Preparing to Implement HITECH

A State Guide for Electronic Health Information Exchange

2009 REPORT FROM THE STATE ALLIANCE FOR E-HEALTH

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PREFACE

Governors, state legislators, and other state leaders are critical to the adoption of health information technology, electronic health record systems, and health information exchange. To help states navigate the legal and policy issues and accelerate progress in health information technology adoption, the National Governors Association Center for Best Practices (NGA Center) created the State Alliance for e-Health.

The State Alliance is a consensus-based body of state elected and appointed officials. It was created in January 2007 to address the unique role that states can play in facilitating adoption of interoperable electronic exchange of health information. It also serves as a forum through which state leaders and other stakeholders can share inter- and intrastate health IT best practices and policy solutions. Support for the State Alliance is provided by the U.S. Department of Health and Human Services' Office of the National Coordinator for Health Information Technology under contract #HHSP23320064106EC.

The State Alliance is co-chaired by Tennessee Governor Phil Bredesen and NGA Chair Vermont Governor Jim Douglas. Its members include state legislators, attorneys general, insurance commissioners, and health officials. The State Alliance also is supported by advisory members from the public and private sectors, who lend their technical expertise to the deliberations. A full roster is listed on the next page.

This report is one of several key products of the State Alliance. It is intended to give interim guidance to state leaders as they begin to implement the Health Information Technology for Economic and Clinical Health (HITECH) Act included in the American Recovery and Reinvestment Act of 2009. At the time of publication, guidance related to grants to the states or their qualified designated entities has not been released. More detailed guidance from the Office of the National Coordinator is expected over the next several months.

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KEY TERMS

Electronic Health Record (EHR)—*an electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be created, managed, and consulted by authorized clinicians and staff across more than one health care organization.*

Electronic Medical Record (EMR)—*an electronic record of health-related information on an individual that can be created, gathered, managed, and consulted by authorized clinicians and staff within one health organization. An EMR provides the underlying data for an EHR, but it is not transmitted among organizations and usually is more robust than an EHR.*

Health Information Exchange (HIE)—*the electronic movement of health-related information among organizations according to nationally recognized standards.*

Health Information Organization (HIO)—*an organization that oversees and governs the exchange of health-related information among organizations according to nationally recognized standards.*

The terminology and definitions used here were developed in 2008 through a collaborative process led by the National Alliance for Health Information Technology and authorized by the Office of the National Coordinator for Health IT. http://www.nahit.org/images/pdfs/HITTermsFinalReport_051508.pdf

Introduction

Health information technology (IT) and electronic health information exchange (HIE) have emerged as a primary means of shaping a health care system that is effective, safe, transparent, and affordable. They are important tools to improve the efficiency of health care delivery. When linked to other system reforms, technology can support better quality health care, reduce errors, eliminate redundant services, and improve population health data. States are committed to promoting technology as a means to improve the nation's health system.

Before 2005, state involvement in health IT and HIE was limited. Much attention was given to the development and viability of stakeholder-led information sharing organizations (often called RHIOs). Some of those efforts struggled to find financially sustainable models, and some were unable to fully achieve their goal of contributing to system improvements. As electronic health records (EHRs) and HIE have increasingly been identified as critical infrastructure for significant health system reform, state government interest and involvement in helping HIE succeed have grown sharply, driven by the hope of improved value through improved health care quality and efficiency. In addition, there is a clear recognition that state policy is key in protecting the privacy of medical records and ensuring a secure network for conducting exchange.

The Health Information Technology for Economic and Clinical Health (HITECH) Act sets a new direction that greatly expands the role of states in fostering health information exchange and the adoption of EHRs. The act set a goal of 2014 to increase dramatically the number of health care providers who have, and effectively use, EHRs and HIE. This goal is to be achieved through an array of financial incentives, education, training, and state-led actions. In particular, states are at the forefront of planning and implementation efforts to establish electronic HIE. Standard terms should be used when planning HIE initiatives (see sidebar).

Differences in how health IT terms are used can cause confusion about what is being purchased or included in policies and regulations.

States must immediately begin planning how they will support this new direction and lead the way for broad deployment and use of HIE. The role of states in modernizing the health care system was already substantial, but it will dramatically expand as the HITECH Act is implemented. The State Alliance for e-Health (State Alliance) has been helping states develop initiatives, and many of its recommendations are relevant to advancing HITECH.

This guide recommends actions states should begin today to ensure successful implementation of HITECH. Many of the actions require decisions within the year. Some states may be in a position to move more swiftly than others in deploying HIE, but all will experience an unprecedented level of new activity and policy challenges.

A New National Priority

The past five years have seen a steep jump in state government involvement in health IT adoption, in the process of information exchange, and in the oversight and accountability functions necessary to support it. Over this period, dozens of bills and executive orders have been enacted establishing new organizational structures to guide electronic HIE and in many cases fund a portion of the planning and deployment. Some states have gone further and invested significant dollars in major HIE components, such as broadband access, secure records storage, and software to receive and transmit data. Nationwide, however, progress has been uneven, and no state today can say that statewide electronic HIE serving the majority of its population is a reality.

Much of the reason can be traced to the fractured nature of the U.S. health care system, which consists of myriad stakeholders including providers (doctors, hospitals, clinical laboratories, pharmacies, and other health care entities), insurance plans and purchasers, government, and consumers. While creation of a health information organization (HIO) should benefit all stakeholders, few have assumed the responsibility for building and operating the system. Instead, different stakeholders have built information systems to address their particular needs. As a result, development of a cohesive, patient-centric system has languished in most areas, and there is little interoperability among existing HIOs.

With the passage of the HITECH Act in February 2009, as part of the American Recovery and Reinvestment Act (ARRA), the picture has changed. By supplying substantial resources for planning, deployment, and use; by setting standards for health IT systems and exchange; and by certifying the EHR functionalities to be used, the federal government has made HIE a national priority. Moreover, President Barack Obama has made HIE a cornerstone of national goals to improve health care quality and efficiency and has called for it to be operational nationwide by 2014.

The act makes clear that much of the planning, implementation, and oversight for HIE will fall to states, creating the need for rapid and thoughtful action on the part of governors and others in state government. Key components of the HITECH Act that will drive HIE initiatives include the following:

- Grants to states or their qualified designated entities to support health information exchange planning and implementation;
- Medicaid and Medicare incentive payments to providers that use electronic health record systems and can exchange data; and
- A requirement that the federal government adopt and use certified technology and standards in all its relevant agencies

The incentives and the transparent availability of the certified technology and standards are intended to accelerate voluntary adoption within the private sector. These components are described in more detail below.

