

Privacy and Security Solutions for Interoperable Health Information Exchange

North Carolina HISPC Final Implementation Plan



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What is NCHICA, RTI, AHRQ?**About the North Carolina Healthcare Information and Communications Alliance (NCHICA)**

The North Carolina Healthcare Information and Communications Alliance, Inc. (NCHICA) is a nonprofit consortium of about 200 organizations dedicated to improving healthcare by accelerating the adoption of information technology. NCHICA members represent the diverse sectors of the healthcare community, including providers, payers, vendors, professional societies, and law firms. To see a list of members, [click here](#).

NCHICA's role is to act as a neutral forum to bring together the many sectors of the healthcare industry. Together its members can address how best to accelerate the adoption of IT in healthcare by considering clinical needs, policy questions, and technology issues.

About the Agency for Healthcare Research and Quality

The Agency for Healthcare Research and Quality (AHRQ) is the nation's lead Federal agency for research on health care quality, costs, outcomes, and patient safety. AHRQ is the health services research arm of the U.S. Department of Health and Human Services (HHS). Health services research examines how people get access to health care, how much care costs, and what happens to patients as a result of this care. AHRQ supports improvements in health, develops strategies to strengthen quality measurement and improvement, and identifies strategies to improve health care access, foster appropriate use, and reduce unnecessary expenditures. AHRQ gives information and technical assistance to State and local policymakers through user-driven workshops on topics that include improving care delivered to children served by state agencies and developing strategies to reduce health disparities.

About RTI International

RTI International is one of the world's leading research institutes, dedicated to improving the human condition by turning knowledge into practice. RTI offers innovative research and technical solutions to governments and businesses worldwide in the areas of health and pharmaceuticals, education and training, surveys and statistics, advanced technology, democratic governance, economic and social development, energy, and the environment. RTI personnel form a research organization of four major groups -- Social and Statistical Sciences, Science and Engineering, International Development, and [RTI Health Solutions](#) - as well as its administrative organization.

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HISPC Background and Purpose

Historical Background

In April 2004, President George W. Bush articulated his vision for the future of health care in the United States by an Executive Order that authorized the Secretary of the Department of Health and Human Services (HHS) Michael Leavitt to establish the Office of the National Coordinator for Health Information Technology. The Office provides leadership for the development and nationwide implementation of an interoperable health information technology infrastructure to improve the quality and efficiency of health care and the ability of consumers to manage their care and safety. The National Coordinator for Health Information Technology is the chief advisor to the Secretary of HHS on the actions needed to meet the President's call for widespread availability of secure, interoperable health information technology.

In October 2005, Office of the National Coordinator for Health Information Technology and the Agency for Healthcare Research and Quality awarded the Privacy and Security Solutions for Interoperable Health Information Exchange contract to RTI International. RTI, in collaboration with the National Governors Association Center for Best Practices, formed the Health Information Security and Privacy Collaboration (HISPC) project and invited the states and territories to submit proposals to participate in the project. The HISPC project was designed to examine privacy and security laws and business practices that affect the ability of every state and territory to exchange electronic health information within itself and among each other.

NCHICA submitted a proposal and in April 2006 was awarded the contract to represent North Carolina. Since the project's commencement, teams of healthcare stakeholders have worked collaboratively through a process of consensus to identify, assess, and develop plans to address variations in organization-level business policies and state laws that affect privacy and security practices that may pose challenges to health information exchange.

Scope of the Report

This final report contains a summary of the Assessment of Variation and Analysis of Solutions reports previously submitted by North Carolina. The report includes an analysis of policy, technological, and legal barriers to exchanging health information within North Carolina and describes in greater detail the proposed solutions intended to reduce or eliminate those barriers.

Limitations

The NC HISPC overcame several obstacles in order to collect the stakeholders' business practices, analyze the information, and create the deliverables. Some of the obstacles the team overcame included:

- Strict time limitations minimized the ability to perform in-depth research of the legal barriers to information exchange
- Limited financial resources were available to the project contributors
- It was difficult to recruit stakeholders to participate in the project
- Stakeholders were hesitant to share their proprietary organizational practices
- Some of the scenarios did not relate to actual practice

Project Governance

As the contractor to the Agency for Healthcare Research and Quality, RTI International provided oversight by assigning a state liaison from RTI International and the National Governors Association to the NC HISPC. RTI's liaison identified and mitigated project risks, established centralized processes, and guided the NC HISPC toward timely submissions of project deliverables. The National Governors Association liaison provided strategic insight and advice on the intersection between HISPC and related projects currently underway through other state and federal initiatives.

Project Management Office (PMO)

The PMO consisted of Holt Anderson, NCHICA Executive Director, as Project Executive; Angie Santiago, Sr. Systems Consultant for TM Floyd & Company, as the Project Manager; and Diana Gildea as the Project Coordinator. The PMO provided policy standards, templates, training, and project tools designed to establish a collaborative framework and positive work experience for the project's participants.

The NC HISPC PMO provided each co-chair with a NC HISPC Project Workbook that contained:

- Workshop training materials
- Project documents
- Contact information
- Policies and procedures
- Confidentiality agreement
- Time tracking
- Milestone report
- Project plan
- Miscellaneous resources

Project Co-Chairs

The Variations Work Group was co-chaired by Jim Murphy from the NC Department of Health and Human Services Office of Medicaid Management Information Systems (NC DHHS MMIS), Mike Voltero, General Counsel to Blue Cross Blue Shield of North Carolina, and Roy H. Wyman, Jr., a partner at Williams Mullen Maupin Taylor. The Solutions Work Group and Implementation Planning Work Group were chaired by Dave Kirby, President of Kirby Information Management Consulting. The Legal Work Group was chaired by Patricia A. Markus, a partner at Smith Moore LLP.

Workgroup Composition

The Variations, Legal, Solutions, and Implementation Workgroups were comprised of attorneys; practice managers; researchers; clinicians; and professionals in public health policy, health information management, and information security specializing in health information privacy and security. The workgroups' members represent health care stakeholders such as consumers, health plans, professional organizations, health care facilities, laboratories, health care software vendors, and public health agencies.

The Variations Workgroup (VWG) conducted individual and group assessments by presenting the stakeholders with the 18 health care scenarios provided by RTI. Members collected the business practice data and identified potential barriers to exchanging health information. The VWG was co-chaired by Jim Murphy from the NC Department of Health and Human Services Office of Medicaid Management Information Systems (NC DHHS MMIS), Mike Voltero, General Counsel to Blue Cross Blue Shield of North Carolina, and Roy H. Wyman, Jr., a partner at Williams Mullen Maupin Taylor.

The Solutions and Implementation Plan Workgroups (SWG and IPWG) reviewed the data collected from the VWG and developed solutions and implementation plans to reduce or remove the identified barriers. The SWG and IPWG were chaired by Dave Kirby, President of Kirby Information Management Consulting. The SWG and IPWG were comprised of members representing the following health care stakeholders: Blue Cross Blue Shield of North Carolina, Duke University Health System, eHealth Initiative, E-Tech Security Pro, NC DHHS Office of Medicaid Management Information Services, NC Department of Mental Health and Substance Abuse, Novant Health, and Radarfind.

During the Implementation Planning phase, the Legal Workgroup (LWG) submitted high-level steps for the stakeholders to consider when planning changes to NC State law or public policy. They also identified potential legal drivers and barriers of the non-legal solutions and implementation plans proposed by the SWG. The LWG was chaired by Patricia A. Markus, a partner at Smith Moore LLP. The LWG was comprised of members representing the following health care stakeholders: Blue Cross Blue Shield of North Carolina, CareSpark, FirstHealth of the Carolinas, LabCorp, Williams Mullen Maupin Taylor, NC DHHS Department of Medical Assistance, NC Hospital Association, NC Medical Society, Pitt County Memorial Hospital, NC Health Information Management Association, Quintiles Transnational, MISYS, NC Office of Information Technology Services, and UNC Hospitals.

With the exception of the PMO, all project participants voluntarily contributed their time and expertise to this project.

A chart describing [NC Stakeholder Involvement](#) is included in the appendices.

Summary of Assessment of Variation and Final Analysis of Solutions Report

Summary of Assessment of Variation

The objective of the first phase was to assess the variations in organization-level business policies and state laws that impede health information exchange in North Carolina and its bordering states. The NC HISPC Variations Work Group (VWG) developed a simple assessment tool to identify the stakeholders' current practices for sharing patient information, the reason for those practices, whether those practices caused any barriers to the exchange of health information, and whether any identified barriers were appropriate to safeguard the patient's information or were inappropriate. The interviews and surveys from the assessment resulted in a vast collection of policies, procedures, barriers, and relevant state or federal laws which have been analyzed by the Legal and Solutions Work Groups. The barriers have been grouped into three main barrier categories: policy, technological, and legal.

Of the approximately seventy-five (75) business practices submitted, health information exchange barriers (BR) have been identified and categorized as followed:

- BR_1. Range within organizations of misinterpretation and/or misapplication of laws or regulation
- BR_2. Lack of business incentives to exchange information
- BR_3. Lack of policy standardization across entities
- BR_4. Lack of security standardization across entities
- BR_5. Lack of interoperability between processes and technology
- BR_6. Lack of workable technology
- BR_7. Conflicting or outdated federal or state laws or regulations

In addition to the barriers identified by interviewees, the VWG, SWG, and LWG also found that some of the stakeholders' inappropriately withheld health information from the patient. The SWG and LWG discovered that release of information policies currently practiced by various stakeholders were designed to reduce the clinician's or entity's liability risks rather than support the consumer's right to privacy.

In addition to addressing the inappropriate withholding of health information from consumers, members of the NC HISPC workgroups and Steering Committee also wanted to ensure that health information technology solutions supported the right of consumers to control access to their private health information and that consumers are given ample opportunity to understand the

impact of health information technology on their health care decisions, and/or participate in the planning, design, and implementation of health information networks, personal health records, or other health information technology related projects designed to exchange their health information.

Therefore, two additional barriers were added to address the issue of consumer empowerment. The consumer empowerment barriers are:

- BR_8a. Lack of consumer understanding or awareness of the benefits of health information technology which results in lack of consumer input into the underlying policy and technology to support health information exchange
- BR_8b. Lack of definition of consumer empowerment and lack of methodology for including it in policy and systems design

Summary of Proposed Solutions

The VWG, LWG, and SWG analyzed the barriers and proposed solutions to reduce or eliminate barriers that delay or prevent stakeholders from exchanging information with each other. Solutions are organized by a characterization of the scope of the practice of information exchange to which each solution would apply, along with organizations that are involved in electronic health data exchange.

The proposed solutions (SOL) are not ranked in accordance to any particular order of priority:

- SOL_1. Establish a pilot project with adequate funding to explore the concept of the person-oriented health information exchange.
- SOL_2. Implement policy standards, such as model policy and legislation, to address the complexity and ambiguity surrounding the release of information.
- SOL_2a. Implement security standards to address the complexity and ambiguity surrounding the safeguarding of health information.
- SOL_3. Implement sound business models to “incentivize” potential information sharing partners to participate in community-based health information exchange.
- SOL_4. Encourage greater collaboration between policy makers, subject matter and technical experts to adopt health information exchange requirements.
- SOL_5. Explore the dependencies between the business processes and their technical components for the purpose of interoperability.
- SOL_6. Address the misinterpretation of laws or regulations by obtaining clarification and developing public and private awareness programs.
- SOL_7. Amend conflicting federal or state laws.
- SOL_8. Develop programs to raise awareness on the risks, benefits, and impacts of health information technology to a cross-section of consumers.

Review of State Implementation Planning Process

Methodology

Employing their collective experiences in privacy and security policy development and implementation, the IPWG and LWG rated the complexity, feasibility, and level of implementation with a ranking of low, medium, and high. The plans in this report are first organized by state, multi-state, and national- level categories. Within each section of the report, the eighteen (18) proposed solutions and implementation plans are further organized by the three solution types; policy, legal, and technological. Due to the interdependencies of the plans, the solutions are not presented by priority; however, considerations to their complexities are addressed within the individual plans.

We began our process by assigning a unique identifier to each barrier, ensuring each barrier was properly categorized and mapped to its relevant solution. Duplicate or similar solutions were consolidated into one comprehensive solution. All potential solutions and implementation plans that were submitted by members of the SWG, LWG and Steering Committee, were documented in the NC HISPC ISWG Solutions and Implementation Worksheet. The ISWG Worksheet was designed to foster creativity among the submitters and ensure structure for the required documentation and deliverables.

The information contained in the ISWG Worksheet and how it is used in this report is as follows:

NC HISPC Solutions and Implementation Worksheet

Background: This 2-3 paragraph description of the barrier is addressed in the proposed solution acts as the introduction to the proposed implementation plan.

Solution(s): The submitter has written a short paragraph describing each solution.

Rationale for Solution: This section describes the potential benefits offered in the proposed solution(s). Because multiple solutions may address the barrier, a rationale for proposing one particular solution over the alternatives is included in this 2-3 paragraph section.

Phase of development: Our implementation plans include the current stage or phase within the Project Management and Systems Development Life Cycles. When considering which information security implementation standards to consider, we elected to utilize the standards developed for the Federal Information Systems and guidelines from the National Institutes of Standards and Technology. Our rationale for this choice was to begin solving the interoperability issues through the adoption of common criteria and to avail the stakeholders of the public documents and guidance available on the National Institute of Standards and Technology website.

1. Concept / exploration (3 - 12 months)
2. Feasibility / planning (3 - 12 months)
3. Demonstration / validation (6 - 24 months)
4. Implementation (6 - 24 months)
5. Operations / maintenance (ongoing)

Implementation plan: It is our hope that these proposed solutions and implementation plans will generate interest within and around North Carolina to stakeholders who will seek collaborative project opportunities. Due to the agreed statement of work, limited scope of the HISPC project, time constraints, and limited resources, we are presenting recommended high-level steps to consider when planning the implementation of the proposed solutions. Our suggestions within these implementation plans are not intended to constitute an "authoritative statement" under the State of North Carolina's policies, general statutes, and regulations. Nor are the suggestions intended to bind the State of North Carolina, NC HISPC, NCHICA, its members, board of directors, committees, or staff, to implement the proposed solutions and implementation plan.

Implementation support: The "implementation support level" designation was derived in three simple steps. First, we presented the barriers and proposed solutions and implementation plans to the project's workgroups, Steering Committee, and stakeholders. Second, we asked the stakeholders what their level of support was: high, medium, or low. Finally, we asked if the participants' organizations would support a solution by adopting it or by collaborating with colleagues to promote or implement the solution.

Anticipated costs: There are three components of costs to consider when planning collaborative projects such as those we are proposing in our solutions. Determining a project's cost is a

detailed estimate of the resources and tools needed to conduct the activities of the project such as consultants, general counsel, administrative support, and collaborative project management tools. Cost budgeting aggregates the detailed estimates into packages to develop a cost baseline to monitor and control costs and identify funding requirements. The cost control process identifies positive or negative variances in the project's budget that can produce unacceptable levels of risk in the project and would need to be resolved. Once the need for a project is established during the initiation phase, such costs would be estimated and included in a Request for Proposal (RFP).

Funding sources: NC stakeholders will seek private and public funding sources such as state and federal-level appropriations, grants, and neutral corporate funding.

Length of implementation: We based our length of implementation estimates on past project scheduling experiences. Upon the initiation of a formal project, project activities and resources will be identified and sequenced. The planning will result in a project schedule that will prioritize task dependencies and estimate the duration of work.

Implementation complexity: Determining the level of a project's complexity is crucial to identifying tasks and resources, and estimating costs or risks related to the project's activities. With the implementation of collaborative projects such as those that we are proposing, the level of complexity will range from medium to high. Our estimates of the plan's complexity was based on level of executive sponsorship, level of project authority, resources and training requirements, and perceived and actual conflicts of interests.

Health Information Exchange barriers addressed: The health information exchange barriers addressed includes the unique identifier of the barrier type which can be traced to our original Variations Workgroup Assessment Tool Worksheet. We have consolidated our barriers into the following major categories:

BR_1. Range within organizations of misinterpretation and/or application of laws or regulation

BR_2. Lack of business incentives to exchange information

BR_3. Lack of policy standardization across entities

BR_4. Lack of security standardization across entities

BR_5. Lack of interoperability between processes and technology

BR_6. Lack of workable technology

BR_7. Conflicting or outdated federal or state laws or regulations

BR_8a. Lack consumer input into the design of policy and technology

BR_8b. Lack of definition of consumer empowerment and methodology to its inclusion in policy and systems design

Health Information Exchange type (Groups 1 - 4): The health information exchange types were derived by determining how the health information was to be used and the parties involved in sending and receiving the information. We categorized our health information exchange types into four sub-groups: 1. Direct Patient Care; 2. Payer; 3. Secondary Use - Operations, Marketing, Research, Law Enforcement; and, 4. State Government / Public Health.

Health Information Exchange models affected (Entity to Entity, Person-Oriented Health Information Exchange): This section describes how the proposed solution relates to the two health information exchange models we explored. In addition to the traditional model of exchanging health information from entity to entity, the SWG explored how the barriers and solutions would differ if the scenarios provided by RTI included the opportunity for the patient, or the person who was subject of the information, to have an active role in the exchange process. We also considered how a person-oriented health information exchange model, which was recently been demonstrated by the Nationwide Health Information Network forum, may be further explored in North Carolina.

Applicability of solution: The applicability of the solution attempts to identify the entities that would adopt and implement the solution.

Stakeholders affected (1 - 18): Although a solution may only apply to particular entities, the solution may impact various stakeholders. The stakeholders affected section of the implementation plan is based on the 18 stakeholder types provided by RTI. A complete list of the stakeholders may be viewed in the appendices section of this report. See, Stakeholders Table.

Privacy and security domains addressed (1 - 9): The HIPAA Security Rule, 45 CFR §§ 160, 162, and 164 Health Insurance Reform: Security Standards; Final Rule is applicable to the majority of our stakeholders and became effective in April 2005. The rule laid the foundation for the adoption of information security standards. We addressed the information technology security domains in one solution - the adoption of information security standards. A complete description of the domains is found in the appendices section of this report. See, [HISPC Domains of Privacy and Security](#).

Domains	
1. Authentication	X
2. Authorization	X
3. Identity matching	X
4. Transmission	X
5. Integrity	X
6. Event audit	X
7. Safeguards	X
8. Data classification	X
9. Policies	X

Potential barriers / issues: As community-based health information exchanges continue to solidify, the implementation of risk management processes will identify potential barriers or issues to those exchanges and determine whether those barriers or issues are acceptable risks to health information exchange or warrant mitigation strategies. Such barriers or issues which may need to be addressed include competing interests, perception of increased risks to privacy, and the exchange's impact on persons who are incapable of making medical decisions.

States affected: When the project requirements are gathered to address a solution, the RFP or discovery team will need to conduct an assessment to determine the type of information to be exchanged, its mode of dissemination (paper or electronic), and whether the exchange route will be restricted within the state's border or will include interstate exchanges. Upon establishing the states affected by the health information exchange, a strategy for coordinating and overseeing the implementation of solutions will need be developed.

State – level Implementation Plans

North Carolina Framework

North Carolina Initiatives

Several strategic health information technology initiatives have been undertaken or currently exist in North Carolina. A collaborative project with IBM, under a contract with the Office of the National Coordinator for Health Information Technology, developed a Nationwide Health Information Network architecture prototype. At a Nationwide Health Information Network forum in January 2007, communities in the Research Triangle, NC and Rockingham County, NC/Danville, VA areas successfully demonstrated an interoperable Nationwide Health Information Network that seamlessly exchanged health information consisting of patients' demographic information, clinical history, medications, and laboratory results.

The North Carolina Healthcare Quality Initiative is a multiple-stakeholder project designed to automate medication, laboratory, and radiology data. The first phase of the project involves providing a list of patient medications to the patient's health care provider at the point of contact, so that the provider can evaluate possible drug-to-drug interactions and prescribe correct dosages. The second phase of the project contemplates the electronic exchange of laboratory and radiology data to further improve care and save time. Consumers will receive all of the above-noted benefits of the project while simultaneously receiving assurance that the privacy and security of their health information is being maintained. Later phases encourage a broader use of electronic health records and personal health records.

Another ongoing initiative is the Automated Adverse Drug Events Detection and Intervention project at Duke University, which establishes an automated surveillance system for detecting, reporting, intervening in, and measuring the incidence and nature of adverse drug events suffered by patients. The system is designed to alert physicians about critical detected events, and certain triggers will result in automated reports that will be evaluated on a daily basis by pharmacists trained in adverse drug event investigation.

The North Carolina Emergency Department Database (NCEDD) project, begun in 1999, created an emergency department data repository for the North Carolina Division of Public Health. NCEDD collected, standardized, and analyzed timely and secure emergency department data. The NCEDD led to the 2005 launch of the North Carolina Hospital Emergency Surveillance System (NCHESS), a mandated emergency department collection system that is expected to assist the State in early detection of and response to public health emergencies or potential biological or chemical terrorist attacks. A related venture is the North Carolina Disease Event Tracking and Epidemiologic Collection Tool (NC DETECT), an early event detection system allowing authorized users to view data from NCEDD and the Carolinas Poison Center, the NC Wildlife Center, and other data sources for a variety of public health surveillance needs.

