CRISP

CHESAPEAKE REGIONAL INFORMATION SYSTEM FOR OUR PATIENTS

A Plan for a Citizen-Centric Statewide Health Information Exchange in Maryland

Presented to the Maryland Health Care Commission and the Health Services Cost Review Commission

MHCC MARYLAND HEALTH CARE COMMISSION

HSCRC Health Services Cost Review Commission

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Executive Summary

We are at a unique moment in Maryland's history when driving forces have coalesced around the willingness, but more importantly, the ability to make transformative changes in the Maryland healthcare system by fostering the widespread deployment of health information technology (HIT). At the federal level, there is a clear commitment to transitioning the nation's healthcare system to electronic health records (EHRs), and the Obama Administration and the U.S. Congress are poised to allocate significant funding through the American Recovery and Reinvestment Act. Challenged by both the real and perceived shortcomings in technology solutions, privacy policies, and financial models that support health information exchange (HIE), many efforts around the country have been plagued by an interminable planning effort remaining within the confines of academic and conceptual discussions without the ability or desire to transition to the necessary and practical realities of implementation.

The Chesapeake Regional Information System for our Patients (CRISP) is an ad hoc collaborative, led by Johns Hopkins Medical Institutions, MedStar Health, The University of Maryland Medical System and Erickson Retirement Communities. In response to the Maryland Health Care Commission, CRISP has enthusiastically engaged in the challenge of planning a statewide Health Information Exchange for Maryland and has committed to the longer-term responsibility of implementation of that HIE. CRISP is a product of a commitment among these Maryland healthcare leaders to HIE and EHR adoption initiatives aimed at improving the quality of care in Maryland by facilitating the delivery of the right data to the right place at the right time within the confines of appropriate privacy policies. The HIE recommended in this report represents a careful balance between strong recommendations where appropriate and restraint when required for the future flexibility and ultimate adoption by the broad spectrum of Maryland's healthcare facilities and providers and their patients throughout the varied communities in Maryland.

CRISP has worked collaboratively with the other collective formed in response to the Maryland Health Care Commission's initiative, the Montgomery County planning group. It has done so believing that the two groups' shared experience will offer greater benefit to the citizens of Maryland. Ultimately, CRISP found that each group independently arrived at similar pathways to a mutual goal. Widespread support of the CRISP effort and understanding of the opportunity within the Maryland healthcare community, in Annapolis, and within the federal government has positioned the state for success and to serve as an example for other efforts around the country.

Through an intensive and deliberative process, CRISP has effectively distilled unavoidably complex issues into a number of key positions to develop and deploy a viable health information exchange for Maryland. Our key recommendations for achieving a viable HIE in Maryland are to:

01 Develop a hybrid technology approach, maintaining the confidential healthcare data at the participating facilities and providers, unless the consumer/patient asks for it to be held in a health record bank account that they control. Use the HIE as a secure and trusted conduit.

There are two general models for an HIE. The centralized model assumes that all participants' medical records will be kept in a central repository

(database), under the control of the HIE and out of the direct control of the participating entities. The other, sometimes referred to as the federated or distributed model, keeps the data at its source facilities or providers and posits the HIE as the conduit, providing a road map to the identification of individual information among participants and, upon receipt of a query from one participant, promptly and securely transmitting a copy of information in the systems of other participants. The CRISP-recommended HIE creates a hybrid of these two approaches and maintains a central Mast Patient Index (MPI) and a registry of the location of electronic health records within the system. The hybrid model also allows the centralization of records when directed by consumers, as discussed below. These functions do not constitute a centralized record, but rather directory information to allow records to be identified and located throughout the distributed system. This hybrid model, CRISP believes, is less threatening to participants and individual patients, because it is less disruptive to existing, trusted relationships between individuals and their care providers and, concomitantly, raises far fewer regulatory issues in today's privacy- and security-focused regulatory environment.

02 Ensure that consumers have access to and control over their health information through health record bank and personal health record applications.

Health record banks (HRBs) and personal health records (PHRs) established by health plans, health systems or commercial enterprises such as Google and Microsoft, are copies of patient health information that can be consumer controlled. Information may be derived directly from the records of healthcare providers or may be entered by the individual. While records from a PHR may not carry the imprimatur of legal accuracy that a healthcare provider's records do, individuals have virtually complete control over entry and access, mitigating, if not obviating, consumer concerns about sharing of their information in ways that individuals would not approve. Individual control can equate to individual trust. CRISP's recommended HIE can integrate with patients' PHRs, if the appropriate technology standards have been used. Most importantly, even if an individual is not willing to permit healthcare providers to share information from their records, the individual can limit the CRISP model HIE access to their HRB / PHR and to only those healthcare providers specifically authorized by the individual. This furnishes an easy entry point to participate in the HIE and is offered with the confident expectation that, once the benefits of an HIE are experienced, most patient will opt for greater participation.

03 Ensure that individuals have freedom to participate or not to participate in the HIE.

CRISP is committed to the principle that individuals have the right to be informed of their provider's participation in the exchange and to elect to "opt-out" of participation. If a consumer elects to opt-out, providers will not have the ability to exchange that consumer's information. This will be implemented through an intensive HIE and of consumers' rights, both through general information initiatives and through an opt-out process implemented at each point of care within HIE-participating healthcare providers.

04 Build an HIE that is consistent with emerging national technology standards.

The CRISP HIE will be based on federally-endorsed standards and integration protocols that bridge proprietary boundaries. Making this a core HIE principle will, CRISP believes, not only ensure that the HIE is invulnerable to vendor selection problems but is also compatible with HIEs being developed though other state and federal initiatives.

05 Act now but build incrementally.

CRISP recommends that the statewide HIE pursue an incremental growth strategy, building from individual "Use Cases"—individual HIE services that have a demonstrated need and demonstrable clinical value to patients and care providers. The alternative, implementation of an HIE that, from its inception, provides widespread exchange of all health information to care providers, in CRISP's estimation, runs a risk of setting such a high initial technological and provider/patient acceptance threshold that it would miss the current window of opportunity and create unrealistic expectations. CRISP participants have already established a working HIE that focuses initially on one

Use Case, the provision of medication information to the emergency rooms of participating facilities. Success is relatively easy to demonstrate and will lead to broader adoption as new Use Cases are adopted. In this way, HIE growth is driven by clinical value and fosters near-term progress while planning for long-term success.

06 Recognize the key role of physician EHR adoption in HIE success.

CRISP understands that the current low adoption rate of EHRs by private physician practices in Maryland cannot be ignored when considering the potential value derived from an HIE. Approximately eighty percent of physician practices in the state have yet to adopt electronic health records. Without enabling broad participation by physicians in the HIE, sustainable value cannot be readily achieved. CRISP is convinced that any successful HIE should include, at minimum, a provider portal for web-based access into HIE-transmitted health information and would preferably include a clear pathway for physician practices to migrate easily from an inquiry portal to an entry-level EHR (with limited functionalities such as e-prescribing and clinical messaging) to a fully-functional, integrated and certified EHR.

07 Develop a financially sustainable HIE.

A successful HIE is one that can sustain itself financially for the long term and is not reliant on long term public or grant support. CRISP believes that its Use Case approach supports this important goal.

08 Focus on the medically underserved.

CRISP participants recognize that the inclusion during the planning phase of communities facing healthcare disparities and inequities has been a critical driver in maintaining focus on that demographic. The inherent challenges of HIE could threaten to exclude this important population as the complexity of basic HIE issues are addressed. The CRISP team has ensured that resources and focus remain directed to this particular component of the overall HIE problem, as it represents an important part of the solution and a key part of the quality, access and cost challenges in healthcare.

In summary, CRISP believes that a Maryland statewide HIE requires a technical approach that is flexible, a policy and privacy approach that is protective yet not prohibitively restrictive, and a financial approach that is sustainable. Most importantly, CRISP has concluded that HIE success hinges on physician inclusion in the HIE deliberation and decision-making process. Health information exchange success in Maryland cannot be developed in isolation from realities of our healthcare system, however progressive its policies or advanced its technology; rather, HIE success will ultimately require that constituents using the exchange play a critical role in its development. By pursuing the strategies outlined above, and discussed in detail in the report that follows, Maryland has an opportunity to create an invaluable resource for the entire healthcare community. The known and yet-to-be discovered benefits of health information exchange, and more broadly, health information technology, will enable opportunities to improve quality, increase safety and ultimately decrease the cost of healthcare in Maryland.

Introduction

Widespread adoption of health information technology (HIT) promises to improve healthcare quality, prevent medical errors, and reduce healthcare costs by delivering essential information at the point of care.[1] A 2006 report commissioned by the U.S. Department of Health and Human Services (HHS), which scanned a wide range of scientific studies and academic research, included in its findings that implementation of comprehensive ambulatory electronic health records (EHRs) improves quality of care. The HHS report suggested tangible clinical benefits from specific implementations of HIT, such as adding various types of information related to laboratory test and prescription ordering to EHR ordering screens improved the quality of care and increased the efficiency of test ordering.[2] Within the context of widespread adoption and interconnectivity, such incremental improvements, both in care quality and cost, offer the prospect of transforming the American healthcare system, where spending on healthcare currently amounts to approximately 16 percent of GDP, according to the U.S. Department of Health & Human Services' national health expenditure data.[3]

[1] The Markle Foundation, for instance, as part of the Connecting for Health initiative, has conducted a rigorous and comprehensive net value analysis of HIT adoption, identifying and beginning to quantify benefits such as additional charge capture, reduction in billing errors, efficiency gains through employee reduction or redeployment, and an environment that allows for performance-based care and incentives. The analysis also highlights a number of key risks, including a misalignment of incentives, high up-front adoption costs, increased operational burdens, and challenges to achieving interoperability. See "Financial, Legal and Organizational Approaches to Achieving Electronic Connectivity in Healthcare" (Markle Foundation).

[2] Shekelle et al. "Costs and Benefits of Health Information Technology" Agency for Healthcare Research and Quality (April 2006).

[3] "NHE Fact Sheet" (Centers for Medicare & Medicaid) http://www.cms.hhs.gov/NationalHealthExpendData/25_NHE_Fact_Sheet.asp#TopOfPage (July 25, 2008).

In spite of this immense promise, significant challenges remain to the widespread adoption and integration of HIT. These challenges include poorly aligned incentives for many providers, concerns around privacy and security, interoperability shortcomings and high costs of implementing and supporting some technologies. Certainly, these challenges are not insurmountable, and the potential benefits warrant a focused, transparent, and collaborative approach to overcoming them.

To this end, the Obama Administration has articulated a goal, originally defined by the Bush Administration, for most American citizens to have an electronic health record by 2014. The Administration has pursued this agenda through the Office of the National Coordinator (ONC), which was created in 2004 when President Bush issued an executive order establishing the position of the National Coordinator for Health Information Technology (NCHIT) within the Office of the Secretary of Health and Human Services (HHS).[4] The mission of the ONC, in the words of President Bush in a speech on January 31, 2006, is to encourage the "wider use of electronic records and other health information technology to help control costs and reduce dangerous medical errors."[5] A number of other initiatives in both the government and private sector are also working to define policy and technical standards for HIT. The most prominent initiatives are:

[4] "Background" (The Office of the National Coordinator) http://www.hhs.gov/healthit/onc/background/ (October 2008).

[5] "Mission" (The Office of the National Coordinator) http://www.hhs.gov/healthit/onc/mission/ (October 2008).

- The American Health Information Community (AHIC) is a federally chartered advisory board, chaired by the Secretary of the Department of Health and Human Services, to be a strategic coordinator for developing national standards for HIE.

- The Certification Commission for Health Information Technology (CCHIT) is an independent, private sector organization focused on certifying health IT products.

- The Health Information Technology Standards Panel (HITSP) is a public/private partnership for bringing together relevant stakeholders to agree on interoperability standards for health IT.

- The Health Information Security and Privacy Collaboration (HISPC) addresses variations in business policy and state law that affect privacy and security.

- The National Health Information Network (NHIN) is focused on interoperability pilots to demonstrate nationwide health information exchange.

Based on on-going statements of support and draft legislation, the Obama Administration is poised to significantly increase the previous administration's attention to and support of HIT. Regardless of the form of the final legislation, state efforts will take a leadership role in driving progress on the ground. Already, Maryland has taken action to position itself among a handful of states that are driving adoption and innovation in HIT.

Leadership in Maryland

For the robust exchange of data (within an appropriate framework of privacy protection) to be achieved, HIT adoption and interoperability are inseparably intertwined. There are three crucial components of an effective and robust HIT future state: widespread use of EHRs by providers, the ability to exchange health information privately and securely, and the engagement of consumers in their own healthcare. The Maryland Health Care Commission (MHCC) has addressed some of these components through the work of two multi-stakeholder efforts:

01 The Task Force to Study Electronic Health Records, a legislatively sanctioned workgroup of twenty-six members studying key policy, privacy and economic issues facing health information exchange in Maryland. The Task Force delivered its report to the Governor and the General Assembly in December, 2007.

02 The MHCC Privacy and Security Study to identify and analyze potential barriers to HIE from the perspectives of various healthcare stakeholders.

The Task Force explicitly declined to recommend a specific design and infrastructure for HIE in Maryland, believing that options had not yet been fully developed and analyzed. Consequently, the MHCC and the Health Services Cost Review Commission (HSCRC) proposed a two-stage strategic plan for advancing statewide HIE in Maryland. Phase one consisted of two parallel planning projects by multi-stakeholder groups so as to uncover the best ideas for HIE throughout the state.[6] Phase two, to commence in 2009, will follow as a single implementation project to build and operate a statewide HIE.

This report constitutes the final work product and recommendations from one of the phase one planning projects, the Chesapeake Regional Information System for our Patients (CRISP). The multi-stakeholder group was initiated by Erickson Retirement Communities and the State's three largest hospital systems, Johns Hopkins Medicine, MedStar Health, and the University of Maryland Medical System, with participation and collaboration from a wide range of other healthcare organizations and stakeholders.

The participants reaffirm that the State has a prominent role to play as a participant in future HIE in Maryland, including but not limited to MHCC and HSCRC

[6] A Citizen-Centric Health Information Exchange for Maryland: Request for Applications (March 2008).

leadership in rate adjustments, legislative proposals to foster adoption and interoperability, and continued thought-leadership and initiative in bringing a wide range of interested parties into dialogue about the operations and governance of the HIE. As described in the preceding section, Maryland has established itself as a leader among states in its proactive and creative approach to encouraging HIT adoption. It is the belief of the CRISP participants that our work has added meaningfully and significantly to the body of knowledge currently being generated by the planning effort. In the report, we have summarized CRISP's considerable progress during the planning phase, while also identifying key risks and challenges, in the process laying out a blueprint for the coming statewide HIE implementation. Further, throughout the report, there is recognition that the health IT landscape is continually being redefined and molded through various public and private efforts. The CRISP team felt, in certain areas, that while robust discussion took place and recommendations were generated that could apply today, in consideration of the constantly changing industry it would be irresponsible to articulate absolute recommendations without the flexibility to react to a changing health IT environment. The sum of this report represents a balance between strong recommendations where appropriate and restraint when necessary for the future flexibility and success of Maryland's HIE efforts.

The CRISP Planning Process

The planning team was led by a steering committee that provided oversight of the nine-month planning process. The steering committee convened for one call per month and one face-to-face meeting per quarter. Membership of the steering group was comprised of leadership from the four principal members of CRISP: Erickson Retirement Communities, Johns Hopkins Medical Institutions, MedStar Health, and the University of Maryland Medical System, as well as the executive director of the Erickson Foundation.[1] This group intends to persist in some form after the planning project, to continue overseeing the ongoing electronic medication history service pilot (described later in this report) and to play a leadership role in the developing statewide HIE. The Erickson Health Information Exchange, LLC, a subsidiary of the 501(c)3 non-profit Erickson Foundation formed to administer the planning grant and functioned as project manager, retaining consultants, contracting for technology services, coordinating with hospital staff, and engaging partners, as directed by the steering committee and the workgroups.

[1] See Appendix B for a complete list of steering committee members and affiliations.

At the outset of the planning process, the steering committee authorized three workgroups to address various elements of the project, providing each with a budget and a mandate. The workgroups included members from the participating hospital systems, Erickson, consulting firms, and various stakeholder groups. The consulting firms included, but were not limited to, Audacious Inquiry, LLC for project management and strategic advisory services, Ober|Kaler for legal and policy review services, and Dynamed Solutions for management and consulting services. The planning group also requested that MHCC resources commit their time, expertise and state perspective to the various workgroup's efforts, and their input was critical to the progress made. Furthermore, the group evaluated the unsuccessful responses to the planning RFA and invited selected stakeholders from those groups to join the planning process via workgroup participation. The group also communicated and coordinated with leaders of the other planning project, The Montgomery County HIE Collaboration, in an effort to maximize the value the state derived from the planning process.

Workgroups and Planning Process

The steering committee authorized three workgroups to address various elements of the project in depth. The workgroups were: Community Interaction & Privacy and Security, Exchange Technology & Clinical Workflows, and Business Development & Finance. The workgroups included members from the participating hospital systems, Erickson, consulting firms, and various other stakeholder groups. The workgroups met monthly, in person, for two hours during the planning project, with detailed minutes taken. Each workgroup had a designated chairperson who served as meeting moderator. Separately, staffers conducted one-on-one meetings with workgroup participants to ensure all participants had the opportunity to contribute and voice perspectives.[2]

[2] See Appendix C for a complete list of workgroup members and affiliations.

Overview of the CRISP Planning Structure

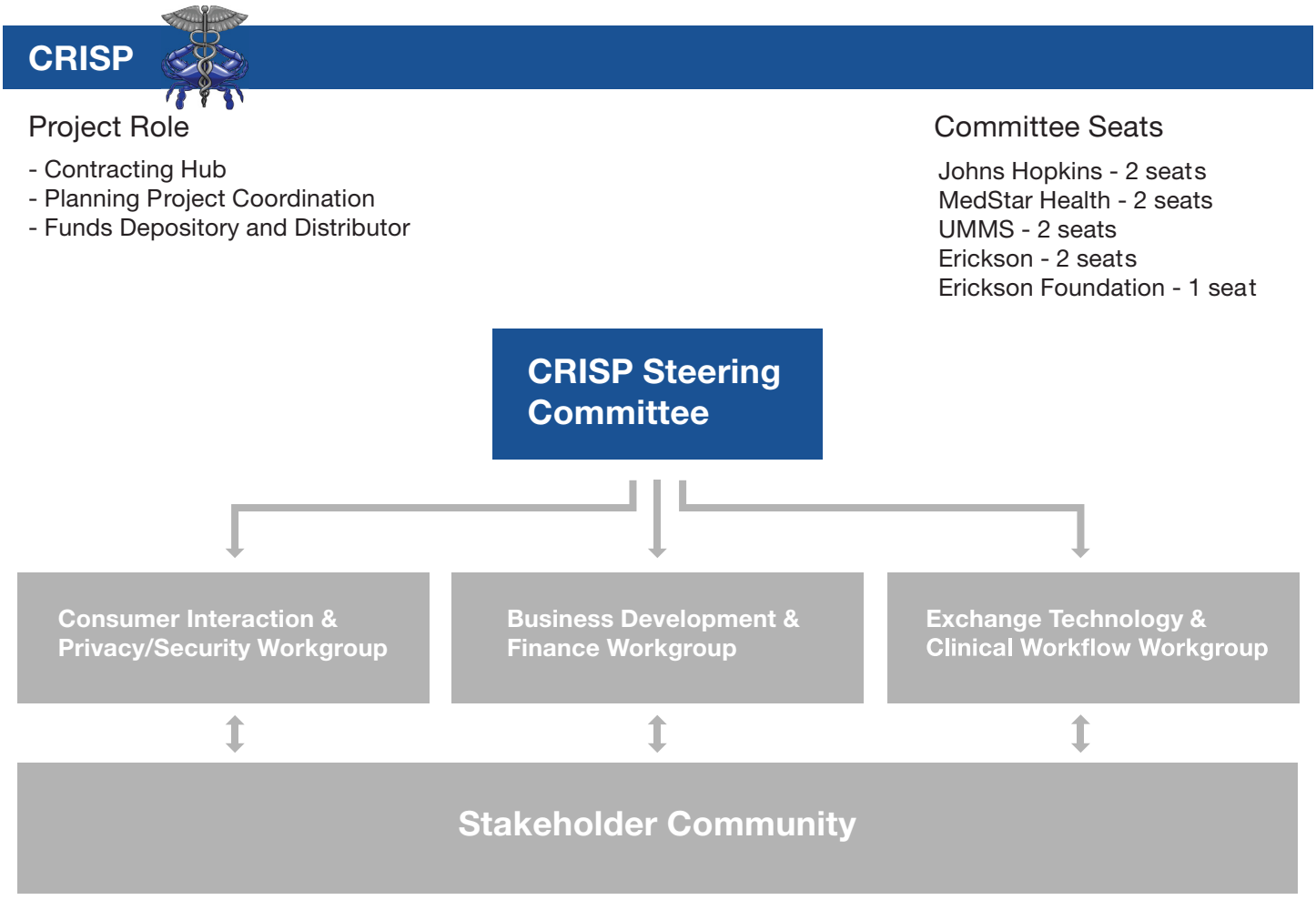

FIGURE 01

Community Interaction & Privacy and Security

The Community Interaction & Privacy and Security workgroup was comprised of members with clinical, legal, technology, and regulatory expertise across a range of healthcare topics. The workgroup included representation of disadvantaged populations and those underserved by the healthcare system in Maryland through:

- Baltimore Medical System, a network of seven clinics serving over 42,000 patients in many of the neediest communities within Baltimore City and Baltimore County—communities with high rates of unemployment and poverty, low levels of education and job skills and few or no health services.
- The Shepherd's Clinic, a non-profit health clinic in Baltimore City providing primary and specialty healthcare to Baltimore residents without medical insurance—people unable to afford the high cost of private insurance but who do not qualify for government healthcare programs.
- The Summit Health Institute for Research and Education, Inc. (SHIRE), a nonprofit organization promoting health and wellness for all people by working to eradicate health disparities and aid vulnerable populations in attaining optimal health.

Discussion during the sessions was guided by the Markle Foundation's Common Framework, a set of privacy and security policies, and model contract language that has

The Markle Foundation's Common Framework (Source: Connecting for Health, 2006)

The Common Framework: Overview and Principles

Policy Guides: How Information is Protected

1	The Architecture for Privacy in a Networked Health Information Environment
2	Model Privacy Policies and Procedures for Health Information Exchange
3	Notification and Consent When Using a Record Locator Service
4	Correctly Matching Patients with Their Records
5	Authentication of System Users
6	Patients' Access to Their Own Health Information
7	Auditing Access to and Use of a Health Information Exchange
8	Breaches of Confidential Health Information
9	A Common Framework for Networked Personal Health Information

FIGURE 02

been tested for the last several years by prototype teams in three states: California, Indiana, and Massachusetts.[3]

Exchange Technology & Clinical Workflows

The Exchange Technology & Clinical Workflows workgroup was comprised largely of clinical professionals from hospitals and other healthcare organizations, with further representation from experts in health IT. The discussion was organized around the Integrating the Healthcare Enterprise (IHE) model, an international approach to implementation plans and guidelines for addressing HIT interoperability challenges. IHE has published a number of technical frameworks, organized into domain areas. While IHE originated in the radiology domain area, the Information Technology Infrastructure and Patient Care Coordination domains specifically address challenges relevant to this report.[4]

[3] "Connecting for Health – Common Framework" (Markle Foundation) http://www.connectingforhealth.org/commonframework (2006).

[4] Deborah Kohn, MPH, RHIA, CHE, CPHIMS, "Integrating the Healthcare Enterprise (IHE): An International Approach to the Development of Implementation Guides for Electronic health records Systems" (HIMSS Technical Paper, 2004).

Business Development & Finance

The Business Development & Finance workgroup was comprised of executive management and financial staff from healthcare organizations as well as healthcare policy experts. The discussion was structured around the eHealth Initiative's Value and Sustainability Model, a publicly-fund methodology for assisting in the establishment of value quantification of HIE participation and articulating a business plan with financial pro-formas.[5] The Value and Sustainability Model was developed during four years of federally-sponsored research through the Health Resources and Services Administration Office for the Advancement of Telehealth (HRSA/OAT).

Overview of Plan Components

The exchange should operate using the standards that have been promulgated by the federal government, through HITSP, and adopted by an increasing number of technology vendors. This approach includes the use of the IHE profiles discussed above, appropriate for supporting both distributed data models and health record banks or personal health records.

Health records banks, in this document, are generally defined as aggregators of many PHRs on behalf of and at the direction of patients. Health record banks and personal health records are thus distinct terms; however they are linked throughout this document, as both can enable consumer engagement, consumer access and consumer control of personal health information. A distributed data HIE is one in which the data, in this case healthcare information, resides in the participating entities' systems. The HIE serves solely as the directory to, and conduit for, the personal health information so that it may be shared among participating hospitals and providers. This is distinct from a centralized model HIE, in which a central repository for patients' personal health information is housed by the exchange.

The distributed model, recommended by the Markle Foundation and others, is easier to establish with participating hospitals and providers than a centralized HIE, since there is no loss of control over the legal medical record. The model is less threatening to individuals concerned about the privacy of their personal healthcare information; and much simpler to establish in terms of federal and state privacy of medical information laws. The HIE that CRISP recommends would also have the capability to draw on data from patient-controlled health record banks or personal health records. Increasingly, individuals are able to establish secure, online personal health records that are independent from any one insurer or provider, enter into the health record bank whatever information the patient chooses, and control designation of third parties, including healthcare providers, who are allowed to have access to the records the individual has chosen to put into the bank. The HIE should be designed and operated to support health record banks as nodes on the broader exchange network.

The core infrastructure of the distributed exchange model should adhere to generally accepted specifications and healthcare technical standards, such as the IHE approach, addressed in more detail in the Infrastructure and Data Management section. However, the model will not exclude, and will ultimately drive towards, the technical capability to develop centralized repositories of health information where it is deemed appropriate, in the interest of the consumer (as defined by the consumer), or for the purpose of using de-identified data for various population health and bio-surveillance purposes. Furthermore, the exchange will be developed to support other commercially viable services and entrepreneurial innovation as the marketplace allows (such as disease management tools and care alert tools), spurring Use Cases not initially anticipated by the CRISP stakeholders but found appropriate within the policy and legal framework agreed upon by the state. While commercially viable, value-add services will inevitably tie into the HIE. The HIE must ensure that there is absolutely no use of patient data for commercial purposes without specific patient authorization.

We recognize that achieving incremental progress and rapid, demonstrable value are critical to the initial germination—and future sustainability—of any HIE. This has been proven again and again during planning and implementation projects in other states.

[5] "Resource Center" (Electronic Health Initiative – Connecting Communities Toolkit) http://toolkit.ehealthinitiative.org/value_creation_and_financing/VSMhome.mspx (June 2007).

Consequently, CRISP recommends a scaled approach to clinical service offerings. This scaled approach builds the HIE incrementally, based on individual HIE service scenarios. Each scenario is a specific Use Case (for example, making an individual's medication history or discharge summaries available to participants) that is a need of participants and is driven by demonstrable clinical value. The basic CRISP Use Cases are discussed elsewhere in this report. In fact, this "Use Case approach" to service deployments is already well underway; concurrent to the planning process, CRISP initiated an electronic medication history service pilot project, funded by the Erickson Foundation. The medication history service went live in its first hospital, the Memorial Hospital at Easton, in the fall of 2008. In addition to validating the value of clinical data exchanges and broader HIT, the medication history service has given the CRISP stakeholders important implementation experience and has introduced countless providers and hospital administrators outside the CRISP planning process to the dialogue about advancing HIE in Maryland.

Principles Overview

Early in the CRISP planning process, the team began discussions of core guiding principles that would help in both setting and maintaining the course of the planning effort. These principles were developed based on in-depth research conducted by CRISP team members of HIEs around the country, robust knowledge of and insight into the Maryland healthcare landscape, and an understanding of, and agreement with, MHCC articulated goals and principles. The intent of these principles is to enable future healthcare quality improvements and patient safety opportunities associated with HIE. Despite deliberation and debate on the complex issues surrounding policy, technology, and finance, the guiding principles established at the outset of the project remained largely unmodified. This underscores the framework by which the CRISP participants believe an HIE in Maryland can be successful. These principles are outlined below accompanied by a brief explanation for each.

Begin with a manageable scope and remain incremental

A fundamental component of the strategy defined in this proposal is the adoption of an incremental approach for the implementation of HIE services referred to as Use Cases. The HIE should begin with services that have the clearest clinical value and technical achievability and fit within the privacy and security framework defined in this report.

Create opportunities to cooperate even while participants still compete in other ways

CRISP recognized early that in order for an HIE to be successful it must not seek to eliminate information technology as a strategic advantage but rather must embrace competition between partner organizations. HIE can indeed create new forms of competition while improving patient safety and quality of care.