Grants for State-Level HIE Efforts

The legislation provides for grants to states to promote HIE. The grants may be awarded directly to states or to their qualified designated entities. Funding will be provided for both state planning and state implementation grants. To receive an implementation grant, a state must have a state plan approved by the Department of Health and Human Services (HHS). Specific guidance for state plan requirements and for the grant programs has not yet been released, but the law specifies that the grants would cover state actions that:

- Increase participation in the use and exchange of electronic health information;
- Provide assistance, and remove barriers, to support exchange that improves quality;
- Support initiatives and infrastructure for intra- and interstate exchange; and
- Provide resources for underserved communities to support EHR adoption and exchange.

Under a separate program, the legislation also allows HHS to establish a loan program for certified EHR technology purchase and implementation costs. The intent of this competitive program is to provide selected states or other grantees with funds to make guaranteed loans available to providers for the purchase and implementation expenses associated with adopting certified EHRs. Because training and workflow analysis and design are known to be critical to successful adoption, the loans could also cover some of the indirect costs, including staff training and maintenance.

Details on both of the grant programs are forthcoming. There is no deadline for the release of the grants, but if the loan program is implemented, it cannot begin until 2010.

Medicare and Medicaid Incentive Program

The HITECH Act provides incentive payments under Medicare or Medicaid for eligible providers who have adopted certified EHR systems and who meet statutory requirements for "meaningful use." To be eligible for Medicaid incentive payments, a certain percentage of the provider's patient caseload must be enrolled in Medicaid. The threshold in this area is generally 30 percent of patients for physicians (20 percent for pediatricians) and 10 percent for hospitals. "Meaningful use" of an EHR system, as defined in the law, includes three key components:

- The EHR system must be certified and include e-prescribing capabilities.
- The technology must provide for EHR exchange with other systems (interoperability).
- The system must produce reports using various yet-to-be-defined clinical and quality metrics.

Medicare will also establish a definition for "meaningful use." Funds to support enhanced payment incentives could become available under Medicare as early as October 1, 2010, for hospitals and other providers starting January 1, 2011. Medicaid payments could begin sooner.

The Centers for Medicare & Medicaid Services (CMS) at HHS will administer the Medicare payment enhancements, but states will administer the Medicaid payment enhancements. Medicaid payments could be combined with loans from the fund described above and other public or private sources, but providers will not be allowed to receive both Medicaid and Medicare payment incentives. States will not be required to match any of federal incentive payments, and CMS will provide states with 90 percent of their costs for related administration and oversight. States may have to alter their Medicaid Management Information Systems to track and administer these payments to providers.

In addition to enhanced payments, eligible providers will be reimbursed up to 85 percent of allowable costs for EHR technology and support services, not to exceed a capped maximum amount (per provider) over five years. This reimbursement would defray the costs of purchase and implementation. Those eligible include non-hospital-based providers, federally qualified health clinics, rural health clinics, children's hospitals, and some acute care hospitals. Other hospitals would likely fall under the Medicare incentive payment program.

States must develop mechanisms for ensuring that providers pass threshold eligibility requirements and that they use the technology meaningfully; this will be a condition for receiving Medicaid incentive payments. The definition of "meaningful use" that HHS is developing for Medicare could guide state efforts. States must also create means to track the use of the funds, to ensure that only certified technology is purchased, and to make certain that providers cannot receive both Medicare and Medicaid incentives.

Standards Adoption, Certification, and Other Relevant Federal Actions

Numerous federal activities are included in the HITECH Act. Many are centered with HHS and the Office of the National Coordinator for Health IT (ONC), but other agencies will also be involved. The plan for implementation is under development; several of the proposed requirements are highly relevant to state activities:

- HHS must adopt standards for health IT systems by the end of 2009. The legislation calls on HHS to form a Health IT Policy Committee and a Health IT Standards Committee to generate recommendations for certification criteria and technology standards for EHRs and other relevant systems and software. The policy committee will make recommendations to the national coordinator for health IT. Those recommendations will be sent for development by the standards committee, and finally to the coordinator and the HHS secretary, who must decide whether to adopt specific standards. All technology implemented through the programs named above must conform to these standards.

- The HITECH Act codifies the existence of the ONC and gives it responsibility for moving toward a nationwide system of information exchange. Several pathways are outlined, and the office is required to submit a plan for achieving the requirements of the act. The act calls for the appointment a new chief privacy officer within ONC and makes several changes to the Health Insurance Portability and Accountability Act (HIPAA), including extending HIPAA requirements to business associates and authorizing state attorneys general enforce HIPAA provisions.

- HITECH also provides federal funding for regional extension centers, to offer health care providers technical assistance and best practices in implementing and using health IT. The act also provides direct funding to community health centers for infrastructure improvements, including health IT. Although states may not directly manage these efforts, they must be aware of them and determine ways to incorporate and coordinate initiatives.

Finally, the American Recovery and Reinvestment Act (ARRA) provides significant federal funding for broadband infrastructure and deployment. A total of $7.2 billion is provided for activities such as infrastructure, mapping of broadband availability, training, and education to spur broadband use in rural, unserved, and underserved communities. Of that amount, $2.5 billion will flow through the Rural Utilities Services Distance Learning, Telemedicine, and Broadband Program (RUS) of the U.S. Department of Agriculture, and $4.7 billion will flow through the U.S. Department of Commerce, National Telecommunications and Information Administration (NTIA) Broadband Technology Opportunities

Program (TOP). Broadband mapping support ($350 million) is available to the states through the NTIA funding. States are eligible to apply for some of the competitive grants as well.

It is important for states to consider how broadband availability would affect health information exchange and what type of broadband projects might help increase HIE coverage. HIE cannot become a reality without broadband access, and the grants could provide valuable transmission capabilities. Educating those in the broadband sector about the sea change that is sought in health care is vital; linking telehealth, broadband, and HIE investments is strategic for states with rural or frontier areas and unserved or underserved populations.

State Roles and Responsibilities in Establishing HIE

Under HITECH, states will lead in two major ways:

- Overseeing planning and deployment of HIE, including applying for and managing grant funds (this may be partially delegated to a state-designated entity); and

- Managing the Medicaid incentive payments to providers and other eligible recipients.

As health IT systems are introduced, states will need to be involved in establishing the HIE governance structure and business plan to ensure its sustainability and in establishing privacy and security policies for the storage and electronic exchange of information. Equally important, to ensure that HIE adds value to health care system performance, states will need to play a role in applying HIE to improve the efficiency and quality of the health care system as a whole.

These are activities that states have the tools and capacity to carry out, but doing so may require new state government organizational structures and oversight authority. In addition, implementation of HIE may occur at the same time that a major health care policy overhaul is under way nationwide. States must strategically consider how HIE can support these system changes and how technology can fuel reforms. State leadership can help ensure that all system components work together.