The University of North Carolina Hospital System is implementing a Perinatal Electronic Medical Record project, involving an electronic version of prenatal medical records integrated into software that will facilitate the input, storage, retrieval, and modification of prenatal medical records. The software also will allow patient access to medical data through a wireless LAN. The data will be transferred to and from a centralized database and can be shared with others over the Internet for clinical and research purposes. Another initiative focusing on children's health care is the Provider Access to Immunization Registry Securely Project (PAiRS) system. Begun in 1998 by the North Carolina Department of Health and Human Services, PAiRS was an early, critical component in North Carolina's development of a statewide immunization registry, which was implemented in 2005.

In the private sector, various health care stakeholders are discussing and taking action to create and participate in regional health information organizations. The Western North Carolina Health Network, Inc., a consortium of sixteen (16) hospitals in the Blue Ridge Mountains, is one of the first regional health information organizations in North Carolina. All of the hospitals are scheduled to be connected by early 2007. The participants currently can view patient data from each of the other participating hospitals through a virtual electronic medical records system, and each authorized user has a standardized view of the data. The second phase of the project contemplates including clinician offices and clinics within the network for additional efficiencies.

The North Carolina health care community continues to demonstrate that when presented with a suitable opportunity and appropriate incentives, trusting partnerships can design and adopt cutting edge technology to share health information to meet their objectives. As a result of the work conducted in the Privacy and Security Solutions for Interoperable Health Information Exchange project, the North Carolina Health Information Security and Privacy Collaboration (NC HISPC) stakeholders were given the opportunity to focus solely on the business practices, policy, and legal drivers that create barriers to the secure and timely exchange of health information.

Given more time, appropriate funding, and resources, the collection of additional business practices and stakeholder and consumer input may have resulted in a clearer understanding of the policy, legal, and technological barriers that impede the exchange of health information in North Carolina. The North Carolina HISPC team was able to identify important barriers that should be addressed if North Carolina intends to participate in health information exchange opportunities such as regional health information organizations, community-based health information exchanges, the Nationwide Health Information Network, electronic medical records, and personal health records.

Mission

North Carolina healthcare stakeholders support improving the quality of health care for individuals seeking treatment in North Carolina by ensuring that the individuals' relevant health information is exchanged in a routine, timely, and secure manner. North Carolina HISPC healthcare stakeholders recommend the development and implementation of a North Carolina Health Information Exchange Framework.

Goals

1. Build leadership and health information technology champions
2. Seek executive-level private and public sponsorship
3. Reduce legal barriers to timely health information exchange
4. Adopt health information policy, legal, and technology standards
5. Increase rural connectivity and the adoption of health information technology
6. Actively engage consumers on the impacts of health information technology

The North Carolina Health Information Exchange framework would begin with building leadership and health information technology supporters among public policy makers, the health care community, and consumers by implementing statewide health information technology awareness programs.

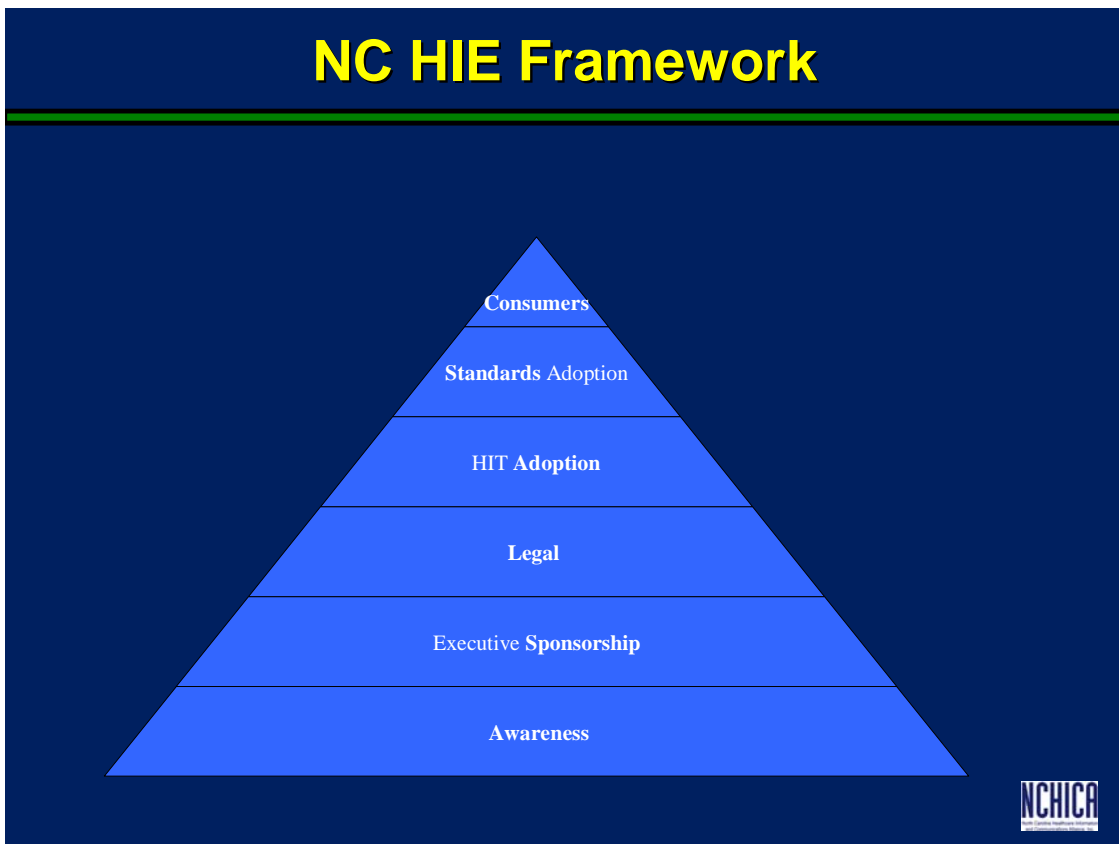
As individuals become aware of the benefits of exchanging health information in an electronic and secure method, North Carolina stakeholders will seek support from their organizations as well as public policy makers at the local and state levels to participate in and fund collaborative demonstration health information technology projects.

The legal community and health stakeholders will seek opportunities to conduct legal analyses of the relevance and effect of current privacy laws as North Carolina moves toward increased use of health information technology.

Participating in any type of regional or nationwide health information exchange is impossible without increasing electronic medical records adoption among North Carolina's provider community. Likewise, health information technology cannot be adopted without increasing rural connectivity. North Carolina stakeholders will seek incentives to invest in rural connectivity and electronic medical records to facilitate local, regional, and nation-wide information sharing opportunities, as permitted by the consumers.

The voluntary adoption of health information technology standards will ensure the interoperability of health information. Awareness campaigns to increase North Carolina's participation in the Health Information Technology Standards Panel may increase voluntary data and security standards adoption. In addition to the adoption of health information technology standards, the North Carolina health care stakeholders will begin exploring opportunities to participate in model policy and legislation research and development.

The final goal of the North Carolina Health Information Exchange Framework is to design and implement an infrastructure for the routine, timely, and secure exchange of health information as authorized by the individual or person responsible for that individual's care.



NC Consumer Empowerment Solutions

The United States health care industry is currently experiencing a technological transformation. Due to recent technological advances, information can be shared among many health care providers, with the goals being to reduce medical errors and to increase quality of care. With U.S. legislative mandates and calls for the adoption of a Nationwide Health Information Network, regional health information organizations, electronic health records, and personal health records, the awareness of patient empowerment is emerging. A survey by the California HealthCare Foundation (Broder, 2006) found that most consumers want to have control over who accesses their medical information and that only three percent used an online medical record service. Janlori Goldman, a privacy advocate and member of the Health Privacy Project (1999), has called for a “reversal of the technological status quo by demanding that technology be designed to empower individuals” that shifts the balance of power between “the individual and those seeking personal information,” for example, through giving control of medical information to the patients. “Since this [PHR] approach empowers individuals to control all access to their own health information, it gives each consumer the freedom to establish their [sic] own personalized privacy policy” (Enrado, 2006) and decide how the information will be shared across organizations such as regional health information organizations and the Nationwide Health Information Network, both of which enable the infrastructure for sharing patient information across organizations such as hospitals and provider offices.

The sharing of medical information extends to external entities who utilize medical information for patient care purposes. Secondary users of health care data include researchers, marketing departments and businesses, public health organizations, insurance payers, and accreditation companies. There are also health record banks which allow patients to decide who has access to their medical records which are stored in a secure repository, similar to a financial bank (Enrado, 2006). These banks, however, are interested in the ability to collect and sell patient information to external parties for research or marketing purposes (AMIA, 2006; Anonymous, June 28, 2006) “The lack of coherent policies and practices for the secondary use of health data presents a significant impediment to the goal of strengthening the US healthcare system” (AMIA, 2006). Ultimately, patients’ trust in the security and privacy of their medical data will affect how they share their information. At present, what is not clear is patients’ awareness of the “trade-offs between legitimate concerns about their privacy and the benefits of making more complete information available to the providers” so that providers can provide optimal care based on more comprehensive information (Tang and Lansky, 2005). The patient is the person with the most at stake and is in the best position to provide information to providers (Markle, 2006). Empowering a patient with the knowledge and ability to determine how his or her medical information is shared will be critical in the emerging technological environment.

Traditionally, records in the health care industry have been paper-based, enabling strict accessibility to records. Due to advances in technology, managing the large amount of information involved in patient care has become much more important. Therefore, information has become the “key organizational currency,” which companies need to manage and control to “harness the power of the politic,” which comes from such control (Davenport, et al, 1992). No federal law states who actually owns the patient’s medical record. Because the control of either the paper-based medical record or electronic medical record is in the provider’s hands, the question has been that of patient access to the record rather than ownership. There are concerns which have risen to question how access to protected health information will be granted. Currently, the patient gives a “blanket statement” for a single entity, but patients may not understand these statements or want to give such generic access across health care entities. Technology must be in place so that protected health information is not shared electronically when the patient opts out of sharing information with specific entities. Technology such as the personal health record gives a feeling of empowerment to the patient for control of his or her information as well as increased participation in the health care process. Literature supports the definition of empowerment as self-determination over one’s own life (Geller et al, 1998) as a

result of having access to information and resources to enable an informed choice (Wowra et al, 1999). Empowerment holds multiple interpretations for the marketplace and business, the community, the public sector, and the political system (Osborne, 1994), and over time, these interpretations have changed (Wilkinson, 1997). For e-healthcare, empowerment involves analyzing patient access and control of medical information for self-determination of who the information will be shared with and for what purpose. Empowerment also inherently entails education of stakeholders as to the responsibilities involved with such empowerment and the impact of technology on patients.

Develop Consumer Programs

NCHICA has formed a new council to engage patients (health care consumers) in providing input and feedback on topics related to health information. The North Carolina Consumer Advisory Council on Health Information is a unique health care consumer group formed for grassroots input to explore ideas and issues surrounding health information. The Council will provide consumers an opportunity to influence both state and national policy with regard to concerns about health information and technology.

In order to achieve a diverse representation of North Carolina health care consumers, the individuals chosen to be members of the North Carolina Consumer Advisory Council on Health Information will have varied backgrounds including gender, age, race, education, geography, health status, recent experience with the health care system, etc. They will serve rotating limited terms, attend monthly meetings, and participate in activities that raise awareness of the effects of health information technology on the consumer. As part of the North Carolina Consumer Advisory Council on Health Information and NCHICA initiatives to gain consumer input, providers will also be interviewed during roundtable sessions to gain insight as to gaps and overlaps in the provider and consumer perspectives of health care information issues. Activities for council members include participation in consumer focus groups and research studies to find ways to educate and empower North Carolina health care consumers. The North Carolina Consumer Advisory Council on Health Information will be assisted by a group of experts who will serve on a resource panel.

Initial calls for nominations of members were sent to organizations on the NCHICA membership roster. Currently there are seven council members, with interests represented in populations such as HIV/AIDS, the aging and elderly, and caregivers. There are six resource panel members who provide support in special topics such as personal health records, privacy, and security. The co-chairs of the council are responsible for administrative processes so that council members are able to focus on discussions of their concerns. The North Carolina Consumer Advisory Council on Health Information meetings have been held monthly since July, 2006. One initiative which is being developed by the council is to investigate the generation of personal health records for seniors, especially for use in crisis situations. Because of its initiatives, the Council can serve as a role model for other states who want to create similar consumer advisory councils.

Rationale for Solution:

Consumers – as the subject of the information to be exchanged and the intended users of personal health records - generally do not have sufficient information to weigh the risks and benefits of health information technology and do not play an active role in technology's design and use. Current health information software design methodology includes processes to identify the business problem automation will solve, plan the project, gather requirements, conduct security analyses, test the application, and implement software. Software developers include clinical experts on their design teams to ensure usability and features to reflect standard clinical processes.

Effective in April of 2003, HIPAA required health care providers and health plans to develop policies and procedures that established the rights of individuals to access, copy, and amend their health information, request restrictions upon its use and disclosure, and file privacy complaints.

In August 2005 an Executive Order established the Office of the National Coordinator for Health Information Technology, whose mission is to provide leadership for the development and nationwide implementation of an interoperable health information technology infrastructure to improve the quality and efficiency of health care and the ability of consumers to manage their care and safety. The same Executive Order established the American Health Information Community, whose activities include coordination of the development of strategies and guidance to create electronic personal health management tools and to enhance informed consumer choice for health care.

As health information begins its transformation towards a consumer-controlled model, presumptions on the needs of the consumers without direct consumer participation could cause design errors that result in distrust and lack of adoption. Developing a program that seeks to define consumer empowerment, researches consumers' use of health information technology, raises awareness on the impacts of health information technology, and provides input on the usability of personal health records can engage consumers in the design and implementation of health care policies and technology.

Upon further study of the numerous American Health Information Community documents regarding consumer empowerment, the members of the council are unsure how American Health Information Community intends to include consumers in the design of the Nationwide Health Information Network or other health information technology initiatives. In North Carolina, medical professionals join associations such as the North Carolina Medical Society or the North Carolina Hospital Association to exchange ideas and participate in collaborative initiatives to improve their profession and the quality of health care. The legal and information security professionals also benefit from awareness and training programs within their associations. The NC Consumer Advisory Council on Health Information will seek to establish itself as an independent body committed to representing the consumer's perspective on the changing landscape of health information technology.

Implementation plan:

The NC Consumer Advisory Council on Health Information desires to move from its current infancy stage to become a consumer resource center on issues pertaining to the adoption and impact of health information technology on North Carolinians. The Council is currently developing a strategy to sustain its membership and fund consumer-related activities. It is currently committed to:

1. Continued involvement of the core resource group assisting the Council in further development of its charter, objectives, mission, and membership.
2. Establish an initial budget. Expand budget over the course of three years. A sample budget is included in the appendices.
3. Seek funding opportunities.
4. Develop and implement a membership program.
5. Develop outreach programs to raise consumer and provider awareness on issues surrounding health information privacy and the risks and benefits of health information technology.
6. Develop a health information consumer toolkit to share with other states interested in starting similar organizations.

7. Seek activities and demonstration projects that support the Council's mission.

Phase of development:

1. Concept / exploration (3 - 12 months) In progress
2. Feasibility / planning (3 - 12 months) In progress

Key Opportunity / Resources:

The Council's membership model will be primarily individuals who are interested in subjects regarding health care related issues. They will also seek opportunities to collaborate with the consumer protection associations and privacy groups where it is appropriate. It will also consider the feasibility of volunteers, paid resources, or a combination to carry on the work of the Council.

Implementation support: high

Anticipated costs: Up to \$182k. Please see a sample of the North Carolina Consumer Advisory Council on Health Information [Draft Budget](#) under consideration by the Council.

Funding sources: Private / Public sources

Length of implementation: 2 years

Implementation complexity: medium

Health Information Exchange barriers addressed:

- BR_1. Range within organizations of misinterpretation and/or application of laws or regulation
- BR_2. Lack of business incentives to exchange information
- BR_3. Lack of policy standardization across entities
- BR_4. Lack of security standardization across entities
- BR_5. Lack of interoperability between processes and technology
- BR_6. Lack of workable technology
- BR_7. Conflicting or outdated federal or state laws or regulations
- BR_8a. Lack consumer input into the design of policy and technology
- BR_8b. Lack of definition of consumer empowerment and its applicability in systems methodology

Health Information Exchange type (Groups 1 - 4): ALL

Health Information Exchange models affected: 1. Entity to Entity, 2. Person-Oriented Health Information Exchange

Applicability of solution: All health care stakeholders, especially consumers and providers

Stakeholders affected (1 - 18): ALL

Privacy and security domains addressed (1 - 9):

Domains	
1. Authentication	X
2. Authorization	X
3. Identity matching	X
4. Transmission	X
5. Integrity	X
6. Event audit	X

7. Safeguards	X
8. Data classification	X
9. Policies	X

Potential barriers / issues:

Current laws regarding privacy and the “no call” registry may prohibit the Council from direct recruiting. To address the “big brother” perception that government is developing a Nationwide Health Information Network “for” them, the Council will develop strategies to overcome the distrust of technology among consumers. Individual consumers are difficult to engage.

States affected: North Carolina

Explore Person-Oriented Health Information Exchanges

Because consumer empowerment is among the top priorities for the development of an interoperable health information network, the Office of the National Coordinator for Health Information Technology established the Consumer Empowerment Workgroup within American Health Information Community. The workgroup will coordinate the development of strategies to create personal health management tools to enhance informed consumer choice for health care.

In an effort to support the Office of the National Coordinator for Health Information Technology’s charge, the SWG and LWG evaluated how the scenarios and identified barriers would have been affected if flow of the health information exchange originated from the person who was the subject of the information to the requesting entities rather than the traditional model of entity-to-entity exchange. As it researched background information on health care consumer empowerment, the SWG considered the consumer-oriented projects such as personal health records as described by the Markle Foundation’s Connecting for Health, and person-centered regional health information organizations such as the Louisville Health Information Exchange.

This important exercise taught the SWG that current policy and information systems are designed to facilitate health information exchange between entities. HIPAA requires the individual’s right to access, copy, amend, and restrict his or her health information. North Carolina general statutes require an individual’s authorization to release health information. NC HISPC theorizes that a person-oriented health information exchange has the potential for assuring high flow in a health information exchange while preserving privacy.

There is uncertainty among the LWG as to how the person-oriented health information exchange fits within current laws and regulations. The North Carolina Consumer Advisory Council on Health Information is cautiously optimistic but has concerns about lack of consumer input into planning, design, and implementation of “consumer-driven” health information systems. The person-oriented health information exchange has intrigued the SWG, and the workgroup anticipates further study of this model. The Steering Committee has recommended further exploration for North Carolina’s health care policy makers, subject matter and technical experts.

Proposed solution: Establish a pilot project with adequate funding to explore the concept of the person-oriented health information exchange

Rationale for Solution

In the last couple of years, considerations of the value of a health data exchange that puts the consumer/patient at the center of the exchange process have emerged in the form of private and public activities (e.g. products, conferences, whitepapers, and projects). The key idea in a person-oriented health information exchange is that the provider of the data sends the data (along with a request to transmit the data) to a

person-controlled software agent. The agent, as configured by the person who is the subject of the data, permits and completes appropriate exchanges and rejects others. This approach draws the patient into the health care process, eases the creation of personal health records and their associated applications, permits individual flexibility related to privacy, and returns the issue of who is included in the information flow related to a patient's care back to a dialogue between the patient and his/her health care providers.

Because it would reduce an entity's responsibility for controlling the elements of an exchange of health information, the person-oriented health information exchange may provide a solution to some of the disparities among state and federal regulations. If the health care consumer, or her/his authorized delegate, is the gatekeeper to personal information, then each instance of exchange would be pre-authorized or made in a pre-defined manner. Potentially this may reduce the need for some regulatory changes. The processes for defining access authentication and delegation of authorization would need to be strict, as would be the overall audit function. The person-oriented health information exchange could also work well with the "original" and "copy" concepts.

The pilot would have to address all data protection issues, contingencies for emergent circumstances whereby the health care consumer is unable to grant access to health care information, the possibility of access barriers for indirect providers such as laboratories, and the impact upon legitimate secondary uses and disclosures that are permissible under existing law.

Many health care consumers are unaware of the implications of access to personal health information and the consequences of unauthorized access and misuse of that information. Initiating a process that places the individual or delegate as the primary agent responsible for granting access would increase a sense of ownership and control to the consumers, and could provide an opportunity to educate individuals about privacy and security issues and responsibilities. The person-oriented health information exchange concept could be the centerpiece in a comprehensive and consistent awareness strategy. Organizational and entity level awareness programs would serve to reinforce the information.

The person-oriented health information exchange concept is one model that would address and may resolve a number of barriers identified in the Variations Report. Individual consumer involvement may also result in an enhanced awareness of privacy and security issues across the general population. The model would need to be supported by carefully defined policies for authentication, authorization, protecting data in transit and at rest, and responsibilities of the individual for the care of his or her records.

In a person-oriented health information exchange, an intermediary agent/agency would make connections with health care providers. As such, a person-oriented health information exchange could help to relieve concerns about direct access to provider networks by other providers. Each endpoint entity would have to be confident of the agent/agency connection. Technical solutions and policy definitions will be necessary to ensure limited access to authorized information.