Affirm that innovation and improvement will be better ensured, in the long run, by competition and market-mechanisms rather than by a central planning committee

While the exchange will "seed" the market with core HIE services, referenced in this document as Use Cases, commercial businesses must have the ability to offer the healthcare community applications and services that can build on and leverage the exchange infrastructure. Ultimately, it is this approach that can improve the quality and relevance of service offerings and build towards sustainability.

Promote and enable consumers' control over their own health information

Consumer access and control is a key component of the CRISP architecture model and the approach to HIE in Maryland. This control allows the healthcare community to engage consumers in new ways, building towards a consumer-centric healthcare model and promoting consumer engagement in their day-to-day health management and wellness.

Be flexible to support both distributed and data bank models

CRISP does not believe that a single HIE architecture model has been widely accepted as an industry standard and preferred solution. To ensure the Maryland HIE has the ability to adapt to a changing environment for technology, policy, and consumer engagement, the model must be able to support both a distributed data model and a consumer-driven centralized model.

Use best practices and standards

In an environment rife with interoperability challenges, the Maryland HIE must ensure review and adherence to generally accepted best practices and standards as they evolve and maintain attention to federally-endorsed standard and practices.

Equally serve the entire Maryland healthcare community

Maryland's successful implementation of an HIE hinges on striving to serve the entire healthcare community instead of specific hospitals, practices or other healthcare organizations. Access to exchange services must not only focus on metropolitan areas, but seek to be inclusive of rural areas and expand HIE services both geographically and organizationally.

Legal & Regulatory Considerations

The early exchange, in which Use Cases will generally be focused on treatment purposes, will respond to concerns about patient control over health information in two ways: by executing transactions to pull health information on an encounter-by-encounter basis, as in the case of medication history, and by providing the patient clear notice of the HIE and a right to opt-out of participation in the exchange.

Health Insurance Portability and Accountability Act

CRISP has reviewed the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and used it as a guide for the design of the HIE recommended in this report. It is clear that HIPAA does not require any patient consent or authorization for the exchange of individual patient's health information among healthcare providers for treatment purposes. A patient's consent to such exchanges is viewed as implicit in the patient's consent to receive medical care. Certain other exchanges are also permitted without either consent or authorization under both HIPAA and the Maryland Confidentiality of Medical Records Act (CMRA), generally for payment purposes and for certain healthcare operations constituting quality assurance, reviewing provider qualifications, and fraud and abuse monitoring or response. In addition, HIPAA permits disclosures to government agencies for a number of lawful purposes, including public health surveillance without patient consent or authorization. Other disclosures, as further Use Cases are adopted, will require patient specific authorization (which the patient can withhold) in a form that meets the requirements of HIPAA.

In December of 2008, the Office of Civil Rights of the Department of Health and Human Services, the HIPAA civil enforcement arm of the Department of Health and Human Services, issued a series of related papers on the HIPAA Privacy Rule and Health Information Technology (the "Guidance").[1] The Guidance constitutes an overview of HHS' positions on the application of the HIPAA Privacy Rule to electronic health information exchanges. In general the Guidance is consistent with, and supportive of, the type of HIE discussed in this report. The Guidance deals with a model of HIE that is, in operational terms, the same as the model CRISP has proposed for Maryland—treatment purpose focused and with the HIE as a conduit for the exchange of information among participants, not as a central repository of participants information. While recognizing that patients' consent to the exchange of their information among healthcare providers for treatment purposes is implied in the general consent to be treated and does not require specific affirmation by the patient, the Guidance favors allowing individuals the opportunity to opt-in or to opt-out of having their information flow through the HIE. The Guidance refers in this regard to the option providers are given in the HIPAA Privacy Rule to seek patient consent for treatment uses and disclosures, even in the absence of a requirement that providers do so. In addition, the Guidance affirms that an HIE, as a business associate, can maintain a master patient index (MPI) and a registry for patients of participating providers, in advance of any actual treatment communications for those patients.

[1] The HIPAA Privacy Rule and Health Information Technology (HIT), posted on the website of the Office of Civil Rights on December 15, 2008.

Maryland Confidentiality of Medical Records Act

The Maryland Confidentiality of Medical Records Act is substantively consistent with HIPAA with regards to implicit consent and the other HIPAA issues discussed in the preceding section. Under the Act, an individual's health information may be exchanged among healthcare providers with only implicit consent for treatment purposes. In addition, the Maryland Attorney general, in 2007, issued an opinion related to the CMRA which addressed the requirement of a patient opt-in versus opt-out policy in an electronic health records system. According to the opinion, "a patient does not have a right under the Act to 'opt-out' of an HIE—to receive services from a healthcare provider while insisting that the medical records related to that service be excluded from the HIE." The Attorney General went on to conclude that "the disclosure of medical record information solely for purposes of clinical care and payment and to the technical personnel needed to keep the system operational, as discussed above, is permitted "without the authorization of" the patient. The phrase "without the authorization" is not compatible with a patient's exercise of a veto over otherwise permissible disclosures. "Opting out" is simply a denial of authorization. A patient, however, has no right to deny that which is not required at all. Thus, in our view, the CMRA does not prohibit an HIE from operating on the basis that participating healthcare providers must make all of a patient's medical records available through the HIE. However, because the law does not dictate appropriate policy, an important caveat to the interpreted allowance is that "making a patient's medical records" available does not imply those records are stored within the exchange. As described earlier in this document, demographic and core encounter information used to locate records that are stored outside of the exchange is the only patient information held centrally in our proposed model. We believe this approach will foster adoption of the exchange by avoiding the negative perceptions of the wholesale transferring or storage of consumer's health information and by reinforcing the sentiment that consumers have rights to the way in which their information is handled and exchanged.

In the opinion, the Attorney general concluded that the CMRA would permit an HIE in which medical records are held by certain providers and referenced in an index (often called a mast patient index, or MPI) facilitating other providers' access to the records as needed "without the authorization of" the patient.[2] This indexing function is a critical element of the approach we have proposed.

Conclusion as to the Medical Information Privacy Regulatory Environment

CRISP views HIPAA and the CMRA, particularly as interpreted in the recent pronouncements discussed above, as consistent with, and in fact supportive of, the type of HIE recommended by CRISP. Both Acts support the transfer of more data earlier in the life of the exchange, for treatment purposes at least, which could lead to greater adoption of both EHRs and in entity participation in the exchange due to the fact that one measure of the value of the exchange will be the amount of data available. The growth rate will accelerate as more data comes online, and an opt-out policy could foster exchange usage.

Further, provider workflow considerations and management of a patient's right to participate or not to participate are also of considerable concern in creating a consent policy. If patient participation rights were to be managed on a provider-by-provider, encounter-by-encounter basis, providers would bear a significant, and potentially prohibitive, technical and workflow burden establishing processes for obtaining and tracking consent of their patients.

In developing a patient participation rights policy for the exchange, ensuring patient privacy and consumer choice protections without handicapping the exchange by excluding large amounts of health information (because of an opt-in consent/participation policy) is a difficult task and one the CRISP workgroup spent significant time deliberating. The challenge is to develop a policy that allows for a robust amount of patient data early on

[2] Maryland Confidentiality Medical Records Act, Maryland Attorney general's Opinion, 2007

in the life of the exchange, thereby increasing the value to participating providers, while still affording consumers notice and the ability to exercise their right of exclusion from the exchange. We believe the proposed opt-out approach is the best way for the exchange to achieve this balance.

Policy Formulation

Exchange Policy Regarding Patients' Rights to Determine Participation

The services of the HIE will operate with the agreement, amounting to the consent, of the patients whose information is being exchanged. As a baseline process, consumers will be notified about the existence of the HIE and their ability to opt-out of all exchange participation, meaning they can prohibit all of their health information from flowing through the exchange if they choose. The notice will describe the HIE, its purpose and its functions. In effect, opting out will be the equivalent of being placed on a "do not call" or global suppression list. Depending upon the Use Case and associated data, additional patient consent protocols will be employed over and above the full exchange opt-out.

In practice this means all patients will be in the exchange by default, unless they ask not to be. For those consumers that participate, the exchange will be available for a variety of purposes, some of which will require additional patient consent or authorization under HIPAA and the Maryland CMRA, and some of which will operate without explicit patient approvals. For instance, a hospital emergency room (ER) will ask verbal approval from any patient capable of indicating consent before they use the HIE to query external sources of medication history. On the other hand, a laboratory will not seek any additional patient consent before transmitting lab results across the HIE to an ordering physician.

Opt-Out as the Baseline Consent Process

As stated, the overall HIE will function on an opt-out principle. By default, demographic information from any patient treated at a participating provider organization could be included in a MPI hosted by the exchange. Basic personal information such as name, gender, address, and birth date would be transmitted, captured, and stored in secure computers owned or contracted for use by the HIE. A separate database, and a component of the core HIE technology, called a registry, will house information, or metadata, for what kind of health information about a particular patient is in the exchange, and where that information can be found (i.e. which participant is storing it). Both technical and privacy justifications drive the need for separate MPI and registry databases, instead of keeping all patient identifying and record locating information in one database. These justifications are discussed in the technical section of the document. It is important to note that consumer's health information will not be captured and stored by the HIE, and will remain with the participating entities. The HIE will only serve as the roadmap and transport mechanism to find and retrieve records.

Consumers will be able to opt-out of the exchange, becoming a non-participant, by calling a toll-free phone number and requesting to be excluded. This means their information would still be present in provider databases available to the exchange, within participating organizations, but the registry information required to locate this information would be erased. The exchange will block access to registry entries for non-participants, thus preventing their medical records from being found or transmitted. In our view, no provider generated exceptions (sometimes referred to as "break glass") to obtain information for a non-participant (an individual who has opted-out) should be permitted. CRISP does not recommend any granular control at the HIE level to exclude some records but include others nor will the HIE allow patients to pick and choose which providers have access to their information.

If they choose, hospitals and other providers will be able to allow patients greater control over which of their records are published to the HIE, only at the local hospital or provider level, by limiting the information that is made available to the participants by that local hospital or provider. However, we would expect many providers to respond to requests from their patients to not publish their records by instructing those individuals to simply opt-out of the exchange. This expectation is based on strong and consistent feedback from providers participating in the medication history project operated by CRISP-participant organizations that the consent

management process must be easy for them to manage. The easiest process for the providers will be to rely on the HIE to manage the opting out of people who choose not to participate. Thus, in most cases consumers will either be all-in or all-out of the exchange, with one exception to be described later.

Even when a consumer opts out, some demographic information will always need to be maintained by the HIE, but only to the extent necessary to ensure the person's current and future records are blocked. Reversing the opt-out decision will be possible. We would expect opting back in to require either an in-person visit and presentation of appropriate identification, or a two-step process in which a letter is mailed to the consumer's address and the consumer must confirm receipt.

The Health Record Bank and Personal Health Record Exception

HRBs and PHRs will be an exception to the all-in or all-out principle. A consumer will have the option of excluding himself or herself from the exchange for every other purpose, while still allowing information to flow from an HRB to a healthcare provider. This is because a patient-controlled HRB will allow a consumer to include critical health information, while excluding sensitive information. This feature of the HIE is designed for consumers desiring more granularity than an "all-out" option. An HRB or PHR will be the best solution for such consumers.

As consumer access applications such as HRBs and PHRs become more available, user controls within those applications will allow the consumer to manage the flow of his or her personal health information within the network. When a query is initiated, the transaction process flow will include a reference to consumer-defined configurations for access to health information. The patient will have the ability to change those control in real-time or near real-time to modify which providers have access to his information, what information they have access to, and the duration of access for a given provider. By creating a health record bank account, consumers can opt-out of the full exchange of their data and exercise greater control over what elements of their health records are shared.

CRISP feels that the ability of the HIE to interoperate with individual health record banks or personal health records systems will facilitate broader and earlier participation by individuals in the HIE, even if it is limited due to issues of patient acceptance of an HIE because it provides a means for granular control by individuals of what information goes through the exchange. This level of control is otherwise, in the view of CRISP, simply not feasible for an HIE at this point in time and for the near future. In many HRB and PHR models, patients have complete control of which categories of information is stored in the application and must specifically authorize individual healthcare providers to have access to that information. Furthermore, a model that encourages participation through HRBs and PHRs helps to achieve the State's mission of a citizen-centric model for HIE.

Data Exchange Policies

The policies in this section address a number of topic areas that relate to the health data flowing through the exchange. These policies establish where the rules governing the release and exchange of information exist (centrally or locally), how and if a core set of health information should be defined, how the HIPAA minimum necessary provision applies to the HIE as well as how to appropriately manage provider liability, whether real or perceived, as the availability of health information increases. A discussion of each of these policy areas and an approach to addressing them within an HIE is included below.

HIE versus Participant Policy for Information Exchange

In developing policies to govern the overall operations of the HIE, one must decide whether those policies should represent a minimum or maximum requirement for HIE participants as to the given policy area. A clear example of this issue is in policy set forth regarding minimum authentication requirements for HIE participants. As

discussed in a subsequent section, the HIE will prescribe a minimum authentication standard requiring that all participants at least meet that standard in order to participate. Setting HIE-defined, central minimum policy standards is a process that contributes to the overall trust and confidence in the HIE. Participants can be confident that all other participants are at a minimum adhering to the defined policy, therefore protecting themselves, other providers and the patients.

However, setting a minimum policy standard indicates that if a participant wishes to adopt and deploy a more stringent policy he is free to do so. This allowance quickly creates challenges and policy discrepancies for the HIE, yet is still a viable option in some cases. Using the example of authentication requirements above, an HIE participant may have the ability to use an access and authentication standard that is more stringent than the HIE prescribed policy. However, applying a more rigorous standard at the participant level would be dependent upon the HIE's technical ability to integrate with that standard.

Defining a Core Set of Health Information

The issue of defining a core set of health information to be exchanged hits upon the need to identify what the HIE infrastructure will enable from a data flow perspective. In identifying Use Cases, the data to be transferred is also identified. For example, for an electronic medication history service to the emergency department, medication history information is naturally the data type to be exchanged. As the exchange becomes more robust, creating a standard set of core health information (i.e. medication, allergies, problems lists, etc.) would be valuable. However, while standardizing the data flowing through the system would be valuable, the challenge in ensuring that each participant always creates and releases the required information could become prohibitively burdensome. Use Cases will likely drive the content of the data flowing through the HIE, but as they begin to focus on the transfer of clinical summary and discharge summary information, there could be great variability in what constitutes these documents. Therefore, while the HIE should certainly encourage participants to create documents using the same data types, the more important effort is to ensure the same technical document standards are being deployed, such as the Continuity of Care Document (CCD) version C32, discussed further in the technical section of this document.

HIPAA's Minimum Necessary Standard

The minimum necessary standard is a provision of the Privacy Rule, which dictates that covered entities take reasonable steps to limit use or disclosure of protect health information (PHI) only to the extent necessary to accomplish the intended purpose. It also requires that covered entities take reasonable steps to limit requests for PHI to the minimum necessary.[1] However, a critical component to the Privacy Rule's minimum necessary standard is that it does not apply to disclosures or requests by a healthcare provider for treatment purposes nor does it apply to disclosures to the individual who is the subject of the information.[2] The exchange opt-out policy, developed around the concept of health information exchange for treatment purposes, aligns well with the minimum necessary standard. Because this standard does not apply to payment and healthcare operations transactions within the exchange, the transactions will have to be addressed as they arise in terms of limiting data disclosure. However, HIPAA is quite clear in allowing standard policies to be developed defining the minimum necessary amount of information for recurring categories of non-treatment exchanges. In addition, HIPAA allows disclosing providers (and by implication the HIE acting on their behalf) to rely on the requesting healthcare provider to only request the minimum necessary amount of information for non-treatment purposes. There is no specific minimum necessary requirement in the Maryland CMRA, except for disclosure of mental health records, so the HIPAA rule would govern under the HIPAA principals of preemption.

[1] Ibid.

[2] 45 C.F.R.§§164.502(b), 164.514(b)

Provider Liability

Participation in an HIE can raise liability issues for participants. Issues relating to breaches of privacy laws have been addressed in other sections of this report. The other key area of concern expressed by participants and their advisors relates to the standard of care in instances of medical malpractice, specifically whether the availability of more information about a patient's medical history will broaden the provider's responsibility for reviewing and considering all such information in making care decisions.

Overall, and perhaps most significantly, CRISP believes an HIE will actually lead to better outcomes and less risk of malpractice by, for example making a more complete medication history readily available at the point of care, leading to a reduction in harmful medication interactions. In Contrast, there is concern that the availability of more information will alter the standard of care by requiring that a provider familiarize himself or herself with a patient's entire available record. CRISP believes that this is not the standard of care in a paper-based system or in an individual provider's electronic health record environment. While provider liability concerns deserve serious consideration, it will take several years for judicial decisions to provide a guide to what, if any, changes in the standard of care as to review of medical records HIEs will generate. Historically, the standard of care is determined by courts, based on testimony of expert witnesses in contested malpractice cases. National organizations of providers may also establish standards. In addition, there are indications that significant legislation, such as HIPAA, may also form a basis for standard of care determinations. In all events, however, the standard of care evolves slowly and has not, to date, required that an individual hospital or provider make the maximum possible use of available healthcare technology. The test is what a reasonable provider would do in a similar circumstance.

This would indicate that, just because an HIE makes more individual patient information available, a provider is not obligated to review and consider all available information in making clinical decisions.

For this reason, CRISP also recommends that the information available be tailored based on provider generated input. For example, in the medication history project, providers said that they were not interested in medication information more than six months old; that it was, under current standard of care, not generally relevant, at least in the emergency room context. The HIE, as proposed by CRISP, would be developed with such input. Such development is particularly congruent with the Use Case approach to the HIE that CRISP recommends, since the available information is tailored to specific uses and to the needs of providers. There are other liability issues inherent in an HIE, such as antitrust issues that could arise if the exchange were used to share competitively sensitive information among competitors, and while CRISP takes all potential legal issues inherent in the exchange seriously, we believe that compliance with privacy laws related to the standard of care is the most significant consideration

Access, Authentication, Audit and Authorization

Access, authentication, audit, and authorization refer to activities within an HIE that describe how participants in the HIE are defined and identified as individual users of the system, how the usage of the system is governed, how users are accurately and appropriately identified, and further, how records of that usage are captured, stored, and used for various audit purposes. This section outlines important aspects of each of the "four A's" and provides a discussion of outcomes from the CRISP Community Interaction & Privacy and Security Workgroup.

Access

Access to the HIE is defined by a participant's ability to obtain data from another source leveraging the HIE. An HIE can bridge gaps that currently exist in data silos between individual institutions but, as a function of that capability, also expands individual access to more patient health information. A commonly cited concern when considering access to an HIE is that as the clinical value of access to greater amounts of health information and the population with access increases, there is a similar increase in the risk associated with managing access and ensuring appropriate usage. Defining roles within each

participating entity and assigning access constraints and allowances to those roles is a logical and scalable approach to resolving a number of access concerns. An assumption in defining particular roles is the existence of identities. An identity, in the context of an HIE, is an individual or entity that needs access to the exchange to perform a particular function or task.[3] Each identity must be appropriately associated with a role.

Role-based access allows for participating entities to control access levels for the various resources within their organizations. Providers who currently utilize health information systems will likely have experience with assigning roles that dictate access level. In considering how role-based identity management is controlled, the question of what entity defines those roles arises. Varying levels of identity management complexities exist, dependent upon whether the HIE intends to allow participants to access the HIE through local integrated systems or through a specific client or web-based application.

The inclusion of an additional application, usernames, and passwords into a participating entity's operations may impose a number of challenges; however, this approach may be more realistic for near-term clinical data exchange. In the case where an HIE elects to offer a portal or secure website as the avenue to access the exchange, role types must be established by the HIE organization. Consideration should be given to the distribution of HIE administrator privileges to the appropriate user within participating entities who will then have the ability to assign usernames and password to individuals within that entity. Further, if a participating entity has already deployed the infrastructure to support single sign-on capability, then concerns of password fatigue could be avoided.[4]

Regardless of the selection of an integrated solution or a portal solution, defining centralized guidelines for role assignment is a critical step in ensuring trust among HIE participants. Managing the level of complexity is a function of determining the granularity in defining each role type. As the number of assignable roles increases, so does the complexity of managing those roles. Role-based access may not be necessary for early Use Cases within the exchange and in fact may add a prohibitive level of complexity without the addition of the intended privacy and security protections. Furthermore, participants must be able to rely on a participation agreement that defines a consistent approach to role assignment in order for the exchange to be successful. Without such an agreement, participants have no assurance that the data they release into the exchange is being used appropriately. Defining the assignment of roles and access protocols in a common HIE policy guide and codifying that definition in a contractual agreement will allow for the trust that is a prerequisite for clinical data exchange.

A Note on Emergency Access to Health Information

There are a number of scenarios that exist whereby a provider may need access to health information that he or she would not normally be permitted to view, or for which a consumer has chosen to restrict access. To account for these circumstances, many HIE efforts have incorporated the concept of the "break the glass" function. Referencing the need to break the protective glass covering of fire alarms, this function would allow a provider to override the access level afforded them by the system's role definitions. The CRISP model allows for an approach to break the glass scenarios whereby providers may gain access to data in critical situations, but only if the patient has not otherwise restricted that function (as discussed earlier) through health record bank control or by making such request through the exchange call center. While the exchange should deploy a notice and opt-out model, that model does not imply that all information will be available to all participants. Role-based access will still define what information is presented to whom. In the event that a break the glass scenario does ensue, and the patient had not restricted that scenario, a manual audit would occur. To avoid abuse of this function, providers would be educated to the fact that if they do proceed to break the glass they will be contacted to verify that they accessed the data for appropriate uses, and their actions may be evaluated.

[3] Markle Foundation, The Connecting for Health Common Framework: Resources for Implementing Private and Secure Health Information Exchange, 2005.

[4] HIMSS Analytics, Things to Consider When Evaluating an Enterprise Single Sign-On Solution, 2006.

Authentication

Authentication of HIE participants refers to the assertion of a particular identity though the provision of a certain set of identifying information.[5] The management of authentication services through the HIE is similar whether access is through local EHR systems or through a portal access solution. In both access models, credentials must be passed into the exchange for authentication and for access to be granted.

The HIE will also need to define the methods for authentication. Varying levels of security measures exist in selecting the mechanism to uniquely assert an identity. The simplest form of authenticating an individual user is through the provision of a username and password, or single-factor authentication. Options that increase authentication security include the use of security tokens or smart cards (two-factor authentication) or perhaps even the use of biometric data (three-factor authentication). While the HIE does not necessarily need to prescribe the exact authentication requirements, a minimum standard must be established. The CRISP workgroup felt, as a minimum, a username and strong password should be used to access the HIE. However, when accessing the HIE through a web-based application, additional security measures should be deployed. Use of a security token, increasing the authentication level to two-factor, can provide adequate security for web-based access. However, it should be noted, that the workgroup discussed at length the challenges with respect to HIE utilization as the requirements for authentication increase.

In short, the HIE must arrive at an appropriate balance between usability and security. If the authentication requirements are too onerous, the HIE could face adoption challenges. However, if the requirements are too relaxed, the exchange will compromise its data protections and security and risk suffering from breaches or the inherent lack of trust in an unsecure network.

[5] Markle Foundation, "The Connecting for Health Common Framework: Resources for Implementing Private and Secure Health Information Exchange," 2005.

Audit

CRISP recommends an HIE that is guided by the HIPAA Privacy Rule. That rule mandates that "a covered entity must have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information."[6] The HIPAA Security Rule is more specific, requiring the implementation of "hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic protected health information."[7] The Security Rule then stipulates that covered entities "implement procedures to regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports."[8]

HIPAA stipulates a minimum auditing requirement; however, participating in an HIE increases both the need for stringent auditing processes and the complexity in executing auditing procedures. The development of an HIE implies an increase in the number of users in the system, the number of transactions, and the diversity of those transactions within the network. With the high volume of transactions flowing through the exchange there is no feasible way to actively and manually monitor each transaction. Since an HIE may include both large and small providers that have varying audit and logging capabilities, an HIE should avoid specific or complex audit requirements at the participant level and account for transactions flowing through the exchange through centralized auditing.

While random auditing can provide for base-level coverage, the HIE should also assess the need for specific rules that trigger audit events. Specific activities, to the extent feasible, could include:

01 Audit of all VIP records

02 Procedures for follow-ups on suspicious activity, such as indications of possible privacy or security breaches

[6] 45 CFR 164.530§(c)(1)

[7] 45 CFR 164.312§(b)

[8] 45 CFR 164.312§(a)(1) (ii)(d)

03 Review of network intrusion detection system activity logs

04 Review of system administrator authorizations and activities

05 Review of physical access to data centers

06 Other review of technical, physical, and administrative safeguards as established by the policies of the HIE.

Similar to the balance that must be found within authentication; a balance exists in defining a robust but achievable audit program in the context of available resources. After the audit policies are defined from a system event and review perspective, mechanisms to disseminate incident reports and breach notifications must be established. Further, accountability actions must be established to handle breaches, investigate complaints, and provide resolution or enforcement activities when such incidents occur.

An underlying theme, throughout business practice areas, is striking an effective balance between restrictive policies and requisite safeguards. Regardless of the final policies of participants, it will be the HIE's responsibility to ensure that all participants adhere to the minimum defined standard.

Authorization

Authorization is closely linked to both access and authentication. After a user has identified himself (access) and proven that he is indeed who he claims to be (authentication), the HIE must now verify what functions the user is authorized to perform.[9] These functions could be as simple as distinguishing between the ability to view data or to view and contribute data, or they may be more complex, such as defining to the ability to see specific types of data and filtering various health data elements. The granularity that the HIE deems appropriate is again a balance between the complexity, usability, and administrative overhead of the exchange.

As a base approach, providers should have the ability to view and save data for the purposes of treatment. Functionality that allows addition of new information and other clinical messaging capabilities will be reliant upon the access point the provider is leveraging. For example, at the lowest end of the spectrum a provider may be receiving a print-out, a form of view only, or may be viewing information through a portal, but not actively entering data. The functionality can expand from that point. Nonetheless, the basic capabilities to view, contribute, and save data are critical components to long-term utilization and value creation.

Consumer Access and Control

As articulated by the Maryland Health Care Commission, developing a "citizen-centric" approach is the paradigm for HIE in Maryland. This approach was in paralleled early thinking by the CRISP team and was confirmed and reinforced by the workgroups throughout the planning effort. The underlying concept in developing a citizen- or consumer-centric HIE model is that the consumer can act as a transformative agent of change in both the overall adoption of health IT and the associated improvements in quality of care, increased population wellness and decreased healthcare spending in the United States. While these are frequently viewed as the longer-term benefits of consumerism, other industries have seen rapid change based on direct consumer engagement. A few examples of the industries that have experienced, and continue to experience, the sweeping change of consumerism include communications, with the introduction of email and voice-over-IP, information search, with engines such as Google, e-commerce, as seen with Amazon.com and eBay, personal finance, with various online banking sites and online financial management tools, and social interaction, as demonstrated through sites such as Facebook.com and MySpace.com.[10] In particular, content and social media have interesting intersections with consumer-centric and consumer-directed healthcare. As consumers become more engaged in their own care through health record banking applications and other patient-engagement tools, new opportunities to deliver relevant content, care alerts, and other health management-related information all become possible.

Nonetheless, an argument exists demonstrating the stark differences between the healthcare industry, and the

[9] Ibid.

[10] Markle Foundation, "A Common Framework for Networked Personal Health Information," June 2008.

economics that govern it and the industries mentioned above. As stated by Douglas Emory, principal investigator of the eHealth Initiative report, Health Information Exchange: From Start up to Sustainability, "the economics of our healthcare system militate against the mobilizations of interoperable data where it is needed—at the point of care." The report continues:

"The manner in which we reimburse care transforms clinical information into institutionally siloed and fragmented information streams. This fragmented information is then easily controlled by mutually non-aligned institutions that have little financial interest in bearing the costs of sharing standardized data. Hence, there is no real market demand for information exchange. In fact, asymmetries give plans and providers powerful incentives to silo information and gain profits over the value that might be produced in a transparent market."[11]

Introducing the consumer as a more active participant in the healthcare market can change the demand for electronic health information, shifting it from traditional data consumers such as providers and insurers, to citizens themselves. It should also be noted that Emory's assessment, while seemingly bleak, concludes that overcoming the challenges of achieving sustainable HIE is indeed possible and that current trends in the healthcare market are driving in that direction.

