

March 31, 2009

Health Information Security and Privacy Collaboration

Intrastate and Interstate Consent Policy Options Collaborative—Final Report

Prepared for

RTI International

230 W Monroe, Suite 2100

Chicago, IL 60606

Jodi Daniel, JD, MPH, Director

Steven Posnack, MHS, MS, Policy Analyst

Office of Policy and Research

Office of the National Coordinator for Health IT

200 Independence Avenue, SW, Suite 729D

Washington, DC 20201

Prepared by

Intrastate and Interstate Consent Policy Options Collaborative
California, Illinois, North Carolina, Ohio

Health Information Security & Privacy
COLLABORATION



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Steven Posnack, MHS, MS, Policy Analyst
Office of Policy and Research
Office of the National Coordinator for Health IT
200 Independence Avenue, SW, Suite 729D
Washington, DC 20201

Prepared by

Kathleen Delaney-Greenbaum, California
Suzanne Giorgi, California
Bobbie Holm, California
Jeff Johnson, Illinois
Laura McAlpine, Illinois
Holt Anderson, North Carolina

Linda Attarian, North Carolina
Trish Markus, North Carolina
Andrew Weniger, North Carolina
Bill Mitchin, Ohio
Stephanie Jursek, Ohio
Mary Crimmins, Ohio

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1. INTRODUCTION

This report summarizes the work of the Intrastate and Interstate Consent Policy Options Collaborative during Phase III of the Health Information Security and Privacy Collaboration (HISPC) project. In Phase I of the project, participating states investigated the reason for variations in organizational-level business and privacy practices among health care stakeholders and state laws that impede interoperable electronic health information exchange (HIE). Through this effort, states identified numerous inconsistent, cumbersome, nontransparent, and inefficient business processes and policies regarding individual privacy and consumer consent to share individual health information with third parties. Additionally, many HISPC Phase I states found that their state laws and regulations imposed varying degrees of restriction on access to or disclosure of diverse types of health information. Because of this significant variance among state laws and health care stakeholder practices and policies, consumers and health care stakeholders perceive considerable risks and liabilities in both intrastate and interstate HIE. These risks are associated with the seemingly widespread inability to understand applicable laws and policies regarding the privacy and security of health information and the attendant noncompliance with such laws and policies.

The HISPC Phase III Intrastate and Interstate Consent Policy Options Collaborative effort began in April 2008, prompted by: (1) mounting evidence that HIE can improve health care quality and efficiency; and (2) the identified need for resources and tools to resolve conflicts arising from variations in state consent laws and organizational consent policies for HIE. In approaching this work, the Collaborative recognized that most of the laws and policies identified in Phase I were developed for a paper-based exchange of health information, where the exchange is limited to the providers delivering health care services with the consumer's knowledge and implicit permission. In the rapidly evolving e-health environment, where health information can be transmitted instantly among numerous entities, states and health care stakeholders must address and possibly restructure their laws and policies on consumer consent to address the privacy and security challenges presented by the migration to HIE. The variations identified in Phase I were found to restrict the exchange of paper-based health information, and such variations could similarly impede HIE, if not addressed.

The mission of the Collaborative was twofold: (1) to examine the relative utility of select legal mechanisms that states might enact to facilitate interstate HIE, and to provide states with tools and resources that would assist them in evaluating which, if any of, such mechanisms their state could successfully employ; and (2) to examine a variety of consent policy alternatives to develop tools and resources that states and health care stakeholders could use to determine what amount of choice consumers should have about the electronic

access to and use and disclosure of their health information. In pursuing this research, the Collaborative identified and evaluated various factors that affect the delicate balance between consumer privacy interests and affordable provider access to reliable health information through HIE. Specifically, the Collaborative sought to determine which consent policy alternative or alternatives would simultaneously foster HIE while acknowledging the importance of personal choice and individuals' legitimate interest in maintaining the privacy and security of their health information.

This report describes the process the participating states used to evaluate the interstate conflict of law solutions and the consumer consent policy alternatives; the identified benefits and disadvantages of each; and the findings, lessons, and possible future application of the work. Other states can use the tools, processes, and templates the Collaborative developed, as well as these findings as they develop and implement strategies to manage and restructure outdated and inconsistent privacy and consent policies among health care organizations within their borders, and to lessen or eliminate variations in state laws that restrict HIE among states.

2. PRIVACY AND SECURITY BACKGROUND

The privacy regulations clarifying the intent of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule do not require covered entities to obtain patient consent to use and disclose patients' identifying health information for treatment, payment, or health care operations. However, the Privacy Rule permits states to require patient consent for such purposes. Some states' laws do provide greater privacy protection for (and, therefore, require more robust consent for exchange of) health information than the Privacy Rule. Such preemption of HIPAA by more stringent state laws has resulted in significant confusion regarding when consent is required or permitted to release identifying health information, and this uncertainty has created significant variation in the way health care entities exchange health information. Variation is exacerbated because in some states, existing case law supersedes or adds to the requirements of statutes and regulations. It is virtually impossible for health care stakeholders to track and maintain knowledge of all these legal factors and continue to fulfill their primary purpose of providing quality health care. As a result, health care stakeholders delay or fail to exchange information due to liability concerns. Costs increase because of duplicate testing, duplicate treatment, prescription drug abuse, etc.

In some states, organizations have opted to require advance patient consent to exchange identifying health information for treatment purposes, largely in an effort to reduce what they perceive as potential legal liability for such exchanges if they do not obtain the individual's consent. Absent further guidance about the effect of intersecting federal and state privacy laws, or standardization of these laws, barriers to interstate exchange will remain in place so long as civil or criminal liability may accrue to health information organizations (HIOs) or health care providers for using or disclosing health information in contravention of state consent laws.

The spectrum of polarized views on the necessity for consent mirrors the variety of conflicts that have arisen in attempts to implement HIE. On one end of the spectrum, our society values informed personal choice and individual privacy. On the other end, practical business needs require sufficient information to provide quality treatment and minimize administrative duplication of effort, thus reducing costs. A diverse public and private health care stakeholder collaborative process is essential to meaningfully address the following questions:

- Should consumers be given a choice regarding the sharing of their health information (and, if so, what degree of choice should be offered, and how can the health care industry accommodate a range of consent choices/directives and still achieve interoperability)?

- Should providers be allowed to place an individual's health information into an HIE system without the individual's knowledge or permission when doing so will enable the patient to receive improved and necessary care?
- If the answer to these questions is "yes," can both of these ends be accomplished through a single consent approach?

In the early stages of health information technology (health IT) and HIE efforts, consumers were not informed that their information was included in an HIE system (i.e., consumers were not given the opportunity to consent). Collaborative research revealed that some states initially took this approach, but these states acknowledge that failing to notify consumers was a mistake (according to the National Governors Association, State Alliance on eHealth, Health Information Protection Task Force). Following consumer backlash to this de facto "no consent" approach, these states began addressing the issue of consumer privacy. Some states had to retrofit their health IT systems so that consumer choice could be addressed. Despite these experiences, current HIE initiatives in many states still do not provide:

- individuals the opportunity to consent to have their health information included in or exchanged through an HIE system;
- a notice to individuals informing them that their information is being included in or exchanged through an HIE system; or
- individuals the opportunity to prevent their sensitive health information from being included in or exchanged through an HIE system.

Decisions about consent related to individual health information become more numerous and complex when stakeholders attempt to build processes that permit individual consent directives, including systems to restrict certain uses or disclosures of specified information to specified entities for specific purposes. In addition, some stakeholders' consent requirements do not differentiate between exchanges of demographic data and exchanges of clinical data. There is a broad range of possibilities for individual consent to release individuals' health information.