Phase of development: 1. Concept / exploration (3 - 12 months)

Implementation plan:

1. Develop a program designed to raise awareness among consumers and providers on current initiatives in personal and electronic health records. Include empowerment projects such as the Nationwide Health Information Network, Louisville Health Information Exchange, and American Health Information Community.

2. Design a pilot project so that providers and consumers are active participants in its design and outcomes.
3. Design three business models to test in pilot project.
4. Include legal analysis of current state and federal privacy laws with regard to person oriented health information exchange.
5. Assemble an RFP team to identify project and funding opportunities.
6. Identify project sponsor(s), resources, and consumers.
7. Attain funding from personal health record vendors as well as other public and private sources.
8. Plan and implement a small pilot project.
9. Publish a case study on the results of the Person-Oriented Health Information Exchange demonstration project.
10. Seek additional funding for larger demonstration projects.

Key Opportunity / Resources:

A collaborative project among North Carolina stakeholders could include Personal Health Record vendors and consultants. Individual organizations such as the NC Consumer Advisory Council on Health Information, NCHICA, and the e-Health Initiative have expressed interest in this pilot project.

Implementation support: medium

Anticipated costs: Under consideration by the NC HISPC project team

Funding sources: Private / Public sources

Length of implementation: 18 months following award

Implementation complexity: high

HEALTH INFORMATION EXCHANGE barriers addressed:

- BR_2. Lack of business incentives to exchange information
- BR_3. Lack of policy standardization across entities
- BR_4. Lack of security standardization across entities
- BR_5. Lack of interoperability between processes and technology
- BR_7. Conflicting or outdated federal or state laws or regulations
- BR_8a. Lack consumer input into the design of policy and technology
- BR_8b. Lack of definition of consumer empowerment and its applicability in systems methodology

HEALTH INFORMATION EXCHANGE type: 1. Direct Patient Care, 2. Payer, 3. Secondary Use: Operations, Marketing, Research, Law Enforcement, 4. State Government / Public Health

Health Information Exchange models affected: 1. Entity to Entity, 2. Patient Centered Health Information Exchange

Applicability of solution: Persons who are subject of the health information exchange, entities

Stakeholders affected (1 - 18): All

Privacy and security domains addressed (1 - 9):

Domains	
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1. Authentication	X
2. Authorization	X
3. Identity matching	X
4. Transmission	X
5. Integrity	X
6. Event audit	X
7. Safeguards	X
8. Data classification	X
9. Policies	X

Potential barriers / issues:

One perception is that the person-oriented health information exchange is a new concept. The person-oriented health information exchange approach, however, has been adopted in the form of a personal health record for the employees of Dell, Walmart, and IBM. Kentucky has also done significant work in this area. Consumer participation is vital to the success of this concept. Therefore, awareness programs should be considered in the planning, design, and implementation of this concept.

The LWG has concerns that there could be a perception to policy makers that a person-oriented health information exchange approach could be misconstrued as regulatory avoidance, therefore, legal analysis of affected North Carolina laws and regulations will be included in the pilot project.

States affected: North Carolina

Proposed NC Policy Solutions

Health Information Technology Adoption Incentives

As the age of health information exchange takes on new form throughout the United States, North Carolina's health care stakeholders should consider the advantages of adopting health information technology and participating in local, regional, and nationwide health information exchanges. In order to realize the objectives of the President's vision for the development and implementation of a nationwide interoperable health information technology infrastructure designed to improve the quality, safety, and efficiency of health care and the ability of most consumers to have electronic health records by 2014, the adoption of electronic health records must increase substantially from the 23% implementation rate that was announced during the 2007 Healthcare Information and Management Systems Society National Conference.

In follow-up discussions with the Variations Work Group, government agencies, facilities, and providers in North Carolina indicated that the most significant barriers to sharing health information electronically with another entity were their fear of non-compliance with HIPAA and their lack of electronic technology. Less than 25% of health care facilities and providers in North Carolina have adopted electronic health records, making participation in local, regional, or nationwide health information exchanges less of a priority. Some reasons for not investing in electronic health records are a mistrust of software vendors, confusion over which technologies to adopt, lack of information technology staff to support a system, integration of electronic health records into other systems and handheld devices, and concerns about usability of the electronic health records for staff. Two additional reported reasons that were frequently cited are the high costs of the new technology and the lack of convincing evidence on the benefits of electronic health records. North Carolina HISPC recommends numerous strategies to encourage the adoption of health information technology and participation in health information exchanges.

Proposed Solution(s)

US Senate Bill 628, "Critical Access to Health Information Technology Act of 2007," if approved, would authorize the appropriation of ten million dollars to improve access to health care in rural areas by improving technology. Under this program, North Carolina could be eligible for up to \$250,000 to be distributed among the State's twenty-four (24) critical access hospitals.

NC HISPC recommends that the NC Hospital Association and the NC Department of Health and Human Services apply for this grant and seek additional sources of funding, such as matching awards, to offset the often underestimated costs of the business process changes required by new technology. The additional funding could be utilized to conduct privacy and security gap analyses, provide HIPAA awareness training for health industry stakeholders and the general public, map business processes and patient flow to technological components, and implement training for IT staff in the areas of privacy, security, and technical support.

In addition to providing health care information technology funding for North Carolina's critical access hospitals, the NC HISPC team also recommends similar programs for individual and group health care practices and facilities.

Finally, the team recommends a mechanism such as an annual study, perhaps sponsored by the NC Attorney General's Consumer Protection Division, to analyze features, costs, benefits, customer satisfaction, current implementations, Certification Commission for Health Information Technology status, and other similar criteria for electronic health records that would equip the potential electronic health record adopters and funders with the knowledge necessary to make informed decisions on health information technology purchases.

Rationale: Supplementing the health care providers' and facilities' investments in health information technology will reduce the cost barriers to adoption.

Currently there is mistrust between providers and vendors of health information technology products. This mistrust is rooted in the mergers and acquisitions of healthcare's leading information systems vendors during the mid-1990s, which resulted in the "sunsetting" of many hospital information systems, as well as in the perceived urgent need to resolve the systems date change for the year 2000. As consumers of health information technology, stakeholders in the health care community began experiencing a shift in which they perceived the vendor and its technology as controlling the direction of their health care practice. This sense of loss of control became especially prominent when providers were required to comply with HIPAA and its implied application security. The HIPAA solutions - as in the case of Y2K - were controlled by application software vendors, who in many cases over stated the effectiveness of the technology. Systems users groups and other organizations grew, allowing stakeholders to convene and learn about new trends in health information technology, participate in studies of their electronic health record implementations, and advocate for application systems standards.

The above proposed solutions of supplemental information technology adoption and annual studies of health information technology benefits are designed to empower health care providers and facilities with sufficient knowledge to make informed decisions about the features and benefits of health information technology applications and to build strategies for implementing those applications.

Implementation plan: 12 - 24 months

Critical Access to Health Information Technology Act of 2007

Pending approval of the bill, NC HISPC recommends that the NC Hospital Association and the NC Department of Health and Human Services assemble a grant committee and project team to apply for the funds, plan, and execute the project should the funds be awarded to North Carolina.

The grant committee would conduct a needs assessment to determine the current health information technology status, including available connectivity, of North Carolina's twenty-four (24) critical access hospitals. The committee would develop eligibility criteria for those hospitals that would seek the technology improvements mentioned in US Senate Bill 628. The committee would also identify the scope of the grant which will allow members to determine if additional funds would be needed to non-technological activities such as process flow mapping, training, and project management. Members would also seek sponsorship from the North Carolina General Assembly to cover additional costs including the continued maintenance of the systems.

Finally, the project's executive committee would ensure that project activities and resources are identified and that a project budget and plan is followed. The executive committee would oversee the planning and execution of the project. The NC HISPC recommends that the executive committee employ the five processes of general project management by the Project Management Institute that include project initiation, planning, executing, controlling, and closing.

Provider Electronic Medical Record Adoption

- 1) Promote awareness to North Carolina's health care community of the existence of the Medical Record Institute's Towards Electronic Patient Records database.
- 2) Commission an annual study on the current status of electronic medical record adoption among North Carolina's provider community.
 - (a) Seek a study sponsor or sponsors for funding. Develop the preliminary purpose of the study, its objectives, the statement of work, and scope of the North Carolina electronic medical record study. Develop a draft budget and project plan. Identify potential project resources. Determine deliverables.
 - (b) Define final scope. Identify tasks, activities, and milestones. Develop work breakdown structure. Estimate project cost and duration. Develop risk management plan. Develop quality control measures. Develop communication plan. Assemble a project team. Develop project charter. Develop a final budget, deliverables and milestone schedule, and project plan.
 - (c) The study sponsors will develop a formal proposal and initiate a Request for Proposals. They will select the organizations to design and conduct the study, award the contract, and authorize the execution of the study. A project manager will manage tasks, resources, risks, and work quality and ensure that deliverables are created and submitted as contracted.
 - (d) The study sponsors will monitor activities and the impact of those activities to the study's project plan. Sponsors also will manage the scope of work, research team, schedule, and costs. They will identify factors that may require adjustments to the study's budget, plan, or outcomes. The study sponsors will require that the study team submit scheduled status reports and provide a project manager to manage the contract.

- (e) Upon the conclusion of the study, the study sponsors will analyze the data and identify trends, issues, improvements, related to the current state of electronic medical record adoption in North Carolina and publish the findings.
- 3) Develop financial incentive programs to increase the adoption of electronic medical records in North Carolina.
- (a) Assemble a discovery team to develop a proposal and strategy to approach the North Carolina' General Assembly with an NC Electronic Medical Record Adoption Appropriations Bill.
 - (b) Seek sponsors to introduce an NC Electronic Medical Record Adoption Appropriations Bill to subsidize electronic medical records adoption among North Carolina's health care community.

Phase of development: 1. Concept / exploration (3 - 12 months)

Key Opportunity / Resources:

Critical Access Hospitals: US Senate Bill 628 specifies that only the state's hospital association and Department of Health and Human Services may apply for this grant. Project sponsors would be the NC Hospital Association and the North Carolina Department of Health and Human Services. The project team(s) could include an executive committee, project manager(s), hospital information systems vendors, implementation specialists, clinical, business, technical analysts, and others. As currently drafted, only critical access hospitals are eligible for funds.

Providers: We are not aware of any federal or state – level sponsorships that could subsidize electronic medical record adoption among the health care provider community.

Implementation support: high

Anticipated costs:

Critical Access Hospitals: \$250,000 - \$1,000,000

Provider Electronic Medical Record Adoption Study and Subsidy: To be determined by the discovery team

Potential funding sources: Public sources, such as the anticipated US Senate Bill 628, allows for a maximum of \$250,000. Other sources may also be obtained. The budget for operating the State of North Carolina government in the 2007 - 2009 fiscal years has already been approved. If additional funds are required, the grant committee would need to identify additional funding resources. In addition to public funding sources, supplemental funding from non-profit or corporate grants or participating hospitals should also be considered.

Length of implementation: 12 - 36 months

Implementation complexity: medium

Health Information Exchange barriers addressed:

BR_2. Lack of business incentives to exchange information

BR_5. Lack of interoperability between processes and technology

BR_6. Lack of workable technology

Health Information Exchange type: 1. Direct Patient Care; 2. Payer; 3. Secondary Use: Operations, Marketing, Research, Law Enforcement; 4. State Government / Public Health

Health Information Exchange models affected: 1. Entity to Entity; 2. Person-Oriented Health Information Exchange

Applicability of solution: Consumers, providers, and potential funders

Stakeholders affected (1 - 18):

1. Clinicians
2. Physician groups
3. Federal health facilities
4. Hospitals
5. Payers
6. Public health agencies
7. Community clinics and health centers
8. Laboratories
9. Pharmacies
10. Long term care facilities and nursing homes
11. Homecare and hospice
14. Medical and public health schools; research institutions
15. Quality improvement organizations
16. Consumers and consumer organizations
17. State government

Privacy and security domains addressed (1 - 9):

Domains	
1. Authentication	X
2. Authorization	X
3. Identity matching	X
4. Transmission	X
5. Integrity	X
6. Event audit	X
7. Safeguards	X
8. Data classification	X
9. Policies	X

Potential barriers / issues:

Worker anxiety and interruption of business flow are common outcomes during implementation of new technologies. Programs to address the organization's training needs and cultural changes should be included in the implementation.

North Carolina's biennial budget for fiscal years 2007 – 2009 has been approved. Funding for new projects that cannot be integrated into existing appropriations may be our biggest obstacle to planning, executing and implementing this particular solution in the near future.

States affected: North Carolina

Health Information Exchange Participation Incentives

One of the key findings in the *Analysis of Solutions Report* is that there often is a lack of business motivation or incentive to carry out appropriate routine electronic health information flow. Business incentives to carry out many exchanges are low enough that almost any barrier (de

minimus liability, minor labor costs, small transaction friction) will nonetheless be high enough to deter appropriate and routine health data exchange. Although addressing business barriers that are largely unrelated to privacy and security concerns is beyond the direct scope of this project, for privacy/security solutions to be useful they must at least not increase these business barriers and should ideally lower them and offer support to other broad health-related goals.

Although funding the adoption of health information technology will partially address the cost of implementation barriers cited by the stakeholders, there remains a lack of incentive to share information with other entities. The stakeholders admitted to guarding health care information even "from" the person who is the subject of the information. They did so out of concern that the information could be used against the stakeholder or that the health information is incomplete or disparately maintained. The stakeholders' biggest concern about sharing health information was that they might lose patients to another provider, facility, or health plan.

Consumers, on the other hand, reported that they thought their health care information already was being exchanged among their different health care providers. Consumers were confused about why they had to sign so many forms to release their health information or obtain copies of that information for themselves. They often experienced delays in obtaining referral or diagnostic appointments because they were missing an order or a report. The consumers also noted that even though their health information didn't always make it to the appropriate place in a timely manner, they received invoices and statements from the health plan, facilities, and providers without delays.

The VWG and LWG concurred that the liability and competitive reasons for not sharing health information are stronger than incentives to share. The LWG and SWG found that given all of the complexities of our fragmented health care system (lack of workable technology, conflicting state and federal laws), proposing incentives for information sharing was an abstract exercise. Although the VWG, LWG, and SWG were able to identify a direct barrier to exchanging health information (lack of incentive to share), they do not believe that a policy, legal, or regulatory solution would eliminate or reduce the barrier. The stakeholders' lack of incentive to participate in health information exchanges is a systemic health care design issue that must be studied further.

Although addressing business models is beyond the scope of the HISPC project, at the same time, developing a valid business model for information sharing is vital to ensuring that our country maintains a sustainable system of quality health care delivery. As such, the NC HISPC team proposes further exploration of health care delivery models.

Proposed solution(s): Explore sound business models to encourage potential information-sharing partners to participate in community-based health information exchange.

Rationale for Solution:

Through the application of data standardization, security practices, and transmission protocols, a successful demonstration of interoperable electronic health information exchanges was exhibited at a recent Nationwide Health Information Network forum in January 2007. The NC HISPC project has successfully identified many of the policy and legal barriers to exchanging health information in North Carolina, and it has proposed solutions to reduce or eliminate these barriers. The NC HISPC team, however, is concerned that building an expensive technologically-based health care system, without first evaluating the underlying financial models available to sustain such a system, could result in a failed system, such as the recent experience of the Santa Barbara County Health Data Exchange in California.

Before North Carolina begins to build community-based health information exchanges, it should first consider identifying and studying viable financial models in order to ensure that the information exchanges are sustainable. A comparative study of the current reimbursement model of health care delivery and several value-driven outcomes-based models would provide policy makers from government-sponsored health care programs, health plans, and the medical community more of the information they need either to develop new models or expand upon current models.

In their March 14, 2007 article in the *Journal of the American Medical Association*, Drs. Porter and Teisberg emphasized that the “purpose of the health care system is not to minimize costs, but to deliver value to patients, better health per dollar spent.” They noted that in a quality-centered health care system, providers are rewarded for improved outcomes, health plans (public and private) contain costs, and patients receive better care. Their model focuses on the interrelated medical needs of the person. They attempt to address the reduction of the practitioner’s “dysfunctional competition” through interdependent treatment practices for certain medical conditions.

The Porter-Teisburg quality-driven model is just one example that North Carolina leaders might explore. North Carolina has resources in its large rural health communities, public and private health plans, malpractice professionals, research and economics experts, and public policy makers. Leveraging all these resources to compare existing and new health care delivery models would align all these stakeholders and focus them on achieving the same, mutually-desirable goal — that of better quality, more cost-effective care.

Implementation plan:

Explore sound business models to encourage potential information-sharing partners to participate in community-based health information exchange. Initiate a project that could develop an NC e-health business strategy that could be adopted by health care stakeholders. The objectives of the e-health business strategy commission would be to:

- Identify and assess business models currently employed by stakeholders engaged in regional electronic health information exchanges.
- Compare and contrast e-commerce models currently employed by other industries.
- Develop and test three business models that could be adopted by stakeholders engaging in electronic health information exchanges.
- Determine the feasibility of adopting model consents and business or data sharing agreements that would comply with HIPAA and North Carolina privacy laws.

Assemble a study commission to:

1. Study and publish the results of the business and legal causes of Santa Barbara County Health Data Exchange’s demise. Identify the data sharing agreements employed by the Santa Barbara County Health Data Exchange.
2. Assess the various business models employed by CareSpark, Western North Carolina Health Network, Louisville Health Information Exchange, alternate regional health information organizations, or other community based regional health information exchanges. Include the review of business and data sharing agreements for consideration as a model agreement to be adopted by community-based health information exchanges.
3. Conduct a comparative study of the current reimbursement model of health care delivery and several value-driven outcomes-based models would provide policy

makers from government-sponsored health care programs, health plans, and the medical community more of the information they need either to develop new models or expand upon current models.

4. Compare and contrast e-commerce models such as retail, service provider, subscription-based and pre-paid access, broker, advertising, portal sites, free access, the virtual mall or community, and the infomediary models currently employed by banking, travel, retail, and Internet-based industries.
5. Conduct a legal analysis of NCGS § 8 - 53 and HIPAA to determine the feasibility of adopting model business and data sharing agreements and consents release information. If necessary, recommend statutory amendments that would enable the appropriate exchange of health information while protecting the privacy rights of the person who is the subject of the information.
6. Develop three model business strategies that could be utilized by individual and physician group practices and stakeholders to integrate e-commerce models into community-based health information exchanges.

Phase of development: 1. Concept / exploration (3 - 12 months)

Potential Key Opportunity / Resources:

NCHICA, Western North Carolina Health Network, e-Health Initiative, physician groups, hospitals, RTI International, NC DHHS, Division of Medical Assistance, business and economics schools, and consulting firms.

Implementation support: medium

Anticipated costs: \$75 - \$125k

Funding sources: Private / Public sources

Length of implementation: 12 - 24 months following award

Implementation complexity: high

Health Information Exchange barriers addressed:

BR_1. Range within organizations of misinterpretation and/or misapplication of laws or regulation

BR_2. Lack of business incentives to exchange information

BR_5. Lack of interoperability between processes and technology

BR_6. Lack of workable technology

Health Information Exchange type: 1. Direct Patient Care; 2. Payer; 3. Secondary Use: Operations, Marketing, Research, Law Enforcement; 4. State Government / Public Health

Health Information Exchange models affected: 1. Entity to Entity; 2. Person-Oriented Health Information Exchange

Applicability of solution: Consumers, providers, and potential funders

Stakeholders affected (1 - 18):

1. Clinicians
2. Physician groups
3. Federal health facilities

4. Hospitals
5. Payers
6. Public health agencies
7. Community clinics and health centers
8. Laboratories
9. Pharmacies
10. Long term care facilities and nursing homes
11. Homecare and hospice
14. Medical; public health schools; research institutions
15. Quality improvement organizations
16. Consumers and consumer organizations
17. State government

Privacy and security domains addressed (1 - 9):

Domains	
1. Authentication	X
2. Authorization	X
3. Identity matching	X
4. Transmission	X
5. Integrity	X
6. Event audit	X
7. Safeguards	X
8. Data classification	X
9. Policies	X

Potential barriers / issues: Providers have expressed concerns over losing patients to other providers.

States affected: North Carolina and other states that seek to exchange health information.

Encourage Collaboration

Building a framework to exchange health information, from consumer to provider and entity to entity, requires a new approach in policy development and systems design. Before North Carolina considers funding large technological initiatives, the NC HISPC team recommends that the North Carolina General Assembly establish and fund a task force to address the interoperability challenges faced by health care stakeholders who desire to participate in local, state, and nationwide health information exchanges such as regional health information organizations or the Nationwide Health Information Network.

Other states, such as Florida and West Virginia, have established a formal independent body to oversee the planning and implementation of the health information technology initiatives in their states. In 2004, Florida Governor Jeb Bush's Executive Order Number 04-93 established the Governor's Health Information Infrastructure Advisory Board. The Advisory Board, consisting of health care policy and information technology experts and representatives from the provider community, advises the Agency for Healthcare Administration (the equivalent of the NC Department of Health and Human Services) as Florida develops and implements a strategy for the adoption and use of electronic health records.

Proposed solution(s):

Encourage greater collaboration among policy makers, subject matter and technical experts to adopt health information exchange requirements.

