation	Med – Low

¹⁹ Electronic Prescribing: Becoming Mainstream Practice. June 2008.

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Barriers to Achieving Buy-in and Adoption

Buy-in from physicians, pharmacies, and payers is critical to achieve the benefits associated with this use case. Maryland is in a fortunate position of already having a relatively large footprint of eRx activity. SureScripts ranks Maryland 5th in a ranking of eRx activity for all 50 states plus Washington D.C.. Ranking is based upon the number of prescriptions routed electronically as a percentage of prescription eligible for electronic routing in 2006.²⁰

A national survey of 407 physicians found that while they believe eRx is a good idea, very few use it.²¹ Eighty-one percent of physicians say eRx's widespread use would reduce medication errors. Sixty-five percent say it would save time. Only 7 percent transmit prescriptions electronically.

Based on the eHealth Initiative reports *Clinician's Guide to Electronic Prescribing* and *Electronic Prescribing: Becoming Mainstream Practice*, the barriers to buy-in include:

- Cost of adoption
 - Cost accruing to physician may include licensing, practice management interfaces, customization, training, maintenance, and upgrades
 - Initial capital and on-going cost exceed financial benefit to physician user
 - Productivity may decrease during the initial weeks of adoption
- Change management and workflow
 - Physicians and staff may be resistant to change or technology adverse
 - Practices often lack adequate resources to support workflow planning changes
 - Significant operational modifications are key to realizing value of eRx technology
 - Regular tasks require additional time during initial implementation
- Technology
 - Vendor selection, negotiation, and implementation may be overwhelming or confusing for physicians/practices without IT expertise
 - Practice uncertainty between selection of an EHR or eRx system
 - eRx IT requirements may be in conflict with current hospital infrastructure
- Pharmacy, payer and PBM connectivity
 - Physician must maintain an additional paper workflow to accommodate pharmacies that are not able to receive or transmit electronic transmissions
 - Physicians may not be able to access all payer/PBM formulary, eligibility, or medication history information
- Medication history and reconciliation
 - Information available in eRx tool may not be comprehensive or accurate
 - eRx tool must have capability to reconcile medication histories from multiple sources
- Standards and controlled substances
 - eRx standards are still under review by CMS and have not been finalized

²⁰ SureScripts. "National Progress Report on E-Prescribing." December 2007.

²¹ Ayres, McHenry & Associates, Inc. "Summary Of Findings Survey Of Physicians Regarding E-Prescribing." June 7 – July 6, 2007.

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Physicians must maintain a paper workflow to prescribe controlled substances until the DEA's ban is lifted.

Financing Options

The most common reason offered why eRx is not a priority is the expense and lack of reimbursement for adopting a new system (Ayres). However, this trend may be changing. Medicare Improvements for Patients and Providers Act (MIPPA) creates e-prescribing incentive bonus payments for providers. In addition, Medicare Part D requires plans to accept eRx transactions by April 2009 including: patients' medication histories, health plan formularies and benefits information.

For ongoing costs, SureScripts-RxHub has already put in place a transaction fee associated with the various access transactions. Payers pay the transaction fee when providers access patient history and eligibility. Pharmacies pay a transaction fee for each prescription that they receive. A low cost transaction fee makes the most sense regardless of utilizing the SureScripts-RxHub Pharmacy HIE or creating a competing network.

Startup cost of getting all of the actors connected to the network will provide the largest hurdle. Since most payers and PBMs are already connected or will be by April 2009, there should not be a very large cost to bring additional payers and PBMs on the network.

Most chain pharmacies are also already connected. But there will be startup cost incurred with making sure they have certified systems and are trained on the system.

Connecting provider organizations will probably be the most expensive of the startup costs. Provider organizations should be phased for implementation, prioritizing larger organizations with the largest 'bang for the buck' of implementation.

Financing options include:

- Piggy-backing on MIPPA and providing enhanced incentives for providers.
- Approach payers to offset start-up costs since they are the largest recipient of medication management's financial benefits to offset start-up costs.
- Approached pharmaceutical companies to participate in the development of the system and offset start-up costs in return for developing the system to assist with the management, control and distribution of free samples.

3. CONSUMER EMPOWERMENT

Overview

There is a large and growing demand to provide consumers with greater access to and control over their personal health information and an interconnection with their clinicians to enhance communication. Studies have demonstrated that even simple online reminder and education programs positively influence patient behavior.

The central goal of this use case is to actively engage consumers with access to their own basic healthcare information and interconnect them to their clinicians to receive disease management information, prevention and wellness reminders and other health education. Additionally, the national emergencies demonstrate the critical need for providing physicians and consumers secure electronic access to critical personal health information for persons injured, evacuated, or displaced by the event.

Definition of the Use Case

This use case will identify the principle stakeholders and flow of events for the authorized and secure access and exchange of consumers' health information, including in an emergency and an interconnecting with their clinicians. The use case is not intended to define all system features; it identifies and describes interactions between key systems and stakeholders and serves as a guide that leads to further development of functional requirements and other products.

The use case scope includes:

- Authenticating consumers, designated caregivers, and providers.
- Querying other organizations for data and matching it to the consumer.
- Accepting "batch" data from other organizations in standardized format and matching to the appropriate consumers.
- Ensuring secure electronic transmission of complete, preliminary, final and updated data.
- Accessing, viewing, and sharing medication information.
- Sending general health information, e.g., disease management, prevention and wellness, emergency response information to the consumer.
- Recording of interactions and transactions to enable access and viewing tracking and generation of system logs.

Anticipated Clinical and Administrative Benefits

The benefits of the consumer empowerment use case are defined by the types of functions they support. For the purposes of this analysis, consumer empowerment functions consist of sharing of complete test results, sharing of complete medication lists, disease management reminders and monitoring, appointment scheduling, medication renewals, pre-encounter questionnaires, and e-visits. The impact of these functions is derived from reducing administrative costs and direct healthcare utilization costs.

ATTACHMENT B: DETAILED ANALYSIS OF HIGH-PRIORITY USE CASES

Patients who have consistently high engagement with their care team may help lower costs through improved lifestyle choices and health behaviors, decreased utilization of health services through better disease management, improved care coordination, and improved adherence to recommended care.^{22,23,24}

In addition, consumer empowerment tools enable providers to deliver better patient care. Pre-encounter questionnaires that capture clinical data can lead to a more complete and accurate patient information that can help providers make more informed clinical decisions. Post-encounter questionnaires help to monitor patients, especially after surgery, such as to detect the reoccurrence of head and neck cancer in patients after cancer surgery.

Evidence also suggests that patients' engagement in their healthcare can result in better outcomes and improved quality via active communications with their provider, improved participation in shared decision making, and improved responsibility for their health.²⁵ Providers are also able to give patients customized content to help them manage their own care and achieve additional administrative benefits by being able to electronically handle referrals to specialists.

Anticipated Workflow Impacts

The potential workflow impact of widespread utilization of consumer empowerment tools depends in large part on how data are provisioned to consumers. The Center for Information Technology Leadership defines consumer empowerment provision along four axes:²⁶

Provider-Tethered. Provider-tethered Personal Health Records (PHRs) represent healthcare delivery organizations that offer a PHR to their patients. Provider-tethered PHRs are internally connected to the database of the provider's EHR and PMS systems. Patients can send messages to payers and other providers via manual communication channels such as secure email but are unable to directly integrate external data. The important distinction is that the provider-tethered PHR reflects the source of the underlying data and not the legislative or business entities supplying the PHR. For example, a provider-tethered PHR could be offered by a software vendor as long as there is only one directly connected and integrated provider data source.

Payer-Tethered. Payer-tethered PHRs represent healthcare insurance companies that offer a PHR to their members. Payer-tethered PHRs are internally connected to their administrative databases. Patients can communicate with providers and other payers via manual communication channels such as secure email but are unable to directly integrate external data. Similar to provider-tethered PHRs, payer-tethered PHRs reflect the source of the underlying data and not the political or business entities that ultimately supply the PHR.

²² Graham, A., Cobb NK, Raymond L, Sill S, Young J. Effectiveness of an internet-based worksite smoking cessation intervention at 12 months. *Journal of Occupational Environmental Medicine*. 2007.

²³ Adler-Milstein J, Bu D, Pan E, Walker J, Kendrick D, Hook JM, Bates DW, Middleton B. The costs of information technology-enabled diabetes management. *Disease Management*. 2007.

²⁴ Bu D, Pan E, Walker J, Adler-Milstein J, Kendrick D, Hook JM, Cusack CM, Bates DW, Middleton B. Benefits of information technology-enabled diabetes management. *Diabetes Care*. 2007.

²⁵ Lansky, D. Patient Engagement and Patient Decision-making in US Health Care. *FACCT - Foundation for Accountability*. 2003.

²⁶ Center for Information Technology Leadership. "The Value of Personal Health Records." October 2008.

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Third-Party. Third-party PHRs are aggregators of healthcare data for users. Third-party PHRs aggregate data through manual data exchanges, which import the data from external sources but are unable to feed the data into clinical or administrative systems in their native format. Users can only contact parties external to the PHR through manual communication channels.

HIE-provisioned. HIE-provisioned PHRs rely on regional aggregation of patient's healthcare data to users. In this scenario, PHRs are populated with data from all regional data sources via standards-based automated data exchange. The connections with these sources would create a record that is more complete than any individual repository (e.g., EHRs, other PHRs, payer claims databases).

Barriers to Achieving Buy-in and Adoption

Currently, adoption of consumer empowerment tools, as measured by PHR use, is low. An estimated 70 million people in the US have access to some form of a PHR, generally through their health insurer.

Patient Adoption. Ultimately, PHRs will only be effective if patients use them. There are many factors that can affect patient adoption of a health technology. One factor that may influence patient adoption is that the targeted population of users may have low computer literacy. Frequent users of the healthcare system are often those who are chronically ill, young, or elderly. One article found that the majority of PHR users had significant issues with computer literacy and thus experienced resulting anxiety.²⁷ Another article found that provider recommendations played a strong role in patient use of the PHR.²⁸ Security and privacy are one of the top concerns cited by patients when interviewed about PHRs.²⁹

Provider Adoption. Most PHR functions involve interactions between patients and providers. Therefore, patient use and provider adoption are equally critical to the success of a PHR. Functions such as e-visits or Internet-based appointment scheduling have no functional use to patients unless their providers adopt these functions as well. Provider adoption of PHRs is affected by the value generated to providers. Some examples of value to providers could include providers being reimbursed for PHR usage, providers having direct costs savings through the use of the PHR, or possibly providers having improved satisfaction in responding to patient demands through a PHR. New incentives may be put into place to encourage provider adoption.

Payer and Employer Adoption. Currently, there are a variety of payer-tethered PHRs in the market. Payers have long recognized the value of increased patient-provider communication. Many payer organizations employ health coaches or case managers to check on patients. Such communication can help control costs by identifying problems and issues earlier to reduce overall costs.

Similarly, employers, who are one of the biggest purchasers of healthcare in the U.S., see potential value in PHRs. Dossia is an important initiative in this regard because it "is a consortium of large employers united in their goal of providing employees, their dependents,

²⁷ Lober WB, Zierler B, Herbaugh A, Shinstrom SE, Stolyar A, Kim EH, Kim Y. "Barriers to the use of a personal health record by an elderly population." *AMIA Annual Symposium Proceedings*. 2006.

²⁸ Ralston JD, Carrell D, Reid R, Anderson M, Moran M, Hereford J. "Patient web services integrated with a shared medical record: Patient use and satisfaction." *Journal of American Medical Informatics Association*. 2007.

²⁹ Markle Foundation. "Americans want benefits of personal health records." 2003.

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retirees and others in their communities with an independent, lifelong health record.” Employer motives for investing in, adopting, and encouraging use of PHRs among their employees will generally be for items such as healthcare cost containment or for distinguishing themselves with this employee benefit among employers.

Financing Options

Regardless of the type of consumer empowerment tool, direct healthcare savings would accrue to both payers and providers, with payers realizing the majority of the cost savings. Depending on the type of PHR, savings to payers could be five to 10 times greater than the savings to providers. Third-party PHRs present a unique case in which entities not controlling or not responsible for direct medical costs (e.g., Microsoft, Google) are providing PHR technology that could entail significant net savings to payers and providers, with minimal or no cost to the payers or providers to date.

The financial motivations to offer a PHR to patients differ based on who is paying for the PHR. Providers and payers are already spending substantial dollars in the healthcare system. Research has shown that health IT could produce significant financial benefits, thus incentivizing providers and payers to adopt these technologies. Payers stand to realize enormous cost savings if their covered populations use PHR applications to manage their health issues. Increased prevalence of chronic conditions is one factor that drives rising healthcare costs, and increased patient monitoring of these conditions can prevent costly hospitalizations and other costs.

For third-party entrants into the PHR marketplace, the value proposition differs. Third party entrants such as Microsoft and Google are not currently invested in the healthcare marketplace with respect to responsibility for direct medical costs in the same ways as providers and payers. To third parties, the value derived from health technologies such as PHRs does not accrue from clinical or financial savings from the healthcare marketplace; it accrues from selling PHR-related products and services. For instance, some third-party PHR vendors may provide the PHR “free of charge,” but then may rely on advertising or selling access to the health information obtained from the PHR.

ATTACHMENT C: APPROACHES FOR SECURING CAPITAL FINANCING

Federal Sources

Federal investments in HIE have focused on policy coordination, privacy and security, technical standards and certification, and discrete demonstration projects. Federal funding for state-level HIEs has been made through grants and contracts or leveraging of the federal matching portion of Medicaid information technology systems.

While leveraged by a handful of state-level HIEs, federal contracts and grants have limited availability and are driven by the particular objectives of the sponsoring federal agency, which may not align with the needs of state-level HIE initiatives. In addition, states' efforts to consolidate health IT capabilities or create shared functionality are often hindered by rules that limit the use of federal funds beyond their originally intended purposes.

The federal government also supports the development of IT capabilities through ongoing support for the Medicaid program's claims processing systems, the Medicaid Management Information Systems (MMIS). State Medicaid agencies can leverage MMIS funding to advance statewide HIE efforts. The nature and implications of using federal or state Medicaid funding to support state-level HIE is governed by federal matching laws.³⁰

The table below highlights the range of federal and state financial participation across state-level HIE deployment scenarios.³¹

Medicaid-State-level HIE Relationship	Eligible Activities (State Portion)	Eligible Activities (Federal Portion)	Examples
Medicaid operates statewide HIE	HIE development costs (state share 10%)	HIE development costs (federal share 90%)	A Medicaid Agency designs, builds, and operates HIE hardware and software. The Medicaid Agency permits access to its data by others. Note: Non-Medicaid agencies and entities must pay for their linkages to Medicaid operated HIE.
	Ongoing administrative costs (state share 25%)	Ongoing administrative costs (federal share 75%)	

³⁰ As a general rule, the federal government match for Medicaid administrative expenditures is 50 percent; however, the match can be higher for certain administrative functions. In fact, for the design, development, and installation of MMIS, the federal match is 90 percent, and for ongoing operational maintenance, the federal match is 75 percent.

³¹ *State Medicaid Agencies' Initiatives on Health Information Technology and Health Information Exchange*, U.S. Department of Health and Human Services, Office of Inspector General (August 2007). Available online at <http://www.oig.hhs.gov>.

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Medicaid- State-level HIE Relationship	Eligible Activities (State Portion)	Eligible Activities (Federal Portion)	Examples
Medicaid contracts with State-level HIE to operate services	Ongoing administrative costs (state share 25%)	Ongoing administrative costs (federal share 75%)	A Medicaid Agency contracts with a state-level HIE to provision Medicaid data to providers. The Medicaid Agency pays the state-level HIE a per member-per month or transaction fee.
Medicaid contracts with entities to participate in State-level HIE	Programmatic costs (state share 50%)	Programmatic costs (federal share 50%)	Through a P4P program, a Medicaid Agency reimburses physicians who participate in the state-level HIE at a higher rate.

While CMS officials recently indicated that states have yet to exercise the MMIS financing mechanism to support state-level HIE, a number of states are reportedly working with CMS and their state Medicaid agencies to explore these options.

As MMIS systems continue to modernize and become more visible parts of a state's HIE portfolio, state governments and state-level HIEs will have to negotiate and navigate technical, policy, and governance relationships at the provider, regional, and state levels.

State Government

Recognizing the potential of HIE to improve the cost, safety, and effectiveness of care, state governments have steadily increased their investments in HIE in recent years, drawing on a mix of capital and operating budgets, assessments, and special purpose funds.

Operating Budgets. State operating budgets include expenditures for a single period of appropriations, either annually or biannually. Across the country, most state-level HIEs have received funding from their state's operating budgets. However, reliance on the legislative budget and appropriation process can prove a precarious strategy. Largely dependent upon revenues which can fluctuate year-to-year, state's operating budgets are also subject to balanced budget requirements that often put funding for discretionary programs at risk during economic downturns.