Consumers' interests in their own healthcare may seem a foregone conclusion; however consumers have been excluded, to a large extent, from the delivery of and payment for healthcare, leading to an overall lack of patient-centered care.[12] Counter to this shortcoming are the basic concepts of why consumers should have an interest in their healthcare, chief among them, the fact that the consumers' lives and health is put at risk when a lack of information causes preventable errors.[13] Further, consumers (patients), as the subject of care, are frequently in the best position to collect and share information with their providers.[14] [15] [16] A number of topics related to consumer–centric HIE arise when considering the policy implications of consumer engagement. These topics are addressed in the subsections below.

Health Record Banks and Personal Health Records – Consumer Access Applications

A critical component of allowing consumers to play a more central role in their care is offering them enhanced access to their own health information. While PHRs have been given much attention and are commonly held as one solution to improve patient engagement, an important distinction must be made. This distinction also explains the lack of PHR adoption by consumers. Current PHR proliferation is largely based on the "tethered" PHR concept, meaning that the personal health record is tied directly to one source of data. These PHRs may offer a consumer insight in a particular, but often limited, data set (insurance claims data converted to clinical data, for example), however they do not allow the consumer a robust, picture of health information from multiple sources, as would be possible through an HIE. Nor do PHRs, for the most part, permit the consumer to interact with health information by, for instance, adding health information and commenting on existing information and, in turn making that information available back through a network.[17] The model discussed by the CRISP team defines the use of HRBs as a networked consumer access point, meaning the application is not tied directly to a particular source, but rather connected to the network directly and acting as a node on the exchange. From a policy perspective, HRBs can act as a means to support the principle of transparency by delivering terms of use and privacy policy information to consumers so they understand the uses and limitations regarding their health information. However, the CRISP team felt that no single HRB should be the statewide solution for

[11] eHealth Initiative, "Health Information Exchange: From Start up to Sustainability," May 2007.

[12] Institute of Medicine, "Crossing the Quality Chasm: A New Health System for the 21st Century" 2001.

[13] Markle Foundation, "A Common Framework for Networked Personal Health Information," June 2008.

[14] Ibid.

[15] Tang P et al. "Personal health records: Definitions, Benefits and Strategies for Overcoming Barriers to Adoption", 2006.

[16] Denton IC. "Will Patients Use Electronic Personal health records? Responses From a Real-Life Experience" 2001.

[17] This concept to be discussed further in the section "Consumers' Control Over the Flow of their Health Information."

consumer access to the HIE. While defining minimum standards relating to terms of use and privacy statements for HRBs, the exchange should promote market development of multiple solutions that can be built on the exchange and allow for a vast array of value-added services to be offered to consumers. The exchange should also promote consumer choice with respect to the selection of a solution that best fits their needs.

Authentication of Consumers

A significant challenge in allowing consumers access to an HIE through HRB applications is the process of authenticating their identity. Consumer authentication poses a different challenge than that of provider authentication due to both the sheer volume of consumers compared with providers and the fact that provider authentication will typically initially occur face-to-face and include some exchange of credentials to bring the provider into the network. Without adequate authentication processes, health information could be released to the wrong individual. Further, consumers could open accounts and make incorrect data available to the exchange if the authentication process were not effective. Both of these scenarios are unacceptable and would be prohibitive to the development of a consumer-centric HIE.

The Markle Foundation has defined the process of verifying a person's identity as "identity proofing."[18] Identity proofing ranges in its complexity, and therefore its cost and the level of effort involved with its implementation vary considerably. The challenges that exist in many other areas of HIE with respect to the privacy and security risk of weak requirements versus the usage barriers of strict requirements are certainly present when addressing consumer authentication through a networked HRB. In light of these challenges, the ideal authentication approach entails a review of a government-issued identification that includes a picture during a face-to-face encounter. While this approach can certainly prevent mass-automated attacks attempting to create accounts, there are a few key problems. First, while face-to-face identity proofing using a government-issued ID has become a standard in multiple industries, there is no evidence to suggest it is more effective than other mechanisms.[19] Second, the costs associated with face-to-face encounters may be a too onerous, especially for new ventures offering HRBs. A second approach is to "bootstrap" existing authentication mechanisms by leveraging the existing processes (or opportunities for face-to-face encounters) of other organizations, such as financial institutions, hospitals, post offices, or the Department of Motor Vehicles.

The Social Security Number (SSN) is a poor identifier for authentication purposes. As noted in a Markle Foundation paper, a reason that the SSN is a bad identifier is that it performs the function of both the public and secret parts of the authentication process. "You have a SSN that points uniquely to you, but you must reveal it as proof that you have it. Without being accompanied by a second, secret token such as a PIN [personal identification number], the SSN is damaged in regard to authentication by the very use that makes it otherwise worthwhile."[20]

The ability to deterministically authenticate an individual and subsequently correctly match that individual with health information may require manual intervention initially to ensure an adequate level of privacy and security protections. Authentication approaches will require further evaluation; however, the HIE must ensure that any solution offered through the HIE has been vetted to ensure an appropriate level of rigor.

Consumer Control over the Flow of Health Information

The consumer's ability to play an active role in his or her healthcare may be improved by enhancing the ability to view and manage one's own health information. Allowing access, through HRB access solutions, can and should be extended beyond the base function of viewing health information.[21] While simply allowing read-only access to consumers would certainly be considered progress, the consumer should be empowered with a greater role by being offered the ability to control both what information is available to the network as well as

[18] Markle Foundation, "A Common Framework for Networked Personal Health Information," June 2008.

[19] Ibid.

[20] Markle Foundation, "The Connecting for Health Common Framework: Resources for Implementing Private and Secure Health Information Exchange," 2005.

[21] Of note, certain psychotherapy notes or other sensitive information in provider notes may not be released to the consumer.

the network participants to whom that information is made available. Some providers have expressed concern that patients may choose to withhold vital information from their HRB record. If no other record is available, then providers are unable to effectively treat the patient due to a lack of information. In a paper-based care delivery system, the same situation exists today in that if a patient chooses to withhold information during a provider interview, then the provider, again unless other information is available, will not have the ability to obtain such information regardless. [22]

Consumers should also have the ability to augment their health record bank information and annotate data that was entered by providers. This does not mean they are modifying any record that exists at a provider site, but rather the copy that is stored in the consumer's own account. Providers have expressed a lack of confidence in health information that is comingled with both patient-entered and provider-entered data. The logic behind the augment and annotate approach is that all data exchanged through the HIE will have source information, including a note if it is consumer-entered, that is readily available to providers to ensure they can either ask further questions if they require clarification from the patient or so that they may place what they deem to be the appropriate level of confidence in the data. This is not a new practice or concept; in today's system, providers still rely on patients to confirm information or to provide additional information, such as if a prescription has been taken after it was prescribed or filled. In the HIE, consumer annotation or provider-entered information will comingle in the same manner, and can provide a physician with critical information about the patient at the point of care.

Secondary Uses: Bio-Surveillance and Public Health Research

There is clear societal benefit to making health information available to various local, state, and national public health agencies for the purposes of early identification of communicable diseases and acute or long-term population health threats. Communication between the appropriate parties during such public health events, as well as on-going and real-time monitoring of public health threats, is vital to any developing HIE infrastructure. A mechanism for collecting and analyzing health data from an HIE and other health data sources across the country is important so that public health professionals can in turn analyze and respond to the data in real-time. This will significantly improve the responsiveness and efficacy of public-health risk remediation and response.[23]

Bioterrorism and outbreak response are not the only alternate uses of HIE clinical data that can provide value to a community. Secondary uses may allow researchers to better understand how various chronic illnesses affect different demographics of a particular community. Although there is great potential benefit of alternate data uses, sound policy development and consumer education regarding the purposes of using health information and how it is protected is critical because of the large risk of misunderstanding or loss of consumer trust if the public determines that secondary uses put privacy and security at risk.

Many CRISP partners, and many potential HIE participants, are already required to submit multiple files for secondary uses by public health officials for monitoring and reporting purposes. The HIE can serve as a conduit to facilitate this existing reporting requirement, easing the burden on the provider community. However, the standards by which health information used for these purposes either remains identified, is de-identified, or is anonymized must be clearly defined.

[22] Of further note, in the current care delivery system providers are often reliant upon patients to advise them if other documentation or records exist with other providers or pharmacies.

[23] Buehler, et al. "Framework for Evaluating Public Health Surveillance Systems for Early Detection of Outbreaks" CDC, May, 2004.

The CRISP Community Interaction & Privacy and Security workgroup felt that it was appropriate and necessary to define the meaning of the three classifications of health information (identified, de-identified, and anonymized) to ensure a consistent understanding among the group that could be proliferated as the HIE develops. As discussed in the workgroup, there are specific requirements for providers to offer files with identified health information, meaning health information that includes individually identifiable health data such as name, address, date of birth, etc., when specific diseases or illnesses are encountered. There are also public health requirements that do not include the immediate need, or in many cases, any need to trace data back to a particular individual. In those cases, de-identified data or anonymized data may be called for. De-identified data is health information that has been stripped of any individually identifiable health information, but that has been tagged with a number so that re-identification is possible if necessary. Anonymizing data implies that all identifying information is stripped and no tag is assigned, therefore eliminating the possibility of tracing the information back to a specific individual.

The workgroup felt that there are many secondary uses of health information but that no single rule or policy can apply to when data should remain identified or when it should be de-identified or anonymized. However, as public health or bio-surveillance needs for data arise, they will require individual assessment and assignment of the appropriate policy by the operating and governing body of the HIE, if that policy has not been predefined either by applicable law or by the state or federal agency requiring the information.

Participation Agreement and Appropriate Use Policy

Any health information exchange will require the development of a participation agreement that will codify the relationship between the HIE organization and the various participants. One of the challenges in creating such an agreement is that multiple participants, each of whom may have its own in-house legal counsel, will have to agree on the components and structure of the document. The logic behind arriving at a consistent participation agreement that is entered into by each participant without substantial or material modification is to ensure that "transitive trust" can be maintained across the entire exchange.[24] Transitive trust is the mutual trust between HIE participants rooted in the knowledge that each participant has entered into a consistent participation agreement defining appropriate usage and requirements for participation, thereby avoiding the participant-to-participant need to know every individual provider and employee accessing the exchange.

The appropriate use policy is a document that should be referenced by, or included in, the participation agreement defining specific appropriate and inappropriate uses of the health information exchange by individuals who have been granted access. It is assumed that any individual accessing the HIE who has not been previously credentialed to do so is accessing the HIE inappropriately. The participation agreement will also articulate the response of the HIE organizations and consequence of misuse, discussed further below.

The incremental, Use Case-driven implementation approach espoused by CRISP impacts the way contracting would occur. This approach acknowledges that agreeing on the terms and conditions in a participation agreement for a future-state, robust health information exchange (including any potential data types) and gaining community-wide agreement by each participant's legal counsel is a difficult task. Arriving at such an agreement, even if possible, is not necessarily advisable considering the rapidly evolving health IT landscape. A more pragmatic approach to contracting, especially in an exchange seeking broad stakeholder participation, is to develop a base terms and conditions document to which amendments are added as exchange services expand and new legal issues arise. This approach ensures that the exchange is able to manage the legal challenges associated with HIE dynamically and over time.

[24] Markle Foundation, "Summary of Policy Recommendations from the Markle Foundation's Connecting for Health Common Framework," April 2007.

Breaches and Misuse of the Exchange

In any health information exchange, it is impossible to completely eliminate the possibility of breaches and misuse of information. Though an HIE itself is not necessarily a HIPAA-covered entity, any related business associate agreements would render the business associate responsible for adequately safeguarding protected health information. As such, it is important to mitigate the probability of breaches and misuse through appropriate systems monitoring and established security, training and reporting procedures.

Pre-emptive measures must be taken to reduce the likelihood that health information is used for purposes other than those for which it was intended. Establishing policies and procedures and training personnel are two important actions that should be taken. All policies and procedures should be clearly written to enforce privacy standards and communicated to staff accordingly. Additionally, workforce members with access to protected health information should be adequately educated to understand privacy standards and should be trained to adhere to procedures that uphold such standards.

In the event that a breach does occur, appropriate sanctions should be in place and enforced against any workforce member who violated proper procedures. Additionally, attempts must be made to rectify the extent of harm caused. For example, the individual whose data was compromised should be informed of the breach so that he or she can take necessary protective precautions. Under established HIPAA doctrines, the HIE recommended by CRISP would be viewed as performing a function or activity on behalf of participating hospitals and providers. The latter are covered entities under HIPAA, while the HIE is a "business associate", not a covered entity but obligated to give the covered entity participants in the HIE satisfactory contractual assurance (in the form of a business associate agreement, or BAA) that it will perform its services in a HIPAA-compliant manner, consistent with the participants' own obligations.

If the HIE is the source of the breach, a BAA would likely require the improper data use to be reported to affected providers. Likewise, any major breaches that originate with covered entities should be reported to the exchange, to the extent possible. Furthermore, if a covered entity learns of repeated data misuse, that entity is required by HIPAA's Privacy Rule to remedy the situation. If the situation cannot be remedied, the covered entity would be obligated to terminate its relationship with the exchange. Depending on how a BAA is structured, it may also be possible for an entity to withdraw from the exchange or for an HIE to be indemnified in certain situations. Though there are many ways to structure such an agreement, considerations may be made around advance notice of withdrawal, terms of withdrawal, or specific situations for which indemnification is appropriate.

Clinical Workflows

A theme that was pervasive during all of our workgroup discussions was the necessity to be mindful of the impacts that new technology and HIE participation could have on provider workflows across a variety of care settings. Nearly every aspect of a provider's clinical workflow is impacted by the introduction of HIT. While workflow was a large consideration in the approaches this report defines to address various HIE challenges, the significance of the issue and its impact on the overall success of any Maryland HIE justifies a more thorough discussion. Even if a perfect technology and policy solution could be developed, accounting for even the greatest of the technology challenges and the most pressing of privacy issues, if that solution does not fit into existing workflow or provide for acceptable new workflows, the HIE will face significant utilization barriers. Two specific areas, patient consent and HIE access, are discussed in more detail below; these areas represent a cross section of workgroup deliberation on the matter of workflows.

Patient Consent and Provider Workflow Impacts

In addressing patient consent for providers to access their health information via the HIE, one must ask if the consent model is viable from a provider workflow perspective. In CRISP's view, this question must be asked in parallel with the perhaps equally important issue of patient privacy rights. While patients' legal rights are paramount, so is designing and implementing a process that adequately accounts for the realities of existing clinical workflows and the change necessary to accommodate new consent processes. Trying to build an HIE without doing so would be an exercise in futility.

One of the key metric in understanding the success of the exchange as it is incrementally developed is provider utilization of services offered through the exchange. While the exchange will dictate specific requirements, as defined in the Consent Policy section, providers will have the ability to implement those consent requirements in various way that best meet their practice's or facility's needs. A clear example of the workflow challenges with respect to consent can be seen with the electronic medication history service. When introducing a new HIE service such as medication history, and therefore also introducing the associated processes and workflows, into a high patient volume area, such as an emergency department registration desk, workflow becomes critical. The simple reality is that process modifications cannot hinder patient throughput at already overcrowded emergency rooms. In this instance, tying the consent process for the new service into current practices was a requirement. However, other care settings may allow for different approaches. These various scenarios must seek to find a balance between the technologies available, the policy approach, and the workflow facts of the care setting.

HIE Access Methods

The impacts of the provider access mechanisms (i.e. via EHR, a portal, or by utilizing a paper print-out from the exchange) on the HIE are instrumental to the challenge of utilization. Providers are constantly challenged by a need to remain efficient because of increasing costs and decreasing reimbursement.[1] While the promise of

[1] Annals of Vascular Surgery, "A Decade of Decline: An Analysis of Medicare Reimbursement for Vascular Surgical Procedures," 2002.

health information exchange has the potential to be a transformative force in American healthcare, delivering data through the appropriate avenues is critical. As is the case with any technical implementation, provider adoption of HIT and participation in the HIE will require significant process redesign accompanied by appropriate change management. A frequent phrase used in describing the goals of HIE is "delivering the right data to the right place at the right time." The "right place" referenced in that phrase can mean any number of different delivery mechanisms but should be understood to mean that the "right place" is somewhere that fits into provider workflow processes.

Communication and Education

Physician Outreach

The move toward accountability in American healthcare has brought about a number of emerging trends that affect the physician community. They include programs such as quality recognition programs, pay for performance/quality programs, and investigations into alternative models of care delivery such as the medical home. Each of these trends is enabled and supported through the use of EHRs and participation in HIE. Still, a significant barrier to creating a successful HIE in Maryland is the generally low adoption of EHRs and HIT among physicians. Physician data input and utilization is critical to the success of any HIE. Overall low adoption of HIT has occurred due to the lack of a well-established value proposition for the physician community. An aggressive physician outreach plan will serve as a means to better understand how to develop a value proposition by including physicians in HIE discussions and providing them a feedback mechanism for change.

The goals of the outreach plan, as articulated in greater detail below, are to engage physicians in the HIE through education, involve them in decisions concerning implementation, and provide a feedback mechanism that will facilitate changes in a timely manner. These components are needed to increase physician EHR adoption and HIE participation and to help understand and create a physician value proposition in light of a healthcare environment that is demanding more accountability.

Physician Education

It is important to provide educational information directly to the physician community. Education should center on explanation, description, and benefits analysis of the exchange in improving healthcare quality and efficiency, preventing medical errors, and reducing healthcare costs by delivering essential information to the point of care. Education will also highlight the usefulness of an exchange for addressing issues such as quality and efficiency measurements, pay-for-performance, pay-for-participation, e-prescribing, and emerging care delivery models such as the Patient Centered Medical Home (PCMH) or, generically, the medical home.

A good approach to implementing physician education would involve first dividing the state into different geographical territories and assigning a Provider Outreach Coordinator (POC) to each. POCs' roles in physician education could include contacting physicians' offices, assessing each office's readiness for HIE, and arranging office meetings to present outreach materials and discuss the merits of EHR adoption and HIE. Office presentations could be supplemented with additional means for physician education, such as presentations at medical and physician-centric conferences, webinar series learning, and collaboration with select EHR vendors and with Maryland's quality improvement organization (QIO), the Delmarva Foundation, to distribute informational brochures.

The following steps could be used as a guide to implement the physician education initiative.

01 Obtain the names, addresses, and phone numbers of all family practice, internal medicine, pediatric, cardiology, and endocrinology specialty physicians in freestanding physician offices in Maryland. Determine the number of physician/physician groups in Maryland using the physician database provided by the Maryland Health Care Commission. Today, there are more than 2,000 Maryland physicians in the above specialties.

02 Divide the state into five geographical territories for outreach and education to physicians.

03 Assign a Provider Outreach Coordinator to each territory. One of the five Provider Outreach Coordinators will also act as Director of Provider Outreach and Education.

04 Each physician office will be contacted by phone to determine level of interest. Prioritization of target physicians/physician groups for outreach will use the following criteria:

- Physicians/groups presently using EHR: schedule visit
- Physicians/groups presently using e-prescribing: schedule visit
- Physicians/groups interested in EHR/HIE: schedule visit
- Physicians/groups not interested in EHR/HIE: mailing

05 Develop an educational program for each target.

In evaluating the effectiveness of any provider outreach program, follow-up mechanisms should be developed, evaluation tools and surveys should be used for data collection, and regular progress reports should be submitted to governing stakeholders.

Physician Feedback Mechanism

During the education and outreach process as well as during participation in HIE, the physician community must have a reliable means for communicating to and participating in the governance of the exchange. This issue deserves significant attention based on the fact that the physician community has been reluctant to adopt HIT due to numerous barriers including misaligned value propositions, the cost of implementation, and the potential workflow impacts that ultimately affect practice revenue. A feedback mechanism will lend clarity to the perceived barriers and allow a deeper understanding of the issues as they relate directly to Maryland physicians. Communicating physician feedback will also allow for the development of tailored solutions. Through the feedback mechanism, physicians can help establish a value proposition for adopting HIT and engaging in HIE.

In establishing a feedback mechanism, evaluation tools and surveys should be used to aggregate data from physicians' offices. Evaluation tools should address physicians' HIT use and barriers and catalysts to HIT adoption. In order to affect change, feedback should then be reported to the HIE's governing organization, who will in turn route the information to the appropriate change agent (payers, legislators, vendors, etc.) Successful creation of a physician value proposition should be measured by increased levels of HIT/HIE adoption. Finally, it is important that the feedback loop be completed and physicians receive acknowledgement of and response to substantive comments for improving the HIE.

Patient and Community Outreach

While HIE offers the promise of bringing about improved quality of care for patients, consumers must be educated on how the exchange operates and the potential benefits of an HIE in order to use it to its full advantage. Patient participation in the exchange is crucial to success, and patients must also be given controls over how their personal health data is managed. The CRISP team is committed to building an HIE that is not only patient-centric but also is as transparent and valuable to patients as possible within the realm of available resources and technology.
Average consumers have limited knowledge of HIT and how their data would be handled within an HIE. The patient and community outreach plan strives to give patients a better understanding of the role of an HIE in managing personal health data and the potential health benefits that could be reaped. In light of the evidence of health disparities among Marylanders, the plan specifically takes into account the underserved and presents mechanisms for addressing their specific healthcare concerns.

Community Outreach

Patients must understand the goals of the HIE effort and feel inspired to advance the exchange. They must also trust that their data is being handled responsibly and understand the consequences of participating in the exchange. Several avenues can be used for community outreach. These include educational marketing materials, presentations at conferences, podcasts, games and simulations, print media, radio, television, and internet. CRISP believes a combination of these means should be deployed, tailoring the media to the audience. While it is important to publicly describe, in general

and non-technical terms, the mechanics of how the exchange services are deployed, this is a secondary issue in defining the message. More important is defining a message around the participant benefits of HIE services, as this will help in building and maintaining community willingness to support the exchange. The benefits of health information exchange can often be lost among fears of liability and privacy concerns. While these issues are deserving of significant attention and deliberation, they should not be treated in the public messaging as insurmountable barriers to progress. The following guidelines can help define a clear message:

- Develop a message around the benefits of each service being deployed
- Understand the target population for the service
- Tailor a message to that population
- Release general information through traditional press avenues regarding the service
- Leverage the existing trust relationships between patients and providers to reinforce the message

A successful HIE "brand" can serve to enhance both consumer and participant support for the exchange. Management of the message or brand does not imply avoidance of difficult and important topics, such as medical identity theft or data breaches, but rather discussing those concerns in the context of the greater benefits of the exchange and the process by which those issues are being addressed. While the planning group emphasizes the importance of a media strategy that leverages traditional press avenues via press releases and participating organizations' media relations offices, it also recognizes the importance of other means of releasing general information which may raise the HIE's visibility. These means could include online marketing, an official HIE-specific blog, or a website with minutes from planning meetings and other relevant functions. In general, the more all stakeholders can do to make the exchange transparent to a wide range of interested parties and the more that stakeholders celebrate the tangible value being realized by the exchange services, the more likely that patients and consumer groups will be supportive of the exchange.

In addition to brand marketing, one-on-one marketing activities will also be a key element of the overall patient outreach strategy. Educational marketing materials could be distributed to patients through doctors' offices, hospitals, clinics, and community centers. Presentations could also be given at patient-centric or health-centric conferences, which bring large groups together and can facilitate healthy community discourse. Recent technologies, such as podcasts, games, and simulations, are also rapidly growing in popularity. It is expected that the number of Podcast users will more than double in the next five years, with 60% of those users living in the urban community. Programs like iTunes could be leveraged as methods of delivery for information. Similarly, electronic games and simulations could create an environment that is both fun and educational to users. More traditional forms of media, such as magazines, newspapers, billboards, radio, and television, could be used to run ads or public service announcements. Finally, the Internet is quickly becoming one of society's primary means for accessing information. Internet blogs, website article marketing, hosting an exchange site, and/or Google Adwords are all effective ways to get information out onto the Internet.

Outreach to the Underserved

Across the country, disparities exist in the receipt of beneficial healthcare services. These disparities are particularly poignant in Maryland, as the State's minority population is a larger portion of the total than in general in the U.S. In 2004, Maryland's minority population accounted for 39.6% of citizens (29.6% African American, 4.9% Asian, 5.4% Hispanic, and 0.4% American Indian). In the same year, Maryland also ranked fifth among states in its percentage of African Americans and seventh among states in its proportion of Asians/Pacific Islanders. Furthermore, of Maryland's more than 5.6 million people, the percentage of uninsured is approximately 16%, with 64% concentrated in Baltimore City, Anne Arundel, Baltimore, Montgomery, and Prince George's Counties.

The underserved often experience low literacy and education levels, language barriers, and limited access to technology. Clearly, targeted efforts must exist to accommodate the unique characteristics of vulnerable populations that could benefit from HIE the most. In previous outreach initiatives, successful strategies that have been employed to reach underserved and uninsured communities include public service announcements (Covering Connecticut's Kids & Families Coalition),

community and corporate partnerships (Covering Kids & Families), and school-based outreach (Covering Kids & Families Southern Nevada Health District). General community outreach plans can also be tailored to target specific populations. For example, informational brochures can target the underserved when strategically placed in faith based organizations, community health clinics, certain schools, and other community based organizations. In consideration of the fact that one in six Americans has a communications disability, all published materials should be multi-lingual and mindful of varying education levels.

Furthermore, outreach via print media, radio, and television can be strategically marketed to certain demographics. Materials can be positioned in newspapers, magazines, radio stations, and cable TV channels traditionally engaged by underserved audiences. Certain conferences, such as the National Conference on Quality Healthcare for the Culturally Underserved and Freedom's Voice Conference, also attract those who work in underserved communities and may be good venues for presentations. Finally, education through community kiosks can be a non-threatening method with which many of the underserved are familiar. Community based kiosks can provide an access point that connects patients to the healthcare system for more effective care coordination. Strategically placed kiosks can also address some of the environmental barriers, such as internet access, for example, often present in accessing quality and equitable care amongst vulnerable populations.

Finally, underserved populations should be actively included in the development of the HIE through a range of activities. Those could include:

01 Focus groups sponsored by community-based organizations such as churches and community health clinics

02 Provision of useful de-identified health data to community health organizations to help them hone their service offerings to targeted populations

03 Convening of a series of workgroups made up of consumers and other stakeholders (such as community activists) who would come together at specific timeframes once a month initially and moving to once a quarter after the first year to discuss the unique challenges to HIE adoption among the underserved and to identify areas of improvement

Governance

A successful HIE will require a public-private partnership with broad participation by diverse stakeholders. It will also be imperative that the oversight mechanism for the HIE, whatever form it takes, operates in a highly transparent manner. This section proposes a governance framework for the Maryland HIE that honors these principles.

A key challenge in HIE governance, and indeed in almost every aspect of HIE formation and sustainability, is that an HIE cannot simply operate as an additional feature of the existing healthcare infrastructure. Instead, an HIE presents an opportunity to transcend existing market structures that often foster conflict—in many cases artificial conflict—among healthcare industry stakeholders, the government, and the public at large. Current structures often work against the concept of information sharing, and some healthcare industry stakeholders acknowledge that the created information asymmetries are stakeholder competitive advantages. The HIE must find ways to circumvent such zero-sum thinking by promoting new opportunities that arise out of ending information asymmetries instead of depending upon them. For example, opportunities to share master patient index information after the HIE has invested in ensuring its accuracy may benefit all participants.

Another reality of the current healthcare market is the ever-growing and entirely legitimate concern by the public for the privacy of their personal health information. By its very nature, HIE encourages the sharing of healthcare information across a potentially large group of people. A primary job of those responsible for governing the HIE is to ensure that, while expanding healthcare information sharing, individual concerns for healthcare information privacy are respected. Transparency, both of what the HIE is doing and why it is being done, will be key to balancing the requirements of the HIE with the public's concerns.

The HIE must foster trust among participants, direct stakeholders, and the population at large. The government must also be directly involved. In May 2008, the Maryland Health Care Commission issued a report entitled *Privacy & Security – Solutions & Implementation Activities for a Statewide Health Information Exchange* (hereafter referred to as the MHCC report). This report states that a "public-private partnership can identify and facilitate the development of appropriate policy and, if necessary, legislation … required to improve the privacy, security, reporting capabilities, and management of electronic health information exchange." CRISP agrees, and we recommend the formation of a non-profit entity, to be contracted by major HIE stakeholders (e.g. hospitals, health systems, state government) as the HIE agent. The contracting entities will appoint advisory board and mission oversight committee members, who will serve alongside representation of other stakeholders and the public. The HIE entity will then hire staff and contract with consultants and vendors to carry out implementation and maintenance activities under the board's guidance. A more detailed explanation of the proposed structure follows.

Governance Board

The advisory board and mission oversight committee will be established in order to establish HIE mission, vision, and strategy, to formulate policy, and to oversee implementation and maintenance activities. While specifics of the board's structure will need to be determined upon its creation, the workgroup agreed on several guiding principles for the board's constitution and activities.