This section outlines a number of actions that states should consider to help them move quickly and strategically to implement HITECH:

- Preparing or updating the state road map for HIE adoption;
- Engaging stakeholders;
- Establishing a state leadership office;
- Preparing state agencies to participate;
- Implementing privacy strategies and reforms;
- Determining the HIE business model;
- Creating a communications strategy; and
- Establishing opportunities for health IT training and education.

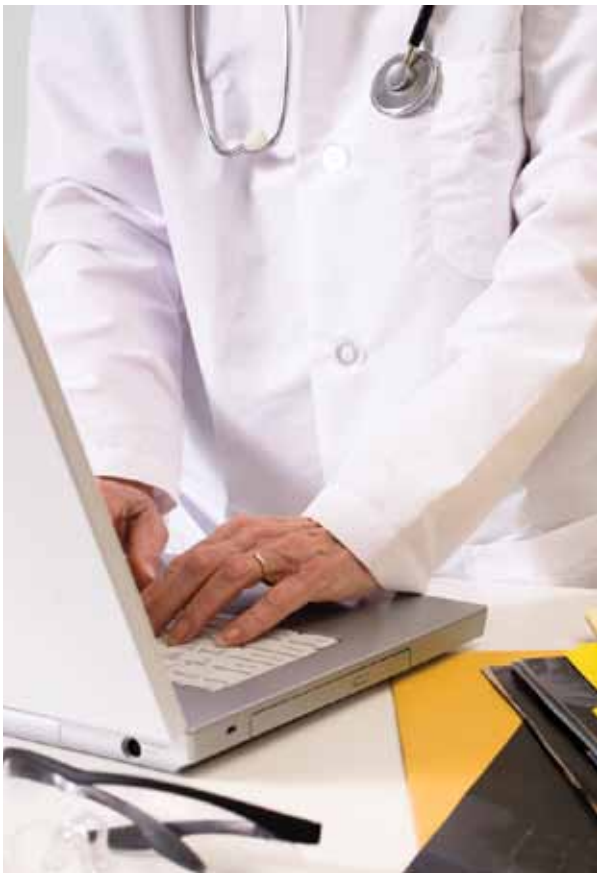
State government must prepare to capitalize on opportunities to advance health IT and commit to helping the public and private sectors collaborate to realize the potential of HIE, including positioning the state so that providers can take advantage of EHR adoption incentives. These efforts must be implemented within the context of health system transformation, with states ensuring connectivity that supports delivery and outcome improvements.

ACTION 1: Prepare or Update the State Plan for HIE Adoption

All states will need to prepare a plan to implement HIE, and those with existing plans will need to update them. New plans will need to outline steps to create a health information organization (HIO) structure and ensure participation by all providers, laboratories, hospitals, and other generators of medical records; to protect the privacy and security of health information in HIOs; to ensure sustainable exchange operations, including financial sustainability; to help ensure that HIE is supporting health system improvements; and to manage incentive payments to Medicaid providers that use EHR systems to exchange health information. It is unlikely that any state plan created before HITECH fully reflects all of these tasks.

Current Plans Will Need to Be Synchronized with Federal Efforts

Even good existing plans must be reviewed for adequacy in light of the new federal initiatives. First, the new law has raised the stakes for state government in ensuring the success of HIE. Putting states in charge of planning and implementation—and making grants available for both—implies the expectation that states will play a central role in the creation of the HIE system. In addition, the federal government is providing resources to help spur the purchase of EHR systems and the exchange of information. Billions of dollars will be invested over the next five years to drive HIE. States must ensure that it works and is sustainable.



Second, the public will expect states to protect the privacy and security of their health information as it is stored and exchanged. Up to now, many states saw exchanges as being primarily financed by the private sector, managed by a consortium of stakeholders, and governed very lightly (state government often played the role of a stakeholder or facilitator). Many exchange designs were based on the premise that voluntary guidelines would ensure privacy and security. With the passage of HITECH the perception of government's role in privacy and security has become more defined and the assurance of government oversight will become part of the fabric of consumer protection. As the exchanges become a reality, states will need to act to ensure that data can be exchanged, and that privacy is protected routinely and evenly, both within and across states. States will need to collaborate to accomplish this objective.

Third, to take full advantage of all that HIE promises, states must be active in coordinating how data are used across public and private programs. Data can be combined with incentive payments to improve the quality of services and can be used to determine population health and analyze the effectiveness of interventions. There will be many requests by research institutions, public agencies, provider groups, and plans to use the data to improve health outcomes. States will need to set strong policy guidelines and broker these requests so as to assure the public that privacy will not be breached and data will not be misused. Moreover, providers must be convinced that the use of EHRs has long-term value. New plans likely will need to provide at least an outline of the state's vision for using HIE in these ways.

States soon will receive guidance on how to apply for planning grants under HITECH. This guidance should inform them of the minimum requirements of a state plan. Even states that choose not to apply still should review the requirements because they likely will be a prerequisite to receiving state implementation grants.

Even before this guidance is available, states can begin to revise their plan or prepare a new one. They should start by assembling a planning group representing key stakeholders (see stakeholder section). The planning group should review the requirements outlined in the law. The group will need to make decisions (or set a schedule to make decisions) around such key issues as the following:

- Determining the basic architecture of exchanges (where data will be housed, how data will be transmitted, and who will participate);

- Identifying a governance and business model for HIE in the state (how it will operate, how rates will be set and who will pay, and who will manage HIOs);

- Determining the state government leadership and oversight structure (though the state will make the final decision on structure, it will want stakeholder input); and

- Identifying a framework or options for ensuring privacy and security of electronic health records, consistent with the goal of a nationwide exchange.

The planning group may not need to make final decisions on all of these issues and others described in the following sections, but it will need to address them and set schedules for making final decisions. Once implementation begins, states may need to establish additional work groups to resolve final choices and oversee building the exchange or exchanges in their state.

ACTION 2: Engage Stakeholders

The sustainability of health information exchange depends on participation and support by stakeholders in the public and private sectors. Electronic HIE typically involves consumers, health care providers, hospitals, pharmacies, insurers, employers, and state and local government agencies. **Figure 1** depicts typical stakeholders for electronic HIE, although individual states may differ.

Figure 1: Electronic HIE Stakeholders

Ensuring that all major stakeholder groups are involved in planning and priority setting is critical in finalizing an implementation strategy. They should be involved in developing, updating, and vetting the state road map. In addition, states should create forums for interested parties to voice their interests and priorities and to learn about ongoing efforts. Specific interests that may prove useful are the telehealth community and people in broadband connectivity, as well as representatives of early adopters and innovators, who may have questions about upgrades and incentives.