Capital Budgets. In 40 states, capital financing mechanisms can be utilized for infrastructure investment needs.³² States issue the bonds to investors with the promise to repay the debt either through the state's taxing authority or the revenue generated from the projects supported by the bonds.

Capital funding has been successfully used in a number states to support statewide health IT projects. In Rhode Island, the state established a \$20 million revenue bond to create a

³² Reed, B. J.; Swain, J.W. *Public Finance Administration*. Sage Publications, Thousand Oaks, CA, 1997.

ATTACHMENT C: APPROACHES FOR SECURING CAPITAL FINANCING

statewide HIE capacity. The revenue bond is contingent on proportional contributions from stakeholders, including State government and the private health plans.

Unlike operating budgets, capital budgets typically provide greater balance between revenue and expenditure flows. However, capital budgeting faces a number of implementation challenges and potential delays: they typically require legislative approval and the creation of fund disbursement mechanisms. Moreover, state-level HIE projects often must compete for a limited, and shrinking, pool of funds against better understood and more traditional capital projects.

Special Purpose Funds. "Special purpose funds" refer to funding sources that are not subject to the traditional legislative appropriation process. Examples of special purpose funds include tobacco settlement funds and federal Medicaid waivers.

In June 2007, Connecticut enacted House Bill 8001 that allocated the transfer of a total of \$1 million over two years from the Tobacco and Health Trust Fund for the Connecticut Health Information Network (CHIN).³³

In addition to tobacco settlement funds, states have also utilized CMS funding through Medicaid Section 1115 waivers to support health IT adoption and HIE development. Section 1115 of the Social Security Act is a broad demonstration authority that allows the Secretary of HHS to permit a state to use federal Medicaid matching funds to pay for expenditures that would otherwise not be allowable under the Medicaid statute (Title XIX of the Act).³⁴

Funds for New York's Health Information Infrastructure derive from special purpose funding from a Waiver called the Federal-State Health Reform Partnership (F-SHRP). Effective October 1, 2006, the Centers for Medicare and Medicaid Services (CMS) approved New York's five-year F-SHRP Demonstration Waiver to reform New York's Medicaid program.

In accordance with the terms of the waiver, New York must invest \$3 billion over the five-year demonstration in healthcare reform initiatives in order to receive \$1.5 billion in federal funding. New York can allocate funding for reform initiatives that promote the efficient operation of the State's healthcare system; right-size New York's acute care system; shift long term care system from institutional to community care; expand e-prescribing, EMRs and RHIOs; and improve ambulatory care.

As part of its matching commitment to the F-SHRP demonstration, the State of New York has leveraged its capital budgeting authority to award over \$158 million to advance a statewide health information network.

Special Assessments. In some respects, special assessments resemble taxes. The primary objective of the special assessment, as in the case of taxes, is to advance a common benefit.³⁵ Unlike taxes, which are paid without reference to specific individual benefits, special assessments are created for specific purposes. In order to support its state-level HIE efforts and

³³ The CHIN is a partnership between the Univ. of Connecticut, Akaza Research, Inc., and Connecticut's state agencies to link diverse databases across agencies. Details available at <http://publichealth.uconn.edu/CHIN.php>.

³⁴ These expenditures can be for populations not otherwise allowable, services not otherwise allowable, or both.

³⁵ Hunter, Merlin H. "Outlines of Public Finance." 1921. New York, London, Harper & Brothers. Full text available online at <http://www.archive.org/details/outlinesofpublic00hunrich>.

ATTACHMENT C: APPROACHES FOR SECURING CAPITAL FINANCING

health IT adoption plans, Vermont used a special assessment to create the Vermont Health IT Fund.

In April 2008, the Vermont passed legislation to create the Vermont Health IT Fund. Drawn down in annual increments by Vermont's state-level HIE, the Vermont Information Technology Leaders, the Vermont Health IT Fund will be used to support both statewide HIE and the adoption of certified Electronic Health Records.

Beginning Oct. 1, 2008, each health insurer operating in Vermont will pay a quarterly fee into the fund. Insurers can choose between paying 0.199% of all healthcare claims paid for their Vermont members in the previous quarter, or a fee based on the insurer's proportion of overall claims in the past year, as calculated by the Vermont Department of Banking, Insurance, Securities and Health Care Administration. Medicaid is making a voluntary annual contribution of approximately \$250,000 per year.

The process to collect funds from payers is being developed through the Vermont Department of Banking, Insurance, Securities and Health Care Administration's rule making authority. Vermont's Health Care Information Technology Reinvestment Fee is expected to raise a total of approximately \$32 million over the next seven years.

Philanthropic Sector

Philanthropies have been a significant source of start-up investments for state-level HIE capacity building. Much like the public sector, philanthropies recognize the potential social value that interoperable HIE presents.

In many states, foundations have provided critical funding to incubate the planning and governance functions of state-level HIE initiatives. In California, CalRHIO has received nearly \$2.5 million in total from the Blue Cross of California Foundation, the Blue Shield of California Foundation, the California HealthCare Foundation, and the Blue Shield Foundation of California.

Charitable organizations, like state budgets, are subject to changing economic conditions. Charitable contributions are highly correlated with stock prices, and contributions can lag or fluctuate significantly during periods of poor market conditions.

Private Sector

In order to support their capital investment needs, a number of state-level HIEs have turned to funding sources in the private sector, including providers, payers, and even vendors and financial institutions. A key distinction between public and private financing is the pressure to return value to private sector stakeholders is more acute in the near term than the demands of public and non-profit investors.

Providers. As noted above, hospitals and physician practices have significant limitations in their ability to bear the capital costs of statewide HIE development. In addition, the recent economic downturn puts additional pressure on providers to reduce costs.

Even hospitals with positive cash flows have challenges amassing the capital internally to make large IT investments, and when they do invest in health IT, it is aligned to support the organizational needs. As a result, IT investments tend to focus on internal, tactical operational needs and funding for participation in and support of HIE are often lower strategic priorities.

ATTACHMENT C: APPROACHES FOR SECURING CAPITAL FINANCING

The ambulatory provider market, which delivers almost 90% of the primary care in the United States, has very limited access to capital. Though some larger practice groups have invested in health IT for strategic advantage, most have been slow to adopt health IT, and very few have engaged in community-based HIEs despite the increasing availability of incentives.³⁶

Payers. As the stakeholder segment expected to derive the greatest value from interoperability, payers have traditionally been seen as a source of capital for state-level HIE efforts. In Rhode Island, for example, the Rhode Island Quality Institute (RIQI) has proposed a “Cost of Care Model” that supports both capital and operating needs and relies on funding from health insurers. According to this model, insurers would pay a percentage of the annual capital and operating needs based on their percentage of covered lives in the state.

Models based on payers must take into consideration the participation of non-domiciled health plans. If the non-domiciled insurers are not mandated to pay for their members’ use of the HIE, or if they increase their premiums to account for their participation, the domiciled insurers could be at a price disadvantage.

Vendors. A number of HIEs have successfully leveraged partnerships with technology vendors to secure funding or in-kind contributions to advance implementation. In Texas, leaders of the state-level HIE effort are exploring the viability and applicability of a unique financing arrangement for statewide HIE services that relies exclusively on financing from technology vendors. The financing approach is modeled after the development and operations of *TexasOnline*.³⁷

While the vendor-financed model is untested in the context of state-level HIE, it is becoming an increasingly attractive financing mechanism in light of the anticipated budget shortfalls in the public sector. The State of Florida is considering a variation to this approach, whereby a no-cost contract would be released calling for a vendor to provide Medicaid claims and medication history services statewide.

Financial Institutions. Financial institutions have long been a source of capital for complex infrastructure projects in which initial development costs exceed the corresponding near term receipt of revenue. In contrast to public and philanthropic investments, the private capital market typically operates on calculus of revenue and risk. Financial institutions can cover the initial start-up costs through “equity,” i.e., purchasing an ownership stake in the organization, or through a “debt” mechanism, i.e., providing a loan.

As most entities overseeing and maintaining state-level HIE operations are not-for-profit entities, financial institutions have little incentive to take equity positions in these organizations. Debt instruments, on the other hand, may offer an attractive vehicle to funders.

In California, the statewide HIE entity, the California Regional Health Information Organization (CalRHIO), is working on a financing strategy that proposes to leverage health plans willingness

³⁶ Grossman, JM and Cohen, G. “Issue Brief: Despite regulatory changes, hospitals cautious in helping physicians purchase electronic medical records.” *Center for Studying Health System Change* (September 2008). Available online at <http://www.hschange.com/CONTENT/1015/>.

³⁷ *Innovative Funding for Innovative State IT: New Trends and Approaches for State IT Funding Version 2.0*. National Association of State Chief Information Officers (November 2003). Available online at <http://www.nascio.org/publications/documents/NASCIO-FundingReport2003.pdf>.

ATTACHMENT C: APPROACHES FOR SECURING CAPITAL FINANCING

to pay for HIE services as collateral for debt from private equity investors. CalRHIO is developing a statewide utility based on a service-oriented architecture, through which authorized and authenticated providers can query the network and receive patient-centric information. In its initial phase, CalRHIO will facilitate the delivery of medication histories and laboratory results to Emergency Departments.

CalRHIO's business model is predicated on three principles:

1. Health information exchange should be a public utility that maximizes benefit to the citizens of California.
2. Health information exchange can be established by a public-private partnership utilizing private funds to finance the development and initial deployment of HIE services; this does not require initial investment from the state, health plans, hospitals, providers, employers, or CalPERS.
3. The long-term sustainability of HIE depends upon financial support from all participating entities that is proportional to the financial benefits received.

In April 2008, the California Public Employees' Retirement System (CalPERS) directed its current health plans – Anthem Blue Cross, Blue Shield of California and Kaiser Permanente – to negotiate contract terms with CalRHIO. Because health plans and their members are projected to be the primary beneficiaries of the benefits derived from accessing patient data, health plans are being asked to pay for the information delivered in Phase 1. Charges will be generated only when data are returned and will appear as part of the ED claim.

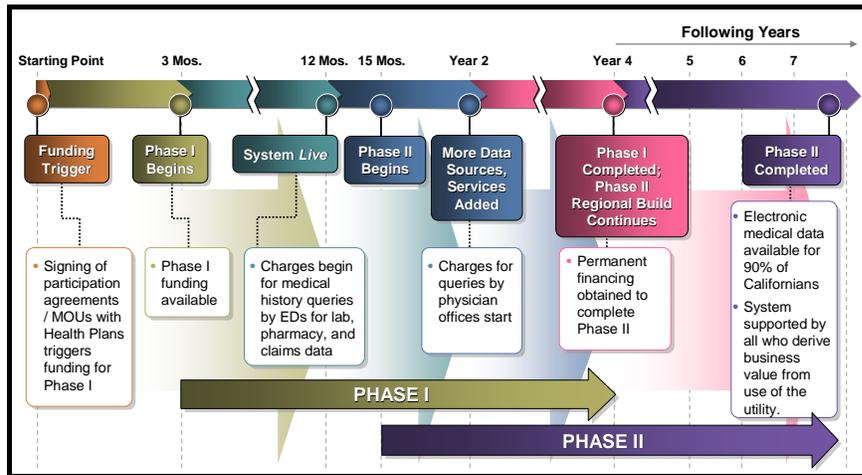
CalRHIO estimates that it will require \$11 million to complete Phase 1, which will allow Emergency Room physicians in 90% of California's hospitals to access patients' medical histories, lab, pharmacy, and claims data. Funding for Phase I will be through private equity based on the ability of CalRHIO to secure commitments from at least three major health plans in California to participate in the CalRHIO HIE initiative. This gating factor is intended to ensure a clinically robust and relevant data set which will drive user adoption, secure an adequate value proposition for participants, and deliver a positive return on the investment.

Round 2 funding will commence upon successful completion of Phase 1 of the technology development, which is estimated to occur at the end of year 4. These funds are expected to be composed of tax-exempt funding i.e., bonding financing. This approach will allow CalRHIO to continue operating as a non-profit utility for all the California healthcare community and complete integration with local/regional EHR systems such that 90% of all Californians will have a record in the system.

By dividing the task into two components—a Statewide On-Demand Information Service (consolidating easily obtained statewide data feeds) and a Regional On-Demand Information Service layer (extracting all sources of patient clinical data in a locality)—CalRHIO can leverage initial financing towards building a revenue engine capable of funding the remainder of the network build-out.

ATTACHMENT C: APPROACHES FOR SECURING CAPITAL FINANCING

An overview of CalRHIO's proposed implementation approach and timeline is provided below.



TEAM LISTS

GOVERNANCE

Katherine Ball, MD, Holy Cross Hospital

Andrew Barbash, MD, Holy Cross Hospital

Gaurov Dayal, MD, Chief Medical Officer, Shady Grove Adventist Hospital

Blair Eig, MD, Sr. Vice President, Medical Affairs Holy Cross Hospital

Steve Galen, President and CEO, Primary Care Coalition of Montgomery County, MD

John Hogarty, Executive Vice President & CFO, Montgomery General Hospital

Roger Leonard, MD, Vice President, Medical Affairs, Montgomery General Hospital

Thomas L. Lewis, MD, Chief Information Officer, Primary Care Coalition of Montgomery County, MD

COMMUNITY PERSPECTIVES

Curtis Brown, National Advisory Council Member, Summit Health Institute for Research and Education, Inc.

Shirley Brown-Ornish, MD, Senior Planner, Prince George's County Health Department

Susan D'Antoni, Executive Director Montgomery County Medical Society

Russell Davis, DPA, President, Summit Health Institute for Research and Education, Inc.

Steve Galen, Executive Director, The Primary Care Coalition of Montgomery County, Inc.

Joanne Genevish, Physician Liaison, Montgomery General Hospital

Karen Green, Executive Director, Healthcare Initiative Foundation

Irene Heinemeier, Director, Physician Services, Adventist Health Care

Barbara Kaufmann, Manager and WIB Director, Division of Workforce Services, Montgomery County Department of Economic Development

Michelle Markey, Community-Based Strategy Specialist, Center for Health Improvement, The Primary Care Coalition of Montgomery County, Inc.

Margaret O'Bryon, President and CEO, Consumer Health Foundation

Marcos Pesquera, Executive Director, Center on Health Disparities, Adventist Health Care

Marcia Thomas-Brown, Healthcare Consultant, Summit Health Institute for Research and Education, Inc.

Ulder Tillman, MD, Health Officer, Montgomery County Department of Health and Human Services

Maria Rosa Watson, DDS, PhD, Research Director, Center for Health Improvement, The Primary Care Coalition of Montgomery County, Inc.

PRIVACY & SECURITY

Christiane Brown, Director of Information Technology, Montgomery General Hospital

Jennie Campbell, IT Compliance Specialist, Adventist HealthCare

Larry Farrell, Customer Site Manager, PHNS/Adventist Healthcare

Evette Fernandes, Customer Site Manager, PHNS/Adventist Healthcare

Joyce Hunter, Principal, Federal Consulting Practice CSC

Leta Kajut, RN, BSN, MHA, Director Health Information Technologies, Primary Care Coalition of Montgomery County, MD

Thomas L. Lewis, MD, Chief Information Officer, Primary Care Coalition of Montgomery County, MD

Karen M. Plá, Senior Official for Privacy, National Institutes of Health

Frank Riccardi, Executive Director of Organizational Integrity & Internal Audit, Chief Privacy & Security Officer, Adventist HealthCare

TECHNICAL INFRASTRUCTURE

Christiane Brown, Director, Information Technology, Montgomery General Hospital

Kathleen Dyer, Vice President & CIO, Adventist Healthcare, Inc.

Leta Kajut, RN, BSN, MHA, Director Health Information Technologies, Primary Care Coalition of Montgomery County, MD

Thomas L. Lewis, MD, Chief Information Officer, Primary Care Coalition of Montgomery County, MD

Arumani Manisundaram, Chief Technical Architect, Office of the CIO, Adventist HealthCare, Inc.