The Intrastate and Interstate Consent Policy Options Collaborative has identified and evaluated a variety of consent alternatives and issues related to HIE within a state. The Collaborative also studied a variety of legal mechanisms that might be employed to resolve conflict of law issues that arise in the context of interstate HIE when states have adopted differing consent policies.

3. METHODOLOGY

The Collaborative comprised four “core” states: California, Illinois, North Carolina, and Ohio. All four states utilized a public-private collaborative structure to analyze and vet consent issues. California and North Carolina focused on consent for HIE within states, or intrastate consent. Ohio, Illinois, and California explored consent for HIE between states, or interstate consent.

Before reviewing the specific processes used for the intrastate and interstate analyses, we note here some of the key definitions the Collaborative used. The following definition of HIE was developed and referenced in the National Alliance for Health Technology Report to the Office of the National Coordinator (ONC) for Health IT:

The electronic movement of health-related information among organizations according to nationally recognized standards.

State use varying definitions of “consent.” The following definition for consent is used in this intrastate analysis and was taken from the Medicare e-prescribing regulations:

Consent is a patient’s informed decision to provide permission for their personal health information to be entered and exchanged in an electronic HIE system.

Because of its broader approach, the templates developed for the interstate analyses used the following definition of consent:

Consent means the patient’s signed approval for the use or disclosure of [health information], which may also be referred to as an “authorization” or “permission” under HIPAA or other applicable federal or state laws.

This report does not address the issue of individual consent to health care treatment.

3.1 Intrastate Exchange

To evaluate the appropriate consent alternatives for a consumer in given situations, California and North Carolina developed, adapted, and implemented a systematic process of reviewing five consent alternatives in eight common health care delivery situations (scenarios) where consent is either permitted or required by law. For each consent alternative, California and North Carolina explored the likely advantages and disadvantages of that alternative, which would either encourage or discourage participation in HIE by consumers and providers. Each state used its own state collaborative stakeholder structure to evaluate consent alternatives in the chosen health care situations and to document and vet the findings. Secondary partner states, which included West Virginia, Kentucky, Arizona, Oklahoma, and New Jersey, then reviewed the analyses and findings.

The public-private stakeholder structures of California and North Carolina developed and executed a detailed work plan, composed of the following efforts.

Identified, reviewed, and summarized relevant consent documents from state, national, and international perspectives to formulate the literature review. This initial California effort provided background information on consent approaches that was distributed to task group or committee members for review (see Appendix A). The task group or committee members then started their analysis with a common understanding of the issue.

Developed or adapted templates and processes to conduct analyses and present findings. The use of common or similar processes and templates facilitated a comparison of analyses of consent alternatives in multiple HIE situations. Although the templates and processes were very similar, adaptation according to each state's environment and needs proved useful. For example, California had a longer time frame in which to analyze the consent alternatives and used a larger collaborative structure, which organized stakeholder participation down to a task-group level. North Carolina adapted California's templates and processes to reflect its smaller, less formalized stakeholder structure. Additionally, each state also chose HIE situations and stakeholder areas of interest to evaluate based on its local environment, including laws.

Identified and defined the major alternatives to consent for HIE. Both California and North Carolina used the following five general consent alternatives, which promoted consistency in the comparison of the states' consent alternative analyses.

- **No Consent:** Patient's records are automatically placed into the HIE system, regardless of patient preferences. This alternative assumes that all records of participating entities will be available to the system.
- **Opt Out:** Patient's records are automatically placed into the HIE system and exchange is allowed for sharing medical information without prior permission provided by the patient. The patient's information remains available for electronic exchange until the patient chooses to opt out of participation in the HIE and revokes permissions.
- **Opt In with Restrictions (granularity of choice):** Patient's prescription records are not automatically placed into the HIE system and exchange is not allowed for sharing medical information without prior permission provided by the patient. Restrictions on which health information may be disclosed, the purpose for the disclosure, or specified health information to be disclosed are also allowed under this option.
- **Opt Out with Exceptions (granularity of choice):** Patient's records are automatically placed into the HIE system and exchange is allowed for sharing medical information without prior permission provided by the patient. The patient's information remains available for electronic exchange until the patient chooses to opt out of participation in the HIE and revokes permissions. In addition, patients have the right to specify that information be removed from the electronic exchange.

- Opt In: Patient's records are placed into the HIE system after the patient provides permission. Exchange of medical information is not allowed without prior permission provided by the patient. This alternative assumes fewer records will be available to the system.

Analyzed the consent alternatives in eight health care scenarios to identify the factors related to each alternative that would tend to support or obstruct HIE.

Initially, California explored consent policy generally, without considering specific HIE situations. Weekly 1-hour webinars, including a diverse cross-section of stakeholders, provided robust information and discussion on the pros and cons of each of the five consent alternatives. However, this was a time-consuming process; vested interest and polarities in perspective made progress quite slow. All comments were captured and included on a template that was shared with North Carolina. This sharing of findings jump-started the North Carolina effort and enabled North Carolina to consider and build on California's efforts, while still permitting North Carolina to engage in its own robust stakeholder discussions.

Further considered each consent alternative against standardized criteria. Although the criteria selected were specific to each individual state completing the analysis, certain criteria remained consistent. For example, each state chose all HIE situations based on individual priorities, but all involved treatment. Each state considered and discussed the major state, national, and international privacy and security principles as a framework for its analysis. Additionally, each state considered its established consent policies and laws. Finally, each state chose certain variables, or stakeholder interest areas, to include on the templates and to evaluate for each consent alternative. This list of variables included quality of care, level of consumer and provider trust and confidence in HIE, savings and cost avoidance, investment, complexity and cost of technology, national efforts, and effect on stakeholder liability.

3.2 Why North Carolina and California Took Different Approaches to the Intrastate Analysis

The California and North Carolina state stakeholder collaborative structures differed significantly, and these differences generated somewhat different approaches to the analysis.

California used a state government-driven collaborative structure, which included multiple task groups to analyze the consent alternatives in various HIE situations. Initial findings were then vetted through a Privacy Committee, and presented to the Privacy and Security Advisory Board. In October 2008, California held a public symposium to discuss and further evaluate the consent alternatives. Because of the number of individuals participating in the analysis and alignment of staff job duties with the project, California was able to engage in a very detailed analysis of the five consent alternatives in several HIE scenarios.

Accordingly, California collaborative stakeholders used four templates to analyze consent alternatives in four HIE situations:

- **Summary**—Identifies the stakeholder committee, statement of the issue, background statement, assumptions, and definitions. Provides a summary of the major pro (+), con (-), or neutral (•) statements relative to the situation.
- **Comparative Summary Analysis**—For each health care situation, provides a comparison of all the pro, con, and neutral statements captured through the task group discussions and analysis by the five alternatives.
- **Scenario(s)**—One or two scenario analyses that provide a step-by-step description of how each of the five consent alternatives would be employed in a specific health care scenario. These analyses were designed to test and demonstrate how a particular consent alternative actually affects the patient.
- **Applicable Laws**—Provides a step-by-step listing of applicable California and federal laws as the scenarios for consent unfold.

California's finalized analyses for each health care scenario, are set forth in Appendices B through E. The extensive time and resources California invested in this evaluative process created the very detailed and comprehensive templates and information contained in this packet. California did not create a summary of the pros and cons that were identified for each consent alternative because it plans to continue evaluating the alternatives in additional HIE situations following the conclusion of HISPC Phase III and before it compares the findings across HIE scenarios.

North Carolina's Collaborative structure consisted of the staff and members of the North Carolina Healthcare Information and Communications Alliance, Inc. (NCHICA), a nonprofit consortium of about 200 organizations dedicated to improving health and care by accelerating the adoption of information technology. The intrastate consent policy alternatives were analyzed by members of the Policy Development Committee of the North Carolina Health Information Exchange (NC HIE) Council, the North Carolina Consumer Advisory Council on Health Information (NC CACHI), and the NC HISPC Legal Work group. Each of these groups was made up largely of volunteers.