Rationale for Solution:

North Carolina organizations have participated in several health information technology collaborative projects in many areas when there has been an incentive to do so, such as HIPAA compliance or a remunerative business arrangement. The methodologies and tools used in those projects, however, are subject to proprietary protections of the companies that developed them, so the knowledge gained and tools used generally are not available to other health care stakeholders interested in participating in health information exchange. Developing information sharing agreements, project tools, training, and implementation plans is very costly and also requires specific skill sets of subject matter experts who usually are not employed by small- to mid-level health care stakeholders. The establishment of a task force, under the leadership of the State of North Carolina, might build public policy and technical infrastructure in conjunction with all interested groups. Stakeholders also would benefit from open forums so that they could have access to tested methods in their individual health information exchange planning and implementations.

Implementation plan:

Develop leadership programs designed to educate North Carolina's public policy makers on:

1. Health information technology initiatives in progress by the American Health Information Community, the North Carolina Healthcare Information and Communications Alliance, State Alliance on e-Health, and the Nationwide Health Information Network
2. What other states are doing in the areas of model policy and legislation, cost containment projects, electronic health records, and health information exchanges
3. The changing landscape of health information technology's impact on North Carolinians
4. The need for improved health information technology adoption in North Carolina
5. The need for a health information exchange and technology framework in North Carolina
6. Their role as North Carolina endeavors to participate in the Nationwide Health Information Network

Phase of development: 2. Feasibility / planning (3 - 12 months)

Key Opportunity / Resources:

Potential project sponsors: NCHICA, National Governors Association

Potential participants: NC Medical Society, UNC School of Public Health, Duke University's Terry Sanford Institute of Public Policy, National Governors Association, National Association of State Legislators, Health Information Management Systems Society, North Carolina Hospital Association, Blue Cross Blue Shield of North Carolina, LabCorp, RTI International, Duke University Health System, UNC Hospitals, Wake Forest University Baptist Medical Center, Novant Health, Carolinas HealthCare System, IBM, e-Health Initiative, and the American Health Information Management Association

Implementation support: high

Anticipated costs: \$75,000

Funding sources: Private / Public sources

Length of implementation: 9 –12 months following award

Implementation complexity: medium

Health Information Exchange barrier addressed:

BR_5. Lack of interoperability between processes and technology

Health Information Exchange type (Groups 1 - 4): 1. Direct Patient Care; 2. Payer; 4. State Government / Public Health

Health Information Exchange models affected: 1. Entity to Entity, 2. Person-Oriented Health Information Exchange

Applicability of solution: The senders and receivers of health information.

Stakeholders affected (1 - 18): All

Privacy and security domains addressed (1 - 9):

Domains	
1. Authentication	X
2. Authorization	X
3. Identity matching	X
4. Transmission	X
5. Integrity	X
6. Event audit	X
7. Safeguards	X
8. Data classification	X
9. Policies	X

Potential barriers / issues:

With the North Carolina General Assembly adjourning in late April, there is no time to seek a legislator to sponsor legislation that would fund such training sessions in this legislative session's agenda. Alternatives sources of funding will be pursued.

States affected: North Carolina

Improve Policy Awareness

Employees often are not aware of their employer's policies or procedures related to appropriate uses and disclosures of health information. From organization to organization, there is a broad range in the manner in which laws related to appropriate use and disclosure of information are interpreted and applied. The LWG attributed this finding to a lack of understanding or education about the law (and a consequent need for such education to be provided), as well as to the possible need for an amendment of existing law.

The NC HISPC team recommends that North Carolina health care entities emphasize education about appropriate release of information for all entities involved in the exchange of health care information - including providers, payers, vendors, and consultants - to ensure that both requestors and releasers of information are familiar with the circumstances under which health information may be used and released.

Solution: Address the misinterpretation of laws or regulations by obtaining clarification and developing public and private awareness programs.

Rationale for Solution:

Health care stakeholders currently provide legally mandated training on topics such as blood borne pathogens, reportable diseases, and OSHA to their employees. A HIPAA and North Carolina law training program that employers require their employees to attend could reduce the misapplication of health information privacy and security standards in North Carolina's health care industry.

Phase of development: 2. Feasibility / planning (3 - 12 months)

Implementation plan:

1. Seek a project sponsor(s) to conduct a needs assessment as to the feasibility of providing funding for this solution.
2. Develop the preliminary purpose, objectives, statement of work, and scope of the proposed educational programs and how such programs could be integrated into the current awareness and educational programs among the NC health care stakeholders.
3. Develop a draft budget and project plan for the development of a state-wide health information privacy and security education program. Identify potential project resources.
4. Determine deliverables and a maintenance schedule.
5. Develop a formal proposal.
6. Announce a call for proposals.
7. Select a developer for the program(s).
8. Execute the project.
9. Design and test the training program(s).
10. Implement the training program.
11. Implement maintenance program to ensure its continual relevance in the face of policy changes.

Key Opportunity / Resources:

Potential project sponsors: State of North Carolina, AHIMA, Healthcare Information and Management Systems Society

Potential project participants: NCHICA, NC Healthcare Information and Management Systems Society, AHIMA, AHEC, NC HISPC project team, NC Health Care Lawyers Association, NC Hospital Association, and others.

Implementation support: high

Anticipated costs: \$25,000 – \$100,000

Funding sources: Public / Private sources

Length of implementation: 6 – 12 months

Implementation complexity: medium

Health Information Exchange barrier addressed:

BR_1. Range within organizations of misinterpretation and/or misapplication of laws or regulation

Health Information Exchange type: 1. Direct Patient Care; 2. Payer; 3. Secondary Use: Operations, Marketing, Research, Law Enforcement; 4. State Government / Public Health

Health Information Exchange models affected: 1. Entity to Entity; 2. Person-Oriented Health Information Exchange

Applicability of solution: Covered entities under HIPAA and requestors of health information

Stakeholders affected (1 - 18): All

Privacy and security domains addressed (1 - 9):

Domains	
1. Authentication	X
2. Authorization	X
3. Identity matching	X
4. Transmission	X
5. Integrity	X
6. Event audit	X
7. Safeguards	X
8. Data classification	X
9. Policies	X

Potential barriers / issues:
Opposition to specific changes is possible.

States affected: North Carolina

Proposed State Law Solutions for North Carolina

In addition to the identified business, technology, and consumer barriers to health information exchange significant legal barriers were identified that should be brought to the attention of the North Carolina General Assembly.

The first, which applies to all levels of health information exchange, is NCGS § 8 - 53, a North Carolina statute that establishes the physician-patient privilege, which protects information patients share with their physicians from release to third parties without the patient's consent or a court order. This state statute was originally designed to encourage patients to share freely their health care information with physicians. This law states, "No person, duly authorized to practice physic or surgery, shall be required to disclose any information which he may have acquired in attending a patient in a professional character, and which information was necessary to enable him to prescribe for such patient as a physician, or to do any act for him as a surgeon, and no such information shall be considered public records under G.S. 132-1. Confidential information obtained in medical records shall be furnished only on the authorization of the patient, or if deceased, the executor, administrator, or, in the case of unadministered estates, the next of kin." Conversely, the HIPAA Privacy Rule states, "A covered healthcare provider may, without consent, use or disclose protected health information to carry out treatment, payment, or healthcare operations," 45 CFR § 164.506 (2).

Generally, NCGS § 8 - 53 has been interpreted as requiring the physician to obtain a patient's consent before releasing the patient's health information for purposes of treatment, payment, and healthcare operations. It seems to be the state statute that most frequently acts as a legal barrier to the exchange of health information among health care stakeholders for treatment and

operations. Virtually all providers who perform third-party billing functions get prior written consent for sharing information needed for payment.

The second, NCGS § 122C-55(i), allows for release of mental health and substance abuse information without patient authorization to the physician or psychologist who referred a patient to the facility, but it fails to provide for release of this information without authorization to any other physician who currently is treating the patient (such as a primary care provider or specialist) or who treats the patient in the future. This prohibition on sharing information for treatment purposes unless the patient authorizes the release hinders the provision of patient care - both mental health and substance abuse treatment and physical medical care.

Model Legislative Solutions

Providers are apprehensive about sharing health information with patients or others legitimately requesting that information because they fear potential liability for inappropriately releasing such information. Competitive interests also cause providers to refrain from sharing such information.

Comments from the Variations phase of this project indicate that providers view many instances of information release as unacceptably risky, in part because the policies related to such releases are too complex and/or vague for the typical releaser to be confident that he or she has correctly interpreted such policies. Therefore, solutions are needed to address the complexity and ambiguity of the current rule set for releasing information. Two proposed solutions have dominated the work to date: (1) simplify the rules (at least from the releaser's point of view) without increasing the risk of a privacy breach or eliminating releases that patients want to occur; and (2) improve the level of training about the rules for health information releasers and requestors.

The LWG discussed a variety of potential solutions, including:

- (1) Have the National Conference of Commissioners on Uniform State Laws create model consent forms that all states may adopt;
- (2) Create a safe harbor that protects any person or entity who in good faith releases protected health information for purposes of treatment;
- (3) Recodify all North Carolina statutes and regulations relating to release of patient health information in one or more consecutive sections within the General Statutes and the Administrative Code for ease of reference;
- (4) Alternatively, create an official compendium of state statutes and regulations that address confidentiality and release of patient health information and make the compendium available to health care stakeholders;
- (5) Specifically for disease reporting and other legally required health information reporting, initiate an Internet repository of directions for health care providers that will answer questions as to who is responsible for reporting what health care information, to whom reports must be made, the periodicity of such reports, and the appropriate reporting mechanisms, and provide appropriate training on how to access and use the repository; and,
- (6) Enact legislation that protects the privacy of health information in electronic form and addresses the circumstances under which release of such information is appropriate, including for

telemedicine and e-prescribing, and have a specific provision that states that the new law supersedes current laws and regulations.

Proposed Solution: Implement policy standards, such as model policy and legislation, to address the complexity and ambiguity surrounding the release of information.

Implementation plan:

Conduct a legal analysis of North Carolina's privacy laws and their application in community-based health information exchanges within and outside of North Carolina's legal jurisdictions.

Phase of development: 1. Concept / exploration (3 - 12 months)

Key Opportunity / Resources:

Project sponsor: NC Department of Health and Human Services
Project participants: University of North Carolina School of Government

Implementation support: high

Anticipated costs: N/A

Funding sources: Public sources

Length of implementation: 12 - 48 months

Implementation complexity: high

Health Information Exchange barriers addressed:

BR_1. Range within organizations of misinterpretation and/or application of laws or regulation

BR_3. Lack of policy standardization across entities

BR_5. Lack of interoperability between processes and technology

BR_7. Conflicting or outdated federal or state laws or regulations

Health Information Exchange type: 1. Direct Patient Care; 2. Payer; 3. Secondary Use: Operations, Marketing, Research, Law Enforcement; 4. State Government / Public Health

Health Information Exchange models affected: 1. Entity to Entity, 2. Person-Oriented Health Information Exchange

Applicability of solution: Public policy makers

Stakeholders affected (1 - 18): ALL

Privacy and security domains addressed (1 - 9): Review the domains description. Populate the domains table this solution addresses.

Domains	
1. Authentication	X
2. Authorization	X
3. Identity matching	X
4. Transmission	X
5. Integrity	X
6. Event audit	X

7. Safeguards	X
8. Data classification	X
9. Policies	X

Potential barriers / issues:

Consumers would need to accept that their right to consent to releases of their health information must be subject to exceptions for disclosures for purposes of protecting the public health, emergency treatment, and the uses and disclosures of health information that do not require authorization for release.

States affected: North Carolina

Recodifying North Carolina Statutes

Currently, laws and regulations pertaining to the confidentiality of health information and the circumstances under which release of such information is appropriate are found in several sections of the North Carolina General Statutes and the North Carolina Administrative Code, including the evidence section, the juvenile code, the insurance section, the mental health and substance abuse section, and the public health section, to name just a few. This creates a fragmented maze of protections, each of which was written based upon the interests and needs of a particular subset of persons who may have access to health information. This maze is difficult to navigate and the fragmentation makes it difficult to quickly and accurately determine whether particular releases of health information are appropriate in given circumstances. Attorneys, health care consultants, and health care providers alike acknowledge that the current organization of information laws in North Carolina serves as a barrier to timely and appropriate exchange of health care information.

Solution: Either recodify the state's health care-related statutes and regulations so that all statutes and regulations regarding release of health care information may be found within a single section or several consecutive sections of the General Statutes and the Administrative Code, or create an official compendium of state statutes and regulations that addresses confidentiality and release of patient health information and that can be provided to health care stakeholders for easy reference.

Rationale for Solution: When stakeholders can more easily determine whether it is appropriate for them to release health information, they will be more likely to participate in appropriate health information exchanges because the fear of liability for inappropriate releases will be diminished.

Implementation plan: The LWG requires additional time to consider the feasibility of this option. No implementation plan is under consideration at this time.

Phase of development: 1. Concept / exploration (3 - 12 months)

Key Opportunity / Resources:

Potential project sponsors: NC General Assembly, National Governors Association
Potential project participants: NC Medical Society, NC Health Care Lawyers Association, National Conference of Commissioners on Uniform State Laws, Florida Agency for Healthcare Administration, West Virginia Health Authority

Implementation support: high

Anticipated costs: To be determined

Funding sources: Public sources

Length of implementation: 24 - 48 months

Implementation complexity: high

Health Information Exchange barriers addressed:

- BR_1. Range within organizations of misinterpretation and/or application of laws or regulation
- BR_3. Lack of policy standardization across entities
- BR_4. Lack of security standardization across entities
- BR_5. Lack of interoperability between processes and technology
- BR_7. Conflicting or outdated federal or state laws or regulations

Health Information Exchange type (Groups 1 - 4): 1. Direct Patient Care; 2. Payer; 3. Secondary Use: Operations, Marketing, Research, Law Enforcement; 4. State Government / Public Health

Health Information Exchange models affected: 1. Entity to Entity, 2. Person-Oriented Health Information Exchange

Applicability of solution: North Carolina General Assembly

Stakeholders affected (1 - 18): All health care stakeholders

Privacy and security domains addressed (1 - 9):

Domains	
1. Authentication	
2. Authorization	
3. Identity matching	
4. Transmission	
5. Integrity	
6. Event audit	
7. Safeguards	X
8. Data classification	X
9. Policies	X

Potential barriers / issues: Recodification will be extremely time-consuming and a practical challenge and special interests (e.g., insurance industry, mental health industry) may prefer to have release of information laws and regulations related to their industry maintained where they are now. Recodification also exposes existing laws to substantive amendment.

States affected: North Carolina

Expand Public Health Reporting

Chapter 10A of the North Carolina Administrative Code contains several chapters in which specific regulations require the reporting of diseases to various state oversight agencies. Once again, because of this fragmented maze of requirements, health care providers often do not know that they have an obligation to report certain information.

Solution: We need to expand communicable disease and bio-surveillance reporting beyond North Carolina's emergency room. Recodify the administrative code sections on

disease reporting, or prepare a compendium of all the requirements and make the compendium available to all health care providers. Alternatively, initiate an Internet repository of directions for providers that will answer questions as to who is responsible for reporting what information, to whom reports must be made, the periodicity of such reports, and the appropriate reporting mechanisms. Training must be offered to all persons or entities required to make reports so that they know where to find the repository and how to use it.

Rationale for Solution: Clarification of the public health and disease reporting requirements and providing easy access to those requirements, as well as providing a format for asking questions about reporting responsibilities, should increase compliance with reporting requirements and improve the accuracy of North Carolina's disease registries.

Implementation plan: Due to the limited scope, resource and time constraints, the LWG will consider the feasibility of this solution and an implementation outside of the HISPC contract.

Phase of development: 1. Concept / exploration (3 - 12 months)

Key Opportunity / Resources:

NC DHHS Division of Public Health, NCDTECT, software system vendors, and physicians groups should collaborate on the planning, design, and implementation of this system.

Increasing the implementation of electronic medical records through North Carolina will automate public health reporting and allow the system to directly report with little to no intervention from the providers.

Implementation support: high

Anticipated costs: To be determined

Funding sources: Public sources

Length of implementation: 2 - 3 years

Implementation complexity: high

Health Information Exchange barriers addressed:

BR_1. Range within organizations of misinterpretation and/or application of laws or regulation specifically, the lack of awareness of what providers are required to report.

BR_6. Lack of workable technology

BR_7. Conflicting or outdated federal or state laws or regulations

Health Information Exchange type (Groups 1 - 4):1. Direct Patient Care, 4. State Government / Public Health

Health Information Exchange model affected: 1. Entity to Entity

Applicability of solution: All healthcare providers, NC Department of Health and Human Services, Division of Public Health. This solution is currently implemented through the North Carolina Public Health Information Network.

Stakeholders affected (1 - 18):

1. Clinicians
2. Physician groups
3. Federal health facilities
4. Hospitals
6. Public health agencies
7. Community clinics and health centers
8. Laboratories
10. Long term care facilities and nursing homes
11. Homecare and hospice
12. Corrections facilities
15. Quality improvement organizations
17. State government

Privacy and security domains addressed (1 - 9):

Domains	
1. Authentication	
2. Authorization	
3. Identity matching	
4. Transmission	
5. Integrity	
6. Event audit	
7. Safeguards	
8. Data classification	X
9. Policies	X

Potential barriers / issues: Opposition to specific changes is possible.

States affected: North Carolina

Amend NCGS § 122C-55(i)

NCGS § 122C-55. Re-disclosure of Mental Health Information.

Original text: Subsection (i) "Upon specific request, a responsible professional may release confidential information to a physician or psychologist who referred the client to the facility."

NCGS § 122C-55(i) allows for release of mental health and substance abuse information without patient authorization to the physician or psychologist who referred a patient to the facility, but it fails to provide for release of this information without authorization to any other physician who currently is treating the patient (such as a primary care provider or specialist) or who treats the patient in the future. This prohibition on sharing information for treatment purposes unless the patient authorizes the release hinders the provision of patient care - both mental health and substance abuse treatment and physical medical care.

Solution:

Amend NCGS § 122C-55(i) to permit, without patient authorization, disclosure of mental health or substance abuse information to any provider who is treating the patient, either for mental or physical health problems.

Rationale for Solution:

The original language was developed before health care delivery became integrated and physical health and behavioral health became accepted as inter-dependent variables of a

person's total health care. The two systems were isolated, with behavioral health viewed more as "social services" and acute/physical health viewed as "health"; now they both are viewed as important components of a person's "health," and the data validates that treatment or failure of treatment of one component effects the other. In addition, the language was written before the expansive use of pharmaceuticals in non-institutional settings; the new, broader use of pharmaceuticals requires knowledge by both physical and mental health providers of what the other provider has prescribed and the consumer has taken. Finally, the original language was written when individuals with major mental health and chemical use problems were institutionalized; as these individuals all were part of an enclosed system, the previously noted issue did not exist. Today, it is a significant issue in many patients' health care.

Amending NCGS § 122C-55(i) will allow a mental health provider to provide crucial patient information to a subsequent or concurrent provider of mental or physical health care. In some instances, a mental health patient is unable or unwilling to share his/her information, but sharing the information may be vital to the effective treatment of the individual. By allowing this information to be shared for treatment purposes, just as physical health information would be shared, care can be provided more efficiently and effectively. The effectiveness of any amendment, however, may depend upon revision to the federal regulations regarding substance abuse treatment information, which are addressed below (42 CFR §§ 2.1 and 2.2).

Implementation plan:

Due to the limited scope, resource and time constraints the LWG will consider the feasibility of this solution and an implementation outside of the HISPC contract.

Phase of development: 1. Concept / exploration (3 - 12 months)

Key Opportunity / Resources:

NC Medical Society, NC Hospital Association, NC Health Care Lawyers Association, NCHICA, National Governors Association, State Alliance for e-Health.

Implementation support: medium

Anticipated costs: N/A

Funding sources: Public sources

Length of implementation: 12 - 24 months

Implementation complexity: high

Health Information Exchange barriers addressed:

BR_1. Range within organizations of misinterpretation and/or application of laws or regulation

BR_3. Lack of policy standardization across entities

BR_4. Lack of security standardization across entities

BR_5. Lack of interoperability between processes and technology

BR_7. Conflicting or outdated federal or state laws or regulations.

Health Information Exchange type: 1. Direct Patient Care; 4. State Government / Public Health

Health Information Exchange models affected: 1. Entity to Entity; 2. Person-Oriented Health Information Exchange

Applicability of solution: Mental health providers, North Carolina General Assembly, NC DHHS divisions of Mental Health, Developmental Disabilities, and Substance Abuse Services

Stakeholders affected (1 - 18):

1. Clinicians
2. Physician groups
3. Federal health facilities
4. Hospitals
6. Public health agencies
7. Community clinics and health centers
10. Long term care facilities and nursing homes
11. Homecare and hospice
16. Consumers and consumer organizations
17. State government

Privacy and security domains addressed (1 - 9):

Domains	
1. Authentication	
2. Authorization	X
3. Identity matching	
4. Transmission	
5. Integrity	
6. Event audit	
7. Safeguards	
8. Data classification	X
9. Policies	X

Potential barriers / issues: Opposition to specific changes is possible. Clients may object to additional individuals receiving their mental health information.

States affected: North Carolina

NCGS § 8 - 53

NCGS § 8 - 53 Communications between physician and patient. This North Carolina statute resides in the evidentiary section of the General Statutes, but it has been interpreted to prohibit uses and disclosures of patient information in other contexts absent the patient's authorization or a court order. This statute has emerged as the most often-cited barrier to exchange of health information in the state.