Manny Ocasio, Vice President, Information Management, Holy Cross Hospital

Christopher Timbers, Vice President and CIO, Suburban Hospital

FINANCE AND SUSTAINABLE BUSINESS

Judith G. Averbach, Grants Coordinator, MGH Health Foundation Montgomery General Hospital

Ron Benfield, Vice President and Chief Financial Officer, Shady Grove Adventist Hospital

Gaurov Dayal, MD, Chief Medical Officer, Shady Grove Adventist Hospital

Blair Eig, MD, Sr. Vice President, Medical Affairs, Holy Cross Hospital

Steve Galen, President and CEO, Primary Care Coalition of Montgomery County, MD

John Hogarty, Executive Vice President & CFO, Montgomery General Hospital

Dr. Gregorio Koss, M.D., F.A.C.C., Medical Director, Proyecto Salud Clinic

Manny Ocasio, Vice President, Information Management, Holy Cross Hospital

Roger Leonard, MD, Vice President Medical Affairs, Montgomery General Hospital

Thomas L. Lewis, MD, Chief Information Officer, Primary Care Coalition of Montgomery County, MD

Gary Vogan, Chief Financial Officer, Holy Cross Hospital

MARYLAND HEALTH CARE COMMISSION

Kathy Francis, Chief, Health Information Exchange Center for Health Information Technology

David Sharp, PhD, Director, Center for Health Information Technology

MANATT HEALTH SOLUTIONS (November 2008 – February 2009)

William Bernstein, Partner, Manatt Health Solutions

Lammot du Pont, Senior Manager, Manatt Health Solutions

Allison Garcimonde, Senior Analyst, Manatt Health Solutions

Susan Ingargiola, Manager, Manatt Health Solutions

Erik Johnson, Managing Director, Manatt Health Solutions

Tim Kwan, Manager, Manatt Health Solutions

Joseph Ray, Senior Manager, Manatt Health Solutions

MOSAICA PARTNERS (May 2008 – November 2008)

Robert Brown

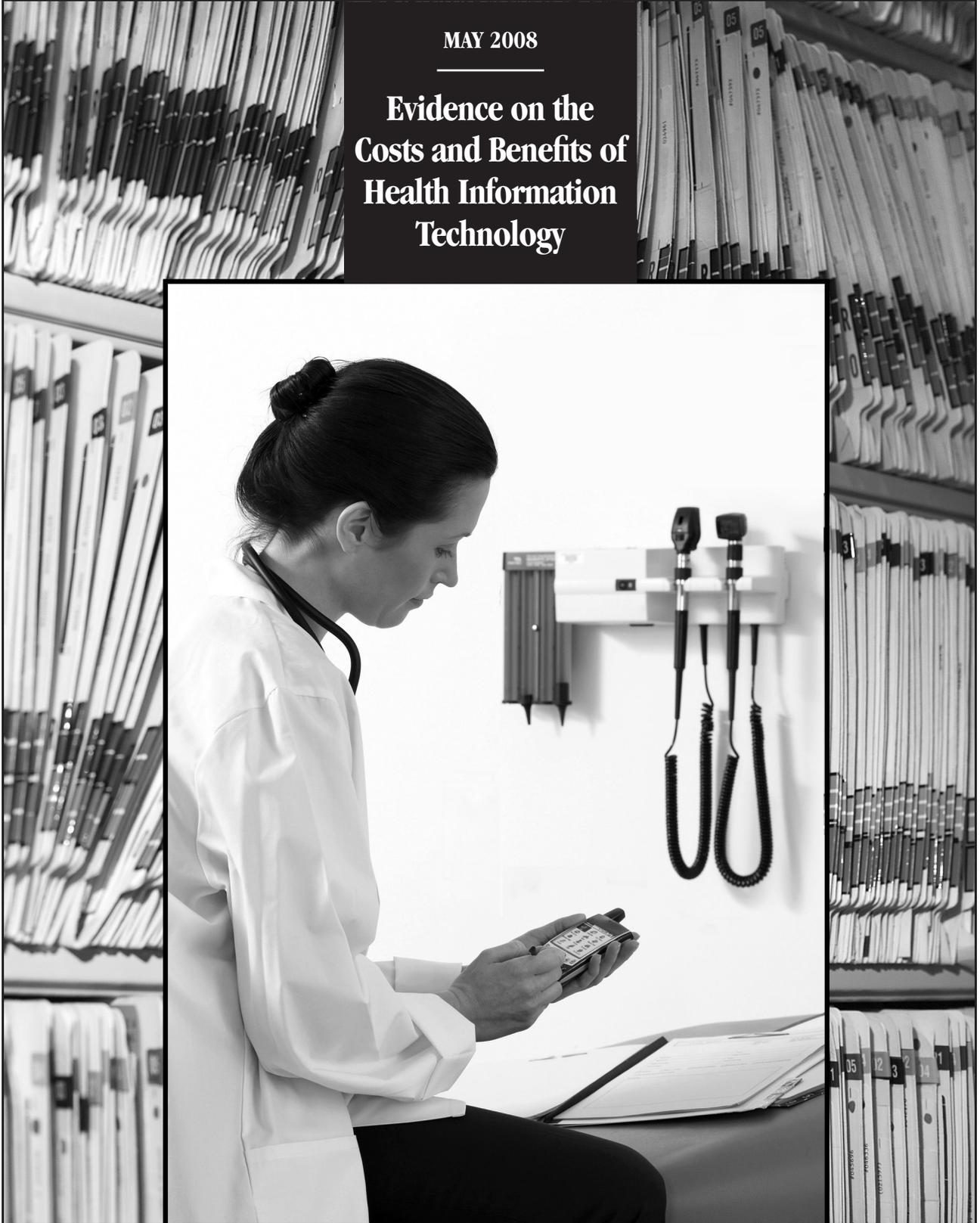
Laura Kolkman, President

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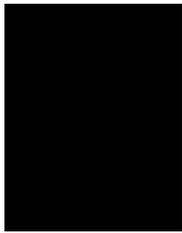
**Evidence on the
Costs and Benefits of
Health Information
Technology**





Evidence on the Costs and Benefits of Health Information Technology

May 2008



Preface

Many people believe that health information technology (health IT) has the potential to transform the practice of health care by reducing costs and improving quality. In this paper, prepared at the request of the Chairman of the Senate Budget Committee, the Congressional Budget Office (CBO) examines the evidence on the costs and benefits of health information technology, possible barriers to a broader distribution and use of it in hospitals and clinicians' offices, and possible options for the federal government to promote use of health IT. In keeping with CBO's mandate to provide objective, impartial analysis, the paper makes no policy recommendations.

Stuart Hagen of CBO's Health and Human Resources Division and Peter Richmond, formerly of CBO, prepared the report under the supervision of Bruce Vavrichek and James Baumgardner. Keisuke Nakagawa provided able research assistance. The report benefited from comments by Tom Bradley, Robert Dennis, Keith Fontenot, Holly Harvey, David Moore, Robert Nguyen, Allison Percy, William Randolph, and Philip Webre, all of CBO. In addition, several briefings organized by the Health Information Management Systems Society provided helpful data. A number of outside reviewers also provided comments: Laura Adams of the Rhode Island Quality Institute, Mark Leavitt of the Certification Commission for Health Information Technology, David Cutler of Harvard University, Richard Hillestad of the RAND Corporation, and Douglas Johnston and Eric Pan of the Center for Information Technology Leadership. (The assistance of external reviewers implies neither responsibility for the final product, which rests solely with CBO, nor endorsement of the conclusions of CBO's analysis.)

Leah Mazade edited the report, and John Skeen proofread it. Maureen Costantino designed and produced the cover and prepared the report for publication. Lenny Skutnik produced the printed copies, Linda Schimmel coordinated the print distribution, and Simone Thomas prepared the electronic version for CBO's Web site.

Peter R. Orszag
Director

May 2008



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Evidence on the Costs and Benefits of Health Information Technology

The complexity of modern medicine exceeds the inherent limitations of the unaided human mind.
— David M. Eddy (1990)

Introduction and Summary

Information plays a key role in health care. Providers such as physicians and hospitals generate and process information as they provide care to patients. Managing that information and using it productively pose a continuing challenge, particularly in light of the complexity of the U.S. health care sector, with its many different types of providers, services, and settings for care. Health information technology (health IT) has the potential to significantly increase the efficiency of the health sector by helping providers manage information. It could also improve the quality of health care and, ultimately, the outcomes of that care for patients.

The term “health IT” generally refers to computer applications for the practice of medicine. Those applications may include computerized entry systems for physicians’ ordering of tests or medications, support systems for clinical decisionmaking, and electronic prescribing of medications. (The appendix provides more information about the different types of health IT and the terminology used in the field.) Some or all of those components are housed in the electronic medical record (EMR). The electronic health record (EHR) is the primary health IT package commonly purchased by a provider. It is an EMR with the capacity to send and receive data electronically and meets the requirements for interoperability.¹

When used effectively, EHRs can enable providers to deliver health care more efficiently. For example, they can:

- Eliminate the use of medical transcription and allow a physician to enter notes about a patient’s condition and care directly into a computerized record;²
- Eliminate or substantially reduce the need to physically pull medical charts from office files for patients’ visits;
- Prompt providers to prescribe generic medicines instead of more costly brand-name drugs; and
- Reduce the duplication of diagnostic tests.

The adoption and proper use of EHRs could also improve the quality of health care. Among other things, they could:

- Remind physicians about appropriate preventive care;
- Identify harmful drug interactions or possible allergic reactions to prescribed medicines, and
- Help physicians manage patients with complex chronic conditions.

-
1. Interoperability describes the capacity of one health IT application to share information with another in a computable format (that is, for example, not simply by sharing a PDF [portable document format] file).
 2. Many physicians use voice dictation to document and report the results of examinations and procedures. Medical transcription is, in its simplest sense, the process whereby those dictated notes about a patient’s care are converted into a typewritten format.

Box 1.**The Office of the National Coordinator of Health Information Technology**

The Office of the National Coordinator of Health Information Technology (ONC) manages the federal government's activities in two main areas: the development of standards necessary to achieve the interoperability of the large number of varying applications of health information technology (health IT) and the facilitation of information exchange.

Developing Standards to Ensure Interoperability

To establish processes for identifying standards with which health IT systems must comply and for certifying that the standards are being met, the Department of Health and Human Services (HHS), through ONC, set up the Health Information Technology Standards Panel (HITSP). The panel's overarching task is to promote interoperability in health care—the ability of systems and applications to communicate with each other. HHS also awarded a three-year contract to the Certification Commission for Healthcare Information Technology (CCHIT) to develop and evaluate certification criteria and create an inspection process for health IT.

As the standards process is currently set up, the HITSP develops industrywide health IT standards and recommends them to the Secretary of Health and Human Services, who first “accepts” them and then one year later officially “recognizes” them for use in federal health IT applications. (Such applications include those used by the federal government—for

example, in the Veterans Health Administration—and by federal contractors.) The panel uses the one-year period to refine the instructions given to vendors for complying with the standards. The standard-setting process is designed to minimize the number of unworkable standards that are issued rather than to maximize the speed with which standards are set. Private-sector health IT users are not required to comply with the federal standards; nevertheless, the federal standards have become the de facto industry measure for achieving interoperability.

Health IT vendors who wish to have their products certified as compliant with new federal standards can submit those products for examination by CCHIT. Certified electronic health record products should be able to communicate and operate with other similarly certified systems.

Facilitating Health Information Exchange

To ease the electronic exchange of health-related information, HHS funded the creation of prototypes for organizing the components of the National Health Information Network (NHIN). ONC describes the NHIN as a “network of networks,” built out of state and regional health information exchanges (and other networks) to link those various networks and the systems they in turn connect. The NHIN's mission is to develop a national capability to exchange standards-based health care data in a secure computer environment.

Many analysts and policymakers believe that health IT is a necessary ingredient for improving the efficiency and quality of health care in the United States. Despite the potential of health IT to increase efficiency and improve quality, though, very few providers—as of 2006, about 12 percent of physicians and 11 percent of hospitals—have adopted it.³ An important question for policymakers, therefore, is whether—and if the answer is yes, how—the federal government should stimulate and guide the adoption of health IT.

The Bush Administration has set the goal of making an EHR available for most Americans by 2014. In 2004, it established the position of the National Coordinator for Health Information Technology in the Department of Health and Human Services to help bring about the broad adoption of health IT (see Box 1). Other federal agencies that finance health care or provide it directly have also taken steps to encourage adoption or to use health IT in their own clinical operations. Proposals before the Congress would expand the federal government's current activities by, among other things, mandating the use of some types of health IT, such as electronic prescribing (“e-prescribing”); offering financial incentives to providers who use health IT; and increasing the funds available for grants to purchase systems for providers.

This Congressional Budget Office (CBO) paper focuses on evidence about the benefits and costs of health IT and identifies and analyzes barriers to its adoption. Research indicates that in certain settings, health IT appears to make it easier to reduce health spending if other steps in the broader health care system are also taken to alter incentives to promote savings. By itself, the adoption of more health IT is generally not sufficient to produce significant cost savings.

The most auspicious examples involving health IT have tended to be connected to relatively integrated health systems. For example, Kaiser Permanente is a large integrated delivery system in which the health plan (primarily a health maintenance organization, or HMO) and the providers (physicians and most hospitals and ancillary

service providers) exclusively contract with one another to provide care to the health plan's enrollees. For such a system, reducing the number of unnecessary office visits (for patients' concerns or issues that could be handled to their satisfaction through telephone or e-mail consultations), for example, benefits the providers, the health plan, and the patients: It may lower the plan's costs for providing health care—and thus improve its “bottom line”—while minimizing inconvenience for patients. Kaiser has implemented a systemwide EHR in its facilities in some regions. In those areas, physicians have used such consultations to reduce the number of unnecessary office visits (compared with the number in regions without electronic systems).

A number of integrated delivery systems, including Intermountain Healthcare, Geisinger Health System, and Partners HealthCare, have also implemented EHRs across their organizations, and officials believe that as a result the systems have improved the efficiency and quality of the care they provide.⁴ Some integrated systems have worked with health IT for decades. Intermountain Healthcare and the Department of Veterans Affairs (VA), for example, both began using computers to help manage clinical data in the 1970s. The VA has successfully implemented a systemwide EHR in a health care system that serves nearly 6 million patients in more than 1,400 hospitals, clinics, and nursing homes (Department of Veterans Affairs, 2008). According to the agency, its use of health IT has reduced its costs and greatly improved the quality of its care. (A recent Congressional Budget Office report [2007a] discusses the VA system in greater detail.)

For providers and hospitals that are not part of integrated systems, however, the benefits of health IT are not as easy to capture, and perhaps not coincidentally, those physicians and facilities have adopted EHRs at a much slower rate. Office-based physicians in particular may see no benefit if they purchase such a product—and may even suffer financial harm. Even though the use of health IT

3. Rates of adoption vary by the definition of health IT used in a particular survey. The rates given here are based on the adoption of health IT systems that include all or most recommended functionalities—such as electronic documentation of providers' notes, electronic viewing of laboratory and radiological results, electronic prescribing, computerized physician order entry, clinical decision support, and interoperability.

4. Those organizations differ from Kaiser in that they generally do not have exclusive contractual relationships with providers. In a typical integrated delivery system, providers are either salaried employees or operate in a close contractual partnership with the organization. Such a system often has a health plan that covers a substantial percentage of its patients but also treats patients who are insured through other, competing plans. Kaiser's exclusive contractual relationship with its providers is uncommon: The arrangement creates financial incentives that more closely resemble those of a staff-model HMO than of a typical integrated delivery system.

could generate cost savings for the health system at large that might offset the EHR's cost, many physicians might not be able to reduce their office expenses or increase their revenue sufficiently to pay for it.

For example, the use of health IT could reduce the number of duplicated diagnostic tests. However, that improvement in efficiency would be unlikely to increase the income of many physicians because laboratories and imaging centers typically perform such tests and are paid separately by health insurance plans. In cases in which a physician performs certain diagnostic tests in the office, reducing the number of duplicated tests would reduce his or her income. As a result, the capacity to avoid duplicating tests might not spur many physicians to invest in and implement a health IT system. Indeed, physicians might have a more powerful financial incentive to purchase additional office diagnostic equipment, for example, than to purchase a health IT system.

The search for improved efficiency in delivering health care has prompted numerous proposals for increasing the adoption of health IT. Two recent studies, one by the RAND Corporation and one by the Center for Information Technology Leadership (CITL), have estimated that about \$80 billion in net annual savings is potentially attributable to such technology. Those studies have received significant attention, but for a number of reasons they are not an appropriate guide to estimating the effects of legislative proposals aimed at boosting the use of health IT. To take the RAND study as an example:

- The RAND researchers attempted to measure the *potential* impact of widespread adoption of health IT—assuming the occurrence of “appropriate changes in health care”—rather than the *likely* impact, which would take account of factors that might impede its effective use. For example, health care financing and delivery are now organized in such a way that the payment methods of many private and public health insurers do not reward providers for reducing costs—and may even penalize them for doing so.
- The RAND study was based solely on empirical studies from the literature that found positive effects for the implementation of health IT systems; it excluded the studies of health IT, even those published in peer-reviewed journals, that failed to find favorable results. The decision to ignore evidence of zero or negative net

savings clearly biases any estimate of the actual impact of health IT on spending.

- The RAND study was not intended to be an estimate of savings measured against the rates of adoption that would occur under current law, but rather against the level of adoption in 2004. That is, the researchers did not allow for growth in adoption rates that would occur without any changes in policy, as CBO would do in a cost estimate for a legislative proposal.