As noted in the MHCC report, the key to building the trust, partnership, and transparency necessary to achieve HIE sustainability is diversity of representation in the governance body. The workgroup suggests

a group of core members representing the major stakeholders, probably consisting of hospitals, health systems, government entities, and large ancillary service providers (such as outpatient lab and radiology service providers), with rotating membership among other ancillary stakeholders and the public. Membership will be voluntary and members will not be compensated.

Bylaws will be formulated in such a way as to avoid domination or coercive pressure by the powerful stakeholders. That is, rotating members must have real input to and influence over decisions and not merely be token members. Certainly, core members will play a central role in policy formation, but policy approval must require at least some portion of the rotating membership to agree.

The leadership will act as, or appoint on its behalf, spokespersons to the public, with board or committee members available in a supporting role. All decisions of the leadership should be in the public domain, and the board should consider forums open to the public for as much of its deliberation and discussion as possible.

As a part of its responsibilities, the leadership will be responsible for formulating, overseeing, and reporting on budgets for the HIE. The leadership will also be responsible for selecting and hiring permanent staff. Finally, the board will formulate quantitative measures of project performance for the paid project leadership team whenever possible, avoiding qualitative measures whenever possible. Compensation to project leadership staff will be tied to performance based on these quantitative measures, again with all such compensation and measurement available to the general public unless circumstances unanimously agreed to by the board membership preclude such transparency (e.g. contract terms with a vendor that would damage that vendor's ability to do business with entities other than the HIE). The board will take care to ensure analyzing of all compensation and bonus structures to avoid perverse incentives that encourage short-term actions that are at odds with long-term HIE goals and objectives.

Project Leadership Team

Project leadership senior staff should be responsible for carrying out HIE implementation and maintenance activities on a day-to-day basis. The senior staff will advise the board, draft policies and procedures, participate in other board deliberations, and have ultimate decision authority. Project leadership staff will be compensated and may consist of full-time employees of the HIE entity or contracted consultants.

Processes must be established, however, to allow leadership staff to effectively run operations, and thus the board may delegate certain responsibility to staff. The board and staff will work together to establish reporting structures and timelines appropriate to allow the board to maintain appropriate oversight over HIE activities, and staff will thereafter be responsible for meeting the agreed upon reporting requirements.

As with the board, exact composition and structure will be determined at a later date, but will at least include a dedicated program management office (PMO). The PMO will be responsible for coordinating activities of each individual project as well as across projects. This means not only offering consistent project management services to individual projects, but also establishing policies and procedures with the advice and consent of the board and senior project leadership, that will apply uniformly to all projects, employees, vendors, and consultants. The PMO will ensure appropriate communication across projects. The PMO will ensure consistent documentation standards across all HIE projects and activities and will ensure proper archiving of all such documentation in such a manner as to promote knowledge management activities. All PMO activities will be conducted, as far as possible, according to broader current industry standards.

Infrastructure and Data Management Approach

Proposed Architecture Model

As proposed in the initial CRISP response to the RFA, we intend to build a hybrid, standards-based HIE. The exchange should operate using a HITSP-endorsed XDS (cross-enterprise document sharing) infrastructure, appropriate for supporting both distributed data and health record banks (i.e. patient controlled personal health records). This flexible approach will accommodate a distributed data model, such as envisioned by the Markle Foundation, with a master patient index and registry (i.e. a mechanism to locate records within the exchange). The distributed model ensures that data is held where it is created, therefore avoiding the negative perceptions and potential privacy and security consequences of storing all patient information in a large central HIE repository. At the same time, we expect health record banking to become prevalent in the marketplace, with consumers actively selecting to create health record bank accounts to exert control of the flow of their health information within the exchange. CRISP supports the emergence of that model, in which health record banks and other PHR applications function as a node on the network. Furthermore, the exchange will be developed to support viable services and entrepreneurial innovation – which we refer to as new "Use Cases", some of which are outlined in detail later in this report.

The flexible, standards-based, hybrid infrastructure that CRISP is recommending will allow for the secure transfer of a defined set of clinical information between participating entities. The core infrastructure will leverage a distributed model developed in adherence to generally accepted specifications and standards. However, the model will not exclude, and will ultimately drive towards, the technical capability to include distributed repositories of consumer-controlled health information where it is deemed appropriate or in the interest of the consumer (as defined by the consumer). While CRISP believes the architecture model described above represents the vision for what the exchange should aim to achieve, the near-term clinical data exchange may only leverage portions of the functionality that would be deployed in the full-scale exchange, for example the limited functionality required to achieve the electronic medication history service. The conceptual diagram on the next page (Figure 03), included in the CRISP RFA response, has been reaffirmed by the CRISP workgroups as a model that demonstrates foresight by positioning Maryland's HIE infrastructure to account for market development in either a distributed or health record bank driven model.

Integrating the Healthcare Enterprise Overview

As suggested in the planning RFA response, CRISP believes that the Integrating the Healthcare Enterprise (IHE) approach to health information exchange represents an approach to standards-based statewide health information exchange that will allow Maryland to achieve cross-organizational interoperability.

"IHE is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care. Systems developed in accordance with IHE communicate with one another better, are easier to implement, and enable care providers to use information more effectively. Standards provide the basis for such a framework, but alone do not solve the

problem. In any standard there are gaps, options, room for conflicting interpretations. No standard maps perfectly to the complex and ever-changing information domain of a healthcare enterprise. Filling the gap between standards and systems integration has, until now, required expensive, site-specific interface development. To close that gap a process for building a detailed framework for the implementation of standards is needed. IHE provides that process." [1]

[1] Integrating the Healthcare Enterprise, Available on the IHE website at http://www.ihe.net/About/index.cfm.

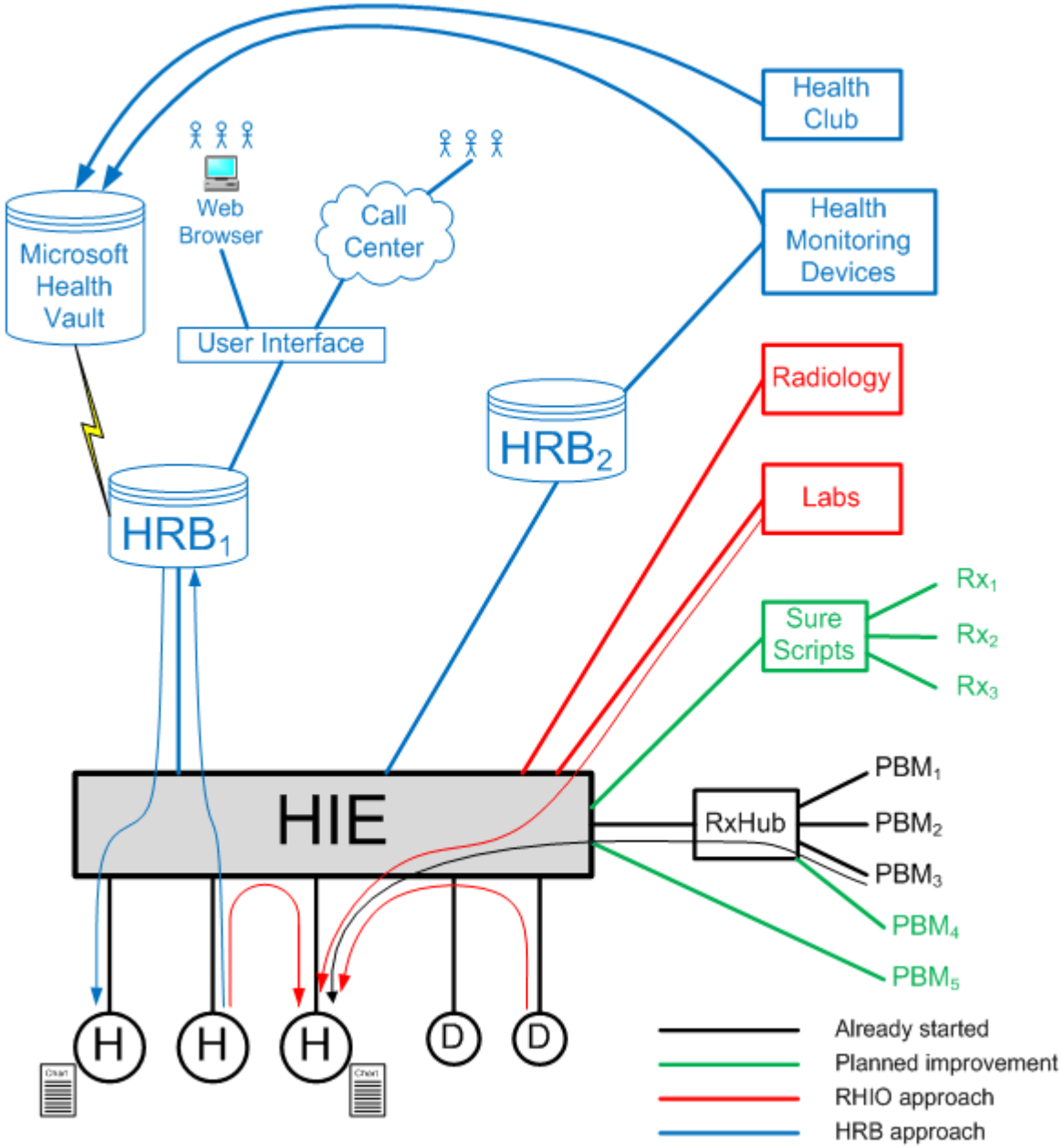

FIGURE 03

IHE has defined specific "profiles" aimed at constraining existing standards to define implementation guides. IHE profiles organize and leverage the integration capabilities that can be achieved by coordinated implementation of communication standards, such as DICOM, HL7, and security standards. They provide precise definitions of how standards can be implemented to meet specific clinical needs.[2] HITSP has endorsed a number of the IHE profiles that will enable broad health information exchange.[3] Furthermore, EHR vendors are beginning to build functionality into their products that can enable interoperability from the native EHR system, in some cases negating the requirement for the installation of an edge device (see Local Edge Device and Shared Edge Devise sections) that would allow an HIE participant to trade data with the health information exchange.[4]

[2] Ibid.

[3] As presented by Charles Parisot, IHE IT Infrastructure Planning Committee Co-Chair, in "IHE and U.S. National Health IT Initiatives."

[4] Evidenced by individual conversations held by Scott Afzal, CRISP project manager, with various EHR vendors.

IHE Integration Profile	Profile Description
Consistent Time (CT)	Ensures system clocks and time stamps of computers in a network are well synchronized (median error less than 1 second).
Audit Trail and Node Authentication (ATNA)	Describes authenticating systems using certificates and transmitting PHI-related audit events to a repository. This helps sites implement confidentiality policies.
Request Information for Display (RID)	Provides simple (browser-based) read-only access to clinical information (e.g. allergies or lab results) located outside the user's current application.
Enterprise User Authentication (EUA)	Enables single sign-on by facilitating one name per user for participating devices and software.
Patient Identifier Cross Referencing (PIX)	Cross-references patient identifiers between hospitals, care sites, health information exchanges, etc.
Patient Synchronized Application (PSA)	Allows selection of a patient in one application to cause other applications on a workstation to tune to that same patient.
Patient Demographics Query (PDQ)	Lets applications query a central patient information server and retrieve a patient's demographic and visit information.
Cross Enterprise Document Sharing (XDS)	Registers and shares electronic health record documents between healthcare enterprises, ranging from physician offices to clinics to acute care in-patient facilities.
Cross-Enterprise Document Media Interchange (XDM)	Transfers XDS documents and metadata over CD-R and USB memory devices, and over email using a ZIP attachment.
Personnel White Pages (PWP)	Provides basic directory information on human workforce members to other workforce members and applications.
Cross-Enterprise Document Reliable Interchange (XDR)	Provides a standards-based specification for managing the interchange of documents that healthcare enterprises have decided to explicitly exchange using a reliable point-to-point network communication.
Cross-Enterprise Sharing of Scanned Documents (XDS-SD)	Defines how to couple legacy paper, film, electronic and scanner outputted formats, represented within a structured HL7 CDA R2 header, with a PDF or plaintext formatted document containing clinical information.
Patient Identifier Cross-Reference and Patient Demographics Query for HL7v3 (PIX/PDQ/v3)	Extends the Patient Identifier Cross-Reference and Patient Demographics Query profiles leveraging HL7 version
Retrieve Form for Data Capture (RFD)	Enables EHR applications to directly request forms from clinical trial sponsors and public health reporting.
Registry Stored Query Transaction for Cross-Enterprise Document Sharing Profile	Adds a single transaction, Stored Query, to the XDS Profile.
Basic Patient Privacy Consents (BPPC)	The BPPC profile specifies a method for an AD to manage a set of simple patient privacy policies and communicate them associated with documents to protect from unwanted access.
Notice of Document Availability (NAV)	The NAV profile specifies a standard message to notify a physician about the availability of one or more documents in XDS registry, while preserving the patient privacy.
Document Digital Signature (DSG)	The DSG profile specifies a type of XDS document to sign other XDS documents with a digital signature standard.

FIGURE 04

In practice, the patient identity cross-reference (PIX) and the cross-enterprise document sharing profile (XDS) encompass a number of exchange transactions within the IHE Information Technology Infrastructure (ITI) and Patient Care Coordination (PCC) domain areas that support the basic transfer of health information through the exchange.[5] While there are a number of components in a fully deployed infrastructure, as shown in Figure 04, from a conceptual perspective (and key in understanding our policy approach) the exchange MPI, registry and distributed repositories are core components and defined in more detail below.

Master Patient Indexing

For a health information exchange to function, providers need a reliable way of matching their patients with available records in the network. This is no trivial task, and even within a single enterprise, matching a person with his or her past records is not always easy. Our aim is accuracy within a framework of achievability and pragmatism. It is our judgment that a plan requiring significant near-term changes to providers' internal systems would be difficult and expensive to implement.

The CRISP team proposes following the IHE patient identity cross-reference (PIX) approach to patient matching. At a high level, the PIX manager is a layer on a master patient index (MPI) that is operated within the exchange. Each record in the PIX contains cross-references to medical record numbers (MRN) located at participating institutions. In essence, the PIX can translate the MRN of one provider to the MRN of another provider. The initial link (linking an MRN to an existing PIX record) is initiated through statistical matching. That matching can be "tuned" to avoid errors and final linking can be resolved through either probabilistic or deterministic matching, which is discussed in more detail below.

The proposed early CRISP Use Cases will not require providers who are consuming/receiving data to write PIX feeds to the exchange MPI. Instead, receiving providers can send demographic data to the exchange to be matched probabilistically to the MPIs of data suppliers/senders (RxHub's Initiate Systems MPI for example) to obtain available data. It is only when an institution becomes a supplier/sender of data that their MPI will need to be fed to the PIX.

MPI Discussion

The objective of the CRISP MPI strategy will be to maximize the positive identification of subject patients while minimizing both false positives and false negatives. The recommended approach should use the IHE Patient Identity Cross-Reference (PIX) Manager integration profile accounting for demographic data variation (first name John vs. Jonathan) and human entry error (zip code or birthday number transposition) with weighted scoring assignments to each data element based on those variations. The MPI will run algorithms against the existing demographic information to preprocess the database to determine the frequency of every attribute and score the match according to the discriminating ability of the specific attributes of that database. The limits of acceptance and rejection will be tailored to the size of the population and the risk tolerance of both false negative and false positives.[6] A key challenge will be to identify the set of demographic / identity information (and arrive at agreement from each participant to use those data sets) used in the PIX feed transactions.

In Figure 05, HIE participants are submitting a standardized patient identity feed to populate the centralized MPI.[7] Based on a centrally defined set of non-clinical patient information, a standard message will be sent into the central exchange MPI. If the subject patient already existed in the MPI, then the inbound transaction would be cross-referenced against the existing record and added to that record as a new medical record number (MRN) associated with the MPI ID. If the patient was a new entry, a new MPI record would be created and all subsequent inbound feeds would be cross-referenced with the new record.

[5] The DSG profile specifies a type of XDS document to sign other XDS documents with a digital signature standard.

[6] Rand Corporation. "Identity Crisis: An Examination of the Costs and Benefits of a Unique Patient Identifier for the U.S. Health Care System," 2008.

[7] While Figures 02, 03 and 04 are presented differently than the conceptual version offered in Figure 01, they represent the same thinking with respect to the architecture model.

A Note on Patient Record Identification Using Statistical Matching Methods

The CRISP Exchange Technology & Clinical Workflows workgroup spent considerable time deliberating on statistical matching approaches from an individual hospital, integrated delivery network (IDN), and statewide health information exchange perspective. The Joint Commission identified accurate patient identification as the number one goal in defining their National Patient Safety Goals for the Hospital Program in 2008, underscoring the importance of this issue in the broader context of a health information exchange.[8] The CRISP workgroup discussed the shortcomings of statistical matching and the difficultly in maintaining an accurate database of demographic information that can correctly identify an individual. The Rand Corporation conducted an exhaustive review of statistical matching methodology outlining the issues stating that the "problem with personal attribute keys such as name and address is that they are usually not unique to the individual, change over time, and are often entered into different systems in different formats. Any data-entry errors, such as misspellings, add to the difficulties with this type of key."[9] The workgroup recognized that while patient matching and creation of a centralized MPI will be challenging, it is not an insurmountable task and existing technologies and processes can achieve a high percentage of successful matching results and avoid, to a large degree, the number of false positive returns.[10]

Comparing Probabilistic and Deterministic PIX Record Linking

As discussed in the section above, there are significant challenges and risks inherent in maintaining an accurate MPI that are rooted in statistical matching techniques. However, effectively mitigating those risks is possible. An understanding of the difference between probabilistic and deterministic record linking within a PIX/MPI is critical in evaluating the overall risk of false-positive and false-negative linking. Relying on a completely automated probabilistic record matching and linking approach requires an extremely high threshold for accuracy to limit the potential for false-positives, thereby increasing false-negative outcomes.

An effective PIX/MPI solution will require some degree of manual intervention and ongoing attention to linking. Deterministic matching includes manual intervention by escalating MPI matching events that do not meet the threshold requirements set by the exchange operators. A resource in an exchange-operated support center would then look at the records and try to determine whether or not they in fact refer to the same person. They will use a combination of intelligence, common sense, and investigation to make this determination. For example, if the last two numbers of the Social Security Number were transposed, the deterministic logic may "kick" the matching request out for inspection. The support resource will determine that the records match and that the numbers were likely transposed. The resource will then manually merge the records. If the matching issue is not as straightforward as a transposition, the resource may need to do some more investigation by perhaps calling the organization where the record originated to see if it has more information on the patient that could help them make a determination. The CRISP workgroups felt that a deterministic matching approach would be required to build trust in the accuracy and effectiveness of the exchange MPI.

Identity Fraud and the MPI

The impact of fraud is harder to predict. Anecdotally, hospitals do report individuals "borrowing" or stealing another person's identity in order to receive treatment that is covered by an insurer. While this behavior is obviously a criminal act, the HIE should be concerned that participants not accidentally misdiagnose or treat the criminal on the basis of the wrong medical history. The consent process will be part of the safety mechanisms, in this case. Yet, we will need to evaluate this risk during the operation of the exchange. It is a risk that also exists in the other approaches to MPI, save perhaps the use of biometric matching at registration.

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[8] The Joint Commission, Available on the Joint Commission website at http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/08_hap_npsgs.htm.

[9] Rand Corporation. "Identity Crisis, An Examination of the Costs and Benefits of a Unique Patient Identifier for the U.S. Health Care System," 2008.

[10] A false positive return is when a patient is inaccurately linked to a different patient's medical record. For a comprehensive review of the Universal Patient Identifier and Statistical Matching issues see Rand Corporation's "Identity Crisis, An Examination of the Costs and Benefits of a Unique Patient Identifier for the U.S. Health Care System."

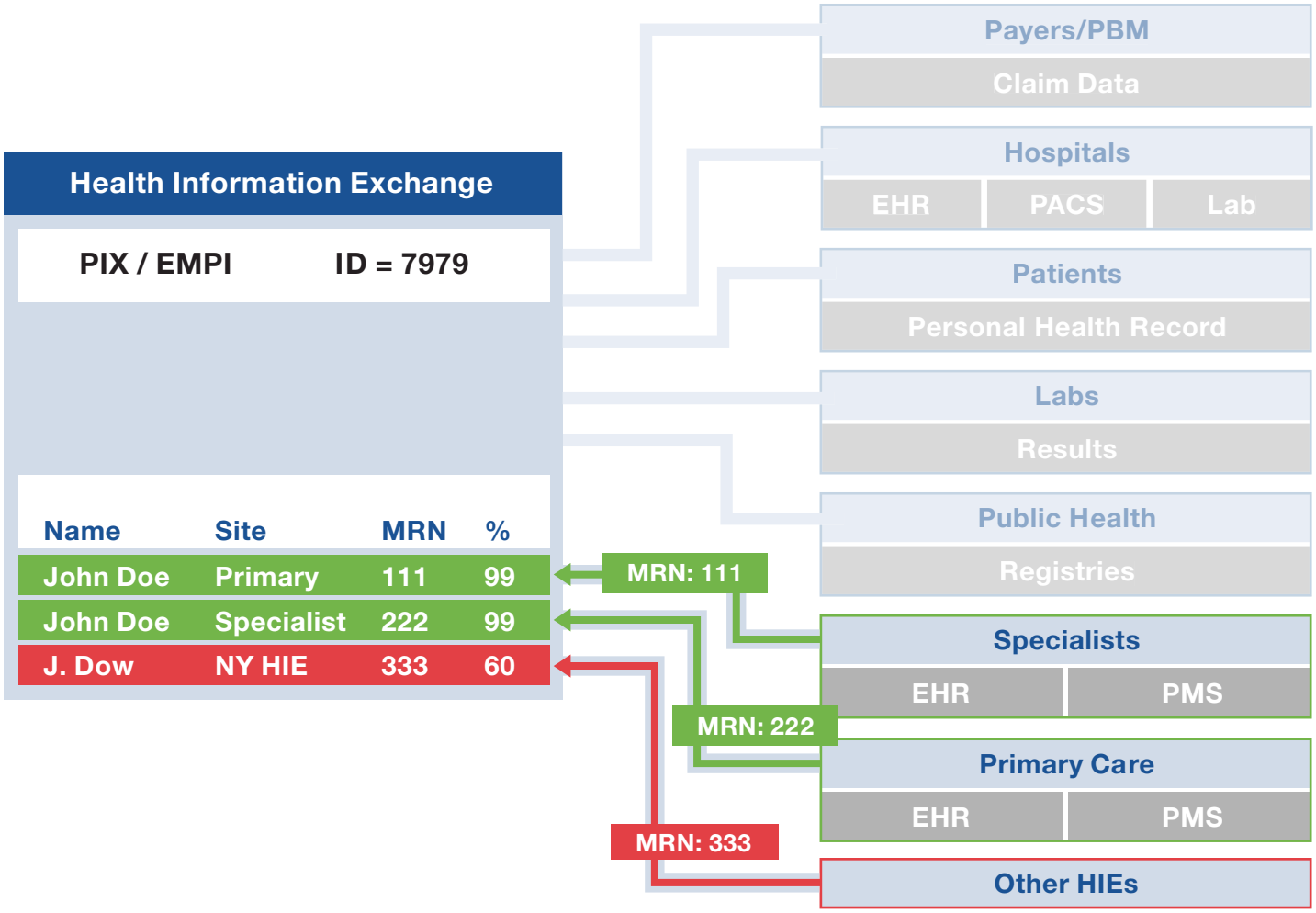

FIGURE 05

The Unique Patient Identifier Approach

Ideally, patient matching could be accomplished using a unique patient identifier (UPI) that unambiguously points to a unique identity, returning records associated with that UPI with near 100% accuracy. The use of a UPI could avoid the shortcomings of statistical matching. The industry broadly considered and then dismissed using the Social Security Number as a UPI. The widespread abuse of that identification number was deemed to make it inappropriate as a UPI. Others have advocated issuing identity cards for use at provider registration. While broad adoption of a UPI could increase the accuracy of patient identification within a health information exchange, it is unrealistic to expect that a successful UPI system could be created on a state-by-state basis. Without federal-government leadership for the issuance of a UPI, we deem this approach impractical. Furthermore, incorporation of a UPI in the short-term would likely require significant investment by providers in their internal systems and workflows. Those systems are not generally equipped to use a UPI, and the expense of near-term conversion would be a barrier to incremental success of the state's HIE effort. Rather, the HIE should monitor nationwide developments on this front, and maintain the ability to incorporate a UPI in the future should there be movement in that area.

HIPAA and the MPI

The United States Office of Civil Rights, the entity with the Department of Health and Human Services that has day-to-day enforcement responsibility for HIPAA, has addressed the question of whether or not an HIE can manage a master patient index on behalf of multiple HIPAA covered entities. They found that an HIE,

"may receive protected health information from multiple covered entities, and manage, as a business associate on their behalf, a master

patient index for the purposes of identifying and linking all information about a particular individual. Disclosures to, and use of, a HIE for such purposes is permitted as part of the participating covered entities' healthcare operations under the HIPAA Privacy Rule, to the extent the purpose of the master patient index is to facilitate the exchange of health information by those covered entities for the purposes otherwise permitted by the Privacy Rule, such as treatment." [11]

[11] The Office of Civil Rights. The HIPAA Privacy Rule and Electronic Health Information Exchange in a Networked Environment, 2008.

The Data Publisher Perspective

Figure 06 illustrates the process by which an HIE participant would submit, store, and register patient health information with the exchange.

Master Patient Index Data Load

As shown in the "Patient Identity Feed" line in Figure 06, non-clinical patient attributes would be submitted to the central MPI leveraging an IHE ITI standard transaction. From a technical perspective, exchange participants could publish patient identity information on a nightly "batch" job basis, or based upon a number of events that could be defined at each participant, depending on various technical and or policy constraints and decisions. This particular transaction was discussed

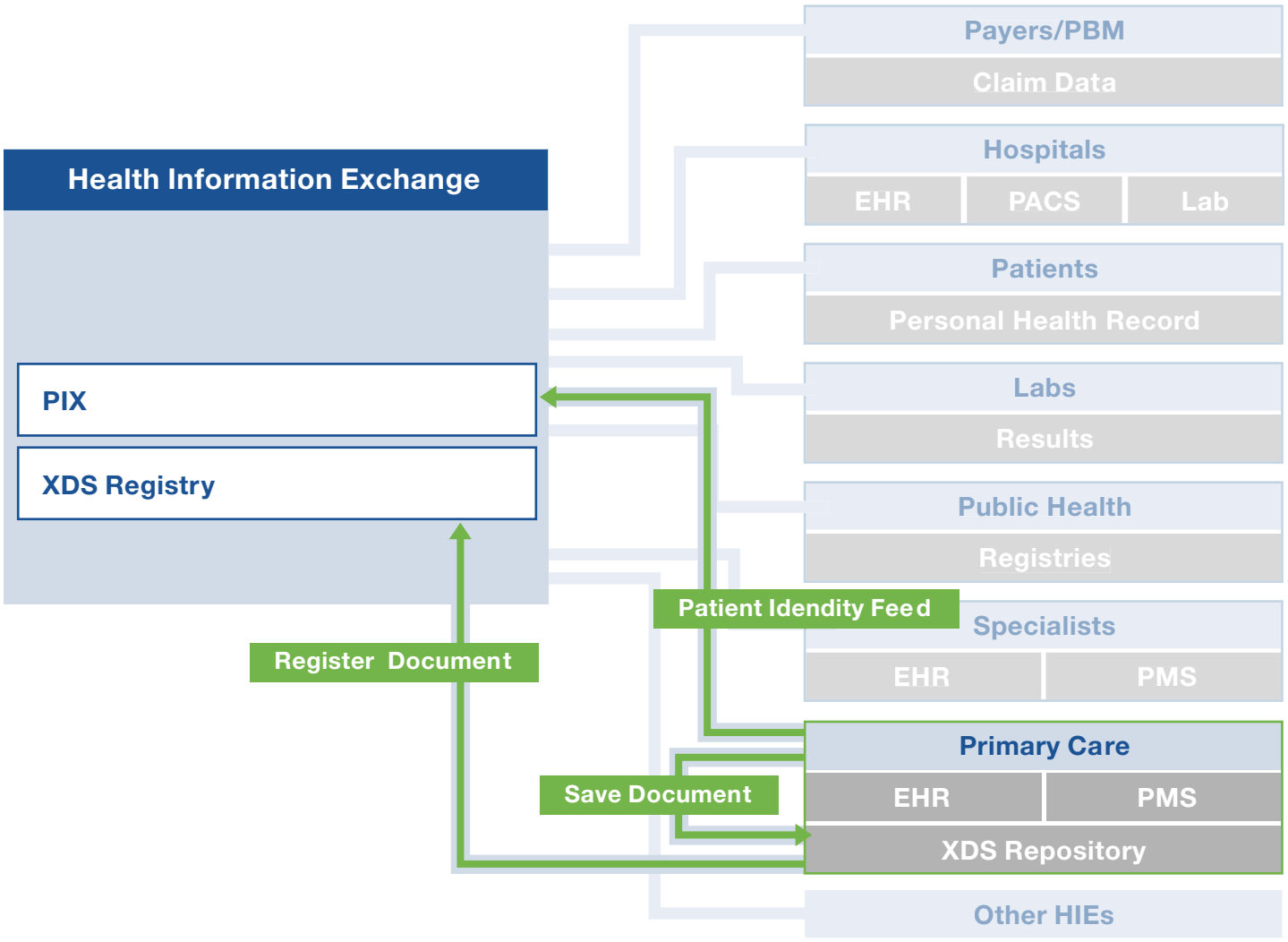

FIGURE 06

in the previous section, however is important in describing the overall approach to publishing clinical information to the exchange.