Initially, states should work with their stakeholders to assess their HIE environment. Many states have existing local or regional HIE efforts and HIOs. This assessment will be important in determining how those networks might be affected by the creation of a statewide HIE. The inventory should examine:

- Existing programs and data efforts that state agencies have under way with private sector data sources (e.g., Medicaid EHR or public health disease registries that draw from community providers);

- Exchange efforts in the private sector (e.g., hospital IT systems, local exchanges); and

- Potential new investments being planned in HIE or EHR systems (it may be prudent to postpone such investments until the full nature of state-level HIE becomes clearer).

The assessment will establish an understanding of how stakeholders are using data for treatment, public health, and quality improvement and can be used to lessen the impact of a transition to state-level HIE. States also can use the assessment for ensuring that key components of the health care system, such as public health, are fully incorporated in developing state-level HIE.

ACTION 3: Establish a State Leadership Office

Development of nationwide HIE is extremely complex. But reforming the health system and controlling its costs will rely heavily on the success of the effort. States will need to maintain ongoing efforts to weave the deployment of technology into the larger picture of health reform. HIE must be evaluated in this broader context and in relation to the public good.

Given the provisions of ARRA and HITECH, states must create a leadership structure to manage at least four phases of HIE implementation—planning, HIE deployment, EHR adoption, and sustained use—as well as the transitions between the phases. The leadership structure must coordinate across publicly funded programs such as Medicaid, interact with the private sector, oversee the dissemination and use of HITECH funds, work with planning and implementation groups (including stakeholders), and ultimately ensure the operation of the exchange. This leadership structure (referred to here as the "Office for Health IT") should be the voice of the state on these issues and the key point of interface with private stakeholders and public agencies at the state, local, and federal levels.

In the short run, as health information exchange is being developed, specific responsibilities of the Office for Health IT should include the following:

- Oversee and direct the use of HITECH funds to plan and implement HIE;

- Provide high-level coordination among planning and implementation groups, as described earlier;

- Establish a framework for HIE operations and financial sustainability; and

- Establish privacy and security policies to guide how the exchange receives, transmits, and stores data.

In the long run, after the exchange becomes operational, responsibilities of the Office for Health IT would include the following:

- Overseeing operation of the state exchange;
- Ensuring that all public programs—including public health and Medicaid—are exchanging health information and that all regulatory requirements are being met;
- Helping identify and prioritize, with stakeholders, how HIE can be used to improve health care; and
- Aligning requirements and program incentives to ensure that governmental investments in HIE and EHR systems are used in ways that offer value.

In between phases, the office will need to help manage the transition to implementation among stakeholders and draft key operational rules. Problem-solving will be another major responsibility during transitional phases and after operation begins.

States should work quickly to secure whatever statutory authorities and oversight structures are needed to create an Office for Health IT. States could form a new division or agency, develop an interagency structure that reports to a new entity, or re-task an existing agency. However, they must move quickly to prepare to receive federal grants and oversee planning and implementation of the various phases.

ACTION 4: Prepare State Agencies to Participate

State leaders must move toward aligning their health information exchange efforts across state programs, particularly Medicaid, public health, and the insurance departments. State employee health plans are also an increasingly important avenue for states to include in promoting this agenda. These programs must be a major focus for early efforts to advance HIE within the state, as they both hold and need information relevant to a robust health information organization.

State chief information officers and administration departments, attorneys general, and other agencies may take on different roles depending on their authorities and interests. Eventually, states should also address corrections, school systems, family services, and other state agencies that collect or use health-related information. Eventually, all relevant agency systems should be able to share information and produce coherent cross-program records.

Preparing state agencies to participate in health information exchange will be critical to its success and value. The previously described Office for Health IT is in the best position to take the lead in organizing cross-agency activities, which might include the following:

- Examining existing information systems for relevance and readiness to contribute to HIOs;
- Formulating relationships across agencies for data sharing and cooperative efforts;
- Ensuring that public health data needs are addressed and identifying surveillance priorities;
- Providing public sector workers with needed training and guidance; and
- Identifying how to adapt existing systems to sharing information electronically or eliminating them.

Assess Current Systems

States have internal IT systems that manage or collect health data and that would be relevant to a health information organization. These systems rely on data that will be drawn from an HIO and also may contribute data that other exchange users need. The following are a few examples:

- Clinical and administrative data systems in public programs need to be able to contribute to HIOs, including public health laboratories, public employee EHRs, and so on.
- Medicaid currently receives much of its data via electronic submission, but it rarely contributes to any HIE efforts. How or whether these systems must be coordinated with HIOs must be examined.
- Public health departments receive a variety of health data that are important for many HIE purposes, including disease registries and immunizations data. This kind of information should flow into an HIO, and public health departments should have the capacity to pull this information from the exchange when needed. State agencies need to decide how to manage these transitions.

Each agency should assess its existing systems and determine their priority and relevance to HIE. This assessment can be conducted in each agency and reported to the Office for Health IT. Once standards are developed, these critical systems must be reviewed for interoperability and slated for needed upgrades.

Establish Interagency Work Groups or a Similar Structure

Coordination and joint priority development by Medicaid and public health authorities present a key opportunity for accelerating implementation. These two agencies likely will be instrumental in broader health care reforms, and a coordinated approach that includes health information exchange will benefit system reform goals. There are various structures and methods for ensuring coordination, and states can put them into place during planning for both health care reform and health IT efforts.

Address Public Health Data Needs in EHRs and HIE Development

Public health monitoring and population health protection are important state responsibilities. States must be proactive to ensure that both electronic health records and health information organizations are developed and used with full public health functionality. Disease tracking and monitoring, bio-surveillance and epidemiology investigations, and immunization records are some of the functions that HIE can contribute to the health system. Identification of necessary public health data elements should be part of HIO planning.

Improve Public Workforce Capacity

The success of health IT and electronic HIE initiatives will be limited by a shortage of capable workforce to negotiate with vendors, implement projects, and reengineer workflows and operations. This skill shortage is pervasive and challenges the state employees in program implementation and oversight.

For state agencies to implement effective health IT projects, leaders and program managers must understand the breadth and complexity of health IT and electronic HIE, as well as the potential impact of technology on their programs and on improving health care quality and safety. These staff members must also understand the policy, business, and technical requirements for launching and sustaining technology projects. States should work with their agencies, community colleges, universities and training centers, and neighboring states to identify ways to improve the skills of the public workforce to support health IT efforts.

ACTION 5: Implement Privacy and Security Strategies and Reforms

For EHR and HIE efforts to be successful, consumers and health care providers must trust that information will be kept confidential and secure. A balance between the need to protect consumers against privacy violations and security breaches and the need to permit appropriate access to electronic data is critical if the benefits of HIE to patients and the system as a whole are to be realized.