Because the Collaborative had a limited amount of time to consult with each of these groups, the North Carolina team reviewed California's templates and then created a modified version of the Comparative Summary Analysis template to evaluate its five HIE scenarios. North Carolina's finalized analyses for each health care scenario are set forth in Appendices F through J. The North Carolina effort was not afforded the same amount of time and resources as California but benefited from and built on the California Collaborative effort. Having California's templates and stakeholder input allowed North Carolina stakeholders to jump into the analysis stage without performing significant independent research, progress further in their analyses, and complete comparative analyses between the HIE situations considered.

The North Carolina Collaborative findings were vetted through the members of the HIE Council and posted on NCHICA's website to obtain additional review and feedback from North Carolina Healthcare Information and Communications Alliance, Inc. (NCHICA) members. Additionally, the North Carolina team developed a feedback tool and provided the tool, along with copies of the Collaborative's findings and comparative analysis, to the members of the NC CACHI, the NC HIE Council, and the Legal Work Group. The responses to the feedback tool comprised a substantial and valuable part of North Carolina's conclusions on the intrastate consent issue.

The Collaborative created a Guide to the Development and Use of Intrastate Consent Policy Options Analysis Templates to assist states in developing and using templates to engage stakeholders in a structured analysis of how much control consumers should have over the access, acquisition, disclosure, or use of their personal health information contained in an electronic health record (EHR). This guide is set forth in Appendix K.

3.3 Interstate Exchange

Ohio, Illinois, and California led the Collaborative's effort in exploring the viability of several statutory options states could implement to remove barriers to interstate HIE when state consent laws and requirements conflict. The Collaborative explored how each option may affect the development of a consistent, nationwide approach to obtaining patient consent to release health information. Four specific statutory approaches were reviewed: uniform state law, model state law, choice of law, and interstate compact.

- **Uniform law** is a legislative proposal approved by the National Conference of Commissioners on Uniform State Laws (NCCUSL). The uniform law is proposed to state legislatures by NCCUSL for their adoption, usually in its entirety, to uniformly govern a matter of interest among adopting states. A uniform law would offer states the option to enact the same law governing consent, which would supersede any conflicting laws between adopting states.
- **Model act** is a legislative initiative proposed by the NCCUSL or an advocacy or trade group for adoption by state legislatures on a matter of interest to all states. The difference between a model act and a uniform law is that a model act may or may not be adopted in its entirety. States frequently modify a model act to meet their own needs or may adopt only a portion of the model act.
- **Choice of law** is a provision that states could adopt to specify which state law governs consent when personal health information is requested to be exchanged between states with conflicting laws.
- **Interstate compact** is a voluntary agreement between two or more states designed to meet common problems of the parties concerned. Compacts that usurp federal power must receive consent of the U.S. Congress as specified in Article I, Section 10 of the Constitution. They usually relate to such matters as conservation, boundary problems, education, port control, flood control, water rights, and penal matters. An interstate compact regarding consent to interstate exchange of personal health information would supersede conflicting laws between states joining the compact.

The Collaborative researched each of these approaches to assess their potential to facilitate HIE among the states. To assist states in conducting their research, the Collaborative developed Interstate Consent templates. These templates provide a foundation for completing a comprehensive and consistent method of evaluation. The Collaborative developed a series of review criteria that require an analysis of state law combined with identification of the pros and cons or positive and negative effects of pursuing a specific legal mechanism. As the templates indicate, the pros and cons can then be used to compare the legal mechanisms in an organized comparative model.

Several questions may arise regarding how to complete the templates, so a guidebook was developed to provide a suggested approach, with interpretive guidance of the evaluation terms used for each reviewing state's consideration. The guidebook and interstate analysis templates are set forth in Appendix L.

Each template begins with a section on definitions and another on assumptions. The intent was to create baseline definitions of the mechanism and terms, and to present a consistent scenario for use by the reviewing states as research and analysis were conducted.

For the purpose of consistency, each of the templates for the evaluation of the four mechanisms uses the same review criteria. A specific definition of each label has not been developed, primarily to allow each state interpretive license without external influence. There is value in diverse interpretation, and our intent was not to impose excessive structure through the definitions. However, recognizing that there may be a need for guidance, the following interpretations represent common points of consideration of each review criterion when conducting the analysis and review.

1. Process for Developing the Option

For each of the four proposed mechanisms, identify the implementation processes the state must complete. The processes may help identify the pros and cons of using a proposed mechanism and may vary according to each state's law(s).

2. Length of Time Required to Formulate

Given that each state's legislative process is governed by different laws, rules, and procedures, what is the typical timeframe for obtaining legislative or other governance approval to implement each proposed mechanism?

3. Implementation Requirements

Identify the balance between pros and cons for the steps required to implement each proposed mechanism. Completing this section will require a thorough understanding of the existing legislative and political or legal policy infrastructures in each state, as well as the resources that would be necessary to implement each proposed mechanism.

4. Impact on Stakeholder Communities

This section recognizes that the pros and cons for each proposed mechanism will affect the various stakeholder communities in different ways. The intent is to identify affected stakeholders and the impact adopting each proposed mechanism will have on those stakeholders.

5. Feasibility

Based on the legislative timetables, agenda, processes, costs, political realities, and public interest for enacting legislation to implement the mechanisms, identify the likelihood that each proposed mechanism could be implemented successfully and within a timely manner.

6. Does the Option Address Liability Concerns?

Liability issues appear to be one of the biggest obstacles to agreeing upon any standard approach to consent. Identify how issues of liability for inappropriate release of health information have been resolved within the state. Identify the relative merits of each mechanism in resolving these liability concerns.

7. Ramifications of Acceptance/Rejection

Based upon the anticipated impact within the state of acceptance or rejection of each proposed mechanism, identify the pros and cons of accepting and of rejecting each proposed mechanism.

8. Conflicts with State or Federal Laws

Initial review should focus on conflicts between each proposed mechanism and existing state law, followed by an evaluation of potential conflicts between each proposed mechanism and federal law. On numerous occasions, wide license is applied when interpreting federal law, and we hope to once again recognize differences in opinion or interpretation.

9. Legal Framework/Rules of Engagement

Consider how the mechanism is structured to work to analyze its various ramifications. For example, a mechanism may be simply drafted to provide that the requesting state or responding state's law applies to resolve conflicts. A more complex approach would be for the development of a new consent framework that would govern interstate exchange of protected health information (PHI). Based on the state's laws and regulations, describe the applicable infrastructure for the proposed mechanism and the rules for state participation.

10. Process for Withdrawal

Assuming the proposed mechanism is implemented, what is the corresponding process for withdrawal/repeal of the mechanism should it be deemed necessary?

11. State Responsibilities

What would state government or policymakers have to do to promote adoption and enforcement of each mechanism? How likely is this to occur?

12. State's Rights

This is a discussion of rights and responsibilities within each proposed mechanism and includes state sovereignty as well as state legislative control over the text of the legislation.

13. Enforcement

How difficult will it be to enforce each proposed mechanism if enacted, and which state agency or organization will assume enforcement responsibilities? How are the state's laws regarding inappropriate release of information or failure to obtain appropriate consent to release information currently enforced, and how, if at all, would the implementation of each proposed mechanism modify enforcement authority?

14. Other Considerations

This is a catch-all category to express ideas or concerns that were not addressed in the previous discussion points.

15. Conclusions

Summarize the key findings in the analysis. It should convey the essence of the analysis for the readers.

This report provides states with the results of our analysis and a systematic process for evaluating these statutory approaches within your own state. If enough states conduct this type of evaluation, it may be possible to align states with similar intrastate approaches into a common interstate mechanism for exchange.