Solution: Prepare or revise statutes to minimize perceived conflicts between NCGS § 8 - 53 and HIPAA with respect to sharing health information for treatment, payment, and operations, and other uses or disclosures for which patient authorization is not required under HIPAA.

Rationale for Solution: Because this statute is generally determined to require patient consent prior to releasing health information for treatment, payment, and health care operations, such a revision to the statutory scheme should clarify that such releases without consent are acceptable and should reduce the delay in exchanging health information for these important purposes.

Implementation plan: Initiatives to address the conflicts between NCGS § 8 - 53 and HIPAA have been ongoing among North Carolina's legal community.

Phase of development: 4. Implementation (6 - 24 months)

Key Opportunity / Resources:

Project sponsor: NC Hospital Association

Project participants: NC Medical Society, NC Health Care Lawyers Association

Implementation support: high

Anticipated costs: To be determined

Funding sources: Private / Public sources

Length of implementation: 12 - 24 months

Implementation complexity: high

Health Information Exchange barriers addressed:

BR_1. Range within organizations of misinterpretation and/or application of laws or regulation

BR_2. Lack of business incentives to exchange information

BR_3. Lack of policy standardization across entities

BR_4. Lack of security standardization across entities

BR_5. Lack of interoperability between processes and technology

BR_7. Conflicting or outdated federal or state laws or regulations

Health Information Exchange type (Groups 1 - 4): 1. Direct Patient Care; 2. Payer; 3. Secondary Use: Operations, Marketing, Research, Law Enforcement; 4. State Government / Public Health

Health Information Exchange models affected: 1. Entity to Entity; 2. Person-Oriented Health Information Exchange

Applicability of solution: North Carolina General Assembly, all covered entities under HIPAA, and other stakeholders

Stakeholders affected (1 - 18): ALL

Privacy and security domains addressed (1 - 9):

Domains	
1. Authentication	
2. Authorization	
3. Identity matching	
4. Transmission	
5. Integrity	
6. Event audit	
7. Safeguards	X
8. Data classification	X
9. Policies	X

Potential barriers / issues: Opposition to specific changes is possible. Need to assess potential unintended consequences of a broad amendment. For those who interpret NCGS § 8 - 53 as a barrier to uses and disclosures of health information, this barrier is insurmountable.

States affected: North Carolina

Multi-state Implementation Plans

Model Policy Solutions

Regional Health Information Organizations and Health Information Exchange Networks

There is confusion in the marketplace about what exactly a regional health information organization or a health information exchange network is and, therefore, what privacy and security protections must exist in order for appropriately protected information exchange within a regional health information organization or health information exchange network.

As these types of health information exchanges evolve, the NC HISPC stakeholders recommend that organizations interested in community based health information exchanges conduct further assessments of the variations in the business agreements exchange agreements, terminologies, financial models, and the privacy and security impacts of these types of arrangements, planning, and implementation tools.

Due to the limited scope and time constraints of the HISPC project, additional study of this barrier should be considered by the stakeholders who wish to participate in these types of exchange agreements within North Carolina and our bordering states.

Solution: Adopt generally accepted models and terms when referring to regional health information exchange organizations, health information exchange networks, or similar entities that engage in electronic health information exchange. We need to have and use a standardized set of definitions and terminology to assure health care literacy, health information technology literacy, and accuracy of information based on the data provided.

Rationale for Solution: Going forward, standardizing terminology and definitions, along with identifying the different models of regional health information organizations and health information exchanges, should assist the health care industry by improving awareness and understanding of the various options for health information exchange.

Implementation plan:

Establish a study commission to:

1. Assess the types of business and exchange agreements currently utilized by regional health information organizations and similar types of organizations within North Carolina and its bordering states and the privacy and security impacts of these types of arrangements.
2. Conduct a legal analysis of mandatory state and federal laws and regulations that impact these types of exchange agreements.
3. Identify the purpose of the exchange agreements and the incentives for the stakeholders' participation, the financial models currently in place to ensure their sustainability, and the types of stakeholders involved including consumers, if any.
4. Develop a crosswalk of the health information terms utilized in these health information exchanges
5. Recommend standardized terms designed to ease the design and applicability of proposed model agreements.
6. Recommend model exchange agreements based on the findings of the legal analysis
7. Develop model exchange agreements for stakeholders to adopt.
8. Develop a program to measure the willingness to voluntarily adopt the model exchange agreements.
9. Develop a strategy to ensure the model agreements are adopted.
10. Develop a maintenance plan to ensure that the model agreements are updated as changes are needed.

Phase of development: 1. Concept / exploration (3 - 12 months)

Key Opportunity / Resources:

Potential project sponsor(s): West North Carolina Health Network, e-Health Initiative, CareSpark, the Agency for Healthcare Research and Quality
Potential project participants: NCHICA, e-Health Initiative

Implementation support: high

Anticipated costs: \$60,000 to \$150,000

Funding sources: Private / Public sources

Length of implementation: 6 – 12 months following award

Implementation complexity: high

Health Information Exchange barriers addressed:

- BR_1. Range within organizations of misinterpretation and/or application of laws or regulation
- BR_2. Lack of business incentives to exchange information
- BR_3. Lack of policy standardization across entities
- BR_4. Lack of security standardization across entities
- BR_5. Lack of interoperability between processes and technology
- BR_7. Conflicting or outdated federal or state laws or regulations.

Health Information Exchange type (Groups 1 - 4): 1. Direct Patient Care; 2. Payer; 3. Secondary Use: Operations, Marketing, Research, Law Enforcement; 4. State Government / Public Health

Health Information Exchange models affected: 1. Entity to Entity; 2. Person-Oriented Health Information Exchange

Applicability of solution: North Carolina General Assembly, Nationwide Health Information Network and regional health information organization participants

Stakeholders affected (1 - 18): ALL

Privacy and security domains addressed (1 - 9): Review the domains description. Populate the domains table this solution addresses.

Domains	
1. Authentication	X
2. Authorization	X
3. Identity matching	X
4. Transmission	X
5. Integrity	X
6. Event audit	X
7. Safeguards	X
8. Data classification	X
9. Policies	X

Potential barriers / issues: Opposition to specific changes is possible.

States affected: North Carolina

Business Processes - Technological Dependencies

Overcoming privacy, security, and other barriers to the routine exchange of electronic health information involves finding ways to interconnect the business and technical processes related to the information exchange. For example, finding a way to ensure that two entities, such as a provider and a health plan, have the same person in mind (identity matching) before they exchange health information about that person requires technical and business process similarities.

Integrating the HIPAA transactions and code set data element mapping processes with generally accepted information security risk management methodologies could assist information privacy and security professionals with the adoption of standard risk management practices.

Proposed solutions: Explore the dependencies between the business processes and their technical components for the purpose of interoperability. Create models for internal business practices to be used in combination with standards of other organizations.

Rationale for Solutions: During the remediation of HIPAA electronic transactions, the process employed by information system developers included the identification and documentation of the health care payment process, the development of business flow diagrams, and the mapping of proprietary data elements in systems to the required X12 standards. Software programs were then developed to convert the propriety data elements into X12 format. A data dictionary containing the definitions and representations of the data elements is either generated by the database management system or created by systems professionals.

A similar methodology during the remediation of HIPAA privacy and security required covered entities to identify individually identifiable information and categorize the protected health information by type (demographic, financial, clinical), the level of sensitivity of the information in the event of a wrongful disclosure or security breach, and the criticality if the information became unavailable, modified, or damaged.

Integrating the information gathered from mapping the transactions and code sets and the categorization, sensitivity, and criticality of protected health information would give health care analysts and systems engineers an initial determination of the business processes and their correlating technological components. The information can be then expanded and shared with the Health Information Technology Standards Panel, which is charged to develop a widely-accepted and useful set of standards to enable and support interoperability among health care software applications. By collaborating with Health Information Technology Standards Panel, North Carolina health care stakeholders can assist in the acceleration of health information interoperability.

Implementation plan:

1. Raise awareness on the work underway by the Health Information Technology Standards Panel and other standards organizations.
2. Join and participate in the Health Information Technology Standards Panel and other standards organizations.
3. Follow IT project management methodology.

Phase of development: N/A

Key opportunity / resources: N/A

Implementation support: medium

Anticipated costs: The solution does not require an estimate of costs as it is not a project *per se*. We are recommending that all information systems projects include the inclusion of this solution in their planning and methodology.

Funding sources: N/A

Length of implementation: N/A

Implementation complexity: high

Health Information Exchange barrier addressed:
BR_5. Lack of interoperability between processes and technology

Health Information Exchange type (Groups 1 - 4): 1. Direct Patient Care; 2. Payer; 3. Secondary Use: Operations, Marketing, Research, Law Enforcement; 4. State Government / Public Health

Health Information Exchange models affected: 1. Entity to Entity, 2. Person-Oriented Health Information Exchange

Applicability of solution: The senders and receivers of health information.

Stakeholders affected (1 - 18): All

Privacy and security domains addressed (1 - 9):

Domains	
1. Authentication	X
2. Authorization	X
3. Identity matching	
4. Transmission	X
5. Integrity	X
6. Event audit	X
7. Safeguards	X
8. Data classification	X
9. Policies	X

Potential barriers / issues: Process flows are labor intensive and costly.

States affected: North Carolina

Technology Solutions

Adopt Security Standards

As the health care industry moves toward the realization of the Nationwide Health Information Network, HIPAA privacy and security requirements become not only a compliance issue, but a sound business practice. The HIPAA Security Rule, 45 CFR §§ 160, 162, and 164 Health Insurance Reform: Security Standards; Final Rule, required by covered entities engaged in the exchange of certain electronic transactions, attempts to ensure the availability, confidentiality and integrity of protected health information. While many health care organizations within North Carolina supported the HIPAA reforms as early adopters, HIPAA's lack of standards and

enforcement continues to present areas of ambiguity and complexity among our stakeholders. Our proposed solutions seek to address areas of ambiguity and complexity indicated by the following examples.

Page 8335 of the Rule states, "In this final rule, we replace the term 'requirement' with 'standard.'" Page 8336 of the Rule states, "In this final rule, we adopt both 'required' and 'addressable' implementation specifications. We introduce the concept of 'addressable implementation specifications' to provide covered entities additional flexibility with respect to compliance with the security standards. In meeting standards that contain addressable implementation specifications, a covered entity will ultimately do one of the following: (a) Implement one or more of the addressable implementation specifications; (b) implement one or more alternative security measures; (c) implement a combination of both; or (d) not implement either an addressable implementation specification or an alternative security measure."

According to the International Information Systems Security Certification Consortium (ISC)², standards are "mandatory activities, actions, rules, or regulations designed to provide policies with the support structure and specific direction they require to be meaningful and effective. It is a specific product or mechanism that is selected for universal use throughout the organization in order to support the policy." The intent of the Rule's flexibility and scalability of the implementation specifications tends to make measuring its effectiveness or compliance to the Rule a subjective exercise.

The processes of authentication and authorization for persons seeking access to electronic health information have often been administered separately, leading to opportunities for inconsistencies in user accounts and actual data access. In our proposed solutions, we consider both processes integral to standard access control management.

In order for individuals to authorize the electronic exchange of their health information, they must have confidence that the system is developed to prevent access to their information unless they have consented to such access. Also, health care entities must be able to trust that the information originated from an authorized sender (authentication) and that it has not been modified while it was being transmitted (encryption).

Another important characteristic of authenticating the validity of a person's identity is a process called "identity matching." This process is important for individual providers who deal with information about a specific patient that comes from several entities, where the individual entities may have different identification criteria. The user enters the information he or she is looking for, and the search engine replies back with multiple choices that match the information entered. The user then clicks on the link to determine if that is what he or she is looking for.

The North Carolina Office of Information Technology Services has developed and is carefully implementing the Identity Management Service (NCID -- see <https://www.ncid.its.state.nc.us/>) for the purpose of authenticating users who subscribe to the state's online services. The State of Florida's Agency of Healthcare Administration has established a record locator service similar to a hospital's e-Master Patient Index. Florida's record locator service works as an identity matching engine and manages access to the information about specific individuals.

By leveraging the infrastructure currently in place and partnering with other states like Florida as it builds the Florida Health Information Network, North Carolina could launch the building of an information security framework needed to participate in an interoperable health information exchange that is consumer-centric, as described in the President's vision.

The industry-wide adoption of information security standards regarding authentication and authorization is critical to building user trust and ensuring the confidentiality, availability, and integrity of the information.

Solution:

We propose the adoption of Health Information Exchange security standards in the areas of authentication and access authorization of the individual, and encryption to safeguard the information while in transit.

Amend the HIPAA Security Rule

45 CFR §§ 164.308, 164.310, and §164.312(e)(1)

Amend the “addressable” implementation specifications to “required.”

Amend the term “requirement” with “standard.”

Require encryption during the transmission of information.

Rationale for Solution:

The intent of the health information exchange security standards is to support the HIPAA Privacy Regulations as required in 45 CFR §164.530 c. These standards will provide specific design requirements and implementation direction to the Nationwide Health Information Network service providers and participants as well as approximately 28 - 45% of covered entities who still seek to comply with the regulations (US Healthcare Industry HIPAA Compliance Survey Results, Winter 2006, Healthcare Information and Management Systems Society and Phoenix Health Systems).

The process by which standards are designed and adopted would first engage policy makers and subject matter and technical experts in the consideration of the various standards currently implemented. The experts would also have the opportunity to collaborate as they explore the dependencies between the business processes and their technical components. The goal would be to adopt a set of security standards that would safeguard the information as it is transmitted.

Adopting a universally accepted information security standard such as the National Institute of Standards and Technology (NIST SP 800-53-1, *Revision 1: Recommended Security Controls for Federal Information Systems*, December, 2006) or ISO / IEC 27001 for Administrative, Physical and Technical Safeguards would address the complexity and ambiguity surrounding the safeguarding of health information as well as the misinterpretation of laws or regulations within HIPAA Privacy and Security.

Proposed North Carolina General Statute Health Data Exchange Act

In the event that the amendment of HIPAA is unfeasible, we propose an alternative solution to ensure that entities engaged in the exchange of electronic health information in North Carolina implement certain required information safeguards.

We propose the introduction a new North Carolina General Statute Health Data Exchange Act that would serve to clarify authorization requirements and inconsistencies that exist in the federal rules. Possible authorization requirements can include:

- Characterizations and delimitations of the actual health care records and information and/or subsets that will be made available for exchange
- Restriction categories (if necessary)
 - Original vs. copy
 - De-identified records
 - Research-appropriate subsets (*ad hoc*, based on research protocols)
 - Local record (entity-specific) versus complete protected health information
 - Time limitations (*e.g.*, regulatory requirements allowing destruction/disposal)

Clear identification of the participants and their roles and responsibilities with protected health information exchange

- Provider entity and representatives
- Provider and alternates (staff, assistants, referrals, etc.)
- Patient
- Person-agent (e.g., parent, guardian, spouse, etc.)
- Entity-agency and representatives
- Government/law enforcement agents/agencies
- Responsibilities, e.g., protection; ownership; ability to consent, delegate, exchange, or destroy

Clearly defined processes, rules, and use cases that enable appropriate access to and exchange of protected health information.

- Protected health information lifecycle access restrictions
- Protection at rest, in use, and during exchange
- Treatment, payment and operation practices and processes
- Create, update, modify, view, disseminate, consent, delegate, delete/destroy
- Violation consequences

Phase of development: 1. Concept / exploration (3 - 12 months)

Implementation plan:

1. Join the Health Information Technology Standards Panel.
2. Participate in the Health Information Technology Standards Panel's standards initiatives.
3. Develop health information security technical white paper on the adoption of security standards.
4. Publish an implementation guide for planning and implementing health information security programs utilizing the Project Management Institute's *Common Book of Knowledge* and National Institute ST SP 800-53-1, *Revision 1: Recommended Security Controls for Federal Information Systems*, December, 2006.

Key Opportunity / Resources:

Potential project sponsor(s): National Institute of Standards and Technology, Project Management Institute

Potential project participants: Health Information Technology Standards Panel, NCHICA, Healthcare Information and Management Systems Society

Implementation support: high

Anticipated costs: \$75,000 - \$120,000

Funding sources: Private / Public sources

Length of implementation: 6 – 12 months

Implementation complexity: high

Health Information Exchange barriers addressed:

BR_1. Range within organizations of misinterpretation and/or application of laws or regulation

BR_3. Lack of policy standardization across entities

BR_4. Lack of security standardization across entities

BR_5. Lack of interoperability between processes and technology
BR_7. Conflicting or outdated federal or state laws or regulations
BR_8a. Lack consumer input into the design of policy and technology
BR_8b. Lack of definition of consumer empowerment and methodology to its inclusion in policy and systems design

Health Information Exchange type: 1. Direct Patient Care; 2. Payer; 3. Secondary Use: Operations, Marketing, Research, Law Enforcement; 4. State Government / Public Health

Health Information Exchange models affected: 1. Entity to Entity; 2. Person-Oriented Health Information Exchange

Applicability of solution: Health information exchange, regional health information organization, HIPAA covered entities and other parties exchanging electronic health information

Stakeholders affected (1 - 18): All

Privacy and security domains addressed (1 - 9):

Domains	
1. Authentication	X
2. Authorization	X
3. Identity matching	X
4. Transmission	X
5. Integrity	X
6. Event audit	X
7. Safeguards	X
8. Data classification	X
9. Policies	X

Potential barriers / issues: Lack of consensus over implementation standards.

States affected: All

National - level Implementation Plans

Proposed Federal Law Solutions

The federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations currently provide that “Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test” (42 CFR § 493.1291(f)). The term “authorized person” is defined in 42 CFR § 493.2 as “an individual authorized under State law to order tests or receive test results, or both.” The term “individual responsible for using the test results” is not defined in the CLIA regulations, and there is considerable uncertainty as to its meaning.

These CLIA provisions pose barriers to laboratories exchanging health care information directly with non-ordering providers to whom the patient is referred and with regional health information organizations, or similar stakeholders who may desire to participate in electronic health information exchange for purposes permitted by HIPAA, but who are not identified as “authorized persons” for the receipt of test results under State law.

Proposed 42 CFR §§ 2.1 and 2.2 Amendment

For release or re-release of substance abuse treatment information to third parties, federal law requires patient authorization or a court order, and it further requires the releasing party to provide notice of these restrictions upon any re-disclosure of such information so that any party accessing this information must observe these restrictions (42 CFR § 2.32).

For facilities that receive federal funding, 42 CFR §§ 2.1 and 2.2 pre-empt NCGS § 122C-55(i). Substance abuse information is specially protected, and a consent form for release must specify release of this information. Some hospitals include a space on their general consent forms for patients to initial in the event that the patient agrees to allow the hospital to release health information regarding the patient’s substance abuse. Because substance abuse information is specially protected, it also needs to be segregated in the medical record to maintain such special protection, whether the record is maintained in paper or electronic format. Some facilities have policies specifying that substance abuse information must be maintained separately in the patient’s medical record.

Solution: Amend 42 CFR §§ 2.1 and 2.2, the federal substance abuse treatment provisions, to allow for re-release of such information to health care providers without limitation for the purpose of treatment.

Rationale for Solution: Due to the requirements within 42 CFR §§ 2.1 and 2.2 for additional authorization from the patient to re-disclose substance abuse treatment information, the treating physician often may treat the patient with incomplete information (*i.e.*, without knowledge that the patient has been or is in treatment for substance abuse). This creates a risk of harm to the patient. Although this sensitive information generally should be protected, treating providers need access to this information in order to make appropriate treatment and drug interaction determinations for the patient.

Implementation plan:

1. Join the State Alliance on e-Health to participate in collaborative projects to review federal and state laws.

2. Identify interested stakeholders who would be interested in collaborative public policy, privacy and health information exchange projects surrounding specially protected health information.

Phase of development: 1. Concept / exploration (3 - 12 months)

Key Opportunity / Resources:

Mental health community, providers, consumers, and legislators have the opportunity to collaborate on reviewing and revising, if appropriate, current mental health laws to ensure the providers have the appropriate information to make clinical decisions. The consumer, as the subject and authorizer of the information, should be encouraged to participate.

Implementation support: High

Anticipated costs: N/A

Funding sources: Public sources

Length of implementation: 1 - 3 years

Implementation complexity: high

Health Information Exchange barriers addressed:

BR_1. Range within organizations of misinterpretation and/or application of laws or regulation

BR_3. Lack of policy standardization across entities

BR_4. Lack of security standardization across entities

BR_7. Conflicting or outdated federal or state laws or regulations

BR_8a. Lack consumer input into the design of policy and technology

BR_8b. Lack of definition of consumer empowerment and methodology to its inclusion in policy and systems design

Health Information Exchange type (Groups 1 - 4): 1. Direct Patient Care; 2. Payer; 4. State Government / Public Health

Health Information Exchange models affected: 1. Entity to Entity; 2. Person-Oriented Health Information Exchange

Applicability of solution: Mental health (including substance abuse) stakeholders including providers, facilities, government, and individuals seeking treatment

Stakeholders affected (1 - 18):

1. Clinicians
2. Physician groups
3. Federal health facilities
4. Hospitals
5. Payers
6. Public health agencies
7. Community clinics and health centers
10. Long term care facilities and nursing homes
11. Homecare and hospice
14. Medical; public health schools; research institutions
16. Consumers and consumer organizations
17. State government

Privacy and security domains addressed (1 - 9):

Domains	
1. Authentication	
2. Authorization	X
3. Identity matching	X
4. Transmission	
5. Integrity	
6. Event audit	
7. Safeguards	X
8. Data classification	X
9. Policies	X

Potential barriers / issues: Complicated federal and state mental health laws may deter participation. In addition, lack of understanding about the patient care consequences of the current law, as well as concern about the sensitivity of this information, may spark disagreement among substance abuse/mental health patient advocates about these proposed solutions.