Storage of Clinical Information

A critical concept in the exchange, and at the core of the architecture model, is that clinical data is not held in a centralized repository on behalf of exchange participants. Nodes on the exchange will store data locally in their own "edge devices" that are in turn made available to the exchange if an allowable request is received.[12] An edge device refers to the hardware and software where participants in the exchange store clinical data that they intend to make available to appropriate requests coming from other participants in the exchange. As EHR products develop towards the HITSP-endorsed and CCHIT-specified standards, direct communication between the exchange and the local EHR may become feasible. Of note, participants in the Maryland HIE will undoubtedly have varying levels of technical capability, and in the case of physician practices, will be unlikely to have any existing technical infrastructure or EHR to connect into the exchange. Alternatives to a locally deployed edge device are discussed in the Exchange Participant Access section below.

An important aspect of the storage of clinical information on an edge device is how consumers with health record bank accounts will interact with it. While discussed in greater detail below, health record bank applications will connect to the exchange in a manner similar to that of any other provider. By observing standard transaction sets and data architecture standards, consumers will be afforded the ability to control data in an edge device (database) separate from the central exchange infrastructure.

Registering Clinical Information with the Exchange

When an exchange participant stores data on an edge device, metadata about the data storage is committed to a centralized document registry. The intent of the document registry is to maintain data about the location and type of documents that exist on the network.

When a participant saves a document (for example a CCD) to the exchange edge device, a standard IHE "register document" transaction is initiated that sends the necessary document identification information to the centralized registry.[13]

The Data Consumer Perspective

Reading the Master Patient Index

When a participant in the exchange is attempting to locate a patient in the exchange, that participant will send a request to the PIX manager by submitting a standardized PIX Query, noted in Figure 07 as the "Query for Patient" line.[14] The PIX Query transaction carries the local MRN and locates that MRN within the PIX manager. Once found, the PIX manager, as the name suggests, will cross-reference the submitted MRN with the other record numbers that have been associated with that MRN when the original PIX feeds were submitted to the exchange.

Providers also have the ability to query the exchange using demographic information for those patient encounters for which no MRN has previously been established or communicated with the PIX manager for cross-referencing. The Patient Demographic Query (PDQ) transaction allows basic patient demographic information to be submitted to the MPI for patient location leveraging statistical matching.

Locating Clinical Information in the Exchange

After successfully locating the patient, a transaction will be executed to locate records for that patient within the centralized registry, illustrated in Figure 07 by the "Query for Documents" line. It is important to note that the data housed in the registry is not clinical data and is only metadata about the location and type of information available on edge devices connected to the exchange. Information in the registry can then be presented to the participant as a list of clinical documents available in the exchange. The list of

[12] The term "allowable" is intended to describe the constraints placed on access of data, even if on edge device, by patient preferences, role-based access rule and proper authentication into the exchange.

[13] IHE Technical Framework available at http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_Supplement_XDS-2.pdf.

[14] IHE transaction available at http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_5-0_Vol2_FT_2008-12-12.pdf.

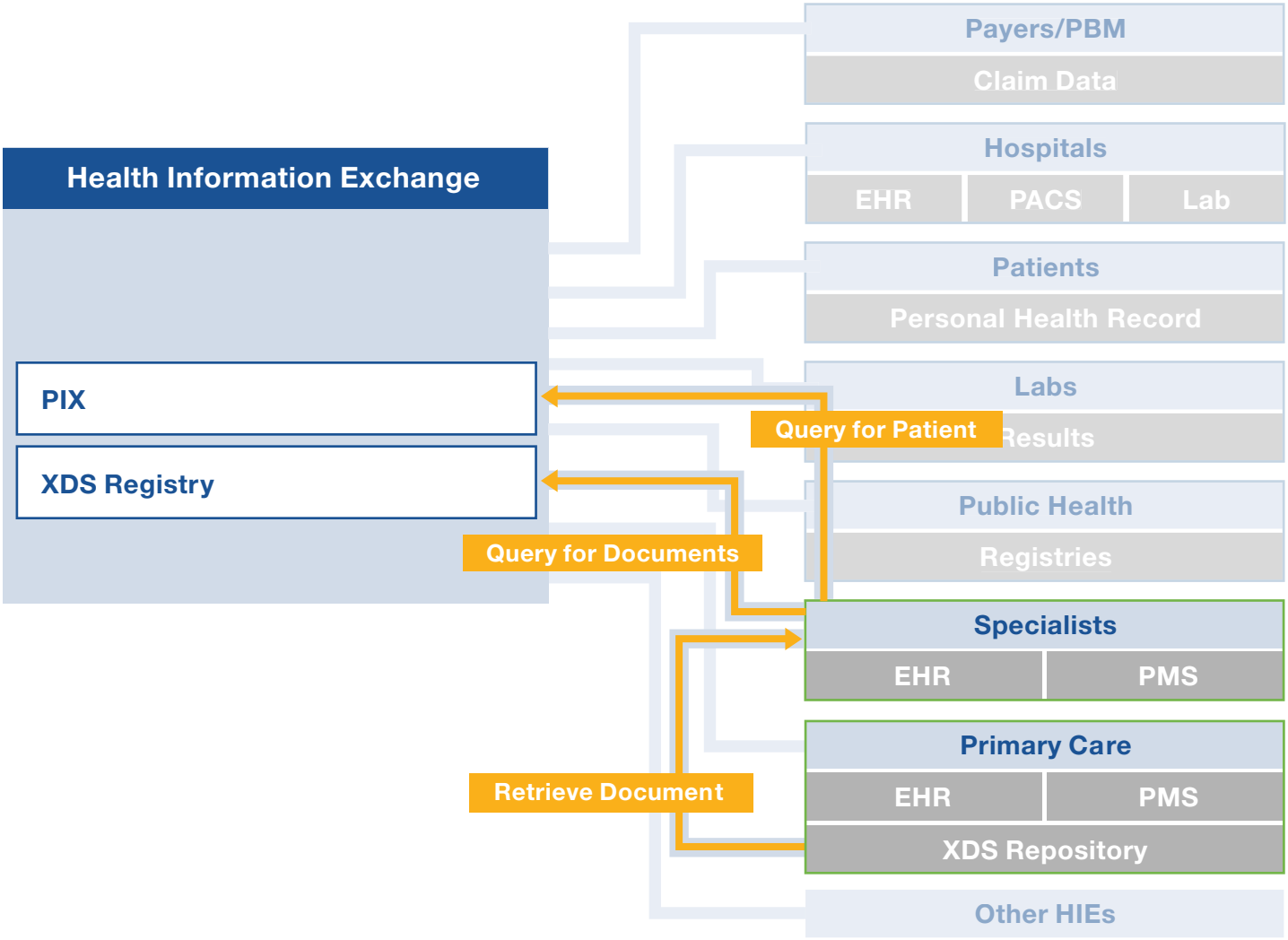

FIGURE 07

documents presented to the participant is dependent upon the access rights defined for the participant role within the exchange. While data may be presented to the participant as a list, other data delivery options exist and are discussed in both the Use Case section of this report and more conceptually in the section below.

Retrieving Clinical Information from the Exchange

Following the initial PIX Query and the subsequent query and response of the exchange registry, the participant has the option to select a document from the registry that he wishes to exchange, again, dependent upon his access rights to view that document. When a participant selects a document from the registry list, an ITI Consumer Document transaction is initiated (noted in Figure 07 as the "Retrieve Document" line) that sends a request to the edge device storing the clinical information; when the request is accepted, that clinical document will be presented to the requesting participant.

The process defined above for the retrieval of clinical information implies a "pause" in the location of patient records at the exchange registry level for review of available documents. However, scenarios exist whereby a participant may prefer to receive core clinical data about a patient without the additional workflow of selecting clinical documents from a list of all available documents. In this scenario, the exchange can identify, locate and delivery a core document, defined by the document type, to be delivered to the requesting provider.

Exchange Participant Access Options

Participants' technical capabilities and willingness to modify their existing technology solutions and clinical workflows are core issues in the exchange service offerings. The Use Case section of this report refers specifically to a number of clinical data delivery scenarios and describes the mechanisms for participants using those services to receive data. The HIE infrastructure will allow participants to access data through the exchange via multiple access points based on both the type of clinical service offering and participants' current (at the time of a service deployment) technical capacity. Clinical data delivery options range from paper print delivery to HIE portal access to full local EHR integration with the HIE.

Paper Print Delivery

As demonstrated with the current medication history service deployed by the CRISP team, paper delivery of clinical information as a print-out to a secure IP printer can be a valuable and technically "lightweight" solution to delivery previously unavailable data through the exchange. While this access method may not have the appeal of an electronic delivery or integrated solution, data delivered is often in a structured format on the back-end and still drives toward an interoperable architecture model by integrating previously disparate data silos to access the health information delivered in paper format.

Portal Access

The portal access solution, as shown in Figure 08, offers a near-term avenue for delivering clinical information electronically to exchange participants. The significant benefit of allowing access to clinical data via a portal is the minimal technical requirement necessary to participate. Reducing the participant cost burden of a partially or fully integrated access solution by offering portal access could drive initial usage of the health information exchange. Further, portal access can build toward a more robust use of HIT, for example by transitioning from a portal to an "EHR lite" to a fully deployed EHR.[15] While an early portal offering may include limited data sets, or perhaps as in the HealthBridge initial model a single data type (lab results), having an existing delivery mechanism deployed and utilized allows the exchange to deliver an increasing amount of data through the exchange via the portal.[16]

While attractive in the short-term, there are certainly challenges in the portal access solution that can affect participant utilization. First, while the technical capabilities necessary to meet the minimum requirements for portal access are relatively lightweight (i.e. computer with Internet connectivity), many Maryland physicians operating in rural communities may not have considered Internet connectivity as essential. Second, adding an additional access point to what may already be a myriad of other websites that participants may already use could cause frustration or confusion.[17] Managing multiple sites, usernames, and passwords can be a daunting and often prohibitively time-consuming task. Lastly, the value of the portal, and from a broader view the entire exchange, will be a function of the amount of quality data that it allows participants to access. A recent survey conducted by Epocrates found that 73% of U.S. physicians access the Internet on a daily basis for clinical information, with 58% of those surveyed indicating they go online at least two times and in some cases more than five times a day.[18]

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[15] CRISP Exchange Technology and Clinical Workflow Workgroup consensus point.

[16] http://www.healthbridge.org/.

[17] For example, participants may be accessing lab results electronically from Quest or LabCorp or verifying eligibility through multiple insurance companies' websites.

[18] Epocrates, "Epocrates Online Physician User Survey," as reference on iHealthBeat at http://www.ihealthbeat.org/Data-Points/2008/How-Often-Do-Physicians-Go-Online-for-Clinical-Information.aspx.

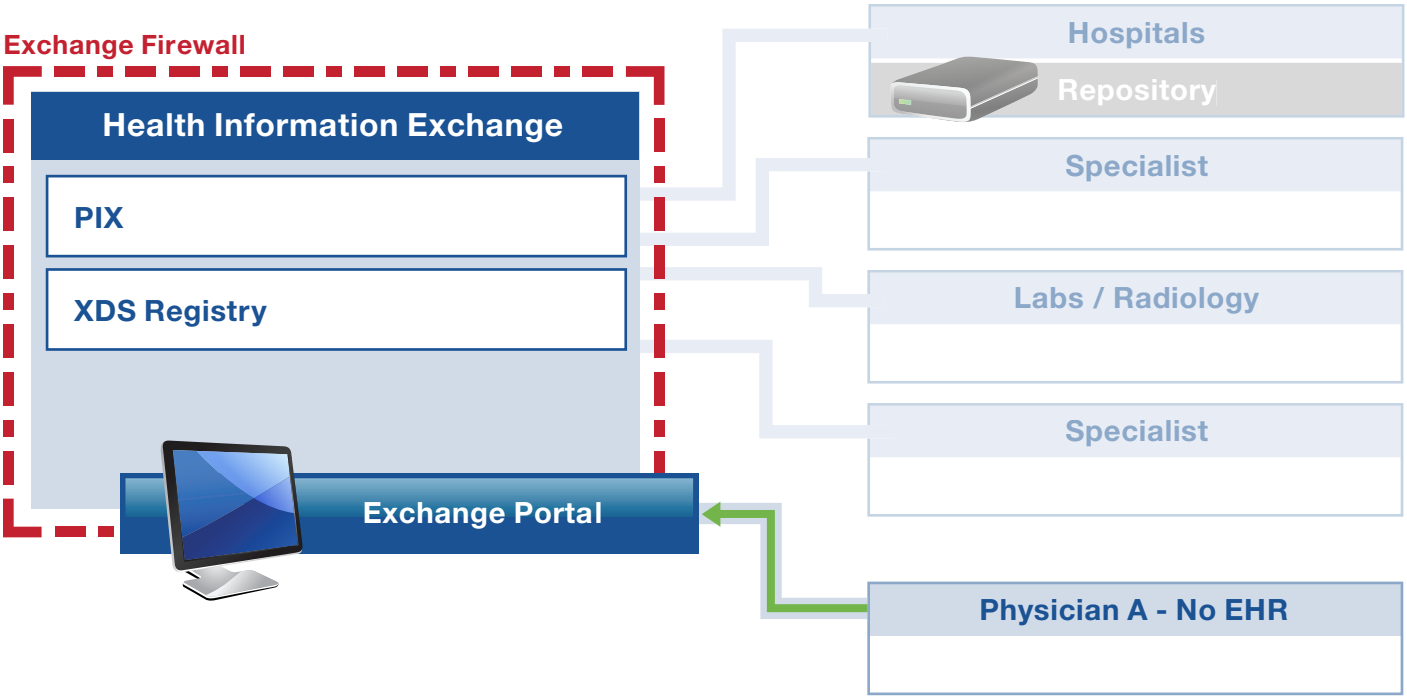
Exchange Firewall
Health Information Exchange
PIX
XDS Registry
Exchange Portal
Hospitals
Repository
Specialist
Labs / Radiology
Specialist
Physician A - No EHR

FIGURE 08

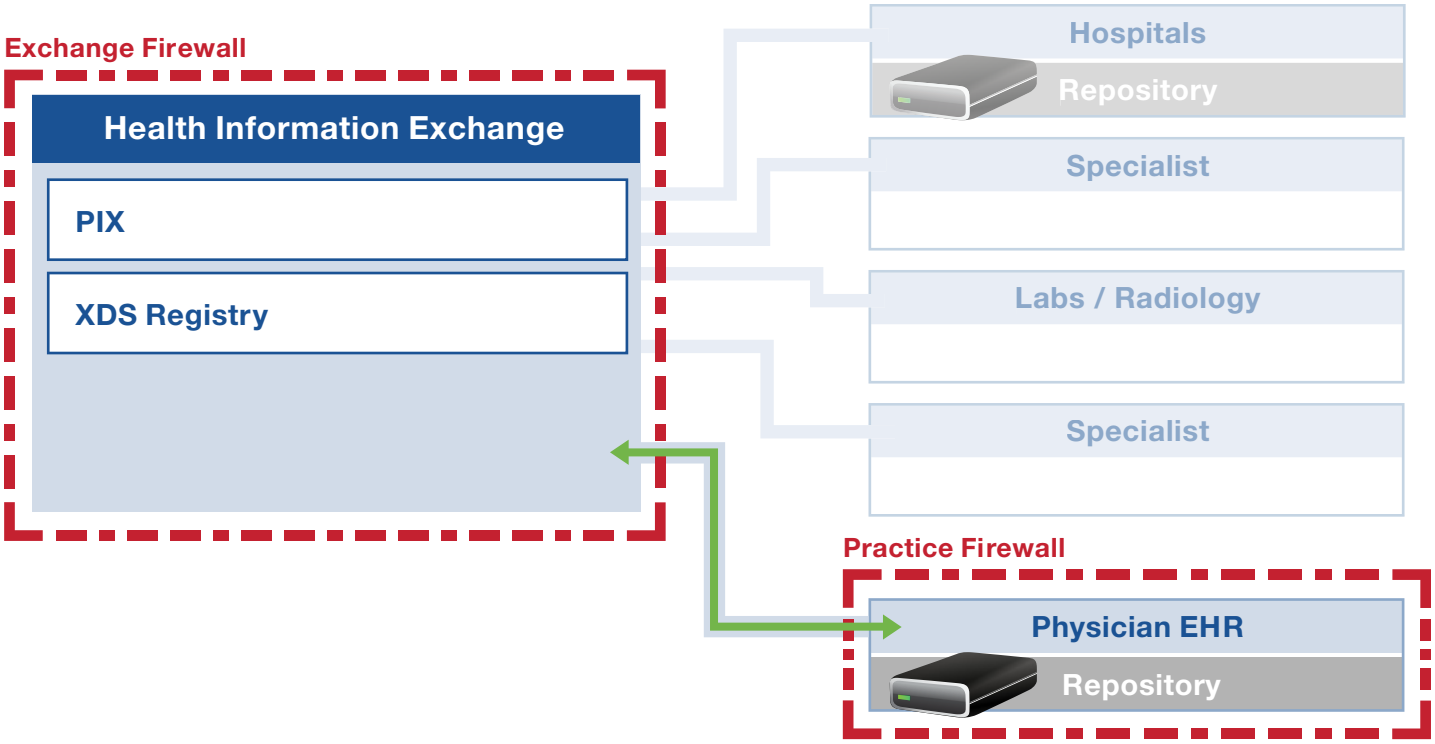

FIGURE 09

Local Edge Device

While not anticipated in the early exchange, participants will have the option of fully integrating their local EHR or hospital information system with the HIE (as seen in Figure 09). By fully integrating local systems with the exchange, participants will have the ability to seamlessly exchange information with the HIE and avoid some of the pitfalls of an alternative access approach.[19] A prerequisite for a hospital or physician practice to integrate with the exchange is having a system deployed locally with which the exchange can be integrated. While an obvious statement, the requirement alludes to the current lack of EHR adoption among Maryland physician practices and the associated inability to integrate with an available exchange. Early technical integration efforts are likely to focus on hospital partners with existing infrastructure that will allow for the local integration to occur. As hospitals are integrated and patients become familiar with the benefits of care supported by HIE and as incentives for adoption enter the marketplace, physician practices will likely feel more compelled to implement EHRs and join the exchange.

[19] These pitfalls, as described in other sections of this report, include multiple applications to manage, password fatigue, potentially prohibitive clinical workflow impacts, etc.

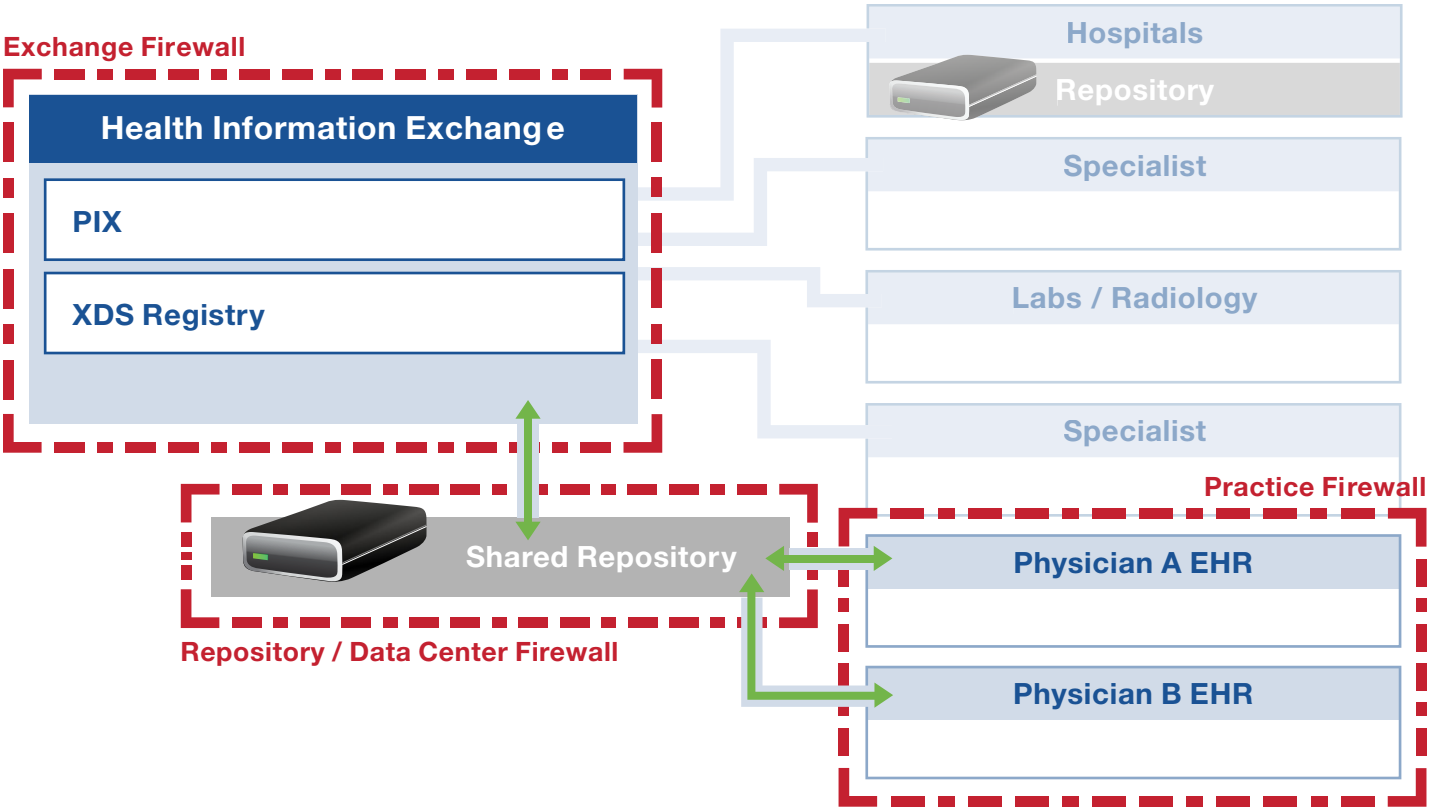

FIGURE 10

Shared Edge Device

A further option for enabling participants to communicate with the exchange is to store data in a shared edge device (as seen in Figure 10). A shared edge device could be deployed through a number of different arrangements. First, exchange participants that have existing relationships, either technical or clinical (such as a hospital/clinic affiliation or a management services organization arrangement), could partner to deploy a single edge device that is integrated with the exchange. This kind of partnership can limit the up-front technical integration costs as well as the ongoing maintenance costs associated with HIE connectivity. Second, as discussed in the Portal Access section, functionality through web-based access (portal) solutions may develop over time, allowing participants to create and commit data to the exchange. In this scenario, the HIE, or perhaps another separate managed services organization, could provide a shared edge device that has connectivity to the exchange and stores data for multiple providers who have opted not to deploy an edge device locally.

Health Record Banking

Health record banking is a concept that is pervasive throughout this report and addressed across many fronts, from consumer access and control rights to how these consumer applications may actually be deployed in an HIE, as discussed in the Use Case section. Because consumer engagement is a significant component of the overall approach articulated in this report, providing a more in-depth review of the technical aspects of HRBs is necessary.

The CRISP workgroup envisioned health record banks and other consumer access applications acting as nodes on the exchange, similar to any other provider participant. In practice, this implies that HRBs will adhere to similar IHE integration standards supporting the standardized transactions discussed earlier in this section. However, as this report suggests, HRBs will likely be offered by commercial businesses targeting specific consumer demographics; therefore the functionality of each application may vary based on that intended target and specifics of the business case. The HIE operators should

seek to define minimum integration standards that HRB vendors can build against and then engage the exchange to implement the product. These standards should leverage the IHE profiles described above, but may also look to deploy the XPRH IHE integration profile, the purpose of which is to support interoperability between PHR systems used by patients and the information systems used by healthcare providers.[20] The exchange must also dictate minimum authentication standards and will most likely have to share the patient authentication burden to ensure the accurate delivery of patient records in HRB accounts.

Commercially available HRBs are not the only means to provide consumers with access and control over their own health information. The HIE should provide a consumer access portal into the exchange, similar to the provider portal, that allows consumers to view their health information and exert control over how it flows through the system. Encouraging consumer engagement by offering a standardized consumer portal solution can act as a catalyst for broader adoptions of consumer health management tools.

Electronic Health Records

The CRISP planning process was neither designed nor intended to address the problem of adoption and use of EHRs in the physician community. However, the challenges of HIE cannot be adequately addressed without acknowledging the absolute requirement of a significant increase in the use and adoption of EHRs. With that increase will come increasing returns to scale in terms of clinical value, as the amount of information available for exchange increases. Two of the three major components of a successful overall HIT plan for Maryland are incorporated in detail into this report: health information exchange and consumer access through health record banks. The third component, electronic health record adoption, has been partially addressed by the Maryland Task Force to Study EHRs.

The Task Force provided a number of key recommendations, some of which are enabled through the completion of the CRISP planning effort.[21] A general recognition exists in the healthcare community that requiring providers to adopt EHRs in the absence of substantial reimbursement increases, performance incentives, and/or subsidization could result in disastrous consequences for practices with rising costs and decreasing reimbursement rates. Ultimately, creating a legislative mandate for EHR adoption in the absence of robust financial support or incentives would be to the detriment of the overall Maryland healthcare system. However, with significant state and federal activity occurring at the time of this report writing around economic stimulus, specifically a focus on HIT, near-term opportunity to affect dramatic change in adoption rates in Maryland based on funding availability appears possible.

While the benefits of EHRs have been well-documented, still many providers have no plans to implement one anytime in the near future.[22] The fact that many of these benefits, both in cost savings and quality improvement, inure to patients and payers should call the State to action in setting a clearly defined goal, or funded mandate, for Maryland physician EHR adoption. Continuing to affirm the EHR adoption goal stated in President Bush's 2004 Executive Order calling for most Americans to have an EHR by 2014, and the re-affirmation of that goal by the Obama Administration, will maintain the focus and market movement toward that goal.

The provider portal discussed earlier in this section can act as a mechanism to drive adoption of more robust EHR solutions as the HIE grows and its value is realized. The concept is that less intrusive IT solutions, such as portal access to the exchange, can allow providers to participate and use external health information during patient treatment without having to deploy intensive EHR solutions locally or significantly modify clinical workflows. As the data becomes more valuable to a provider's day-to-day practice, we expect he or she will seek the ability to consume more information through

[20] http://wiki.ihe.net/index.php?title=PCC_TF-1/XPHR#Exchange_of_Personal_Health_Record_Content_Integration_Profile_.28XPHR.29, Accessed January, 2009.

[21] "The Maryland Healthcare Commission Task Force to Study Electronic Health Records," The Maryland Healthcare Commission, 2008 Accessible at http://mhcc.maryland.gov/electronichealth/taskforceinfo.html (October 2008).

[22] AAFP Center for Health Information Technology, http://www.centerforhit.org/x1117.xml. Accessed January, 2008.

fuller HIE participation. At that point, transitioning to more robust solutions, such as an "EHR lite", a hosted EHR, or a locally-deployed EHR system can occur.

At the time of this report writing, the American Recovery and Reinvestment Act, the proposed federal economic stimulus bill, allocates significant funding to the technological modernization of our healthcare system, including EHR deployments to physician practices. The act also dictates loose certification standards that should be adhered to in order to ensure that technology funded by the legislation is interoperable with developing health information exchanges. However, in its current form, the legislation remains silent on which certification organization it will rely on to determine which products are considered certified. Based on the bill's current language, a legitimate concern exists that EHR lite applications will not be eligible for federal stimulus funding. However, the language in the legislation is not overly specific, stating only that the funds should not be used to "make significant investment" unless they are certified products. Therefore, it is not an unwarranted assumption based on the language that a multi-offering platform where larger subsidies or other incentives are available for those adopting certified technologies (dependent upon how that definition evolves) could be deployed effectively using federal stimulus funds.