Strict privacy policies can seriously slow the adoption of health IT systems and decrease the value of exchange. Too-lenient policies can erode public trust and encourage providers to create their own, nonstandard restrictions to protect patients. States should weigh their options and determine early in the process how to align their approach to privacy with those of other states and with the federal privacy and security framework. Specifically within the privacy arena, states should move forward in these ways:

- Ensure alignment with the new requirements for privacy included in the HITECH Act;
- Set the state's privacy principles and establish the criteria by which to assess new and existing policies and practices; and
- Revise state policies and laws and help providers adopt statewide standards on privacy policy and practices.

In the longer run, states also will need to move toward interstate exchange, including harmonization of policies and agreements with other states.

Align with HITECH Privacy Requirements

The HITECH Act places a focus on privacy and security, expanding current federal privacy and security protections under HIPAA (the Health Insurance Portability and Accountability Act). HIPAA requirements will now apply directly to business associates, and state laws may have to change to reflect the new requirement if any conflict is present. Examples of business associates include disease management companies, quality assurance organizations, or personal health record vendors. State attorneys general also have new authority to enforce HIPAA. They may need to develop new policies and capacities to address this change. Working closely with the HHS Office for Civil Rights will help to harmonize interpretation and support clarity about the availability of information under various circumstances. This clarity will be critical to providers.

The act also establishes the first federal data security breach notification law, which requires entities to notify affected individuals of a breach involving personal health information. Because many states already have procedures or laws on this topic, they should review them for alignment with the new standard.

Determine the State's Privacy Approach

States should evaluate their existing policies and revise or adopt privacy rules as appropriate to guide electronic exchange of health information. Making these privacy rules operational may require changes in law and protocols for HIE operation. The types of rules can be grouped into three broad categories:

1. Privacy controls that strongly control whether information goes to an HIO (e.g., consumers opt wholly in or wholly out of exchange, except for certain conditions that may be specially protected in state law);

2. Privacy controls that exert strong controls on who can access the information in an HIO; and

3. Privacy controls with multiple variables on both what goes in and who has access (e.g., information goes to and from the HIO only to certain entities under certain conditions).

Controls on information often are triggered by patient consent, but they also may arise from blanket laws that prohibit certain information from being transferred. In such cases, consent may be needed to override the restrictions.

Restrictions on data exchange raise the issue of balance: facilitating exchange while maintaining appropriate levels of consumer privacy. For example, the second category of rules could permit a robust HIO, to be created while allowing the patient to determine who should have access to his or her information. The other two approaches could suggest a less-complete record, which could be of less value. In any case, states will need to determine an appropriate level of privacy to be enforced in the HIO.

Stakeholder input is required for the development of privacy rules. States should consider publication of the principles and rationale of their privacy policies and must also plan for early and sustained communication on these issues—particularly with the key constituencies of providers, consumers, and vendors—as they move into electronic exchange.

Continue State Privacy Studies Already Under Way

Through HHS, most states already have begun to examine their chief legal challenges and provider practices in privacy through the Health Information Security and Privacy Collaboration (HISPC). Under HISPC, states and territories have taken the opportunity to review several categories of their laws and understand their state-specific challenges.

Most states identified some barriers and inconsistencies in their own laws, and many have already moved to address them. Much more common is wide variation in the privacy practices of providers, often with no basis in law. States should review their HISPC findings and determine whether particular challenges will affect their direction for HIE, or whether new priorities have emerged under the principles and criteria set in HISPC. States should then continue to resolve conflicting policies and help providers adopt standardized practices and technology that meet the privacy goals of the exchange.

Prepare for Interstate Exchange

The national vision is eventually to have a system of nationwide exchange. States must focus on their own privacy policies and environment, but they also should consider how their decisions and policies will affect interstate exchange. Adopting new privacy policies that diverge greatly from those of neighboring states will affect their ability to move to interstate exchange.

A near-term approach is available in which states could begin to align their privacy policy with those of surrounding states and/or their medical trading partners (e.g., providers to seasonal populations). In this approach, states would develop direct agreements with other states that share large patient populations. An examination of "medical trading areas" would provide states a map of where their populations are receiving care. If these trading areas frequently cross state lines, the state should examine its privacy practices to determine whether there are impediment to interstate health information exchange in an electronic environment. HHS, through an additional HISPC phase, developed several tools to aid in interstate alignment.

Through the HISPC Interstate Disclosure and Patient Consent Requirements Collaborative, participating states revealed that it is often difficult for organizations to determine—in the context of interstate electronic health information exchange—when appropriate disclosure requirements have been met by both the requesting and the providing organization. The collaborative successfully documented the state law requirements for disclosure of health information for treatment purposes both within states and across state lines. The collaborative identified steps that could facilitate interstate health information exchange. Additional information is available at http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10779_872309_0_0_18/C1_1_1_Final_Rpt.pdf.

To ensure that interstate exchange is possible in the long run, states must address and harmonize state privacy laws, including sections on patient consent; liability for improper disclosure; alignment around particular types of specific health information (HIV, mental health, etc.); and when consent is needed and how it is obtained.

ACTION 6: Determine the HIO Operational and Business Model

One of the most important HIE decisions a state will face is the operational and business model for health information organizations within the state. In effect, the state will need to answer four questions with respect to each HIO that manages the transfer of EHRs among participants:

- What entity runs the day-to-day operation of the HIO?
- How will coordination among HIOs be accomplished?
- What rules govern the day-to-day operations of the HIO and what entity enforces those rules?
- Who is responsible for sustainable operation of HIOs, including allocation of costs and collection of revenue?

States will have to review a number of considerations and decide the type of role they will take in facilitating HIE. After the state determines its role, there are several operational and business models to choose from.

Determine the Overall State Role

The state first needs to decide how strong a role it will exert in two key areas:

- Ensuring the privacy and security of citizens' electronic health information, no matter what entity or entities operate the exchange, and

- Assuring providers, patients, and insurers that health information exchanges will operate in a sustainable, dependable, and efficient manner through fair and equitable charges to participants.

If the state determines that public expectations are high for a strong government presence in both areas, then it will likely choose an exchange model that is relatively easy to supervise, accountable to the state for privacy and security, and financed by fees and charges set through a transparent, government-sanctioned process. This approach would give the state leadership office significant oversight responsibility and would encourage a minimum number of HIOs, to permit easy supervision. Operating HIE as a utility would be one such approach (see Model 2 below).

If a state chooses to be less involved in overseeing HIE and determining the business model, then it can let other actors—such as an independent, nonprofit entity created by stakeholders—operate an HIO (see Model 3 below). The state can still enforce privacy rules and hold HIOs responsible for data stewardship but would rely more on the HIOs themselves and on citizens to monitor operations. In addition, the state would not necessarily care how many exchanges exist or how their fee structures operate, as long as there is functioning coordination among the organizations.