One significant potential benefit of health IT that has thus far gone relatively unexamined involves its role in research on the comparative effectiveness of medical treatments and practices. Widespread use of health IT could make available large amounts of data on patients' care and health, which could be used for empirical studies that might not only improve the quality of health care but also help make the delivery of services more efficient.

By making clinical data easier to collect and analyze, health IT systems could support rigorous studies to compare the effectiveness and cost of different treatments for a given disease or condition. Then, in response to the studies' findings, they could aid in implementing changes in the kinds of care provided and the way those services were delivered, as well as track progress in carrying out the changes. Such comparative effectiveness studies could lead to reductions in total spending for health care because of the tendency in the current health care system to adopt ever more expensive treatments despite the lack of solid evidence about their effectiveness. The likelihood of such reductions in spending could be increased if the studies' findings were linked to the payments that providers received or the cost sharing that patients faced, particularly if sufficiently strict cost-effectiveness thresholds were used (Congressional Budget Office, 2007b).

If the federal government chose to intervene directly to promote the use of health IT, it could do so by subsidizing that use or by imposing a penalty for failing to use a health IT system. From a budgetary perspective, the subsidization approach is less likely than a penalty to generate cost savings for the federal government because of the costs of the subsidies: Payments would end up going to those providers who would have adopted a health IT system even without a subsidy as well as those providers for whom the subsidy made the difference in their decision to adopt one. However, providers may respond differen-

tially to a subsidy or a penalty depending on how those interventions are presented.

Evidence on the Adoption of Health Information Technology

A well-functioning EHR—comprising electronic documentation of providers' notes, electronic viewing of laboratory and radiological results, e-prescribing, and an interoperable connection via a health information exchange with all other providers and hospitals in a community—could have a significant impact on medical practice (Jha and colleagues, 2006). For example, consider a physician without a health IT system. The physician has a paper chart for each patient, and the following steps may then be involved in the patient's care:

- For each visit, the physician writes notes in the chart—or dictates them for later transcription—about the patient's condition and treatment. The nurse who takes the patient to the exam room records vital statistics (pulse, blood pressure, and temperature) in the paper chart. The physician writes out any needed prescriptions and gives them to the patient to fill at a pharmacy. If the chart contains information on the patient's allergies, the physician might check it to make sure the prescribed drug will have no adverse effects.
- If the physician decides to refer the patient to a specialist for a consultation, a portion of the patient's chart will go to that provider in the form of a letter. In many instances, however, the specialist does not receive a letter and has no information other than what might be noted in a referral form. The patient must then fill out a medical history and other forms required by the specialist. Moreover, unless the referring physician includes results from recent lab and radiology procedures, the specialist may well order similar diagnostic tests. If the physicians are both part of a multispecialty medical group that sees patients in multiple locations, the entire medical chart may need to be delivered to the specialist's office for the visit, risking the loss of the chart.
- Following the patient's visit, the specialist sends a letter back to the referring physician, detailing the results of the encounter. If the condition is serious, the specialist will probably communicate by telephone.

By contrast, consider a physician who uses an EHR. In that case:

- The physician might use a “drop-and-click” menu to note some elements of the patient's condition, reducing the need for handwriting or dictation and eliminating the delay—typically at least a week—in getting the transcribed notes into the chart.
- The EHR would automatically check any prescriptions for errors in dosing, allergies, and drug interactions; if the patient's health insurance plan included a formulary (a list of prescription drugs approved for use), the physician could discuss information about prices and copayments while the patient was still in the office. The EHR might also have a feature that could suggest a drug that might be a better choice, given the specifics of the patient's condition. The prescription would then be delivered electronically to the patient's pharmacy.
- A referral to a specialist would also be handled electronically. The clinical information necessary for the visit to the specialist would be automatically transmitted to that office and would include the results of any diagnostic procedures that the referring physician had ordered, including digitized images from radiological procedures.
- Following the consultation with the specialist, that physician's notes and recommendations would be electronically transmitted back to the referring physician's office, where they would become part of the patient's chart. Ideally, the EHR would substantially simplify operations in physicians' offices; it would have a similar if not a stronger impact in hospitals, given their more complicated care and treatment regimens.

As interest in health IT has grown, several surveys have attempted to measure current levels of its adoption.

- A survey sponsored by the Robert Wood Johnson Foundation (and summarized in Jha and colleagues, 2006) estimated that 24 percent of office-based physicians used an EHR of one type or another.⁵ Physicians who worked in solo practices were less likely to have a health IT system than were physicians who worked in

5. The full report of the survey is at www.rwjf.org/files/publications/other/EHRReport0609.pdf.

larger offices (adoption rates of 16 percent versus 39 percent, respectively).

- A 2006 survey of nonfederal office-based physicians by the National Center for Health Statistics reported that 12.4 percent of them used a comprehensive health IT system, and an additional 16.8 percent said they used some type of system.⁶
- Another study, by the Center for Studying Health System Change, compared rates of health IT adoption for two periods: 2000 to 2001 and 2004 to 2005. The study found that adoption of health IT by large practices continued to exceed adoption by smaller practices by as much as 38 percentage points (Grossman and Reed, 2006).

The rates of adoption of EHRs by hospitals appear to be similar to those of physicians, according to recent analyses:

- Although the Robert Wood Johnson Foundation study mentioned above did not estimate the prevalence of EHRs in hospitals (because the available evidence was too limited), it concluded that only 5 percent of hospitals used computerized physician order entry (CPOE) systems, which are a key component of hospital EHRs (George Washington University, Massachusetts General Hospital, and Robert Wood Johnson Foundation, 2006).⁷
- That conclusion is consistent with the findings of a 2005 study by Cutler, Feldman, and Horwitz, which found that 4 percent of hospitals were in full compliance with standards for CPOE, although an additional 17 percent of hospitals had made progress toward obtaining the technology. The Cutler team concluded that hospitals' profitability was not associated with the use of CPOE—a possible reason for the low adoption rates.

6. In the survey, reported by Hing, Burt, and Woodwell in 2007, an EMR system was deemed comprehensive if respondents answered "yes" to questions about computer applications for ordering prescriptions and tests and for test results and clinical notes.

7. Computerized physician order entry systems are electronic applications that physicians use to order medications, diagnostic tests, and other services.

- A more recent survey by the American Hospital Association, reported in 2007, found that 11 percent of nonfederal hospitals had fully implemented EHRs. Such hospitals were more likely to be large urban or teaching hospitals than to be small community facilities.

Some international comparisons are available that measure investment in health IT and other parameters, such as rates of adoption and the functionalities that implemented systems provide. That research suggests that the United States lags behind other Western countries (specifically, the United Kingdom, Germany, Australia, the Netherlands, and New Zealand) although perhaps not dramatically, if the measure being used is the adoption of sophisticated IT systems. In several of those countries, rates of adoption of health IT systems among physicians are at or above 80 percent (Schoen and others, 2006). Although the data show that U.S. physicians are far less likely than physicians in those countries to use EHRs in their offices, they are just as or even more likely to use more-sophisticated electronic functions—such as accessing their patients' records remotely. That finding points to the difficulty of comparing rates of adoption—some countries may report high rates, but it is not clear whether their systems are particularly sophisticated or fully utilized (Schoen and others, 2006). In most countries in which rates of adoption are high, the government has heavily subsidized the acquisition of health IT systems by providers (Anderson and others, 2006).⁸

Evidence on the Benefits of Adopting Health Information Technology

No aspect of health IT entails as much uncertainty as the magnitude of its potential benefits. Some analysts believe that the adoption of such systems could provide substantial savings by lowering the cost of providing health care, eliminating unnecessary health care services (such as duplicate diagnostic tests), and improving the quality of care in ways that might reduce costs (by diminishing the likelihood of adverse drug events, for example). Other analysts expect little effect on costs but some improve-

8. Some analysts point to those trends as indicating that the U.S. government could increase adoption of health IT systems through subsidization but that such support would not necessarily result in the adoption or use of those systems' more sophisticated features. See the later discussion on the question of a potential role for the federal government in speeding adoption of health IT.

ment in the quality of care. Another school of thought holds that health IT could bolster the quality of care but also increase expenditures on health care services—because improvements in quality would stimulate demand for additional services.

Wider adoption of health IT has the potential to generate both internal and external savings:

- Internal savings are those that can be captured by the provider or hospital that purchases the system; they are most likely to be in the form of reductions in the cost of providing health care—that is, improvements in the efficiency with which providers and hospitals deliver care.
- External savings are those that the provider or hospital that purchases the system cannot realize but that accrue to another such provider or perhaps the relevant health insurance plan or even the patient. Such savings might arise, for example, from the newfound ability of participants in the health care sector to exchange information more efficiently.

For integrated systems (such as Kaiser Permanente and the VA), more savings are internal than would be the case for providers that are not part of an integrated system. For example, integrated systems often have contracts with health insurance plans entailing that the systems assume the financial risk for the cost of prescription drugs and diagnostic tests, among other things, for the patients covered by those plans. As such, the systems can capture the savings from shifting their prescribing patterns toward generic drugs and reducing the number of duplicated diagnostic tests.

Different reimbursement arrangements might also shift savings from the external to the internal category in instances in which a provider is not part of an integrated system. A provider who was not affiliated with an integrated system but who treated HMO patients might be similarly rewarded for appropriate formulary management, which would shift those savings from being external to internal. But if the provider was paid purely on a fee-for-service basis, the savings would remain an external benefit.

The extent to which the use of health IT generates savings and how those savings are distributed across the health care sector can greatly influence the speed of

broader adoption and use of those technologies. If health IT's adoption primarily produced internal savings for the providers and hospitals that purchased the systems—that is, if the purchasers of the systems were able to capture most of the cost savings that arose from using the technology—then the adoption of health IT would probably proceed apace without any need for intervention by the federal government. But if health IT appeared primarily to provide external savings—that is, if those who adopted the systems were unable to garner a sizable share of the benefits—then the adoption of such systems might proceed very slowly without additional governmental support.

Of the research to date, most studies examine how health IT might make the delivery of health care services more efficient, and they tend to focus on a particular clinical practice or area of potential savings. The evolving nature of the U.S. health care marketplace and of health IT has made it difficult to apply the results of such research to national estimates of the impact of health IT on the costs and quality of care. The few studies that have attempted to do so appear to have substantial shortcomings that limit their usefulness in analyzing legislative proposals. And some potential areas of research and analysis remain largely unexamined. They include the ways in which the delivery of health care services might change in response to the efficiencies that health IT offers and how the large amounts of clinical data available through EHRs could contribute to analyses of the comparative effectiveness and cost-effectiveness of different treatments.

Underlying any consideration of the potential benefits of health IT are the financial incentives that influence the behavior of health care providers, hospitals, health insurance plans, and patients. The use of information technology might lead to greater efficiency in delivering health care and to higher-quality services, but financial incentives could constrain many of those positive changes. For example, EHRs could provide physicians with a useful tool for reducing the number of unnecessary or duplicated laboratory tests that they ordered, but the likelihood of such reductions could depend on factors such as whether physicians were compensated for controlling the use of laboratory testing (as in some managed care plans) or whether they derived income from ordering more tests. How well health IT lives up to its potential depends in part on how effectively financial incentives can be realigned to encourage the optimal use of the technology's capabilities.

A general indication of health IT's usefulness in improving efficiency and quality can be seen in the adoption of such applications by integrated health care delivery systems (such as staff-model HMOs). By their nature, those types of systems are able to garner more of the benefits of health IT than nonintegrated providers can. Not surprisingly, such entities have relatively high rates of adoption of health IT.

Estimates of the Potential National Savings from Widespread Adoption of Health IT

Two studies, one by the RAND Corporation and one by the Center for Information Technology Leadership, report estimates of the potential net benefits that could arise nationwide if all providers and hospitals adopted health information technology and used it appropriately. (For the RAND research, see Girosi, Meili, and Scoville, 2005; and Hillestad and others, 2005. The CITL study is reported by Walker and colleagues, 2005, and Pan and others, 2004.) Both studies estimated annual net savings to the health care sector of about \$80 billion (in 2005 dollars), relative to total spending for health care of about \$2 trillion per year. The studies, however, measured different sources of such savings. The RAND research focused primarily on savings that the use of health IT could generate by reducing costs in physicians' practices and hospitals, whereas the CITL study limited its scope to savings from achieving full interoperability of health IT, explicitly excluding potential improvements in efficiency within practices and hospitals.

Neither the RAND nor the CITL study, however, is an appropriate guide to the budgetary effects of legislative proposals aimed at increasing the use of health IT. For example, both studies attempt to measure the *potential* impact of widespread adoption of health IT, not the *likely* impact; a CBO cost estimate, by contrast, would estimate the likely effect. And whatever the net savings to the health care system as a whole, the impact on the federal budget would be far smaller than that. Medicare and the federal share of Medicaid together account for only about one-fourth of total spending for health care services. Moreover, some types of savings, such as those from improved efficiency within a physician's office, could not be realized by Medicare without revising payment rates to physicians, which usually requires legislation. There are also other reasons, discussed in detail below, that the studies are not appropriate for estimating the impact of a legislative proposal. The bottom line is that both studies

appear to significantly overstate the savings for the health care system as a whole—and by extension, for the federal budget—that would accrue from legislative proposals to bring about widespread adoption of health IT.

The RAND Analysis. The RAND analysis itself notes that its estimate is of health IT's potential savings and costs: "We use the word *potential* to mean 'assuming that interconnected and interoperable EMR systems are adopted widely *and used effectively* [emphasis added]." Thus, our estimates of potential savings are not predictions of what will happen but of what could happen with HIT [health information technology] *and appropriate changes in health care* [emphasis added]" (Hillestad and others, 2005, p. 1104). By incorporating the assumption of "appropriate changes in health care," the study's estimate deliberately does not take into account present-day payment incentives that would constrain the effective utilization of health IT, even if the technology was widely adopted. A key reason for the currently low rate of adoption of health IT may be that, given the way health care financing and delivery are now organized, the payment methods of both private and public health insurers in many cases do not reward providers for reducing some types of costs—and may even penalize them for doing so. Most providers are paid on a fee-for-service basis; if they were to reduce health care costs by providing fewer or less expensive services, they would have to submit lower charges to insurers, and as a result, their payments would decline. If technologies were adopted without changing those incentives, then the RAND estimate would be too high because the "appropriate changes in health care" assumed in the study would not have been made.

Another issue raised by the RAND study is that it was based solely on empirical studies from the literature that found positive effects for the implementation of health IT systems. Researchers offered this rationale: "We chose to interpret reported evidence of negative or no effect of HIT as likely being attributable to ineffective or not-yet-effective implementation" (Hillestad and others, 2005, p. 1105). However, a number of studies of health IT published in peer-reviewed journals have failed to find favorable results (for example, Garrido and others, 2005; Overhage and others, 2001). Consequently, the decision to ignore evidence of zero or negative net savings clearly biases—possibly quite substantially—any estimate of the actual impact of health IT on spending.

The methods researchers used in the RAND study would not be appropriate for assessing the savings that a legislative proposal would generate because, unlike the procedures used for a CBO cost estimate, savings were not measured relative to a current-law baseline. Instead, RAND researchers used the level of health IT adoption in 2004 as a baseline and assumed for comparison purposes that adoption remained at that level during the period over which they projected savings. A CBO cost estimate, however, would reflect the continuing growth in health IT adoption that would occur without any change in law. To the extent that health IT adoption has grown since 2004 and will continue to grow, that growth reduces the possible cost savings, compared with RAND's estimate, that could come about by encouraging wider adoption.

In several specific parts of the RAND analysis, the savings that would accrue from widespread adoption of health IT appear to be overstated. For example, it is likely that the RAND researchers significantly overestimated savings for health IT from reductions in the average length of stay in a hospital.⁹ The RAND researchers assumed that reductions in lengths of stay would result in proportional reductions in costs. They noted, though, that health IT would primarily reduce lengths of stay by speeding up how quickly procedures were performed. If that is the primary channel through which lengths of stay are reduced, at least some costs will simply be shifted to earlier days in the stay and not eliminated—which argues for a reduction in costs that is less than proportional to the reduction in the average length of stay.¹⁰

9. The study also makes what are probably optimistic assumptions about the savings from more efficient use of prescription drugs (for example, from switching to generic medications). It relies on the results of three studies of the effects of health IT on drug utilization, each of which has significant drawbacks. Two of the studies were conducted by a private consulting firm and were not published in a peer-reviewed journal; one of those studies was based on the experiences of only one clinic, and the other was an estimate of potential savings from using a particular vendor's e-prescribing product. The third study was based on the opinions of an expert panel, which estimated savings only for capitated plans and not for fee-for-service plans. (In capitated plans, providers give specified services to patients for a fixed monthly fee, regardless of the amount of care each patient actually receives.) The RAND researchers implicitly assumed that savings in the fee-for-service sector would be the same as those in the capitated sector. That assumption probably overstates the impact of the use of health IT because it ignores the very different set of economic incentives that capitated providers face compared with those faced by providers who are paid on a fee-for-service basis.