Review of Industry-Defined Standards

An ongoing challenge for health IT advocates and stakeholders is the use of standards and efforts to consistently deploy those standards across organizations to ensure that effective communication can occur between information systems. Standards have been or are being developed by a multitude of organizations and have numerous and frequently inconsistent applications, leading to the interoperability shortcomings of the existing infrastructure. As these standards mature and are implanted through frameworks, specifically the IHE integration profile defined in this document, the burden of interoperability should become manageable. The intent of listing the standards below is not to prescribe which standards should be used, but rather to foster awareness of what standards currently exist and to encourage careful and consistent attention to the progress of these standards bodies and the applicability of the standards to specific Use Cases and integration profiles. In some cases, the information below does not represent a specific standard or standards body but rather a generally accepted approach. CRISP would like to recognize the Vermont Information Technology Leaders (VITL) and their president, Gregory Farnum, for assisting the CRISP group in this area and sharing the associated documentation they have developed during the life of their organization.

Messaging Standards				
Oversight Body	Standard	Application	Description	Source
Accredited Standards Committee (ASC)	ASC X12 Standards Release 004010	Message Formatting/ Transport	Electronic Data Interchange (EDI) standards with a specific Insurance/Health Series (INS) relevant to insurance and other health-related business transactions.	http://www.x12.org
Centers for Disease Control and Prevention (CDC)	Public Health Information Network (PHIN) Standards	Message Formatting/ Transport	PHIN develops standards to facilitate secure and interoperable exchange of public health data.	http://www.cdc.gov/phin/
Digital Imaging and Communications in Medicine (DICOM)	PS 3 – 2007	Message Formatting/ Transport	Medical imaging standards that address storage, transmission, and data structure of medical images.	http://medical.nema.org
ebXML	Business Protocol	Message Formatting/ Transport	Protocol enabling the exchange of messages and the conduction of business via the Internet.	http://www.ebxml.org
Health Information Technology Standards Panel (HITSP)	Interoperability Specifications	Message Formatting/ Transport	HITSP standards are built around Use Cases. The panel works to unify existing healthcare IT standards; all standards promoting interoperability should be adhered to.	http://hitsp.org
Health Level 7 (HL7)	Version 2.n Messaging Standard	Message Formatting/ Transport	Provides definitions of electronic messages used to support nearly all aspects of hospital workflow.	http://www.hl7.org
Health Level 7 (HL7)	Version 3.0 Clinical Document Architecture (CDA/CDA R2)	Version 3.0 Clinical Document Architecture (CDA/CDA R2)	Gives standards for constructing clinical documents for electronic exchange. It addresses document content, structure, and encoding.	http://www.hl7.org
Health Level 7 (HL7)	Version 3.0 Messaging Standard	Message Formatting/ Transport	A newer version of HL7 standards that is supposed to gradually replace v2.	http://www.hl7.org
Integrating the Healthcare Enterprise (IHE)	Profiles and Technical Frameworks	Message Formatting/ Transport	This framework offers guidance on how to effectively implement established standards.	http://www.ihe.net/ Technical_Framework/
National Council for Prescription Drug Programs (NCPDP)	SCRIPT Standard Version 8.1	Message Formatting/ Transport	Standards dealing with the electronic transmission of pharmacy and prescription data.	http://www.ncpdp.org
SOAP	Business Protocol	Message Formatting/ Transport	Protocol enabling the exchange of messages and the conduction of business via the Internet.	http://www.w3schools.com/soap/default.asp
WebServices	Business Protocol	Message Formatting/ Transport	Protocol enabling the exchange of messages and the conduction of business via the Internet.	http://www.webservices.org

FIGURE 11

Coding Standards			
Overseeing Body	**Code**	**Description**	**For More Information**
Centers for Disease Control and Prevention (CDC)	Race and Ethnicity Codes	An established code set for coding race and ethnicity.	http://www.cdc.gov
Centers for Medicare & Medicaid Services (CMS)	Healthcare Common Procedure Coding System (HCPCS)	Based on the American Medical Association's (AMA) Current Procedural Terminology (CPT), this system standardizes coding for common processes involved in healthcare delivery. Level I outlines medical procedural terminology and Level II addresses non-physician processes.	http://www.cms.hhs.gov/MedHCPCSGenInfo/
Federal Drug Administration (FDA)	National Drug Code (NDC)	Code used for reporting drug products to the FDA; each product is mapped to a unique, three-segment number.	http://www.fda.gov/cder/ndc/index.htm
International Health Terminology Standards Development Organization (IHTSDO)	Systemized Nomenclature of Medicine-Clinical Terms (SNOMED CT)	Internationally recognized standard for clinical healthcare terminology.	http://www.ihtsdo.org/snomed-ct/
National Center for Health Statistics (NCHS) and Centers for Medicare and Medicaid Services (CMS)	International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)	Based on codes originally developed by the World Health Organization (WHO), this system provides standards for coding hospital diagnoses and procedures.	www.cdc.gov/nchs/about/otheract/icd9/abticd9.htm
National Center for Health Statistics (NCHS) and Centers for Medicare and Medicaid Services (CMS)	International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)	ICD-10-CM is an updated version of ICD-9-CM codes. This version is more comprehensive than ICD-9-CM and has significantly more codes. Though it is not yet widely used in the US, the Department of Health and Human Services is pushing for the replacement of ICD-9-CM with ICD-10-CM within the next three years.	http://www.cdc.gov/nchs/about/otheract/icd9/abticd10.htm
National Library of Medicine (NLM)	Unified Medical Language System (UMLS) RxNorm	Standardized nomenclature for clinical drugs.	http://www.nlm.nih.gov/research/umls/rxnorm/
Regenstrief Institute, Inc.	Logical Observation Identifiers Names and Codes (LOINC)	HL7 preferred code set for laboratory test names.	http://loinc.org/

FIGURE 12

Technical and Web-Based Standards			
Area	**Standard**	**Description**	**For More Information**
Application Integration	Clinical Context Object Workgroup (CCOW)	HL7 standard protocol that uses context management to allow coordination of different applications and integration into a unified end-user interface.	http://www.hl7.org/library/standards_non1.htm
Authentication	Single Sign-On (SSO)	SSO gives users access to multiple systems through a single sign-on.	http://secude.com/htm/806/en/White_Paper_Section%3A_Single_Sign-On.htm
Authentication	User Name and Password/Public Key Infrastructure (PKI)/Hardware Tokens/Biometric Devices	Common methods for authenticating users. Consideration should be given to the most accurate and relevant methods.	http://www.evidian.com/iam/enterprise-sso/wp-strongauth.php
Data Encryption	Transport Layer Security (TLS) Version 1.0/Secure Socket Layer (SSL) Version 3.0	Data encryption standards to ensure security and integrity of data transport via the Internet.	http://technet.microsoft.com/en-us/library/cc784450.aspx
Database Management	Structured Query Language (SQL)	Standard language structure for managing databases and querying data.	http://www.sql.org
Directory Access	Lightweight Directory Access Protocol (LDAP) Version 3.0	IETF Internet protocol for accessing directories.	http://tools.ietf.org/html/rfc4510
Interoperability Infrastructure	IHE IT Infrastructure	A guide for implementation of standards-based interoperability standards.	http://www.ihe.net/IT_infra/committees/index.cfm
Interoperability Infrastructure	IHE Patient Care Coordination	A system addressing integration issues related to processes involving physicians, patient problems, and time.	http://www.ihe.net/pcc/committees/index.cfm
Website Application	Hypertext Transfer Protocol (HTTP) Version 1.1	Web browser must be compatible with the baseline IETF protocol for managing hypertext.	http://www.w3.org/Protocols/
Website Application	Transmission Control Protocol/Internet Protocol (TCP/IP) Version 4	A standard Internet protocol that details IP addressing, datagram formatting, datagram transmission, and application delivery.	http://www.juniper.net/techpubs/software/junos/junos57/swconfig57-getting-started/html/software-overview47.html
Website Application (Architecture Option I)	Multi-Tiered Architecture	A multi-tiered structure in which data management and application services are distinctly separate processes. This architecture is advantageous for scaling and security needs.	http://edocs.bea.com/wls/docs100/cluster/planning.html#wp1115757
Website Application (Architecture Option II)	Service-Oriented Architecture (SOA)	Business application architecture targeted toward loosely coupled network applications.	http://webservices.xml.com/pub/a/ws/2003/09/30/soa.html

FIGURE 13

Interoperability

Interoperability has been a consistent and difficult challenge for healthcare providers and represents one of the key underlying challenges for health information exchanges. The IHE interoperability approach is to support the use of existing standards, such as HL7, ASTM, DICOM, ISO, IETF, OASIS, and others as appropriate rather than to define new standards. IHE integration profiles then further constrain configuration options in these standards to ensure that they can be used in their respective domains in an integrated manner between different participants.[23] Health IT has suffered from inconsistent definitions of industry terms as basic as "EHR" and "RHIO," causing widespread ambiguity in definitions within the industry and confusion among the public.[24] In an effort to articulate and define interoperability, the standards-setting body HL7 published a white paper dividing interoperability into three categories that include technical, semantic and process interoperability.[25] A review of the categories of interoperability follows.

Technical Interoperability

Technical interoperability focuses on the physical transmission and receipt of health data.[26] The challenge of physical transmission of data exists within individual hospitals and is compounded as the scale of any HIE effort increases. The deployment and use of systems that were built on proprietary standards has created a technical environment in which system-to-system and provider-to-provider communication and information transfer is a significant hurdle often requiring intensive time, human resource, and financial commitment to overcome. However, the work of a number of federal agencies and private organizations has created progress in a direction that will enable interoperability—and ultimately has the potential to foster seamless transfer of information between HIE participants.

[23] Integrating the Healthcare Enterprise, IT Infrastructure Technical Framework, Volume 1, December 2008. http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_5-0_Vol1_FT_2008-12-12.pdf.

[24] NAHIT Report to the Office of the National Coordinator for Health IT, Defining Key Health IT Technology Terms, April, 2008.

[25] Health Level 7, EHR Interoperability Workgroup, Coming to Terms: Scoping Interoperability for Healthcare, February, 2007.

[26] Ibid.

Semantic Interoperability

Semantic interoperability focuses on the shared meaning between sending and receiving partners, ensuring that the meaning of what is sent is consistent with the meaning of what is received.[27] Much of the work in this area is focused on medical terminologies that can be referenced consistently by all parties. While use of many of these semantic standards will vary widely across potential HIE participants, a critical evaluation of their application to exchange services is important to ensuring common understanding of shared data.

Process Interoperability

Many health IT projects fail due to the fact that project managers did not consider how existing clinical workflows may need to be changed in order to best utilize the new technology. Further, clinical staff may not adopt technology if not properly trained and educated on the technology's benefits. Process interoperability focuses on higher-order workflow concepts that make data sharing a richer and more valuable experience for caregivers and, ultimately, the patient receiving care.[28] Work in this area involves understanding how shared health data supports the specific activities and workflow of the organizations that use it as well as the integration of health data into the work setting. Examples include process considerations related to usability and timeliness.

Recommended Data Architecture

The Exchange Technology & Clinical Workflows workgroup discussed a number of document standards to define the way in which discrete data elements can be stored in edge devices and health record banks and transferred through the HIE. The workgroup discussed the use of continuity of care records (CCR), clinical document architecture (CDA) and the collaborative continuity of care document (CCD). The CCD, according to the standards bodies that developed it, "is a joint effort of HL7 and ASTM to foster interoperability of clinical data to allow physicians to

[27] Ibid.

[28] Ibid.

send electronic medical information to other providers without loss of meaning, which will ultimately improve patient care."[29] The workgroup recognized that the HIT industry is moving toward the CCD standard for the exchange of clinical documents, but that CCD version C32 definitions do not constrain the document to a degree that creates a consistent document for exchange. Therefore, the group recommended using the CCD version C32 as a document standard with the recognition that further definition and constraints within that document would need to be applied. This recommendation is built upon and reinforced by CCHIT identifying the CCD as a document standard in its 2008 certification criteria.[30]

Other Infrastructure Considerations

System Availability and Redundancy

A distinction must be made related to system availability in the context of the proposed CRISP infrastructure. In light of the hybrid approach, a vast majority of the edge device technology will be deployed within the organizations and technical boundaries of participants. Because of the scope of the exchange, an inherent variety of technical capability will exist across various enterprises extending into individual practices. An acknowledgement of these variances is necessary to arrive at a policy and expectation around system availability. The intent of the exchange is to allow participants to access the exchange at all times, year round. However, if technology supporting the exchange (edge devices) is managed by each participant, then the HIE becomes reliant on each participant's ability to maintain sufficient availability so that all other participants are able to access the data held in its edge device. For larger and more advanced participants, system availability requirements are already at ideal levels. The exchange core infrastructure, such as the MPI and registry, housed and operated by the exchange entity, will require an availability level of the highest possible degree, consistent with requirements of advanced participant organizations. Less technically advanced institutions may opt for shared edge devices, as discussed earlier in this section, or choose to host data at advanced hosting centers meeting the connectivity and security requirements of the exchange.

Similar to availability requirements, most major healthcare systems have data back-up and recovery processes in place. The exchange, for the central components, should also deploy a redundancy and fail over capability to allow for a seamless transition in the event of a failure at the primary site.

Infrastructure Location and Network Security

Regardless of the infrastructure location, network security requirements must adhere to standards consistent, or exceeding, the standards of the largest participant organizations in the HIE. To ensure on-going compliance with network security requirements, the HIE operators should, on a recurring basis, contract for independent auditing of HIE system security. The core infrastructure components can technically be hosted at any data center meeting the requirements of system availability, network security, cost, and a number of other factors. It is logical to suggest, and CRISP recommends, that the core infrastructure components be deployed within Maryland, regardless of the technology vendor's geographic locations.

[29] HL7 and ASTM Joint Press Release on CCD Interoperability Standards, February 2007.

[30] http://www.cchit.org/choose/index.asp Accessed February, 2009.

Finance and Sustainability

CRISP has based its analysis of financial considerations and sustainability on the "Health Information Exchange: From Start Up to Sustainability" report (hereafter referred to as the eHI report) and accompanying tool set released by the U.S. Department of Health and Human Services Health Resources and Services Administration on May 22, 2007. These materials, developed under a grant from the Office for the Advancement of Telehealth, provide a template for planning and implementing HIEs that will be sustainable over the long-term. The eHI report draws on the experience of several organizations and projects, including:

- HealthBridge of Cincinnati, Ohio, which implemented an HIE for order entry, eligibility verification, portal services, and clinical messaging;
- IHIE of Indiana, which implemented an HIE for clinical messaging; and
- THINC of the Hudson Valley in New York, which implemented an HIE for hosted electronic health records (EHRs).

The toolkit accompanying the eHI report includes several spreadsheet-based modeling tools that assist HIE planners in developing sustainability plans.

The first of these is the Market Readiness Assessment Tool, or MRAT, which analyzes market structure and social capital in the region where the HIE is to be implemented. In this context, social capital refers to the combination of relationships, goodwill, and agreement in attitudes that will support the development of HIE. The tool compiles qualitative assessment of areas of perceived strength and weakness and converts them into a quantitative value that is used to feed into the next component, the Risk Estimation Tool.

The Risk Estimation Tool (RET) identifies the sources and magnitude of various risks to project success. It requires the planning entity to identify the types of HIE services it is interested in implementing and allows various combinations to be tested to determine the optimal number of services or constituent projects given the planning entity's maturity level. It also helps to evaluate the impact of buy versus build decisions. The RET produces a risk-adjusted discount rate (RADR) that feeds into the next component, the Value Model.

The Value Model, or Value Cube Framework, uses the RADR to produce risk-adjusted net present value calculations for each initiative and cumulatively. It permits modeling of various pricing scenarios and helps to identify the impact on sustainability of divergent interests among stakeholders.

The remainder of this section describes each of the calculations in greater detail and explains how the CRISP Business Development & Finance workgroup applied the eHI framework to our thinking, assumptions, estimates, and forecasts during the planning process. The result is a preliminary sustainability model for statewide HIE in Maryland.

Service Area and Initial Participants

The first step in developing a financial model for the HIE involves defining the parameters that will serve as base assumptions throughout the effort to evaluate sustainability. The first of these parameters is the definition of the region and population that will be served by the exchange. The workgroup agreed that the region will be limited to the state of Maryland, and the population will include all 5.6 million Maryland residents. Given the significant overlap in healthcare activities across state lines, particularly in the greater Washington D.C. area, it is likely that either some aspects of the exchange will be implemented in surrounding areas or the Maryland exchange will eventually need to tie in with exchange efforts in those surrounding areas. For purposes of the planning effort, however, we have concentrated on Maryland alone.

The next step in the eHI methodology is to select which of the healthcare entities and functions will be included in initial exchange development efforts. In selecting participants and functions, a balance must be struck between anticipated benefit to participants, market considerations, and technical considerations. For most functions of an HIE, a critical mass of participation is important. Too little participation could undermine the value of the exchange. For providers, too little information may not only reduce the value to users but could potentially mislead providers into thinking that the information is more complete than it is. For information recipients, too little participation will create sustainability problems in funding the exchange, as discussed later in this section.

The following list shows all of the initial participants considered by the workgroup, with those selected highlighted in bold:

- Ambulatory Surgery Centers
- Behavioral/MH Providers
- CMS/Medicare
- Community Outreach Clinics
- Employers/Plan Administrators
- Health Plan Enrollment Stations
- Health Plans
- **Hospitals (and Emergency Rooms)**
- Inpatient Pharmacies
- **Laboratories**
- Non-Radiology Procedure Centers
- Therapists (OT/PT)
- Outpatient Pharmacies
- Patients or Caregivers
- **Pharmacy Benefit Managers (PBMs)**
- Pharmaceutical/Device Manufacturers
- **Primary Care Physicians and Clinics**
- Public Health Agencies
- **Radiology Centers**
- Regulators (FDA, DEA)
- Researchers
- Skilled Nursing Facilities
- Specialty Care Physicians and Clinics
- State Medicaid

Exclusion as an initial participant does not imply that these entities will not be eventual HIE participants. In fact, two categories, health plans and patients or caregivers, are likely to be early participants, but were not included in this analysis due to uncertainties in how they may be engaged and difficulties in establishing concrete data for use later in this analysis.

Initial Functionality

The working model assumes that many participants will be expected to pay for participation at some level. The initial package should thus include services that have the broadest value and appeal as part of a base service for a base fee. Additional incremental services that may only be of interest to certain participants may be introduced in later phases, possibly with optional participation and payment.

Those services that are easiest to implement may not, for that reason alone, be attractive early-stage services. A good example is the integration of claims-based data sources with the exchange's provider participants. Such sources are readily available, and insurers would likely favor the use of this data in order to maximize the utility of the exchange for their own operations. According to the workgroup's discussion, however, many providers feel that claims-based data is only of limited value in the clinical setting. Thus, sources may include claims-based data, but this data is unlikely to be sufficient on its own to establish a sustainable and broadly valuable exchange.

In selecting services for initial implementation, the workgroup sought to strike a balance between cost and ease of implementation and broad clinical benefit. The following list shows all of the services considered for initial implementation, with those actually selected in bold.

- Case Management
- Care Coordination
- Claims Management
- Clinical Document Sharing
- **Discharge Summaries**
- Enrollment Verification
- Historical Allergy List
- Historical Procedure List
- Historical Visit/Hospitalization List
- **Medical Record (Chart Summaries)**
- Rx Decision Support
- Rx Formulary Check
- **Historical Rx List**
- E-Prescribing
- **Patient Access to Health Records**
- Patient Alerts or Reminders
- **Patient to Provider Communication**
- Price/Cost Information
- Procedure or Test Ordering
- Procedure/Referral Authorization
- **Provider to Provider Communication**
- Public Health Information to Clinicians
- Public Health Reporting
- Referral/Consultation Management
- Disease Management Registry
- Public Health Surveillance Registry
- Immunization, Medication, or Device Registry
- Quality or Safety Performance A&R
- **Results Delivery**
- **Historical Results List**

As with initial participants, the fact that a service was not selected for initial implementation does not imply that it will never be implemented. Some services are excluded because they are components of a service that has been selected. For example, chart summaries are likely to encompass all or most of the information included in all of the historical listings not selected. Some of the services not selected may actually be implemented as a means of implementing a selected service. For example, a determination may be made during implementation that the most effective way to enable historical medication lists is to implement e-prescribing via the exchange. Finally, some services for which the cost-value proposition is unclear, or where the cost-value proposition seems unattractive during the current planning stage, may look considerably more attractive once the initial exchange is up and running and mature functionality can be leveraged.

The following is a high-level description of the value proposition for each selected service. For full details on each, please refer to the Use Case section of this document.

Medication History to Emergency Departments and Hospitals

RxHub is a company that has created an HIE that includes many pharmacies and PBMs for e-prescribing purposes and that may be leveraged for other HIE efforts. Since a high percentage of prescription information is available from this single source, implementation of a medication history service is far less complex than if direct connections to numerous PBMs was required. The clinical value proposition is clear and outweighs a small anticipated increase in administrative costs. There are no perceived stakeholder conflicts of interest. There are also possible applications of the information beyond hospitals and emergency departments. For all these reasons, medication history is a good candidate for early implementation. Note that the decision to pursue initial implementation with a large entity such as RxHub does not preclude participation by individual PBMs and pharmacies during initial implementation or later.

Lab Results Delivery

A relatively small number of vendors dominate the outpatient laboratory services market in Maryland, with the two largest vendors, Quest Diagnostics and LabCorp, holding a large proportion of all the information available. HIE in this case does little to affect clinical value since exchange is already taking place. Rather, the value for lab results delivery lies in administrative efficiency for the providers requesting them.

Radiology Results and History Delivery

As with the labs market, two vendors, Advanced Radiology and American Radiology, dominate the radiology center business, and as such there is high data concentration among the largest vendors. Radiology results delivery is important for administrative efficiency. Radiology history is valuable both for administrative efficiency and for replacing transfers that are currently taking place via largely manual processes; it also adds clinical value by making information readily available to treating providers who otherwise may not be able to access it.

Discharge Summaries

Discharge summaries could be sent both from a facility to a physician or clinic and from facility to facility. Clinical value is gained by increasing the frequency with which this information is exchanged. Where this information is already being exchanged today, the HIE offers the opportunity for significant administrative savings. There are no current centralized repositories for this information, but the workgroup does not feel that this decentralization presents an issue. Unlike medication or radiology history, there is little risk and fair value even if some facilities are not connected to the exchange in the short-term.

Chart Summaries Accessible to both Hospitals and Physicians/Clinics

While the establishment of electronic health records (either through personal health records or proliferation of linked EHRs) for all 5.6 million Maryland residents is certainly a daunting challenge, the value proposition in allowing providers throughout the system to have access to a well-structured, single record for each of their patients is clear. Moreover, as recognized in government and media commentary, EHRs are the foundation of any number of possible other HIE functions, such as care management, care coordination, historical allergy, procedure and encounter listings, patient alerts and reminders, public health analysis, and disease management.

From a finance and sustainability standpoint, universal access to consolidated patient data brings the most constituents to the table, thus offering the most widespread value and spreading costs over the largest possible group. Despite the broad constituency and many technical challenges and privacy concerns, there are no obvious conflicts in enabling this service.

Other Functions

Not all functions covered in the Use Cases section are included in this financial analysis. In the case of clinical messaging (provider to provider communication and perhaps future patient to provider communication) the workgroup had insufficient information to make educated estimates for the value models. Moreover, in this case the function is largely, if not entirely, enabled via work that is conducted to establish other functions of the HIE. While we believe that the results discussed below would be similar for this function, the workgroup opted not to explicitly include clinical messaging in the analysis.

Another function considered by the workgroup as a likely candidate for early implementation is patient access to health records via HIE-interoperable PHRs and HRBs. Patient access is a critical first step to a broad range of potential additional functionality and consumer engagement opportunities. The workgroup agreed that the HIE effort should drive towards patient-access as a near-term goal but chose not to include it in this analysis due to the fact that, at this stage, a financial value proposition would be very difficult to establish.

Finally, providers seeking to verify patient eligibility and benefits cause a significant administrative burden in the current environment, with additional administrative costs also incurred to the health plans that need to maintain service staff. Including eligibility and benefit verification via the HIE in the initial phase of implementation would thus provide an administrative value proposition and enhance the incentive for health plans and physicians to participate. Nonetheless, the workgroup believed that the added complexity and the introduction of administrative transactions justified the exclusion of these types of transactions in our financial modeling.

Market Readiness Assessment

As important as identifying attractive services is assessing community readiness for HIE based on market structure, project leadership, and provider readiness to

adopt. Taken together, these factors may be referred to as the readiness index, or the social capital index. The four questionnaires described below each had less than twenty Likert scale, multiple choice, and true/false questions and were developed by the planning project staff based on discussions with workgroup members and results from previously conducted provider surveys.

Market Readiness Survey Results	
Survey	**Result**
HIE Organization Readiness	69%
Market Readiness	45%
Physician Readiness	51%
Hospital Readiness	55%
Overall Market Readiness	56%

FIGURE 14

01 The HIE organization questionnaire assessed whether there is strong leadership for HIE based on shared vision and objectives, government support, designation of champions, and so forth.

02 The market questionnaire examined the number and types of providers (facility and non-facility) in the HIE's operating area and estimated the percentage of those providers who are already operating with HIT systems. It also considered the relationships between hospitals and physicians and their interest in HIE as demonstrated through funding planning efforts.

03 & 04 The physician and hospital questionnaires assessed how ready providers are for HIE based on how they are currently using technology, how they interact with other players in the healthcare community, their perception of HIE value, and their willingness to pay for or invest in HIE.

The scores from the four surveys were weighted, with the first two each counting for one-third of the final score and the hospital and physician questionnaires each counting for one-sixth. The final calculated market readiness index was 56%. The workgroup interprets this to mean that the conditions in Maryland are relatively favorable for an HIE effort and there is significant interest from participants; however, without external pressures, significant steps towards statewide HIE are unlikely to be taken in the short-term.

The surveys also revealed the importance of ensuring perceived fairness in the prices providers are asked to pay for participation in the exchange. A system that accounts for size of operation may be a more appealing alternative to one-size-fits-all pricing, assuming it does not price the larger providers out of participation. For this reason we have assumed a per-physician pricing model rather than a per-practice pricing model.

Similarly, a purely transaction-fee based system will likely not be effective. While such a fee-for-service system is the purest method of placing the most burden on those who use the system the most, it introduces an incentive for participants to carefully monitor and perhaps budget their use of the system. Such self-restriction of use would be in conflict with the larger objectives of the HIE. Again, a system that accounts for the number of patients being served and the value of the HIE for those patients is almost certainly preferable.

Risk Estimation

A risk-adjusted discount rate (RADR) was calculated for use as the discount factor in net present value calculations in the value analysis. The RADR functions just as a discount rate does in conventional net present value calculations. Calculation of the RADR is based on four factors: implied

risk-free rate, operating, market, and execution risk adjustments, complexity adjustments, and the market readiness index computed in the MRAT above.

Next is a complexity adjustment calculation based on the number of types of stakeholders and the number of functionalities offered. Using the participant types and functionalities previously described, the eHI model

Risk-Adjusted Discount Rate Calculation	
Factor	**Result**
Current Industry Stage	Early
Implied Risk-Free Rate of Return	34%
Risk Adjustment	-6.7%
Complexity Adjustment	39%
Computed RADR	55.4%

FIGURE 15

The first factor in the computation of the RADR is the baseline risk-free rate of return, adjusted for the current phase of the industry: early, stable or mature. Since this planning project comprises the initial implementation of HIE in Maryland, the industry phase is early. Per the eHI model, this translates into a 34% implied baseline rate. The RADR can never drop below this baseline rate.

Next, the baseline rate is adjusted for a series of risk factors, as measured by responses to sixty weighted yes/no questions. Operating risk is derived from how the HIE is structured (e.g. Are all key stakeholders represented? Are there power asymmetries? Is there separation between governance and execution teams?) and details of basic logistics (e.g. compliance considerations, resource and budget constraints, and information technology vendor assumptions including solvency, track record, and contractual arrangements). Market risk reflects readiness for adoption (i.e. if stakeholders understand the value of the HIE and what is expected of them) and how well marketing plans meet market needs and obstacles. Execution risk is the ability to manage complexity based on the experience of project leadership and participants and the focus of effort (i.e. is there a project plan and does it have contingency strategies?) Taken together, net operating, market, and execution risk adjustments come to -6.7%. This can be taken to mean that the coordination, organization, and collaboration behind the CRISP effort reduce the risk associated with achieving positive results.

yields a complexity adjustment of 39%—more types of participants and a higher number of initial services increase the complexity risk. These three rates are added together and then multiplied by an adjustment factor based on the market readiness index to yield the final RADR, in this case 55.4%. As is evident, this is a very large discount rate, owing mainly to the only marginally favorable market readiness index and a considerable degree of complexity. The main purpose of the RADR is to discount the projections of future value to arrive at an appropriate net present value (NPV) which can be used to justify the various pricing models offered to participants.