These examples represent points along a spectrum of options that states may choose and tailor to their culture and needs. The initial level of involvement can change over time as HIE is established and stabilized statewide.

Three Different Models

In a study recently completed for the State Alliance, researchers at the University of Massachusetts Medical School Center for Health Policy and Research examined three possible governance models for HIE. The three models were intended to capture the range of likely choices:

- Government-led electronic health information exchange;

- Electronic HIE as a public utility with strong state oversight; and

- Private sector-led electronic HIE with government collaboration.

Details about each model can be found in the report *Public Governance Models for a Sustainable Health Information Exchange Industry*, available at www.nga.org/center/ehealth. Each model is summarized in the pages that follow.

RECORDS STORAGE AND HIE

Policy researchers have debated how to store electronic health records. Some have advocated storing EHR information only on provider systems (e.g., doctors' offices, hospitals, and laboratories), with an HIO serving as a registry that connects provider records with a patient identifier. Such a distributed system would require providers to make data available to the Internet 24/7 and would require each provider to install high levels of security to protect the records from online intruders.

In contrast, some have advocated central storage of EHRs based on updated data from providers. In this approach, providers, laboratories, and other patient record sources would send EHR information to an HIO, which would store and make available to authorized users a complete patient EHR. A full electronic medical record could still reside at each patient's provider office, but they would be offline and not connected to the Internet. Storage, processing, and security would be the responsibility of the HIO(s).

In either approach, the considerations that apply to HIE and HIOs in these sections would still apply for the most part. However, privacy and security protections implemented by the HIO would be more difficult in a distributed EHR environment. (Record storage and security at providers' offices would be similar to current practices under either approach.)

MODEL 1: Government-Led Electronic HIE

In this model, state government essentially decides to put HIE under direct government supervision. This may be an option for small states that may have difficulty attracting private sector investment beyond immediate stakeholders. A government agency or contractor might govern HIE, but day-to-day operations generally would be closely overseen by state personnel. In addition, the state would be responsible for the following tasks:

- **Convene health care stakeholders and reach consensus on architecture, operations, and financing.** With government as convener, the state and other stakeholders would need to reach consensus on the framework for HIE, including the technical architecture and operational model both initially and after startup. The state would need to facilitate alignment of policies and procedures among all stakeholders and to accommodate incorporation of existing systems (which may be deployed in state Medicaid programs). The state would need to work with the stakeholders to agree on any HIE services that go beyond the minimum set by HITECH. Appropriate financing and fee structures would need to be determined.

- **Own and operate HIE.** In this model, the government directly owns and operates HIE, or it directs a subsidiary, such as a state university, to operate an HIO. This model does not preclude the government from having contractors operate HIE under government supervision.

- **Establish and implement privacy and security policies.** As the HIE operator, state government would be responsible for managing privacy and security and data exchange agreements.

- **Establish agreements and contracts for participating in and financing HIE.** Through contracts, the state would establish long-term user agreements with hospitals, labs, providers, and insurers in the state. These contracts also would establish user fees to finance HIE (government would be included as a user).

- **Finance the development of HIE.** The state will need to develop and execute a financing strategy for HIE. This may include a mix of bond financing, federal grants, state funds, and private capital. Once the state has operational HIE, user fees may help to repay some or all of the costs.

- **Review and decide requests for use of HIE data.** The state will be responsible for monitoring and approving various uses of the exchange data, including use for research and other purposes.

The advantage of a government-led HIE is that it might be able to use some of the state's existing IT infrastructure (such as facility space, equipment, and excess computing capacity) in assembling the exchange. In addition, citizens may be more comfortable with a state government entity managing their health records than a private entity. Setting HIE policies, with input from stakeholders, also might be easier if the state takes the lead and assumes the responsibility for policy choices.

Building and financing HIE also might benefit from the state's ability to tap low-cost public financing and state resources. Other nongovernment HIE partners—such as local hospitals or insurance plans—might also contribute to the initial financing. Finally, with the state taking on the initial risk of developing HIE, it may be easier to gain the trust and commitment of stakeholders for long-term user arrangements that would alleviate some of the competitive challenges and help ensure HIE sustainability.

Disadvantages to this approach start with the fact that government is rarely considered a leading-edge user or operator of technology. Government likely could competently manage the HIE process but may not place a priority on upgrades and maintaining state-of-the art capabilities. Government also may be reluctant to ask stakeholders to pay for HIE upgrades. Such shortcomings may limit the potential for using HIE data to analyze the quality of clinical outcomes or conduct public health surveillance activities.

MODEL 2: Electronic HIE as a Public Utility with Strong State Oversight

In this model, the state authorizes a nongovernment entity to design, own, and operate one or more health information organizations. The state still would regulate industry behavior but would grant greater operational flexibility than under Model 1. The independent entity would be responsible for system architecture and would be allowed to earn a reasonable rate of return to attract outside capital and support system improvements. To ensure investors that a certain level of participation was guaranteed, the state could give the HIO an exclusive right to operate within a given market, either through contractual arrangements with stakeholders or by awarding the HIO an exclusive franchise.

Under this approach, the state would fulfill the following functions:

- **Convene health care stakeholders and reach consensus on a governing authority (utility commission) to oversee exchange operations.** With government as convener, the state and other stakeholders would need to reach consensus on the governing authority overseeing HIE. The governing body could resemble a utility commission, consisting of HIE stakeholders appointed by the governor or legislature. The responsibilities of the commission would include choosing an entity to build the exchange, reviewing rates set for the HIO, approving HIE system upgrades, and reviewing operations.

- **Establish and enforce privacy and security policies.** State government would be responsible for setting privacy and security policies and enforcing them. However, the state could make the HIO governing authority (commission) responsible for overseeing compliance with the policies.

Responsibilities of the exchange utility would be as follows:

- **Finance, construct, and operate the exchange.** In this model, the utility would be responsible for building and operating the exchange. It also would be responsible for raising the funds needed for construction and proposing a fee structure for sustaining exchange operations, including depreciation and system upgrades. The policies governing the utility would need to allow for periodic review and adjustment of rates by the commission.

- **Operate the exchange.** The HIE utility would operate the exchange and be responsible for adhering to required privacy and security practices.

Responsibilities of the HIE utility commission (possibly in partnership with the state Office for Health IT) would be as follows:

- **Review rates** to determine reasonableness and ensure that they allow the HIO to provide its defined services and provide a reasonable rate of return;

- **Review and determine requests for use of data within the exchange** for research and other purposes; and

- **Ensure compliance** with privacy and security policies.