States affected: North Carolina

Proposed Clinical Laboratory Improvement Amendment

Clinical laboratories face significant regulatory obstacles in delivering test results to persons other than the physician or other authorized person who ordered the test, even when the requests for such results are for legitimate purposes in furtherance of consensus public policy objectives such as quality improvement, disease management, patient safety, elimination of duplicative testing, and reducing health care costs. The successful achievement of these policy goals will depend upon the ability of laboratories to deliver both real-time and historical test results to persons who are in many cases not currently authorized to receive them under existing law. These difficulties arise primarily from regulations promulgated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and state law.

Under the CLIA regulations, 42 CFR § 493.1291(f) currently provides that “Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test.” The term “authorized person” is defined in 42 CFR § 493.2 as “an individual authorized under State law to order tests or receive test results, or both.” The term “individual responsible for using the test results” is not defined in the CLIA regulations, and there is considerable uncertainty as to its meaning.

CLIA’s deference to state law for purposes of determining the permissible recipients of laboratory results is problematic because many state laws very narrowly proscribe those persons who are authorized to order tests or receive test results, and variation among state laws has created a patchwork of different standards. For example, in Arizona, the result of a test must be reported to the person who authorized it, and those authorized persons are limited to podiatrists, chiropractors, dentists, physicians, or a person licensed to practice medicine in another state (A.R.S. § 370-40 (A) and (B)). In Georgia, test results must be reported only to, or as directed by, a licensed physician, dentist, or other authorized person requesting the test (GA Rules and Regulations § 290-9-8-.25). In North Carolina, state law does not specifically address the issue of who is authorized to receive test results, so under CLIA, only those who are authorized to order tests under North Carolina law are authorized to receive results. Persons or entities that are not

expressly identified in these typical provisions include non-ordering physician specialists to whom a patient has been referred by a primary care physician, regional health information organizations, quality improvement organizations, disease management companies, health plans, and even the Centers for Medicare and Medical Assistance Services, all of whom are seeking lab result data for legitimate purposes. While in many states labs are permitted to deliver test results to persons or entities authorized by the ordering physician to receive them, obtaining or confirming such authorization is often very impractical.

Background

We are proposing three alternative regulatory amendments involving 42 CFR §§ 493.1291(f) and 493.2 to solve these CLIA issues. The intent of these proposed amendments is solely to expand the list of permissible recipients of lab results, not to expand the purposes for which those results may be disclosed. Therefore, these amendments would not permit a disclosure that the HIPAA Privacy Regulations would prohibit (in the absence of state law restricting the list of permissible recipients of test results), and they would not permit the disclosure of a test result where state law prohibits disclosure of test results of that type due to their sensitive nature (*e.g.*, HIV results). Instead, the proposed amendments are aimed at situations where the disclosure would be permitted by HIPAA but would be prohibited by state law merely because the intended recipient is not defined as an “authorized person” for receipt of lab results from a laboratory. The alternatives are listed below in order of preference.

CLIA Amendment Alternative 1: Revision of 42 CFR § 493.1291(f)

Test results must be released to the authorized person who ordered the test. In addition, notwithstanding any contrary state law defining who is an individual authorized to order tests or receive test results or both, test results may be released to:

- (1) The laboratory that initially requested the test, if applicable;
- (2) Any person designated to receive the test results by the authorized person who ordered the test;
- (3) A “covered entity”, as defined in 45 C.F.R. § 160.103; and,
- (4) A “business associate” of a covered entity, as defined in 45 C.F.R. § 160.103.

This section shall not be construed to permit the disclosure of any specific type of test result to any of the persons or entities named herein where the disclosure of test results of that type is otherwise prohibited by state or federal law.

Rationale for CLIA Amendment Alternative 1

The first alternative is to revise 42 CFR § 493.1291(f), which currently provides that test results must be released only to authorized persons, and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test. The proposed revision would require that test results must be released to the authorized person who ordered the test, but would provide that in addition, notwithstanding contrary state law, test results may be released to certain other listed recipients. These recipients would include a referring laboratory; anyone designated by the authorized person who ordered the test; and a “covered entity” or a “business associate” as defined in the HIPAA Privacy Regulations. This alternative eliminates any reference to the undefined term “individual responsible for using the test results”; makes a distinction between mandatory and permissive test result disclosure; and responsibly expands the group of permissible recipients of test results by ensuring that those who receive the results are either closely associated with the patient’s care or are governed by HIPAA-related safeguards. This alternative would permit states to define those to whom results must be disclosed, but would prohibit states from disallowing result delivery to the additional persons named in this section.

CLIA Amendment Alternative 2: Addition to 42 CFR § 493.2

“Authorized person” means an individual authorized under state law to order tests or receive test results or both. In addition, notwithstanding any contrary state law defining who is an individual authorized to order tests or receive test results or both, “authorized person” means:

- (a) Any person designated to receive the test results by the authorized person who ordered the test;
- (b) A “covered entity”, as defined in 45 C.F.R. § 160.103; and,
- (c) A “business associate” of a covered entity, as defined in 45 C.F.R. § 160.103.

This definition shall not be construed to permit the disclosure of any specific type of test result to any of the persons or entities named herein where the disclosure of test results of that type is otherwise prohibited by State or Federal law.

Rationale for CLIA Amendment Alternative 2

The second alternative is to revise the definition of “authorized person” by amending 42 CFR § 493.2 to add that in addition to an individual authorized under State law to order tests, receive tests, or both, it includes a referring lab, any person designated by the authorized person who ordered the test, and any covered entity or business associate, notwithstanding any state law to the contrary. Like the third alternative, this definition would further clarify the meaning of 42 CFR § 493.1291(f), and would responsibly expand the group of permissible recipients of test results by ensuring that those who receive the results are either closely associated with the patient’s care or are governed by HIPAA-related safeguards. This alternative would also continue to permit states to define “authorized person”, but would prohibit states from disallowing result delivery to the persons expressly included in the new definition.

CLIA Amendment Alternative 3: Addition to 42 CFR § 493.2

Individual responsible for using the test results means, notwithstanding any contrary state law defining who is an individual authorized to order tests or receive test results or both:

- (a) Any person designated to receive the test results by the authorized person who ordered the test;
- (b) A “covered entity”, as defined in 45 C.F.R. § 160.103; and,
- (c) A “business associate” of a covered entity, as defined in 45 C.F.R. § 160.103.

This definition shall not be construed to permit the disclosure of any specific type of test result to any of the persons or entities named herein where the disclosure of test results of that type is otherwise prohibited by state or federal law.

Rationale for CLIA Amendment Alternative 3

The third alternative is to define the term “individual responsible for using the test results”, which appears in 42 CFR § 493.1291(f) but is currently undefined, by adding its definition in 42 CFR § 493.2. As proposed, the term would include any person designated by the authorized person who ordered the test and any covered entity or business associate, notwithstanding any state law to the contrary. This definition would further clarify the meaning of 42 CFR § 493.1291(f) and would responsibly expand the group of permissible recipients of test results by ensuring that those who receive the results are either closely associated with the patient’s care or are governed by HIPAA-related safeguards. This alternative would also continue to permit states to define “authorized persons”, but would prohibit states from disallowing result delivery to the persons expressly included in the new definition.

Phase of development: 2. Feasibility / planning (3 - 12 months)

Implementation plan:

1. Obtain buy-in and letter of support from American Clinical Laboratory Association.

2. Inform and solicit support from the American Health Information Community, National Committee on Vital and Health Statistics, and other relevant bodies.
3. Engage the State E-health Alliance in the promotional efforts.
4. Receive endorsement of proposed CLIA amendments from HHS.
5. The NC HISPC stakeholders request the Centers for Medicare and Medical Assistance Services to issue proposed and final rules amending the CLIA regulations in accordance with one of the proposed alternative amendments.

Key Opportunity / Resources: NCHICA and the American Clinical Laboratory Association

Implementation support: high

Anticipated costs: N/A

Funding sources: N/A

Length of implementation: 18 months

Implementation complexity: medium

Health Information Exchange barriers addressed:

BR_1. Range within organizations of misinterpretation and/or application of laws or regulation

BR_3. Lack of policy standardization across entities

BR_5. Lack of interoperability between processes and technology

BR_7. Conflicting or outdated federal or state laws or regulations

Health Information Exchange type: 1. Direct Patient Care, 2. Payer, 3. Secondary Use, 4. State Government / Public Health

Health Information Exchange type (Groups 1 - 4): 1. Direct Patient Care; 2. Payer; 4. State Government / Public Health

Health Information Exchange models affected: 1. Entity to Entity; 2. Person-Oriented Health Information Exchange

Applicability of solution: The Centers for Medicare & Medical Assistance Services, North Carolina General Assembly

Stakeholders affected (1 - 18):

1. Clinicians
2. Physician groups
3. Federal health facilities
4. Hospitals
5. Payers
7. Community clinics and health centers
8. Laboratories
10. Long term care facilities and nursing homes
12. Corrections facilities
13. Professional associations and societies
14. Medical; public health schools; research institutions
15. Quality improvement organizations
16. Consumers and consumer organizations
17. State government

18. Other regional health information organizations, Nationwide Health Information Network, American Clinical Laboratory Association, ONC

Privacy and security domains addressed (1 - 9):

Domains	
1. Authentication	
2. Authorization	X
3. Identity matching	
4. Transmission	
5. Integrity	
6. Event audit	
7. Safeguards	X
8. Data classification	X
9. Policies	X

Potential barriers / issues: Perception of increased risks to privacy. Determine scope of secondary uses of information.

States affected: All

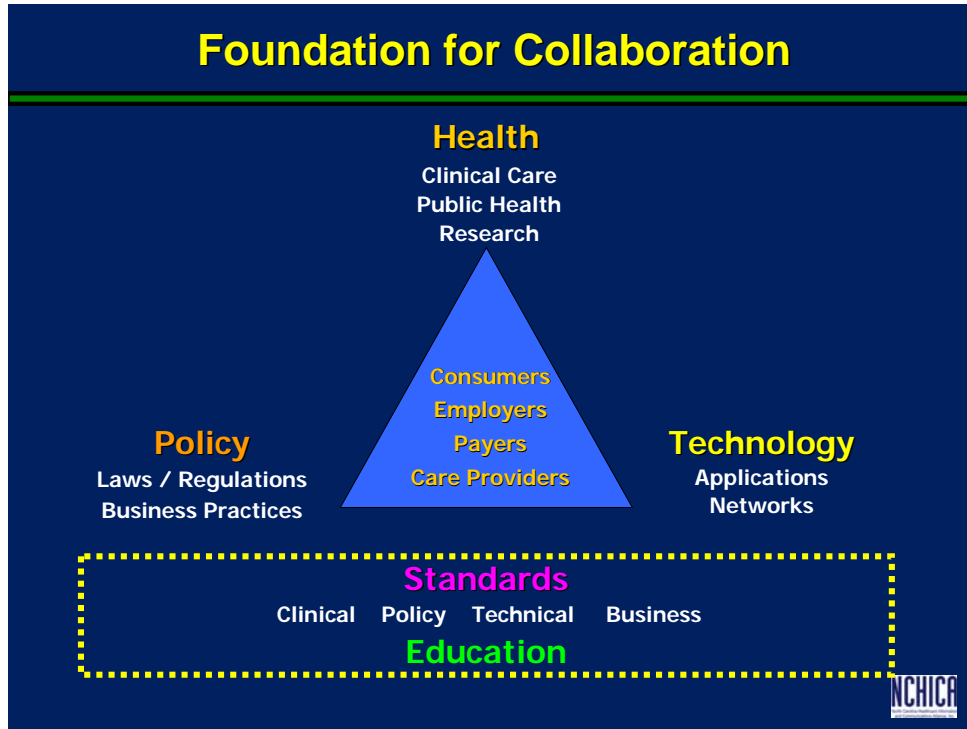
Conclusions and Next Steps

The NC HISPC Final Implementation Plan Report fulfills the final deliverable of Subcontract No. 37-321-0209825. The Final Implementation Plan Report proposes high-level steps for interested stakeholders to consider if they choose to implement the proposed solutions.

The HISPC project has convened a core group of North Carolina consumers and health care professionals from varying segments of the health care industry. The discussions within the VWG, LWG, SWG, Steering Committee, and Consumer Advisory Council meetings have generated interest to continue exploring the barriers to health information exchange and will consider implementing either the solutions proposed in this report or alternatives. The implementation challenge to the North Carolina stakeholders is that there is no State of North Carolina mandate or sponsorship to implement the solutions at this time.

The North Carolina stakeholders will consider the continuation of these collaborative efforts based on sound business decisions that meet their organizations' mission. The next steps for the North Carolina stakeholders will be to:

1. Raise awareness on the benefits of health information technology adoption.
2. Develop health information technology leadership development programs.
3. Develop strategies to engage the General Assembly in improved health, quality of care, and health information technology initiatives.
4. Cultivate the NC Consumer Advisory Council on Health Information.
5. Seek opportunities to participate in collaborative projects such as the ones proposed in this report.



To participate in the continuing efforts or to view more information on the NC HISPC efforts, please see the NCHICA site at: <http://www.nchica.org/NCHISPC/intro.htm>

Appendices

The North Carolina Consumer Advisory Council on Health Information Draft Budget

NC CACHI Annual Budget Draft

Expenses

	Estimated	Actual
Total Expenses	\$181,100.00	\$0.00

	Estimated	Actual
Program Development		
Consumer Awareness Projects (Person Oriented Health Information Exchange and Nationwide Health Information Network)	\$30,000.00	
Privacy Issues	\$20,000.00	
Focus Groups (2 @ 2500)	\$15,000.00	
	\$5,000.00	
Totals	\$70,000.00	\$0.00

	Estimated	Actual
Office and Utilities		
Office space	\$3,000.00	
Utilities	\$1,200.00	
Phone	\$3,000.00	
Totals	\$7,200.00	\$0.00

	Estimated	Actual
Travel Reimbursement		
Lodging	\$10,000.00	
Mileage	\$7,000.00	
Food	\$7,000.00	
Totals	\$24,000.00	\$0.00

	Estimated	Actual
Technology		
Copier	\$2,000.00	
Webex	\$2,000.00	
Computer Equipment	\$3,000.00	
Website	\$5,000.00	
Totals	\$12,000.00	\$0.00

	Estimated	Actual
Membership Development		
Stipends CAC (15)	\$18,000.00	
Publicity	\$2,400.00	
Totals	\$20,400.00	\$0.00

	Estimated	Actual
Labor		
PT Director (Optional)	\$25,000.00	
Administration staff	\$10,000.00	
Totals	\$35,000.00	\$0.00

	Estimated	Actual
General Administration		
Postage	\$2,000.00	
Supplies	\$5,000.00	
Printing	\$5,000.00	
Fax services	\$500.00	
Totals	\$12,500.00	\$0.00

Business Practice Data

As instructed, the business practices data have been uploaded to the Agency for Healthcare Research and Quality's HISPC portal.

Scenarios

Group 1 - Patient Care

1. Patient Care Scenario A

Patient X presents to emergency room of General Hospital in State A. She has been in a serious car accident. The patient is an 89 year old widow who appears very confused. Law enforcement personnel in the emergency room investigating the accident indicate that the patient was driving. There are questions concerning her possible impairment due to medications. Her adult daughter informed the ER staff that her mother has recently undergone treatment at a hospital in a neighboring state and has a prescription for an antipsychotic drug. The emergency room physician determines there is a need to obtain information about Patient X's prior diagnosis and treatment during the previous inpatient stay.

2. Patient Care Scenario B

An inpatient specialty substance abuse treatment facility intends to refer client X to a primary care facility for a suspected medical problem. The two organizations do not have a previous relationship. The client has a long history of using various drugs and alcohol that is relevant for medical diagnosis. The primary care provider has requested that the substance abuse information be sent by the treatment facility. The primary care provider intends to refer the patient to a specialist and plans to send all of the patient's medical information, including the substance abuse information that was received from the substance abuse treatment facility, to the specialist.

3. Patient Care - Scenario C

At 5:30pm Dr. X, a psychiatrist, arrives at the skilled nursing facility to evaluate his patient, recently discharged from the hospital psychiatric unit to the skilled nursing facility. The hospital and skilled nursing facility are separate entities and do not share electronic record systems. At the time of the patient's transfer, the discharge summary and other pertinent records and forms were electronically transmitted to the skilled nursing home.

When Dr. X enters the facility, he seeks assistance locating his patient, gaining entrance to the locked psychiatric unit, and accessing the patient's electronic health record to review the discharge summary, I&O, MAR and progress notes. Dr. X was able to enter the unit by showing a picture identification badge, but was not able to access the EHR. As it is Dr. X's first visit, he has no login or password to use their system.

Dr. X completes his visit and prepares to complete his documentation for the nursing home. Unable to access the skilled nursing facility EHR, Dr. X dictates his initial assessment via telephone to his outsourced, offshore transcription service. The assessment is transcribed and posted to a secure web portal.

The next morning, from his home computer, Dr. X checks his e-mail and receives notification that the assessment is available. Dr. X logs into his office web portal, reviews the assessment, and applies his electronic signature.

Later that day, Dr X's Office Manager downloads this assessment from the web portal, saves the document in the patient's record in his office and forwards the now encrypted document to the long-term care facility via e-mail.

The skilled nursing facility notifies Dr. X's office that they are unable to open the encrypted document because they do not have the encryption key.

4. Patient Care - Scenario D

Patient X is HIV positive and is having a complete physical and an outpatient mammogram done in the Women's Imaging Center of General Hospital in State A. She had her last physical and mammogram in an outpatient clinic in a neighboring state. Her physician in State A is requesting a copy of her complete records and the radiologist at General Hospital would like to review the digital images of the mammogram performed at the outpatient clinic in State B for comparison purposes. She also is having a test for the BrCa gene and is requesting the genetic test results of her deceased aunt who had a history of breast cancer.

Group 2 Payers and PBM

5. Payment Scenario

X Health Payer (third party, disability insurance, employee assistance programs) provides health insurance coverage to many subscribers in the region the healthcare provider serves. As part of the insurance coverage, it is necessary for the health plan case managers to approve/authorize all inpatient encounters. This requires access to the patient health information (e.g., emergency department records, clinic notes, etc.).

The health care provider has recently implemented an electronic health record (EHR) system. All patient information is now maintained in the EHR and is accessible to users who have been granted access through an approval process. Access to the EHR has been restricted to the healthcare provider's workforce members and medical staff members and their office staff

9. Pharmacy Benefit Scenario A

The Pharmacy Benefit Manager (PBM) has a mail order pharmacy for a hospital which is self-insured and also has a closed formulary. The PBM receives a prescription from Patient X, an employee of the hospital, for the antipsychotic medication Geodon. The PBM's preferred alternatives for antipsychotics are Risperidone (Risperdal), Quetiapine (Seroquel), and Aripiprazole (Abilify). Since Geodon is not on the preferred alternatives list, the PBM sends a request to the prescribing physician to complete a prior authorization in order to fill and pay for the Geodon prescription. The PBM is in a different state than the provider's Outpatient Clinic.

10. Pharmacy Benefit Scenario B

A Pharmacy Benefit Manager 1 (PBM1) has an agreement with Company A to review the companies' employees' prescription drug use and the associated costs of the drugs prescribed. The objective would be to see if the PBM1 could save the company money on their prescription drug benefit. Company A is self insured and as part of their current benefits package, they have the prescription drug claims submitted through their current PBM (PBM2). PBM1 has requested that Company A send their electronic claims to them to complete the review.

Group 3 - Secondary Use of Information

6. Regional Health Information Organization Scenario

The regional health information organization in your region wants to access patient identifiable data from all participating organizations (and their patients) to monitor the incidence and management of diabetic patients. The regional health information organization also intends to monitor participating providers to rank them for the provision of preventive services to their diabetic patients.

7. Research Data Use Scenario

A research project on children younger than age 13 is being conducted in a double blind study for a new drug for ADD/ADHD. The research is being sponsored by a major drug manufacturer conducting a double blind study approved by the medical center's IRB where the research investigators are located. The data

being collected is all electronic and all responses from the subjects are completed electronically on the same centralized and shared data base file.

The principle investigator was asked by one of the investigators if they could use the raw data to extend the tracking of the patients over an additional six months and/or use the raw data collected for a white paper that is not part of the research protocols final document for his post doctoral fellow program.

8. Scenario for access by law enforcement

An injured nineteen (19) year old college student is brought to the ER following an automobile accident. It is standard to run blood alcohol and drug screens. The police officer investigating the accident arrives in the ER claiming that the patient may have caused the accident. The patient's parents arrive shortly afterward. The police officer requests a copy of the blood alcohol test results and the parents want to review the ER record and lab results to see if their child tested positive for drugs. These requests to print directly from the electronic health record are made to the ER staff.