4. SCOPE OF WORK

4.1 Overall Project Technical Approach

The project had two components: (1) identify or develop an intrastate approach to individual consent that will further HIE, and (2) identify or develop an interstate approach to individual consent that will further HIE. Research, analyses, vetting, and documentation were completed for both components, but each participating state took on specific tasks and subtasks.

4.2 Objective

The objective was to comprehensively research and evaluate alternative approaches to streamlining intrastate and interstate consent; compile findings, and vet findings through participating states' stakeholder structures; and prepare a final report outlining findings, lessons learned, and potential future applications. Other states may use this foundational work to (a) make informed decisions when considering or determining intrastate or interstate consent policy; and (b) thereby promote HIE within and between states.

4.3 Levels of Participation

Ohio led the interstate exchange analysis, with Illinois and California contributing. California led the review of the intrastate consent issues, with North Carolina contributing. Core Team states of California, Illinois, North Carolina, and Ohio reviewed and commented on multiple team products; some were vetted through the reviewing state's stakeholders.

In addition to the Core Team states, secondary tier review states including West Virginia, Kentucky, Arizona, New Jersey, and Oklahoma assessed the Core Team templates and processes. These findings are addressed in the Interstate findings. All Core Team members documented and compared findings and helped prepare the final report.

4.4 Requirements

To achieve this objective, the Core Team states:

- Monitored national and global efforts related to the consent issue, and sought awareness and coordination of efforts with all Office of the National Coordinator (ONC)-related programs and definitions.
- Facilitated, coordinated, and integrated their state Collaborative efforts through regular conference calls, monthly Steering Committee meetings, and periodic in-person meetings.
- Participated in nationwide collaboration through HISPC national conferences and shared posted findings, recommendations and deliverables within and between Collaboratives.
- Committed time and resources beyond HISPC Phase III reimbursement.

4.5 Key Stakeholder Representation

Collaborative states endeavored to include the following stakeholders when they vetted their products:

- clinicians
- physicians and physician groups
- federal health facilities
- hospitals
- employers
- payers
- public health organizations
- community clinics
- laboratories
- pharmacies
- long-term care facilities
- hospices
- correctional facilities
- professional associations
- educators
- quality improvement organizations
- consumers
- government

4.6 California Stakeholder Collaborative Structure

Bobbie Holm and Kathleen Delaney-Greenbaum served on the Core Team of the multistate Collaborative and formed a conduit to the state project team, which provided support to the state stakeholder structure, the California Privacy and Security Advisory Board (CalPSAB), and committees. The key members of the California project team had the following roles:

- Bobbie Holm—Project lead and supporting manager to the CalPSAB.
- Kathleen Delaney-Greenbaum—Supporting manager to the Privacy Committee and its Task Groups.
- Anne Drumm—Supporting manager to the Education Committee and its Task Groups.
- Suzanne Giorgi—Supporting manager to the Legal Committee.

- Elaine Scordakis—Supporting manager to the Security Committee and its Task Groups.
- Seven consultants—Two conducting research, one for information technology/security, one for project management, one for privacy and security, and two, part-time, for private industry interaction and meeting logistics.
- The CalPSAB structure consists of:
 - California Privacy and Security Advisory Board: Advisory Board members were appointed by California Health and Human Services (CHHS) Secretary, Kim Belshé. Members were nominated from government positions, associations representing private health care stakeholders in California, consumers, and educators. The CalPSAB makes recommendations concerning privacy and security standards to the CHHS Agency Secretary. On average, Advisory Board meetings were held every 2 months.
 - Four committees report to the Advisory Board: Privacy, Security Legal, and Education. Membership is open and meetings occur every 4 to 6 weeks; task group meetings are every 1 or 2 weeks. Approximately 400 active members and interested parties participate in the CalPSAB Collaborative structure.

4.7 California Stakeholder Collaborative Process

California completed a majority of the research on consent, identified and defined the five consent alternatives, and developed both the research and analysis templates. Additionally, California reviewed multiple sources of HIE principles and combined the key elements into a final set of privacy principles, which the Collaborative adopted. California shared all of its research materials, templates, and initial and ongoing findings with other Core Team states through the RTI portal.

By April 2008, California realized that there would not be a single easy answer to the question of individual consent. Accordingly, the stakeholder structure decided to evaluate the pros and cons of the five consent alternatives in a variety of HIE situations and made it a priority to assess certain situations first. California's initial hypotheses were:

- Where release of information is mandated by law, no consent is required or should be permitted.
- Because various federal and state laws may or may not require consent for release of sensitive health information, such releases of information require greater privacy and security safeguards and, therefore, greater patient choice.
- In most other situations, some compromise may be reached.

Diverse collaboration of both private and public stakeholders was recognized as vital, as well as the need for direction and oversight of the effort by the Advisory Board, and coordination between the efforts of the Privacy, Security, Legal, and Education Committees.

For the interstate effort, California created and vetted its analysis of the four mechanisms through the Legal Committee that supports CalPSAB. The Legal Committee has

approximately 20 active members who represent a wide variety of stakeholder interests. Background research was performed by staff and subject matter experts who are also members of the CalPSAB Legal Committee. The background research was submitted to the CalPSAB Legal Committee members before regularly scheduled meetings and was part of the agenda for discussion and development of findings. The background research was supplemented by comments by members of the CalPSAB Legal Committee at the general meetings. We held two additional task group meetings to develop the analysis on uniform law and model law. A comparative summary was presented for one last review and comment on September 19, 2008.

4.8 North Carolina Stakeholder Collaborative Structure

Linda Attarian and Trish Markus served on the Core Team of the HISPC Intrastate and Interstate Consent Policy Options Collaborative and acted as liaisons to the Interorganizational Agreement (IOA) Collaborative. The key members of the North Carolina project team had the following roles:

- Holt Anderson, Project Executive, provided general project oversight and policy direction for this Collaborative, as well as for the NC IOA Collaborative. He is a member of the HISPC Technical Advisory Panel (TAP), the Governance Workgroup for the Nationwide Health Information Network (NHIN), and a co-chair of the Data Use and Reciprocal Support Agreement (DURSA) Workgroup of the NHIN.
- Linda Attarian, Policy Advisor, was responsible for North Carolina legal and policy research, as well as regulatory and legislative implementation approaches.
- Trish Markus, Project Legal Counsel, coordinated all project legal activities, including intersection with the IOA Collaborative and NC's NHIN activities, the DURSA Workgroup effort, and stakeholder implementation approaches; she was also co-chair of the NC Legal Work Group.
- Andrew Weniger, Project Manager, provided project support, coordinated NC HISPC project deliverables, and was the primary contact with RTI.
- The NC HIE Council served as the Steering Committee. The Council consists of representatives from health industry stakeholder groups. The Council serves as a statewide coordination body for North Carolina's HIE efforts and develops recommendations for long-term strategy and short term tactics for achieving statewide, interoperable HIE.
- The NC HIE Policy Development Committee, composed of 55 volunteers affiliated with NCHICA member organizations, supports the NC HIE Council by addressing pertinent HIE issues including data use, confidentiality and privacy policies, data sharing agreements, and user agreements. The goal of the Committee is to build statewide HIE policy based on evidence and supported by consensus.
- The NC HISPC Legal Work Group, composed of 52 volunteer members of the NCHICA community, was convened during HISPC Phase I to examine challenges that existing privacy and security laws and policies pose to interoperable HIE, and to identify best practices and solutions for maintaining appropriate privacy and security protections for health information while enabling HIE.

- NC CACHI consists of 14 health care consumers. Its purpose is to try to find a balance between consumers' privacy interests and health care stakeholders' need for access to health information, and it considers the value and associated risks of electronic HIE to consumers.