The RAND estimate also failed to take into consideration that hospitals often achieve reductions in their average-length-of-stay measures by shifting patients to another health care site, such as a skilled nursing facility. That practice produces fewer net savings because although such shifts reduce costs in the hospital sector, they increase them in the skilled-nursing sector.

Another issue raised by the RAND analysis is the method that the researchers used to estimate savings from eliminating or reducing the use of paper medical records: They based their findings on the experiences of recent adopters of electronic medical record systems and then applied the savings to all physicians' offices. Yet that assumption might not be realistic for small practices (those that have fewer than four practitioners) because the same person who pulls charts in those offices typically also schedules appointments, administers billing, and performs other administrative tasks. Thus, although the overall workload of such staff might be diminished, those practices would find it difficult to reduce their costs by eliminating support staff positions. About half of physicians are in small practices; consequently, RAND's estimate of savings in this area is probably overstated.

Finally, the RAND study did not consider the broader impact that reducing at least some types of health care costs would have on the utilization of services. If the widespread use of health IT reduced the cost of health care services, that decline would eventually be reflected in lower prices and copayments for patients—and as prices fell, patients would demand more care. Even if the researchers' underlying assumptions about savings are accurate, the net effect of more use of health IT would probably still be lower overall costs than would otherwise be the case—but the reduction would not equal the amount that the RAND analysis has suggested.

The Study by the Center for Information Technology Leadership. Many of the same concerns raised by the

10. Furthermore, the estimate of the reduction in the average length of stay was based on the average reduction reported in three studies. Two of them were single-hospital case studies that reported very different reductions—5 percent and 30 percent—in average stays; the third study was based on data from 1996, a period during which hospitals were significantly reducing their costs per admission in response to pressures from the spread of managed care. Today, more than 10 years after hospitals first experienced such forces, it is unlikely that additional savings would be as easy to obtain as they were during that earlier period.

RAND analysis apply to the study conducted by CITL. For one thing, the authors did not fully consider the impact of financial incentives in their analysis; they did not take into account the effect of those incentives on the use of health IT by providers, hospitals, and insurers or the effect on patients' demand for health care services in the event that health IT reduced the cost of care. The CITL analysis also estimated the \$80 billion in potential savings against a baseline of little or no information technology use. Savings would come, the study suggests, by moving the U.S. health care sector from Level 1 (with completely nonelectronic data and with all information written down or shared verbally) to Level 4 (with all standardized machine-interpretable data). The impact of moving from the current level of adoption to Level 4 would be much smaller because many of the nation's health care providers already operate above Level 1 in their use of technology. (For example, Level 2 includes the use of fax machines, which are widely available in physicians' offices today.) As the report by Pan and others (2004) states, "the model [used in the study] does not account for the 'current state of affairs'" (p. 17).

Like the assumptions in the RAND analysis, some of those that the CITL study used appear to be overly optimistic:

- The CITL study estimated that the administrative cost of a laboratory test (encompassing both the provider's and the lab's expenses) was about \$40 and that widespread interoperability could save about \$38 per test—producing estimated national savings on lab tests of about \$25 billion annually. However, the results of another analysis (Baker, 2005) raise doubts that the administrative cost of a lab test could possibly be as high as \$40 to begin with.
- The CITL researchers assumed that fully interoperable health IT systems would eliminate 95 percent of avoidable tests, resting that assumption on the belief that physicians would choose to override the system's warnings on such tests only 5 percent of the time. Other estimates of avoidable tests typically report higher override rates, however (Bates and colleagues, 1999b).
- The CITL study also assumed that at the highest level of health IT adoption, only 0.001 percent of prescriptions would require a phone call between a pharmacist and a prescribing physician. Certainly, greater imple-

mentation of health IT could significantly reduce the number of those telephone calls, but the reduction that the CITL researchers assumed does not appear to be attainable.

Evidence on Improvements in Efficiency from Adoption of Health IT

The potential of health IT to reduce spending for health care depends in large part on its ability to make care more efficient by cutting the cost of delivering services, avoiding redundant services, and improving providers' productivity. Evidence from the literature on health IT, however, does not uniformly support the possibility of such savings. The potential for savings appears to depend heavily on their source and whether that source is in a hospital or in an ambulatory care setting (such as a clinic or a physician's office). In addition, savings are difficult to assess because the trimming of costs in one area of a physician's practice, for example, may be offset by increased costs or reduced efficiency in another area.

Estimating the impact of some potential sources of savings, especially those arising from greater exchange of information among providers, insurers, and patients, is especially difficult because health IT networks are in an early stage of development. Furthermore, health care providers and hospitals that were early adopters of health IT may have been motivated by particular characteristics of their organizations or operations that made them more likely than nonadopters to achieve benefits from health IT—in which case the outcomes they have seen might not be generalizable. Evidence of savings in the health care sector as a whole from adopting health IT is also limited.

Nevertheless, savings could accrue in a number of areas: the handling of medical records, the redundancy of diagnostic tests, the prescribing and use of drugs, the productivity of caregivers, and the length of hospital stays. Savings could also arise if a comprehensive interoperable health IT system, including a health information exchange that facilitated the sharing of health care information, was implemented.

Eliminating Paper Medical Records. Providers typically adopt EHRs with the intention of replacing their paper medical record systems. Research has shown that physicians' offices can realize savings from reducing the pulling of paper charts and the use of transcription services (Wang and others, 2003). Those savings might not apply

in very small practices, however, because such offices typically have low but relatively fixed costs related to medical records and the physicians who work there are much more likely than those in larger practices to write notes manually in the charts. Savings from less pulling of charts is typically accomplished by reducing the number of staff required to do so. But that type of staff reduction may be impossible in a small practice if the employee who pulls charts also performs other tasks (such as scheduling and billing), as is usually the case.

The extent of savings to be gained from eliminating paper medical records would also depend on how well a physician used the new system. For example, most EHRs allow physicians to create templates that can significantly reduce the amount of time spent typing in notes, ordering medications, and so forth. But making effective use of templates and other features of EHRs would require a physician to make a substantial up-front investment in time to create templates suited to his or her style of practice and to learn how to use them effectively.

Moreover, many physicians would have to alter the way they practiced medicine to make a health IT system work for them, and not all physicians appear willing to make such changes. For example, some providers who have already installed EHRs continue to maintain paper charts; Miller and colleagues (2005) noted that 10 of 14 practices they examined stopped pulling charts—which implies that 4 practices still did not. Presumably, as physicians became more accustomed to the new electronic systems, they would stop using paper charts.

Avoiding Duplicated or Inappropriate Diagnostic Tests.

The possibility of duplicating diagnostic tests arises when patients are seen by different physicians in multiple facilities or when records make it difficult to discern which tests have or have not been administered. Inappropriate testing can also occur because of a physician's habits or preferences, and a pattern of such testing may be easier to identify and change if information is in an electronic format. For the most part, any savings from avoiding duplicate or inappropriate diagnostic tests would be realized primarily by a health insurance plan, not a health care provider. Thus, the extent to which savings in this area would actually benefit providers is unclear.

Despite somewhat mixed results, most evidence suggests that EHRs have the potential to reduce the number of

inappropriate laboratory tests. Bates and colleagues (1999b) found that providers canceled 69 percent of lab tests when alerted by an electronic notice that a test appeared to be redundant. That result, when combined with a related estimate that 9 percent of all lab tests appeared to be redundant (Bates and colleagues, 1998b), implies that EHRs with a notice of redundancy could reduce the number of laboratory tests by about 6 percent (69 percent of 9 percent). Consistent with this estimate, research by Tierney and others (1987) found that showing physicians information about a patient's previous lab work when they ordered a test in a clinic's order entry system and reminding them of the date of the patient's last test reduced the volume of tests ordered by about 6 percent. A second study reported by Tierney and colleagues in 1988 found a drop of about 9 percent in lab charges. The Tierney research, however, is based on data collected in the mid-1980s, and its applicability in today's health care environment is questionable.

By contrast, an evaluation of laboratory services in the outpatient facilities of two separate Kaiser Permanente regions that adopted health IT systems did not find a difference in the number of duplications as a result (Garrido and others, 2005). It is unclear what specific methods the systems used to prevent the duplication of tests and whether using the same methods shown to be effective in other studies would also have been effective for the Kaiser facilities. Moreover, as a fully integrated HMO, Kaiser may have already used non-health IT methods to reduce the number of unnecessary tests. For that reason, the results of the study may not be applicable to the non-HMO health care sector.

Reducing the Use of Radiological Services. Less information is available about the impact of EHRs on the use of radiological services. The Garrido team's 2005 study of Kaiser facilities also examined imaging and, as was the case with laboratory testing, found no change following the adoption of health IT. A study by Harpole and others (1997) found that providing physicians with evidence-based critiques of certain types of imaging at the point at which a provider orders a radiological study (that is, providing a clinical decision support system) had no significant effect on whether or not a test was ordered but did influence the types of radiological images that were taken. Health IT thus appears to ease the job of monitoring the use of radiological services, but there is little evidence that it helps control costs.

Promoting the Cost-Effective Use of Prescription Drugs.

Evidence suggests that in hospitals, features of EHRs—specifically, clinical decision support (CDS) and computerized physician order entry—could help reduce the cost of prescription drugs by prompting providers to use generic alternatives, lower-cost therapies, and, for more complex drug regimens, cost-effective drug management programs (Mullett and others, 2001; Teich and others, 2000). In outpatient settings such as clinics and physicians' offices, health IT—specifically, e-prescribing—could alter prescribing practices in the direction of lower-cost drugs.¹¹

Little empirical evidence exists, however, on the effectiveness of health IT to help manage the use of prescription drugs in either hospital or outpatient settings. One factor limiting cost savings is that physicians generally do not benefit financially from effectively managing the utilization of drugs. Instead, any financial gain is usually realized by health plans or pharmacy benefit management companies (PBMs). Moreover, because of their strong incentives to hold down costs, health plans and PBMs may already be capturing a substantial portion of those savings.

Improving the Productivity of Nurses and Physicians.

Several analyses have investigated whether EHRs in hospitals and outpatient facilities might increase the productivity of nurses and physicians. A 2005 summary of research by Poissant and others suggests that when health IT systems were in use, nurses in hospitals saw drops in the time required to document the delivery of care but physicians saw increases in documentation time. That finding implies that hospitals might be able to reduce their spending on nurses but not necessarily on physicians. Those studies, however, may have identified a short-term effect among physicians—that is, before providers had become accustomed to the new system and incorporated the new methods into their daily routine. In addition, most studies have examined health IT in teach-

ing hospitals, and the generalizability of their results to more typical community hospitals may be limited.

Few studies have measured the effect of EHRs on physicians' efficiency in outpatient settings, and those that have show mixed results (Pizziferri and others, 2005; Overhage and others, 2001). The lack of demonstrated gains in productivity as a result of implementing health IT systems may be partially due to some providers' tendency to duplicate the system's functions by continuing to do some tasks manually, such as maintaining paper records (Gans and others, 2005; Overhage and others, 2001). Physicians that eliminate or reduce their use of transcription services by adopting a health IT system may see savings, though. Intermountain Healthcare maintains that its savings from reducing transcription costs alone (as high as \$12,500 per year for some physicians) contributed substantially to paying for its EHR, which cost about \$2,500 per physician.¹²

The measures of productivity that researchers have used in such studies are relatively narrow and do not exhaust the ways in which the use of health IT might affect health care workers' productivity. For example, the improvements in documentation that EHRs provide might help physicians improve their caregiving: If such systems led providers to spend more time documenting the care they delivered, the end result might be higher-quality care. Health IT systems might also enable a physician to provide other services for patients, such as helping them get appropriate preventive care, providing better education about their health, and assisting them in making choices from among an array of treatment options.

Reducing the Length of Hospital Stays. Some research (Mekhjjan and others, 2002) suggests that health IT could reduce the average length of a hospital stay by 5 percent or more by speeding up certain hospital functions (such as ordering and completing tests, ordering and administering medications, and collecting information and preparing for patients' discharge) and by avoiding costly errors (such as adverse drug reactions that could lead to delays in discharging patients). Other research has produced mixed results.

11. Wang and colleagues (2003) estimate that health IT systems in the offices of primary care physicians could save 15 percent of total drug costs per year in capitated plans, but that number is based on the opinions of an expert panel and not on actual data. Given that capitated plans already have a powerful incentive to encourage the use of less expensive drugs, an effect of 15 percent may be overly optimistic. Some research also indicates that some providers apparently have trouble using the prescribing functions in health IT systems (Wang and others, 2003; Grossman and others, 2007).

12. Personal communication to CBO from Len Bowes, Senior Medical Informaticist, Intermountain Healthcare, May 18, 2008; Clayton and others (2005).

As discussed earlier with regard to the RAND study, reductions in the average length of hospital stays are unlikely to result in cost savings of a similar proportion to the reduction in average length of stay, such as that found by the Mekhjian research team (that is, of 5 percent or more). In particular, reductions in stays that stem from performing various hospital functions more quickly are not likely to cut costs as much as will reductions that result from improving care—for example, by diminishing the number of adverse drug reactions. Reducing the length of time required to process a lab test or diagnostic image from the time it is ordered to the moment the results are delivered only speeds up the delivery of care; it does not necessarily reduce the amount of care provided or its associated cost.

Moreover, the promise of shortening the average length of time that a patient stays in the hospital might not be very compelling to a typical institution because it already faces a sizable financial incentive to pare its costs per admission. Payment incentives in the Medicare program that encourage hospitals to reduce their per admission costs have been in place since the early 1980s; the average length of stay has fallen steadily since then, although recently, the downward trend has slowed (National Center for Health Statistics, 2007). In all likelihood, the majority of hospitals have already made most of the changes necessary to maximize their payments for the care of Medicare patients, and the additional money they would get from the next increment in reducing the average length of stay might not be worth the additional investment in health IT needed to produce it. Moreover, the payment methods for hospital stays that are common among private health plans—per diem payments (that is, a set fee per day in the hospital)—may work against shortening those stays.

Evidence on Improvements in the Quality of Care from Adoption of Health IT

The use of health IT applications has the potential to increase patients' safety within the overall health care system and improve the quality of the care that physicians and other caregivers provide. When used for prescribing medications, EHRs and their computerized physician order entry features can help prevent costly medical errors by checking patients' medical records and the list of medications they are taking, screening the list for possible drug allergies and drug interactions, and alerting physicians to any potential conflicts. The quality of health care could be improved through the use of clinical decision

support systems to remind physicians to schedule tests, help diagnose complicated conditions, and more effectively implement appropriate protocols for treatment. In addition, the extensive data about patients that the use of EHRs generates might allow researchers to inform evidence-based guidelines and compare the effectiveness of different treatments for different patients as well as the effectiveness of different designs for the delivery of care.¹³

Like the benefits from delivering care more efficiently, however, benefits that stem from improving the quality of care—and the potential cost savings that accompany them—are primarily realized by patients and insurers rather than the providers who generally make the investment in health IT that leads to those benefits. Seldom are providers directly compensated for improvements in the quality of their care. Indeed, if those improvements, for example, cut down the number of hospitalizations and office visits, they might actually reduce a provider's compensation, especially in the case of providers paid on a fee-for-service basis (as is commonly the case). Improvements of that kind might enhance a provider's reputation and thereby attract more patients over the long run. But those outcomes would not necessarily increase a provider's income or lower his or her costs. (Also, some providers might discount the value of those benefits because they already had what they considered to be a sufficient number of patients and felt no need to add new ones.)

A possible benefit of improving care through the use of health IT, however, might be to lower malpractice insurance costs for providers. A number of firms that sell liability insurance for physicians are beginning to offer discounted premiums to practices that use EHRs.¹⁴

Avoiding Adverse Drug Events. One of the most common types of medical error—and a focus of much research—is a so-called adverse drug event, in which a patient has an adverse reaction from being administered an inappropriate medication. Research examining serious errors in the medications that patients receive in hospitals has shown that such mistakes are both common and potentially expensive and that they could be substantially reduced through greater use of health IT. Studies have found

13. Evidence-based guidelines are recommended methods of treatment that are based on empirical research.

14. Personal communication to CBO staff from Mark Leavitt, Executive Director, Certification Commission for Healthcare Information Technology, February 7, 2008.

potential reductions in error rates from the use of health IT of between 50 percent and over 90 percent (Potts and others, 2004; Bates and others, 1999a, 1998a; Evans and others, 1998).¹⁵ In a few other studies (Han and others, 2005; Nebeker and others, 2005; Upperman and others, 2005), researchers did not find that the rate of adverse drug events was lowered—although that result might have had more to do with the quality of the health IT systems being used than the performance of such systems in general.

Much less evidence is available on how EHRs affect adverse drug events in outpatient settings. One study (Gandhi and others, 2005) found no evidence of reductions in such errors but qualified those findings by pointing out the lack of sophistication of the systems used by the physicians in the study.