11. Healthcare Operations and Marketing - Scenario A

ABC Health Care is an integrated health delivery system comprised of ten critical access hospitals and one large tertiary hospital, DEF Medical Center, which has served as the system's primary referral center. Recently, DEF Medical Center has expanded its rehab services and created a state-of-the-art, stand-alone rehab center. Six months into operation, ABC Health Care does not feel that the rehab center is being fully utilized and is questioning the lack of rehab referrals from the critical access hospitals.

ABC Health Care has requested that its critical access hospitals submit monthly reports containing patient identifiable data to the system six-sigma team to analyze patient encounters and trends for the following rehab diagnoses/ procedures:

- Cerebrovascular Accident (CVA)
- Hip Fracture
- Total Joint Replacement

Additionally, ABC Health Care is requesting that this same information, along with individual patient demographic information, be provided to the system Marketing Department. The Marketing Department plans to distribute to these individuals a brochure highlighting the new rehab center and the enhanced services available.

12. Healthcare Operations and Marketing - Scenario B

ABC hospital has approximately 3,600 births/year. The hospital Marketing Department is requesting identifiable data on all deliveries including mother's demographic information and birth outcome (to ensure that contact is made only with those deliveries resulting in healthy live births).

The Marketing Department has explained that they will use the patient information for the following purposes:

1. To provide information on the hospital's new pediatric wing/services.
2. To solicit registration for the hospital's parenting classes.
3. To request donations for construction of the proposed neonatal intensive care unit
4. They will sell the data to a local diaper company to use in marketing diaper services directly to parents.

14. Employee Health Information Scenario

An employee (of any company) presents in the local emergency department for treatment of a chronic condition that has exacerbated which is not work-related. The employee's condition necessitates a four-day leave from work for illness. The employer requires a "return to work" document for any illness requiring more than 2 days leave. The hospital Emergency Department has an EHR and their practice is

to cut and paste patient information directly from the EHR and transmit the information via email to the Human Resources department of the patient's employer.

Group 4 State Government / Public Health

13. Bioterrorism event

A provider sees a person who has anthrax, as determined through lab tests. The lab submits a report on this case to the local public health department and notifies their organizational patient safety officer. The public health department in the adjacent county has been contacted and has confirmed that it is also seeing anthrax cases, and therefore this could be a possible bioterrorism event. Further investigation confirms that this is a bioterrorism event, and the State declares an emergency. This then shifts responsibility to a designated state authority to oversee and coordinate a response, and involves alerting law enforcement, hospitals, hazmat teams, and other partners, as well informing the regional media to alert the public to symptoms and seek treatment if feel affected. The State also notifies the Federal Government of the event, and some federal agencies may have direct involvement in the event. All parties may need to be notified of specific identifiable demographic and medical details of each case as they arise to identify the source of the anthrax, locate and prosecute the parties responsible for distributing the anthrax, and protect the public from further infection.

15. Public Health - Scenario A - Active carrier, communicable disease notification

A patient with active TB, still under treatment, has decided to move to a desert community that focuses on spiritual healing, without informing his physician. The TB is classified MDR (multi-drug resistant). The patient purchases a bus ticket - the bus ride will take a total of nine hours with two rest stops across several states. State A is made aware of the patient's intent two hours after the bus with the patient leaves. State A now needs to contact the bus company and other states with the relevant information.

16. Public Health - Scenario B -Newborn screening

A newborn's screening test comes up positive for a state-mandated screening test and the state lab test results are made available to the child's physicians and specialty care centers specializing in the disorder via an Interactive Voice Response (IVR) system. The state lab also enters the information in its registry, and tracks the child over time through the child's physicians. The state public health department provides services for this disorder and notifies the physician that the child is eligible for those programs.

17. Public Health Scenario C- Homeless shelters

A homeless man arrives at a county shelter and is found to be a drug addict and in need of medical care. The person does not have a primary care provider, and he is sent there for medical care. Primary care provider refers patient to a hospital-affiliated drug treatment clinic for his addiction under a county program. The addiction center must report treatment information back to the county for program reimbursement, and back to the shelter to verify that the person is in treatment. Someone claiming to be a relation of the homeless man requests information from the homeless shelter on all the health services the man has received. The staff at the homeless shelter is working to connect the homeless man with his relative.

18. Health Oversight: Legal compliance/government accountability

The Governor's office has expressed concern about compliance with immunization and lead screening requirements among low income children who do not receive consistent health care. The state agencies responsible for public health, child welfare and protective services, Medicaid services, and education are asked to share identifiable patient level health care data on an ongoing basis to determine if the children are getting the healthcare they need. This is not part of a legislative mandate. The Governor in this state and those in the surrounding states have discussed sharing this information to determine if patients migrate between states for these services. Because of the complexity of the task, the Governor has asked each agency to provide these data to faculty at the state university medical campus who will design a system for integrating and analyzing the data. There is not existing contract with the state university for services of this nature.

Stakeholder Involvement

Stakeholder Group	HISPC WORK GROUPS				OUTREACH TO STAKEHOLDERS		
	Steering Committee (X)	VWG (X)	LWG (X)	SWG (X)	Variations assessment (N)	Solutions Input (X)	Implementation Input (X)
Clinicians (1)	0	0	0	1	2	0	0
Physicians and Physicians Groups (2)	0	0	3	5	2	0	0
Federal Health Facilities (3)	0	0	0	0	0	0	0
Emergency Medicine							
Hospitals / Health Systems (4)	0	0	3	6	5	0	0
Community Clinics and Health Centers (7)	0	0	0	0	0	0	0
Mental Health and Behavioral Health							
Long Term Care Facilities and Nursing Homes (10)	0	0	0	0	0	0	0
Homecare and Hospice (11)	0	0	0	0	0	0	0
Laboratories (8)	1	0	3	1	3	0	0
Pharmacies / Pharmacy Benefit Managers (9)	0	0	0	2	1	0	0
Safety Net Providers							
Professional Associations and Societies (13)	7	0	2	0	4	0	0
Quality Improvement Organizations (15)	0	0	0	0	0	0	0

Medical and Public Health Schools / Research (14)	3	0	1	4	3	0	0
Public Health Agencies or Departments (6)	0	0	0	0	2	0	0
Medicaid / Other State Government (17)	4	1	3	4	4	0	0
County Government							
Regional Health Information Organizations							
Payers (5)	2	1	3	6	5	0	0
Individual Consumers and Consumer Organizations (16)	0	0	1	1	8	0	0
Consumer Organizations and Advocates							
Employers							
Law Enforcement and Correctional Facilities (12)	0	0	0	0	5	0	0
Legal Counsel / Attorneys							
Health Information Management organizations							
Privacy and Security experts / Compliance officers							
Health IT consultants							
Electronic Health Records experts							
Technology Organizations / Vendors							
Other (specify): _____ _____	3	1	5	2	0	0	0

Other (specify): Private practice attorneys					3		
Other (specify): IT Consultants					3		
Other (specify): Technology Vendors					3		
TOTAL NUMBER	20	3	24	32	53	0	0

NC HISPC Solutions and Implementation Worksheet

Instructions:

The purpose of this worksheet is to develop a high level implementation plan to the solutions we have already recommended. Please complete the areas highlighted and return to **me no later than 3/9/07** to be included in the Final Implementation Report.

Please ensure that your comments are:

1. Directly related to the health information exchange barriers addressed
 - BR_1. Range within organizations of misinterpretation and/or application of laws or regulation
 - BR_2. Lack of business incentives to exchange information
 - BR_3. Lack of policy standardization across entities
 - BR_4. Lack of security standardization across entities
 - BR_5. Lack of interoperability between processes and technology
 - BR_6. Lack of workable technology
 - BR_7. Conflicting or outdated federal or state laws or regulations.
 - BR_8a. Lack consumer input into the design of policy and technology
 - BR_8b. Lack of definition of consumer empowerment and methodology to its inclusion in policy and systems design

2. Directly related to the proposed solutions
 - SOL_1. Establish a pilot project with adequate funding to explore the concept of the Person-Oriented health information exchange.
 - SOL_2. Implement policy standards, such as model policy and legislation, to address the complexity and ambiguity surrounding the release of information.
 - SOL_2a. Implement security standards to address the complexity and ambiguity surrounding the safeguarding of health information.
 - SOL_3. Implement sound business models to encourage potential information sharing partners to participate in community based health information exchange.
 - SOL_4. Encourage greater collaboration between policy makers, subject matter and technical experts to adopt health information exchange requirements.
 - SOL_5. Explore the dependencies between the business processes and their technical components for the purpose of interoperability.
 - SOL_6. Address the misinterpretation of laws or regulations by obtaining clarification and developing public and private awareness programs.
 - SOL_7. Amend conflicting Federal or State laws.
 - SOL_8. Develop programs to raise awareness on the risks, benefits, and impacts of health information technology to a cross-section of consumers

3. Can interface with Nationwide Health Information Network

Background: Write short description of the issue. 2 - 3 paragraphs

Solution: Write short paragraph describing your solution.

Rationale for Solution: Explain how your solution will reduce or eliminate the barrier.

Phase of development:

What stage is this solution currently in?

1. Concept / exploration (3 - 12 months)
2. Feasibility / planning (3 - 12 months)
3. Demonstration / validation (6 - 12 months)
4. Implementation (6 - 24 months)
5. Operations / maintenance (3 months - ongoing)

Implementation plan: List the basic high level steps to implement this solution.

Key Opportunity / Resources: List potential persons or organizations that may plan and implement the solution.

Implementation support: high, medium, low

Anticipated costs: Please include estimate of cost to implement this solution among the HISPC stakeholders.

Funding sources: Private / Public sources

Length of implementation: Include an estimate of summing up the Phases of Development.

Implementation complexity: high, medium, low

Health Information Exchange barrier(s) addressed: Write a short paragraph describing the barrier you are addressing.

Health Information Exchange type: 1. Direct Patient Care; 2. Payer; 3. Secondary Use: Operations, Marketing, Research, Law Enforcement; 4. State Government / Public Health

Health Information Exchange models affected: 1. Entity to Entity; 2. Person-Oriented Health Information Exchange

Applicability of solution: Identify organization types this solution applies to.

Stakeholders affected (1 - 18): Remove the HISPC stakeholders who are not affected by this solution.

1. Clinicians
2. Physician groups
3. Federal health facilities
4. Hospitals
5. Payers
6. Public health agencies
7. Community clinics and health centers
8. Laboratories
9. Pharmacies
10. Long term care facilities and nursing homes
11. Homecare and hospice
12. Corrections facilities
13. Professional associations and societies

- 14. Medical; public health schools; research institutions
- 15. Quality improvement organizations
- 16. Consumers and consumer organizations
- 17. State government
- 18. Other (Specify)

Privacy and security domains addressed (1 - 9):

Domains	
1. Authentication	X
2. Authorization	X
3. Identity matching	X
4. Transmission	X
5. Integrity	X
6. Event audit	X
7. Safeguards	X
8. Data classification	X
9. Policies	X

Potential barriers / issues:

Please predict possible objections. 2 - 3 short phrases.

States affected: North Carolina

The HISPC Domains of Privacy and Security

RTI supplied the NC HISPC team with a set of domains to consider as the SWG and LWG considered solutions. This set of domains is derived from standard information security principles. Domains 1 - 6 are relevant to organizations that have implemented electronic health information systems. Due to the limited amount of implemented technology among the interviewees, most of the barriers that were identified centered around domains 7 - 9.

1. User and entity authentication to verify that a person or entity seeking access to electronic personal health information is who they claim to be.
2. Information authorization and access controls to allow access only to people or software programs that have been granted access rights to electronic personal health information.
3. Patient and provider identification to match identities across multiple information systems and locate electronic personal health information across enterprises.
4. Information transmission security or exchange protocols (*i.e.*, encryption, etc.) for information that is being exchanged over an electronic communications network.
5. Information protections so that electronic personal health information cannot be improperly modified.
6. Information audits that record and monitor the activity of health information systems.
7. Administrative or physical security safeguards required to implement a comprehensive security platform for health IT.
8. State law restrictions about information types and classes, and the solutions by which electronic personal health information can be viewed and exchanged.
9. Information use and disclosure policies that arise as health care entities share clinical health information electronically.

Related NC Legal Drivers

NCGS § 90-21.13(a). Informed Consent.

If patient is not capable, NCGS § 90-21.13(a) allows for consent by the patient's spouse, parent, guardian, nearest relative, or other person authorized to give consent. Consent provision may be able to be bypassed pursuant to the emergency exception (NCGS § 90-21.13(a)(3)), which applies when the delay necessary to obtain consent would be dangerous to the patient and the emergency is such that "a reasonable person, under all the circumstances, would have undergone such treatment had he been advised by the healthcare provider."

NCGS § 8-53. Communications between physician and patient.

"No person, duly authorized to practice physic or surgery, shall be required to disclose any information which he may have acquired in attending a patient in a professional character, and which information was necessary to enable him to prescribe for such patient as a physician, or to do any act for him as a surgeon, and no such information shall be considered public records under G.S. 132-1. Confidential information obtained in medical records shall be furnished only on the authorization of the patient, or if deceased, the executor, administrator, or, in the case of unadministered estates, the next of kin. Any resident or presiding judge in the district, either at the trial or prior thereto, or the Industrial Commission pursuant to law may, subject to G.S. 8-53.6, compel disclosure if in his opinion disclosure is necessary to a proper administration of justice. If the case is in district court the judge shall be a district court judge, and if the case is in superior court the judge shall be a superior court judge." (1885, c. 159; Rev., s. 1621; C.S., s. 1798; 1969, c. 914; 1977, c. 1118; 1983, c. 410, ss. 1, 2; c. 471.)"

NCGS § 122C-55(d) and (e). Mental Health Information.

Pursuant to NCGS 122C-55(d) and (e), a mental healthcare provider may release mental health information about patient (i) where there is an imminent danger to the patient's health or safety, or (ii) to a physician providing emergency services to the patient.

NCGS § 130A-148. HIV Confidentiality. "A test for AIDS virus infection may also be performed upon any person solely by order of a physician licensed to practice medicine in North Carolina who is rendering medical services to that person when, in the reasonable medical judgment of the physician, the test is necessary for the appropriate treatment of the person; however, the person shall be informed that a test for AIDS virus infection is to be conducted, and shall be given clear opportunity to refuse to submit to the test prior to it being conducted, and further if informed consent is not obtained, the test may not be performed. A physician may order a test for AIDS virus infection without the informed consent of the person tested if the person is incapable of providing or incompetent to provide such consent, others authorized to give consent for the person are not available, and testing is necessary for appropriate diagnosis or care of the person."

NCGS § 58-3-215. Genetic Information and Health Insurance. "For the purpose of this report, routine physical measurements, blood chemistries, blood counts, urine analyses, tests for abuse of drugs, and tests for the presence of human immunodeficiency virus are not to be considered genetic tests. . . .

(c) No insurer shall:

(1) Raise the premium or contribution rates paid by a group for a group health benefit plan on the basis of genetic information obtained about an individual member of the group.

(2) Refuse to issue or deliver a health benefit plan because of genetic information obtained about any person to be insured by the health benefit plan.

(3) Charge a higher premium rate or charge for a health benefit plan because of genetic information obtained about any person to be insured by the health benefit plan."

NCGS § 95-28.1A. Discrimination against persons based on genetic testing or genetic information prohibited.

“(a) No person, firm, corporation, unincorporated association, State agency, unit of local government, or any public or private entity shall deny or refuse employment to any person or discharge any person from employment on account of the person's having requested genetic testing or counseling services, or on the basis of genetic information obtained concerning the person or a member of the person's family. This section shall not be construed to prevent the person from being discharged for cause.

(b) As used in this section, the term "genetic test" means a test for determining the presence or absence of genetic characteristics in an individual or a member of the individual's family in order to diagnose a genetic condition or characteristic or ascertain susceptibility to a genetic condition. The term "genetic characteristic" means any scientifically or medically identifiable genes or chromosomes, or alterations or products thereof, which are known individually or in combination with other characteristics to be a cause of a disease or disorder, or determined to be associated with a statistically increased risk of development of a disease or disorder, and which are asymptomatic of any disease or disorder. The term "genetic information" means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member.”

NCGS § 90-401. Referral fees and payment for certain solicitations prohibited.

“A healthcare provider shall not financially compensate in any manner a person, firm, or corporation for recommending or securing the healthcare provider's employment by a patient, or as a reward for having made a recommendation resulting in the healthcare provider's employment by a patient. No healthcare provider who refers a patient of that healthcare provider to another healthcare provider shall receive financial or other compensation from the healthcare provider receiving the referral as a payment solely or primarily for the referral. This section shall not be construed to prohibit a healthcare provider's purchase of advertising which does not entail direct personal contact or telephone contact of a potential patient.”

NCGS § 130A -131.8. Report of blood levels in children. “All laboratories doing business in this State shall report to the Department all blood lead test results for children less than six years of age and for individuals whose ages are unknown at the time of testing. Reports shall be made within five working days after test completion on forms provided by the Department or on self-generated forms containing: the child's full name, date of birth, sex, race, address, and Medicaid number, if any; the name, address, and telephone number of the requesting healthcare provider; the name, address, and telephone number of the testing laboratory; the laboratory results, the specimen type — venous or capillary; the laboratory sample number, and the dates the sample was collected and analyzed. The reports may be made by electronic submissions.”

NCGS § 130A - 131.17. Confidentiality of Information; Research.“(a) All information collected and analyzed by the Program pursuant to this Part shall be confidential insofar as the identity of the individual patient is concerned. This information shall not be considered public record open to inspection. Access to the information shall be limited to Program staff authorized by the Director of the State Center for Health and Environmental Statistics. The Director of the State Center for Health and Environmental Statistics may also authorize access to this information to persons engaged in demographic, epidemiological, or other similar scientific studies related to health. The Commission shall adopt rules that establish strict criteria for the use of monitoring Program information for scientific research. All persons given authorized access to Program information shall agree, in writing, to maintain confidentiality.

(b) All scientific research proposed to be conducted by persons other than authorized Program staff using the information from the Program, shall first be reviewed and approved by the Director of the State Center for Health and Environmental Statistics and an appropriate committee for the protection of human subjects which is approved by the United States Department of Health and Human Services pursuant to Part 46 of Title 45 of the Code of Federal Regulations. Satisfaction of the terms of the Commission's rules for data access shall entitle the researcher to obtain information from the Program and, if part of the research protocol, to contact case subjects.

(c) Whenever authorized Program staff propose a research protocol that includes contacting case subjects, the Director of the State Center for Health and Environmental Statistics shall submit a protocol describing the research to the State Health Director and to an appropriate committee for the protection of human subjects which is approved by the United States Department of Health and Human Services pursuant to Part 46 of Title 45 of the Code of Federal Regulations. If and when the protocol is approved by the committee and by the State Health Director pursuant to the rules of the Commission, then Program staff shall be entitled to complete the approved project and to contact case subjects.

(d) The Program shall maintain a record of all persons who are given access to the information in the system. The record shall include the following:

- (1) The name of the person authorizing access;
- (2) The name, title, and organizational affiliation of persons given access;
- (3) The dates of access; and
- (4) The specific purposes for which information is to be used.

The record required under this subsection shall be open to public inspection during normal operating hours.

(e) Nothing in this section prohibits the Program from publishing statistical compilations relating to birth defects that do not in any way identify individual patients.”

NCGS § 130A - 152. Immunization Required.“(a) Every child present in this State shall be immunized against diphtheria, tetanus, whooping cough, poliomyelitis, red measles (rubeola) and rubella. In addition, every child present in this State shall be immunized against any other disease upon a determination by the Commission that the immunization is in the interest of the public health. Every parent, guardian, person in loco parentis and person or agency, whether governmental or private, with legal custody of a child shall have the responsibility to ensure that the child has received the required immunization at the age required by the Commission. If a child has not received the required immunizations by the specified age, the responsible person shall obtain the required immunization for the child as soon as possible after the lack of the required immunization is determined.

(b) Repealed by Session Laws 2002-179, s. 10, effective October 1, 2002.

(c) The Commission shall adopt and the Department shall enforce rules concerning the implementation of the immunization program. The rules shall provide for:

- (1) The child's age at administration of each vaccine;
- (2) The number of doses of each vaccine;
- (3) Exemptions from the immunization requirements where medical practice suggests that immunization would not be in the best health interests of a specific category of children;
- (4) The procedures and practices for administering the vaccine; and
- (5) Redistribution of vaccines provided to local health departments.

(c1) The Commission for Health Services shall, pursuant to G.S. 130A-152

and G.S. 130A-433, adopt rules establishing reasonable fees for the administration of vaccines and rules limiting the requirements that can be placed on children, their parents, guardians, or custodians as a condition for receiving vaccines provided by the State. These rules shall become effective January 1, 1994.

(d) Only vaccine preparations which meet the standards of the United States Food and Drug Administration or its successor in licensing vaccines and are approved for use by the Commission may be used.

(e) When the Commission requires immunization against a disease not listed in paragraph (a) of this section, or requires an additional dose of a vaccine, the Commission is authorized to exempt from the new requirement children who are or who have been enrolled in school (K-12) on or before the effective date of the new requirement.”

NCGS § 130A - 153. Obtaining immunization; reporting by local health departments; access to immunization information in patient records; immunization of minors.“(a) The required immunization may be obtained from a physician licensed to practice medicine or from a local health department. Local health departments shall administer required and State-supplied immunizations at no cost to the patient. The Department shall provide the vaccines for use by the local health departments. A local health department may redistribute these vaccines only in accordance with the rules of the Commission.