4.9 North Carolina Stakeholder Collaborative Process

North Carolina approached the intrastate consent analysis by engaging the members of the NC HISPC Legal Work Group, the NC HIE Policy Development Committee, and the NC CACHI. The North Carolina Collaborative team participated in existing scheduled meetings of those groups and also scheduled biweekly NC HISPC Policy Options Task Force meetings, attended primarily by members of the HISPC Legal Work Group and each lasting approximately 2 hours. The purpose of these meetings was to engage a broad spectrum of health industry stakeholders in a discussion about the role of consumer consent in HIE. Participants came from nearly all HIE stakeholder groups.

The North Carolina project team's research informed the discussions at meetings and the eventual findings related to consumer consent and health information privacy and security law and policy. Because the relatively limited project time frame required the North Carolina team to adopt a high-level approach to the analysis, North Carolina adapted slightly revised versions of California's analysis templates, assumptions, and privacy principles to guide its analysis of the five consent alternatives. North Carolina chose five common ambulatory care scenarios through which to evaluate the five consent alternatives. The North Carolina project team prepared a Comparative Analysis for each scenario; these are set forth in Appendices F through J. The scenarios included: (1) Laboratory Results; (2) Outpatient Care Coordination ; (3) Substance Abuse Consultation; (4) Minor Seeking STD Testing; and (5) Reportable Disease. The project team summarized the findings for each consent policy alternative for each ambulatory care setting in a comparative chart. Additionally, the project team summarized in a comparative chart the pros and cons of each consent alternative, when measured against the alternative's potential effect on quality of care, provider business processes, consumer and provider confidence in HIE, and provider liability.

As noted previously, the team also developed a feedback tool to gauge stakeholders' agreement with the findings, pros, and cons enumerated. The summary documents and the feedback tool were sent to all members of the HISPC Legal Work Group, HIE Policy Development Committee, and NC CACHI. The feedback tool requested: (1) feedback regarding the North Carolina team's findings, including the extent to which respondents agreed with those findings; (2) opinions as to which of the five consent alternatives would be their first and second choices for use in North Carolina; and (3) a ranking of the five consent alternatives based on their work in the health care industry, as well as their identities as consumers of health care, and their understanding of consent policy alternatives.

4.10 Ohio Stakeholder Collaborative Structure

William Hayes, PhD, served on the core Collaborative team. He is the private sector co-chair of the Ohio Health Information Partnership (OHIP) Advisory Board (replaced HISPC Steering Committee). Other members of the team include:

- R. Steve Edmunson—public sector co-chair OHIP Advisory Board (replaced HISPC Steering Committee)
- Rex Plouck—state of Ohio agency coordination, Office of Information Technology
- William Mitchin—HISPC Project Director Phase III
- Philip Powers—Health Policy Institute of Ohio (HPIO) CIO and HISPC Phase III technical support
- Stephanie Jursek—Coordinator, Legal Work Group HISPC Phase III
- Mary Crimmins—I/T technical advisor HISPC Phase III
- Socrates Tuch—Legal Work Group and Ohio Department of Health liaison
- Ketra Rice—HISPC Phase III business process research and development
- Terri Moore—HISPC Phase III research and support

4.11 Ohio Stakeholder Collaborative Process

The Ohio project team conducting the interstate analysis was primarily composed of members of the HISPC Legal Work Group (LWG). To complete analysis of the mechanisms, Ohio split the LWG into two distinct groups. Group 1 conducted the review and analysis of the choice of law and interstate compact mechanisms while Group 2 performed the same tasks for model acts and uniform law. Groups were created by allowing members to select their group based on their specific area of legal practice. Upon completion of the initial analysis, the findings were consolidated and redistributed to the entire LWG for review and comment. Ohio is a state with "sunshine laws" that require all meetings involving state employees to be open to the public; this allowed for input from numerous stakeholder groups not part of the LWG. The Ohio team also opened the meeting to colleagues from other HISPC states and incorporated their comments where applicable. The final product is a result of the combined efforts of all involved and facilitated a list of common observations presented later in this report.

4.12 Illinois Stakeholder Collaborative Structure

Jeff Johnson served on the core Collaborative team and is the conduit to the Illinois state team. The key members of the Illinois project team had the following roles:

- David Carvalho, Deputy Director, Office of Health Policy and Planning, Illinois Department of Public Health (IDPH), HISPC-Illinois project chairman, provided

general project oversight and policy direction. Also chaired HISPC Steering Committee.

- Jeff W. Johnson, Executive Assistant to the Director for Customer Service, IDPH, Project Director, coordinated project deliverables and was the primary contact with RTI.
- Marilyn Thomas, Chief Legal Counsel, IDPH, Project Legal Counsel, coordinated all project legal activities. Chair of the Legal Work Group.
- Elissa Bassler, Executive Director, Illinois Public Health Institute (IPHI), Project Management Contractor provided project support.
- Peter Eckart, Director of Health Information Technology, IPHI supervised research and administrative staff, reviewed documents, and assisted the project director by participating in meetings.
- Kathy (Karsten) Tipton, MPS, Program Associate, IPHI, Project Management Contractor, provided project support.
- Heidi Echols, McDermott Will & Emery LLP, Legal Consultant, provided research and writing on the legal ramification of interstate consent issues.
- Laura McAlpine, McAlpine Consulting for Growth, Research Consultant, provided research and writing on interstate consent issues.
- The Steering Committee provided oversight and feedback for HISPC-Illinois, which included approving evaluations, the preliminary report, and the final report. The Steering Committee consists of 10 members representing business, consumers, government, providers, and health IT experts. In addition to approving the evaluations, the Steering Committee noted their research priorities and reviewed Collaborative reports.
- The Legal Work Group conducted the evaluation of the four statutory policy options and presented the findings to the Steering Committee. The 27-member group consisted of representatives from business, consumer groups, government, payers, and providers.

4.13 Illinois Stakeholder Collaborative Process

The Illinois approach to evaluating the four mechanisms for eliminating barriers to the interstate exchange of health information involved convening a stakeholder group, the LWG, to review the four interstate options. This 27-member group consisted of representatives of an employer-focused health care coalition: consumers, payers, community health centers, hospitals/health systems, long-term care facilities, pharmacies/pharmacy benefit managers, physicians, and government officials. Although the LWG was primarily composed of attorneys, non-attorneys were asked to participate to ensure the broadest possible representation. The LWG met to identify research/information that the members felt would be necessary to perform the evaluations. The Steering Committee reviewed and approved the LWG's evaluations.

HISPC-Illinois project staff conducted research consistent with the recommendations of the LWG and Steering Committee pertinent to each of the four options. Staff created discussion documents that covered each of the criteria. The LWG was provided with information on the work of six national organizations that have been studying various aspects of interstate transfer of EHRs: National Conference of Commissioners on Uniform State Laws; National Governors Association; National Conference of State Legislatures; Office of the National Coordinator; American Health Information Community; and State Level Health Information Exchange Consensus Project.

The LWG devoted one meeting to discuss each of the four mechanisms. In evaluating the mechanism, the LWG used three scenarios of how the mechanisms would be structured to address the barriers to exchange.

5. FINDINGS AND RESULTS

5.1 Intrastate

California and North Carolina evaluated five intrastate consent alternatives in a total of eight different HIE situations, each involving treatment. All intrastate findings are set forth in Appendices B through J. Each state separately defined its strategy to complete the analysis and identified the appropriate tools for the study based upon its state legal and regulatory landscape. As a result of the analysis, both California and North Carolina broadened their understanding of health information consent policy. Both states learned that consent to exchange health information through a networked HIE system involves policy considerations that are complex, multidimensional, and interrelated. The notion of consumer consent or consumer participation in HIE in simple one-to-one exchanges between trusted providers is no longer the applicable paradigm in the 21st century, as the United States migrates toward a networked HIE environment.

5.2 California

Consent was recognized as a threshold issue that needed resolution before HIE could be accomplished. The following processes and forms were developed to successfully explore consent:

- Work plan: meeting schedules, roles and tasks identified, staff assigned, documents designed to facilitate the effort.
- Literature review templates: Executive Summary of Pertinent Facts and Summary of Pertinent Facts (Included in Appendix K).
- Principles.