By maintaining a list of a patient's allergies and current medications, a health IT system makes it easier for doctors to check for drug and drug-allergy interactions and for contraindications (stemming, for example, from the results of a laboratory test) to prescribing a particular medication. Health IT systems can also speed providers' access to lists of possible side effects of particular drugs, which allows physicians to quickly verify whether a drug is appropriate for a given patient. Most EHRs (with or without a CPOE feature) automatically check for allergy and drug interactions and for the appropriateness of a particular medication and warn the physician of potential conflicts. Such systems can also provide doctors with standardized dosing amounts or recommended dosing guidelines that can help prevent errors in overmedicating and undermedicating patients. Further, the automated prescribing practices possible with CPOE features may help reduce errors resulting from miscommunication among physicians, pharmacists, patients, and nurses.

Because medical errors can lead to the use of additional health care services, health IT systems that successfully reduce such errors may also diminish expenditures on health care. The effectiveness of health IT in reducing errors, however, depends largely on the type, setting, and quality of the systems. One study (Jha and others, 2001)

15. Not all serious medication errors, however, lead to adverse drug events. About 57 percent of all such errors have no adverse effect on the patient; they are often called "potential adverse drug events" (Bates and others, 1988a).

found that 1.4 percent of hospital admissions were caused by adverse drug events, and 28 percent of those were considered preventable. The average cost of treating the consequences of a preventable adverse drug event, researchers estimated, was more than \$10,000. Another study (Honigman and others, 2001) determined that adverse drug reactions that arose through care provided at an outpatient facility and that required hospitalization occurred at an average annual rate of 3.4 for every 1,000 patients. Avoiding even a fraction of the errors that now occur in inpatient and outpatient settings could yield significant savings.

Some of the potential savings from errors originating among outpatient providers, however, are probably already being realized by existing electronic systems. Even though today very few prescriptions (an estimated 7 percent in 2008) are handled exclusively through electronic means, some aspects of prescribing are almost universally electronic. For example, nearly all pharmacies connect electronically to health plans when they enter a patient's prescription into their computer system. At that point, the health plan has data on most if not all prescriptions that the patient has—and the pharmacist has that information through the health plan's system—and both the health plan's and the pharmacy's systems typically check for drug interactions and possible allergic reactions. (If a PBM is also involved, it may undertake some checking as well.) A provider's health IT system might still contribute to improving the quality of a particular patient's care if, for example, the patient had a result from a recent lab test that might suggest something about his or her response to a particular medication—although it is becoming more common for health plans also to have access to lab results (SureScripts, 2007).

Expanding Exchanges of Health Care Information. The adoption of interoperable health IT systems could ease exchanges of health care information, which might not only improve the quality of care but also reduce costs. The effects of expanding such exchanges include:

- Lessening the duplication of diagnostic procedures (because results could more easily be made available to other providers);
- Preventing medical errors (because providers would have more accurate and more complete information about the patients they are treating); and

- Lowering administrative costs (because automated transfers of test results, clinical information, and prescriptions among health insurers, physicians' offices, hospitals, laboratories, imaging facilities, pharmacies, and public health agencies would be less costly than manual transfers).

The realization of other benefits from greater exchange of information, such as the availability of more data for medical research, lies further in the future (see the later discussion).

An increased capability to exchange information is not sufficient, however, to reduce costs and improve the quality of health care because existing mechanisms for paying providers do not create incentives to reduce costs by acting on that information. Indeed, in some cases, those mechanisms create incentives that discourage efforts to cut costs. For example, a provider who is paid on a fee-for-service basis might refrain from ordering a diagnostic test if the results of the same test recently ordered by another provider were in the patient's EHR (owing to health information exchange); however, that fee-for-service physician would have no financial incentive to do so. Moreover, if the physician could perform the diagnostic test in his or her office by using office-based equipment (such as an X-ray machine), the stronger financial incentive would be to ignore the previous test's results.

One potential source of empirical evidence on the benefits of health information exchange is the experience of integrated health systems that use systemwide EHRs—although separating out the impact of expanded information exchange from other health IT-related effects is difficult. The case of the VA illustrates some of the empirical challenges. The agency reports that its cost per patient has stayed relatively flat over the past several years, which it attributes in part to reducing the number of full-time-equivalent employees per 1,000 patients by 37 percent at the same time that the cost of medical care has been rising by about 6 percent per year (Evans, Nichol, and Perlin, 2006). After an adjustment for changes over time in the mix of patients that the VA sees, its spending per enrollee grew by a total of 1.7 percent in real terms from 1999 to 2005 (0.3 percent annually)—a rate significantly below Medicare's real rate of growth in costs per capita of 29.4 percent (4.4 percent per year) over the same period (Congressional Budget Office, 2007a).

Those results cannot be attributed solely to the impact of the VA's health IT program, however, because the VA differs in many ways from Medicare and other parts of the health system. In addition, the VA adopted other efforts to control costs during the 1999–2005 period; for example, it switched from a labor-intensive inpatient system to a system of outpatient clinics.

Expanding the Practice of Evidence-Based Medicine. Part of the motivation for the broader adoption of health IT has come from evidence of deficits in the quality of health care in the United States and large unexplained geographic variations in the utilization and cost of care (McGlynn and others, 2003; Congressional Budget Office, 2008).¹⁶ Many health IT systems have some type of clinical decision support function—such as automated reminders about preventive care—that could help physicians adhere to evidence-based guidelines, avoid preventable errors, reduce the use of procedures that have no demonstrated clinical value, ultimately improve the quality of the care that they provide, and possibly cut costs. Measuring the effects of using clinical decision support on the costs and outcomes of care for patients is difficult, though. At this stage, empirical research has shown that the use of health IT in general and CDS features in particular can improve the quality of patients' care, but it has not shown that improving care can, in turn, improve patients' health or reduce costs.

Several studies suggest that CDS features can improve the quality of health care:

- Garg and colleagues (2005) reviewed studies on clinical decision support and found that most such functions improved the performance of practitioners. Reminders about using established guidelines for preventive care were found to be the most effective feature. However, few of the studies that Garg reviewed also reported improved outcomes for patients.
- Asch and others (2004) found that the quality of care received by patients in the VA system, which uses an EHR that includes CDS tools, was superior to that received by a nationally representative sample of the

16. For example, the rate of back surgeries varies by state from just under 2 per 1,000 Medicare enrollees in Hawaii to more than 9 in Wyoming.

population.¹⁷ The VA practitioners' adherence to recommended-care guidelines was greatest for indicators of quality care that were associated with a VA performance measurement program (in which the care that practitioners provide is tracked and monitored and feedback is given to each practitioner about his or her performance). However, as CBO's 2008 report on geographic variation in health care spending notes, the VA medical system varies substantially across the nation in patterns of clinical practice, despite the fact that managers track providers' compliance with national guidelines for the treatment of many medical conditions.

- Consistent with the results from the VA, recently released data from a Medicare demonstration project of the Centers for Medicare and Medicaid Services (CMS) suggest that practitioners respond to rewards for high-quality care (Lindenauer and others, 2007). In that study, researchers coupled a CDS system with incentives to achieve a higher level of quality.

Yet a CDS capability does not always improve the quality of patients' care, and even if it could, that improvement might not have the desired effect on costs. According to a broad range of research (Crosson and others, 2007; Linder and others, 2007; Sequist and others, 2005; Tierney and others, 2005, 2003; Murray and others, 2004; Subramanian and others, 2004; Harris and others, 1998), CDS functions have failed to increase physicians' adherence to evidence-based standards of treatment for a wide variety of conditions, including chronic obstructive pulmonary disease, heart disease, diabetes, coronary artery disease, chronic heart failure, chronic renal insufficiency, and hypertension.

The failure to find positive effects from the use of CDS tools for those conditions could be due more to misaligned financial incentives than to limitations in the technology itself, or it could be attributable to the poor quality of some CDS features. Like all aspects of health IT, such tools are not uniform, nor are they all used equally well. The systems have been variously criticized as

“cookbook” medicine, as not fitting well with the particular patterns of work in a given practice, or as unable to positively affect providers' behavior (Frisse, 2006; Sittig and others, 2006; Bates and others, 2003). With time, the quality of such systems may improve, and users may be better able to routinely achieve the positive effects noted in some studies.

Better CDS tools could also boost spending in some ways. For example, the use of some features (such as reminders to practitioners about screening tests and other preventive services) could increase spending for health care by encouraging the utilization of some additional services. Moreover, physicians might order some recommended preventive treatments that were not cost-effective—because even though such practices might improve the health of patients, their costs might not be completely offset by reductions in future health care spending.

Generating Data for Research on Comparative Effectiveness and Cost-Effectiveness of Treatments. Proponents of the adoption of health IT note its potential to provide a massive source of new health care data—once patients' identifying information has been removed and the data have been standardized and assembled in a repository—for research on the comparative effectiveness and cost-effectiveness of medical treatments. The data could provide more-comprehensive information about the health histories of different patients and about the outcomes of their treatments than has previously been available. And the depth and breadth of the data would make it easier to take into account the differences among patients who receive different treatments and allow researchers to assess a broad set of outcomes.

Some work of that nature is being conducted through the HMO Research Network and through a broader network of centers having access to electronic databases that was established in 2005 by the Agency for Healthcare Research and Quality (Congressional Budget Office, 2007b). The knowledge gained from such studies could:

- Improve treatment protocols and methods,
- Lead to better outcomes for patients,
- Lower costs for health care,

17. Judged on the basis of 348 indicators used to assess the treatment of 26 conditions, best-practices care was provided for 67 percent of VA patients compared with 51 percent of non-VA patients. Particularly large differences between the two kinds of patients were seen in quality measurements of chronic disease care and preventive care.

- Improve postmarketing surveillance of pharmaceuticals (to ensure that a drug is effective and has no unexpectedly harmful side effects) that have been approved by the Food and Drug Administration,
- Help target public health efforts, and
- Support early detection of outbreaks of diseases.

The Costs of Implementing Health Information Technology

Implementing a health IT system, whether in a single physician's practice or in the multiple venues of an integrated health care delivery system, involves significant expenditures. Total costs for a health IT system include:

- The initial fixed cost of the hardware, software, and technical assistance necessary to install the system;
- Licensing fees;
- The expense of maintaining the system; and
- The “opportunity cost” of the time that health care providers could have spent seeing patients but instead must devote to learning how to use the new system and how to adjust their work practices accordingly.

The costs of implementing health IT systems vary widely among physicians and among hospitals, depending on the size and complexity of those providers' operations and the extent to which a system's users wish to perform their work electronically.

Owing in part to the wide variation in costs, evidence on expenditures for implementing health IT systems tends to be limited and somewhat conflicting. The initial investment and the cost of maintenance can be fairly easily determined—providers can obtain bids for a system from one or more vendors and thus have a relatively accurate estimate of what those costs will be once they have selected a vendor. Much less predictable is the productive time lost in learning to use the system and in adjusting patterns of work. Yet that nonmonetary investment may be an important factor in whether providers will be able to use the system effectively.

Social costs may also be a factor in providers' adoption and use of health IT, and one such potential cost is the

risk of lost privacy. Purchasers of health IT systems, which must comply with stringent federal and state rules and standards intended to protect patients' privacy, bear the monetary costs associated with such protection. Given the ease with which information can be exchanged between health IT systems, patients whose physicians use them may feel that their privacy is more at risk than if paper records were used. (Health IT might also, though, support efforts to strengthen privacy by making it easier to track who accesses a patient's medical record.)

The Cost of Health IT Systems for Physicians' Offices

Estimating the total cost of implementing health IT systems in office-based medical practices is complicated by differences in the types and available features of the systems now being sold and differences in the characteristics of the practices that are adopting them. Many existing studies of the costs of implementing such systems lump together all direct costs (for hardware, software, licensing fees, installation, and training), do not include estimates of indirect costs (for example, practitioners' reduced productivity during the early stages of adoption), and spread the costs of implementation over different time frames.

The few detailed studies available report that total costs for office-based EHRs are about \$25,000 to \$45,000 per physician (Gans and others, 2005; Kibbe and Waldren, 2005).¹⁸ Estimates of annual costs for operating and maintaining the system, which include software licensing fees, technical support, and updating and replacing used equipment, range between about 12 percent and 20 percent of initial costs, or \$3,000 to \$9,000 per physician per year (Miller and others, 2005; Wang and others, 2003).

Those studies indicate that smaller groups of physicians typically pay more per physician than do larger offices to implement health IT systems (Gans and others, 2005). Other possible savings may not depend on the size of a practice. Nearly all physicians already use information technology to manage the business side of their practices. Thus, many offices may already have much of the hardware necessary to operate a health IT system and need only purchase the software.

18. The studies that CBO examined commonly report costs on a per-physician or per-hospital-bed basis. Some costs may vary in a given setting along those dimensions; others are more fixed.

Moreover, the prices of health IT products appear to be falling (Kibbe and Waldren, 2005). In particular, some Internet-based applications that are becoming available might substantially limit costs to an annual subscription fee that could be as low as \$2,000 per physician.¹⁹ (However, extremely low prices might signal lower quality and fewer components or features.) If prices continue to fall over time, the quantity and quality of the health IT systems that are purchased should increase.

Physicians who implement health IT systems typically experience an initial loss in productivity as they learn how to use the system and adjust the ways in which they practice. In a survey of health IT adoption conducted by Gans and others (2005), many physicians' practices reported that after they implemented a system, productivity in their offices dropped by between 10 percent and 15 percent for at least several months. A study by Miller and colleagues (2005) found that among a sample of 14 small physicians' offices implementing a health IT system, the average drop in revenue from that loss of productivity was about \$7,500 per physician. That amount may understate the actual loss in productivity, however, because in some practices, physicians worked longer hours to keep the practice's income the same as it was before the adoption.

The Cost of EHR and CPOE Systems for Hospitals

A few studies have examined the cost of implementing EHR and computerized physician order entry systems in hospitals.²⁰ Such calculations are difficult: Hospitals vary widely in size and type; a variety of different health IT applications may be implemented, and there is a general lack of data on costs. Those challenges limit the generalizability to other institutions of any single hospital's experience in implementing a health IT system.

For example, two studies—one in 2003 by First Consulting Group and the other reported in 2006 by Kaushal and colleagues—were carried out in teaching hospitals, making their results potentially unrepresentative of what would happen in a typical community hospital. First Consulting Group researchers used case studies of five

hospitals or multihospital groups to develop a model for estimating hospitals' costs for adopting a CPOE system. According to that model, a large 500-bed hospital would incur initial costs of \$7.9 million and annual operating costs of about \$1.35 million; a smaller 250-bed hospital would incur initial costs of about \$3 million and annual operating costs of approximately \$700,000. On average, implementation costs for the health IT system amounted to about \$14,500 per bed, and annual operating costs were about 19 percent of those one-time costs, or \$2,700 per bed.

The study by the Kaushal research group considered the cost of implementing a CPOE system at Brigham and Women's Hospital, a 720-bed academic hospital in Boston affiliated with Harvard Medical School. That study reported costs totaling about \$16,000 per year per bed for both implementation and maintenance between 1993 and 2002.

Researchers from the RAND Corporation (Giroi, Meili, and Scoville, 2005) estimated the costs of implementing CPOE systems using data from 27 teaching and nonacademic hospitals. That study reported a considerably higher average cost—nearly \$63,000 per bed. The RAND researchers estimated that annual costs for maintaining and updating the system would equal 30 percent of acquisition costs—a figure that is higher than the corresponding proportion in other estimates and that adds \$18,900 per bed per year. Although the RAND study used observations from a larger group of hospitals than the investigations discussed earlier, its sample was still quite small, and its estimates, as well as those of other researchers with small samples, should be viewed with caution.

Other factors may contribute to the variation in estimated costs for implementing hospitals' health IT systems. They include differences in the amounts and types of associated training and labor costs (for operating the system) that researchers may take into account and differences in the years from which the data are taken (because of changes from year to year in the technologies, in costs, and in other factors). The RAND analysts observed a relatively linear relationship between the number of beds in a hospital and the hospital's costs for implementing a health IT system and posited that health IT costs were budget driven; that is, such costs are influenced by the amount of money that the hospital has allocated for spending on health IT in general, and various

19. A list of those products and their prices as of September 2006 is available at www.physicianspractice.com/files/pdfs/theGuide_sep06.pdf.

20. EHR systems in hospitals generally include a CPOE component, so discussions of health IT in hospitals may use the two terms interchangeably.

projects, including an EHR or CPOE system, are funded as they rise to the top of the hospitals' list of priorities. Budgets for information technology for hospitals typically range from 1 percent to 3 percent of overall operating expenses. Hospitals that are part of integrated delivery systems with very sophisticated clinical IT capabilities (including those in outpatient settings) may have budgets for information technology that equal or exceed 4 percent.²¹

Possible Factors to Explain the Low Rates of Adoption of Health IT

In spite of the seeming advantages that health IT offers to physicians and hospitals, the proportion of those providers that actually use such systems is relatively small. Several factors may explain the low rate of adoption, including the challenges that arise in implementing the systems, the inability of providers to capture all of the financial returns of the health IT systems that they purchase, the possibility in the case of health insurance plans that the efficiencies they garner through the use of health IT will benefit their competitors, and uncertainty about the value of the advantages to be gained from adopting a health IT system and the evolution of laws affecting its acquisition and financing.