(b) Local health departments shall file monthly immunization reports with the Department. The report shall be filed on forms prepared by the Department and shall state, at a minimum, each patient's age and the number of doses of each type of vaccine administered.

(c) Immunization certificates and information concerning immunizations contained in medical or other records shall, upon request, be shared with the Department, local health departments, and the patient's attending physician. In addition, an insurance institution, agent, or insurance support organization, as those terms are defined in G.S. 58-39-15, may share immunization information with the Department. The Commission may, for the purpose of assisting the Department in enforcing this Part, provide by rule that other persons may have access to immunization information, in whole or in part.

(d) A physician or local health department may immunize a minor with the consent of a parent, guardian, or person standing in loco parentis to the minor. A physician or local health department may also immunize a minor who is presented for immunization by an adult who signs a statement that he or she is authorized by a parent, guardian, or person standing in loco parentis to the minor to obtain the immunization for the minor.”

NCGS § 130A-155. Submission of certificate to child care facility, preschool and school authorities; record maintenance; reporting.“(a) No child shall attend a school (pre K-12), whether public, private or religious, a child care facility as defined in G.S. 110-86(3), unless a certificate of immunization indicating that the child has received the immunizations required by G.S. 130A-152 is presented to the school or facility. The parent, guardian, or responsible person must present a certificate of immunization on the child's first day of attendance to the principal of the school or operator of the facility, as defined in G.S. 110-86(7). If a certificate of immunization is not presented on the first day, the principal or operator shall present a notice of deficiency to the parent, guardian or responsible person. The parent, guardian or responsible person shall have 30 calendar days from the first day of attendance to obtain the required immunization for the child. If the administration of vaccine in a series of doses given at medically approved intervals requires a period in excess of 30 calendar days, additional days upon certification by a physician may be allowed to obtain the required immunization. Upon termination of 30 calendar days or the extended period, the principal or operator shall not permit the child to attend the school or facility unless the required immunization has been obtained.

(b) The school or child care facility shall maintain on file immunization records for all children attending the school or facility which contain the information required for a certificate of immunization as specified in G.S. 130A-154. These certificates shall be open to inspection by the Department and the local health department during normal business hours. When a child transfers to another school or facility, the school or facility which the child previously attended shall, upon request, send a copy of the child's immunization record at no charge to the school or facility to which the child has transferred.

(c) Within 60 calendar days after the commencement of a new school year, the school shall file an immunization report with the Department. The child care facility shall file an immunization report annually with the Department. The report shall be filed on forms prepared by the Department and shall state the number of children attending the school or facility, the number of children who had not obtained the required immunization within 30 days of their first attendance, the number of children who received a medical exemption and the number of children who received a religious exemption.

(d) Any adult who attends school (pre K-12), whether public, private or religious, shall obtain the immunizations required in G.S. 130A-152 and shall present to the school a certificate in accordance with this section. The physician or local health department administering a required vaccine to the adult shall give a certificate of immunization to the person. The certificate shall state the person's name, address, date of birth and sex; the number of doses of the vaccine given; the date the doses were given; the name and addresses of the physician or local health department administering the required immunization; and other relevant information required by the Commission."

NCGS § 130A - 441. Reporting. "(a) Health assessment results shall be submitted to the school principal by the medical provider on health assessment transmittal forms developed by the Department and the Department of Public Instruction.

(b) Each school having a kindergarten shall maintain on file the health assessment results. The files shall be open to inspection by the Department, the Department of Public Instruction, or their authorized representatives and persons inspecting the files shall maintain the confidentiality of the files. Upon transfer of a child to another kindergarten, a copy of the health assessment results shall be provided upon request and without charge to the new kindergarten.

(c) Within 60 calendar days after the commencement of a new school year, the principal shall file a health assessment status report with the Department on forms developed by the Department and the Department of Public Instruction. The report shall document the number of children in compliance and not in compliance with G.S. 130A-440(a)."

NCGS § 143B - 147. Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services — creation, powers and duties (Child Welfare and Protective Services)."(a) There is hereby created the Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services of the Department of Health and Human Services with the power and duty to adopt, amend and repeal rules to be followed in the conduct of State and local mental health, developmental disabilities, substance abuse programs including education, prevention, intervention, screening, assessment, referral, detoxification, treatment, rehabilitation, continuing care, emergency services, case management, and other related services. Such rules shall be designed to promote the amelioration or elimination of the mental illness, developmental disabilities, or substance abuse problems of the citizens of this State. The Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services shall have the authority:

(1) To adopt rules regarding the a. Admission, including the designation of regions, treatment, and professional care of individuals admitted to a facility operated under the authority of G.S. 122C-181(a), that is now or may be established;

b. Operation of education, prevention, intervention, treatment, rehabilitation and other related services as provided by area mental health, developmental disabilities, and substance abuse authorities, county

programs, and all providers of public services under Part 4 of Article 4 of Chapter 122C of the General Statutes;

c. Hearings and appeals of area mental health, developmental disabilities, and substance abuse authorities as provided for in Part 4 of Article 4 of Chapter 122C of the General Statutes; and

d and e. Repealed by Session Laws 2001-437, s. 1.21(a), effective July 1, 2002.

f. Standards of public services for mental health, developmental disabilities, and substance abuse services.

(2) To adopt rules for the licensing of facilities for the mentally ill, developmentally disabled, and substance abusers, under Article 2 of Chapter 122C of the General Statutes.

(3) To advise the Secretary of the Department of Health and Human Services regarding the need for, provision and coordination of education, prevention, intervention, treatment, rehabilitation and other related services in the areas of:

a. Mental illness and mental health,

b. Developmental disabilities,

c. Substance abuse.

d. Repealed by Session Laws 2001-437, s. 1.21(a), effective July 1, 2002.

(4) To review and advise the Secretary of the Department of Health and Human Services regarding all State plans required by federal or State law and to recommend to the Secretary any changes it thinks necessary in those plans; provided, however, for the purposes of meeting State plan requirements under federal or State law, the Department of Health and Human Services is designated as the single State agency responsible for administration of plans involving mental health, developmental disabilities, and substance abuse services.

(5) To adopt rules relating to the registration and control of the manufacture, distribution, security, and dispensing of controlled substances as provided by G.S. 90-100.

(6) To adopt rules to establish the professional requirements for staff of licensed facilities for the mentally ill, developmentally disabled, and substance abusers. Such rules may require that one or more, but not all staff of a facility be either licensed or certified. If a facility has only one professional staff, such rules may require that that individual be licensed or certified. Such rules may include the recognition of professional certification boards for those professions not licensed or certified under other provisions of the General Statutes provided that the professional certification board evaluates applicants on a basis which protects the public health, safety or welfare.

(7) Except where rule making authority is assigned under that Article to the Secretary of the Department of Health and Human Services, to adopt rules to implement Article 3 of Chapter 122C of the General Statutes.

(8) To adopt rules specifying procedures for waiver of rules adopted by the Commission.

(9) To adopt rules establishing a process for non-Medicaid eligible clients to appeal to the Division of Mental Health, Developmental Disabilities, and Substance Abuse Services of the Department of Health and Human Services decisions made by an area authority or county program affecting the client. The purpose of the appeal process is to ensure that mental health, developmental disabilities, and substance abuse services are delivered within available resources, to provide an additional level of review

independent of the area authority or county program to ensure appropriate application of and compliance with applicable statutes and rules, and to provide additional opportunities for the area authority or county program to resolve the underlying complaint. Upon receipt of a written request by the non-Medicaid eligible client, the Division shall review the decision of the area authority or county program and shall advise the requesting client and the area authority or county program as to the Division's findings and the bases therefore. Notwithstanding Chapter 150B of the General Statutes, the Division's findings are not a final agency decision for purposes of that Chapter. Upon receipt of the Division's findings, the area authority or county program shall issue a final decision based on those findings. Nothing in this subdivision shall be construed to create an entitlement to mental health, developmental disabilities, and substance abuse services.

(b) All rules hereby adopted shall be consistent with the laws of this State and not inconsistent with the management responsibilities of the Secretary of the Department of Health and Human Services provided by this Chapter and the Executive Organization Act of 1973.

(c) All rules and regulations pertaining to the delivery of services and licensing of facilities heretofore adopted by the Commission for Mental Health and Mental Retardation Services, controlled substances rules and regulations adopted by the North Carolina Drug Commission, and all rules and regulations adopted by the Commission for Mental Health, Mental Retardation and Substance Abuse Services shall remain in full force and effect unless and until repealed or superseded by action of the Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services.

(d) All rules adopted by the Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services shall be enforced by the Department of Health and Human Services."

NCGS § 90-109.1 - "(a) A person may request treatment and rehabilitation for drug dependence from a practitioner, and such practitioner or employees thereof shall not disclose the name of such person to any law-enforcement officer or agency; nor shall such information be admissible as evidence in any court, grand jury, or administrative proceeding unless authorized by the person seeking treatment. A practitioner may undertake the treatment and rehabilitation of such person or refer such person to another practitioner for such purpose and under the same requirement of confidentiality.

(b) An individual who requests treatment or rehabilitation for drug dependence in a program where medical services are to be an integral component of his treatment shall be examined and evaluated by a practitioner before receiving treatment and rehabilitation services. If a practitioner performs an initial examination and evaluation, the practitioner shall prescribe a proper course of treatment and medication, if needed. That practitioner may authorize another practitioner to provide the prescribed treatment and rehabilitation services.

(c) Every practitioner that provides treatment or rehabilitation services to a person dependent upon drugs shall periodically as required by the Secretary of the North Carolina Department of Health and Human Services commencing January 1, 1972, make a statistical report to the Secretary of the North Carolina Department of Health and Human Services in such form and manner as the Secretary shall prescribe for each such person treated or to whom rehabilitation services were provided. The form of the report prescribed shall be furnished by the Secretary of the North Carolina Department of Health and Human Services. Such report shall include the number of persons treated or to whom rehabilitation services were provided; the county of such person's legal residence; the age of such person; the number of such persons treated as inpatients and the number treated as outpatients; the number treated who had received previous treatment or rehabilitation services; and any other data required by the Secretary. If treatment or rehabilitation services are provided to a person by a hospital, public agency, or drug treatment facility, such hospital, public agency, or drug treatment facility shall coordinate with the treating medical practitioner so that statistical reports required in this section shall not duplicate one another. The Secretary shall cause all such reports to be compiled into periodical reports which shall be a public record."

NCGS § 131E-67. Specialty Hospitals. “All functions, powers, duties, and obligations heretofore vested in the Board of Directors of the North Carolina Specialty Hospitals and Eastern North Carolina Hospital are hereby transferred to and vested in the Department. All appropriations heretofore made to such Board of Directors or to any of the hospitals are hereby transferred to the Department. The Secretary of the Department shall have the power and duty to adopt rules for the operation of these facilities.”

NCGS § 90-21.20B. Access to medical information for law enforcement purposes.

“(a) Notwithstanding any other provision of law, if a person is involved in a vehicle crash:

- (1) Any healthcare provider who is providing medical treatment to the person shall, upon request, disclose to any law enforcement officer investigating the crash the following information about the person: name, current location, and whether the person appears to be impaired by alcohol, drugs, or another substance.
- (2) Law enforcement officers shall be provided access to visit and interview the person upon request, except when the healthcare provider requests temporary privacy for medical reasons.
- (3) A healthcare provider shall disclose a certified copy of all identifiable health information related to that person as specified in a search warrant or an order issued by a judicial official.

(b) A prosecutor or law enforcement officer receiving identifiable health information under this section shall not disclose this information to others except as necessary to the investigation or otherwise allowed by law.

(c) A certified copy of identifiable health information, if relevant, shall be admissible in any hearing or trial without further authentication.

(d) As used in this section, "healthcare provider" has the same meaning as in G.S. 90-21.11."

Related Federal Legal Drivers

45 CFR § 164.506. HIPAA: Consent for Treatment, Payment and Operations.

“(2) A covered healthcare provider may, without consent, use or disclose protected health information to carry out treatment, payment, or healthcare operations, if:

- (i) The covered healthcare provider has an indirect treatment relationship with the individual; or
- (ii) The covered healthcare provider created or received the protected health information in the course of providing healthcare to an individual who is an inmate.

(3)(i) A covered healthcare provider may, without prior consent, use or disclose protected health information created or received under paragraph (a)(3)(i)(A)-(C) of this section to carry out treatment, payment, or healthcare operations:

- (A) In emergency treatment situations, if the covered healthcare provider attempts to obtain such consent as soon as reasonably practicable after the delivery of such treatment;
- (B) If the covered healthcare provider is required by law to treat the individual, and the covered healthcare provider attempts to obtain such consent but is unable to obtain such consent; or
- (C) If a covered healthcare provider attempts to obtain such consent from the individual but is unable to obtain such consent due to substantial barriers to communicating with the individual, and the covered healthcare provider determines, in the exercise of professional judgment, that the individual's consent to receive treatment is clearly inferred from the circumstances.

(ii) A covered healthcare provider that fails to obtain such consent in accordance with paragraph (a)(3)(i) of this section must document its attempt to obtain consent and the reason why consent was not obtained.

(4) If a covered entity is not required to obtain consent by paragraph (a)(1) of this section, it may obtain an individual's consent for the covered entity's own use or disclosure of protected health information to carry out treatment, payment, or healthcare operations, provided that such consent meets the requirements of this section.

(5) Except as provided in paragraph (f)(1) of this section, a consent obtained by a covered entity under this section is not effective to permit another covered entity to use or disclose protected health information.”

45 CFR § 164.514 (h)(1). Verification of Identity and Authority of Persons Requesting PHI.

“(i) Except with respect to disclosures under § 164.510, verify the identity of a person requesting protected health information and the authority of any such person to have access to protected health information under this subpart, if the identity or any such authority of such person is not known to the covered entity; and

(ii) Obtain any documentation, statements, or representations, whether oral or written, from the person requesting the protected health information when such documentation, statement, or representation is a condition of the disclosure under this subpart.”

45 CFR § 164.510. Uses and disclosures requiring an opportunity for the individual to agree or to object.

CLIA 42CFR § 493.1291(f) Test results must be released only to **authorized persons** and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test.

CLIA 42 CFR § 493.2 “Authorized person” means an individual authorized under State law to order tests or receive test results, or both.

NC HISPC Reference Library

The NC HISPC team found the following websites and documents to be insightful.

Federal Health Information Technology Sites

US Department of Health and Human Services
<http://www.hhs.gov/healthit/>

Office of the National Coordinator on Health Information Technology

American Health Information Community
<http://www.hhs.gov/healthit/community/background/>

Privacy and Security

HIPAA
<http://www.cms.hhs.gov/HIPAAGenInfo/>

Healthcare Information and Management Systems Society HIPAA Compliance Survey
<http://www.hipaadvisory.com/action/surveynew/results/summer2006.htm>

North Carolina General Statutes
<http://www.ncleg.net/gascritps/Statutes/StatutesTOC.pl>

Community Health Information Exchanges, Regional Health Information Organizations

E Health Initiative
<http://www.ehealthinitiative.org/>

Nationwide Health Information Network

US Department of Health and Human Services Nationwide Health Information Network
<http://www.hhs.gov/healthit/healthnetwork/>

Nationwide Health Information Network Watch
<http://nhinwatch.com/>

Personal Health Records

Markle Foundation Report on Consumers and PHR
http://www.connectingforhealth.org/resources/phwg_survey.pdf

NCHICA Members

Advanced Home Care
Alamance Regional Medical Center
AMTELCO/1Call Healthcare
Appalachian Regional Healthcare System
Appalachian State University
Argosy Omnimedia, Inc.
ARINC
AT&T
Austin-CMS, LLC
Authentidate
Bailey & Dixon, LLP
bcc: Consulting
Beaufort County Hospital
Blue Cross and Blue Shield of NC
Blue Ridge Healthcare
Blue Wave Labs
Boice-Willis Clinic
Buncombe County Health Center
Cabarrus Family Medicine, PA
Calence, LLC
Cannoy, Sherrie
Cansler Fuquay Solutions, Inc.
Cape Fear Valley Health System
Carol Woods Retirement Community
Carolina Cardiology Associates
Carolina Eye Associates, PA
Carolina Renal Care, Inc.
Carolinas Center for Medical Excellence
(formerly MRNC)
Carolinas HealthCare System
Carteret General Hospital
Catawba County Health Department
Catawba Valley Medical Center
Cato Research Ltd.
CCA Medical
Chatham Hospital
CIGNA Corporation
Cisco Systems, Inc.
Clinipace, Inc.
CMS, Region IV
Columbus County Government
Columbus Regional Healthcare System
Computer Service Partners
Concerto Networks
Confidant
County of Fairfax
Covisint (formerly ProviderLink)
Craven Regional Medical Center
CrossCurrent, Inc.
Crutchfield, Trisha
CTG HealthCare Solutions
DataFlux
Dell, Inc.
Design Research, Inc.
Dixon Hughes
Doshier Memorial Hospital
DrFirst
Duke University Health System
Eastern AHEC
Eastern Carolina Internal Medicine
ECU Brody School of Medicine
Edifecs
EDS
Edward B. Ermini MD, PA
eHealth Ohio
EI, Inc. (USA)
Empire State Medical Scientific & Educational
Foundation
e-NC Authority
Evigi Technologies
Fazzino Consulting Services
FirstHealth of the Carolinas
Florida Department of Elder Affairs
Foothills IT Solutions, LLC
Foresight Corporation
Gamewood, Inc.
GlaxoSmithKline
Granville Medical Center
Greensboro Pathology Associates, P.A.
Halifax Regional Medical Center
Haywood Regional Medical Center
Healthcare Business Associates
Henderson County
High Point Regional Health System
HIMformatics
HIPAA Collaborative of Wisconsin
HITS
Hutchison Law Group PLLC
IBM Corporation
Ingemi, Joseph
Initiate Systems, Inc.
Internetwork Engineering
Iredell County Health Department
John C. Parmigiani & Associates, LLC
Kennedy Covington Lobdell & Hickman, LLP
Kentucky Governor's Office of Technology
Kirby Information Management Consulting
Laboratory Corporation of America Holdings
(LabCorp)
Lenoir Memorial Hospital
Madden, John
Marquardt, Daniel
Maryland Health Care Commission
Massey, Nina
MedCost, LLC
MercuryMD, Inc.

Mi-Co
Misys Healthcare Systems
Morehead Memorial Hospital
Moses Cone Health Systems
Mountain AHEC
Nanticoke Health Services, Inc.
Nash Health Care System
National Power Corporation
NC Area Health Education Centers
NC Association of Free Clinics
NC Association of Local Health Directors
NC Association of Pharmacists
NC College of Emergency Physicians
NC Department of Justice
NC DHHS Division of Facility Services
NC DHHS Division of Information Resource
Mgmt
NC DHHS Division of Medical Assistance
NC DHHS Division of MH/DD/SAS
NC DHHS Division of Public Health
NC DHHS Office of the Secretary
NC Health Information Management Association
NC Medical Group Managers
NC Medical Society
NC Nurses Association
NC Office of Information Technology Services
NC Office of MMIS Services
NC Office of Research, Demonstrations & Rural
Health Development
NC Office of the Governor
NC Psychiatric Association
NC Psychological Association
NC State Health Plan
NCHA
New Hanover Regional Medical Center
North Carolina Board of Pharmacy
North Carolina Healthcare Information and
Communications Alliance, Inc.
Northern Arizona Regional Behavioral Health
Authority
Novant Health System
NWN Corporation
Peak 10, Inc.
Person County Health Department
Person Memorial Hospital
Physicians EHR, LLC
Pitt County Memorial Hospital
Poyner & Spruill LLP
Prematics, Inc.
Princeton Community Hospital
ProActive Networks & Security
Proventys
Quintiles Transnational Corporation
RadarFind Corporation
Religent, Inc.
Rex Healthcare, Inc.
Robeson County Health Department
RTI International
Rural Health Group, Inc.
Rutherford Hospital, Inc.
RxHub, LLC
Sampson Regional Medical Center
SAS Institute Health Care Center
SAS Institute Inc.
Satinsky Consulting, LLC
Scotland Health Care System
SEC Associates, Inc.
Secure Enterprise Computing, Inc.
Sheps Center for Health Services Research
Siemens Health Services
Slepin, Jennifer
Smith Moore LLP
Source4 - Healthcare Solutions Group
South Carolina Department of Health and
Human Services
Southeastern Regional Medical Center
Spectrum Laboratory Network
Spencer, MD, Donald
St. Joseph of the Pines Health System
Strategic Management Systems, Inc.
SureScripts
The North Carolina Eye Bank
The SSI Group, Inc.
Thomas Edison State College
TM Floyd & Company
Topsail Technologies, Inc.
UNC Charlotte College of Information
Technology
UNC Health Care System
UNC School of Public Health
University of Virginia Health System
University Physicians, Inc.
VCU Health System
VigilantMinds Inc.
Visantis Healthcare Solutions
VisionShare Inc.
Voltage Security, Inc.
Wake Forest University Baptist Medical Center
Wake Radiology
WakeMed
Williams Mullen
Wilson Medical Center
WNC Health Network, Inc.
Womble, Carlyle, Sandridge & Rice, PLLC
WSSU Student Health Service
Zarb Consulting
Zix Corporation