However, our efforts did not prepare us for the complexity of consent. Aligning with the vision of enabling electronic transfer of health information to improve the quality of care in a way that fosters trust, we first determined that the consent analysis would be limited to treatment. Next we discovered that there could not be one alternative to consent. Consent would have to be explored by the scenario in which it was permitted or required. The spectrum ranged from:

- No consent for legally mandated health information sharing, such as public health.
- Opt in with exceptions for highly sensitive health information sharing, such as HIV or substance abuse.
- Opt out or opt in for the majority of HIE between the two extremes.

Four HIE scenarios of consent were identified to analyze the consent issue from multiple perspectives. Task groups were formed to analyze consent in the following treatment situations:

- e-prescribing,
- emergency departments,
- laboratories, and
- mental health in the public setting.

The first consent scenario we explored was e-prescribing. Initially, discussions of the pros and cons of the five consent alternatives proved difficult and lengthy. These discussions revealed subjective perceptions of the pros and cons that conflicted with an opposing perspective. This difficulty was similar to the metaphor where various blindfolded individuals feel different parts of an elephant and insist their perspective is accurate based on their personal experience. Review of existing research helped stakeholders compromise somewhat on a more unified perspective. As group dynamics developed, stakeholders began moving through completion of the template. Compromise in discussions was facilitated by exploring consent directives that provide consumers with a granularity of choice. [Illustrated in the Canadian Infoway architecture, the HIPAAT consent directive applications and the Healthcare Information Technology Standards (HITSP).] Based on this compromise, the task group presented a recommendation of “Opt In with Restrictions” at the June 11, 2008, Privacy Committee meeting.

There were strong reactions to the findings and additional Privacy Committee meetings were scheduled to continue vetting consent in the e-prescribing scenario. The following polarities became apparent and carried through all subsequent analyses of consent situations:

- opt in with restriction vs. no consent;
- less info exchanged vs. more info exchanged;
- consumer vs. provider;
- privacy policy vs. security implementation;
- multiple firewalled business IT systems vs. one interoperable system;
- low transparency = low trust vs. high transparency = high trust; and
- mistrustful patients vs. knowledgeable patients.

The relevance of polarities is that they can derail a collaborative effort if not recognized and addressed. Principles and a genuine belief that HIE can be achieved while still recognizing the need for appropriate privacy protection are key to moving the collaborative effort forward.

Additionally, polarities of divergent stakeholders made it difficult to identify a single recommendation. Instead of making a recommendation to the Board, the Privacy Committee presented findings based on the analyses. The Board requested additional analysis to be completed to ascertain if the original goals would be met. For example, how

would each consent alternative address adverse drug reactions and prescription fraud in the e-prescribing analysis? The Privacy Committee accomplished this task and used this format for the subsequent analyses of consent situations.

After the detailed analysis of e-prescribing, it became apparent that some of the pros and cons identified through the e-prescribing analysis also applied to laboratories, emergency departments, and mental health situations. For example, the alternative “No Consent” will most likely yield the highest quality of care because of the availability of patient health information. However, this alternative will also result in the least amount of patient choice. Alternatively, “Opt In with Restrictions” will most likely yield the least potential for high quality of care and the most patient choice, in the current architecture. Three additional task groups were set up concurrently with diverse stakeholders and subject matter experts to analyze laboratories, emergency departments, and mental health situations.

5.3 North Carolina

North Carolina evaluated each of the five consent alternatives by using five common ambulatory care scenarios. The North Carolina project team explored the role of consumer consent and specifically, the extent to which varying levels of consumer consent or choice would likely impact the quality of care provided, the providers’ business processes, including costs, provider and consumer confidence in HIE, and the potential risks of liability for health care providers.

As the project and the evaluation progressed, it became increasingly evident to the North Carolina project team that consumer consent is not synonymous with consumer control, and that consent is not the only factor relevant to finding the balance between consumer control over and provider access to health information that appears necessary to promote HIE. The North Carolina team learned that true consumer control depends upon consumers’ awareness of how their information is to be used and exchanged in the HIE system and is affected by the extent of security and privacy safeguards adopted and enforced by the HIE system participants.

When the North Carolina team assumed that the HIE system abided by and enforced rigorous privacy and security principles, and that the participating providers would inform consumers in advance about what information would be exchanged through the HIE system and for what purposes, the importance of consumer consent appeared to diminish in comparison to the interests of providers in accessing all necessary health information for appropriate purposes. The North Carolina team also learned that the degree of sensitivity of the health information was an important variable. When the team assumed that highly sensitive patient information was to be exchanged through the HIE system, the importance of consumer consent appeared to increase in comparison to the interests of providers in

accessing health information, because of the potential increasingly severe consequences to consumers following inappropriate access, use, or disclosure of such sensitive information.

5.4 California and North Carolina Joint Findings

The California and North Carolina stakeholder Collaborative efforts reached similar conclusions. It was apparent from the beginning that what consumers want and what health care providers want appear to conflict.

Consumers want their health information to be exchanged to enhance their treatment and reduce health care costs. They support their physicians having immediate access to all the information that is necessary for their treatment. However, they also want this exchange to be safeguarded to prevent misuse of their health information.

Providers also want immediate access to health information to administer high-quality care to patients. In addition, they want that access to health information to support receipt of timely payment, to facilitate pay for performance and other initiatives to improve care, and to contain costs. But health care providers and payers believe that obtaining consumer consent for these purposes, when it is not currently required by law, would delay timely access to needed information and, thereby, decrease quality of care, increase costs, and discourage the adoption of electronic records and other initiatives to improve care and decrease costs. Some providers want consistency of consent policy across organizations to avoid delayed treatment and potential liability. New legislation may be needed to mandate a standardized consent structure.

Layered on top of this dynamic between consumers and providers is the complexity of the consent issue. That complexity is fueled by varied, conflicting, or nonexistent laws about consent. Attempts to move stakeholder perceptions about the appropriate role of consent in the current paper-based, HIE landscape toward the appropriate role of consent in the electronic HIE landscape were resisted. We discovered that the collaborative process was an effective way to reach a common vision of how addressing appropriate consent for electronic HIE potentially could meet the needs of all stakeholders and build trust.

All phases of HISPC demonstrated that trust is necessary to achieve HIE. In addition to collaboration, trust can be engendered in numerous ways, but education was critical. Consent to HIE in a networked HIE system is distinct from, and requires greater consumer and stakeholder education than, consent to release paper-based information. Trust comes more easily when you reveal information to your physician in confidence, whereas it is more difficult to trust individuals you do not know or an electronic HIE system.

We discovered that as the amount of consumer consent decreases, the amount of consumer participation in HIE is likely to decrease, unless there is significant consumer education. That education needs to include HIE privacy and security principles, how consumers' health

information will be used (and not used), and the potential treatment consequences of not participating in HIE. Such education is needed before consumers can provide informed consent to electronic HIE.

Education is also needed for providers and their staff if privacy protections are to be implemented consistently. Consistent enforcement is needed to ensure consistent implementation of the applicable privacy and security rules. Consistent safeguards, implementation, and enforcement likely will lead to increased trust in electronic HIE by providers and consumers alike.

A few issues appeared to affect consumer confidence in HIE. As the sensitivity of the information increases, consumers' sense of risk increases, undermining their confidence that their information will be protected. Additionally, 42 C.F.R. pt. 2 requires that consent be obtained before substance abuse information may be released. In addition to sensitive information needing extra safeguards, consumers believed that only the minimally necessary amount of information should be exchanged through HIE and that the information should only be used for the original purpose for which it was requested.

Detailed analyses provided in the templates can be summarized in the following trends.