Advantages of this approach are several. First, it allows for vendors with expertise to build and operate the exchange. Second, it allows the use of private capital to finance the exchange. Third, the rate-setting process could be used to establish performance rewards and to cover system upgrades. System costs would be reviewed and approved by the commission, which could include appointed stakeholder representatives.

A utility also would be able to focus on system innovation, including uses of the data for authorized health care research. For example, the utility might be allowed to enter into fee-for-service arrangements with participants in the exchange, such as insurance providers, to provide certain types of data analysis. Such arrangements could be factored into the overall costs of running the system, reducing rates. Finally, even though the utility would be given an exclusive franchise, new entrants into the marketplace could be permitted as the utility arrangements expire and are reviewed for performance.

Some potential downsides exist. Private companies may not want to operate under the strictures of a utility arrangement and states thus could face a lack of applications. Requiring the utility to operate as a self-financed entity may result in high initial user fees as HIOs get under way. Finally, the entity chosen to operate HIE could fail, requiring the state to step in.

MODEL 3: Private Sector-Led Electronic HIE with Government Collaboration

In some states, private sector electronic HIE efforts may be relatively mature and organized among stakeholders. Agreements on the technical architectures and services that provide value to stakeholders may already be in place. In cases where private sector organizations and electronic HIE stakeholders have reached this level of consensus and commitment, the state may decide that this approach is sustainable and continue to support it without imposing significant oversight.

In this model, the organizing entity of the exchange—the HIO—would have primary governing responsibility over its operations. State government would support and participate in the HIO and, where appropriate, provide regulation or the threat of regulation to ensure appropriate industry behavior. It also would take action against privacy and security violations and continue to protect consumer interests. In this model, state government behaves more as a collaborative stakeholder than regulator or manager and would do the following:

- Participate in the governing body of the HIO;
- Support and participate in the development and use of appropriate electronic HIE standards that align with intrastate, interstate, and federal standards;
- Support the development of contractual agreements to operate the exchange;
- Ensure that public programs and public health care delivery systems are appropriately represented and included in electronic HIE;
- Monitor the HIO to ensure that consumers are being protected and electronic HIE is developing in a fair and equitable manner; and
- Develop intervention strategies and regulatory options to address market failures should they occur.

In contrast, the HIO that runs the exchange would be responsible for the following actions, subject to a collaborative process and consistent with standards:

- Creating rules of operation for the exchange and the collaborative, including effective surveillance, supervision, and enforcement powers over participants and stakeholders;
- Creating a transparent process for setting fees and charges to sustain the exchange and collaborative; and
- Establishing an oversight process to protect the privacy and security of records in the exchange and a process for approving data requests for research purposes.

In the private sector-led electronic HIE model, state governments can formally oversee the HIE industry in a number of ways. They can formalize their relationship with existing nongovernmental HIOs through legislation or executive order, through sanctioning or “deeming” a particular nonprofit corporate entity as the primary HIO in the state, or by identifying a particular HIO through which it will conduct business. By formalizing their relationships with HIOs, state governments can ensure that all health care interests are being represented and that certain operating rules are established. In addition, enabling legislation may allow the HIO to accept gifts and grants to support start-up.

A State government also may participate on the board of an existing public–private HIO. The multistakeholder HIO would operate as directed by itsboard of directors, which would include the state government but not be controlled by it. (State governments must carefully review the structure of such organizations to ensure and that its participation on the board does not negatively affect its ability to enforce consumer protections related to health information exchange.)

The advantages of such an approach are highly dependent on the maturity of the HIO in the state and whether its performance demonstrates that it can facilitate health information exchange. If it does, then this approach avoids establishing new organizations and governance structures and takes advantages of strong existing relationships among stakeholders.

But the success of this model also depends on the ability of the HIO to police itself. And without a strong state role, the public may question how data are being used in the exchange, as well as the fairness of charges associated with exchange operations. There also exists the question of responsibility should the exchange fail after receiving public investments and how to maintain the public service of HIE in the wake of such a failure. Finally, there is the question of competition. This model would not prevent competing exchanges from entering the market, and that could degrade the financial viability of the original exchange, complicate oversight, and potentially introduce different fee structures in the service area.

Evolution of HIE Models

The three models presented here for state government oversight and regulation of the electronic HIE industry are not the only options available to states, nor are they mutually exclusive. Hybrids also are possible. For example, the state could choose to build and sponsor HIE initially (Model 1) and then transform it into a public utility after it is up and running (Model 2). Likewise, the state could assume a greater managerial role in Model 3 to move that model closer to Model 1 or 2. In any case, the three models illustrate the range of considerations states likely will face.

The appropriate role of state government in overseeing electronic HIE depends greatly on the specific health care, electronic HIE, demographic, and stakeholder environments in each state. In addition, the state government's role will likely change over time as electronic HIE evolves. The oversight structures states create need to be flexible to adjust to industry, policy, and stakeholder changes. Regardless of the structure states choose, they will need to ensure that their systems promote interstate interoperability and are compatible with national networking efforts.

ACTION 7: Create a Communications Strategy

Communication initiatives should be part of states' health IT strategies. Two key constituencies to which the state must reach out are the consumer and provider communities in the state. States should develop mechanisms to keep these groups informed about health IT and electronic HIE to gain their buy-in for state efforts and investments.

Consumers

Because electronic HIE success depends on public trust and buy-in, states should conduct stakeholder outreach and engage consumers early on. In creating a communications strategy for consumers, states could consider the following strategies:

- Host town hall meetings, webcasts, and other forums to educate and seek input from health care consumers and their representative associations on specific topics relating to the adoption and use of health IT.

- Develop culturally and linguistically targeted educational materials, maintain a Web site, and disseminate publications on health information technology and health information exchange issues, including updates on public and private sector activities and privacy protections. Tailor materials for special populations, such as those in foster care, mental health services consumers, and special needs populations.

- Encourage and support the use of technologies—such as e-prescribing and personal health records—that build public experience in using electronic health records.

Through the HISPC Education and Consumer Engagement collaborative, eight states created resources to educate and engage consumers about health IT and electronic health information exchange. The tool kit they created includes an inventory of current educational materials that are available to states, a patient guide for understanding HIE consent, a summary document on the risks and benefits of HIE, and a summary of frequently asked questions concerning privacy and security in electronic HIE. Additional information is available at http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10731_848186_0_0_18/HISPCConsumerEd.pdf.

Health Care Providers

States should work closely with provider groups to introduce them to the benefits of health IT, increase their trust in health IT systems and HIOs, and encourage adoption. Key messages should address privacy and security and the ways in which health IT and HIE will improve their health care practice and otherwise benefit providers.

Provider-oriented communications could include the following:

- Support for peer-to-peer education and outreach, including electronic and face-to-face opportunities;

- Partnering with medical associations to send messages to their membership; and

- Creating educational materials, such as newsletters, presentations, brochures, and journal articles.