Challenges in Implementing Health IT Systems

Adopting a health IT system involves more than just deciding to spend money; it is a major organizational commitment that, for hospitals in particular, will probably last for several years. To take full advantage of such a system may require physicians to substantially redesign the way they practice medicine. EHRs are only as helpful as the information that goes into them. Some of that information is part of the system when it is purchased, but much of the technology's value comes when physicians devote considerable time to training, to personalizing the system, and to adapting their work processes to achieve the maximum benefits. Not surprisingly, the adoption rates for health IT systems are higher among younger physicians, who in general are more familiar with computers than their older colleagues (who were trained with paper charts as an integral part of patients'

care and who may be more comfortable using such tools in their practices; Grossman and Reed, 2006).

In implementing a health IT system, providers must choose from among a wide array of vendors and options. With so many choices (for example, more than 40 different EMR vendors) and rapidly developing technologies, many providers may be concerned about buying the wrong kind of system for their practice, acquiring technology that has already become outdated, or purchasing a poor-quality system. They may wish to postpone the decision until more of their colleagues have purchased systems, allowing them to benefit from others' experience. Research suggests that providers who have purchased an EHR system tend to be in practices in which at least one physician is technically savvy and able to champion the cause of health IT (Miller and Sim, 2004). But relatively few practices include such a physician, which may lead many providers to wait until the systems become more standardized and demand coalesces around fewer but better-known choices. The large number of vendors and products may slow down adoption in the short run, but the winnowing process that occurs as some vendors leave the market is likely to identify the products that deliver the greatest value per dollar spent.

As noted earlier, the prices of health IT systems are falling, and over time that decline should lead to an increase in purchases. One question is whether such increased demand would be constrained by supply problems for qualified technicians to install and maintain the systems. Indeed, hospitals and large provider groups have already begun to complain about the difficulty of finding qualified technicians to maintain their systems.

Providers' Inability to Capture Financial Returns from Health IT

Many, if not most, providers would like to make more use of health IT in their practices, recognizing the technology's potential to improve the quality of the care they provide, increase convenience for their patients, and perhaps reduce costs in their office. But many of those benefits accrue to others rather than to the providers who purchase the health IT system. As a result, many providers cannot generate the additional income necessary to justify the significant investment in time and money that the adoption of such a system would require.

Some benefits to be derived from health IT increase in value as the network of those using the technology

21. Personal communications to CBO staff from James Walker, Chief Information Officer, Geisinger Health System, May 19, 2008; and Len Bowes, Senior Medical Informaticist, Intermountain Healthcare, May 18, 2008.

expands—that is, as other providers also purchase health IT systems. Providers who can perform functions electronically (such as communicating with each other, sending and receiving medical records, prescribing medications electronically, and ordering laboratory and imaging procedures) gain when other providers develop similar electronic capabilities. For example, the cost to a primary care physician of sending medical data to a consulting specialist is far lower with a health IT system—as long as the consulting specialist has an interoperable system that can receive the data electronically. However, some so-called network benefits accrue mainly to patients or health insurance plans and only indirectly to providers. Examples include less duplication of diagnostic tests or increased availability of patient data in accessible repositories, which could lead to more research on the best practices for treatment and care.

Health IT can contribute to improvements in the quality of health care that providers deliver, but it is relatively rare for providers to be compensated for such improvements. Pay-for-performance programs are in effect in some managed care plans in the Medicaid program and as pilot programs in the fee-for-service sector of Medicare. Such programs do not create a strong incentive to invest in health IT systems, though, because the payments are fairly modest. Another approach that Medicare has adopted is to *not* pay for poor performance in some areas. CMS recently began a program under which it will not pay for certain occurrences that it calls “never events” or “serious preventable events” (Department of Health and Human Services, 2008). Never events include such incidents as leaving an object in a patient’s body during a surgery; operating on the wrong patient or on the wrong body part of the right patient, or performing the wrong surgery; precipitating an air embolism as a result of surgery (in general, an air embolism is a bubble of air in a blood vessel that may cause trouble if it moves to the heart or brain); and providing incompatible blood or blood products. Never events occur rarely, and not paying for a service that leads to such an event is unlikely to have a big effect on providers’ behavior in adopting health IT.

Other than through such programs, the financial rewards for physicians and hospitals from improving the quality of their care (or avoiding the provision of poor-quality services) are indirect. A physician’s reputation for providing high-quality care might improve as a result of investing in health IT, and patients might want to see a physician who uses an EHR because they believe they will get

better-quality care. Health plans, in recruiting doctors for their networks of physicians, might eventually find that doctors who used health IT systems were more attractive to patients than physicians who did not—provided that the plans could determine whether those doctors actually helped them attract and retain enrollees or lowered the cost of treating them.

Most networks of physicians today, however, cover nearly all the doctors in a given area, so physicians who were considering an investment in health IT would probably not include in their calculations whether their use of the technology would make their services more attractive to health insurers. They would also probably not expect to increase their income by improving the quality of the care they provided; thus, that factor would probably not be a key consideration for them. However, they might change their thinking if they knew that they would be directly compensated for implementing a health IT system or if they could report data on the quality of care that they provided—data for which they were being compensated—only by using such a system.

Other benefits, such as lower costs for maintaining medical records and transcribing clinical data, clearly accrue to the provider who purchases the health IT system. For example, Intermountain Healthcare reports that its savings from reducing transcription costs alone (as high as \$12,500 per year for some physicians) contributed substantially to paying for its EHR, which cost about \$2,500 per physician.²² But many providers, especially primary care physicians in small practices, might gain relatively little from implementing such a system because their practice would be too small to benefit from the efficiencies it would create. (For example, many providers would not save on transcription costs by purchasing a health IT system because they were not using transcription to begin with.)

Competition Among Health Insurance Plans

Health insurance companies may have an incentive to help providers acquire health IT systems: The technology could help lower the companies’ costs by improving both the quality of the care that providers deliver and patients’ health. But competition may limit the amount of assistance insurers give to providers to implement health IT

22. Personal communication to CBO from Len Bowes, Senior Medical Informaticist, Intermountain Healthcare, May 18, 2008; Clayton and others (2005).

systems because the same savings and improvements in quality that such a payer might reap if providers used a health IT system could also benefit competing health insurance plans.

For example, suppose Plan A paid an additional amount per unit of service to providers who used EHRs in their offices. That additional payment would probably be determined by the benefit per patient that the plan expected to receive from the physician's use of the system (a benefit that the physician could not capture). But Plan A could not realize all of that benefit, either because some of it would go to other payers—for example, Plan B, a competitor of Plan A, whose participants were seen by the same physician. If Plan B contracted with the same physicians that Plan A used but made no additional payment for the adoption of health IT, it would obtain the same benefit that Plan A obtained from improved quality and lower costs but would not have to pay for it. Thus, even though payers might gain many of the benefits that providers are unable to garner, a payer's inability to prevent competitors from also gaining those benefits may limit the assistance it is willing to give providers to obtain the technology.

Health insurance plans might also hesitate to help pay for the adoption of health IT systems by providers because they cannot fully capture the returns from improving the quality of health care services that such systems may bring. Health plans undergo open enrollment each year, and many enrollees switch from one plan to another during that time. Unless the improved quality of care yielded savings quickly, it would probably do little to motivate insurers to help providers adopt health IT. In fact, health care plans largely address the quality of health care services only to the extent that the employers who purchase coverage for their employees demand it. Many employers are beginning to ask plans to take steps to improve the quality of health care. However, even very large employers may have little leverage with insurance companies to encourage improvements because their workers are usually dispersed across the country. And few employers have enough employees in any one community to enable them to demand changes. In addition, the outcomes for people's health that improvements in the quality of care might provide are still unknown in many cases because not enough research has been done.

Rather than help providers obtain EHRs for their offices, some insurers use other types of electronic records, such

as personal health records (PHRs) and payer-based health records (PBHRs). The PHR is controlled by the patient, the PBHR by the health insurance plan (see the appendix for additional information). Both types of electronic record deliver at least some of the network benefits to payers that would be available if physicians used health IT systems, and they present fewer issues related to competition. For example, even though the information in PBRs and PBHRs is not at the same level of detail as the data in EHRs, such records could still help eliminate duplicate diagnostic tests and identify current medications and medical conditions through the data on insurance claims that they do include—information that would be helpful, for example, in a hospital emergency room. But even these alternatives to EHRs have encountered obstacles to implementation related to competition. Payers in some markets have been reluctant to share claims data and other information, fearing that competitors could use it to their detriment.

Worries that the use of health IT will benefit competitors are not limited to health plans. Hospitals and other providers may be concerned that such systems will cause them to lose some degree of control over what they may consider to be proprietary information: the information in their patients' charts. Patients always have the right to access their medical records, but if the records are paper, the impediments to doing so (including the need to make copies) naturally limit the number and nature of the inquiries they are likely to make. Medical data that are stored electronically, however, coupled with the growing availability and popularity of personal health records, imply less control of health data by providers and more control by patients—and potentially greater access to those records by other providers and health plans.

The increased availability of that information through the use of EHRs improves the quality of care for patients. (For example, a hospital emergency room with access to a patient's primary care physician's medical record can better treat that patient, and researchers have more data for evaluating the effectiveness of various medical treatments.) But some providers could lose patients to competitors; the fact that electronic medical records can be so easily transferred makes it easier for patients to change physicians. Providers might also worry that the ease of documentation and emphasis on greater transparency could have a negative impact if it showed them to be less competent than other competing providers.

Box 2.**The Federal Government's Activities as a Payer**

The federal government can influence the development and growth of health information technology (health IT) through its operation and management of federal programs that finance health care—in particular, Medicare, which accounts for about 20 percent of all third-party (insurance) payments in the United States, and Medicaid, a joint program with the states for which the federal government's share of spending accounts for 8 percent of third-party payments. In addition to those two programs, the federal government pays for or provides health care through the Military Health System, the Veterans Health Administration, the Indian Health Service, and the Federal Employees Health Benefits Program.

What exactly the government should require of health care providers in those programs is beyond the scope of this paper. It is reasonable, however, to expect that the government would ask the same questions asked by private health insurance plans about the costs versus benefits of various health IT systems and that it would either encourage or require participating providers to use systems that are consistent with sound management of federally managed or funded health care programs. Because the government is not concerned about competitive issues, its efforts with regard to health IT are not constrained by fears of benefiting health insurance plans in the private sector.

The Centers for Medicare and Medicaid Services (CMS), which runs Medicare, has undertaken a number of initiatives and programs that encourage the adoption of health IT:

- The Medicare Care Management Demonstration provides financial incentives to medical practices on the basis of their performance on 26 measures of clinical quality. Physicians who use an electronic health record (EHR) certified by the Certification Commission for Healthcare Information Technology and who submit performance data to CMS electronically receive additional payments.
- In another demonstration announced in October 2007, CMS will make bonus payments to small physician practices that use certified EHRs. All participating practices will be required to use a certified EHR to perform specific functions, such as clinical documentation and electronic ordering of prescriptions (e-prescribing), that can positively affect the quality of patients' care. The core incentive payment to the practices will be based on their performance on measures of quality, with an enhanced bonus based on how well integrated the EHR is in helping physicians manage care.
- In accordance with a recently passed law, CMS is implementing the Physicians Quality Reporting Initiative, through which physicians receive extra compensation for submitting data to CMS on the quality of the care they deliver. (Although physicians are not required to use health IT systems to prepare and transmit those reports, such systems facilitate that reporting.)
- CMS is working with Medicare Advantage plans, the program's managed care option, to encourage them to offer personal health records (described in the appendix) to their members.

Continued

Box 2.

Continued

The Federal Government's Activities as a Payer

- CMS published a rule in 2006 and recently proposed another that would establish standards for e-prescribing for the Medicare program. The rules do not require providers to use e-prescribing in their practices; however, if providers are planning to use such an application to prescribe medication for their Medicare patients, they must abide by the CMS standards.

In addition to creating payment incentives to encourage providers to adopt health IT, CMS is working—as are a number of private health insurance plans—to develop policies for the use of health IT and standards for the systems. For example, CMS is a member of the American Health Information Community (a federal advisory committee established by the Department of Health and Human Services, or HHS) and participates in many of its working groups. In 2007, CMS administered a total of \$98 million in grants to states for the Medicaid Transformation program; the bulk of those grants were focused on implementing e-prescribing, EHRs, and the capability for health information exchange. CMS also provides technical assistance to small and medium-sized physician practices to help them obtain health IT systems and coaching for practices that acquire health IT practice management systems.

Other federal agencies that purchase health care are also involved in efforts to further the development and broad adoption of health IT. The Department of Defense (DoD), the Department of Veterans Affairs (VA), and the Office of Personnel Management (OPM) have worked with HHS to adopt health information standards for use by all federal health agencies. As part of the Consolidated Health Informatics initiative, more than 20 federal agencies have

agreed to endorse standards that enable information to be shared among agencies and that can serve as a model for the private sector. OPM has agreed to create incentives aimed at encouraging providers to adopt health IT in its contracts with insurers that participate in the Federal Employees Health Benefits Program.

The VA and DoD are both extensive users of health IT. For several years, the VA has used an EHR, the Veterans Health Information Systems and Technology Architecture (VistA), in providing care to U.S. military veterans and, according to some empirical studies, has improved the efficiency of its health care delivery and the quality of the care it provides. The VA has made VistA an “open source” system—available to the public at no charge—thereby lessening the cost to providers of adopting health IT.¹ DoD has developed and is in the process of implementing an EHR—known as AHLTA [armed forces health longitudinal technology application]—for its health care system. Currently, AHLTA gives health care providers access to data about the conditions that beneficiaries are being treated for and their prescriptions and diagnostic tests, as well as additional information. DoD is also working with the VA to develop a way by which health information can be transmitted seamlessly and instantaneously between the two agencies.

1. The open-source version of VistA is known as WorldVistA. Although it is free, it is a relatively sophisticated system that may be intimidating for providers who have little experience with computers. An additional drawback for such providers is that WorldVistA may not come with the same level of on-call technical support and other similar types of assistance that are typically part of the EHR products of for-profit vendors.

The perceived loss of control of health data that makes some providers reluctant to adopt health IT may also make them hesitate to share information if they implement EHRs in their practice. Such reluctance has been a major stumbling block in efforts to establish and maintain regional health information organizations and to support greater exchange of health care information.²³

Regulatory Impediments

State and federal regulations regarding health IT are evolving. One major issue concerns federal rules related to donations of health IT that hospitals and other large providers may want to make to providers with whom they work. Recent changes in such rules have created so-called safe harbors that allow those donations to take place without violating prohibitions on physician self-referrals. But some providers, payers, and other participants in the health care sector may be reluctant to make or accept donations until the rules regarding them are clearer.

The Departments of Health and Human Services (HHS) and Justice have attempted to clarify those rules, but other agencies, including the Internal Revenue Service (IRS), are still developing their regulations. The IRS has addressed the question of nonprofit hospitals' donations of health IT to physicians, but it is still studying related issues, such as the tax-exempt status of regional health information organizations and of organizations formed by payers and others to promote the adoption of health IT.

A major aspect of policymaking in regard to health IT has to do with ensuring that proper safeguards are in place to protect confidentiality and patients' privacy. The ability of health IT systems to speed the exchange of data and expand the amount of information that is shared also increases the risk that the confidentiality of personal health care information could be compromised (although in one sense EMR and other systems could lessen that risk by making it easier to monitor who accesses a person's medical record). Efforts to clarify and update federal and state laws regarding privacy are well under way, but the final form of those laws is uncertain—another factor that could be constraining the widespread adoption of health IT.

23. More information on the challenges in establishing regional health information is available at www.ehealthinitiative.org/toolkit/alifin/VSMFiles/HRSA_CCBH_Report_Summary.pdf.

The Federal Role in Implementing Health Information Technology

The federal government is both a purchaser of health care services and a regulator of health IT. As a purchaser, the government has an interest in improving the quality and the value of the care provided by Medicare, Medicaid, and other federal health care programs (which together account for about one-third of total national expenditures on health care). If, indeed, health IT improves the quality of care while lowering its costs, then the federal government as a payer might consider actions that would facilitate the adoption of health IT, as long as the costs of those actions did not exceed the savings expected from them or the value of the improvements in care. (Box 2 on page 22 describes federal activities relating to the government's role as a purchaser of health care services.)