Value

The goal of the value analysis is to determine net present value of eventual value received by HIE participants balanced against estimates of what the participants will pay in order to receive that value. The model examines NPV over a five-year period starting with when the first function is brought into production. In order for the HIE to be sustainable, NPV calculations must prove to be as positive, or at least neutral, both in the aggregate and for individual participants after being discounted using the RADR calculated above. Thus pricing must be tied to value at the individual level, including some method of passing along costs to non-users who derive value from the overall system. The model provides a complex, detailed, and guided approach to analyzing costs and benefits in a systematic manner in order to determine if projected concepts are sustainable.

The first step for a comprehensive financial model is to determine the pair-wise relationships for each planned function of the HIE. These pair-wise relationships are intricately related to the Use Cases mentioned earlier. Figure 16 shows the eleven relationships examined in this study. Note that for each, the planned implementation year is given, assuming a start date for the HIE implementation in 2009.

The value model then requires the market population. As discussed earlier in this document, we are assuming the market population to be the 5.6 million Maryland residents. The value model also requires numbers for each type of participant. These include:

- Forty-seven hospitals and emergency departments
- Two laboratories and about fifty local labs
- Two radiology centers and about fifty local radiology centers
- 7,000 primary care physicians and clinics (referred to hereafter as physicians)
- One PBM (functionally only one would be connected since we propose connecting to RxHub rather than to PBMs directly)

We then conducted a guided analysis for each pair-wise function to quantify costs and savings. Instead of walking through each case in detail, the following charts provide a good illustration of the process.

Consider the delivery of lab results from national laboratories to physicians. According to workgroup members with relevant experience, there are approximately 1.5 lab transactions per person per year in Maryland for the national laboratories. We assume about 80% of these would transition to flow through the HIE in year one and that this percentage would not appreciably change over time. The reason for the high adoption assumption in year one is that the data suppliers needed for this service (LabCorp and Quest) account for a large percentage of the market share.

Regarding the expected administrative cost savings for physicians, the average transaction costs approximately $2.00, about 80% of which could be avoided via the HIE in saved materials and staff time handling the currently faxed results. The $2.00 rate is based on five minutes of time for an office associate making $40,000 per year plus the standard 30% benefit load. The actual rate may differ for certain physicians, particularly in the handful of offices that have already established direct feeds from a lab vendor into their EHR, or where other semi-automated processes have been introduced. We expect, however, that such offices would be relatively late adopters of the service, and the five minute rate is probably reasonable for earlier adopters eager to replace burdensome manual processes.

Planned Pair-Wise Functionality

Data Supplier	Data User	Functionality	Implementation Year
PBMs	Emergency Departments and Hospitals	Medication List (Historical)	2009
Laboratories	Primary Care Physicians and Clinics	Results Delivery	2009
Hospitals	Primary Care Physicians and Clinics	Results Delivery	2009
Laboratories - Local	Primary Care Physicians and Clinics	Results Delivery	2009
Emergency Departments and Hospitals	Primary Care Physicians and Clinics	Discharge Summary	2010
Emergency Departments and Hospitals	Emergency Departments and Hospitals	Discharge Summary	2010
Patients or Caregivers	Emergency Departments and Hospitals	Medical Record	2010
Patients or Caregivers	Primary Care Physicians and Clinics	Medical Record	2010
Radiology Centers	Primary Care Physicians and Clinics	Results Delivery	2010
Hospitals	Primary Care Physicians and Clinics	Results Delivery	2010
Radiology Centers - Local	Primary Care Physicians and Clinics	Results Delivery	2010

FIGURE 16

We do not expect cost savings for labs where the delivery is largely already automated, and therefore we expect that implementation costs and ongoing fees will be borne by physicians and not the labs. Initial setup costs to connect to the exchange for the large lab companies are probably negligible since they already have the data in a standardized transaction format—from the lab company perspective it is merely the delivery method that is changing. For purposes of this study we assume an annual subscription fee of $120 per physician using the HIE for lab results delivery.

Taking into account the volume of lab tests, the assumed cost savings per result delivery, and the assumed adoption rate of the service in the marketplace, the value to physicians is nearly $6.4 million in the first year, growing to about $15.9 million in the fifth year.

Figure 17 illustrates administrative savings for each service and NPV for each participant.

For nearly all services, cumulative NPV becomes positive immediately, or within the first two years of operation. The only exception is medication history, where perceived clinical value outweighs the relatively small negative NPV driven by increased administrative expense. Aggregate predicted fully discounted NPV over the first five years of the HIE to all stakeholders for these functions is $52.7 million. Please note that the model includes some assumptions of quality improvements for various functions but in no case do these assumptions translate into assigned financial value. While we are confident that there is such a value, we have preferred to use the conservative approach and have thus counted only administrative savings when looking for NPV.

Stakeholder 5-Year Net Present Value	
Primary care physicians and clinics	**$40,968,514**
Emergency Departments and Hospitals	**$7,304,387**
Laboratories - Local	**$4,066,603**
Radiology Centers - Local	**$356,499**
Net Value -- HIE Participants	**$52,696,003**

FIGURE 18

Service	Participant	Administrative Savings Per Year*	Cumulative Net Present Value Y1	Y2	Y3	Y4	Y5
Historical Medication List	PBMs	$0	$0	$0	$0	$0	$0
	Hospitals and ERs	($235,000)	($151,223)	($248,535)	($311,155)	($351,451)	($377,382)
National Lab Results Delivery	National Labs	$0	$0	$0	$0	$0	$0
	Physicians and Clinics	$9,912,000	$6,378,378	$10,482,869	$13,124,111	$14,823,752	$15,917,473
Hospital Lab Results Delivery	Hospitals and ERs	$1,792,000	$448,153	$1,190,208	$1,667,721	$1,975,000	$2,172,735
	Physicians and Clinics	$1,624,000	$1,045,045	$1,717,532	$2,150,278	$2,428,750	$2,607,947
Local Lab Results Delivery	Local Labs	$2,688,000	$1,479,730	$2,592,812	$3,309,081	$3,770,001	$4,066,603
	Physicians and Clinics	$2,436,000	$1,567,568	$2,576,298	$3,225,417	$3,643,126	$3,911,921
Discharge Summaries to Physicians	Hospitals and ERs	$4,300,800	($453,668)	$1,327,264	$2,473,294	$3,210,766	$3,685,329
	Physicians and Clinics	$3,880,800	$0	$1,607,012	$2,641,126	$3,306,579	$3,734,798
Discharge Summaries to Hospitals	Hospitals and ERs (Sending)	$268,800	$0	$111,308	$182,935	$229,027	$258,687
	Hospitals and ERs (Receiving)	$268,800	$0	$111,308	$182,935	$229,027	$258,687
Clinical Summaries	Hospitals and ERs	$1,112,000	$0	$460,472	$756,785	$947,463	$1,070,165
Clinical Summaries	Physicians and Clinics	$12,600,000	$0	$5,217,573	$8,575,084	$10,735,645	$12,125,967
National Radiology Results Delivery	National Radiology Companies	$0	$0	$0	$0	$0	$0
	Physicians and Clinics	$1,730,400	$0	$716,547	$1,177,645	$1,474,362	$1,665,300
Hospital Radiology Results Delivery	Hospitals and ERs	$716,800	($453,668)	($156,846)	$34,159	$157,071	$236,165
	Physicians and Clinics	$632,800	$0	$262,038	$430,660	$539,168	$608,993
Local Radiology Results Delivery	Local Radiology Companies	$537,600	($160,875)	$61,741	$204,995	$297,179	$356,499
	Physicians and Clinics	$411,600	$0	$170,441	$280,119	$350,698	$396,115
Totals		$44,677,400	$9,699,440	$28,200,042	$40,105,192	$47,766,163	$52,696,003

* Assuming approximately 80% of transactions flowing through HIE

FIGURE 17

Cost Model

While the eHI model includes a tool that can be used to prepare simulated standardized financial statements, we have chosen to present a simplified version to show the estimated costs associated with the proposed exchange. Two models are offered in this section. The first model assumes an initial investment ceiling of $10 million. The second removes this ceiling and represents what the committee believes to be the most rapid implementation possible. Accelerating the timeline requires considerable additional implementation resources. In both cases, sustainability (positive cash flow) is reached in the fifth year, but more rapid deployment of services translates to more rapid adoption and thus higher positive cash flows in out years. These higher cash flows mean that the initial investment is rewarded sooner and there is more money available sooner for enhancement or expansion of the exchange. In addition, by achieving higher adoption of these early services more quickly, the exchange will be able to consider additional services and participants sooner rather than later.

Please note that all numbers are estimates based on multiple vendors' pricing models, effort estimates, and hardware and software costs. These numbers are unlikely to be exact, but the workgroup believes that they will be within an acceptable range of deviation for budgetary planning purposes.

$10 Million Investment Cost Model

An initial step in developing the cost model is to determine the costs associated with implementation of each individual service. First, this includes the cost of the hardware, software, and communications technology that allows for the exchange of information. There are both initial interface costs and ongoing maintenance costs that reflect the operational maintenance costs and assumed costs to upgrade or replace equipment as necessary. For example, we estimate about $30,000 ($15,000 each) to create the interface infrastructure for each of the national labs to enable lab results delivery and about $10,000 in ongoing costs, inflated at a rate of about 3.5% annually. In some cases, there is a hospital interface funding line immediately following the interface line (as with emergency department/hospital discharge summaries). This line is used to account for the fact that facilities will, for the most part, be expected to maintain their own interface infrastructure.

The model then considers software configuration costs, or the work that needs to be done to create data maps and information translation routines. Since few systems are static, there are again initial costs associated with getting the HIE up and running and ongoing maintenance costs to modify mapping as new information is created. Again using national lab results delivery as the example, we estimate about $20,000 initial configuration costs and about 10% of that for ongoing costs, again inflated at a rate of about 3.5% annually.

The model then shows revenue for each function. Revenue for each year is calculated based on anticipated adoption rates, also provided in the cost model. Adoption rates applied here are slightly different from those used in the value model because the rates used in the value model reflect percentage of total activity adopted, where the cost model uses percentage of providers adopting the service. Adoption rates start at either 10% or 30% in the first year of operation and then increase by 20% per year to a maximum of 90% adoption. We believe that some services may never actually reach the 90% goal, while others will show more rapid adoption than our assumption. Thus actual revenue will certainly vary from the figures shown in the cost model, but we believe the estimates used to be on the conservative side.

In the case of national lab results delivery, first year revenue equals 7,000 physicians multiplied by a 30% adoption rate multiplied by the $120 per year assumed participation cost, or in total $252,000. This rises to $420,000 in year two and reaches its maximum value of $756,000, assuming 90% adoption, by year four.

The sum of all interface and configuration costs and revenue results in the HIE service margin for each service. In the example of national lab results delivery, this is positive $202,000 in year one. For many services, the HIE service margin is negative in the first year and becomes positive in later years once sufficient adoption rates are achieved.

Figure 19 illustrates the adoption rate assumptions used in the $10 million investment cost model.

Figure 20 on the next page illustrates the cost model for each of the services.

In addition to the individual function-related costs, there are core infrastructure costs. This includes the hardware and software costs that are not unique to a specific function but are rather required to create the exchange

immediately. In years one and two, the only permanent staff member hired is the HIE executive director. The staff is increased to seven in the third year as the permanent staff takes over implementation duties from consultants and assumes maintenance responsibilities. It again increases to ten members in year five and reaches the full fifteen members in year six.

Put together, the core infrastructure costs and the marginal income from HIE services yields the

Model Assumptions

Use Case	Subscription Per Month	Assessment Unit	Adoption Rates Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
National Lab Results Delivery	$10	per doc	30%	50%	70%	90%	90%	90%	90%
Hospital Lab Results Delivery	$2	per doc	0%	10%	30%	50%	70%	90%	90%
Local Lab Results Delivery	$3	per doc	0%	10%	30%	50%	70%	90%	90%
ED/Hospital Discharge Summaries to Physicians/Clinics	$10	per doc	0%	0%	30%	50%	70%	90%	90%
ED/Hospital Discharge Summaries to ED/Hospital	$1,000	per facility	0%	0%	30%	50%	70%	90%	90%
Clinical Summary to Emergency Departments	$2,000	per facility	0%	0%	30%	50%	70%	90%	90%
Clinical Summary to Physicians/Clinics	$10	per doc	0%	0%	10%	30%	50%	70%	90%
National Radiology Results Delivery	$5	per doc	0%	30%	50%	70%	90%	90%	90%
National Radiology Results History	$1,000	per facility	0%	30%	50%	70%	90%	90%	90%
Hospital Radiology Results Delivery	$1	per doc	0%	0%	10%	30%	50%	70%	90%
Hospital Radiology Results History	$350	per facility	0%	0%	10%	30%	50%	70%	90%
Local Radiology Results Delivery	$2	per doc	0%	0%	10%	30%	50%	70%	90%
Local Radiology Results History	$650	per facility	0%	0%	10%	30%	50%	70%	90%
Max Subscription - All Services	***$43***	***per doc***							
Max Subscription - All Services	***$5,000***	***per facility***							

FIGURE 19

as a whole, the cost of the exchange platform and portal license, and the enterprise master patient index. It also includes the cost of human resources to implement and maintain the exchange. As with the individual service costs, a 3.5% annual inflation rate has been assumed for all ongoing core infrastructure costs. In addition to direct human resource costs, which include salary and benefits, a 10% overhead factor has been added to cover office space, computers, office supplies, and so forth.

Of note, the unit cost for the eight resources needed to implement is higher than the unit cost for the fifteen permanent resources needed to maintain the HIE. This is due to the fact that implementation resources generally require a highly specialized skill set, as well as the fact that while the maintenance staff is envisioned to consist of full-time employees, the implementation staff will include many shorter engagement consultants. Furthermore, not all permanent resource roles are filled

anticipated cash flow from the HIE in each of the first seven years of operation. The first year outlay of about $4.3 million drops to $3.7 million in year two and continues to drop until year five when the HIE becomes self-sustaining. Total startup investment in the HIE, spread over the first four years of implementation, is just over $10 million.

HIE Services	Number	Unit Cost	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
National Lab Results Delivery									
Interface	2	($15,000.00)	($30,000)	($10,000)	($10,350)	($10,712)	($11,087)	($11,475)	($11,877)
Software Configuration	2	($10,000.00)	($20,000)	($2,000)	($2,070)	($2,142)	($2,217)	($2,295)	($2,375)
Revenue ($10/doc/mo)	7,000	$120.00	$252,000	$420,000	$588,000	$756,000	$756,000	$756,000	$756,000
HIE Service Margin			**$202,000**	**$408,000**	**$575,580**	**$743,145**	**$742,695**	**$742,230**	**$741,748**
Hospital Lab Results Delivery									
Interface	47	($15,000.00)	$0	($141,000)	($141,000)	($141,000)	($141,000)	($141,000)	$0
Hospital Interface Funding	47	$0.00	$0	$141,000	$141,000	$141,000	$141,000	$141,000	$0
Software Configuration	47	($20,000.00)	$0	($188,000)	($188,000)	($188,000)	($188,000)	($188,000)	$0
Revenue ($2/doc/mo)	7,000	$24.00	$0	$16,800	$50,400	$84,000	$117,600	$151,200	$151,200
HIE Service Margin			**$0**	**($171,200)**	**($137,600)**	**($104,000)**	**($70,400)**	**($36,800)**	**$151,200**
Local Lab Results Delivery									
Interface	50	($5,000.00)	$0	($50,000)	($50,000)	($50,000)	($50,000)	($50,000)	$0
Lab Interface Funding	50	$0.00	$0	$50,000	$50,000	$50,000	$50,000	$50,000	$0
Software Configuration	50	($20,000.00)	$0	($200,000)	($200,000)	($200,000)	($200,000)	($200,000)	$0
Revenue ($3/doc/mo)	7,000	$36.00	$0	$25,200	$75,600	$126,000	$176,400	$226,800	$226,800
HIE Service Margin			**$0**	**($174,800)**	**($124,400)**	**($74,000)**	**($23,600)**	**$26,800**	**$226,800**
Medication History									
Interface	1	($15,000.00)	($15,000)	($5,000)	($5,175)	($5,356)	($5,544)	($5,738)	($5,938)
Software Configuration	1	($10,000.00)	($10,000)	($1,000)	($1,035)	($1,071)	($1,109)	($1,148)	($1,188)
Transaction Fees paid to data vendor	1		($300,000)	($600,000)	($900,000)	($1,200,000)	($1,500,000)	($1,500,000)	($1,500,000)
Revenue (financing mechanism TBD)	47	$35,000.00	$330,000	$660,000	$990,000	$1,320,000	$1,650,000	$1,650,000	$1,650,000
HIE Service Margin			**$5,000**	**$54,000**	**$83,790**	**$113,573**	**$143,348**	**$143,115**	**$142,874**
Emergency Department/Hospital Discharge Summaries									
Interface	47	($15,000.00)	$0	$0	($141,000)	($141,000)	($141,000)	($141,000)	($141,000)
Hospital Interface Funding	47	$0.00	$0	$0	$141,000	$141,000	$141,000	$141,000	$141,000
Software Configuration	47	($100,000.00)	$0	$0	($940,000)	($940,000)	($940,000)	($940,000)	($940,000)
Revenue ($10/doc/mo)	7,000	$120.00	$0	$0	$252,000	$420,000	$588,000	$756,000	$756,000
Revenue ($1000/hospital/mo)	47	$12,000.00	$0	$0	$169,200	$282,000	$394,800	$507,600	$507,600
HIE Service Margin			**$0**	**$0**	**($518,800)**	**($238,000)**	**$42,800**	**$323,600**	**$323,600**
Clinical Summary to Emergency Departments									
Interface	1	($15,000.00)	$0	$0	($15,000)	($5,000)	($5,175)	($5,356)	($5,544)
Software Configuration	1	($100,000.00)	$0	$0	($100,000)	($10,000)	($10,350)	($10,712)	($11,087)
Revenue ($2000/ED/mo)	47	$24,000.00	$0	$0	$338,400	$564,000	$789,600	$1,015,200	$1,015,200
HIE Service Margin			**$0**	**$0**	**$223,400**	**$549,000**	**$774,075**	**$999,132**	**$998,569**
Clinical Summary to Physicians/Clinics									
Interface	1	($15,000.00)	$0	$0	($15,000)	($5,000)	($5,175)	($5,356)	($5,544)
Software Configuration	1	($100,000.00)	$0	$0	($100,000)	($10,000)	($10,350)	($10,712)	($11,087)
Revenue ($10/doc/mo)	7,000	$120.00	$0	$0	$84,000	$252,000	$420,000	$588,000	$756,000
HIE Service Margin			**$0**	**$0**	**($31,000)**	**$237,000**	**$404,475**	**$571,932**	**$739,369**
National Radiology Results Delivery									
Interface	2	($15,000.00)	$0	($30,000)	($10,000)	($10,350)	($10,712)	($11,087)	($11,475)
Software Configuration	2	($10,000.00)	$0	($20,000)	($2,000)	($2,070)	($2,142)	($2,217)	($2,295)
Revenue ($5/doc/mo)	7,000	$60.00	$0	$126,000	$210,000	$294,000	$378,000	$378,000	$378,000
Revenue ($1000/hospital/mo)	47	$12,000.00	$0	$169,200	$282,000	$394,800	$507,600	$507,600	$507,600
HIE Service Margin			**$0**	**$245,200**	**$480,000**	**$676,380**	**$872,745**	**$872,295**	**$871,830**
Hospital Radiology Results Delivery									
Interface	47	($15,000.00)	$0	$0	($141,000)	($141,000)	($141,000)	($141,000)	($141,000)
Hospital Interface Funding	47	$0.00	$0	$0	$141,000	$141,000	$141,000	$141,000	$141,000
Software Configuration	47	($20,000.00)	$0	$0	($188,000)	($188,000)	($188,000)	($188,000)	($188,000)
Revenue ($1/doc/mo)	7,000	$12.00	$0	$0	$8,400	$25,200	$42,000	$58,800	$75,600
Revenue ($350/hospital/mo)	47	$4,200.00	$0	$0	$19,740	$59,220	$98,700	$138,180	$177,660
HIE Service Margin			**$0**	**$0**	**($159,860)**	**($103,580)**	**($47,300)**	**$8,980**	**$65,260**
Local Radiology Results Delivery									
Interface	50	($5,000.00)	$0	$0	($50,000)	($50,000)	($50,000)	($50,000)	($50,000)
Hospital Interface Funding	50	$0.00	$0	$0	$50,000	$50,000	$50,000	$50,000	$50,000
Software Configuration	50	($20,000.00)	$0	$0	($200,000)	($200,000)	($200,000)	($200,000)	($200,000)
Revenue ($2/doc/mo)	7,000	$24.00	$0	$0	$16,800	$50,400	$84,000	$117,600	$151,200
Revenue ($650/hospital/mo)	47	$7,800.00	$0	$0	$36,660	$109,980	$183,300	$256,620	$329,940
HIE Service Margin			**$0**	**$0**	**($146,540)**	**($39,620)**	**$67,300**	**$174,220**	**$281,140**

FIGURE 20

The maximum income reached in the out years would eventually start to erode because we assumed inflation for everything except the pricing charged to participants. Long-term sustainability will require periodic examination of and increases to participant fees.

Figure 21 illustrates the core infrastructure costs and cash flow from the HIE, operating under the $10 million investment cap model.

CRISP HIE Cost Model - $10 Million Investment Assumed									
Core Infrastructure	**Number**	**Unit Cost**	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**
Exchange Platform and Portal License	1	($3,000,000)	($1,500,000)	($1,500,000)	($600,000)	($621,000)	($642,735)	($665,231)	($688,514)
Enterprise Master Patient Index (EMPI)	1	($350,000)	($350,000)	($200,000)	($207,000)	($214,245)	($221,744)	($229,505)	($237,537)
Hardware/Supporting Software	1	($500,000)	($500,000)	($166,667)	($172,500)	($178,538)	($184,786)	($191,254)	($197,948)
Implementation Resources	8	($230,000)	($1,840,000)	($1,840,000)	$0	$0	$0	$0	$0
Permanent Resources	15	($125,000)	($125,000)	($129,375)	($937,322)	($970,128)	($1,434,404)	($2,226,912)	($2,304,854)
Overhead (10% of resources)			($196,500)	($196,938)	($93,732)	($97,013)	($143,440)	($222,691)	($230,485)
Total Core Costs			**($4,511,500)**	**($4,032,979)**	**($2,010,554)**	**($2,080,923)**	**($2,627,109)**	**($3,535,592)**	**($3,659,338)**
Marginal Income/(Loss) from HIE Services			**$207,000**	**$361,200**	**$244,570**	**$1,759,898**	**$2,906,138**	**$3,825,503**	**$4,542,390**
Cash Flow			**($4,304,500)**	**($3,671,779)**	**($1,765,984)**	**($321,026)**	**$279,029**	**$289,911**	**$883,052**

FIGURE 21

Increased Implementation Pace Cost Model

The second cost model assumes that a) additional funding is available and b) decision-makers wish to accelerate the implementation of the HIE so that the initial development is completed as rapidly as possible. Most of the assumptions regarding the cost of implementation for individual services remain unchanged, but the implementation schedule has been accelerated. For example, discharge summaries are moved from implementation in year three to implementation in year two. Figure 22 shows the new adoption rate assumptions for this model, reflecting the changes made to the implementation schedule.

The accelerated adoption also changes the core infrastructure costs, specifically with regards to personnel costs. Temporary implementation resources have been increased from eight to twenty resources for the first two years. Increased speed of implementation and adoption also means that the ramp-up of the permanent staff must move faster. In this model, the permanent staff starts at five and increases to the full fifteen in year three. In addition to increased permanent resources to more

	Subscription	**Assessment**	**Adoption Rates**						
Use Case	**Per Month**	**Unit**	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**
National Lab Results Delivery	$10	per doc	30%	50%	70%	90%	90%	90%	90%
Hospital Lab Results Delivery	$2	per doc	10%	30%	50%	70%	90%	90%	90%
Local Lab Results Delivery	$3	per doc	10%	30%	50%	70%	90%	90%	90%
ED/Hospital Discharge Summaries to Physicians/Clinics	$10	per doc	0%	30%	50%	70%	90%	90%	90%
ED/Hospital Discharge Summaries to ED/Hospital	$1,000	per facility	0%	30%	50%	70%	90%	90%	90%
Clinical Summary to Emergency Departments	$2,000	per facility	0%	30%	50%	70%	90%	90%	90%
Clinical Summary to Physicians/Clinics	$10	per doc	0%	10%	30%	50%	70%	90%	90%
National Radiology Results Delivery	$5	per doc	0%	10%	30%	50%	70%	90%	90%
National Radiology Results History	$1,000	per facility	0%	10%	30%	50%	70%	90%	90%
Hospital Radiology Results Delivery	$1	per doc	0%	10%	30%	50%	70%	90%	90%
Hospital Radiology Results History	$350	per facility	0%	10%	30%	50%	70%	90%	90%
Local Radiology Results Delivery	$2	per doc	0%	10%	30%	50%	70%	90%	90%
Local Radiology Results History	$650	per facility	0%	10%	30%	50%	70%	90%	90%
Max Subscription - All Services	***$43***	***per doc***							
Max Subscription - All Services	***$5,000***	***per facility***							

FIGURE 22

rapidly assume responsibilities from consultants due to the faster time table, additional provider and public relations personnel are needed to facilitate the more rapid adoption.

Figure 23 illustrates the revised core infrastructure costs and cash flow from the HIE operating under the rapid implementation model.

Under the increased implementation pace model, $8.5 million is required in the first year and $8.1 million in the second year. Outlay drops sharply in years four and five until sustainability is reached in year five. Total investment for this model is $19.2 million. As noted earlier, this more rapid implementation reaches positive cash flow at about the same time as the earlier model, but the positive cash flows in year six and seven are considerably higher due to the higher adoption rates and thus higher income from participant fees. Not only do services included in the initial implementation get rolled out faster, but the higher revenues in years six and seven are large enough to finance the implementation of additional services.

Core Infrastructure	Number	Unit Cost	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Exchange Platform and Portal License	1	($3,000,000)	($1,500,000)	($1,500,000)	($600,000)	($621,000)	($642,735)	($665,231)	($688,514)
EMPI	1	($350,000)	($350,000)	($200,000)	($207,000)	($214,245)	($221,744)	($229,505)	($237,537)
Hardware/Supporting Software	1	($500,000)	($500,000)	($166,667)	($172,500)	($178,538)	($184,786)	($191,254)	($197,948)
Implementation Resources	20	($230,000)	($4,600,000)	($4,600,000)	$0	$0	$0	$0	$0
Permanent Resources	15	($125,000)	($625,000)	($646,875)	($2,008,547)	($2,078,846)	($2,151,606)	($2,226,912)	($2,304,854)
Overhead (15% of resources)			($783,750)	($787,031)	($301,282)	($311,827)	($322,741)	($334,037)	($345,728)
Total Core Costs			**($8,358,750)**	**($7,900,573)**	**($3,289,329)**	**($3,404,455)**	**($3,523,611)**	**($3,646,938)**	**($3,774,581)**
Marginal Income/(Loss) from HIE Services			**($139,000)**	**($187,600)**	**$1,366,170**	**$2,680,448**	**$3,826,652**	**$4,833,636**	**$7,343,683**
Cash Flow			**($8,497,750)**	**($8,088,173)**	**($1,923,159)**	**($724,007)**	**$303,040**	**$1,186,698**	**$3,569,102**

FIGURE 23

Health Information Exchange Use Cases

A Use Case is a specific service that is enabled by the exchange, providing benefits to patients and/or providers. The CRISP team believes that the selection and sequencing of services to operate through the exchange should ultimately be driven by the marketplace and not a committee. Nevertheless, it is an appropriate role of the HIE to promote development of Use Cases and to "seed the market" with initial services. Since some potentially valuable Use Cases will require cooperation among many institutions, the HIE also has a role coordinating the efforts of disparate organizations to bring certain Use Cases to fruition.

The Use Cases presented here have been deemed by the CRISP participants to be valuable early pursuits. They are presented in a priority order, with the priority having been set by a combination of factors including clinical value, ease of implementation, and financial sustainability. The list should not be considered immutable. The market reception of these services will ultimately determine if and when these services are deployed.

The HIE should also encourage the introduction of new Use Cases. As an organization accepting a certain public trust, the HIE will equally serve all hospitals, healthcare providers, and entrepreneurs. While we will ensure that sound policy and consumer protection accompany any new service, we will allow these services to develop without discriminating against ideas and ventures from the community.