In another HISPC initiative, several states developed materials to educate providers about health IT and electronic HIE. The materials include a Web site, videos, and presentations. For more information, visit www.secure4health.org. The training opportunities discussed in the next section also offer a venue for provider communication on state HIE efforts.

ACTION 8: Establish Opportunities for Health IT Training and Education

ARRA calls for the Department of Health and Human Services to set up regional extension centers for training and to support existing professional schools in educating about health IT and electronic HIE. Training and supporting providers in using health IT will be critical to the success of EHR efforts. Providers, both individuals and institutions, that have adopted EHRs clearly express the importance of training, mentoring, and ongoing support. However, the technical issues are only part of the challenge. Physicians, clinics, nurses, hospitals, and office managers must have guidance in reengineering workflow to ease implementation and ensure ongoing use and exchange.

States should encourage their medical schools, nursing schools, and schools of public health to apply for financial support that is available for health IT curriculum development. Further, states should encourage education institutions, particularly their community college system, and nonprofit groups to apply to participate in the regional extension center program. States should work to ensure complete access to these centers, so that both rural and urban providers can benefit from the educational opportunities.

States should also consider other options to encourage providers to receive training—for example, by incorporating education requirements into their licensure process or into requirements for financial incentives to purchase EHR systems. The state's strategic plan should incorporate training opportunities into its HIE adoption strategy.

In the Long Run

The preceding sections and recommendations outline many opportunities and challenges that states should begin to address today. Planning and implementation along these lines will lead to more successful and widespread initiatives and help them meet national goals of health information exchange. But this is just the beginning of the work that must be done to ensure improvements to health and health care.

Implementation of electronic health records and health information exchange will have value, but the majority of benefit will come through improvements in care and better health outcomes. States have been moving to improve delivery systems and quality of care through a variety of mechanisms, but often these have not been linked to the electronic availability of health information. With the HITECH Act, states will have new resources to support health IT and HIE initiatives, and they must make a concerted effort to align those resources with existing efforts around quality improvement, population health, and system reform.

This report addresses the most immediate and necessary state actions. Without a doubt, other challenges and policy needs will emerge. For example, states may find that they need to reorganize their agencies. Oversight mechanisms must be sufficiently flexible to allow for new technology developments and shifts in consumer demand. Interstate harmonization also will become an important theme in nationwide exchange. To overcome new challenges, states will need to evaluate their efforts continually, share lessons learned, and adapt to evolving needs.

Health IT Resources

Organizations and Projects

State Alliance for e-Health, National Governors Association Center for Best Practices. www.nga.org/center/ehealth

State-Level Health Information Exchange (SLHIE) Consensus Project, American Health Information Management Association. www.slhie.org

Health Information Technology Champions Project, National Conference of State Legislatures. www.hitchampions.org

Health Information Security and Privacy Collaboration, RTI International. http://healthit.hhs.gov/portal/server.pt?open=512&objID=1240&parentname=CommunityPage&parentid=8&mode=2&in_hi_userid=10882&cached=true

Office of the National Coordinator for Health Information Technology. Http://healthit.hhs.gov

National Resource Center for Health Information Technology, Agency for Healthcare Research and Quality. http://healthit.ahrq.gov

Nationwide Health Information Network, ONC. http://healthit.hhs.gov/portal/server.pt?open=512&objID=1194&parentname=CommunityPage&parentid=36&mode=2&in_hi_userid=10741&cached=true

Medicaid Information Technology Architecture, Centers for Medicare and Medicaid Services. http://www.cms.hhs.gov/MedicaidInfoTechArch/

Certification Commission for Healthcare Information Technology. www.cchit.org

Healthcare Information Technology Standards Panel. www.hitsp.org

Reports

"Accelerating Progress: Using Health Information Technology and Electronic Health Information Exchange To Improve Care." National Governors Association Center for Best Practices, September 2008. Available at: http://www.nga.org/Files/pdf/0809EHEALTHREPORT.PDF

"Defining Key Health Information Technology Terms." National Alliance for Health Information Technology, April 2008. Available at: http://www.nahit.org/images/pdfs/HITTermsFinalReport_051508.pdf

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"Facilitating Electronic Health Information Exchange in State Publicly Funded Health Programs, University of Massachusetts Medical School Center for Health Policy and Research, National Governors Association Center for Best Practices, February 2008.
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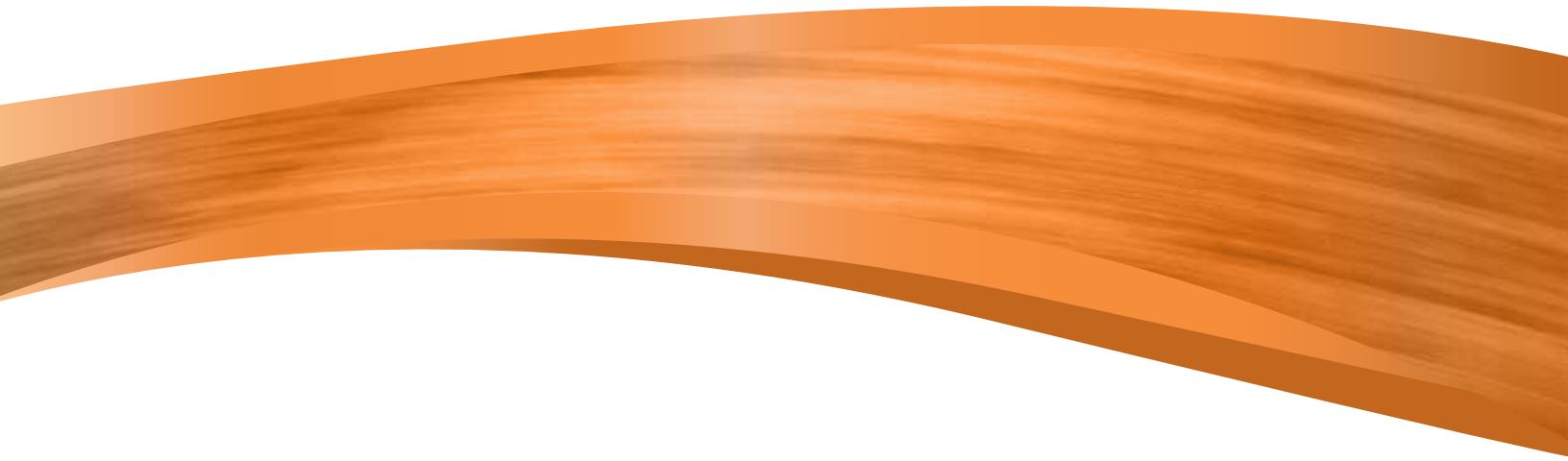

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