As a regulator, the government is helping coordinate and facilitate the development and use of health IT. In general, its regulatory actions have been limited to functions (such as developing standards for interoperability) that would appear to be more difficult, more time-consuming, or more costly than those that the private sector could deal with on its own. (Box 3 describes federal activities relating to the government's role as a regulator.)

Issues for Consideration

As the prominence of health IT has grown—in terms of its potential for increasing the efficiency and improving the quality of health care—policymakers have debated the appropriateness of the federal government's being involved in stimulating and guiding its adoption. Two factors lend support for such a role. The first is the federal government's position as a major purchaser of health care services through such programs as Medicare and Medicaid. As the manager of those programs, the government is responsible for running them efficiently and maintaining a level of quality in their services that reflects the views of the electorate as expressed by policymakers. As a payer, the federal government assesses the benefits and costs of health IT in its various forms, determines which elements of the technology should be required to run federal health care financing programs efficiently and at the desired level of quality, and takes appropriate steps to achieve the level of use of health IT that meets those criteria.

The second factor lending support to possible federal intervention in furthering adoption of health IT is that the technology has some characteristics of a public

Box 3.**The Federal Government's Activities as a Regulator and Funder**

The Department of Health and Human Services (HHS), through the Office of the National Coordinator for Health Information Technology (ONC), leads the federal government's efforts to encourage the adoption of health information technology (health IT). ONC's primary responsibilities are to coordinate the development of standards for health IT systems to ensure interoperability (the systems' capability to communicate with each other) and the development and implementation of a national health information network through which interoperable health information can be exchanged. (For additional information, see Box 1 on page 2.)

To help spur adoption of health IT, HHS has established a new rule—which was developed by the Centers for Medicare and Medicaid Services and the HHS inspector general—to make it easier for hospitals and other entities to give health IT systems to physicians. (The incentive for a hospital to provide health IT equipment and technical assistance to physicians who are associated with it is that such interoperable health IT systems may enable the hospital to better control its costs and improve the quality of the care it provides.) The new rule creates two new exceptions to a so-called physician “self-referral” law, which prohibits a physician—unless an exception applies—from referring Medicare patients for certain designated health services to entities with which the physician has a financial relationship. The two new exceptions are as follows: First, entities that furnish the designated health services may give to physicians interoperable electronic health record (EHR) software, information technology, and training services; and second, hospitals and other entities may provide physicians with hardware, software, or other information technology and training necessary and used solely for the electronic prescribing of medications. The rule also specifies that recipients of such health IT donations pay at least 15 percent of the price of the system.

HHS has also supported the development of health IT through grants administered by ONC and the activities of other HHS agencies. The department has funded efforts to enhance the privacy and security of personal health information, promote antifraud activities for EHRs, support the development of standardized measures of adoption for such records, and organize groups of qualified experts to advise the federal government in its activities concerning the clinical decision support feature of many EHRs. The Agency for Healthcare Research and Quality within HHS funds research and development to support and stimulate investment in health IT, especially in rural and underserved areas. The agency also created the National Resource Center for Health Information Technology, which provides technical assistance on health IT. The Health Resources and Services Administration within HHS provides technical assistance as well to health centers and other grantees in adopting model practices and technologies.

HHS has also provided funds to other entities. In 2005, it established the American Health Information Community (AHIC), a federal advisory committee made up of public- and private-sector leaders who represent a broad spectrum of health care stakeholders. AHIC was established to make recommendations to the Secretary of Health and Human Services on how to make health records digital and interoperable and ensure that the privacy and security of the records are protected; it is charged with accomplishing those goals by relying as much as possible on the private sector. (Other private-sector entities established with the assistance of HHS funding include the Health Information Technology Standards Panel and the Certification Commission for Healthcare Information Technology; see Box 1 for additional information.)

good—that is, a good that would be provided in a less-than-optimal amount by private markets if the government did not intervene. A fundamental characteristic of a public good is the presence of a free-rider problem, whereby some of the parties that directly benefit from the good are able to secure its advantages without being charged for them. Such goods are undersupplied because the receipts that they generate for their producers do not adequately represent their value to individuals (because consumers of the good can obtain its benefits without paying for them).

One feature of health IT that may qualify as a public good is the wealth of information that can be captured through EHR systems. (As discussed earlier, if researchers combined data from the EHRs of the population, they might be able to understand the spread and prevention of various diseases and injuries—and eventually develop cures and treatments; assess the effectiveness of various treatments; and more readily detect potential treatment hazards.) Some analysts contend that because such information is a public good—once generated, it would not be feasible to restrict its use—it is unlikely to be produced without the government’s intervention. According to that argument, the government has an interest in the adoption of health IT systems that could readily generate such data and therefore a reason to become involved in standardizing coding systems and methods. In addition, the government would want to encourage the recording of such information and subsequent analytical studies as well as the dissemination of results.

Health IT also resembles a public good because of its network effects: Some of its benefits increase in value as more providers purchase and use interoperable systems. Those benefits include, for example, being able to exchange relevant medical information electronically, a less expensive option than the use of paper. The additional user of health IT provides a benefit to existing users in the community that is available to all of them at little or no additional cost and from which it is difficult to exclude an existing user. Because a would-be purchaser of health IT fails to account for the value of the network’s expansion in calculating the benefits to be gained from implementing such a system, too few people (relative to the number that would enhance overall economic well-being to the greatest degree) will purchase health IT systems.

Given that the returns of health IT to the providers who invest in such systems are less than the returns to society as a whole, an argument could be made that the federal government’s intervention is necessary to raise the rate of the technology’s adoption to be more in line with its total returns. But the fact that health IT has some characteristics of a public good does not necessarily mean that the federal government must intervene, nor does it prescribe an appropriate form of intervention. Another alternative for enhancing adoption might be private-sector cooperative arrangements to help providers purchase systems that would be jointly funded by the participants and that would benefit the market as a whole. Some areas of the country, such as Indiana, boast successful regional health information organizations that, without federal assistance, facilitate the broad exchange of health care information within a community. Similarly, markets for products that have networklike benefits have developed in other cases without the government’s help. The market for fax machines, a product that provides network benefits, is an example.

Relying on private markets to act, however, would probably lead to a slower rate of adoption than if the federal government intervened. Private-sector participants would have to engage in time-consuming negotiations to reach agreements acceptable to most parties. By contrast, the government could either limit its intervention to such activities as setting standards and supporting the development of regional networks for health information exchange or act more broadly to encourage health care providers and payers to purchase health IT systems.

The government may also have a special interest in protecting individuals’ rights with respect to health information, especially in regard to privacy and people’s access to personal health records. Competing interests are involved in relation to privacy issues. On the one hand, people expect and hope that their individual privacy will be protected in electronic transactions regarding their health care. On the other hand, researchers seeking to improve health care outcomes would like relatively free access to health care data for use in their work. Many analysts believe that given those competing interests, the government’s involvement is critical in developing rules to protect individuals’ privacy in health care transactions but still facilitate relatively unfettered access to personal health records for the purposes of research.

Options for Federal Efforts to Promote Adoption of Health IT

If the federal government chose to intervene directly to promote the use of health IT, it could do so by subsidizing that use or by requiring it. Steps might include, for example, having Medicare pay an additional amount per billed service to providers who used EHRs or requiring that providers who wished to participate in Medicare obtain an EHR by a specified date or pay a penalty. From a budgetary perspective, the subsidization approach is less likely to generate cost savings for the federal government because of the direct budgetary costs of the subsidy.

Paying a bonus to providers that used health IT (in an amount less than or equal to the value of the providers' use of the technologies) would enable practitioners to capture more of the benefits that their use of health IT would produce and give them a stronger financial incentive to invest in a system. But that approach would be likely to lead to a net cost for the government—and possibly a large one. Even a small bonus could be expensive because it would be paid not only to those providers who newly purchased health IT but also to providers who already had such systems. Because a small bonus would attract relatively few takers, the bulk of the bonus would be paid to providers that already had health IT. A large bonus would entice more new purchasers, but it would add further to the overall net cost of the federal subsidy. (An alternative approach might be to target a subsidy to

various types of providers, the amount of which would depend on their ability to capture the financial benefits of health IT. Thus, providers who were associated with staff-model HMOs and other highly integrated organizations would receive relatively small subsidies, whereas solo providers would receive relatively larger amounts.)

A mandate to purchase health IT, or to purchase a particular functionality such as e-prescribing, by contrast, would probably induce nearly all providers to adopt it at a small cost to the government, and might produce net savings in health care spending. The requirement could be enforced either by not paying providers who failed to adopt such a system for other health care services that they delivered, or by imposing a specific penalty on those who did not comply. A less prescriptive version would involve paying providers without a health IT system less for any given procedure than providers with a health IT system were paid, which would create an implicit penalty for failing to adopt the technology. Either of those approaches, though, would come at a cost to providers, and that cost would be greatest for providers who were least able to capture the financial benefits of health IT systems. If policymakers are interested in promoting health IT, some version of a requirement or an explicit or implicit penalty for providers who fail to adopt health IT is likely to be more cost-effective for the federal government than a subsidy.



Appendix: Common Terms in Health Information Technology

Health information technology (health IT) is a broad term that is commonly used to describe the use of computers and electronic applications in providing and documenting medical care. The most common health IT terms include several types of health records—the electronic medical record (EMR), the electronic health record (EHR), and the patient health record (PHR)—as well as computerized physician order entry (CPOE), clinical decision support (CDS), electronic prescribing (e-prescribing), and interoperability. EMRs, particularly those in hospitals, in many cases include CPOE and CDS applications. Also part of the health IT landscape are the health information exchanges (HIEs) and regional health information organizations (RHIOs).¹

The *electronic medical record* is equivalent to the paper-based medical record that a health care provider maintains for a patient. The National Alliance for Health Information Technology defines it as “[a] computer-accessible resource of medical and administrative information available on an individual collected from and accessible by providers involved in the individual’s care within a single care setting.” The EMR contains demographic information and clinical data (related to the practice of medicine) on the individual, including information about medications, the patient’s medical history, and

the doctor’s clinical notes (Moshman Associates, Inc., and Booz Allen Hamilton, 2006). The EMRs currently in use vary considerably. Basic systems include patient information, doctors’ clinical notes, and results from diagnostic tests. Systems that are more sophisticated also include such features as e-prescribing and warnings about drug and allergy interactions. The most advanced EMRs add CPOE (see below), registry functions that support population management, and clinical decision support.² The variation in what different EMRs can provide has complicated measurements of the rate of their adoption and led to seemingly contradictory estimates.

An *electronic health record* is defined as “[a] computer-accessible, interoperable [see below] resource of clinical and administrative information pertinent to the health of an individual.” An EHR differs from an EMR in that information is drawn from multiple clinical and administrative sources and used primarily by a broad spectrum of clinical personnel involved in the individual’s care, enabling them to deliver and coordinate care and promote the person’s wellness. Any ambulatory-care EMR that meets the certification requirements of the Certification Commission for Healthcare Information Technology (see Box 1 on page 2 for more information) and that includes access to data sources beyond the physician’s office would be termed an electronic health record with the EMR embedded in it. Despite their differences, the terms “EMR” and “EHR” are often used interchangeably.

1. The definitions included here draw heavily on an interim draft document prepared by the National Alliance for Health Information Technology, with guidance from BearingPoint, Inc. The effort is funded by the Office of the National Coordinator for Health Information Technology to achieve consensus on definitions for five health IT terms: electronic health record, electronic medical record, personal health record, regional health information organization, and health information exchange.

2. Registries generally track patients who have a particular disease or who have received a specific treatment. They collect additional information (such as measures of health status or test results) that is typically not contained in insurance claims records.

A *personal health record* is another type of electronic record that is distinguished in part by who controls it: A PHR is controlled by the patient, whereas the EHR is controlled by the provider. The PHR is defined as “[a] computer-accessible, interoperable [see below] resource of pertinent health information on an individual. Individuals manage and determine the rights to the access, use, and control of the information. The information originates from multiple sources and is used by individuals and their authorized clinical and wellness professionals to help guide and make health decisions.” In contrast to the EHR, in which providers enter data, people who use a PHR manage the data contained in it. As a result, the quality and comprehensiveness of the information in a PHR vary considerably, depending on how much effort the patient wishes to expend and his or her access to data.

PHRs may and frequently do include data on insurance claims for medical services that the patient has received. (Some health insurance plans now provide PHRs to their members and insert their claims data.) By comparison, EHRs typically contain data that are more clinical in nature, such as the physician’s notes on treatment or services provided. (They may also contain data from other providers if the patient was referred to a specialist.) In essence, the PHR’s data are broad but not especially deep, whereas the EHR’s data are less broad but much deeper. The PHR, however, has the potential to be the basis for the electronic health record, the repository for all health data on a particular patient.

Many health plans and some employers now offer the use of PHRs to their members or employees, but while such a record can be a benefit to consumers, it may also raise questions about who owns the record, how it can be used, and whether the data in the record can be transferred if the person switches health plans or employers. Firms such as Google and Microsoft are now (or soon will be) offering a PHR product.

A *payer-based health record* (PBHR), yet another type of electronic health record, is owned and administered by a health plan. It includes whatever data are available to the health plan but primarily those related to claims. It may also include demographic information provided by the patient at the time of enrollment. It does not contain clinical notes; however, owing to the increasing amount of data required in submitting claims to payers, a PBHR may comprise laboratory results, radiological readings,

prescriptions, and complete reports for inpatient and outpatient hospital care, as well as other types of information. A PBHR may be useful—for example, when a patient visits a hospital emergency room—because hospital staff can access the record to obtain critical data on the patient, such as information that could help prevent adverse drug events.

Computerized physician order entry systems are electronic applications that physicians use to order medications, diagnostic (laboratory and radiology) tests, and ancillary services (Poon and others, 2004). Typically, such systems are used in hospitals, often with an EHR; however, many outpatient EHRs also provide CPOE functions. Because EHRs and CPOE are so often connected in hospitals, a facility’s health IT system may be described as either an EMR, an EHR, or a CPOE system, adding to the confusion over what system the hospital is actually using. (Studies that examine the effects of health IT in hospitals often measure reductions in duplicate orders for laboratory tests, and those reductions are possible only if the hospital has both an EHR and a CPOE system.)

Clinical decision support systems are often used in combination with CPOE functions in hospitals to assist physicians with decisionmaking by providing reminders, suggestions, and support in diagnosing and treating diseases and conditions. The range of features that CDS systems offer includes drug-dosing assistance, checks for drug allergies and drug-drug interactions, access to the latest evidence-based protocols, reminders about preventive-medicine tests, and guidance for complex antibiotic management programs. Both CPOE and CDS systems vary considerably in their complexity and capabilities.

E-prescribing is the electronic transfer of a prescription from the prescribing physician’s office to the pharmacy, which allows a patient to make only a single trip to the pharmacy to pick up the prescription once it has been filled. E-prescribing has received a great deal of attention but is not very common. Many physicians who have EHRs in place could easily generate prescriptions using the electronic record—and thus benefit from the CDS function that many EHRs include—but in the end they often print out a prescription for the patient to take to the pharmacy. Using the EHR to generate a paper prescription may reduce transcription errors and reduce the physician’s time and effort, but the patient must still deliver the prescription to the pharmacy.

Interoperability describes the capacity of one health IT application to share information with another in a computable format (that is, for example, not simply by sharing a PDF [portable document format] file). Sharing information within and across health IT tools depends on the use of a standardized format for communicating information electronically—both among the components that constitute a doctor’s office EHR (clinical notes, lab results, and radiological imaging and results) and among providers and settings that use different health IT applications. An interoperable health IT system would allow a hospital physician to view the contents of an EHR from a patient’s primary care physician and enable the primary care physician in turn to view all notes and diagnostic tests from the patient’s hospital visit. Interoperability is the feature that would allow the creation of a single comprehensive medical record that could follow a person throughout his or her life and from one geographic area to another.

A key component of interoperability is the establishment of a *health information exchange*, an “information highway” of sorts. An HIE is defined as “the electronic movement of any and all health-related data according to an agreed-upon set of interoperability standards, processes

and activities across nonaffiliated organizations in a manner that protects the privacy and security of that data; and the entity that organizes and takes responsibility for the process.” Without such an arrangement, a physician could still receive lab results in a computable format and use e-prescribing, but a hospital could not, for example, access information on a patient that is stored in the physician’s office EHR. Health information exchanges are even less common than EHRs; however, some integrated health care delivery systems, such as Intermountain Healthcare in Utah and southern Idaho and the Veterans Health Administration, share information within their networks and operate much like health information exchanges. However, because they have access only to data within the network, they may not have a comprehensive view of a patient’s record.

A *regional health information organization* is defined as “a multi-stakeholder governance entity that convenes non-affiliated health and healthcare-related providers and the beneficiaries they serve, for the purpose of improving health care for the communities in which it operates. It takes responsibility for the processes that enable the electronic exchange of interoperable health information within a defined contiguous geographic area.”



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