Throughout the explanation and definition of the Use Cases, the concept of health record banking and consumer access is universal. Use Cases have been identified and described by the type of data moving through the exchange as well as the producers and consumers of that data. However, an overlying concept that consumers should have access to the data flowing through the system is present throughout, and while consumers are not referenced explicitly as data consumers, there is an assumption that as soon as technically feasible, consumers will have the ability to access any data flowing through the system about them, regardless of the primary consumer.

Medication Histories in Emergency Departments / Hospitals

Summary

The parties to this planning effort are conducting a pilot project to deliver electronic medication history information to Maryland emergency departments. The Erickson Foundation is providing startup funding for the pilot with the CRISP Steering Committee acting in an oversight capacity. The first hospital began using the service on October 1st, 2008, and all three hospital participants have planned at least one member hospital that will pilot the service. Due to the fact the service is already being piloted, delivery of medication history is the first Use Case for the standards-based HIE in Maryland.

The electronic medication history service functions when, at the time of hospital registration, a query is sent to an HIE infrastructure and then routed to RxHub, who in turn queries the PBMs in the network and returns a list of prescription medications to a printer at the hospital. The communication occurs across a secure VPN connection.

The prescription medication list is derived from insurance claims information and does not have 100% coverage of all medications a patient may be taking; some patients are not in the system and some medications may have been obtained in a manner that is not captured by PBMs. Rather, the list is an aid to the physician during the medication reconciliation interview required by JCAHO, helping to create a more accurate medication history than could otherwise be obtained. The first location is returning results for approximately 55% of patients who consent to participation.

Clinical Value

The core clinical value and the primary objective of the medication history service is to streamline the mandatory process of taking a medication history when a patient presents in a number of care settings. This process customarily begins when a caregiver asks the patient (if the patient can respond) what prescription and non-prescription medications he is taking. The data collected is often inaccurate, as patients are frequently forgetful and rarely know the exact names and doses of their current and recent prescriptions. At times, a patient will describe the color or characteristics of a certain pill without knowing its brand or generic name. This interaction—however useful or not—is typically the first source of data. Next, the clinician might pull charts or search other hospital data or internal systems if available, or they might even try to call a pharmacy to obtain records (assuming the pharmacy is open). Typically all of this information is fragmented, requiring a cumbersome, time-consuming, and challenging process with highly variable results. By delivering ED providers a robust electronic medication history, the medication reconciliation process is meaningfully improved.

Ease of Implementation

Implementing the electronic medication history service has a minimal level of effort from a technical perspective. Existing networks that have the ability to accept demographic information to query data sources (RxHub / SureScripts), and existing medication reconciliation workflow processes are generally supportive of additional information being injected into the process.

Consent

Under the law, the electronic medication history service requires no additional consent beyond implied consent for treatment, though the pilot service is requiring informed consent to be obtained verbally by the registrar and supported by patient education information. The pilot project has incorporated a minimal modification of emergency department registration systems to capture patient consent at the time of registration.

Lab Results Delivery to Physicians and Clinics

Summary

One of the most financially successful services deployed by RHIOs and HIEs around the country has been that of lab results delivery to physicians and clinics. Most of the large national laboratories (including LabCorp and Quest) already offer electronic delivery of results to ordering physicians through proprietary portals. The services offered through CRISP would include the national labs as well as hospital and local/regional laboratories. By consolidating multiple sources into a single report, physicians will realize efficiencies by not having to access multiple portals, faxes, or mailed reports to obtain results for patients. As far as hospital labs are concerned, they are mostly utilizing paper to mail results to physicians today. By enabling electronic delivery, hospitals can reduce the administrative costs of paper and postage.

This service would simply route lab results from the processing lab to the ordering physician, along with any requested copies to other physicians. Because this is a direct "push" of data from one provider to another, there would be no need to access the EMPI or patient registry.

Clinical Value

While realizing tremendous administrative savings and simplifying workflows, there is no improvement in clinical value realized through delivery of lab results. This Use Case replaces an existing function with a more efficient one, but no new clinical value is derived.

Ease of Implementation

Because the national labs are already delivering results electronically, it will be relatively simple to re-purpose existing messages to flow into the exchange and be available to the ordering provider. The ease of implementation will likely vary widely from hospital to hospital and from local lab to local lab based on the use of homegrown (non-standard) code sets and the level of electronic enablement present in each system.

Consent

Since information is flowing from a processing lab directly to the physician who ordered the test, there is no need for patient consent in this Use Case. By altering the means of transportation of the clinical message but not the recipient or subsequent access to the data, there should be no need to alter any existing consent forms or processes.

Clinical Messaging Services to Provider Portals

Summary

Clinical messaging allows providers to route reports, records, or notes to other authorized users of the exchange. This service is similar to secure email, where each time a user logs onto the exchange, he will see messages in his inbox. Those messages may be a request for consult, a lab result delivery, a discharge summary making a PCP aware that one of his patients was in the emergency room, or any other form of message that could be sent from one user to another.

Clinical Value

In addition to being the backbone of the clinical data exchange, there is clinical value because messaging services allow physicians to route records to other physicians for consults or second opinions. While this function does exist today, it is often cumbersome and requires either the transfer of paper records or the scheduling of additional patient visits for personal evaluation.

Ease of Implementation

As clinical messaging is at the core of most HIE efforts, there is little additional work required to implement this functionality. However, clinical messaging is dependent on the full deployment of the exchange's core infrastructure, so while little additional effort is required for this Use Case, the base functionality must exist before it can be used. Each unique exchange user must be associated with a unique secure inbox for message receipt and a unique identity for sending messages. This will be included in the user setup protocols for the core infrastructure.

Consent

In cases where clinical messaging is utilized to deliver data that would have been delivered by other means in the past, no additional patient consent should be required. While the routing of patient data from one physician to another for consult purposes may be covered under the Treatment, Payment and Operations sections of HIPAA, it will likely be advisable to obtain explicit consent from the patient prior to routing that patient's records to another clinician. Today, referrals for consults are often made verbally or written on a prescription pad. It is up to the patient to determine whether to follow through on the referral or not, and the patient is free to disclose whatever data he or she desires to the second clinician. Patients should maintain that right in the future by actively consenting that another clinician be given access to their records through the HIE for purposes of additional treatment.

Emergency Department / Hospital Discharge Summaries to Physicians and Clinics

Summary

Delivering emergency department and hospital discharge summaries to physicians and clinics is a critical Use Case that enables the transfer of key information following an acute health event so that appropriately informed follow-up care can take place. However, not all emergency room care is for emergent situations. Maryland has experienced ER crowding due in part to poor access to primary care and in part to poor patient awareness of how to effectively receive primary care for non-emergent health events. This Use Case supports appropriate use of emergency rooms by supplying physicians and clinics with detailed discharge

information but also informs clinics of patients who may not have a primary care physician, thus allowing for outreach efforts to be employed and seeking to discourage non-emergent use of the ER while promoting primary, clinic-based care when appropriate.

Clinical Value

The inclusion of emergency room discharge information is powerful during follow-up care to ensure an accurate understanding of the previous episode of care is conveyed to the next provider. Enabling this improvement in the continuity of care through sharing of discharge summaries is a clear example of the core clinical benefits of health information exchange.

Ease of Implementation

Implementation challenges for this Use Case include defining the elements and structure of a discharge summary, similar to the need to define the elements of a clinical summary. Early deployments of this Use Case may rely on unstructured documents delivered through the exchange as discharge summaries, still delivering the clinical content but without the ability to effectively integrate that content with other data sources.

Consent

Patient consent for this Use Case is not explicitly required for each encounter, since consent is implicit for treatment purposes. However, as in other Use Cases, this does not make robust patient education unnecessary and informed consent should still be pursued.

Emergency Department / Hospital Discharge Summaries to Emergency Departments / Hospitals

Summary

This service is similar to that described in the Use Case above, however the recipient of information in this case is another emergency department, removing the element of ER diversion. This Use Case delves into hospital-to-hospital data sharing, which the CRISP group believed to be viable but perhaps unlikely in the context of alternative consumer-centric delivery models, such as health record banks. Nevertheless, the hybrid model is intended to account for unanticipated market demands; a number of consumer-engagement strategies can ultimately be supported.

Clinical Value

The clinical value of this Use Case is the ability to inform emergency room providers of critical information that may not otherwise be available. This Use Case expands upon the value of the electronic medication history service by expanding the scope of the health information delivered to the point of care, thus increasing the ability of providers to quickly respond and provide care to patients who may be unable to communicate effectively or may not recall their past encounters.

Ease of Implementation

Implementation of this Use Case is quite similar to the discharge summary to physicians and clinics Use Case discussed above. Key challenges include defining the structure of the document and/or developing the ability to transfer information in an unstructured format.

Consent

Patient consent for this Use Case is not explicitly required for each encounter as consent is implicit for treatment purposes, which is the purpose for which discharge summaries would be exchanged. As in other Use Cases, this does not excuse the inclusion of robust patient education and pursuit of informed consent opportunities.

Chart Summaries to Emergency Departments / Hospitals

Summary

Chart summaries provide a concise but holistic view of an individual's overall healthcare experience. The workgroups felt that the term "clinical summary" is relatively broad without any existing widespread definition. However, the group agreed that a clinical summary should contain demographics (name, date of birth, address, sex), medications, allergies, conditions/problems, results when available, and past hospitalizations and surgeries where possible. The chart summary should

be in a structured document (CCD) format but may vary on the data elements depending on what is available. We would encourage the inclusion of those outlined above and perhaps expand our definition as we move into any implementation and further our understanding of what is important to our deploying stakeholders.

Potential sources of information for a chart summary include electronic health record systems from participating providers, ancillary service provider systems, personal electronic health records or health record banks, and claims systems for payers. The CRISP model will seek to integrate all sources available to the exchange and would be sufficiently flexible to permit the addition of new data sources as they become available.

Clinical Value

The primary advantage of the chart summary to emergency departments and hospitals is the ability to quickly understand a patient's medical history. Like the medication history service described above, the purpose of the chart summary is not to replace conversation with the patient but rather to provide a reference source for the conversation that may help to avoid accidental or deliberate miscommunication or forgetfulness on the patient's part.

Not only would caregivers get a view of conditions currently affecting the patient, but the chart summary may give the provider indications of how long conditions have been affecting the patient, how effectively they are being treated, and perhaps even clues regarding the patient's compliance with treatment regimens. All of this information may assist the provider in diagnosis and treatment of current symptoms and may help to prevent medical errors. For example, something in the patient's chart summary may raise concerns about a planned course of treatment and prompt more examination.

Ease of Implementation

Chart summary implementation is more complicated than specific data type services, such as the medication history service. Technical analysis will be required to determine available information and create a summary structure appropriate to the information. Additional analysis will be required to ensure that the structures and information selected are presented in the most effective way to make it clinically valuable for providers. As noted above, flexibility in structures is critical to allowing the addition of new data sources as they become available.

Implementation of chart summaries also involves a significant education and training effort for the providers who will receive the information. Good design should render interpretation of the presented information largely intuitive, but care must be taken to ensure that providers understand the limitations of the presented information, lest errors of omission undermine the clinical value of the chart summary.

Consent

The chart summaries to emergency departments and hospitals Use Case is similar to the medication history Use Case from a consent perspective. The chart summary service requires, by law, no additional consent beyond implied consent for treatment, though CRISP suggests requiring informed consent to be obtained verbally by the registrar and supported by patient education information, or a more stringent process, should the participant deem it appropriate. Assuming chart summaries are implemented after or at the same time as the medication history service, the minimal modification of emergency department registration systems to capture patient consent at the time of registration implemented for medication history should also support the necessary consent for chart summaries.

Chart Summaries to Physicians and Clinics

Summary

The summary of this service is identical to that for chart summaries to emergency departments and hospitals provided above.

Clinical Value

The clinical value description for chart summaries to emergency departments and hospitals also applies to chart summaries to physicians and clinics, with some additional value. Physicians may use the chart summary to identify gaps in recommended preventive care or care for maintenance of a chronic condition and thus use the chart summary to enhance their overall health

management efforts. Further, chart summary delivery to clinical and other primary care settings can be used as an ER diversionary tactic, easing the volume burden on already overflowing emergency rooms.

Ease of Implementation

The implementation process is as described for chart summaries to emergency departments and hospitals, with the understanding that the organization and presentation of the chart summary may be different for physicians. Also, given the much larger number of physicians and clinics compared with hospitals, efforts to develop training materials and programs will undoubtedly be more expansive.

Consent

Patient consent for the chart summary service is no different than the consent a physician or clinic requires to interact with other providers or payers on the patient's behalf and is likely covered under existing consent documentation in use by providers today. Nonetheless, CRISP recommends that physicians and clinics either modify their existing consent documents to explicitly describe the use of the HIE chart summary service or ensure that patients are aware that they are participating in the HIE.

Radiology Reports to Emergency Departments / Hospitals

Summary

The CRISP planning process found that the delivery of radiology reports to emergency departments and other hospital settings could be immensely valuable. This finding contradicted an initial feeling among workgroup members that radiology reports would not be valuable, partly based in the underlying fact that imaging is a profit center for most institutions who do it, and reducing the need for images would be detrimental to that revenue stream. Instead, the workgroup concluded that revenue from radiology is not at risk from report sharing because many images would be re-taken anyway; generally providers will want to ensure that the health issues requiring an image have not deteriorated or otherwise changed since the original image by reviewing the report. The services offered through CRISP would include connectivity with the national radiology centers as well as hospital and local/regional centers.

Clinical Value

The clinical value of sharing radiology results is the ability to benchmark against prior images and report and assess the progression of any particular health issue. As the exchange grows and matures, functionality allowing for more rapid interpretations of historical radiology reports will likely become available, thus increasing the overall value of this particular Use Case.

Ease of Implementation

This Use Case includes varying levels of implementation challenges dependent upon the degree of integration and the pursuit of structured data. For example, delivery of an unstructured text radiology report as a document through the exchange does not present as many implementation challenges as exchanging radiology images or structured results data. The benefit of this reality is that this Use Case can be an early entrant to the HIE and provide near-term clinical value.

Consent

Patient consent for this Use Case is not explicitly required for each encounter since consent is implicit for treatment purposes. However, as in other Use Cases, this does not make robust patient education unnecessary and informed consent should still be pursued.

Radiology Reports to Physicians and Clinics

Summary

The summary of this service is identical to that provided for radiology reports to emergency departments and hospitals.

Clinical Value

The clinical value of sharing radiology reports is the ability to benchmark against prior images and report and assess the progression of any particular health issue. As the exchange grows and matures, functionality allowing for more rapid interpretations of historical radiology reports will likely become available, thus increasing the overall value of this particular Use Case.

Ease of Implementation

This Use Case includes varying levels of implementation challenges dependent upon the degree of integration and the pursuit of structured data. For example, the delivery of an unstructured text radiology report as a document through the exchange does not have as many implementation challenges as exchanging radiology images or structured results data. The benefit of this reality is that this Use Case can be an early entrant to the HIE and provide near-term clinical value.

Consent

Patient consent for this Use Case is not explicitly required for each encounter as consent is implicit for treatment purposes, which is the purpose for which radiology reports and images would be exchanged. However, as in other Use Cases, this does not make robust patient education unnecessary and informed consent should still be pursued.

The Future State

The promise of a citizen-centric HIE in Maryland is a future in which patients and providers alike enjoy improved healthcare quality and meaningful cost savings. In a rapidly changing and competitive environment, it is important that Maryland invest in an HIE infrastructure that is technically flexible enough to meet future needs and allow for future innovation. It is equally important that a wide range of stakeholders, from policymakers to providers to technologists, espouse a collaborative spirit and a long-term vision. In this regard, the CRISP planning process was heartening—the leadership of hospital systems, government agencies, advocacy groups for consumers and the underserved, and private-sector healthcare organizations set aside competitive impulses to develop this plan which, we all believe, will serve Marylanders well as we move into an HIT-enabled future.

In this future state, information will be routed to the point of care accurately and efficiently. The HIE will have consistent and controlled access to health data so that it may be made available at the right time, by the right people, for the right reasons, for the right length of time, and with appropriate authorization. Further, by laying the appropriate policy and technical framework, the HIE will be able to "understand" and share data with multiple organizations, patients, consumers, and platforms using acceptable standards. The exchange will expand incrementally based upon a Use Case methodology, allowing a broad set of services based on stakeholder needs.

The CRISP planning group recognized at an early stage that an HIE that clearly demonstrates its value to all stakeholders has the best chances to reach sustainability. Further, it must develop and maintain sufficient trust among the various stakeholders so that the HIE occurs unimpeded. To achieve and maintain this trust, the HIE will require a lightweight but responsive and effective staff and board to effectively and efficiently manage the requirements of HIE. Equally important to sustainability—as we have learned from the challenges of RHIOs and HIEs in the past—is a viable and transparent financial model; we believe that a combination of transparency, evident value, government support through the HSCRC and other stakeholders, and a vibrant community of private-sector business developing services and applications for the exchange will lead to this viability.

In the end, careful planning, innovative uses of technology, and sustained investment can only take the HIE effort so far. To achieve a truly citizen-centric healthcare landscape in Maryland that fully leverages the power of health IT and HIE, we must engage patient and consumers—showing them the value, both in terms of quality of care and in savings, of HIE and ensuring that their privacy and security rights are honored. To this end, the Maryland HIE will have clearly defined, agreed upon, and well-understood rules for the appropriate use of data with known and applied penalties for inappropriate use; furthermore, through aggressive outreach, these rules will be transparent to the public. The HIE will be able to consistently and clearly define and communicate reasonable liability limits. The HIE will also correctly differentiate one patient's records from any other patient's records, with special attention paid to limiting false positive matches to the greatest extent possible, and ensure that the responses to specific data requests are complete and accurate. Finally, consumers will be empowered to play an active role in the ownership of their personal health information and in the administration of their healthcare through tools such as integrated health record banks.

All of the CRISP constituents believe this report constitutes the best possible roadmap to guide Maryland's healthcare stakeholders towards this future state. We would like to thank all of our colleagues for their commitment and vision. We look forward to continuing this important work together on behalf of the citizens of Maryland.

Appendices

Appendix A: Acronyms

AHIC:	American Health Information Community
AHIMA:	American Health Information Management System
AHRQ:	Agency for Healthcare Research and Quality
AMA:	American Medical Association
AMIA:	American Medical Informatics Association
AMR:	Ambulatory Medical Record
ANSI:	American National Standards Institute
ASC:	Accredited Standards Committee
ASP:	Application Service Provider
BAA:	Business Associate Agreement
CCD:	Continuity of Care Document
CCHIT:	Certification Commission for Health Information Technology
CCR:	Continuity of Care Record
CDA:	Clinical Document Architecture
CDC:	Centers for Disease Control
CDS:	Clinical Decision Support
CHI:	Consolidated Health Informatics
CIS:	Clinical Information System
CMS:	Centers for Medicare & Medicaid Services
CPOE:	Computerized Physician/Provider Order Entry System
CPT:	Current Procedural Terminology
CRISP:	Chesapeake Regional Information System for our Patients
DICOM:	Digital Imaging and Communications in Medicine
DOQ-IT:	Doctor's Office Quality-Information Technology
DSL:	Digital Subscriber Line
ED:	Emergency Department
EDI:	Electronic Data Interchange
eHI:	eHealth Initiative
EHR:	Electronic Health Records
EKG:	Electrocardiogram
EMPI:	Enterprise Master patient index
EMR:	Electronic Medical Record
FDA:	Federal Drug Administration
GUI:	Graphical User Interface
HHS:	Health and Human Services
HIE:	Health Information Exchange
HIEN:	Health Information Exchange Network
HIMSS:	Healthcare Information and Management Systems Society
HIPAA:	Health Insurance Portability and Accountability Act
HISPC:	Healthcare Information Security and Privacy Collaboration

HIT:	Health Information Technology
HITSP:	Health Information Technology Standards Panel
HRB:	Health Record Bank
HRSA:	Health Resources and Services Administration
HTTP:	Hypertext Transfer Protocol
ICD:	International Classification of Disease
IEEE:	Institute of Electrical and Electronics Engineers
IETF:	Internet Engineering Task Force
IHE:	Integrating the Healthcare Enterprise
IOM:	Institute of Medicine
ISP:	Internet Service Provider
HIPAA:	Health Insurance Portability and Accountability Act
HITSP:	Health Information Technology Standards Panel
HL7:	Health Level 7
LHII:	Local Health Information Infrastructure
LOINC:	Logical Observation Identifiers Names and Codes
MHCC:	Maryland Health Care Commission
MITA:	Medicaid Information Technology Architecture
MPI:	Master patient index
MRAT:	Arket Readiness Assessment Tool
MRN:	Medical record number
MS HV:	Microsoft HealthVault
NAHIT:	National Alliance for Health Information Technology
NCDCP:	National Council for Prescription Drug Programs
NHII:	National Health Information Infrastructure
NHIN:	National Health Information Network
ONC:	Office of the National Coordinator
P4P:	Pay for Performance
PACS:	Picture Archiving and Communication System
PBM:	Pharmacy Benefit Manager
PHI:	Protected Health Information
PHIN:	Public Health Information Network
PHR:	Personal Health Record
PIX:	Patient Identifier Cross-Reference
PKI:	Public Key Infrastructure
QIO:	Quality Improvement Organization
RFA:	Request for Applications
RFID:	Radio Frequency Identification
RFP:	Request for Proposals
RHIO:	Regional Health Information Organization
RLS:	Record Locator Service

SAHIE:	Service Area Health Information Exchange
SHIRE:	Summit Health Institute for Research and Education
SQL:	Structured Query Language
SSN:	Social Security Number
UI:	User Interface
UMMS:	University of Maryland Medical System
UPI:	Unique Patient Identifier
VITL:	Vermont Information Technology Leaders
VPN:	Virtual Private Network

Appendix B: Steering Committee Members

Name	Title	Organization
Dr. Peter Basch	Medical Director for eHealth	MedStar Health
Patty Brown	President	Johns Hopkins Healthcare, LLC
Jon Burns	CIO and SVP	University of Maryland Medical System
Rick Grindrod	CEO	Erickson Retirement Communities
David Horrocks	SVP	Erickson Retirement Communities
Dr. Mark Kelemen	SVP and CMIO	University of Maryland Medical System
Dr. Matt Narrett	EVP & Chief Medical Officer	Erickson Retirement Communities
Dr. John Parrish	Executive Director	The Erickson Foundation
Stephanie Reel	CIO and Vice Provost for Information Technology	Johns Hopkins Medicine
Catherine Szenczy	CIO and SVP	MedStar Health

Appendix C: Workgroups and Workgroup Members

Community Interaction & Privacy and Security Workgroup

Full Name	Title	Organization
Alex Eremia (Chair)	Vice President, Deputy General Counsel and Chief Privacy Officer	MedStar Health
Scott Afzal (Staff)	Director	Audacious Inquiry, LLC
Edmond Magny (Staff)	Principal	Audacious Inquiry, LLC
James Wieland (Staff)	Principal	Ober|Kaler
Curtis L. Brown	President	Mariel Group, LLC
Booker Carter	Vice President	CareFirst
Gary Christoph PhD	HHS Client Executive	Northrop Grumman
Russell Davis	President	SHIRE
Cindy Friend	Chief, HIT Policy Development	Maryland Health Care Commission
David Horrocks	SVP	Erickson Retirement Communities
Jeff Huddleston	VP, Information Security & Administration	University of Maryland Medical System
Joyce Hunter	Principal	CSC
Donna Jacobs	SVP, Government & Regulatory Affairs	University of Maryland Medical System
Steve Johnson	Counsel	MedChi
Darren Lacey	CISO	Johns Hopkins Medicine
Eunice Pak	Health Policy Analyst	Maryland Health Care Commission
David Sharp	Director, Center for Health IT	Maryland Health Care Commission
Marshall Spurlock	President	Marcohealth
Marcia Thomas Brown	Project Manager	SHIRE
Jack VandenHengel	Executive Director	Shepherd's Clinic
Daniel Wilt	Vice President	Erickson Retirement Communities
Jay Wolvovsky	CEO	Baltimore Medical System

Exchange Technology & Clinical Workflows Workgroup

Full Name	Title	Organization
Mark Kelemen (Chair)	SVP and CMIO	University of Maryland Medical Systems
Scott Afzal (Staff)	Director	Audacious Inquiry, LLC
Karen Barker	CIO	LifeBridge Health
Mrinal Bhasker	Principal	Audacious Inquiry, LLC
Rich Boehler	CMO	St. Joseph Medical Center
Beverly Boies	Manager, Systems Development	Johns Hopkins Medicine
Alan Coltri	Chief Systems Architect	Johns Hopkins Medicine
Mike Fierro	Principal	Dynamed Solutions
Cindy Friend	Chief, HIT Policy Development	Maryland Health Care Commission
Peter Greene	CMIO	Johns Hopkins Medicine
David Grinberg	Director	Dynamed Solutions
David Horrocks	SVP	Erickson Retirement Communities
Tom Lewis	CIO	Primary Care Coalition
Stephen Mannion	AVP Information Systems	MedStar Health
Mary McKenna	VP Clinical Systems	University of Maryland Medical System
Michael Payne	VP Technology Services	University of Maryland Medical System
Bill Russell	SVP	Erickson Retirement Communities
David Sharp	Director, Center for Health IT	Maryland Health Care Commission

Business Development & Finance Workgroup

Full Name	Title	Organization
Lenora Booth (Chair)	Executive Vice President	Erickson Retirement Communities
Mike Fierro (Staff)	Principal	Dynamed Solutions
Scott Afzal	Director	Audacious Inquiry, LLC
Salliann Alborn	CEO	CHIP
Christopher Brandt	Managing Partner	Audacious Inquiry, LLC
Alison Brown	SVP, Business Development	University of Maryland Medical System
Mike Cardamone	Finance Director	Johns Hopkins Medicine
Cindy Friend	Chief, HIT Policy Development	Maryland Health Care Commission
David Grinberg	Director	Dynamed Solutions
David Horrocks	SVP	Erickson Retirement Communities
Jeff Joy	COO	Johns Hopkins HealthCare
Erika Linnander	Administrative Fellow	Johns Hopkins Medicine
Eunice Pak	Health Policy Analyst	Maryland Health Care Commission
Keith Persinger	SVP, Finance	University of Maryland Medical System
David Sharp	Director, Center for Health IT	Maryland Health Care Commission
Jay Wolvovsky	CEO	Baltimore Medical Systems

Appendix D: CRISP Workgroup Planning Schedule

CRISP Workgroup Meeting Schedule

Exchange Technology & Clinical Workflows

Mtg#	Date	Time	Location
1	July 21st	3pm to 5pm	UMMS
2	Aug 18th	3pm to 5pm	UMMS
3	Sep 15th	3pm to 5pm	UMMS
4	Oct 20th	3pm to 5pm	UMMS
5	Nov 17th	3pm to 5pm	UMMS
6	Dec 15th	3pm to 5pm	UMMS
7	Jan 19th	3pm to 5pm	UMMS
8	Feb 16th	3pm to 5pm	UMMS

Community Interaction & Privacy and Security

Mtg#	Date	Time	Location
1	July 14th	3pm to 5pm	ERC (RLTV)
2	Aug 11th	3pm to 5pm	ERC (RLTV)
3	Sep 8th	3pm to 5pm	ERC (RLTV)
4	Oct 13th	3pm to 5pm	ERC (RLTV)
5	Nov 10th	3pm to 5pm	ERC (RLTV)
6	Dec 8th	3pm to 5pm	ERC (RLTV)
7	Jan 12th	3pm to 5pm	ERC (RLTV)
8	Feb 9th	3pm to 5pm	ERC (RLTV)

Business Development & Finance

Mtg#	Date	Time	Location
1	July 21st	9am to 11am	MedStar
2	Aug 18th	9am to 11am	MedStar
3	Sep 15th	9am to 11am	MedStar
4	Oct 20th	9am to 11am	MedStar
5	Nov 17th	9am to 11am	MedStar
6	Dec 15th	9am to 11am	MedStar
7	Jan 19th	9am to 11am	MedStar
8	Feb 16th	9am to 11am	MedStar

Appendix E: Participant Organization Overview

Partner Hospital Systems
- Johns Hopkins Medicine
- MedStar Health
- University of Maryland Medical System

Participating Organizations
- Erickson Health Information Exchange, an Erickson Foundation Company

Consulting Partners
- Audacious Inquiry, LLC
- Dynamed Solutions

Legal Counsel
- Ober|Kaler

Other Participants
- Baltimore Medical System (BMS)
- CareFirst
- Community Health Integrated Partnership (CHIP)
- Erickson Retirement Communities (3 Maryland CCRC Communities)
- Lifebridge
- Maryland Health Care Commission
- MedChi
- Northrup Grumman
- Primary Care Coalition
- The Shepherd's Clinic
- St. Joseph Medical Center
- The Summit Health Institute for Research and Education, Inc. (SHIRE)