As the degree of consumer consent increases:

- consumer trust in HIE increases,
- provider confidence in the quality of data in the HIE system and the cost effectiveness of HIE decreases,
- provider liability for violation of state and federal consent laws likely decreases, and
- provider liability for medical malpractice may increase (due to incomplete health records) or may decrease (due to providers' defense that the patient withheld consent, making health information unavailable).

As the amount of consumer consent decreases:

- the amount of time and money required to implement consent policies may decrease.

Most stakeholders believe that "no consent" will ensure access to the highest volume of records through electronic HIE at the lowest cost. This alternative, however, may force consumers who have concerns about the privacy of their sensitive health information to avoid seeking health care, to use multiple physicians and pay in cash, or to omit sensitive details from their health histories. Opt-in and opt-out options offer consumers who have concerns regarding the privacy of their sensitive information an "all or nothing" choice, and if the consumers choose to restrict access to sensitive information, access to nonsensitive information is also restricted. Granular consent policies (e.g., opt out with exceptions, opt in with restrictions) are more expensive to implement and to train staff and patients than straight opt-in or opt-out alternatives.

In summary, quality of care and trust in HIE appear to be incompatible, but it is possible for technology to accommodate both, for a cost. Economies of scale and innovative delivery formats could reduce this cost to providers. Finally, privacy rights are at the root of the consent issue, especially in states that grant constitutional privacy protection. National privacy policies and security standards, beyond HIPAA, are essential to the goal of interoperable HIE.

5.5 Interstate

Ohio, Illinois, and California conducted the analysis of interstate mechanisms, defined in the Methodology section of this report. The mechanisms represent approaches states can pursue on their own initiative to respond to barriers to the interstate exchange of health information caused by conflicting consent laws. Each state set out to analyze the pros and cons of the four statutory options mentioned above to determine the steps required to adopt a particular option. Each state's analysis was based on their state law as well as an interpretation of federal laws. This variation is the result of our interest in allowing an unencumbered approach to completing independent research and allowing each state to take interpretive license considering the state's law structure and availability of legal resources.

Short of a federal law that preempts state consent laws, it is doubtful that any mechanism will eliminate all barriers to the exchange of health information among states within the foreseeable future. To reach this goal would require the adoption of a consistent approach by all 50 states. However, to effectively address the barriers to interstate HIE, the mechanism needs to provide a uniform or standardized approach for dealing with the consent issues.

The results of each state analysis were shared among the three participating states and comments were submitted for consideration. Despite using different processes to conduct the analysis, our end result reflected common themes for each legal mechanism. The consolidated interstate analyses are set forth in Appendix M. Because of the volume of material, the Collaborative also prepared a consolidated interstate considerations summary document; this is set forth in Appendix N.

5.6 Joint Findings

Model act and choice of law would be difficult to use to resolve conflicts of consent laws between states.

- While choice of law may be the easiest to implement, it is not, in and of itself, an option for addressing HIE. It provided the least transparency and ability to harmonize multiple states with conflicting laws. Instead, choice of law is more appropriate as a discussion point for the remaining true options (i.e., model act, uniform law, and interstate compact), because it is a legal concept that underlies all interstate transactions. Also, using choice of law as the mechanism would be

cumbersome, politically problematic, and legally complicated. Additionally, specifying a choice of law in disclosure matters might be a difficult approach because of the interest of each state in allowing its statutes to govern all matters affecting its citizens.

- While the model act process for drafting and adoption is credible, the lack of emphasis on verbatim adoption may thwart the adoption of an understandable framework for addressing conflicting state consent laws. Costs to draft, adopt, educate, and implement the mechanism will be considerable, yet the risk of a lack of uniform adoption and, thus, an ineffective response to the removal of barriers to interstate HIE is fairly high.

Uniform code or a model act was most consistent with preserving states' rights, but if there is limited adoption or vast changes in the adopting states, it will not foster the exchange of health information.

Interstate compact and uniform law were both reasonable and appropriate processes to address conflicts among states. They are most likely to provide a uniform or standardized approach, while facilitating input by state legislators, health providers, and consumers. The length of time required to draft and enact either mechanism was fairly lengthy, 3 to 9 years for interstate compact and 5 to 7 years for uniform law. But these would potentially be within the timeframe anticipated for significant adoption of EHRs, resulting in the opportunity to participate in HIE systems by health providers.

Interstate compact is both a consensus-building approach and is legally binding for participating states, and could be enacted faster in a regional context. A compact can serve as a pilot project for nonparticipating states to study.

One of the overarching issues to be resolved for an interstate compact is whether Congressional consent is required. The requirement for Congressional consent for interstate compacts is set forth in the U.S. Constitution, Article I, Section 10: "No State shall, without the Consent of Congress...enter into any Agreement or Compact with another State..." A literal reading of the provision suggests that Congressional consent is required for every interstate compact; however, the U.S. Supreme Court held that only those agreements affecting the power of the national government or the "political balance" within the federal government require the consent of Congress.

Some state compacts have addressed the issue of Congressional consent by including provisions that the respective states' Attorneys General will seek Congressional consent if they deem such consent to be necessary.

Congressional approval, or lack thereof, can be expected to be an issue in litigation challenging the exchange of PHI in a manner consistent with the interstate compact, but not with one of the participating state's consent laws.

The enforceability of an interstate compact may also be questioned without Congressional approval. However, there is precedent for compacts created without Congressional approval that address the enforcement issue in the language of the agreement.

An interstate compact, in and of itself, does not directly alter intrastate legal expectations. That is, a potential interstate compact enacted to govern the exchange of health information through an HIE system that spans state boundaries can be limited only to the management of that HIE system. However, states could use an interstate compact as a mechanism to adopt generalized standards for all health information exchanged electronically across state boundaries. For example, states could utilize an interstate compact to agree on access control standards and other policies related to consent for the exchange of health information between participating states.

In summary, the interstate compact mechanism may provide more flexibility to quickly address policy and technological changes if the terms of the compact permit changes that will apply to member states without a lengthy ratification process.

5.7 Intrastate and Interstate Secondary State Review Summary

The Intrastate and Interstate Policy Option Collaborative was interested in validating the processes we developed throughout Phase III. As a result, five additional HISPC states were invited to review the templates we created to collect data and facilitate our analysis. Our primary interests were determining if the templates could be used in the secondary review states as replicable processes and if the secondary states believed the templates added value and understanding of the issues for their states.

Four states responded to the request; all four indicated that the templates were well thought out and helpful in defining an approach states could use to conduct their own review. Each state agreed that the templates would be of value to them and that the information provided as a result of the Collaborative's work was valuable as a starting point. Several states indicated they would like additional instructions on how to use the templates. This issue is addressed in the template guidebooks that were not available to the secondary states at the time of their review.

5.8 Lessons Learned

Common lessons regarding consent policy emerged across all four states in the Collaborative, and are noted as follows:

States can and should leverage the efforts of other states or entities in developing consent policy.

This Collaborative effort strategically leveraged the efforts of others in several respects. First, the California intrastate literature review assisted the Collaborative

members in identifying the broad range of issues involved in consent policy and enabled the Collaborative to build on the knowledge and experiences of the consent efforts of others. Second, the interstate participants used template formats on which they jointly agreed. After concurrent research and analysis, a comparative interstate analysis was created noting each state's efforts and findings. Third, North Carolina leveraged templates, processes, and guides developed by California to save time and avoid re-inventing basic documents and concepts. This Collaborative expects that other states will leverage our work in HISPC Phase III to strategically avoid duplicate or unnecessary effort as they determine how to approach intrastate and interstate consent to HIE and progress toward achieving HIE.

Public comment on and participation in a transparent process is essential for creating solutions to consent issues.

Different stakeholder groups identified a variety of concerns about each of the consent alternatives, and lengthy discussions were needed to ensure that all stakeholders had at least a threshold level of knowledge about this complex topic, and to reach consensus. Reaching consensus on appropriate consumer consent policy, particularly in an HIE system, requires that decision makers balance the legitimate interests of all stakeholders in accessing information against individual privacy rights. Creating a transparent process for these discussions that brings together affected public and private parties is critical to ensure the credibility of that process. Although many stakeholders may have unique requirements for satisfying consent, all share a common interest in achieving interoperable HIE and, accordingly, will need to compromise by improving patient access to and control over individual health information.

Guiding principles and common definitions are essential for meaningful discussion and analysis of consent alternatives.

Consumers have legitimate privacy concerns about the dissemination of their health information through HIE. Therefore, electronic exchange of health information requires those participating and accessing information through the exchange to commit to and abide by privacy principles. State policy leaders may be reluctant to change consent laws because such changes could either dilute existing privacy protections or impose additional costly and burdensome process requirements on health care providers. However, such reluctance may diminish among policy leaders who participate in the creation of such guiding principles.

State constitutional rights to privacy raise nationwide questions about how to address the individual's role in the use and disclosure of his or her personal health information.

Ten state constitutions provide individuals with some form of a right to privacy. Existing case law also instructs on the use of a balancing test to resolve conflicts between privacy and consent requirements. Exploring individuals' appropriate interests in the use and disclosure of their health information will be central in drafting appropriate consent legislation. Existing (and nonexistent) laws that address disclosures of health information with or without consumer consent impede progress toward interoperable HIE; those laws either must be changed or an alternative solution must be achieved.

Education of providers and consumers will be necessary before interoperable HIE can be achieved.

Consumers will need to be educated before they can be expected to decide whether to consent to their health information being exchanged in an HIE system. Additionally, providers will need to be educated as to what obtaining such consumer consent would involve and how obtaining consent would impact their operations, especially in terms of the costs of HIE. Without such education, resistance from both providers and consumers could sabotage the vision for HIE.

Moving from paper-based, provider-to-provider exchange to an interoperable HIE system creates an electronic, many-to-many exchange that highlights the need to address legitimate consumer concerns about the privacy and security of their health information.

This move offers new opportunities for consumers to become engaged in the management of their health and health care, as well as for improved quality and efficiency in health care delivery. It simultaneously requires a new approach for ensuring health information privacy and security. Most laws governing HIE were developed for a paper-based, non-networked health care environment, and many states have not yet adopted laws addressing consent or privacy in the context of a networked HIE environment. It can be difficult to visualize future policy options, given unfamiliarity with enabling and evolving technology, but such envisioning will be an essential marker along the road to HIE.

5.9 Challenges

Developing and enacting new laws to implement a legal mechanism for interstate HIE will take significant time and effort. Obtaining consensus for how to handle health information in a HIE system will be difficult, particularly with respect to sensitive health information (e.g.,

information regarding mental health, AIDS/HIV, genetics, and substance abuse). This will make legislation difficult to draft, let alone be adopted consistently by the states. Another challenge is to resolve varying opinions on whether and under what circumstances individual consent to HIE is necessary.

Inclusion of an arbitration clause in an interstate compact presents a challenge for state agency members. The state enjoys sovereign immunity except to the extent it has consented to be sued, and in Ohio, for example, that consent to be sued specifies the Court of Claims as the appropriate venue for claimants against the state. Arbitration exposes the state to recovery in an alternative venue. Also, the Attorney General is the designated counsel/legal representative for state agencies, and the authority to compromise or settle a claim on behalf of the state rests with the Attorney General.

Typically, interstate compacts are narrowly drawn to a specific purpose. Accordingly, a compact for HIE across state boundaries would not address the process for intrastate HIE. If there are separate intrastate and interstate HIE processes, health care stakeholders will incur extensive time and expense, and possibly encounter significant confusion in their efforts to comply with the legal requirements for both intrastate and interstate exchange.

5.10 Future Application

The Collaborative's goal was to identify the best consent policy alternatives to encourage intrastate and interstate HIE. We attempted to determine the appropriate balance between consumers' legitimate interests in controlling the use and disclosure of their health information and providers' legitimate interests in having timely access to reliable and complete patient information at an affordable cost. We found that consumers can only provide meaningful, informed consent if they understand all of the ways in which their health information may be used, and by whom, and if they understand the consequences of their consent decisions.

Likewise, providers need a common understanding of their essential role in furthering HIE, in addition to acknowledging the privacy and security concerns that are important to consumers.

- We recognize the opportunity to implement education efforts using HISPC Collaborative products from the consumer and provider education groups. Such education will begin developing a nationwide collective understanding of the benefits and risks of electronic HIE and the implications of such HIE on consumers and providers.

We did not reach consensus on which of the intrastate consent alternatives evaluated might be the single best alternative. This is probably appropriate, given the complexity of the social and legal issues surrounding consent and, more specifically, privacy rights.

Additionally, how much control consumers think they should maintain over the use of their health information appears to correlate directly to the sensitivity of their health information

and the degree of protection applied to that information. We need to better understand the legal implications, on consumers and providers, of permitting consumers to consent for their health information to be exchanged through an electronic HIE system.

- North Carolina and California recognize the opportunity to pursue an innovative approach (that may draw on all five consent alternatives) through a consent directives pilot. A consent directive is the record of a consumer's decisions about whether to grant or withhold consent, in different circumstances, to various uses and disclosures of the consumer's personally identifying health information. Consent directives can be applied to reflect jurisdictional and organizational requirements pertaining to consent, such as mandatory reporting laws. The use of consent directives could be tested through a single-state or multistate HIE system and evaluated to determine whether consent directives can (1) achieve cost-effective management of granular consumer privacy preferences, and (2) eliminate or reduce liability risks arising from the variation among jurisdictional and organizational laws and policies pertaining to consent. The pilot could be instructive on whether consent directives might be accepted by consumers and stakeholders and used successfully within the NHIN architecture. Such an approach would need to draw from the HISPC III Collaborative efforts of consumer and provider education, harmonizing state laws, and other consent efforts and could coordinate with ongoing efforts related to interstate compacts.

Interstate compact was identified as one of the best approaches to addressing the barrier to HIE caused by conflicting state consent laws. However, further discussion is needed on enforcement issues and whether an arbitration process should be included in the terms of a compact.

- Pilot an interstate compact effort between several states that will develop the legal language to facilitate interstate HIE and resolve the differences in participating states' individual legal structures. Such a pilot would build on the HISPC III Collaborative efforts of consumer and provider education, interorganizational agreements, harmonizing state laws, standards of security, and the ongoing intrastate consent findings.

Initially, the Collaborative divided resources in half, pursuing intrastate and interstate analyses separately. After initial findings were collected and considered, we identified a relationship between intrastate and interstate efforts. An interstate legal mechanism had been considered as a way to avoid the need to harmonize consent laws in every state or to identify a single consumer consent alternative to achieve nationwide HIE. However, we soon realized that an interstate exchange mechanism would not avoid the need for each state to make policy decisions regarding individual consent and privacy rights. Although development of an interstate compact can be pursued, the fundamental questions of state consent and individual privacy rights need to be pursued concurrently. These ongoing intrastate consent efforts would continue to address fundamental privacy issues during the minimum 3-year period it would take to implement an interstate compact.

We recognize the opportunity to:

- Coordinate with HITECH future health care reform efforts, especially regarding secondary uses and disclosures of health information. Address minimum necessary use, de-identification and re-identification, limiting use or disclosure to the original purpose for which the information was collected, and properly safeguarding consumer health information from abuse, misuse, loss or theft.

The analyses conducted by the Intrastate and Interstate Consent Policy Options Collaborative can serve as a foundation for consent actions at the state and federal levels and facilitate adoption and enforcement of consent standards, which in turn will increase nationwide participation in HIE.